
INSTITUTIONAL RESOURCES

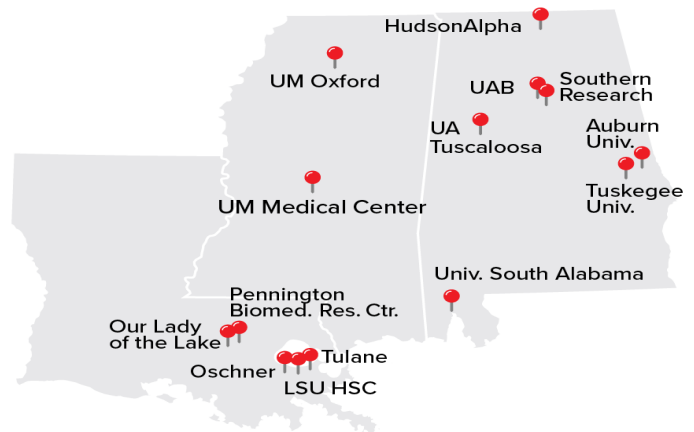
Building on research strengths at the University of Alabama at Birmingham (CCTS Hub), the CCTS continues to engage a 12 Institution Partner Network spread across a Southern Tri-State Region (Alabama, Mississippi, and Louisiana) to create a vibrant scientific environment to improve and accelerate translational research and workforce development. The Institutional Resources herein provide detail on the CCTS facilities and technology, followed by detailed descriptions of CCTS Partners' resources, starting with the Hub and followed by Partners in alphabetical order.

CENTER FOR CLINICAL AND TRANSLATIONAL SCIENCE (CCTS)

To speed the translation of research into improved human health, the CCTS and its Partner Network are committed to increasing research capacity, accelerating research processes, developing, and supporting excellence in the research workforce while providing creative and innovative approaches to major health and health care delivery challenges. The CCTS aims to fortify the advancement of translational science through community engagement and vibrant connections within the CCTS Partner Network. The CCTS offers access to a number of resources and capacities through its co-leadership of the Clinical Trials Initiative as well as the Training Academy and the Research Commons.

CCTS Partner Network

In synergy with the resource strengths available at UAB, the CCTS has established Institutional Partnerships to improve and accelerate translational research. The CCTS Partner Network crosses institutional boundaries to improve human health and health care delivery. This innovative partnership is well integrated into the fabric of the CCTS and provides the foundation for addressing health disparities through collaborative research and training efforts. Building on some initial relationships from the Deep South Network for Translational Research, we have significantly expanded to create new and more formal partnerships with regional institutions for mutual benefit. Regional partners are working together to facilitate and promote unique opportunities, including (but not limited to) drug discovery and development, genomics, advanced magnetic resonance imaging, population health and outcomes research. Each partner brings a diverse yet unique research framework that fortifies the CCTS Partner Network as a whole and fulfills the CCTS mission of excellence. Partners include UAB (Hub), Southern Research, Auburn University, University of South Alabama, HudsonAlpha, LSU Health Services Center, University of Mississippi Medical Center, Pennington Biomedical Research Center, Tulane University, University of Alabama-Tuscaloosa, and Tuskegee University. Building on this culture of collaboration, the CCTS has expanded its relationship with other affiliate institutions to advance programmatic synergies (University of Mississippi (Oxford), Our Lady of The Lake, Ochsner Health).



Clinical Trials Initiative

The mission of the UAB Clinical Trials Initiative is to promote, foster, and enhance high-quality clinical research at the University of Alabama at Birmingham. UAB's initiative is to provide, support and direct the implementation of cutting-edge human subject research. By promoting clinical research, the effort will help the UAB community meet its mission goals of excellence in patient care, education, research, and community service. The Institution is committed to providing world-class patient care with innovative therapies to treat disease, promote health and wellness, and provide opportunity for patient participation in clinical research. As an academic medical center, it is our responsibility to participate in research that leads to new discoveries and advances the art and science of medicine for future generations. This collaboration provides services to:

- UAB researchers and research teams, assisting with feasibility assessment, methodologic rigor, study start-up, implementation, and reporting.
- Patients and the general public, providing opportunities for study participation.
- Sponsors, helping them identify UAB investigators for participation in their research.

As part of this effort, the CCTS mission addresses four programmatic tasks: 1) performance standards to meet and exceed national standards; 2) educated and knowledgeable workforce; 3) implementation of scientifically reproducible research; and 4) services to support rigorous design and interpretation. Toward these goals, the CCTS Hub has developed a multi-modal implementation strategy overseen by the **Clinical Trials Administrative Office**, **Clinical Trials Administrative Committee** (CTAC), guidance in **Quality and Efficiency**, and training via Regulatory Knowledge and Support.

Clinical Trials Administrative Office: The Clinical Trials Administrative Office is operationally responsible for the various policies, procedures, systems, and initiatives supporting the clinical trials conducted across the Schools at the University of Alabama at Birmingham. It enhances the efficiency, tracking, and management of clinical research activities throughout the lifecycle in order to see innovative therapies brought to our patients more quickly. In order to do so, the CTAO works collaboratively with the institutional administrative offices for both the University and the Health System, in addition to Departments and Centers. Additionally, the CTAO is home to the Office of Clinical Billing Review (CBR) which is responsible for conducting Medicare Coverage Analysis on all studies that incorporate clinical billable activities by the UAB Health System in order to ensure a compliant billing environment.

Clinical Trials Administration Committee (CTAC): UAB's President Watts recently charged the Clinical Trials Administration Committee (CTAC) in 2018 with overseeing continuous quality improvement to ensure an ethos of excellence in clinical trial administration at the Hub. The Committee, which consists of senior administrators and investigators throughout the institution, meets monthly to refine the expectations in the conduct of trials, consistent with institutional and national objectives, and to provide guidance to the Clinical Trials Administrative Office. It continually monitors processes, policies, and infrastructure to enhance effectiveness and efficiency while upholding the highest standards of transparency, patient safety, ethical conduct, and regulatory compliance. The CCTS Director, Dr. Robert Kimberly, chairs the Committee, which reports directly to the President of the University. The director of CCTS Network Capacities, Dr. Jason Nichols, oversees CTAC's Time to Activation Initiative and represents the Partner Network in the context of multi-site studies. CTAC is transforming the organizational culture at the Hub to support trials through the comprehensive integration of institutional workflows, best practices in performance, education, information technology and data systems, financial management, and participant safety in coordination with other research administrative offices (Sponsored Programs, IRB, Financial Affairs, Human Resources, etc.).

Quality and Efficiency: The CCTS supports the design and conduct of ethical and scientifically valid clinical trials in an environment predicated on good clinical practice and implemented by a well-trained research workforce. The CCTS works with individual investigators and research teams and with the enterprise to ensure quality and efficiency in scientific investigation involving human subjects. CCTS Institutions have organized tools, expertise, and facilities to help investigators succeed at every stage of trial development and implementation:

- Pre-Implementation and Study Start-up (e.g., Training & Education in Good Clinical Practice, BERD expertise for study design & methods, informatics assets for feasibility assessments, regulatory support, scientific review of human subjects protocols, guidance for budgeting and contracting, specialized capacity for multi-site investigation).
- Study Activation and Implementation (e.g., informatics tools for recruitment & retention, point of care trial notifications, experienced recruiting teams, integrated clinical trial management system (OnCore), state-of-the-art facilities, trained pool of research coordinators)
- Analysis, Reporting and Close-out (e.g., CTAC monitoring, ClinicalTrials.gov assistance, user-friendly data management and archival systems, OnCore tracking, project panels for publications)
- Regulatory Knowledge and Support (e.g., workforce development courses addressing clinical operations, fiscal management, recruitment & retention)

Pre-Implementation and Study Start-up

Training: (see CCTS Training Academy, below) CCTS Clinical Research Support Program (CRSP) serves a vital role in workforce education by supporting a comprehensive portfolio of complementary programs to introduce and to reinforce skills needed to succeed in translational research, especially as it applies to clinical trials (see RM-RKS). Accessible across the Partner Network, these activities embrace established competencies defined by the national CTSA Consortium and address investigator needs at any stage across the career arc.

Study Design: (see Biostatistics, Epidemiology, and Research Design – BERD, below) BERD engages expert methodologists spanning the Partner Network to support a diverse array of study design and analytic needs in the performance of clinical and translational research. All investigator-initiated trials work with biostatisticians to optimize study design, power, and analytic strategies early in the development of the study. This collaborative effort also defines the key components (e.g., outcome measures) needed for federal registration and reporting expectations, including clinicaltrials.gov.

Feasibility Assessment: (see Informatics, below) Prior to initiating a clinical protocol, a comprehensive feasibility review is conducted by the academic department of the investigator through the Scientific Review Process to determine whether a given trial has the potential to succeed relative to multiple dimensions. This assessment addresses the rigor of science, expertise, and availability (effort) of the investigative team and the competitive landscape for duplicative trials. CCTS Informatics has created both self-service and analyst-facilitated query strategies of electronic health record data through i2b2 to assess cohort feasibility.

Regulatory: The CCTS CRSP (see Clinical Research Services, below) is available to work with investigators in the establishment and ongoing management of human subjects protocols. In the case of multi-site, interventional, human subjects research, all CCTS Network Partners have formally agreed to use IRB reliance and have joined NCATS' Streamlined, Multi-site, Accelerated Reliance for Trials (SMART) Internal Review Board to harmonize and streamline processes to support the protection of human subjects in research in multi-site research. The CCTS also assists investigators with IND/IDE applications, including protocols related to repurposing existing drugs for new indications, evaluating drugs in new patient populations, new biological-based imaging agents, and gene therapy vectors.

Budgeting & Contracting: As each new protocol is submitted to the IRB, it is also assessed for appropriate billing to sponsors. Members of CRSP are available to advise and assist investigators in the development of study budgets that are allowable and appropriate. In collaboration with the clinical study team, the Clinical Billing Review group evaluates each budget to ensure that the cost of each study procedure is appropriately assigned to the sponsor and that Medicare-assigned costs and/or standard of care costs are accounted for within the budget. Budget negotiations are handled by the department and/or the study team, and contracting is handled by the Office of Sponsored Programs. The CCTS Hub has worked with the National CTSA Consortium in the development, adoption, and use of master contracts to support multi-site study execution, including the Accelerated Research Agreements (ACTA, ACDA) to streamline the negotiation of nondisclosure agreements and clinical trial contracts and to reduce the time that it takes to initiate clinical trials.

Multi-site Trials: The CCTS Southeastern Health Alliance for Research (SHARe) provides the streamlined frame within which to conduct multi-site clinical, translational, and comparative effectiveness research across the Partner Network as it serves the health challenges of the diverse populations of our region (see Net Cap). SHARe represents the CCTS Network as it interfaces with NCATS' Trial Innovation Network (TIN) (see Network Capacities). The CCTS Hub and several Partners have also established a partnership with TriNetX, a federated clinical data network of providers and pharmaceutical companies that uses i2b2 to accelerate trial site and patient recruitment. The CCTS currently receives weekly invitations to participate in trials from TriNetX, representing a variety of adult and pediatric diagnoses related to hematology, oncology, nephrology, neurology, and genetics.

Study Activation and Implementation

Recruitment and Retention: Trial recruitment is enabled at the point of care by Cerner PowerTrials[®], allowing for a seamless integration of the research recruitment process into normal clinical practice. Community-based recruitment is enabled by the Hub's Recruitment and Retention Shared Facility (RRSF), providing hands-on assistance to investigators with recruitment materials and strategies, linkages to communities, culturally appropriate techniques for the recruitment of minority subjects, and maintenance of a Recruitment Database. With the appropriate IRB approvals, CCTS Informatics supports analyst-facilitated data requests defined by study inclusion/exclusion criteria and can return detailed data, including PHI (e.g., name, contact information), to facilitate direct recruitment. For multi-site trials, similar queries against i2b2-SHRINE networks (e.g., SE-SHRINE and ACT Network) can then be used locally to map to specific individuals by collaborators. The CCTS has also established strategies, including patient navigation, to increase both the enrollment and the retention of underrepresented minorities in clinical research. The CCTS is leading a consortium effort to develop, test, and disseminate an integrated multi-level, culturally sensitive intervention to engage African Americans and Latinos in translational research (STRIDE). The CCTS also leverages XpertTrials, a proprietary search algorithm to match trials available at the Hub in ClinicalTrial.Gov with participant inquiries. Individuals interested in clinical trials can search for research opportunities based on medical conditions, procedures, symptoms, or clinical specialties. The CCTS connects the potential participant with the appropriate study team.

Trial Management: OnCore[®] Enterprise is the Hub's Clinical Trial Management System (CTMS), used to manage protocols, subjects, finances, coverage analysis, biospecimens, scientific review process, ordering of clinical services and electronic data capture. Study teams, in partnership with the CCTS OnCore team and Department-based experts, build their trial in the CTMS, integrating calendar, billing, and regulatory components to improve communications, achieve greater efficiencies and enhance regulatory compliance across teams. OnCore also has the capability to improve patient safety by providing clinicians with important information about a patient's involvement in a trial at the point of care through Cerner PowerTrials, a module now integrated in the Hub's electronic health record. The CCTS CRSP team oversees initial training and continuing education in the use of OnCore and PowerTrials to manage clinical trials.

Monitoring: The CCTS CRSP can provide experienced monitors to assist with independent verification of data, regulatory documents, and the ethical conduct of research. Through the education effort described above, tools are available to other research sites, including those across the Partner Network, to enhance site-specific QA/QC processes. Current practices and reciprocal guidance are shared with Partner Network institutions interested in working with a similar model.

Facilities and Expertise: (described below under Clinical Research Services). As the driver of clinical and translational research at the Hub, the CCTS offers a number of clinical resources to investigators, available on a recharge basis, including state-of-the-art physical space and trained expertise to support clinical research encounters across the lifecycle.

Analysis, Reporting and Close-out

Clinical Trial Oversight and Assistance: With the University's integrated research portal (IRAP) and the enterprise adoption of the OnCore CTMS to manage protocol approvals and trial accruals. This structure allows the rapid identification of trials that may be struggling to launch, to recruit or to meet milestones. The CCTS works with these teams to explore ways to overcome such issues in an efficient and effective way. Occasionally, despite best efforts to partner with investigators to meet the aims of a trial, unanticipated challenges may prevent a study from succeeding. In such cases, the CTAC works with the researcher and the affiliated Department to close studies early.

Reporting: Researchers conducting clinical trials have the responsibility to create and maintain records on ClinicalTrials.Gov. CRSP personnel review all human subjects applications at the Hub to identify eligible trials, and, together with BERD, advise investigative teams on how to register studies and to provide annual reports

on a timely basis. The CTAC also monitors the publication of trial results to ensure that research results are disseminated publicly.

Data management and archiving: The CCTS supports REDCap (Research Electronic Data Capture) as a secure, web-based application for building and managing online surveys and databases. This instance has been approved by the IRB and the Hub’s data security team to manage protected health information. For more complex studies, the CCTS BERD, in collaboration with the Hub’s School of Public Health, is able to create custom data management structures. CCTS BERD has also established a data management toolbox, including templates informed by partner experience, web-based tools (e.g., DMPTool) and a series of ‘how to’ guides for data collection, management, and archiving (see BERD).

Close Out: OnCore serves as the central system to track protocol activity from startup to closeout. The CTAC has established enterprise-wide standard operating procedures to guide study closure. These are implemented in partnership with research administration and grants and contracts accounting.

Regulatory Knowledge and Support

Foundational to the success of these strategies is the development of a research workforce, equipped with the skills and knowledge of good clinical practice and the safe and appropriate conduct of research. CCTS educational programs are available network-wide and are archived on the Center’s website. To complement its educational platform, the CCTS maintains a comprehensive, web-based set of resources tailored to every stage of implementation, which have been updated to meet the evolving standards and expectations of clinical research implementation.

Standard Operating Procedure Template	
Clinical Operations	Fiscal Management
<ul style="list-style-type: none"> Adverse Event and Serious Adverse Event Reporting Eligibility Confirmation Monitor Visits, on-site and remote (SIV, IMV, COV) PI Oversight Source Document Development Data Management: CRF Completion and Query Resolution 	<ul style="list-style-type: none"> Reviewing the Protocol for Financial Impact COI Reporting Monthly Reporting and Reconciliation Billing Compliance
Regulatory Management (includes device studies)	
<ul style="list-style-type: none"> SOP Development Regulatory Document Management Process (Initial and Continuous Submissions) Sponsor, CRO, and Internal Audits Required Training Note to File 	<ul style="list-style-type: none"> 1572 Management Site Specific Informed Consent Form Administrative Hold Closing a Study Record Storage FDA Audits Drug Accountability

The CCTS is dedicated to the initial training and continuous education of all members of translational research teams throughout the Partner Network to ensure a deep and thorough understanding of good clinical practice and high standards of regulatory adherence in clinical investigation. Within the CCTS Training Academy, CRSP manages a comprehensive portfolio of training and enrichment activities. Through a combination of Miami CITI training, hub-based research orientation, basic clinical studies, and trials implementation skills, and tailored continuing education, CRSP supports clinical research education that is accessible across the Partner Network, embracing established competencies defined by the national CTSA Consortium and addressing investigator needs at every stage across the career arc. These educational venues also serve to create a

substantial network of clinical research team members, faculty, and staff alike, that provides another level of support and reference. CRSP Educational offerings provide academic training in the principles essential for success in the clinical research environment. All investigator and research team members involved in the conduct of human subjects research are required to fulfill compliance-based training for clinical research, good clinical practice, and conflict of interest. This is accomplished by a combination of CITI-based modules and custom courses developed in partnership with each Network institution.

Building on this preliminary IRB training, the **Research Orientation Program (ROP)** is a high-level overview intended for researchers, faculty, staff, and trainees alike, as an entry into the principles required to excel in today's dynamic clinical research environment. The half-day activity, offered every other month, addresses the key fundamental principles across the life-cycle of a study, including roles and responsibilities of members of the research team, pre-study activities (e.g., IRB approval process, ClinicalTrials.gov registration, recruitment strategies, study feasibility), study implementation (e.g., consenting, cultural humility, data collection, QC/QA, DSMB, AE/SAE reporting, billing compliance, monitoring & audits) through post-study issues (e.g., last visits, data archiving, study closure, reporting). The **Research Training Program (RTP)** for staff and the **Clinical Investigator Training Program (CITP)** for faculty build on ROP concepts to enhance strategies for implementing and managing a clinical study or trial, utilizing GCPs as the backbone of the curriculum, with an emphasis on the unique considerations, roles & responsibilities, IRB procedures, trial management, recruitment & retention, and other key topics associated with trials. Twice annually, CITP and RTP meet for 4 hours weekly over four to seven weeks. For the last week, participants work as teams to apply their newly obtained knowledge to case studies. These advanced courses use a strategy of pre - and post-examination to assess knowledge-gain and competency and to identify topics that may require more or less attention to ensure understanding. Programmatic impact is assessed through follow-up surveys, structured interviews, and tracking career metrics. To meet a demonstrated need during this year's pandemic, "CITP on the Go" podcasts were introduced. These short informational recordings provide investigators with a quick refresher on key elements in clinical research. The 10-15 minute presentations highlight topics that range from Informed Consenting to Recruitment and Retention, Team Building and Communication to Roles and Responsibilities of the PI. Plans are underway to add even more topics to the podcast library.

The **CCTS Clinical Trials Lunch & Learn** (meets quarterly) provides a continuing education opportunity with critical guidance on new or changing requirements in the conduct of clinical research. All clinical research teams across the network, regardless of study type or discipline, are encouraged to send at least one person to attend and disseminate updates to their team and home office. These events routinely draw ~200+ team members and address issues related to IRB, clinical billing review, informatics tools (OnCore, PowerTrials), ClinicalTrials.gov, and contracting. This has become an essential venue for research teams to stay attuned to changing policies and expectations at the national and local levels. They have also served to foster a community of clinical researchers who can be approached outside of such enrichment activities to get real time guidance to questions or concerns. CRSP has also recognized that there are a variety of topics, updates and considerations that are specific to special populations. Responsive to growth in pediatric trials across the Network, CRSP has launched an additional **Lunch & Learn: Pediatrics series** that is dedicated to child health research. Based on this experience, the CCTS will continue to survey the needs of its research base to develop similarly tailored events and series for other disparity populations. The **CCTS Research Seminar Series** (biweekly) also provides continuing education to fill in any gaps in, and to expand on, topics with information related to the implementation of clinical trials. The special topics also provide the opportunity to dive deeper into a particularly complex issue (e.g., budget building, ClinicalTrials.gov (see below) and effort reporting). Routine surveys of investigators and their research teams, as well as guidance from subject matter experts, are used to identify topics for upcoming seminars. In addition to trial-related subjects, the Research Seminar Series takes a holistic approach in training to explore complementary issues like strategies for clinical research during COVID-19, remote monitoring, IRB updates & best practices, recruitment strategies, clinical billing, informed consenting, HIPAA during COVID-19, team building & communication, and time management.

CCTS Training Academy

Mission and Vision: *The CCTS promotes the continuous development of knowledge and skills for learners at all academic and career stages through a portfolio of robust and innovative training programs implemented*

through didactic, experiential, and self-directed approaches. Our multidisciplinary research workforce strives for the advancement of human health and healthcare.

The CCTS is an innovative and evolving network of research professionals and visionary faculty that performs exemplary work in the clinical and translational science research communities while carrying high standards set by the National Center for Advancing Clinical and Translational Science (NCATS). The CCTS Training Academy domain offers interdisciplinary, educational programs and enrichment activities for research teams across the academic career arc from graduate and postgraduate students to early career and senior faculty. The Training Academy is continuously enhancing CCTS Training Programs and finding creative methods to deliver stellar programs conducive for success in the translational science workforce. The CCTS provides training in specific foci such as grant writing, mentoring, leadership, career development, informatics, and more. The CCTS also utilizes didactic, experiential, and self-directed programs that are tailor-made to fit different learning styles and academic disciplines. An archive of previously recorded training sessions is available in the CCTS Hub. Archived and current news/events, including the CCTS Digest e-newsletter, can also be found in the CCTS Hub.

Clinical and Translational Science

CCTS provides a package of didactic and experiential educational programs geared towards developing doctoral scholars, researchers, and staff at all stages of their respective career and academic arc. The CCTS aims to expand and enrich a diverse, vibrant, and highly-skilled research team that will be prepared to bring innovative scientific discoveries to the populations we serve.

- ***Translational Research Summer Series Training:*** The CCTS supports a Translational Research Summer Series Training program for trainees from Partner Network institutions. The 8-week Summer Program provides mentored research training experiences for health professional students or other clinically-oriented doctoral students that have completed their first year of training. Subject matter experts introduce translational methods to translate questions into projects, research methodology to prepare a scientific abstract, and drafting research documents. (June and July).
- ***Clinical and Translational Science Training Program (CTSTP, Epi 680):*** The Clinical and Translational Science Training Program occurs over a six-month period (January-June) for two hours per week. CTSTP course content includes key areas such as clinical trials, epidemiology, biostatistics, ethics, clinical genetics research, behavioral research, outcomes research, dissemination of results, and grant writing and funding opportunities. Approximately 50 hours of didactic instruction are dedicated to this robust certificate program that spans across numerous disciplines. All sessions are presented by experienced investigators or individuals with special expertise in areas such as grants, research methodology, contracts, and regulatory issues.
- ***Friday Fellows:*** Partnering with the Center for Outcomes and Effectiveness Research and Education, Friday Fellows provides the opportunity for investigators, trainees, and others interested in population and health outcomes research to discuss best practices. T32 pre-doctoral and post-doctoral scholars, investigators, and others interested in population and health outcomes research are encouraged to attend this course. In addition, Friday Fellows offers one credit hour towards their coursework (Course: Epi 690). Attendees are encouraged to share their latest projects in a supportive "discipline agnostic" environment, find new collaborators, develop foundational skills in study design, outcomes measurement, evaluation. Interactive activities for the development of critical "soft" career skills such as public speaking, networking, and providing/accepting constructive feedback. Friday Fellows aims to provide the opportunity for investigators, trainees, and others interested in population and health outcomes research to discuss best practices.
- ***Translational Training Symposium:*** CCTS Training Academy's flagship annual symposium convenes scholars from across the career arc, translational spectrum, and Partner Network with structured sessions conducted by expert speakers, as well as informal networking sessions. This two-day event provides a breadth of training opportunities to meet the needs of early career investigators starting in translational science.

Clinical Research Training

In partnership with the CCTS Clinical Research Support Program (CRSP), the CCTS Training Academy supports educational offerings that detail the principles essential for success in the clinical research environment. In-person, classroom-based, and online courses relevant to investigators, study coordinators,

financial staff, regulatory coordinators, and other research staff are available, with emphases on Good Clinical Practices (GCP), compliance, and other key topics.

- **Research Orientation Program (ROP):** The Research Orientation Program is a standalone session offered every two or three months. The program is for early career investigators and research staff who are new to research, as well as any who could use a refresher course in key aspects of a clinical trial. The ROP provides basic tools, familiarizes attendees with research study terms, and helps those new to research avoid common pitfalls. The CCTS strongly encourages new faculty, coordinators, budget, and regulatory staff to attend. CME credit is offered for the ROP sessions.
- **Clinical Investigator Training Program:** The Clinical Investigator Training Program (CITP) aims to promote excellence in Good Clinical Practice (GCP), acquaint investigators with research capacities and expertise available in the CCTS, and improve awareness of ways to expedite clinical trials in a safe and rigorous manner. CITP is designed for those with MDs, DOs, DMDs, and PhDs, emphasizing the responsibilities of investigators conducting human subjects research.
- **Research Seminar Series:** The CCTS presents the Research Seminar Series for the purpose of filling any gaps in information related to the implementation of clinical trials that have been identified by investigators and their research teams. The sessions are held the first and third Thursday of each month and topics such as IRB Updates, Clinical Trial Recruitment, Clinical Trial Billing, Best Budget Practices, Informed Consenting, HIPAA Regulations. The topics will be of interest and relevance to clinical research personnel including investigators, regulatory personnel, study coordinators and financial administrators. CME (Continuing Medical Education) credit is offered for attending the seminars.
- **CCTS Lunch and Learn Series:** The CCTS Lunch & Learns is a quarterly event that aims to provide critical guidance on new or changing requirements and support the conduct of clinical research at the CCTS Hub and throughout the Partner Network. All clinical research teams, regardless of study type or areas of focus, are encouraged to send at least one person to attend and take back updates to their team and home office.
- **Clinical Investigator Training Program (CITP) on the Go Podcast:** The CITP on the Go Podcast is a self-directed web series providing a complementary training method for the CCTS Clinical Investigator Training Program. The program is an abbreviated curriculum for clinical investigators and trialists and promotes excellence in clinical practice and educates on the research capacities and expertise available to support clinical trials.
- **OnCore:** OnCore is the Clinical Trial Management System (CTMS) utilized by the CCTS Hub, which tracks protocols and participants involved in clinical trials and other studies through the life cycle of the protocol. OnCore integrates study calendars and billing management to ensure rigorous oversight of study conduct. OnCore offers financial management including coverage analysis, budgeting, tracking protocol milestones, invoicing, and the recording of sponsor payments. OnCore also has extensive built-in reporting features as well as custom reporting capabilities. The CCTS Training Academy, in partnership with the OnCore and CRSP teams, provides OnCore training for all users across the research enterprise. This includes in-person classroom-based training and training materials that are available for download.

Community Engagement Institute

As a dedicated focus and important component of the core values of CCTS, our Engagement of Communities domain creates dialogue among scientists, citizens, and stakeholders alike to identify pivotal health priorities in the region. CEI incorporates the use of social events, forums and panels, and research to explore issues concerning issues in the community such as health equity, advancements in health research, and underserved communities across the Deep South. CEI is a partnership with the UAB Center for the Study of Community Health, a CDC-sponsored Prevention Research Center.

- **Bioethics Forum:** This annual event brings together researchers, bioethicists, students, community members, front-line researchers, and clinical staff to discuss special ethics topics in research. The Bioethics Forum creates a safe space for speakers and participants to openly express and reflect on ethical approaches to form best practices individually, institutionally, and collectively while

complying with established policies and laws. The goal of translational scientists is to focus on the improvement of the health of individuals and the public through ethical behaviors and research methods.

- **Community Engagement Institute (CEI) Perspectives:** The CEI hosts necessary conversations that address focused topics of interest to communities. Attendees and speakers present diverse points of view and to serve as a call to action for science, service, and solutions. Drawing on a combination of formal presentations and moderated panels, this venue provides an agile and consistent setting to respond to pressing issues.
- **Community Engagement Institute (CEI) Symposium:** The CEI hosts an annual symposium addressing the barriers to health equity and ways that communities can work together to build momentum toward sustainable change. The CEI Symposium is a multifaceted event focused on issues related to health equity and social justice. The CEI Symposium is a collaboration of the CCTS Partner Network, the Center for the Study of Community Health, the Forge AHEAD Center, and the communities we serve.
- **Community-Based Participatory Research (CBPR) Immersion Course:** Community-based participatory research (CBPR) is based on the assumption that communities are more likely to participate in, accept the results of, and put those results of research to use if they have participated and provided input across all stages of the research project. CBPR is a joint effort that involves researchers and community representatives in all phases of the research process. The joint effort engages community members, employs local knowledge in the understanding of health problems and the design of interventions, and invests community members in the processes and products of research. In addition, the collaborative is invested in the dissemination and use of research findings to improve community health and reduce health disparities. Spearhead by the Center for Palliative & Supportive Care at the CCTS Hub, the immersion course engages academic investigators over the course of one week to understand pivotal considerations in CBPR.

Leadership and Team Science

The ability to work as part of a team is a critical skill for translational scientists, who by definition, collaborate with scientists from other disciplines, institutions, generations, countries, and stages along the translational research continuum. Increasingly, translational science teams also include community members with limited knowledge of scientific concepts and terms. CCTS offers experiential workshops and seminars taught by experts in team conflict and cohesion to introduce you to key principles for successfully participating on a scientific team.

- **Learn Enhance Advance Drive (LEAD):** This is a one-year, cohort-based program is designed to enable junior faculty and director-level staff to enhance their interpersonal skills, professional skills, and leadership skills. LEAD also focuses on creating a pipeline of future leaders and innovators. LEAD uses the Leadership Competency Model to provide the framework for the chosen topics. The cohort meets face to face for 1.5-2 hours monthly to learn about themselves, enhance their interpersonal effectiveness, advance objectives through building quality teams, and learn to drive change. In between the monthly sessions, participants will complete tasks they set as part of their goal-setting activity. Cohort participants will improve their interpersonal, professional, and leadership skills.
- **Case Studies in Collaboration & Teamwork:** Transdisciplinary efforts are becoming more critical for scientific discovery and translational research efforts, and through this program, participants will learn tips and techniques to effectively develop, lead, and manage teams. In this eight-week, case-based course, utilizing the National Institute of Health's Collaboration and Team Science Field Guide, 2nd Edition, along with included brief case studies, scientists learn the basics of team science and collaboration as well as how to navigate the challenges of working in interdisciplinary teams.

Mentoring

For mentoring and career development, the CCTS works with all learners to identify individual training needs and navigate the many resources available. Through individualized consults, learners identify additional competencies needed for specific clinical and translational research domains as well as the

necessary training and research resources. Mentoring is a crucial and foundational piece of the CCTS Training Academy.

- **Individualized Development Plans:** The CCTS provides assistance with Individual Development Plans (IDPs), which can facilitate dialogue between mentors and trainees as they establish training goals. An IDP is now strongly encouraged for many funding mechanisms. Information on creating IDPs is available on the CCTS website, along with information pertaining to related seminars and our entering mentoring curriculum.
- **Case Studies in Mentoring:** This didactic training program is open to investigators across the CCTS Partner Network at any level. From pre-doctoral students and clinical research professionals to seasoned faculty members who mentor developing research scientists, participants complete eight weekly hour-long topics in the Case Studies in Mentoring series. Successful completion of the mentoring series will result in the awarding of a certificate documenting Excellence in Mentoring suitable for departmental review and academic promotion. The series is held tri-annually with a spring, summer, and fall session, all of which are completed over a nine-week duration to enable participants to complete the series as time allows.

Diversity, Equity, and Inclusion and Access (DEIA)

For diversity, equity, and inclusion, CCTS focuses on cultivating a formidable culture centered around a mission that includes DEI in the forefront. CCTS's mission is accomplished through activities such as award recognition, professional development, grant matchmaking, mentoring, and advocacy.

- **DRIVEN:** In partnership with the Center for Outcomes and Effectiveness Research and Education, Driving Research: An Interdisciplinary, Vibrant, Engaged Network (DRIVEN) aims to cultivate a community of interdisciplinary clinical and translational investigators and promote their individual and collective professional development, recognition, and advancement to foster an inclusive, equitable and diverse research workforce. DRIVEN also promotes and supports diversity and inclusion initiatives through networking, social events, matchmaking for funding opportunities, and collaboration in the community and across the network.
- **UAB/Tuskegee FIRST (Faculty Institutional Recruitment for Sustainable Transformation (FIRST) program):** UAB and Tuskegee bring a history of collaboration and dedicated effort to eliminate health disparities using their complementary strengths. As a world-renowned research institution, the University of Alabama at Birmingham offers research and infrastructure, including scientists, facilities, and resources. Tuskegee has a rich history of talented researchers and educators dedicated to educational excellence and diversity. The *FIRST Benjamin-Carver Scientists program* is funded in part through the NIH Common Fund's FIRST program. Scientists selected to participate are deemed a "Benjamin-Carver Scientist" and will benefit from relationships with both the University of Alabama at Birmingham and Tuskegee University. Ultimately, the Partnership is designed to support inclusive excellence in research at both institutions. Benjamin-Carver Scientists are committed to advancing diversity, equity, and inclusion in research areas pertaining to health disparities. This program aims to create a model for systemic and sustainable institutional culture change. With an ultimate goal of achieving health equity, the work of Benjamin-Carver Scientists focuses on research areas where disparities are particularly evident in our region.

Grant Writing

The CCTS offers a comprehensive list of training program offerings focusing on grant writing and group reviews. The programs provide extensive and intense instruction that thrives on the preparation and execution of successful grants written by investigators and reviewed by grant writing experts and panels. Our grant writing programs have a proven track record of securing funding for research efforts.

- **Grant Writing Intensive Program (GRIT):** In partnership with the Center for Outcomes and Effectiveness Research and Education, the Grant Writing Intensive Program (GRIT) cohort program provides structured activities over a 4-6 month timeline to assist cohorts of K-scholars in their preparation of a first R-series application. Leveraging successful existing CCTS programs, like Nascent Project Panels, and Panels Done Quickly, innovative offerings including a Specific Aims Workshop, R Writing Group, and Mock Study section, which are grounded in Team Science

principles, provide K scholars with a roadmap and resources towards developing a competitive R series application. GRIT has a proven track record of success with an over 65% success rate in securing K and R series grants.

- **Mock Study Section:** The mock NIH study section uses real applications that were submitted, received an insufficient funding score, resubmitted, and then successfully funded. The mock study places participants in the role of a grant reviewer while reviewing actual K and R grant submissions. During each two-hour session, the mock reviewers will be assigned grants to preview and explore what an NIH study section considers when critiquing the applications based on scientific merit, assessing key elements of a successful application, and uncovering any issues that might hurt an applicant's chance of being funded.
- **Specific Aims Intensive:** In collaboration with the UAB School of Nursing, this three-session Intensive features presentations by the School of Nursing faculty, followed by discussions and workshops via breakout rooms. Participants are expected to attend all three two-hour sessions and will be asked to complete tasks related to their specific aims page before each session. In addition, participants will receive written & verbal feedback on their drafts from reviewers and fellow cohort participants. This opportunity is open to the CCTS Partner network and is targeted to faculty who are in a good position to apply for NIH funding with any R-mechanism for the next NIH cycle, with the opportunity for others to be considered.
- **Biostatistics, Epidemiology, and Research Design (BERD):** The CCTS Biostatistics, Epidemiology & Research Design (BERD) unit comprises a multidisciplinary team of expert biostatisticians, epidemiologists, and methodologists. In support of rigorous methodology and scientific reproducibility in clinical and translational research, the CCTS BERD team collaborates with investigators at any stage, from student to senior faculty, across the CCTS Partner Network, pairing expertise with study-specific needs and providing state-of-the-art study design, data management, and statistical analysis. In addition, we specialize in supporting studies during the critical design and initial implementation phases, ensuring a successful launch.
- **Kaizen:** The Kaizen training platform, developed by CCTS Informatics, is based on the philosophy of continual improvement, and is designed to enhance education through a competitive format. Kaizen is an app-based, educational gaming platform built to provide a fun, yet competitive learning environment. Developed as an innovative quiz game, the aim is to provide a fun and flexible way to learn new competencies and test retention. Thousands of investigators across numerous institutions have been trained through the Kaizen training platform.
 - **Kaizen R2T (Rigor, Reproducibility, and Transparency):** The NIH requires formal instruction in Scientific Rigor, Reproducibility & Transparency (R2T) for all federally funded trainees. In support of the high-quality investigation and our commitment to scientific integrity, the CCTS-based R2T-Kaizen course upon the review of articles focusing on common errors and fallacies in scientific research as well as the (4) focus areas of R2T: scientific premise, authentication of chemical and biologic resources, consideration of sex and other biologic variables in study design and statistical rigor. All T, K, and F awardees are encouraged to play, but it is open to all investigators.
 - **Kaizen GO! (Grant Orienteering):** The CCTS team developed a fun and highly interactive game created in honor of the 2022 World Games. Participants put forth their best orienteering skills to navigate online resources that support grant development. The foundational premise behind the creation of the game is to promote continual improvement of their grant writing skills with a sports-themed and competitive spirit.

The Kaizen-Education platform also offers a variety of other games for coursework such as Kaizen Nursing (UAB School of Nursing), Kaizen-Introduction to Clinical Medicine (UAB Heersink School of Medicine), Kaizen-SOPH-MPH Orientation (UAB School of Public Health), Biostatistics, CCTS Clinical and Translational Science Training Program (CTSTP) and CCTS Good Clinical Practices (GCP).

- **Panels:** Project Panels utilizes the overarching community of scholars across the CCTS Partner Network to brainstorm on innovative ideas and entrepreneurship while collaborating on enhancing research methodology processes. Multidisciplinary teams are integral to our strategy to enhance the scientific aims, methodologic rigor, and presentation of proposed research by early career investigators and trainees. Panels assemble teams of experienced reviewers to assist investigators

as they hone their study design and analytic strategy for grant proposals. The CCTS brings methodologists and subject matter experts to participate in panels. The CCTS also invites established investigators with closely aligned yet distinct interests and disciplines to the discussion to improve the focus and impact of the scientific plan.

Informatics

CCTS Informatics provides the resources and expertise (both bioinformatics and clinical informatics) to support biomedical collaboration and consultation across the translational research spectrum. The CCTS vision is to build a vibrant community of collaborating informaticians not only across the CCTS Hub with its academic medical system, but also across the regional CCTS Partner Network and national CTSA Consortium.

- ***i2b2 Training:*** The Informatics team offers help with study design; access to summary, limited (de-identified), and fully identified data sets (analyst facilitated with IRB approvals in place); innovative tools to support clinical, translational, and outcomes research; and data analytic services. Accessing Clinical Data for Research with i2b2 can help investigators: determine study feasibility (sample cohort size), identify potential participants for recruitment, perform simple data analyses of de-identified patient data, explore hypotheses for clinical studies/trials.
- ***Informatics Institute Powertalk Seminar Series:*** This seminar series is developed and sponsored by the UAB informatics Institute. It educates individuals on research innovations in biomedical informatics. There are two tracks: Clinical Informatics (1st and 3rd Fridays) and Bioinformatics (2nd and 4th Fridays). Clinical informatics seminars focus on the application of informatics for improving healthcare delivery and using health data for research. It includes diverse topics such as design, implementation, and clinical decision support. Bioinformatics seminars present late-breaking computational techniques, tools, and applications. It includes genomics and other “-omics”. Some areas of informatics, such as precision medicine, natural language processing, and image processing, span clinical informatics and bioinformatics and have greater crossover appeal. In addition to educating, Informatics also strives to make these seminars a collaborative social gathering for the UAB clinical informatics and bioinformatics communities. We encourage you to attend to learn more about biomedical informatics and related disciplines and discover new opportunities for collaboration.

Professional Development

The CCTS takes pride in the continuous development and training of scholars and professionals throughout the Partner Network in all phases of their academic and career arcs. Through mentoring, vigorous instruction, and action planning, the training programs for career development positions learners for success in their chosen professions.

- ***Training Interdisciplinary Emerging Research Scholars:*** The Training Interdisciplinary Emerging Research Scholars (TIERS) incorporates structured career development lectures on topics identified by trainees and senior mentors through research presentations by scholars and unstructured time to foster relationships and create community among investigators. The mission of the CCTS TIERS program is to provide beneficial information on career planning and development in a relaxed environment that promotes collaborative learning, networking, and problem-solving. Topics are tailor-made to match the NIH grant cycle to focus discussion on shared writing challenges.
- ***Mini-Sabbaticals:*** As investigators develop their IDP (Individual Development Plans), they will be encouraged to incorporate a mini-sabbatical, achieved through short-term and experiential training activities at another research site, to facilitate the acquisition of specific clinical and translational research skills. The Training Academy will collaborate with each individual campus site and off-campus site to create the experience desired by the investigator. The Multi-CTSA mini-Sabbatical Evaluation and QUality ImproveMent (SEQUIN) Project will expand and improve the use of mini-sabbaticals for the early-stage translational research workforce in the United States.

Innovation & Entrepreneurship

In the spirit of encouraging innovative and entrepreneurial scientific research, the CCTS offers a set of cutting-edge training programs to nurture the creative enterprise skills of investigators and scholars. The programs are delivered through an experiential format that is pertinent to the success and effectiveness of our training.

- ***I-Corps@NCATS***: The I-Corps@ NCATS program is a 5-week course, based upon the successful National Science Foundation I-Corps and I-Corps at NIH Entrepreneurial Training Program, which combines business model training with a customer discovery process. The short course helps prepare teams to apply to go on to a national program at NSF or NIH, and is designed to help all participants, regardless of the stage of development of their innovation. This program gives an opportunity for trainees to be the trainers in a creative role-playing experience. The program offers a flexible team structure to bring together diverse skillsets conducive to innovation. The CCTS will enhance the process of scientific translation by taking the demonstrated lessons learned and best practices from the I-Corps@NCATS program and disseminating them across a wider network of Clinical and Translational Science Awards (CTSA) Hubs.
- ***Innovation Panels (iPanels)***: Innovation Panels are a group of individuals with expertise in science, tech transfer, and business development who are brought together to help innovators chart a path forward. This 1-hour panel can be useful for those looking to further develop intellectual property, submit an SBIR/STTR, create a company, or disseminate non-patentable, evidence-based system interventions. The CCTS has established a consortium-wide memorandum of understanding regarding scientific integrity and confidentiality. Participation in an iPanel does not qualify a discussant for inventor credit. Criteria for inventorship (a person who conceives the subject matter of at least one claim of an Industry Position disclosure/patent) still applies.
- ***Heersink Institute for Biomedical Innovation (HIBI)***: The Heersink institute for Biomedical Innovation (HIBI) aims to stay ahead of the pace of innovation and entrepreneurship in health care while achieving excellence during an industry-wide downturn in quality and rising costs. To achieve this, The HIBI alters how educating future health care providers and leaders is accomplished. Catalyzing the health, health care, and social and economic development of the community begins with competence development. The HIBI is creating new processes, systems, and organizational structures to solve problems and implement solutions across a range of business models. In addition, the HIBI is integrating programs and opportunities to deliver training to current and future health care providers in health care transformation and economic development while building partnerships and reinforcing a reputation to strengthen our reach.

CCTS Research Commons

Through the Research Commons, investigators can access research-related services and resources available at UAB and our Partner Network institutions. The Commons provides individualized assistance to all investigators, from trainees to full professors. CCTS personnel facilitate scientific connections by directing investigators to appropriate capacities, facilitation of scientific interactions, and promotion of CCTS opportunities. One resource available to investigators across the CCTS Partner Network that is especially useful to junior faculty and trainees is the Panels Program. The CCTS offers (1) a large, multi-disciplinary ***Nascent Projects Panel (NPP)***, (2) smaller, more agile ***Panels Done Quickly (PDQs)***, and (3) ***Innovation Panels (iPanels)*** oriented toward commercialization opportunities. They may be requested by investigators via the Research Commons online portal or direct request. All three provide consultation in early phase project design, grant proposal development, evaluation and revision of unfunded grant proposals, implementation of research protocols, and interpretation and or dissemination of experimental results.

- The ***NPP*** includes over a dozen faculty members and staff who are experts in their fields and are able to provide multi-disciplinary feedback in areas relevant to clinical and translational research including, but not limited to regulatory knowledge, ethics, study design, analytic methodology, epidemiology, health disparities, community-based participatory research, comparative effectiveness research, participant and clinical interactions and outcomes research. Each session may also include content-specific experts chosen after discussion with presenters. Presenters provide a brief 15-minute overview of their research, followed by 20-30 minutes for the NPP members and presenter to discuss the project. CCTS personnel provide a written summary of the discussion to presenters. The NPP

Chair, other panel members, and members of the Research Commons meet one-on-one with investigators to solicit feedback about the value of the NPP and to identify areas in which additional or ongoing assistance would be helpful.

- **PDQs** are available to investigators seeking more rapid and targeted feedback. In contrast to the NPPs, PDQs are relevant for specific phases of research, such as project development, implementation, interpretation and/or dissemination. Meetings are coordinated by the Commons and a member of the CCTS Executive Committee. Relevant materials are submitted for review and within 10 working days of the initial request, a PDQ is convened. As with the NPP, there is an emphasis on multiple viewpoints and content-specific expertise, but from a smaller group of experts (usually two to four). For those who seek additional opportunities to assess progress and identify opportunities for improvement, follow-up PDQs may be convened. In order to provide continuity, at least two of the original members serve as part of the follow-up PDQ. As with the NPP, written as well as oral feedback is provided to the investigator who requested the session.
- The CCTS also facilitates **Innovation Panels (iPanels)**, which are geared toward bringing together expertise on aspects of Intellectual Property Disclosure, Patents, Licensure, Small Business Innovation Research awards, Small Business Technology Transfer (STTR) awards, and NSF's Innovation Corps program (I-Corps), etc. The goal is to bring many of the relevant stakeholders to the table to discuss entrepreneurial potential and next steps for the commercialization application of scientific discoveries, technology development or novel process. Due to the nature of this work, UAB's Institute for Innovations and Entrepreneurship is a close collaborator.

CCTS Grant Library

The CCTS developed a Grant Library, which is a compendium of best practice grant writing samples provisioned by the NIH and funded investigators from across the CCTS Partner Network. The goal of this resource is to inform investigators about funding types and share the wisdom of award-winning communications about scientific excellence and discovery. Samples in the library include extramural and institutional fellowship and mentored career development grants, federal and foundation research project grants, as well as, SBIR/STTR grants. The CCTS Research Commons maintains and updates this resource to keep current with evolving sponsor requirements.

CCTS Biostatistics, Epidemiology and Research Design (BERD)

The CCTS Biostatistics, Epidemiology and Research Design (BERD) unit is a multidisciplinary team of biostatisticians, epidemiologists, and methodologists who collaborate with CCTS researchers to provide fundamental, clinical, and translational research methodology needs. The BERD mission is to provide consultation, guidance, and expertise for study design, data management, and statistical analysis. Its goal is to gather methodological expertise as a single coordinated resource and match individual methodological skills and interests with study-specific needs to advance research. BERD achieves this goal by providing methodological training (short courses, on-line video library), study design consultation (in person clinics, online ZOOM conference), methodology review of grant applications and clinical trials (panels), and collaborations for intermural and extramurally funded research.

The extent and intensity of services vary by collaboration. These services include study design, sample size and power calculations, development of statistical analysis plans, conduct of statistical analyses, graphical representation of data and interpretation of analytic results. The BERD provides these services through walk-in clinics as well as scheduled online ZOOM calls. Responsive to investigator demand, these standing venues are available daily. During the design of studies, BERD methodologists assist researchers in addressing NIH's four components of Rigor, Reproducibility, and Transparency (rigor of prior research, authentication of biologic and chemical resources, sex as a biologic variable, and statistical rigor). The CCTS BERD also has developed templates and guidance to help researchers meet NIH's requirement of Data Sharing and Management Plans which will be implemented January 2023. For independently funded clinical trials and other studies requiring sustained methodologic contributions, BERD experts participate as co-investigators, effort funded and addressed through the grant/contract, to guide standard operating procedures and to ensure accuracy and reproducibility of scientific results.

BERD provides this large array of methodological services to CCTS clinical and translational researchers across all levels of translational science. The services provided are dependent upon the nature the mechanism being developed or conducted (Pilot Design, Clinical Trial, K Awards, F-Series, R-series, Investigator Initiated Electronic Health Record Study). BERD tailors the development of the essential methodologic components including statistical analysis plan, data management plans, and sample size/power calculations to the specific aims of the study.

CCTS Informatics

CCTS Informatics is responsible for providing a broad range of informatics collaborative opportunities and analytical services in support of basic and clinical research. These collaborative services extend from support for basic genomics and bioinformatics analyses to clinical informatics research for population health and outcomes research and health care informatics operations. Specifically, in support of the computational analysis needs of UAB investigators, CCTS Informatics formed the Informatics Consulting Service to provide consultation and collaborative assistance on the collection and analysis of data derived from basic biomedical research (Bioinformatics) to clinical, outcomes, public health, and health services research (Clinical and Health Informatics). Our expertise extends from traditional sequence and genomics analysis, microarray gene expression analysis, protein and RNA structural prediction, and the analysis of data from next generation sequencing (NGS) technologies, to the analysis of data derived from clinical research studies. We have extensive experience in the analysis of NGS data including data derived from whole genome and exome sequencing studies, genome methylation studies, RNASeq data, and microbiome and metagenomic analyses.

CCTS Informatics currently consists of 7 Bioinformaticians (5 PhD level, 1 MS, and 1 BS); 4 Clinical Informaticians (3 PhD, 1 MSHI); an Informatics Architect who designs and implements data management and analytical frameworks for the storage and processing of all our bioinformatics data; and 5 Programmer/Analysts who support the consultation, analytical, training, and educational aims of the service. CCTS Informatics participates in the Southeastern Informatics Consortium, offering consultation services and collaborative opportunities across the CCTS Partner network. (for more information see UAB Informatics Institute and Information Technology)

All data maintained by CCTS Informatics that contains PHI (protected health information) is housed within the HSIS HIPAA-compliant data processing facility, or Cheaha, UAB's HIPAA-compliant High Performance Computing system (see Equipment). All other systems outside of these secured facilities contain only non-PHI, de-identified datasets.

I2b2 Data Summary		
Category	Distinct # of Facts	Distinct # of Patients
AGHI Chromosomes-Genes-RSs	1093909324	6231
AGHI Participant	226950	6311
Allergies (to Medications)	815660	412406
Anatomical Pathology	3217130	423345
Clinical Events (All)	4308356079	1242670
CPT Procedure Codes	27518201	1047375
Diagnosis/Problems (ICD10-ICD9-SNOMED-IMO)	133347734	1274667
Documents	38670853	1179774
DRGs - Inpatient Classification Systems	928322	278185
ICD-10 Procedure Codes	951700	206540
ICD9 Procedure Codes	261459	73722
Lab Tests and Results	741503557	932644
Louisiana Consortium Biobank	5456	5456
Medications	85311243	1052204
Microbiology	7218977	341916
Oncore Studies	487925	43476
Orders (All)	287570370	1401440
Patient Social History (self-reported)	13967926	921360
PowerForms	1017860212	1027059
PRO (Patient-Reported Outcomes)	505822	5771
Radiology	9454281	811844
Rheumatology (Powernote and Ready Rheum Pro)	200378	11737
Social Determinants of Health (SIREN20)	109900831	1024007
Standardized Assessments	167719951	755982
Surgery Detail	9404573	369445
Tissue Collection and Banking Facility	5357195	26111
Transchart Transplant Data	32966	15692
Tumor Registry	4240154	143287
Vital Signs	420931295	1066681

UAB Biomedical Research Information Technology Enhancement (U-BRITE): U-BRITE assembles new and existing HIPAA-compliant, high-performance informatics tools to provide researchers with a means to better manage and analyze clinical and genomic data sets and implements a “translational research commons” to facilitate and enable interdisciplinary team science across geographical locations. Notable benefits of the U-BRITE program are:

- Access to clinical data from Clinical Data Repository to build cohorts
- Access to genomic and other omics data from Omics Data Repository to perform detailed analytical characterizations
- Provides self-service analysis to biologists via Jupyter Notebooks and other Analysis Gateway abstractions
- Encourages participation in Jupyter Notebook, git, conda, and Docker ecosystems, which facilitate more reproducible research and team science
- Brings clinical researchers in closer contact with data scientists, informatics architects, and computer programmers
- Enables quick prototyping for new methods and tools
- Enables sharing of complex data to bioinformaticians

i2b2 (Informatics for Integrating Biology and the Bedside): i2b2 is a scalable informatics framework designed for translational research. i2b2 was originally designed to support cohort identification, allowing users to perform an enterprise-wide search on a de-identified repository of health information to determine the existence of a set of patients meeting certain inclusion or exclusion criteria. Building on this precedent and with the appropriate regulatory approvals, i2b2 can also facilitate recruitment of this cohort when the study is launched. The informatics tool is also instrumental in addressing population health questions and comparative effectiveness and outcomes research. *i2b2 data facts and patient stats are provided (see inset).*

SHRINE (Shared Health Research Information Network): SHRINE is a web-based platform that connects i2b2 instances and facilitates queries of available data at multiple institutions to compile insights on large groups of well-characterized patients. Investigators may use i2b2/SHRINE to determine the aggregate number of subjects at participating institutions who meet a given set of inclusion and exclusion criteria (e.g., demographics, diagnoses, medications, and selected laboratory values). This information can provide the collaborative basis for clinical study feasibility and population-based research.

UAB Foundational Ontology (UFO): The UAB Foundational Ontology (UFO) is an enterprise terminology management system, currently under development, that brings together controlled terminologies used for capturing clinical and research data at UAB. In the UFO, terminologies are merged to support system interoperability. The UFO will also include additional classification (new classes and multiple classification), improved term naming, synonyms, and other knowledge to improve the usability and usefulness of controlled terminologies in clinical and research systems, such as i2b2 (see above).

Natural Language Processing and Clinical Phenotyping: One of the major initiatives of CCTS-Informatics has been to develop a Natural Language Processing (NLP) infrastructure to support the processing and analysis of unstructured clinical text and identify clinical phenotypes of interest. This NLP infrastructure is deployed within the UAB Health System and used to support the State of Alabama Cancer Registry reporting requirements by facilitating cancer case detection (Osborne et al, 2016). This NLP infrastructure processes UAB Health System clinical text nightly to detect cancer concepts as defined by the National Association of American Cancer Registries (NAACR), and then ascertains patient reportable cancer in conjunction with structured data by machine learning. We have improved cancer case detection throughput by 41% and process approximately 1,000 cases each month. We have extended this system (Osborne et al, 2018) to support cohort detection for retrospective research and actionable clinical phenotypes, including but not limited to COPD flares (Wells et al, 2018), opiate use disorder (Feldman et al, 2022) and incidental findings requiring intervention including adrenal gland

“incidentalomas (Vezev et al, 2022). Our NLP infrastructure also supports de-identification of clinical text through transfer learning (Osborne et al, 2020) and our IRB permits distribution of UAB clinical text (Osborne et al, 2020 last reference) under the terms of the HIPAA Safe Harbor standard after de-identification using both machine learning and manual review.

Development of this infrastructure through a partnership with the UAB Department of Computer and Information Sciences has also included utilization of NLP to improve the medical documentation skills of our medical students, and we are currently exploring opportunities to utilize NLP to facilitate national reporting in our transplant programs. We are also working on extending these tools to support the processing of records derived from clinical research studies to both support the research goals of the study as well as to support the entry of NLP-derived structured data directly into patient's electronic health record.

Clinical Research Services

The CCTS supports cutting-edge expertise and facilities for investigators conducting human subjects research. A centralized hub provides a supportive environment for early phase and task-intensive clinical research in humans. The CCTS provides cost-effective and high quality services that exemplifies best practice for every stage of the clinical research study lifecycle, from start up through implementation to close out. The CCTS Clinical Translation staff also offers trainings, from a lunch and learn series to a 6-month certificate program in the latest clinical and translational research competencies, to strengthen the research skills of every member of your team. The environment ensures safety and provides standardized pathways for the administration of investigational agents and the management of valuable patient samples essential for translational advances. CCTS clinical services include the **Clinical Research Unit (CRU)**, the **Phase I Clinical Trials Unit**, the **Child Health Research Unit (CHRU)**, the **Clinical Trials Administrative Office (CTAO)**, the **Clinical Research Support Program (CRSP)**, the **Specimen Processing and Analytical Nexus (SPAN)**, **CCTS Biorepository**, and the **Bionutrition Unit**. The Phase I Unit, the Bionutrition Unit and part of SPAN are housed on the 15th floor of Jefferson Tower, in immediate proximity to the CRU, which was renovated to become the central location for CCTS clinical services. The CHRU is located on the UAB campus within Children's Hospital of Alabama.

Clinical Research Unit (CRU): The CCTS has 15,450 square feet of dedicated clinical research space located on the 15th floor of Jefferson Tower. This space has two clinical units; The Clinical Research Unit (CRU) and the Phase I Unit. The CRU provides clinical services for investigator initiated clinical studies and Phase II and III clinical trials and the Phase I Unit provides services for Phase I clinical trials. The nursing staff support a wide range of clinical research including, but not limited to aging, Alzheimer's disease, diabetes, hepatic disease, obesity, pain, psychiatry, reproductive health, nutrition, and various cancers. These units are supported by two nurses' stations and a pneumatic tube station to allow for quick transport of specimens to the hospital lab as well as receipt of some pharmaceuticals. The CRU is located on the west wing of JT 15 and has five examination rooms besides an infusion suite with six infusion chairs. In addition, the west wing has storage space for equipment and/or supplies that are specific to investigator needs. If inpatient care is required, the CRU has access to inpatient beds located on the 8th floor of UAB Hospital. Inpatient utilization focuses on studies requiring hospitalization of participants for proper study activities, ranging from 24 hour sample collection protocols to studies for which participant safety is best served by an inpatient setting. Pankit Vachhani, MD, is the Medical Director of the CRU, and Joshua Vernon, RN serves as the Nurse Manager for the CRU. The nursing staff includes four full-time nurses, one part-time nurse, and seven nurses who work on an as needed basis. CRU nurses have extensive research experience with the infusion of research medications, monitoring of participants, collection of PK, PD, PG, and biomarker samples, data collection, and use of scientific research equipment. All nurses complete required hospital competencies, human subjects training, certification on pharmacokinetics and Good Clinical Practice (GCP) training.

Phase I Clinical Trials Unit: In 2013, the CCTS expanded the CRU by adding a 7,950 square foot Phase I Clinical Trials Unit. The unit is located on the 15th floor of Jefferson Tower, adjacent to the existing CRU and the sample processing facility. It is comprised of seven rooms to accommodate patients for the administration of research agents. Each room has the flexibility to be used as private or semi-private to

allow for maximum space utilization and appropriate participant monitoring. The unit also includes the capacity for the administration of standard of care drugs and routine infusions, which enhances the nurses' focus on the care given to those receiving Phase I agents. A centrally located nurses' station supports the unit. The Phase 1 Program supports phase 1 trials including 'first-in-human' clinical trials in a variety of disease conditions, especially oncology. The Phase I program has an active working group with oncologists who are passionate about early phase clinical trials. Dr. Aparna Hegde, a thoracic oncologist, leads the Phase I program. Currently, the phase I program has cutting edge novel molecules encompassing immunotherapy, targeted therapies and precision oncology treatments.

Child Health Research Unit (CHRU): The CHRU was developed to provide a platform to improve our understanding of child health and childhood disease pathogenesis, and to accelerate the development of new treatments for diseases that are manifested in childhood. The CHRU is a partnership between Children's of Alabama, one of the largest and busiest centers for child health care and the third largest free standing pediatric hospital in the US, the UAB Department of Pediatrics and the CCTS. Its mission is to provide outpatient research space to pediatric investigators that reduce barriers to the conduct of scientifically rigorous clinical and translational research. The CHRU facilitates the execution of safe and age-appropriate clinical research protocols in a flexible fashion to accelerate our understanding and treatment of childhood diseases.

The CHRU has expanded in May 2017 to establish a reception/registration area, triage room with scales and stadiometer, six well-equipped exam rooms, office and conference space, workspace with monitors & locked storage, lab space with centrifuge and freezer for short-term storage and an equipment storage room. Additional space is available to support primarily for ambulatory patients with special needs (e.g., respiratory conditions, such as asthma and cystic fibrosis) and it includes four outpatient beds (suitable for long-duration PK studies), a specimen processing laboratory, a state-of-the-art biospecimen storage facility with real-time monitoring and specimen-tracking capabilities, a nasal potential difference laboratory. Specialized equipment housed for CFTR clinical science are also housed in the satellite CHRU, including two sweat iontophoresis devices (each compatible with the Macroduct collection system), two sweat evaporimeters (Cyberderm RG), a carbon monoxide monitor, a Lung Clearance Index measurement device (EcoMedics) for use by the nitrogen washout technique, nasal and exhaled nitric oxide measurement (EcoMedics), two spirometers with calibration equipment (NSpire), the "Bento Box" isolation device for live nasal imaging of mucociliary transport in patients with acute respiratory disease, an EKG machine, a Code cart, and general laboratory supplies. Investigators and research coordinators have access to CHRU research space and equipment. All protocols that utilize the Unit must have a designated, protocol-specific physician with primary responsibility for the safe conduct of the study and must have IRB or WIRB approval. Details for study implementation are developed on a project by project basis, with input provided by the Clinical Research Support Program. The hours of utilization are flexible and can include after-hour visits.

Daniel Feig, MD, PhD, MSCI, and Isabel Virella-Lowell MD jointly serve as Co-Directors of the CHRU. In this capacity they oversee operations, set policies and procedures, assign project responsibilities, and in collaboration with the Clinical Research Support Program, review budget development for industry contracts, review IRB submissions and renewals, and direct weekly team meetings that include junior investigators and evaluation of potential projects. Dr. Feig is the Director of the Division of Pediatric Nephrology. He has broad training in Pediatrics, Biochemistry and Clinical Research. He is the former Chair of the American Board of Pediatrics Sub-Board in Nephrology, is currently on the American Academy of Pediatrics, Section of Nephrology Executive Board, and services as Education Director for the International Pediatric Hypertension Association. He has served as both an internal and external mentor for several K-awarded junior faculty members and is the Nephrology Training Program Director for the Pediatric Nephrology Fellowship Program at UAB. He is an expert in childhood hypertension, nephrotic syndrome, and renal transplantation. His current research focuses on the role of uric acid in early onset hypertension and progression of chronic kidney disease. Dr. Virella-Lowell serves directs the Cystic Fibrosis (CF) Therapeutics Development Network at UAB, as well as is a member of the UAB Lung Health Center. She has broad training in Pediatrics and Basic and Clinical Research. Dr. Virella-Lowell is also an

expert on studies that address fundamental aspects of CF disease, including studies examining CFTR modulators, relationships between CFTR activity and CFTR biomarkers, and new assay development.

Clinical Research Support Program (CRSP): The current research environment has been impacted by the increase in regulatory requirements, the decrease in funding due to the economy, and the challenge for research sites to manage unexpected events. Additionally, novice research coordinators and limited educational experience of study coordinators leaves research sites unable to cope with these challenges. In late 2010, the Center for Clinical and Translational Science (CCTS) developed the Clinical Research Support Program (CRSP) for the exclusive purpose of functioning as a modified institutional clinical research organization. This program was designed to provide any or all support for implementing a clinical (or non-clinical) study at UAB.

CRSP provides a pool of trained, certified research coordinators to assist investigators with study implementation, including interpretation and adherence to regulatory requirements, organizational and budget management, communication with sponsors, internal quality measures, and data management. Resource pooling provides flexibility and limits the need for individual investigators or programs to overstaff in order to handle sporadic needs. Additionally, trained and experienced research staff are capable of managing and implementing research studies more efficiently and effectively. CRSP personnel function in a flexible manner and provide services when and where needed. Most services and support are conducted at the study investigator's site. All staff received CCTS training, in addition to the standard human subjects training, certification on pharmacokinetics, and GCP training. Staff are also certified for working in UAB Hospital, the BVAMC, and Children's Hospital. Staff have experience in cardiology, cancer, endocrinology, nephrology, neurology, pediatrics, School of Public Health, infectious diseases, pulmonary, CV surgery, GI, and continues to expand. CRSP personnel ensure that investigators have the required research implementation resources and that research teams have the knowledge and skills for conducting protocols. They assist with pre-study activities such as site and study feasibility assessments, staff education and training, budget development and negotiations, DSMB plans, regulatory preparation (e.g., IRB, IND/IDE, Clinical Trials.gov, institutional requirements, sponsor requirements), site assessment visits, and study initiation meetings. They also provide study implementation services, which include subject visits and assessments, study report generation, maintenance of regulatory documents, budget maintenance, safety reporting, quality management assessments, monitoring/preparation for monitor visits, subject retention efforts, and data and specimen management. Finally, CRSP staff provide services related to study closure, including study closeout visits, reconciliation of final data, final study reports, and archiving.

Additionally, CRSP provides educational programs to better serve the research needs of the CCTS Partner Network by building courses to increase knowledge and training for all members of the investigative team. Some of the programs that have been implemented so far are bi-weekly comprehensive research seminars that incorporate Good Clinical Practice training (GCPs), monthly research orientation program, bi-annually research training program, an investigator training program, various workshops (budget, IRB, Clinical Trials.gov) and templates for Standard Operating Procedures (SOPs).

Specimen Processing and Analytical Nexus (SPAN): SPAN is the central clearinghouse for sample collection, login, handling, and storage for clinical research studies at UAB. SPAN also assists investigators in specimen distribution to other UAB analytical Cores, investigator laboratories and outside laboratories. SPAN consists of two laboratories on campus, all within a two-block radius. The clinical trials specimen-processing laboratory (704 sq ft) is located within the CRU and Phase I clinic in Jefferson Tower and facilitates centralized collection and preparative activity of specimens from participants in clinical trials. This laboratory is equipped for BSL2 level work including use of laminar flow biosafety cabinets. Specimen processing capacity for the handling of blood, urine, CSF, and other liquid specimens includes two refrigerated centrifuges, eight non-refrigerated centrifuges and tube rockers. Centrifuges can accommodate all specimen collection tubes and can achieve centrifugation speeds of up to 4740xg. Specimen storage capacity includes a refrigerator, a non-cycling -20°C freezer and three -80°C freezers. More sophisticated laboratory space for specimen processing and specimen long-term storage is located in the Shelby Interdisciplinary Research Building (2350 sq ft that includes wet lab space, data management-computer space and dedicated freezer space). This laboratory provides more specialized procedures

including DNA/RNA isolation and quantitation/quality control and the capacity to isolate and cryopreserve or immortalize peripheral blood mononuclear cell from blood. Equipment includes 3 refrigerated centrifuges (Beckman and IEC capable of up to 3210xg), 6 non-refrigerated centrifuges (Hettich and IEC), tube rockers, pipets, incubators, and fume hood. Sterile cell isolation and culture facilities include 4 laminar flow biosafety cabinets, 3 Forma CO2 incubators, inverted Olympus microscope and 2 Invitrogen Countess automated cell counters. DNA extraction capacity includes an Autogen Flexstar automated DNA extraction system. DNA quality control is assessed by both absorbance and fluorescence based systems including a Tecan Infinite Pro 200 (absorbance + fluorescence) with nanoquant adaptor, the Trinean Dropsense (absorbance) and the Thermo Qubit (fluorescence).

Both laboratories are capable of packaging and shipping biospecimens domestically and internationally. Staff are fully trained in IATA shipping standards and the labs have standing orders for dry ice. All SPAN activities are fully integrated with CCTS/UAB clinical activities using the OnCore clinical trials management system. Within OnCore, a full specimen inventory of all biospecimens handled in the lab is maintained at the individual tube level. Relevant specimen associated collection information can also be associated with each individual specimen aliquot. This system has full reporting capabilities and a record of chain of custody. SPAN actively works with investigators to develop specimen process protocols that meet the needs of each individual study and develops/implements new methods as required. Studies utilizing the core cover a broad range of translational research. SPAN protocols range from complex therapeutic clinical trials with PK/PD blood processing needs, to glucose tolerance tests in healthy controls with frequent blood sampling to simple phlebotomy of healthy controls for preparation of blood-derived materials (serum, plasma, buffy coats, PBMC, DNA). A strict quality control plan is in place that includes daily validation of all data entry into our inventory system and documentation of all storage (freezer, refrigeration, ambient) temperatures. There are also regular assessments of inventory integrity and freezer temperature mapping. We participate in an international proficiency testing program (IBBL, Luxembourg) to validate our aliquoting, DNA isolation and PBMC isolation/viability techniques. There are standard operating procedures in place for all methods used in the lab including the use of barcoded labeling to facilitate specimen tracking. We also prepare individualized SOPs for every protocol that uses our laboratory. These SOPs are referenced each time a protocol's specimens are accessioned into the lab.

Biorepository: The CCTS Biorepository, also in the Shelby laboratories, provides access to standard operating procedures for biobanking and a full spectrum of long-term specimen storage options for studies using the CCTS. We currently have 967 sq ft of dedicated freezer storage space available for long-term biospecimen storage. Total storage capacity includes an array of 16x -80°C and 7x liquid nitrogen cryogenic freezers. All cryogenic freezers are equipped with automatic LN2 filling valves. Freezers are inventoried to the individual tube level using the Biospecimen Management module of OnCore. All freezers throughout the CCTS SPAN Biorepository are centrally monitored for alarms with call lists in the event of a freezer malfunction. In addition, every freezer has an independent NIST-certified temperature probe monitored by an on-line temperature monitoring system Temptrak (Cooper-Atkins) that provides escalating text/email/phone notifications in the event of a malfunction or an out of range temperature value. In addition to physical sample management, the CCTS has established a link with the UAB i2b2 instance where available specimens are linked to available EHR data through the MRN. UAB Investigators can search for specimens in an aggregate basis associated with clinically relevant parameters to enable scientific investigation and enhance our capacity to serve our populations. The CCTS Biorepository would act as an honest broker to connect the recruiting study team with the requesting investigator. This process connects investigators but does not obligate sample sharing; rather it connects investigators to determine whether they would like to pursue a collaborative relationship that may involve biospecimens.

Bionutrition Unit: The Bionutrition Unit, Clinical Research Unit (CRU), fosters the integration of nutrition into clinical and translational research by providing nutrition research expertise and resources for investigators. The Unit offers a number of core services.

- **Research design, development, and implementation**—this includes one-on-one assistance with the initial research design, calculating research diets, providing menus and meals as required by protocol, help with participant recruitment and retention, development of nutrition data collection forms, and data collection.

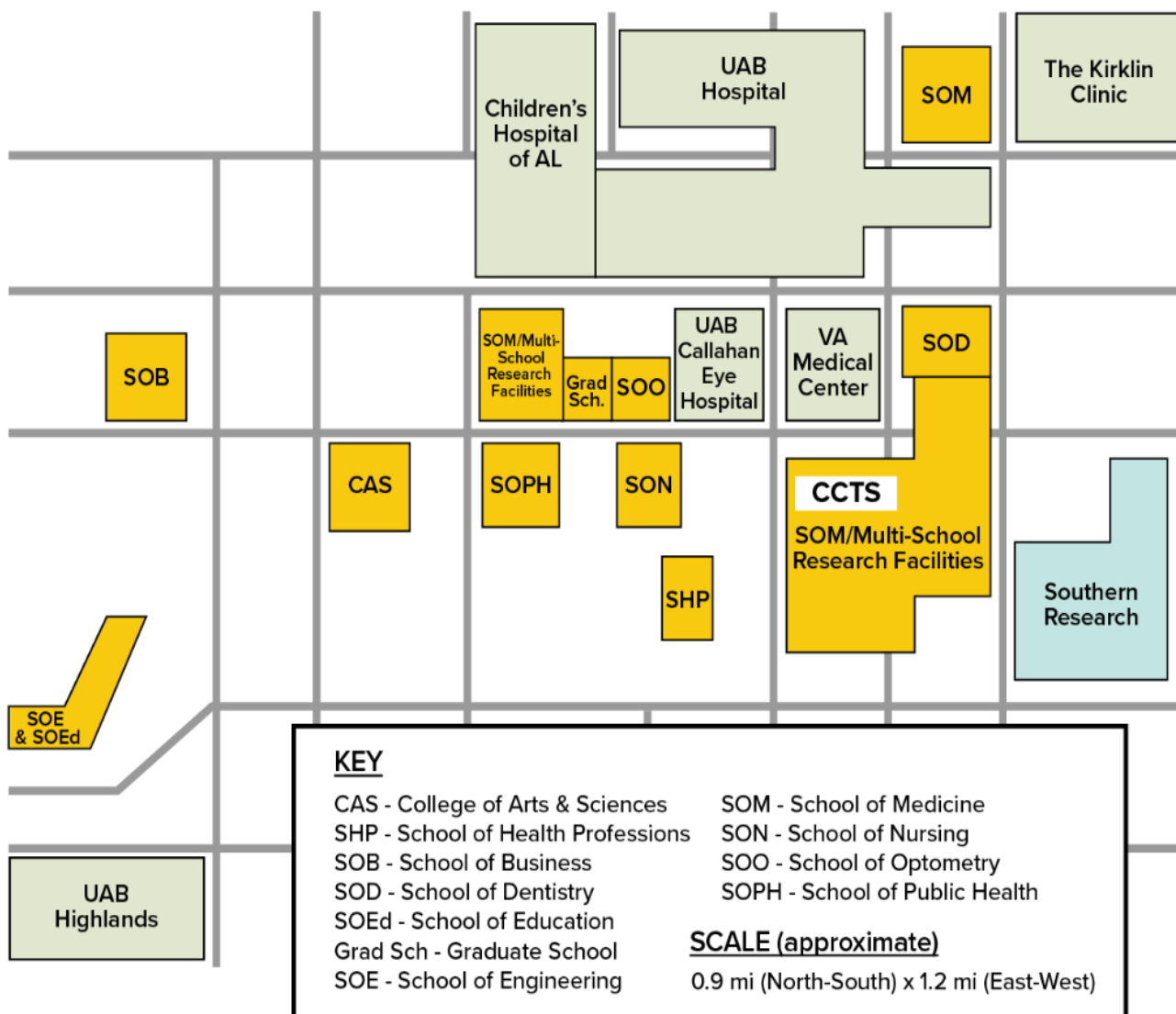
- **Nutrition education**—assistance with educating participants about dietary protocols and assistance with specific diet prescriptions and other individual or group counseling as needed.
- **Body composition analysis**—standardized height and weight measurements, anthropomorphic measurements (skinfold thickness and body circumferences), and bioelectric impedance analysis (BIA) to determine body composition (fat free mass, body fat mass, percent body fat), using a Tanita body composition analyzer TBF-310 and BC-418, a Scaletronic digital scale, a Biodynamics bio-impedance analyzer, a stadiometer to measure height electronically, and Lange calipers.
- **Nutrient Intake Analysis**—analysis of 24-hour food recalls, multiple-pass food records using Nutrient Data System for Research (NDS-R) software, a comprehensive nutrient calculation software that can perform analyses of 139 nutrients, nutrient ratios, and other food compounds. Customized research menu development for controlled feeding studies-using ProNutra dietary analysis software to plan, manage and analyze food as well as creating customizable reports and printouts of production sheets, labels, and menus. A state-of-the-art Metabolic Kitchen that provides ideal infrastructure to prepare specially-designed research diets for participants in outpatient-based studies; a multi-purpose room is also available for nutrition studies that require on-site feeding. The staff includes one full-time and one part-time research dietitians and five designated research cooks that have many years of experience implementing detailed nutrition interventions studies.

Recruitment and Retention Shared Facility

Since 1997 the Recruitment and Retention Shared Facility (RRSF) has offered recruitment of participants for any study, including help with developing recruitment and retention plans; identifying participants and targeting them with culturally relevant messages; consenting, enrolling, and scheduling participants; providing databases in requested format; generating standard or customized reports; access to data analysts, statisticians, and epidemiologists with expertise in health disparities; and retention services for follow-up data collection. The RRSF is collaboratively supported by the CCTS and overseen by the Minority Health Equity Research Center. It provides an experienced team that has enrolled more than 50,000 participants for more than 117 studies since 1997. Our Team includes project planners and coordinators, telephone interviewers, data managers and analysts, community outreach personnel, and patient navigators. We have experience with population-based studies, therapeutic clinical trials, behavioral intervention trials, telephone surveys, focus groups, and in-person qualitative interviews, as well as a proven record of recruiting African Americans and women.

UNIVERSITY OF ALABAMA AT BIRMINGHAM (UAB; CCTS Hub)

UAB is a comprehensive urban university with over 22,000 students from across the US and internationally. As a state-affiliated institution, UAB ranks 12th nationally federal research support among public universities, with a sponsored projects portfolio exceeding \$849 million (FY2021). The University of Alabama at Birmingham, one of three autonomous institutions within The University of Alabama System, is the only four-year, public university in the state's largest metropolitan area. The University spans more than 100 blocks in the city center with over 245 buildings providing over 400 acres and 18 million gross square feet of building space. UAB is Alabama's largest employer with an annual economic impact exceeding \$7.15 billion. As of the fall of 2022 (most recent data), the University employed over 24,000 people, had a faculty of 3,096 (46.7 percent of whom are female), and had a student enrollment of 22,289 at the undergraduate through doctoral levels. The graduate student population is 67.7 percent female and 41.5% are among minority ethnicities. UAB is comprised of 10 academic colleges and schools in the health sciences and academic areas. The UAB Academic Health Center includes the Schools of Medicine, Dentistry, Nursing, Optometry, Public Health, Health Professions, the Graduate School, and the Lister Hill Library of the Health Sciences. The University's academic campus consists of the College of Arts and Sciences, the Collat School of Business, the Schools of Education and Engineering, the Graduate School, and the Mervyn Sterne Library. The university has 244 endowed chairs/professorships. The Institution has been ranked among the top quarter of all U.S. colleges and universities by The Princeton Review, and among the top 10 for diversity for several consecutive years. The University is also a pillar for employee excellence as a top10 employer in the South.



INSTITUTIONAL RESEARCH ENVIRONMENT & EXPERTISE IN CLINICAL AND TRANSLATIONAL SCIENCE

UAB Office of Research: In support of the research endeavors of a dynamic institution, the administration reporting to the Office of the Vice President for Research develops and improves processes and services that promote research and scholarship by faculty, staff, and trainees, that foster an environment of integrity in research and scholarship, that improve the quality of research, and that enhance economic development. The Office of Research also works with the University, school administrations, and city and state leaders to establish new programs and research directions that promote and enhance the UAB's contribution to new knowledge and the growth of the economies across the city and the state. Administrative units include the Office of Sponsored Programs (OSP), Conflict of Interest Review Board (CIRB), Institutional Review Board (IRB), Animal Resources Program (ARP), Institutional Animal Care & Use Committee (IACUC), Occupational Health and Safety (OH&S) and the Office of Sponsored International Programs (OSIP). Working in close affiliation with UAB Research Administration and individual Offices, the CCTS serves translational researchers to optimize business and oversight practices in support of research and training. The CCTS training programs have implemented to bolster the development efforts of researchers and the promotion of research excellence.

UAB Institutional Review Board (IRB) and Office of the IRB (OIRB): The UAB IRB is a committee established under federal regulations for the protection of human subjects in research (45 CFR 46). Its purpose is to help protect the rights and welfare of human participants in research conducted under the auspices of UAB. The UAB IRB requires Principal Investigators and all other research team members to complete and document appropriate training in the protection of human subjects. Additionally, the IRB monitors ongoing research for adherence to applicable regulations, policies, and procedures. The UAB IRB is located in the UAB Administration Building, with 4,526 square feet of office space and conference rooms, and housing 23 staff.

UAB Office of Sponsored Programs (OSP): The UAB Office of Sponsored Programs (OSP) is a central office reporting to the Vice President for Research and Economic Development. The OSP offices are located in 6913 square feet of office space within one and a half city blocks from the Veterans Affairs (VA) Medical Center and Coordinating Center in Faculty Office Towers (FOT). The OSP assists UAB's faculty and staff in their efforts to secure and fulfill extramurally sponsored programs by performing pre-award and non-financial post-award administration. The OSP is charged with the following (including but not limited to): performing preliminary review and approval of all proposal submissions, submitting proposals through most awarding agency portals including Grants.gov, and serving as representative of the UAB business office with official signing authority. The UAB OSP also negotiates execution of clinical trial agreements and other extramurally sponsored projects to include research, selected services, non-sponsor funded collaboration, master agreements, continuing professional education agreements, and confidentiality/data use agreements. The OSP provides ongoing training for the campus, principal investigators, department administrators, and center administrators to include workshops and other structured opportunities. The UAB Research Administration Listserv from the OSP distributes latest updates, news, and information to the UAB community. There are 10 OSP officers supporting federal grants management and 8 officers assigned to non-federal awards. In addition, the OSP staffs 10 data processing specialists for the data management of the OSP activities including UAB's Integrated Research Administration Portal (IRAP). IRAP's software consists of a suite of modules developed by InfoEd Global Inc. These modules support electronic submission of funding applications and compliance forms and will seamlessly connect the operations of the OSP with the Institutional Review Board for Human Use (IRB) and UAB Research.

University-Wide Interdisciplinary Research Centers: The University-Wide Interdisciplinary Research Center (UWIRC) program was proposed in 1995 to promote interdisciplinary research, education, and service. It was implemented with initial funding in 1997 for ten "full" centers and seven "pilot" centers. Since its inception, this program has played a major role in promoting interdisciplinary, cross-institutional research collaboration at UAB. The UWIRC program serves to catalyze cross-cutting research and discovery while adding to the generation of new scientific knowledge and its applications to benefit society. University-wide thematic centers provide a framework for research and training. These multidisciplinary centers are open to all investigators with interests consistent with the mission of the given center. The centers assist in coordinating thematically

oriented efforts for extramural grants and contracts, in developing center-associated core facilities and in integrating enrichment programs that are important trainee resources. Approximately every five years, each UWIRC was selected through a competitive selection process. To be designated a UWIRC, centers require sponsorship from at least three UAB schools, substantive interdisciplinary faculty involvement; contribution to the intellectual environment in order to enhance faculty and student recruitment, development, and retention; an extramural financial base to support center and core activities; internal and external review processes to ensure quality and productivity; and leadership in the integration of research and service including community outreach or partnerships. Through a competitive review process, the Deans of sponsoring Schools and the Provost provide modest funds for research cores, pilot and feasibility studies and selective enrichment activities. The Center for Clinical and Translational Science, a university-wide center, integrates essential resources and services for clinical and translational research for all faculty and centers and has developed a jointly sponsored pilot program in translational research.

UAB Minority Health & Health Equity Research Center (MHERC)

The UAB Minority Health & Health Equity Research Center (MHERC) is a University-Wide Interdisciplinary Research Center approved by the University of Alabama Board of Trustees. The Center provides UAB faculty with an infrastructure for conducting innovative research to improve the health status of vulnerable and disadvantaged populations and expands the participation of minorities in research and education. Gaps in health outcomes exist between the general population and groups of people who experience systematic obstacles to health based on their race or ethnicity, socioeconomic status, geographic location, or other characteristics linked to exclusion. Nowhere are such health gaps more evident than in the South, home to some of America's poorest communities. These communities lack resources such as a clean environment, grocery stores, and safe streets. As a result, their residents are exposed to multiple daily stressors and bear the burden of many chronic diseases. Strategically located in the heart of the region, the UAB MHERC provides a critical connection between investigators and vulnerable populations. The MHERC research and training programs enable young scientists to pursue research on health disparities. In contrast, our community outreach program identifies urgent health questions and needs and implements evidence-based strategies to reduce health disparities and promote health equity. Our work highlights the millions of underserved minority men, women, and children whose lives are impacted through our efforts.

O'Neal Comprehensive Cancer Center

The O'Neal Comprehensive Cancer Center at UAB is Alabama's only cancer center designated by the National Cancer Institute and is a national leader in driving cancer research, advancing new cancer treatments, engaging communities in cancer prevention and early detection initiatives, and training the next generation of cancer physicians and scientists. From bench to bedside, the O'Neal Comprehensive Cancer Center is at the forefront of improving cancer prevention, diagnosis and treatment, and scientists and clinician-scientists at UAB have pioneered advances in chemotherapy, surgery, radiotherapy, immunotherapy and nutrition. Our community outreach efforts reach vulnerable populations by providing the region with educational and prevention programs. The O'Neal Comprehensive Cancer Center offers a full array of treatment options from multidisciplinary clinics filled with experts from across cancer fields to the latest state-of-the-art technology. The center is home to an outstanding faculty of roughly 400 clinicians, scientists and clinician-scientists, many of whom are internationally and nationally recognized for their expertise in oncology. The O'Neal Cancer Center treats approximately 20,000 patients annually, with an estimated 5,000 new patients each year.

Center for the Study of Community Health (CSCH)

Founded in 1993, the UAB Center for the Study of Community Health is one of the 26 Prevention Research Centers across the US funded by the Centers for Disease Control and Prevention. The Center focuses on reducing health risks among underserved populations throughout the state of Alabama and plays a leading role in developing community-based participatory research (CBPR) at the University of Alabama at Birmingham (UAB). One of the original awardees and continuously funded since 1997 by the UAB UWIRC Program, the Center offers a unique prevention research environment that involves Center Scholars from each of UAB's schools and the College of Arts & Sciences, including clinicians, social and behavioral researchers, health-related professionals, and community leaders who are collaborating to improve the lives of Alabamians and others around the world. The CSCH has as its geographic focus a defined rural

region (the Alabama Black Belt) and an urban setting (Birmingham-Hoover MSA). Three primary community partnerships have developed as a result of the Center's educational, research, and service activities in communities that make up these regions. With support from the Center, the West Central Alabama Community Health Improvement League (WCACHIL), Congregations for Public Health (CPH), and Birmingham United Neighborhoods (BUN) formed infrastructures that enabled them to incorporate as nonprofit organizations. To expand support for our core research project and other initiatives in the urban setting, the Jefferson County Community Participation Board provides ongoing, broad-based community input and guidance in the planning and implementation of Center research, education, and service activities.

UAB's Harbert Institute for Innovation and Entrepreneurship: The Bill L. Harbert Institute for Innovation and Entrepreneurship (HIIE) assists UAB faculty, staff, and students to protect and commercialize their inventions. HIIE fosters an ecosystem that promotes and sustains innovative and entrepreneurial excellence through the building of relationships between research and industry in the local community, and beyond. HIIE strategically evaluates, protects, and licenses technology while also providing resources for patenting, funding, and startup formation. With total research expenditures exceeding \$602 million, UAB is a powerhouse for academic, clinical and research innovation. The HIIE facilitates rapid development of new ideas, products and technologies and prepares faculty, students, and researchers to become entrepreneurs in an increasingly technology-driven ecosystem. To date, the HIIE office has received more than 2,800 intellectual property disclosures, facilitated the issue of more than 600 U.S. patents, and assisted with the creation of nearly 75 companies based on UAB technologies, generating more than \$100 million in total revenue.

Innovation Depot

Innovation Depot is an off-site business incubator facility and program in Birmingham, AL, that resulted from a public-private economic development effort funded by the Birmingham regional business community, the Community Foundation of Greater Birmingham, and other local private foundations. Innovation Depot is home to approximately 110 startup companies that employ more than 1,500 individuals. Innovation Depot has worked to propel economic growth and job creation in the region by supporting the development of emerging technology, biotechnology, and life science businesses for over 30 years. In addition to offering business incubation space, The Depot runs three signature programs focused on helping founders successfully envision, launch, and scale up their companies. UAB, the City of Birmingham, and Jefferson County have all collaborated with Innovation Depot to form one of the largest co-working spaces in the Southeast and the largest nonprofit tech incubator building in the country. With over 100 entrepreneurial companies located in-house, Innovation Depot offers UAB students unmatched networking, professional opportunities, and an entrepreneurial learning environment that is truly "real-world.". Centrally located within close proximity of the UAB academic health center, the financial district, and the entrepreneurial district, Innovation Depot provides a wide range of support to infrastructure for emerging biotechnology/life science start-ups, information technology operations and service businesses for UAB.

UAB Center for Teaching and Learning

The purpose of the UAB Center for Teaching and Learning (CTL) is to provide UAB faculty with professional and teaching support programs and to encourage teaching effectiveness and innovation on campus. To align with the objectives of the UAB Strategic Plan, the CTL is on the leading edge of the University's efforts to promote innovative instructional practices, develop UAB's world-class faculty members, align teaching, learning, and mentorship development programs, and foster a culture of learning that supports and encourages academic, professional and personal development for UAB students, faculty, and staff. Through CTL workshops, individual and group faculty consultations, and school and departmental presentations, the CTL promotes student learning by helping UAB faculty to develop the knowledge and skills to become better teachers. The CTL is open to all UAB faculty and is focused on supporting excellence in teaching across the UAB campus. Each year the CTL offers more than 200 workshops for faculty that earn points and badges towards certification. Research shows that effective teaching by University faculty leads to higher levels of student success and higher rates of student recruitment and retention. The Center also plays a key role in supporting the University's ongoing accreditation efforts and the Quality Enhancement Plan. The QEP theme, "Learning in a Team Environment" is focused on increasing the use of effective team-learning strategies in

UAB classrooms. In the spirit of professional development, CTL programs provide certification avenues that fortifies the CCTS Hub workforce and elevates our CCTS training acumen.

UAB Informatics Institute

The Informatics Institute was established in the School of Medicine in 2015 to accelerate and enhance these activities within the school and coordinate with relevant activities in other schools. The Institute is the de facto home for an informatics faculty, drawn from multiple clinical and basic science departments, who collaborate with other biomedical researchers and each other, to apply informatics solutions to biomedical research and healthcare tasks as a means to understanding fundamental challenges. This understanding, in turn, serves as the basis for their own research into developing new informatics methods and tools for addressing the future tasks. The Institute is also establishing undergraduate, graduate and postgraduate educational programs to train the next generation of informatics practitioners and researchers. Informatics Institute faculty and staff lead and conduct research across the biomedical informatics spectrum. Our faculty and staff have expertise in bioinformatics, computational and systems biomedicine, translational informatics, clinical research informatics, and clinical informatics. Informatics contributes toward timely prevention of diseases in individuals and communities, and is rapidly advancing health care and biomedical research. The Informatics Institute's members contribute their expertise to facilitate medical, biomedical and translational research at UAB and around the world, through partnerships and collaborations with experimentalists and clinicians. The Informatics Institute is training the next generation of informatics researchers by offering educational programs and teaching informatics at the undergraduate, graduate and postdoctoral level. The Institute offers a dynamic learning environment for students with a variety of courses available and the opportunity to participate in cutting-edge research within the Institute. The Informatics Institute, in collaboration with CCTS Informatics, provides:

- Tenured and tenure-track faculty who can advise and collaborate on the design and execution of biomedical research studies generating and utilizing large datasets.
- Consultation services that comprise software, hardware, data sets and methodologies, to provide “one stop shopping” informatics support.
- Support for researcher access to clinical data through the Enterprise Clinical Data Warehouse and the i2b2 data repository.
- Research and development on creating new tools and extending existing ones (such as i2b2).
- Education and training of undergraduate, graduate, and postgraduate trainees through courses, journal clubs, seminars, and research opportunities.

Schools and Colleges

School of Medicine (*est. 1945; Anupam Agarwal, MD, Dean and Senior Vice President of Medicine Chair, Health Services Foundation Board*)

As the largest School within the University of Alabama at Birmingham, one of the South's premier research universities, the Heersink School of Medicine is dedicated to the education of physicians and scientists in all of the disciplines of medicine and biomedical investigation. The school provides medical education and internship opportunities for students throughout the world. Its comprehensive approach to teaching future physicians covers all facets of medicine, including medical education, research, and patient care -- delivered in one of the most technologically advanced medical facilities in the country. The school is made up of nearly 800 students, more than 1100 residents, and over 1600 full-time faculty in 27 academic departments. The UAB School of Medicine has nationally recognized clinical programs in many areas including, but not limited to, Oncology, Neurology, Psychiatry, and Immunology/Rheumatology. UAB is also a national leader in organ transplantation. Many of UAB's most productive extramurally-funded research centers are based in the UAB School of Medicine, including the Comprehensive Cancer Center, Comprehensive Diabetes Center, and Center for AIDS Research. The UAB School of Medicine is also a national leader in research with a long track record of proven success being ranked in the top 30 of NIH funded Schools of Medicine for more than 20 years.

- **Department of Medicine:** The department is driving medical education, accelerating discovery, and delivering competent and compassionate patient care. It offers clerkships, residencies, fellowships, and professional development for students. The department ranks #17 in the nation in NIH research and has award-winning scientific discovery programs. Research focuses range from whether pig kidneys

can alleviate the transplant shortage to how to encourage healthy lifestyles in disadvantaged communities.

- **Department of Pediatrics:** The department is dedicated to improving the health of children; discovering and applying important new knowledge to improve the outcomes for pediatric disorders. The faculty educates patients, families, and health care providers to become future leaders in children's health. Ranking among the top 20 departments of pediatrics in the country in NIH funding, the research focuses on neonatology, infectious diseases, and rare diseases.
- **Department of Family and Community Medicine:** The department is a recognized leader in the fields of clinical care, premedical education, practice-based research, and student health services. The department provides education programs and curricula for medical students including residencies, fellowships, and preceptorships. It also coordinates practice-based research on a local, regional and national scale. Key research areas include health disparities and chronic disease, lifestyle medicine, women's health, mental health, and brain health.
- **Department of Genetics:** The department is committed to genetics and genomics research, education, and clinical care. The faculty focuses on performing laboratory and clinical research, providing consultation services, and offering state-of-the-art genetic diagnostic testing. The department offers undergraduate, graduate, and clinical training, and seminars for students. The key research focus is along the continuum from fundamental studies to preclinical investigations, to bench-to-bedside translation, to clinical practice and community implementation.
- **Department of Surgery:** The department is committed to impacting the field of surgery through innovative clinical, basic and translational research, paving the way for improved treatment options for patients. Faculty lead residency programs and fellowships dedicated to training a new generation of surgeons. With millions in funding, the research focuses on understanding and application of advanced surgical procedures. The depth and breadth of the department's faculty's expertise provide patients with superior care and surgical treatments.
- **Joint Health Sciences:** Within the academic health system, the Joint Health Sciences (JHS) represents a set of coordinated units embraced by the Schools of Medicine, Optometry and Dentistry that are based on shared goals in teaching and research missions. These include the Departments of Biochemistry & Molecular Genetics; Biomedical Engineering (in the School of Engineering); Cellular, Developmental, and Integrative Biology; Genetics; Microbiology; Neurobiology; Nutrition Sciences (in School of Health Professions); Pathology; and Pharmacology & Toxicology. In order to leverage the expertise throughout these programs, the JHS Departments provide faculty leadership in graduate/first professional training, mentorship, curricula development, interdisciplinary research as well as participating in institutional roles in multiple schools.

School of Public Health (*est. 1981; Paul C. Erwin, MD, DrPH, Dean*)

The UAB School of Public Health (SOPH) offers the opportunity to join a vibrant community of professionals and scholars whose world-class research and scholarship is exploring complex problems like HIV/AIDS, obesity, and therapeutic intervention in creative and unusual ways. The UAB School of Public Health is also the only accredited school of public health in the state of Alabama. The interests of the faculty and staff extend from community organization in the Black Belt regions of rural Alabama to understanding the dynamics of the HIV epidemic in Sub-Saharan Africa. The institution offers a highly interdisciplinary, collaborative atmosphere to support the missions of training and research excellence. With active research programs in diabetes, cardiovascular diseases, cancer, infectious diseases, and Alzheimer's disease, School of Public Health faculty interact with key researchers within the CCTS Network Partnership. The Department of Epidemiology offers a Master of Science in Public Health in Clinical and Translational Research, a one-year MSPH program available for CCTS TL1 trainees to complete during their training (please see TL1 description).

- **Department of Biostatistics:** The Department of Biostatistics at the School of Public Health at UAB is a leader in collaborative medical, public health, and statistical genetics research. Biostatistics is the statistical analysis of health related data and how data from clinical trials and population studies impact human and public health. Students who concentrate in biostatistics are interested in how data, population studies, and health intersect. They study advanced statistical methodologies and apply them to better understand health trends among populations. They interpret results of statistical analyses from public health studies and translate the information into easily understandable facts for scientific and

non-scientific audiences. Faculty in the department work hand-in-hand with researchers in public health, medicine, nursing, and other health-related disciplines to help improve health.

- **Department of Environmental Health Sciences:** The mission of the Department of Environmental Health Sciences is to foster excellence in scientific research, teaching/training, outreach, and practice in EHS with the goal of identifying, understanding, and preventing environmentally and occupationally related diseases and injuries in Alabama, our region, the United States, and globally. Environmental Health Sciences (EHS) focus on protecting human health from environmental and occupational pollutants and exposures, such as those that arise from poor outdoor and indoor air quality, poor water quality, waste products, and workplace hazards. Environmental health professionals seek ways to improve our environment and reduce exposure to pollutants to promote health and prevent disease. Those trained in EHS keep people safe and healthy in the community, at home, and at work.
- **Department of Epidemiology:** The Department of Epidemiology studies trends, patterns, and causes related to disease in populations. Students who concentrate in epidemiology are interested in how diseases spread among given populations. Epidemiologists create complex analytical models to help us understand the causes of and solutions to these diseases more clearly. Graduates of the UAB Epidemiology program have found employment in academia, research organizations and foundations, industry, public and private health services delivery organizations, and international agencies.
- **Department of Health Behavior:** The Department of Health Behavior addresses the behavioral, social, and cultural factors related to or driving individual and population health and health disparities. Students in this program apply social and behavioral science theories and methodology to predict and explain health-related behaviors as well as develop and evaluate health promotion and disease-modifying and prevention programs. Emphasis is placed on the importance of community-based participatory research and the application of research findings through a variety of behavioral and social science health promotion strategies. Classes are engaging, interactive, and relevant to current health issues.
- **Department of Health Policy and Organization:** Students in the Department of Health Policy and Organization (HPO) develop skills in managing and leading the development of policy in a variety of settings. Students in UAB School of Public Health concentrations learn policy skills relevant to the practice and scholarship of public health. Health Policy and Organization focuses on skills needed for leading and managing public health organizations. Health Policy focuses on building the analytical skills required to recommend or evaluate systems or policy changes. Those students with a particular interest in the complex health considerations for the Maternal and Child Health (MCH) population can gain additional skills in comprehensive systems development and evaluation from a Life Course approach. Outcomes Research, emphasizing the clinical side of public health, focuses on the evaluation of the effectiveness and cost-effectiveness of specific health care interventions or treatments. UAB faculty, staff, and students are highly engaged in “real world” public health. We partner with local, state, national, and international agencies to understand the impact of policies on populations and systems.

School of Health Professions (*est. 1969; Andrew J. Butler, MPT, MBA, Ph.D., Dean*)

The UAB School of Health Professions, one of the largest health professions schools in the nation with more than 25 innovative programs, shapes the future of healthcare through teaching, research, and translation of discoveries into practice. The UAB School of Health Professions has the #1 ranked MSHA program in the nation and is the highest ranked academic program at UAB. The UAB SHP also provides several programs that are exclusive to UAB in the state of Alabama. To improve the quality of health around the world, UAB SHP listen to needs and identify real-world problems while focusing our resources and expertise to address those problems. Collaborative efforts are made to tailor innovative teaching and research to solve problems and partner with strategic community, business, and global leaders to expand the impact of our efforts. The UAB School of Health Professions' strategy uniquely positions us to lead efforts to inspire quality health and living of individuals, communities, and the world.

- **Department of Clinical and Diagnostic Sciences:** The Department of Clinical and Diagnostic Sciences is comprised of academic programs essential to today's healthcare system. The U.S. Bureau of Labor Statistics says healthcare is one of the fastest growing occupational sectors from 2010-2020, adding 3.4 million more new jobs. To help prepare students to enter this quickly growing field, the department's undergraduate and graduate programs provide academic and hands-on experience that

can be applied to many different professions in health care. They are taught in a variety of disciplines ranging from diagnosis of illness and disease, administration of advanced treatment therapies, and performance of vital roles in surgical suites, plus outpatient and inpatient healthcare settings. CDS programs are essential to today's healthcare system. Graduates work in disciplines diagnosing illness and disease, administering advanced treatment therapies, and performing in surgical and trauma settings plus outpatient and inpatient healthcare.

- **Department of Health Services Administration:** Home to the top ranked program at UAB – the #1 in the nation Master of Science in Health Administration – HSA has been shaping the future of health care for more than 50 years. They will continue to do so for the next 50 years and beyond with top-ranked education programs taught by world-renowned scholars.
- **Department of Nutrition Sciences:** The UAB Department of Nutrition Sciences is the global leader in lifestyle wellness, incorporating nutrition and lifestyle research and education to prevent chronic disease and facilitate optimum health and wellness in everyone. We also translate the science of nutrition and lifestyle into real-world programs and initiatives that improve people's lifestyle wellness in order to create a happier, healthier world.
- **Department of Occupational Therapy:** The UAB Department of Occupational Therapy focuses on providing opportunities for education, training, and research to allow students to explore the different avenues for their careers. Our faculty works closely with each student throughout their entire time at UAB, and for the Master of Science in Occupational Therapy applicants, this relationship starts during the interview process. Students also have access to training in specialized areas in the Post-Professional Clinical Doctorate in Occupational Therapy (OTD) and can take both this degree and the Low Vision Rehabilitation Graduate Certificate program online (the certificate program has an on-campus requirement).
- **Department of Physical Therapy:** The Department of Physical Therapy has offered outstanding educational programs in physical therapy since 1964. Currently, UAB offers the Doctor of Physical Therapy program for students who want to become physical therapists, an interdisciplinary PhD in Rehabilitation Science program, and a Neurologic Physical Therapy Residency program for physical therapists interested in specializing in neurologic physical therapy

School of Nursing (est. 1969, *Maria Rodriguez Shirey, PhD, MBA, MS, RN, NEA-BC, ANEF, FACHE, FNAP, FAAN, Dean*)

The UAB School of Nursing offers innovative bachelor's, master's, and doctoral programs under the leadership of an interdisciplinary clinical and research faculty vested in developing the next generation of compassionate nurses committed to contributing to the improvement of the health and quality of care for individuals, families, and populations. Among these are the oldest and most honored PhD in Nursing and a Doctor of Nursing Practice (DNP) and Nurse Anesthesia Track; a Master of Nursing program with more than 15 nurse practitioner specialty tracks with dual degree options, advanced nursing executive majors in administration and informatics, and an Accelerated Master's in Nursing Pathway (AMNP) program for students who already have one degree, among other unique opportunities. Most graduate courses are taught in a distance accessible format with on-campus intensives. The UAB School of Nursing is designated as a Pan American Health Organization/World Health Organization Collaborating Center for International Nursing, one of 10 in the U.S. Additionally, the School is one of three Paul D. Coverdell Peace Corps Fellows programs and is one of the leading VA Nursing Academic Partnerships in the US. The UAB School of Nursing is a leader and trendsetter in collaborative science and home to the state's only nursing-specific research initiative with a diverse funding portfolio supporting scholarship in oncology, international nursing, HIV/AIDS, pediatrics, occupational health, aging, among others, and offers students opportunities to learn and investigate with faculty and student teams from nursing, medicine, dentistry, health professions, public health, and optometry. The UAB School of Nursing is home to an innovative nursing simulation and skills laboratory, which provides faculty and students with interprofessional learning opportunities. Faculty hold more than 70 appointments in university-wide research centers.

School of Dentistry (est. 1945; *Nicolaas Geurs, DDS, MS, Dean*)

The University of Alabama at Birmingham School of Dentistry was created by an act of the state legislature in 1945, the same year that the School of Medicine moved to Birmingham from the university campus in Tuscaloosa and became a four-year school. The School of Dentistry admitted its first class of students in

October 1948 and blends the rich tradition of a school founded over 70 years ago with cutting-edge technology and contemporary programs and facilities. The UAB School of Dentistry is comprised of seven academic departments and a variety of educational programs that span the major dental specialties. The goal of the UAB SOD is to educate a progressive oral health workforce and advance science to optimize oral health throughout our state, the nation, and the world. We offer a premier learning experience, abundant lifelong learning opportunities, and cadre of auxiliary programs supported by internationally recognized faculty and a strong network of alumni and community partners. Students are exposed to both depth and breadth of clinical experiences, while students and faculty can participate in both clinical and laboratory research within areas like craniofacial development/genetics, biomaterial science, oral microbiology and infection/host response, oral cancer, and clinical outcomes/implementation science. Through our comprehensive clinical operations, innovative practices, and robust community collaborations, we provide high-quality patient care for residents of Alabama and surrounding areas.

School of Optometry *(est. 1969; Kelly K. Nichols, OD, MPH, PhD, FAAO, Dean)*

The School of Optometry was established in 1969. Since that time, the School of Optometry has grown to include graduate degrees (MS, PhD) in Vision Science and post-doctoral residency education in addition to the 4-year professional program. The UAB School of Optometry is located within the UAB Academic Health Center, which affords our students the opportunity to be surrounded by health professionals and researchers in a variety of disciplines. Students can also participate in combined OD/MS, OD/MPH, OD/MBA degree programs with other health professional students, unique to our university. As one of the smaller optometry schools in the country, the school offers a competitive enrollment that benefits the world-class educational environment with a family feel. Also, as one of the top optometry programs in the nation, UAB School of Optometry is the first in the U.S. to be fully integrated into an academic health center. Recently re-accredited to 2025, the School of Optometry has a first-rate reputation for educating optometrists and vision scientists from across the country, primarily from the South-Eastern region. Their faculty is among the best known in the country through their lectures, research and publications including many national and international textbooks, service on editorial boards, and Newsletters for optometrists. Their clinical service is widely respected for the excellent patient care including several new specialty clinics, myopic control clinic, dry eye clinic, and vision therapy clinic in the UAB Eye Care clinic, a 34,000 square foot state-of-the-art facility that covers everything from primary eye care, including the dispensing of glasses and contacts, to the treatment of ocular disease and pediatric vision care. The school also houses and supports the Vision Science Research Center (VSRC), a campus-wide center with over 80 investigator members from across campus, with the common commitment to vision research. The core facilities allow vision researchers to successfully compete for research funding and this support has aided the School of Optometry research profile to remain among the top schools and colleges of optometry. Collectively, these commitments help the school in its mission to educate optometry students, residents, and future scientists; to discover and broadly communicate new principles and concepts in eye care and vision science; to translate these ideas into clinical practice; and deliver health care with integrity and compassion.

School of Education and Human Sciences *(est. 1971; Teresa Taber Doughty, PhD, Dean)*

The School of Education and Human Sciences provides an innovative environment that promotes professionals in education, health, and wellness in collaboration with content experts in associated academic areas. The UAB SOE is driven to create the most prepared, inspired, and dynamic practitioners in the workforce today with cutting-edge programs that prepare professionals to serve in a diverse world. We want to help each and every one of our students become the absolute best-prepared practitioner fully capable of working in any setting, whether it be urban, suburban, or rural. This collaboration in developing strong professionals is emblematic of UAB's interdisciplinary, collaborative culture, strengthening cooperation between departments and programs for excellence in research and scholarship where students can thrive in an open environment with a bold, innovative approach to education.

School of Engineering *(est. 1971; Jeffrey W. Holmes, MD, PhD, Dean)*

The UAB School of Engineering embraces a collaborative mission, supporting projects that bring engineers together with medical professionals, business leaders, and fellow scientists from other disciplines, in order to push the envelope and discover new, innovative solutions for the challenges in the world. With renowned faculty spread across five academic departments, the School of Engineering provides undergraduate students

with a solid foundation in engineering fundamentals with a curriculum focused on experiential learning opportunities and progressively advanced hands-on applications. With more than 15 graduate degree programs and tracks to choose from at the master and Ph.D. level, as well as a variety of certificate programs, UAB offers highly adaptable programs that range from traditional M.S./Ph.D. pathways to online Master of Engineering degree tracks for working professionals. It is likewise committed to training at the undergraduate and graduate levels, where student engagement in design projects is prioritized throughout the curriculum.

Collat School of Business (*est. 1971; Christopher L. Shook, PhD, Dean*)

Located in the heart of Alabama's business center, UAB's Collat School of Business offers an engaging learning environment with classrooms extending well beyond the walls of the UAB campus. The school's unique location allows faculty to integrate the practical experiences of the State's leading companies - from Fortune 500 corporations to entrepreneurial startups - into the programs it offers. Students gain valuable, real-world experience through a wide variety of internships, career coaching and planning, and other opportunities in the business community. The Collat School of Business is accredited at the baccalaureate and master's levels by AACSB International and holds supplemental AACSB International accreditation for our undergraduate and master's programs in accounting, an accomplishment held by less than 2% of business schools worldwide. The school offers eight undergraduate programs in accounting, economics, finance, human resource management, industrial distribution, information systems, management, and marketing. It offers three graduate programs in accounting, business administration and management information systems as well as certificates in technology commercialization and entrepreneurship, social media, enterprise systems, and professional sales. All undergraduate and graduate programs are delivered in Face-to-Face and Online formats to serve the varying needs of students.

College of Arts and Sciences (*est. 2010; Kecia M. Thomas, PhD, Dean*)

The UAB College of Arts and Sciences was formed in 2010 with the integration of the schools of Arts and Humanities, Social and Behavioral Sciences, and Natural Science and Mathematics. Today, the college is home to 19 academic departments, 9 interdisciplinary programs, and 5 centers. The College of Arts and Sciences also offers 40 baccalaureate undergraduate majors and 23 graduate programs. In addition to our more than 5,000 majors, nearly every student pursuing a baccalaureate degree at UAB takes their core curriculum classes in the College of Arts and Sciences. To ensure that each student leaves UAB with the tools they need to succeed in an expanding and increasingly complex world, the College of Arts and Sciences is dedicated to helping them develop the following skills and competencies: ethical and moral reasoning, the Scientific Method, communication, cultural competence, and confidence in the "Face of Complexity". The college includes more than 300 full-time faculty members, approximately 59% percent of whom are tenured.

- **Department of Computer Science:** The Department of Computer Science at the University of Alabama at Birmingham provides an excellent learning environment for both undergraduate and graduate students, and is proud to be part of UAB, one of the top universities in the nation that are ranked as "R1: Doctoral Universities — Highest Research Activity" in the Carnegie Classification of Institutions of Higher Education. Continuing our success in scholarly research, department faculty are challenging the boundaries of knowledge in four focused research areas, including cyber security, data science and analytics, biomedical applications, and advanced cyber infrastructures (encompassing cloud computing, high-performance computing, and the Internet of Things). Our faculty's research has been funded by both major federal agencies and industrial technology giants. Additionally, we collaborate closely with researchers from other universities, industries, and government agencies.
- **Department of Criminal Justice:** The J. Frank Barfield Jr. Department of Criminal Justice offers undergraduate programs in Criminal Justice and Digital Forensics, and graduate programs in Criminal Justice, Forensic Science, and Cyber Security. We also offer a graduate-level joint degree program in Criminal Justice/Master of Public Administration in partnership with the Department of Political Science and Public Administration. We are the proud home to the university's Pre-Law Program, jointly sponsored with the Department of Political Science and Public Administration and the Department of Philosophy. The department is affiliated with UAB's Institute for Human Rights and the UAB Computer Forensics Lab. Our comprehensive undergraduate curriculum prepares our students for careers in law enforcement, the courts, corrections, juvenile justice, cybercrime/computer forensics, graduate school,

and law school. Our Master of Science in Forensic Science program is one of only 16 FEPAC-accredited programs in the United States and one of the oldest, laboratory-based graduate training programs in North America. Our Master of Science in Criminal Justice program is now available 100% online and is geared to working professionals seeking an advanced degree. Our Master of Science in Cyber Security program is one of the few programs of its type in the world and is geared toward training the next generation of cybercrime investigators and cybersecurity specialists—specialties that continue to be in high demand. Faculty in the J. Frank Barfield, Jr. Department of Criminal Justice are active research scholars who are also committed to excellence in classroom teaching.

- **Department of Sociology:** The UAB Department of Sociology offers the only PhD program in medical sociology in the state of Alabama, and more than 50 alumni having graduated with a PhD in medical sociology from UAB. With UAB's prestigious medical school, seven hospitals, and several on-campus clinics and medical research centers, there are numerous opportunities and fellowships for research and training. The Department of Sociology features faculty who are either teaching specialists or leaders in research in a research-intensive environment. The Social Determinants of Health Core of the Mid-South Transdisciplinary Collaborative Center investigating the health of African Americans in the Mid-South is housed in our department. It is funded by the National Center on Minority Health and Health Disparities (NCMHD) through the Division of Preventive Medicine at UAB and involves the participation of several graduate students, PhD alumni, and faculty. With the exception of few alumni who hold administrative positions, about half of graduates teach and conduct research in universities, while the other half conduct research full-time. Some are affiliated with medical schools (e.g., UAB, Harvard, South Carolina, Texas, Miami), schools of public health (e.g., UAB, Brown), and various colleges and universities in the US (e.g., UAB, William & Mary, Mary Baldwin, Tuskegee, Mississippi State, Western Kentucky, Middle Tennessee, Akron) or abroad in Europe and Asia.
- **Department of Social Work:** The mission of the UAB Department of Social Work is to promote social justice and advance health equity for vulnerable populations through anti-racist and anti-oppressive teaching, research, and service designed to effect change at local, state, national, and global levels. The Bachelor of Science in Social Work (BSSW) program prepares students for generalist social work practice with diverse populations. Our Master of Social Work (MSW) program is one of the few in the nation that has a sole focus on clinical/medical social work, and it prepares students for practice in health and behavioral health settings. Both programs are fully accredited by the Council on Social Work Education (CSWE). UAB's Undergraduate Social Work Program was established in 1976 and was fully accredited in 1977. Since its inception, Social Work at UAB has partnered with several departments, such as Political Science and Public Administration, Anthropology, Public Health, and Sociology. In 2011, Social Work became an independent department within the College of Arts and Sciences and has remained committed to evidence-based research, innovative teaching models, and service leadership. The UAB Department of Social Work remains housed in University Hall, a state-of-the-art facility overlooking the Campus Green.

UAB Libraries (*est. 1945, Kasia Gonnerman, PhD, Dean*)

The UAB Libraries provide access to an array of rich and diverse scholarly resources that inform intellectual, cultural, social, and economic transformation of its community. It also provides the essential expertise to support excellence in education, research, patient care, and community outreach that collectively advance the success and impact of the University of Alabama at Birmingham. The UAB Libraries' collections include over 1.4 million volumes and more than 40,000 journals and serials, in addition to extensive electronic resources, rare books, microforms, and audio-visual materials. The UAB Libraries host nearly 1 million patrons each year and support students and faculty in advancing their learning, research, and teaching. UAB Libraries administratively merged in 2015 to provide shared services, such as a single catalog, and achieve economies of scale while collectively expanding access to digital resources. UAB Libraries encompass the Lister Hill Library of the Health Sciences, the Lister Hill Library at University Hospital, the Mervyn H. Sterne Library, UAB Archives, UAB Digital Collections, Reynolds-Finley Historical Library, the Alabama Museum of the Health Sciences, and an off-site storage facility termed the "801 Building".

- **Lister Hill Library of the Health Sciences:** The largest biomedical library in Alabama, was established in 1945. Located in the heart of the academic medical center, LHLHS provides a variety of reference and educational opportunities ranging from one-on-one instruction at point of need to scheduled

workshops on using library resources. The collections of the library span seven centuries of knowledge with medieval manuscripts and some thirteen thousand rare books, bound journals and books in the various health science disciplines, archival records and photographs, and electronic access to thousands of online journals and books. Access to electronic resources is available across the campus and remotely to authorized users. The library catalog is also available on the web and can be used to search for print, electronic, and media holdings. The library has a liaison program with its constituent schools. It also provides a variety of reference and educational services plus extensive education opportunities through one-on-one instruction at the point of need or in scheduled workshops that address the library's resources, information retrieval, and emerging technologies. A recent renovation of physical space increased group study rooms from 7 to 18 and added ergonomic furniture for individual study in public spaces and access to 3-D printers.

- **The Lister Hill Library at University Hospital:** The Lister Hill Library at University Hospital (LHL@UH) is a branch location of the Lister Hill Library of the Health Sciences. The library primarily serves hospital staff and is not open to the general public. The mission of LHLUH is to provide the staff of University Hospital with accurate, reliable, and timely information in support of patient care, education, and research. LHLUH is located in the West Pavilion and provides clinicians onsite support for education, research, and patient care.
- **Mervyn H. Sterne Library:** When UAB was formed in 1969, a small extension division library existed. From that beginning, the Mervyn H. Sterne Library emerged and has developed into a major academic library through numerous expansions and renovations since inception. The Sterne Library's collections support teaching and research in the arts and humanities, business, education, engineering, natural sciences, mathematics, and social sciences. In addition to more than 1 million print and electronic books and subscriptions to over 41,000 periodicals, the library also provides users with access to specialized databases, audio-visual materials, microforms, and other electronic resources. The Sterne Library has seating for more than 1,150 users. In addition to serving the University community, Sterne Library provides support to users from schools and businesses within the city and the state through various partnership agreements and maintains a collection of over one-million items and rapidly expanding access to digital resources in support of teaching and research in arts and humanities, business, education, engineering, natural science and mathematics, and social and behavioral sciences. The Sterne Library recently consolidated services to a new single desk and added ergonomic study spaces. A Maker Space is staffed by engineering students.
- **UAB Digital Collections:** UAB Digital Collections is an online repository for UAB Libraries and the university's digital collections, enabling the preservation, access to, and promotion of the collections. UAB Digital Collections was established in 2006. The mission of UAB Digital Collections is to identify and deposit material which reflects the needs of the University's academic, research, and service programs. The digital collection supports the library's goal of accessibility to provide "the members of the University community with access to the highest quality information resources required for teaching, scholarship, research and service." Some of the items in the collections include historical and health-science related materials, UAB publications, electronic theses and dissertations, audio and visual materials, digitized books and manuscripts, faculty- and course-related materials.
- **UAB Archives:** The function of the UAB Archives is the appraisal, collection, organization, description, and reference use of the University of Alabama at Birmingham's (UAB) official records of enduring historical value. Reference service is provided to both the university community and the general public. All persons who visit the UAB Archives to conduct research are interviewed by staff to determine the scope of research and the most effective research strategy in the usage of UAB records. Staff will explain applicable usage restrictions during this interview. Patrons are also required to register during their research visit. For members of the university community, the UAB Archives accepts mail, telephone, e-mail and in-person reference requests and provides research support on a case-by-case basis. The archives does not conduct research for students or complete student assignments. When the UAB Archives is unable to provide research support due to staff availability, time or financial constraints, members of the university community will be encouraged to utilize the UAB Archives in person to conduct research. For members of the general public, the UAB Archives accepts ready reference requests via mail, telephone, e-mail, or in-person. Ready reference implies easily obtainable, quickly disseminated public information which does not have to be tabulated for dissemination and which is readily obtainable from archives sources.

- **Reynolds-Finley Historical Library:** Named in 2014 due to a gift from Sara J. Finley and Randall W. Finley that honors their father, Dr. Wayne H. Finley. A new endowment was established for the continued enhancement and expansion of the medical historical collections. In recognition of this significant gift and of Dr. Finley's longstanding commitment to medical history at this university, the Reynolds Historical Library was renamed the Reynolds-Finley Historical Library (along with Dr. Lawrence Reynolds. The Reynolds-Finley Historical Library, a growing collection of over 20,000 rare books, manuscripts, journals, and pamphlets pertaining to the history of medicine, science, and health care, dating from the 1300s through the mid-1900s. The library is free and open to the public.
- **Alabama Museum of the Health Sciences:** The Alabama Museum of the Health Sciences is dedicated to the preservation and display of equipment, instruments, and objects that represent the history and development of the health sciences in the areas of education, research, and practice in the United States with special emphasis on the state of Alabama and its contributors to the practice of medicine. Notable artifacts include small ivory 16th and 17th century anatomical models, a collection of wax moulage and an antique iron lung. The scope of the collection includes but is not limited to the following fields: medicine, nursing, ophthalmology, dentistry, public health, and allied health. The Alabama Museum of the Health Sciences is currently undergoing renovation and expansion.
- **The 801 Building:** The 801 Building has a treasure trove of vinyl albums, CDs, and other formats of music and spoken word recordings. Music genres in the collection include jazz, classical, rock, country, musicals, and more. The collection also includes spoken word recordings, such as poetry and plays. Most items in the collection can be found in the central database, OneSearch. The 801 Building is a remote storage facility where less-frequently requested items in the collection are kept. These items remain available to library users and can be requested through our courier service. A sampling of items stored here include journals from the Sterne Library dating from 1999 and back, microfilm, microfiche, cassettes, albums, kits, and print books. Many of the items here may be of interest to individuals doing historical research.

GRADUATE EDUCATION AND POST-GRADUATE TRAINING

UAB offers over 85 doctoral, master's and educational specialist programs designed to help you obtain a rewarding career aligning with your professional goals. In addition, UAB offers the Office of Professional Studies and Experiential Learning (OPSEL) to further hone skills and competencies for graduate scholars. OPSEL hosts the Interdisciplinary Graduate Studies MA and MS degree programs (IGS) as well as numerous opportunities for professional, leadership, and career development experiences.

Graduate School (*est. 1970; Shadi Martin, PhD, Dean*)

Established in 1970, the UAB Graduate School offers doctoral programs in 40 areas, post-masters education specialist programs in 8 areas, and master's level programs in 55 areas, spanning across the disciplines. There are multiple support systems – administrative, financial, health care and career counseling. To facilitate the wide spectrum of ongoing research, state-of-the-art facilities are found all over campus. UAB's research centers, lecture halls, labs, classrooms, dorms, greenways, hospitals, libraries, student center, recreation center and performing arts center occupy 82 city blocks inside Birmingham, Alabama. The Graduate School supports graduate students and post-doctoral fellows with an extensive Professional Development Program, as well as monthly Discoveries in the Making events connecting students to the community. The diverse makeup of UAB Graduate School includes students, faculty, and staff who proudly represent over 100 countries, including 7,665 graduate students involved in research.

Graduate Biomedical Sciences Program (*David Schneider, PhD, Associate Dean*)

The Graduate Biomedical Sciences (GBS) program at UAB encompasses approximately 380 graduate students and 375 faculty. Trainees participate in multiple interdisciplinary thematic programs that integrate more than 25 departments in the School of Medicine; partner schools throughout the university; Southern Research (an affiliated drug discovery and development institute); and HudsonAlpha Institute for Biotechnology. UAB is consistently among the top 25 institutions in the US for NIH research funding and is currently in the top 15. The GBS program provides its graduate students the flexibility, guidance, resources, and training to become highly competitive for outstanding postdoctoral and professional positions. UAB offers eight interdisciplinary training pathways in the Graduate Biomedical Sciences, including: Biochemistry, Structural, and Stem Cell Biology; Cancer Biology; Cell, Molecular, and

Developmental Biology; Genetics, Genomics, and Bioinformatics; Immunology; Microbiology; Neuroscience; and Pathobiology and Molecular Medicine. Working closely with the GBS Program, the CCTS has been instrumental in developing a Translational & Molecular Sciences certificate program to enhance the graduate curriculum.

Office of Postdoctoral Education (*est. 1999*)

The University of Alabama at Birmingham Office of Postdoctoral Education is committed to the development and success of outstanding postdoctoral scientists. Nearly 300 postdocs are training currently in a variety of disciplines, including but not limited to engineering, medicine, natural sciences & mathematics, public health, and optometry. The goal of the OPE is to provide postdoctoral fellows with the opportunities and skills they need to be successful in their chosen careers. The UAB Office of Postdoctoral Education and the UAB Postdoc Association work together to develop career opportunities that enhance and define the training experience for all postdoctoral scholars at UAB. Past and continuing events include courses in grant writing, lab management, translational science, & job skills, structured programs in teaching and business entrepreneurship, and awards for career enhancement, travel, grant incentives, and internships. The possibilities for academic and research-related careers are ever changing. As such, OPE aims to prepare postdoctoral fellows for these possibilities.

Office of Professional Studies and Experiential Learning (OPSEL)

OPSEL is home to UAB's Interdisciplinary Graduate Studies degree programs (MA & MS), multiple graduate certificates, and numerous other academic, leadership, and professional development opportunities. Offerings are open to anyone affiliated with UAB interested in advancing their knowledge, skills, and career with post-baccalaureate studies. UAB Undergraduate Students may also enroll in our academic courses with permission from their academic advisor and the course instructor. OPSEL embodies UAB's education mission by offering interdisciplinary academic and professional development programs designed to support leadership and career advancement among diverse student populations. Everyone is welcome to take a class, earn a certificate, attend a free informational seminar, or workshop, or drop by for holistic academic support or career transition consultations.

UAB Division of Continuing Medical Education (*Ronan O'Beirne, EdD, MBA, MSEE, Director*)

The Division of Continuing Medical Education (CME) at UAB strives to be a national leader in defining and delivering meaningful learning opportunities for healthcare professionals to improve patient and community health. The Division's CME program strengthens the UAB Health System through the quality, scope, and diversity of its educational activities. Topics include traditional areas of basic science, clinical medicine, patient care, and public health, as well as more contemporary themes of quality improvement, patient-centered care, leadership, and others within the Accreditation Council for Graduate Medical Education's professional core competencies. The mission of the Division of CME is to develop and provide a professional development program for physicians and physicians-in-training that is effective in increasing knowledge, awareness, and competence; enhances physician performance; and improves patient and community health. UAB CME sponsors a wide variety of educational initiatives including single- and multi-day live courses, regularly-scheduled series, print and Internet enduring materials, journal-based activities, and performance improvement activities. The type of educational format used to deliver educational content is determined by a number of factors but is driven by the needs of the target audience, evidence of desired outcomes, and important principles of adult learning and theories of human behavior change. The CME group supports the broader School of Medicine's tri-part mission of research, education, and clinical practice, working together with other units within the spectrum of medical education, faculty development, and quality improvement.

Information Technology (UAB IT)

CCTS Informatics Facilities: CCTS Informatics personnel are located in offices in the in the Beville Biomedical Research Building (BBRB) (500 sq. ft.), the Tinsley Harrison Tower (900 sq. ft.), and the Kaul Human Genetics Building. A small Data Center is located in BBRB (250 sq. ft.) that houses several development and backup servers. Most computational hardware is located in facilities allocated to the Research Computing unit of Central UAB-IT (see below).

CCTS Informatics Computer Equipment: The CCTS has direct use of a large collection of servers, storage systems, workstations, laptops and peripherals. Most servers have now been migrated to virtual machines supported by Central UAB-IT, though several stand-alone application and data storage systems are maintained directly by CCTS personnel in CCTS facilities. Separate servers are utilized for web sites, database systems (MySQL, SQL Server, Oracle), data entry and curation databases, application development, database development, web site development, bioinformatics analysis, backup, and failover. A combination of Windows and Linux operating systems are utilized by server systems. These systems include CCTS-supported Dell PowerEdge (PE) servers and Dell PowerVault (PV) storage systems that provide in excess of 350 TB of disk storage. These systems includes three Dell PE R710 servers, two with 192 GB RAM and 7 TB of storage and the third with 96 GB of RAM and 7 TB of storage; two PV NX3200 storage arrays, each with 48 TB of SAS disk storage; two PE R730x systems each with 72TB of SAS storage; one PV MD3400 with 96TB of SAS storage; and 4 PE 2950/2850 servers. All servers are connected to the campus network backbone using 1GE (gigabit per second ethernet) network connections to the building's router. The building utilizes a 10GE connection to the 40GE campus backbone as described below. Additional petabyte-scale storage utilized by the CCTS is provided locally within the UAB Research Computing infrastructure. In total, CCTS activities have 1-2 PB of storage directly available for use, with the ability to grow that as needed. All data is backed up using a combination of local network-attached disk storage arrays, long-term S3-based backup storage provided by Research Computing, and essentially unlimited off-site archival storage provided through UAB's contract with Box. All data maintained by CCTS Informatics that contains PHI (protected health information) is housed either within the Health System's HIPAA-compliant data processing facility or the HIPAA-compliant high performance computing system provided by Research Computing (Cheaha) (described below). All other systems outside of these secured facilities contain only non-PHI, de-identified datasets.

CCTS personnel utilize a combination of PC and Macintosh desktop and laptop computers for daily activities. All data is stored either in Box, or in UAB's shared high-performance computing (HPC) environment.

UAB Information Technology Operations: The responsibility for campus network, IT resources, and IT security resides with the UAB Office of the Vice President for Information Technology. UAB Health System IT operations are provided by the Health System Information Services (HSIS) unit. The CCTS utilizes services and resources provided by both UAB-IT and HSIS. Within UAB-IT, the Research Computing unit provides shared, subsidized access to computing resources supporting all research, including CCTS-conducted and supported projects. Most resources provided by Research Computing are provided at no cost for routine processing needs. A cost schedule can be arranged for large capacity needs (more than several hundred TB of storage or reserved allocations of high capacity HPC nodes to individual projects).

UAB Information Technology Facilities: In 2021 UAB IT moved into a new building, the 37,500 square foot Technology Innovation Center (TIC) that houses the campus data center, data storage facility, campus and offsite network connectivity, IT administrative offices, and a colocation facility for partners in distributed IT. High-capacity power and cooling is supplemented by a Tesla Powerpack battery system. In addition, to serve as an offsite compute and storage facility, UAB IT leases space within DC BLOX, a private entity that provides a data center in downtown Birmingham, within 2 miles of the UAB campus. DC BLOX has available a 31,000 square foot colocation facility providing 48U lockable cabinets, 100/200 GE connectivity, and high-capacity power and cooling.

UAB Network Infrastructure

On-campus Network Connectivity: The campus network backbone is based on a 40 GE redundant Ethernet network with 480 gigabit/second backplanes on the core L2/L3 Switch/Routers. Connection between UAB IT's Research Computing facilities that support local high performance computing resources, local campus storage facilities, and off-campus hosted storage and compute facilities at DC BLOX is served by a 200 GE network. For efficient management, a collapsed backbone design is used. Each campus building is connected using 10 GE links over single mode optical fiber. Within multi-floor buildings, a 10 GE building backbone over multimode optical fiber is utilized. Category 6 or better unshielded twisted pair wiring is used to connect desktops to the network with 1 GE default desktop connections. Computer server clusters are connected to the building entrance using Gigabit Ethernet. All CCTS servers and desktops have 1 GE connections. The campus wireless

network blankets classrooms, common areas and most academic office buildings. The UAB network has the capability to establish high speed connections between data intensive research facilities across the institution. This network can support very high-speed secure connectivity between nodes for high speed transfer of very large data sets without the concerns of interfering with other traffic on the campus backbone; thus ensuring predictable latencies.

Off-campus Network Connections: The UAB network supports direct connection to high-bandwidth regional networks. UAB connects to the Internet2 via the University of Alabama System Regional Optical Network (UASRON), a University of Alabama System owned and operated DWDM Network offering 100 GE connections to the Southern Light Rail (SLR)/Southern Crossroads (SoX) in Atlanta, Ga. The UASRON also connects UAB to the University of Alabama in Tuscaloosa, and the University of Alabama in Huntsville, and the Alabama Supercomputer Center. UAB is also connected to other Alabama universities and schools (including CCTS Hub sites) through AREN (Alabama Research and Education Network). Connection to the commodity Internet is via Gigabit Ethernet, of which UAB currently uses approximately 3.0 Giga-bits-per-second (expandable as needed).

High Performance Computing Resources

UAB Shared High Performance Computing (HPC) Facility: The UAB HPC Facility provides UAB and CCTS researchers with a shared software and hardware infrastructure along with the necessary support for high performance parallel and distributed computing, numerical tools and information technology-based computing environments, and computational simulation. Expansion and use of this computational and storage infrastructure is subsidized by UAB-IT and the office of the Vice President for Research. Through these subsidies, investigators are provided access to all shared HPC resources at no cost for routine processing needs (such as for the analysis of next generation sequence data).

Primary campus HPC Facility: The core computer resources for the Research Computing System is Cheaha, a commodity cluster totaling over 8,192 CPU cores and 72 GPUs. Compute nodes are interconnected via an InfiniBand network and provide over 1,240 TFLOP/s of aggregate theoretical peak performance. Over 15 petabytes (PB) of raw, high-performance storage is also available and connected to these compute nodes via the InfiniBand network. Cheaha, including processing and storage, has been certified as HIPAA-compliant, and is therefore available to store data sets obtained from electronic health records and human research protocols that contain PHI.

Cheaha provides users with both a web-based interface via open OnDemand and a traditional command-line interactive environment via SSH. These interfaces provide access to many scientific tools that can leverage a dedicated pool of local compute resources via the SLURM batch scheduler. The local compute pool provides consists of five generations of computer hardware based on the x86 64-bit architecture. Gen6 (2015-2016) includes 96 nodes: 2x12 core (2304 cores total) 2.5 GHz Intel Xeon E5-2680 v3 compute nodes. Of the 96 compute nodes, 36 nodes have 128 GB RAM, 38 nodes have 256 GB RAM, and 14 nodes have 384 GB RAM. There are also four compute nodes with Intel Xeon Phi 7210 accelerator cards and four compute nodes with NVIDIA K80 GPUs. Gen7 (2017) is composed of 18 nodes: 2x14 core (504 cores total) 2.4GHz Intel Xeon E5-2680 v4 compute nodes with 256GB RAM and four NVIDIA Tesla P100 16GB GPUs per node. Gen8 (2019) is composed of 35 nodes with 2x12 core (840 cores total) 2.60GHz Intel Xeon Gold 6126 compute nodes with 21 compute nodes at 192GB RAM, 10 nodes at 768GB RAM and 4 nodes at 1.5TB of RAM. Gen9 (Q2 2021) is composed of 52 nodes each with 2x24 cores (2496 cores total) 3.0GHz Intel Xeon Gold 6248R processors and 192GB RAM each. Current compute nodes combine to provide over 1,240 TFLOPS of dedicated computing power. UAB Research Cloud Resources.

UAB Research Cloud Resources: Research Computing provides an OpenStack (private) cloud virtual machine resource to UAB investigators. This platform is used to support application development and DevOps processes to research labs across campus. This fabric is composed of five Dell R640 48 core 192G RAM compute nodes for 240 cores and 960GB of standard cloud compute resources. In addition, the fabric features four NVIDIA DGX A100 nodes that include 8 A100 GPUs and 1TB of RAM each. All these resources are available to the research community for provisioning on demand via the OpenStack services (Ussuri release).

This implementation further supports researchers by making their hosted services available beyond campus, while adhering to standard campus network security practices. Scientific software developers have access to the full stack for limitless development opportunities. with a frictionless migration path to public cloud providers as may be needed for specific research projects. A Kubernetes environment is also available to support automated workflows using Singularity and Docker containers.

Storage Resources: The compute nodes on Cheaha are backed by high performance, 6.6PB GPFS raw storage on DDN SFA14KX hardware connected via an EDR /FDR InfiniBand fabric and located in the TIC facility. An additional 10TB of traditional SAN storage is also available for home directories. Three new storage systems have been added in 2021. All three systems are based on Ceph with different hardware configurations to address different usage scenarios. The fabrics are a 6.9PB archive storage fabric built using 12 Dell DSS7500 nodes, an expanded 1.3PB nearline storage fabric built with 14 Dell 740xd nodes, and a 248TB SSD cache storage fabric built with 8 Dell 840 nodes.

Other Available High Performance Computing Resources: UAB is a member of the SURAGrid Virtual Organization (SGVO) on the Open Science Grid (OSG). This is a national computer network and consists of nearly 80,000 computer cores aggregated across national facilities and contributing member sites. The OSG provides operational support for the interconnection middleware and facilitates research and operational engagement between members. UAB and CCTS investigators also have access to the Alabama Supercomputer Center (ASC), a State-wide resource located in Huntsville, Alabama. The ASC provides UAB investigators with no cost access to a variety of high-performance computing resources. These resources include:

- A Dense Memory Cluster (DMC) HPC system with 3740 CPU cores and 26.1 terabytes of distributed memory. Each compute node has a local disk (up to 7.5 terabytes of which are accessible as /tmp). Also attached to the DMC is a high-performance Spectrum Scale storage cluster, which has 93 terabytes of high performance storage accessible as /scratch from each node. Home directories as well as third party applications use a separate BeeGFS volume and share 750 terabytes of storage. The DMC is connected to the internet via a 10 GE connection.
- A large number of software packages are installed supporting a variety of analyses including programs for Computational Structural Analysis, Design Analysis, Quantum Chemistry, Molecular Mechanics/Dynamics, Crystallography, Fluid Dynamics, Statistics, Visualization, and Bioinformatics.

Integrated Research Administration: UAB has implemented an Integrated Research Administration Portal (IRAP). The underlying software consists of a suite of modules developed by InfoEd Global Inc. IRAP supports electronic submission of funding applications and compliance forms and currently consists of eight fully integrated modules supporting the operations of the Office of Sponsored Programs (OSP), Institutional Review Board for Human Use (IRB), Institutional Animal Care and Use Committee (IACUC), Materials Transfer office, Environmental Health and Safety including the Chemical Safety Committee and the Radiation Safety Committee, and the Conflict of Interest Review Board. Other features of the system provide access to potential collaborators and automated notification of funding opportunities meeting user specified criteria. Additional applications support administration processes (Oracle), animal facility management (Bioware), and intellectual property submissions (Sophia).

Institutional Software Licenses (Partial Listing): A variety of software packages are available through institutional licenses maintained by UAB-IT. These include:

- Institutional campus-wide license for Oracle RDBMS.
- Institutional campus-wide Microsoft Campus Agreement and Microsoft Select programs that provide licenses for desktop and server operating system upgrades, SQL Server, Microsoft Office, and Microsoft program development tools.
- Access to the complete catalog of Microsoft products for STEM programs through Microsoft Dreamspark/Imagine.

- Institutional campus-wide licenses for Antivirus software (Sophos and Microsoft), EndNote, GraphPad Prism, Mathematica, MATLAB, LabView, IBM/SPSS, SAS, Qualtrics, Adobe Creative Cloud, VMWare, and others.
- The UAB Department of Biostatistics provides investigators with access to a wide range of statistical software including SAS, S-plus, SPSS, and R. They also maintain many more specialized software programs including some specifically for statistical genetics such as SAGE, SIMWALK, ALLEGRO, DANDELION, GENEHUNTER, MERLIN, MX, PEDCHECK, PHASE, PREST, SOLAR, FASTLINK, VITESSE, SIMLA, and SUPERLINK amongst others. For software development purposes, the group has access to compilers for Fortran, C/C++, Perl, and Java as well as Fortran and Java IMSL libraries.

CCTS Software Tools: CCTS Informatics supports a variety of bioinformatics tools that are available to be run from Cheaha. These include statistical packages such as R and MATLAB, a variety of standalone packages supporting quality control (fastQC, Picard Tools), alignment (Abyss, Velvet, BWA, Bowtie) visualization (IGV), variant calling (GATK, SnpEff, annoVar), RNAseq (STAR) and microbiome and metagenomic analysis (QIIME2, MOTHUR, PyNAST, UniFrac, HUMAnN3, MEGAN, MetaPhlan2,). We have also developed and make available an automated pipeline for 16S microbiome data analysis, QWRAP, that is based on QIIME2 and other components (PMCID: PMC4383038). These are just a few of the tools available from Cheaha. CCTS Informatics also maintains licenses and provides investigators with access to the Ingenuity Pathway Analysis tool suite and database that provides the ability to mine genomic and other –omics data for information on pertinent biological systems, networks, and pathways.

Operational Healthcare Information Systems

The UAB Health System (UABHS) through HSIS houses and supports over 3,600 servers and more than 350 applications and databases in a mostly virtualized computing infrastructure with a mix of operating systems including Windows, AIX, Linux (both Red Hat and SUSE), Solaris, zOS and Macintosh. The current storage for UABHS resides mostly on Hitachi Data Systems and provides over 10 Petabytes of storage across a redundant fiber channel network. Both data centers run on a 10Gig backbone, utilizing Cisco Nexus equipment, and have redundant 40 Gig connections between the primary and secondary data centers. Backups are done on tape and multiple disk arrays.

- Clinical, financial, and administrative data are managed on behalf of the UAB Health System and include patient demographics records available in the **Enterprise Master Member Index (EMMI) system**; lab results dating back over ten years; documents dating back over ten years; encounter records, showing paths of patients across the UAB Health System; clinical images, including CT, MRI, X-rays, and more; user audit trails, showing the usage of the data by operational and clinical staff. Multiple systems are in place, and an active program to enhance integration / interoperability has been underway for several years.
- **Horizon** is a UAB-developed web portal used across the UAB Health System. Horizon includes all inpatient discharge and operative notes, all The Kirklin Clinic outpatient documents and notes and all laboratory and imaging results, each of which is integrated with EMMI to ensure valid patient demographics on the front end of the process. No documents can be created without first selecting a valid EMMI patient, and this occurs via a self-developed CORBA PIDS (Patient Identification Service) implementation wrapped around EMMI.
- **The Cerner Millennium Core Clinical system** is used as our core clinical system, supporting a complete clinical environment, with medication management, bedside device integration, and clinical decision support via alerts and content as some of the primary features. Cerner Millennium objects allows for object based access to the Cerner system for the purpose of integration. Although we have direct database access as well, this is a preferred abstraction layer that protects both Cerner and their customers from breakage due to changes in the database layer.
- **The Cerner PowerInsight Clinical Data Warehouse** is used to support reporting, analytics, quality measures and data extraction for research, clinical and administrative operations within UABHS. PowerInsight feeds data into our i2b2/SHRINE (version 1.7) informatics framework.
- **Oracle SiteMinder** supports clinical trials with tools for scheduling patient visits, tracking completion targets, and tracking expenses and billings to enhance optimal protocol performance and appropriate financial management for the study sponsor. To date, the major focus has been financial management.

- **Forte Systems OnCore eClinical Solution** is used by the Comprehensive Cancer Center and the CCTS Clinical Research Unit for management of clinical trials.

Software Licenses (Partial Listing)

A variety of software packages are available through institutional licenses maintained by UAB-IT. These include:

- Institutional campus-wide license for Oracle RDBMS.
- Institutional campus-wide Microsoft Campus Agreement and Microsoft Select programs that provide licenses for operating system upgrades, SQL Server, Microsoft Office, and Microsoft program development tools.
- Access to the complete catalog of Microsoft products for STEM programs through Microsoft Dreamspark/Imagine.
- Institutional campus-wide licenses for Antivirus software (Sophos and Microsoft), EndNote, GraphPad Prism, Mathematica, MATLAB, LabView, IBM/SPSS, SAS, Qualtrics, Adobe, VMWare, and others.
- The UAB Department of Biostatistics provides investigators with access to a wide range of statistical software including SAS, S-plus, SPSS, and R. They also maintain many more specialized software programs including some specifically for statistical genetics such as SAGE, SIMWALK, ALLEGRO, DANDELION, GENEHUNTER, MERLIN, MX, PEDCHECK, PHASE, PREST, SOLAR, FASTLINK, VITESSE, SIMLA, and SUPERLINK amongst others. For software development purposes, the group has access to compilers for Fortran, C/C++, Perl, and Java as well as Fortran and Java IMSL libraries.
- CCTS Informatics maintains licenses and provides investigators with access to the Ingenuity Pathway Analysis tool suite and database that provides the ability to mine genomic and other –omics data for information on pertinent biological systems, networks, and pathways.

UAB and UAB Health System (UABHS) Security Policies and Practices

UAB-IT and the HSIS maintain a unified and comprehensive privacy and information security program that preserves and protects the confidentiality, availability and integrity of all information assets including patients, research, customer and business data. The integrated security program upholds values and provides high standards of service, trust, confidentiality and responsiveness to patients, customers, employees and business associates. The security program includes the following:

- IT security policies designed to help ensure a secure state of operations and information management.
- Technical security standards that document baseline security requirements for key technologies and platforms such as major operating systems, databases, network device operating systems, firewalls, web-server security, email, encryption, secure file transfer protocols, virus defense, media reuse and media disposal.
- A comprehensive risk management program.
- A computer security incident response plan that is supported by cross-functional response and recovery teams.
- User system access is tightly controlled and meets standards required by various regulations and accrediting agencies such as HIPAA, JCAHO and CAP. Two-factor authentication is utilized for many of the shared systems. Users must agree to maintain password confidentiality, log-off terminals at the end of each user session and alert management when security violations become known. We also must routinely demonstrate compliance with Federal granting agencies and the corresponding security requirements such as the NIH, FISMA and the VA.
- An Institutional Firewall for perimeter and layered protection.
- Network Intrusion Detection Systems (NIDS) and Network Intrusion Prevention Systems (NIPS) have been strategically deployed to continuously monitor Internet, Extranet and Internal communications.
- A perimeter Email gateway with spam prevention and virus scanning.
- Encrypted VPN tunnels for business associates, staff remote access, or partner VPN connectivity,
- Capability to support encrypted secure file transfers.
- Virus protection agents and comprehensive patch management programs installed on all computer workstations and servers to protect against malware infections.

- Whole disk encryption software that is required for all laptops.
- In-depth security training that is provided for all Faculty, Staff and students.

UAB has an extensive infrastructure to secure HIPAA-defined Electronic Protected Health Information (ePHI) from its creation and throughout its lifecycle. Secure web portals are utilized to make the required information accessible only to those who need access. The existing wireless infrastructure and secure VLAN architecture make the required ePHI portable but secure and transmissions are encrypted. UAB/UABHS applications are designed and developed using a comprehensive set of security standards. Areas addressed within application security standards include: password construction, strength and control, browser technologies, authentication and access control, security administration, and logging, auditing, and monitoring. All systems require 2-factor authentication for access. Internet applications mandate TLS encryption with strong cipher suites for the transmission of any sensitive data. Before going into production, all new Internet applications must be submitted for security testing. All identified security issues that could impact the confidentiality / integrity / availability of our data must be corrected prior to production release. Applications are retested on a regular schedule that coincides with major release cycles. A comprehensive change management system is utilized for updates, production changes, quality control and revision management.

Physical security is controlled by the following:

- Access to data center facilities is electronically controlled using card access systems. The access to computing facilities is granted on an as needed basis based upon the employee's job function.
- Access to the data center is removed as soon as the employee leaves or changes jobs within the UAB/UABHS. Authorizing approvers perform periodic reviews of employees with data center access. All IT personnel are required to submit to pre-employment security background screening.
- Access of personnel entering the data center area is monitored by operators in the Control Room. Operators are authorized to permit access of individuals such as vendors who may be required to support a system in the data center, but do not have a card that permits them access and provide escort while on site.
- A video surveillance system is in place to monitor the main data centers. This system is managed and monitored by physical security and operations personnel.

Environmental security is integral at each data center. All data centers are equipped with smoke and heat alarm systems, water sensors, fire suppression systems, fire extinguishers, emergency lights, air conditioning, humidity control systems, and backup power (UPS and Emergency Generators). UAB/UABHS has comprehensive provisions for Business Continuity and Recovery Systems. UAB contracts with third party vendors for rapid emergency equipment shipping and are currently implementing a "hot site" alternative-processing center. Supplemented by on-site technical and administrative personnel, this solution will facilitate the exercise of a recovery plan, thus enabling the institution to rebound from an unplanned outage should a critical IT disruption occur.

Data Security Plan

Each CCTS Partner Network site maintains a unified and comprehensive privacy and information security program that protects the confidentiality, availability, and integrity of all information assets (i.e., patient, research, customer, and business data). In addition, the CCTS is committed to providing an IT environment focused on ensuring compliance with all applicable laws, regulations, and guidelines for investigators at all Partner institutions. The information security environment maintained by each institution is described in the Institutional Resources section of this proposal. Generally, these security programs are the responsibility of the institution and its health system IT office working as necessary with institutional personnel to provide the required services and resources. Below we describe in general, the environment that all CCTS institutions provide to protect the security and privacy of human subject research data, and more specifically, the environment available at the UAB hub.

- **Policies, Standards, and Controls:** Review and consolidation of existing security policies and requirements is a continual process, involving individuals from each Partner and their respective health system. Information security policies establish controls based on educational and research needs, patient care, governmental guidelines, and other best practices. Data security controls are a part of IRB

review as well. Each health system follows HIPAA policies and undergoes review by the Joint Commission on Accreditation of Healthcare Organizations. Each academic organization complies with Family Educational Rights and Privacy Act controls for student information. Every Partner institution dealing with PHI has an appointed HIPAA Entity Security and Privacy Officer. Compliance with IT Security policies and local and federal laws and regulations is further ensured through review by each institutional health system and its internal audit organization. UAB has also adopted the NIST Risk Management Framework (NIST SP 800-37) – a security life cycle approach that consists of Categorization, Selection, Implementation, Assessment, Authorization and Monitoring, as the basis of its Information Security Program to ensure compliance. In addition to HIPAA requirements, the Federal Information Security Management Act of 2002 (FISMA) requires a minimum set of security controls and protection of the sensitive data created, stored, or accessed by either the federal government or any entity on behalf of the federal government. Investigators will work with the CCTS, Office of Sponsored Programs, IRB, and UAB-IT to identify how the information and information systems detailed in their grants and contracts have been categorized by NIH or other federal agencies to determine the level of control needed meet the required security and privacy standards. UAB-IT has established policies (uab.edu/it/home/policies/data-classification/data-protection-rule_) and provides guidance to investigators (uab.edu/it/home/policies/data-classification/restricted-data) to help with this assessment and with meeting any requirements. Security categorization provides a structured way to determine the criticality and sensitivity of the information and to assign a security impact value (low, moderate, high) to meet the objectives of confidentiality, integrity or availability. Once the overall security impact level of the information system is determined, an initial set of security controls is selected from the corresponding FISMA or HIPAA standards.

- **Implementation, Management, and Enforcement:** All Partners working with clinical data also have HIPAA-compliant data processing facilities to support their research needs. At UAB, to ensure that these systems continue to protect patient privacy, adhere to updated or new standards, and meet the needs of investigators, UAB-IT and HSIS of regularly review technical standards and revise policies and procedures as necessary. The CCTS also supports training for investigators handling covered research data to familiarize them with the data security plan as well as the use of the RDE to store and process their own datasets. We will also work with IRB staff and Board Members to ensure that they have the knowledge necessary to support their review of the data security requirements of each covered study

TRANSLATIONAL RESEARCH INFRASTRUCTURE

Core Facilities

UAB's shared Core Facilities offer state-of-the-art instruments, resources and technologies that are beyond the reach of the individual laboratory, available to investigators and trainees throughout the Hub and Partner Network research enterprise. Scientific capacities that include animal models, biomolecular analysis, imaging, genomics, proteomics and metabolomics, exercise medicine, structural biology, biological sample repositories and many others are available to CCTS investigators to support fundamental and translational research.

UAB Institutional Research Core Program (IRCP): The Institutional Research Core Program was created to promote the development and operation of outstanding Core Facilities that can serve the needs of UAB investigators. The IRCP boasts 15 Institutional Research Core facilities and as of 2020 has received over \$638.9 Million in research awards (\$358 Million from the NIH). The program is designed to provide assistance to Cores in developing sound business plans, preparing, and implementing robust standard operating and quality assurance procedures, providing customer-focused service to facilitate the advancement of research and scholarship, and to assist in maintaining the financial stability of the core.

The Current IRCP Cores:

- *Advanced Materials Characterization*
- *Animal Behavioral Assessment*
- *Biological Data Sciences*
- *Comprehensive Flow Cytometry*
- *Comprehensive Genomics Core*
- *High Resolution Imaging Facility*
- *Human Imaging*
- *Macromolecular Structure*

- *Mass Spectrometry and Proteomics*
- *Metabolism*
- *Microbiome Research*
- *Nuclear Magnetic Resonance*
- *& Genetically Engineered Models*
- *Preclinical Imaging*
- *Research MRI*
- *Transgenic*

Select examples of research cores at the Hub:

- ***Animal Behavioral Assessment Core:*** The Behavioral Assessment Core provides a facility for the behavioral testing of mice and rats. Newly created transgenic mice can be analyzed using the most-accepted battery of behavioral tests, the SHIRPA (Rogers et al. 1997). This battery will include a primary neurological screen, sensory and motor test (including rotarod, spontaneous locomotor activity, walking coordination, etc.), an open field test for emotional and exploratory activity, and an elevated plus maze for anxiety. Motor function testing is available, and cognitive testing is provided with the Morris water maze, Barnes maze, hole board maze and eight-arm radial maze tasks. Other, more complex, tasks are also available.
- ***Flow Cytometry and Single Cell Core Facility:*** Comprehensive Flow Cytometry Facility provides state-of-the-art equipment and services for UAB investigators to advance basic and clinical research.
- ***Genomics Core Laboratories:*** The Genomics Core Laboratory has the capability of performing standard fluorescent and Next-Generation Sequencing (NGS), high and low throughput custom genotyping from 1 SNP to more than 5 million SNPs.
- ***High Resolution Imaging Facility:*** The High-Resolution Imaging Facility (HRIF) provides state-of-the-art imaging resources and technical support to the UAB community.
- ***Human Imaging Shared Facility:*** The Human Imaging Shared Facility (HISF) provides advanced medical imaging resources and services in support of campus wide research, including the O'Neal Cancer Center clinical studies.
- ***Macromolecular Structure Core:*** Cryo-EM and X-ray crystallography are complementary techniques that work in concert to resolve mechanistic aspects of biological processes. The MSC addresses the needs of investigators for both XRC and Cryo-EM in one unified core facility.
- ***Mass Spectrometry/Proteomics Shared Facility:*** Mass Spectrometry/Proteomics Shared Facility provide state-of-the-art capabilities and training in mass spectrometry, proteomics, and bioanalytic technologies to support the research needs of UAB Cancer Center members.
- ***Metabolism Core:*** Metabolism Core provide state-of-the-art assessments of human energy expenditure, substrate metabolism, body composition, body fat distribution, and bone quality.
- ***Microbiome Core:*** The UAB Microbiome Core provides 16S rRNA gene sequencing of fecal and other biological samples for microbiome analysis.
- ***Nuclear Magnetic Resonance:*** The NMR Facility consists of seven NMR spectrometers located in six research laboratories in UAB's Department of Chemistry building. The facility is designed to allow researchers direct 24/7 access to all spectrometers. It also provides NMR expertise for researchers needing NMR data through submitted samples, either on a service basis or as part of a collaborative research project.
- ***Preclinical Imaging Shared Facility:*** The Preclinical Imaging Shared Facility supports multimodality imaging in preclinical models to accelerate the translation of basic research to human trials. Imaging conducted in the facility currently provides rapid, repeated, accurate, and cost-effective evaluation of new cancer treatments in preclinical models, using the most sophisticated technologies available.
- ***Research MRI Core:*** Research MRI provides resource at UAB for state-of-the-art MRI neuroimaging experiments and analyses for examining brain and body anatomy and function both in health and disease.
- ***UAB Biological Data Science Core (U-BDS):*** The UAB Biological Data Science Core (U-BDS) offers access to computational biology capabilities. This newly founded Institutional Research Core provides services supported by Masters and Ph.D. level scientists who are experts in Computational Biology and Biomedical Data Sciences.

- **UAB Transgenic & Genetically Engineered Models Core (TGEMs):** UAB Transgenic & Genetically Engineered Models Core include the production of mouse models using gene targeting and DNA and ES cell injection methods. Our most recent service is in creating gene knockouts using the TALEN and CRISPR/Cas9 nucleases in mice, rats, and zebrafish.

Biomolecular Analysis: To assist in the characterization of molecular interactions, signal transduction pathways and other fundamental analyses, Core expertise and technology are available to help define mechanisms of action and clinical and translational applications of research discovery.

- **Pharmacokinetic and Pharmacodynamic Shared Facility:** The PK/PD Shared Facility offers pre-clinical and clinical trial design to support sample analyses for drug and metabolite quantitation as well as PK/PD determinations. Data analysis and interpretation is also available.
- **Cystic Fibrosis Transmembrane Conductance Regulator (CFTR) Expression Core:** The CFTR assists investigators interested in CF with the complex technology necessary to efficiently express CFTR in experimental systems. It maintains a repository of reagents for studying CFTR, including over 50 constructs containing mutations that lead to disease and CFTR plasmid molecules used as part of gene therapy protocols in CF patients in the past. Expertise is available to assist with expression using vaccinia, adenovirus or other methodologies and to detect expression using antibody directed against CF related gene products.
- **Islet Resource Facility:** The Islet Resource Facility provides state-of-the-art islet isolation and in vitro/in vivo assessment of functionality. The Islet Resource Facility is equipped to process human and non-human tissues and isolating islets. A complementary facility, the Beta Cell Biology Core assists investigators with islet morphology and measurements of whole pancreas beta cell mass, whole pancreas insulin content, whole pancreas beta cell morphometry, and whole pancreas islet visualization (stitching).
- **UAB Vector Production Facility:** The UAB Vector Production Facility provides the UAB translational research community with the capability of producing viral vectors and cell-based proteins in compliance with current Good Manufacturing Practices (cGMP) for FDA-directed preclinical studies and early phase human clinical trials of cancer.
- **Tissue and Immunopathology Core Facility:** The Tissue and Immunopathology Core Facility has extensive experience in collecting, processing, storing/banking, and distributing a wide range of cancer-related tissues. The Core has established a bank of well characterized tumor specimens and matching normal/control specimens from patients who have given informed consent for their tissues to be used in genetic and other types of research so tissue can be supplied to investigators along with clinical data including outcome and familial histories of ovarian, breast, and related tumors. Fresh, frozen and paraffin preparations of tissues can be supplied as well as unstained tissue slides, tissue matrix arrays, microdissection and other histology services. The Core also provides light microscopic and immunocytochemical interpretation of animal and human tissues and cytologic materials including methods to detect gene products within transfected cells and adjacent tissues.
- **Multidisciplinary Molecular Interaction (Biacore) Core (MMIC):** The MMIC uses a GE Biacore T200 optical biosensor to detect biomolecular interactions of proteins, nucleic acids, carbohydrates, and lipids. Characterization of interactions includes binding specificities, kinetics, affinity, concentration and epitope mapping.
- **Targeted Metabolomics and Proteomics Laboratory (TMPL):** TMPL is organized to provide a variety of analytical and technical services using mass spectrometry to UAB and consortium investigators. The laboratory is well equipped to analyze the metabolome, including a triple quadrupole instrument (SCIEX 4000) and a quadrupole-linear ion trap instrument (SCIEX 6500Qtrap), both of which have been combined with microflow LC systems to improve analyte sensitivity. The SCIEX 6500Qtrap is fitted with a SelexION interface for performing ion mobility separations of isomeric species. In addition, there is a quadrupole-TOF (SCIEX 5600 TripleTOF™) which is combined with nanoLC to carry out highly quantitative and comprehensive SWATH analysis of proteins. The SCIEX 5600 TripleTOF™ is also particularly powerful for comprehensive and targeted lipidomics and metabolomics. These technologies are instrumental in characterizing host molecules, those coming from the diet and those produced by bacteria. The latter represent the link between the microbiome and chronic diseases such

as cancer, diabetes, neurodegeneration and obesity. TMPL also offers training in data analysis, particularly for statistical evaluation of the data obtained from comprehensive analyses.

- **Southeastern Biosafety Laboratory (SEBLAB):** Southeastern Biosafety Laboratory is a 43,500 s.f. facility that houses state-of-the art biosafety level 2 and level 3 laboratories as well as animal biosafety level 3 laboratories. SEBLAB's design includes flexible and secure laboratories, animal housing and procedure space, and laboratory support space. Specialized resources at SEBLAB include an aerobiology suite, imaging suite, irradiator, vaporized H₂O₂ decontamination and a decontamination chamber.

UAB Heflin Center Genetics/Genomics: The Heflin Center for Genomic Sciences (HCGS) was founded in 2002 as a University Wide Interdisciplinary Research Center (UWIRC) with the goal of enhancing resources to enable UAB investigators to incorporate genetic and genomic approaches in their research. UAB cores support fundamental, routine capacities in sequencing and genotyping, DNA Sequencing as well as leading-edge technologies in next-generation genomics on a low-throughput scale to establish proof-of-concept among a broad research portfolio.

- **Laboratory:** The Genomics Core is dedicated to basic and applied research in genomics and genetics. The Core, which opened in 2001, is housed on the fourth floor of the Kaul Human Genetics Building and the facility is well-equipped state-of-the-art laboratories. The Core laboratory is 2,500 square feet in area and has bench and desk space for all the staff required to run the facility and all the standard equipment for molecular biology, genetics, and genomics work, including several PCR machines, refrigerators, freezers, centrifuges, incubators, water baths, etc. The Core provides the necessary expertise in Next-Generation Sequencing library production. To that end, the core has the Covaris S2 sonicator to randomly shear genomic DNA for whole genome-based library production that is housed in a separate room on the 4th floor of the Kaul building. The core utilizes an Illumina NextSeq500 and a MiSeq Next-Generation sequencing systems from Illumina to generate NGS related data. The Genomics Core Laboratory has the capability of performing standard fluorescent and Next-Generation Sequencing (NGS), high and low throughput custom genotyping from 1 SNP to more than 5 million SNPs, whole genome linkage and association studies, targeted and whole genome gene expression, and targeted and whole genome assays. In addition, the core can also process Illumina genotyping microarrays for SNP and methylation-based studies. Finally, the core is the provider of Sanger sequencing data of individual clones for campus.
- **Computer:** UAB IT Research Computing maintains high performance compute and storage resources for investigators. UAB IT Research Computing maintains the Cheaha Supercomputer. Named after the Cheaha mountain, or Mount Cheaha, the highest natural point in Alabama. Cheaha is currently the largest and fastest supercomputer in the state of Alabama with a theoretical throughput of approximately 528 TFLOPS and consists of over 3500 CPU cores and 72 NVIDIA-P100 GPU's. Cheaha is supported by a high-speed parallel filesystem that can store 6 PB of data (raw) interconnected by a high speed infiniband network. Cheaha is a campus resource dedicated to enhancing research computing productivity at UAB. UAB researchers use Cheaha for wide variety of research such as genomics, neuro-imaging, machine learning, statistical genetics, cancer detection etc. Cheaha is available to members of the UAB community in need of increased computational capacity.
- **Major Equipment:**
 - Illumina Next-Seq500 and MiSeq instruments for Next-Generation sequencing data.
 - An Illumina iScan instrument. Located in a dedicated equipment room adjacent pre-PCR room, the Illumina scanner includes full robotics and are staffed by a team of three dedicated technicians.
 - Tecan Evo robot for liquid handling and Illumina microarray processing.
 - Human EPIC Methylation bead chip from Illumina, which contains approximately 850,000 CpG sites within the human genome.
 - Applied Biosystems AmpFISTR system is used to screen 15 different small tandem repeat (STR) markers and the Amelogenin locus for gender determination. This service is intended for Human Cell line identification and is for research purposes only.
 - Agilent 2100 Bioanalyzer, available for the analysis of total RNA. The system can also perform quality control for NGS ready libraries.

- Roche 480 LightCycler for real-time quantitative PCR using with Taq-man or fluorescent detection.

Animal Models: To enable proof of principle investigation and studies of biological function / significance, model systems play an essential role in clinical and translational science. UAB has an extensive animal resources program (UAB ARP) that provides support to the animal research community. To facilitate investigators in the identification and access of the best animal models, CCTS established, the human to animal model (H2M) consultative service, which won an AAMC innovative practices award in 2014. The H2M works closely with the UAB ARP to ensure investigators have access to cutting edge animal models and resources. The UAB ARP is accredited by the AAALAC, is registered as a research facility by the USDA, and has an Assurance of Compliance on file with the Public Health Service Office of laboratory Animal Welfare. The UAB ARP encompasses ~225,000 sf of animal housing and procedure space in 17 buildings. The program provides husbandry, veterinary care, diagnostic and research histopathology, facility and equipment management for approximately 450 animal researchers with approximately \$150M in extramural funding. The average daily census of animals at UAB is approximately 28,000 cages of rodents, 2,000 aquaria of fish and 350 larger animals such as rabbits, tree shrews, pigs, ferrets, guinea pigs, and dogs. The UAB ARP has ~90 husbandry staff, 10 veterinary staff and the necessary personnel to manage the administrative, financial, safety and personnel responsibilities of the program. The UAB ARP program also has the needed support of other institutional units such as the Facilities and Maintenance, Department of Occupational health and Safety, Human Resources Management, Project Management, Police, Physical Security, Communications, and Information Technology. The following are examples of the animal cores integrated within the UAB ARP providing specialized services.

- **UAB Animal Model Systems Facility:** Genetically modified murine models continue to be the most tractable system to examine the role of an identified genetic variant associated with human disease, as well as creating much needed translational models for developing novel therapeutics. The facility provides expertise and technical service related to the creation of genetically modified rodent models. The Core works with investigators to devise targeting strategies and will facilitate DNA or ES cell microinjection, ES cell gene targeting, assisted reproduction and line cryopreservation. Additionally, it provides unique services for in vitro fertilization, embryo and sperm cryopreservation, long-term storage of cryopreserved embryos and sperm, and assistance with reproduction / re-derivation of transgenic animals.
- **Small Animal Imaging Shared Facility:** The Preclinical Imaging Core Facility is to support sustainable and responsive multimodality imaging in preclinical oncology models for UAB University and Medical Center investigators through advanced preclinical imaging acquisition and analysis. The facility provides a multimodality imaging approach to provide a molecular understanding of disease processes in animal models, allows for therapeutic assessment of response, supports the development of novel imaging contrast agents, and facilitates translational preclinical imaging studies precluding clinical trials. To facilitate those goals, UAB has a team of four faculty scientists (Director, three Associate Directors) whose expertise range from ultrasound imaging, magnetic resonance imaging (MRI), computed tomography (CT), nuclear imaging, including positron emission tomography (PET) imaging and single photon emission computed tomography (SPECT), and optical imaging. The team routinely collaborates with imaging scientists and non-imaging scientists to help design experiments and enable preclinical imaging in many animal models. To enable imaging data acquisition, UAB also has a staff of professionals, including an MRI-trained PhD scientist, a PET-trained PhD scientist, a core lab manager with over 20 years of preclinical imaging experience, two staff researchers, and a program administrator. Along with experimental design and acquisition, the facility also offers data analysis and image processing and secondary biological studies (associated with imaging) such as radioactive biodistributions of animal models. Importantly, many of the technologies applied are similarly applied in UAB clinical trials. The Director of the Preclinical Imaging Core (Departments of Radiology and Biomedical Engineering) has a research program centered around preclinical imaging in oncology as well as a role in translational clinical research, including clinical trials utilizing imaging, therefore will be involved in ensuring the evolution of new techniques is available in the preclinical imaging core facility. The Small Animal Imaging Facility is supported by the O'Neal Comprehensive Cancer Center and the O'Brien Center for Acute Kidney Injury Research.

- **UAB Zebrafish Research Facility:** The UAB Zebrafish Research Facility (ZRF) welcomes all UAB investigators and others interested in working with zebrafish. The Facility occupies ~ 5000 net square feet in the Research Support Building and includes a recirculating aquaria system (Aquaneering, Inc.) with central water conditioning/purification supplying 27 racks (>2200 3 L tanks). The ZRF Procedural Laboratory provides numerous embryo processing stations (each made of a dissection microscope, injector, and micromanipulator), incubators, a pipette puller, and two fluorescent microscopes, as well as other equipment needed for embryo manipulation and fish work. There is a separate zebrafish quarantine facility on the 4th floor of the RSB building.
- **Small Animal Microsurgical Core:** The UAB Small Animal Microsurgical Core Facility (UMCF) was originally established by the Departments of Medicine and Surgery in 2007 with the assistance of an HSF-GEF award to fulfill an acute need for complex rodent microsurgical services in a cost-effective and timely manner on the UAB campus. The UMCF is now supported by the P30 funded UAB-UCSD O'Brien Center for Acute Kidney Injury Research, the Nephrology Research and Training Center (NRTC) and by The Office of the Vice President for Research. Specific procedures include organ transplantation, models of ischemia reperfusion injury, cannulations, and other microvascular procedures. The core also provides customized surgical services for individual investigators. The primary function of this core is to provide access to complex small animal microsurgical procedures for investigators in a cost-effective and timely manner. The core also offers the use of surgical workstations, which consist of ARP-approved laminar flow hoods, microscopes, an isolation room, and gaseous anesthesia delivery systems. The facility is located on the 6th and 9th floors of the Zeigler building with ancillary space on the fourth floor of the Lyons-Harrison building. There are three operating rooms on the 9th floor. Two of these (200 sq. ft. each) include an operating microscope and a videocapture/recording system that is used for documentation and for teaching purposes. The third room (400 sq. ft.) is dedicated to open and low complexity procedures (nonsurvival surgeries or terminal tissue acquisition). The 6th floor location occupies about 400 sq. ft. of space. This is used in conjunction with primary cell culture isolations performed in a separate space (~900 sq. ft.) on the 4th floor of the Lyons Harrison Building. Animal housing is located on the 8th floor of the Zeigler Building. By providing critical pre-clinical research capabilities, the UMCF serves as a unique venue for collaborations among investigators across unit boundaries on the UAB campus and around the country.
- **Animal Physiology Core Facility:** The Animal Physiology Core (APC) provides for diabetes related phenotyping in small animal models. Services offered include the assessment of body composition, energy balance, glucose homeostasis, and transgenic animals models. The core takes comprehensive assessments of metabolic rate (indirect calorimetry), food intake, fecal output, activity, and body temperature. The facility also performs whole-body composition analysis by chemical carcass analysis, dual-energy X-ray absorptiometry (DXA), quantitative magnetic resonance (QMR), and micro-computed tomography (μ CT) It can also facilitate animal imaging including bioluminescence and fluorescence imaging, gamma ray imaging, SPECT/CT, microPET/CT, bioluminescence, fluorescence, magnetic resonance (MR) imaging and ultrasound imaging. This technology has been used to detect tumor location and mass, receptor expression (tumors, brain, etc.), organ function, metabolism, perfusion, and response to therapy.
- **Behavioral Assessment Core:** The Behavioral Assessment Core provides a facility for the behavioral testing of mice and rats. Newly created transgenic mice can be analyzed using the most-accepted battery of behavioral tests, the SHIRPA (Rogers et al. 1997). This battery will include a primary neurological screen, sensory and motor test (including rotarod, spontaneous locomotor activity, walking coordination, etc.), an open field test for emotional and exploratory activity, and an elevated plus maze for anxiety. Motor function testing is available, and cognitive testing is provided with the Morris water maze, Barnes maze, Hole board maze and eight-arm radial maze tasks. Other, more complex, tasks are also available. The Managing Director can also assist investigators in the development of tools/testing methods that are needed by them for a more detailed assessment of specific behaviors or behavioral deficits.
- **Gnotobiotic Mouse Core:** The UAB Gnotobiotic Mouse Core facility (GMC), provides gnotobiotic animal services to UAB investigators. These services include access to existing gnotobiotic mouse models, assistance in developing new gnotobiotic models, and transplantation of human and mouse archived microbiota. GMC staff have extensive experience in derivation and maintenance of gnotobiotic mice. Since our establishment in 2002, we have derived 18 different genotypes of mice and have

colonized and maintained mice with various limited microbiota and human intestinal microbiota. The facility employs two highly capable full-time gnotobiotic technicians and occupies over 1,700 sq. ft. on the 9th floor of the Zeigler Research Building. The facility has dedicated high-vacuum autoclave; new heating, ventilating, and air-conditioning (HVAC) system, high-efficiency LED lighting, and emergency backup electrical service. Housing for gnotobiotic mice includes 10 Trexler-type plastic film isolators, 28 30" Park Bioservices semi-rigid isolators, and 16 Park Bioservices MiniQ™ semi-rigid isolators, for a total of 54 isolators for breeding and experiments. We also have two 70-cage Tecniplast Isocage™ positive pressure isolation cage systems, which are used for short-term experiments such as housing mice colonized with human microbiota.

Imaging: These facilities offer pre-clinical research support with a range of cutting-edge imaging modalities and assistance with protocol development and analyses. The resources are available to CCTS Partner network investigators, trainees and partners. These core capacities support imaging across the research spectrum.

- **High Resolution Imaging Facility:** The High Resolution Imaging Facility (HRIF) is a cutting-edge facility providing a variety of microscopy services for UAB Scientists. The HRIF supports research by offering access to a comprehensively equipped Shared Resource. Available are confocal laser scanning microscopy, transmission and scanning electron microscopy, Ca²⁺ imaging, FRET, FRAP, and FLIM imaging, 3d time lapse with extensive digital analysis for cell fluorescence quantification, colocalization and image processing, Imagestream, high throughput fluorescent imaging, Nanosight system for studying exosomes and nanoparticles, and a laser capture microdissection system. In addition, the facility offers STORM and SIM super resolution imaging capability.
- **Civitan International Neuroimaging Laboratory:** The Civitan International Neuroimaging Laboratory (CINL) is located on the first floor of UAB Highlands Hospital in a newly renovated 5000 sq. ft. suite. It houses a research dedicated Siemens Prisma 3T whole body scanner for structural and functional brain and body imaging, MRI preparation rooms and interview rooms for pre- and post-scan patient monitoring and testing, and a fully-equipped experimental suite for behavioral and physiological recording. Research equipment is housed in a dedicated room adjacent to the scanner room with a dedicated research penetration panel. The Siemens MAGNETOM Prisma MRI Scanner offers a 3T whole body MRI platform for the highest quality MRI research. Its design delivers maximum performance under prolonged high-strain conditions. Unmatched 3T full body magnet homogeneity, XR 80/200 gradient coil, parallel transmit architecture for shaped excitation and B₀ shimming, and at-the-scanner 64 channel receiver architecture.
- **Advanced Imaging Facility and UAB Cyclotron Facility:** The UAB Cyclotron Facility enables a broad scope of research and cutting-edge patient care through initiatives ranging from novel isotope production to developing and supplying state-of-the-art molecular imaging agents for clinical trials and routine patient care. Isotope production at the UAB Cyclotron facility is enabled by our TR24 cyclotron capable of variable energy proton acceleration. Four target stations allow for versatile isotope production through a variety of different production routes. UAB's cyclotron is in immediate proximity to our cGMP radiochemistry facility and nuclear pharmacy. Additionally, it is in proximity to the UAB Advanced Imaging Facility equipped with two TOF-PET/CT's and the only PET/MRI in the state. In addition to the production of commonly used PET radioisotopes such as fluorine-18, carbon-11, and nitrogen-13 we specialize in the production and shipping of unique radiometals for clinical and preclinical use. The UAB Cyclotron Facility makes use of faculty chemistry expertise in isotope production and the radiosynthesis of novel molecules to bring new agents online in a timely fashion. Collaborations with basic scientists in Chemistry, Biochemistry and Biomedical engineering are also ongoing. Molecular imaging is a powerful technique that can be applied to basic, translational, and clinical research as well as to routine patient care. Molecular imaging allows spatial localization and quantification of biological processes such as metabolism, enzyme activity, cell proliferation, receptor density and cellular transport that are not readily assessed with conventional anatomic imaging techniques. The Cyclotron Facility positions UAB to be a leader in molecular imaging and enables new research and clinical endeavors directly relevant to UAB's mission.

The UAB Cyclotron Facility serves as a key resource for the UAB community, the Southeast, and, for some applications, the entire United States. Through collaborations with clinical faculty and preclinical

and basic researchers, we aim to maintain a program which operates in close synergy with other investigators at UAB. The Cyclotron Facility provides human use radiopharmaceuticals to investigators with programs in molecular imaging and educates potential new investigators about the use of molecular imaging in their research. The Cyclotron Facility also provides physicians and patients at UAB with access to molecular imaging tracers not available at most other centers in the United States. The facility leverages existing strengths in the UAB Cancer Center in immunology and experimental therapeutics to enable the use of molecular imaging for personalized medicine. Pilot projects establish the techniques and are used for materials for outreach to other investigators. The development and application of diagnostic molecular imaging agents directly coupled to therapy is a major emphasis. The Cyclotron Facility provides clinicians in Neurology, Psychiatry, and related fields as well as neuroscientists at UAB access to the tools needed for molecular neuroimaging in disease models and patients. Tracers include amyloid, tau and neuroinflammation imaging agents that are revolutionizing our understanding of Alzheimer's disease and other neurodegenerative processes. The availability of molecular imaging agents adds a new dimension to already strong clinical and research programs centered on neurological diseases and neuroscience. Cardiovascular imaging at both the preclinical and clinical levels benefit from molecular imaging agents available through the Cyclotron Facility. In addition to tracers specific to cardiovascular applications, imaging agents already in demand by investigators at the cancer center are leveraged for use in investigating cardiovascular metabolism and other parameters of interest such as hypoxia. The Cyclotron facility at UAB makes use of existing and new faculty chemistry expertise in isotope production and the radiosynthesis of novel molecules to bring new agents online in a timely fashion. Collaborations with basic scientists in Chemistry, Biochemistry and Biomedical engineering are also ongoing.

Structural Biology: A comprehensive structural biology capacity at UAB has been developed, leveraging the robust expertise and technological investment to enable high resolution microscopy and proteomics, including mass spectrometry, post-translational modification analysis, X-ray crystallography and high-field NMR. Together, these bioanalytical resources are a critical feature available to the biomarker and drug-discovery initiatives.

- **Mass Spectrometry/Proteomics (MSP) Shared Facility (SF):** The Institutional UAB & CCC MSP-SF provides a variety of analytical and technical services using mass spectrometry to UAB investigators. The UAB O'Neal Comprehensive Cancer Center Mass Spectrometry/Proteomics (MSP) Shared Resource (SR) is a research resource that provides services to UAB O'Neal CCC members to identify, characterize, and quantify proteins, and protein post-translational modifications isolated from cells, biological fluids, and tissues. The over-arching goal of the MSP-SF is to provide state-of-the-art capabilities and training in mass spectrometry, proteomics, and bioanalytic technologies to support the research needs of UAB Cancer Center members. Standard workflows include 1) help with experimental design, 2) complete sample preparation, 3) quantitative high-resolution MS driven proteomics, 4) in addition to advanced informatics, statics, and systems biology analysis. In addition to standard sample preparation and separation equipment, the Facility is also equipped with multiple high-end MS systems: two LTQ Orbitrap Velos Pro's, two LTQXL's with CID & ETD, and an Ultraflex III MALDI TOF/TOF. All of these instruments are paired with updated UPLC's and nano-HPLC systems, in addition to software tools that include MASCOT, MASCOT Distiller, SEQUEST, and Proteome Software (Scaffold, Scaffold PTM, and Q+S modules) to offer the very best outcomes for a wide range of proteomics-driven procedures.
- **UAB Central Alabama High Field NMR Facility:** The UAB High-Field NMR Facility is one of the best equipped and state-of-the-art NMR facilities in the Southeast and provides instrumentation and expertise for elucidating the structure and dynamic behavior of macromolecules, perform solution metabolite analysis, and characterize small molecule structure and binding. The NMR Facility consists of seven NMR spectrometers located in six research laboratories in UAB's Department of Chemistry building. The facility is designed to allow researchers direct 24/7 access to all spectrometers. It also provides NMR expertise for researchers needing NMR data through submitted samples, either on a service basis or as part of a collaborative research project. The NMR Facility is an essential university-wide resource dedicated to supporting structural biology and drug discovery, and to making this powerful analytical technique available to researchers throughout UAB and elsewhere in the scientific

community. It provides unique training opportunities for faculty, staff, and students on the application of NMR spectroscopy for their research. The facility provides enables analysis of molecular interactions critical for both understanding basic mechanistic structures and using that information to refine potential therapeutics for a variety of diseases. The facility is equipped with Bruker 600 (Avance III), 700 (Avance II), and 850 (Avance III) MHz NMR spectrometers with cryoprobes. In addition, a 500 MHz Bruker Avance NMR Spectrometer with TXI and TBI probes is also available.

- **X-ray Crystallography Shared Facility:** Cutting-edge technology and expertise are available to study protein-protein/ligand interactions using differential scanning, isothermal calorimetry, and surface plasmon resonance. High-throughput aqueous and membrane protein crystallization robots, protein crystallization imagers, high throughput crystal growth optimization and structure determination via in-house or national synchrotron x-ray systems.
- **Cryo-Electron Microscopy:** The Cryo-Electron Microscopy Facility provides capabilities for high-resolution electron microscopy and tomography of stained and unstained specimens. Cryo-EM allows the observation of biological samples in their native environment, in the absence of the distortions and artifacts associated with traditional sample preparation methods, and is suitable for proteins and protein complexes, viruses, fibers, liposomes and intact prokaryotic cells up to about 1 μ m thickness. A recent upgrade to the Gatan K2 direct electron detector and SerialEM automated acquisition software enables near-atomic resolution imaging for suitable specimens as small as 150 kDa. The facility is equipped with an FEI Tecnai F20 FEG microscope and is located in the basement of Shelby Biomedical Research Building (SHEL B40). An FEI Vitrobot, a Leica cryo-ultramicrotome, lab space for sample preparation and a dark room for film processing are available.

DATA RESOURCES AVAILABLE TO CCTS INVESTIGATORS, SCHOLARS, AND TRAINEES (Examples)

1. Medicare, Medicaid, and Administrative Databases from Private Insurers

CCTS HUB faculty have considerable experience in managing and analyzing the Medicare 5% sample and (50 state) Medicaid (MAX) data. Work to date has predominately focused on the epidemiology of osteoporosis, bone mass measurement, the longitudinal comparative effectiveness and safety of biologic medicines, and the prevention and treatment of cardiovascular disease. The data management and analysis team includes 14 faculty members in the Schools of Public Health and Medicine, supported by a senior systems analyst, 2 senior statisticians, and 19 statistician/analysts. Data management and analysis tasks and resolution of study design and statistical analysis issues are coordinated through monthly Medicare/Medicaid Data Group meetings, attended by investigators and project staff and weekly meetings dedicated to specific projects.

- CMS encourages researchers to use its diagnosis and treatment database. They will provide a file that contains all records submitted with date of birth, gender, and date of death information. The Medicare ID returned on this file is an encrypted ID that contains no identifying information including no component of the SSN. The encryption is uniquely created for this proposed study and does not correspond in any way to Medicare data obtained for other studies. CMS has well established, secure procedures for linking research subjects' identifiers to Medicare files for purposes such as this. They uniquely encrypt IDs for each project. Thus, the Medicare data received cannot be combined with Medicare data from any other source or project without CMS assistance.
- One strength of Medicare and Medicaid is that the computerized pharmacy records provide an objective, detailed, high-quality, and relatively low-cost measure of drug exposure. Inpatient, outpatient, nursing home, and other files provide information on outcomes and other important study variables. Although the limitations of these data always must be considered, Medicare and Medicaid databases have long been recognized as an essential resource for pharmacoepidemiology and health services research.
- Data security and integrity is accomplished by a combination of hardware and software protocols. Comodo and Microsoft firewall software packages are used to prevent access from unauthorized computers. Microsoft Forefront is used to provide anti-virus protection. Access to the server is restricted to computers located on the UAB campus with specific IP addresses. Data containing individually identifiable data are stored in encrypted, password-protected datasets that can only be accessed

through a Remote Desktop Connection to the server. Data integrity is accomplished by a nightly backup routine and by replicating the data to a secure, off-site server. The UAB Office of Internal Audit conducted an audit of the facility where the data are housed. Based on their recommendations, additional security protocols were implemented, and the User Authorization Agreement was amended to reflect stricter CMS guidelines. The auditor was pleased with the attention to detail and also gave suggestions for maintaining a secure environment. All project personnel are required to have current IRB and HIPAA training and will be signatories to Data Use Agreements in order to access any research identifiable data.

2. Coronary Artery Risk Development in Young Adults (CARDIA)

The Coronary Artery Risk Development in Young Adults (CARDIA) Study is a study examining the development and determinants of clinical and subclinical cardiovascular disease and their risk factors. It began in 1985-86 with a group of 5115 black and white men and women aged 18-30 years. The participants were selected so that there would be approximately the same number of people in subgroups of race, gender, education (high school or less and more than high school) and age (18-24 and 25-30) in each of 4 centers: Birmingham, AL; Chicago, IL; Minneapolis, MN; and Oakland, CA. These same participants were asked to participate in follow-up examinations during 1987-1988 (Year 2), 1990-1991 (Year 5), 1992-1993 (Year 7), 1995-1996 (Year 10), 2000-2001 (Year 15), 2005-2006 (Year 20), 2010-2011 (Year 25), and 2015-2016 (Year 30). A majority of the group has been examined at each of the follow-up examinations (91%, 86%, 81%, 79%, 74%, 72%, 72%, and 71%, respectively). While the specific aims of each examination have varied, data have been collected on a variety of factors believed to be related to heart disease. These include conditions with clear links to heart disease such as blood pressure, cholesterol and other lipids, and glucose. Data have also been collected on physical measurements such as weight and body composition as well as lifestyle factors such as dietary and exercise patterns, substance use (tobacco and alcohol), behavioral and psychological variables, medical and family history, and other chemistries (e.g., insulin). In addition, subclinical atherosclerosis has been measured via echocardiography during Years 5, 10, 25, and 30, a chest CT scan during Years 15, 20, and 25, an abdominal CT scan during Year 25, and carotid ultrasound during Year 20. A brain MRI was performed on a subset of participants at Years 25 and 30. The CARDIA cohort, born between 1955 and 1968, has been influenced substantially by the obesity epidemic at ages younger than participants in other established NHLBI cohorts. Further investigation of the mechanisms linking obesity to derangements in cardiovascular structure and function and the etiology of clinical events promises to generate important new knowledge to inform health promotion and disease prevention efforts.

While the specifics of each examination have differed somewhat, data have been collected on a variety of factors believed to be related to heart disease. These include conditions with clear links to heart disease such as blood pressure, cholesterol, and other lipids. Data have also been collected on physical measurements such as weight and skinfold fat, as well as lifestyle factors such as substance use (tobacco and alcohol), dietary and exercise patterns, behavioral and psychological variables, medical and family history, and other chemistries (e.g., insulin and glucose). In addition, subclinical atherosclerosis was measured via echocardiography during Years 5 and 10, computed tomography during Years 15 and 20, carotid ultrasound during Year 20, and Brain MRI during Years 25 and 30. Lewis and K. Saag have mentored trainees using CARDIA data.

3. REDCap (Research Electronic Data Capture)

REDCap (Research Electronic Data Capture) is a secure, web application designed to support data capture for research studies, providing user-friendly web-based case report forms, real-time data entry validation (e.g. for data types and range checks), audit trails and a de-identified data export mechanism to common statistical packages (SPSS, SAS, Stata, R/S-Plus). REDCap also provides a powerful tool for building and managing online surveys. The research team can create and design surveys in a web browser and engage potential respondents using a variety of notification methods. REDCap data collection projects rely on a thorough study-specific data dictionary defined in an iterative self-documenting process by all members of the research team with planning assistance from the system owner. The iterative development and testing process results in a well-planned data collection strategy

for individual studies. REDCap provides a secure, web-based application that is flexible enough to be used for a variety of types of research, provide an intuitive interface for users to enter data and have real time validation rules at the time of entry. The system was developed at Vanderbilt University but is now part of an international and multi-institutional consortium which includes The University of Alabama at Birmingham (UAB). REDCap has been disseminated for use locally at other institutions and currently supports 4296 academic/non-profit consortium partners in 137 countries on six continents and over 927K projects with 1.3M research end-users, 10,357 articles utilizing REDCap have been published.

4. Survey Research Unit (SRU)

The mission of the SRU is to provide scientifically valid survey results for clients to reach their research goals and objectives. SRU data has been published in over 300 peer-reviewed journals and used in presentations and posters for scientific conferences. The SRU conducts approximately 40,000 surveys annually for UAB investigators, local and state health departments, and other state and national agencies. Services include survey design, sample design, computer-assisted telephone interviewing (CATI), and field survey research. With a well-trained, IRB-certified staff of 80 interviewers, the SRU can conduct large-scale data collection projects. SRU provides professional assistance for all stages of survey research such as data collection, data entry, pilot studies, presentations, program evaluation, report preparation, sample design, and survey design. SRU staff combines a broad knowledge of advanced survey methodology with extensive experience in project management to offer services such as CATI(computer-assisted telephone interviewing), face-to-face surveys, field surveys, focus groups, mail, fax, or web-based surveys. Developments are underway for smartphone app data collection.

5. Consortium for the Longitudinal Evaluation of African Americans with Early RA (CLEAR)

The CLEAR Registry and Repository is a National Institute of Arthritis and Musculoskeletal and Skin Diseases (NIAMS)-funded project established through a contract in 2000 and renewed in 2006. The goals of this registry were to compile extensive demographic, socioeconomic, clinical, and radiographic data on African-Americans with rheumatoid arthritis and to collect biological samples (genomic DNA, RNA, serum) to allow a comprehensive analysis of factors influencing disease susceptibility and severity in African-Americans with RA. The CLEAR Registry provides a unique and valuable resource for the scientific community to explore genetic and non-genetic factors that influence disease occurrence and outcomes. The CLEAR Registry is composed of African-Americans RA patients with both early disease (≤ 2 years) who were followed longitudinally, as well as a cross-sectional cohort at various disease durations. CLEAR was a collaborative effort among five institutions: University of Alabama at Birmingham (Coordinating Center), Grady Hospital/Emory University, Atlanta, GA, University of North Carolina, Chapel Hill, NC, Medical University of South Carolina, Charleston, SC, and Washington University, St. Louis, MO. The CLEAR Registry is the largest available cohort of African-American RA and has a wealth of data, including radiographic, genetic, and autoantibody data.

6. COVID Enterprise Biorepository and Registry

Working with the Division of Infectious Diseases, Departments of Microbiology and Pathology, as well as other UAB divisions and departments and coordinated by the CCTS, the IRB has endorsed an Enterprise Research Platform for COVID-19 to shepherd the safe and efficient consent process and collection of specimens and clinical data, which is ongoing. The COVID-19 Enterprise Biorepository is approved to collect a wide-variety of specimens, including research-specific samples as well as remnant clinical and autopsy specimens. CCTS Informatics, with the Center for Outcomes & Effectiveness Research, Informatics Institute, and multiple schools, is coordinating clinical data and longitudinal follow-up for rigorous secondary analysis that ensures efficient and respectful engagement of research participants. In addition, the COVID-19 Collaborative Outcomes Research Enterprise (CORE) is leading the initial and longitudinal data collection and information curation to support a broad set of research goals. Through the CORE, investigators benefit from the permissions established by the COVID-19 Enterprise Research Platform to use clinical data (HIPAA Limited and Detailed Data Sets), to access protected health information and to allow longitudinal follow up. This new Enterprise Platform will serve to anchor and enable all COVID-19-related human subjects research across the campus.

7. (ENCOURAGE): Evaluating Community Peer Advisors and Diabetes Outcomes in Rural Alabama

ENCOURAGE is a group-randomized, controlled implementation trial in partnership with the UAB DRTC and established community coalitions. Diabetes is highly prevalent in the South and rural residents have a higher incidence of negative outcomes. This cluster randomized trial was conducted to determine if volunteer peer support added to diabetes education is superior to education alone in improving diabetes outcomes. It is designed to improve diabetes health outcomes in adult patients (> 18 years of age) with uncontrolled diabetes living in Alabama's Black Belt region. Peer advisors with diabetes or familiar with its management will counsel and link patients to clinical care and community resources. Part of the 12-month, weekly intervention for 8 weeks, followed by monthly contacts for the remainder of the year, is empowering/activating patients to self-manage their diabetes. Four community coordinators, 36 peer advisors, and 424 research participants were enrolled for the full study. The infrastructure established through the initial study has led to four additional projects. The first is examining the cost-effectiveness of using peer advisors. The second will assess peer support intervention for patients with diabetes and chronic pain. The third will examine peer advisor roles and integration into a larger health care team. Finally, investigators will look to implement the program in Birmingham. All of these projects will provide junior investigators with the opportunity to conduct research in disadvantage areas and engage both patients and other community stakeholders in research.

8. The Global Longitudinal Study of Osteoporosis in Women (GLOW)

GLOW is an international study that collects, analyzes, and distributes data to understand ways in which practice patterns influence the care of patients at risk for osteoporotic fragility fractures. GLOW is a prospective, longitudinal, observational study of women 55 years of age and older who visited a primary care physician during the two years prior to the study. A major study objective is to characterize the clinical and demographic attributes of patients at risk of fracture from representative sites in Europe, North America, and Australia in order to improve patient outcomes. Data on osteoporosis risk factors, treatment approaches, patient behavior, and fracture outcomes with an annual patient survey over a 5 year period are collected. The aim of the GLOW study is to collect uniform data to: (1) describe the distribution of risk factors for osteoporosis-related fracture; (2) apply published fracture risk assessment tools in a population of older women; (3) identify differences in physician patterns of diagnosis and management of osteoporosis (e.g., how health care providers are identifying individuals for treatment; characteristics of women being treated); (4) characterize factors that influence patient persistence with treatment, including patient characteristics, awareness of fracture risk and comorbid conditions; (5) assess the real-world effectiveness of care on the incidence of fracture; and (6) evaluate the cost effectiveness of interventions for the prevention and management of osteoporosis from the perspective of the health care provider. GLOW participants are from 10 countries, 17 regional sites with 706 (337 in the US) physicians enrolled and 60,461 (31,074 in the US) women enrolled. K. Saag has mentored trainees using GLOW data.

9. The Osteoporotic Fractures in Men (MrOS) Study

The Osteoporotic Fractures in Men (MrOS) Study (Lewis, CE PI) funded by the National Institute of Arthritis and Musculoskeletal and Skin Diseases (NIAMS), the National Institute of Aging (NIA), and the National Cancer Institute (NCI), began in July 1999. MrOS a 7-year multi-center prospective, longitudinal, observational study examining risk factors for vertebral and all non-vertebral fractures in older men, and of the sequelae of fractures in men enrolled approximately 6000 men aged 65 and older). The specific aims of the MrOS study include: (1) to define the skeletal determinants of fracture risk in older men, (2) to define lifestyle and medical factors related to fracture risk, (3) to establish the contribution of fall frequency to fracture risk in older men, (4) to determine to what extent androgen and estrogen concentrations influence fracture risk, (5) to examine the effects of fractures on quality of life, (6) to identify sex differences in the predictors and outcomes of fracture, (7) to collect and store serum, urine and DNA for future analyses as directed by emerging evidence in the fields of aging and skeletal health, and (8) define the extent to which bone mass/fracture risk and prostate diseases are linked. Lewis and Curtis have mentored trainees using this cohort.

10. The Multicenter Osteoarthritis Study (MOST)

Knee osteoarthritis (OA) is a common chronic painful disorder that is the most frequent cause of mobility disability in older people. The MOST study has been a major source of new knowledge about the course of this disease and factors that affect its course. Since the study began in 2003, it is increasingly recognized that by the time people develop chronic symptoms of knee OA, they usually have advanced structural findings of disease on MRI. Findings such as meniscal tears, malalignment and cartilage loss drive further structural deterioration and almost certainly limit prevention opportunities. MOST investigators believe that prevention opportunities are likely to be greater if started in those who do not yet have severe continuous knee pain or advanced structural findings of disease, and that there are opportunities to develop treatments and disease prevention strategies that have been unexplored, and that by using new technologies and focusing on persons at a milder or earlier disease stage than previous studies, we can identify such opportunities. While continuing to follow the existing cohort, originally over 3000 participants, MOST is recruiting a new mild disease cohort of 1500 participants to identify new risk factors for disease and to study consequences of disease. The goal is to find new strategies to prevent disease at an early stage and to limit the impact of disease once it has occurred.

11. Reasons for Geographic and Racial Differences in Stroke (REGARDS)

Funded in 2003 (R01) by the National Institute of Neurological Disorders and Stroke (NINDS), the Reasons for Geographic and Racial Differences in Stroke (REGARDS) cohort, is a prospective study of 30,239 community-dwelling Caucasian and African American adults aged 45+ who were sampled from 1,866 of the approximate 3,000 counties in the continental US. The cohort was oversampled for African Americans (~42%) and residents of the Southeastern Stroke belt (~56%). Drs. George and Virginia Howard lead the study. The purpose of the REGARDS project is to understand why people in some parts of the country develop more strokes than people in other parts of the country, and why African-Americans develop more strokes than whites. However, the study has been enriched by over 100 funded ancillary studies, both adding new and novel exposures (childhood socio-economic status, air pollution, direct measures of physical activity, kidney biomarkers, etc.) and outcomes (cognitive change, myocardial infarction, sepsis, venous thrombosis, etc.). Participants are randomly sampled with recruitment by mail then telephone, where data on stroke risk factors, socio-demographic, lifestyle, and psychosocial characteristics are collected. Written informed consent, physical and physiological measures, and fasting samples are collected during a subsequent in-home visit. Participants are followed via telephone at 6-month intervals for identification of stroke events. A second in-home assessment approximately 10 years after the baseline assessment is currently being completed on approximately 15,000 of the participants. The study has recently been funded through 2022 for the continued follow-up of the cohort, an increased emphasis on disparities in cognitive change and the development of dementia, and biomarkers for the development of cardiovascular risk factors including diabetes and hypertension. The novel aspects of the REGARDS study allow for the creation of a national cohort to address geographic and racial differences in a wide range of diseases.

12. Systolic Blood Pressure Intervention Trial (SPRINT) Study

The University of Alabama at Birmingham serves as one of the NIH/NHLBI Clinical Center Networks (CCN; Oparil, PI; Lewis, Co-PI) and Tulane serves as one of the clinic sites (Krousel-Wood, Site-PI) for the Systolic Blood Pressure Intervention Trial (SPRINT). The Systolic Blood Pressure Intervention Trial is a multicenter, randomized, controlled trial that compares two strategies for treating systolic blood pressure: one targets the standard target of <140 mm Hg, and the other targets a more intensive target of <120 mm Hg. Enrollment focused on volunteers of age ≥50 years (no upper limit) with an average baseline systolic blood pressure ≥130 mm Hg and evidence of cardiovascular disease, chronic kidney disease, 10-year Framingham cardiovascular disease risk score ≥15%, or age ≥75 years. The Systolic Blood Pressure Intervention Trial recruitment also targeted three pre-specified subgroups: participants with chronic kidney disease (estimated glomerular filtration rate <60 mL/min/1.73 m²), participants with a history of cardiovascular disease, and participants 75 years of age or older. The primary outcome is first the occurrence of a myocardial infarction (MI), acute coronary syndrome, stroke, heart failure, or cardiovascular disease death. Secondary outcomes include all-cause mortality, decline in kidney function or development of end-stage renal disease, incident dementia, decline in cognitive function, and small-vessel cerebral ischemic disease. For the trial, 9361 people from 102 clinics were

recruited and randomized. This includes 3331 women, 2648 with chronic kidney disease, 1877 with a history of cardiovascular disease, 3962 minorities, and 2636 ≥ 75 years of age. The major findings of SPRINT were a 25% reduction in the primary outcome and a 27% reduction in all-cause mortality. The extension of SPRINT, SPRING-ASK (Alzheimer's, Senior and Kidney), is ongoing. Oparil, Lewis, Krousel-Wood, and Muntner are available to mentor trainees using this cohort.

13. Study of Aging (SOA)

The Study of Aging is a prospective, observational study of a population-based sample of 1000 community-dwelling Medicare beneficiaries, stratified by sex, race, and urban/rural residence ending its 3rd cycle of R01 funding from NIA in 2015. The results of this study were used to identify the distribution of life-space changes associated with specific events and help identify factors that moderate precipitous life-space mobility changes in community-dwelling adults aged 75 years and greater and will guide the development and testing of interventions to optimize life-space mobility in late life. The hypothesis underlying this major research initiative is that potentially modifiable factors predict mobility (life-space) trajectories associated with aging among community-dwelling African Americans and whites. Brown and Locher have mentored trainees using this cohort.

14. Healthcare Cost and Utilization Project (HCUP) - HealthSouth

The Healthcare Cost and Utilization Project (HCUP) is a family of health care databases and related software tools developed through a Federal-State-Industry partnership to build a multi-State health data system for health care research and decision making. HCUP is the Nation's most comprehensive source of hospital care data, including information on inpatient stays, ambulatory surgery and services visits, and emergency department encounters. HCUP enables researchers, insurers, policymakers and others to study health care delivery and patient outcomes over time, and at the national, regional, State, and community levels. HCUP is sponsored by the Agency for Healthcare Research and Quality (AHRQ) as part of its mission to improve the quality, safety, efficiency, and effectiveness of the Nation's health care system. HCUP databases bring together the data collection efforts of State data organizations, hospital associations, private data organizations, and the Federal government to create a national information resource of patient-level health care data. HCUP includes the largest collection of longitudinal hospital care data in the United States, with all-payer, encounter-level information beginning in 1988. These databases enable research on a broad range of health policy issues, including cost and quality of health services, medical practice patterns, access to health care programs, and outcomes of treatments at the national, State, and local market levels. The Lister Hill Center for Health Policy at CCTS HUB (Muntner, Director) has HCUP National Inpatient Sample (NIS) data through 2015. It is available to all Lister Hill scholars and trainees through a sponsoring Lister Hill Scholar. Kilgore has expertise and experience mentoring trainees using this data.

15. Atlanta Research Data Center (ARDC)

Located at the Federal Reserve Bank of Atlanta, the Atlanta Research Data Center (ARDC) seeks to provide qualified researchers in Atlanta, and around the Southeast, with the opportunity to perform statistical analysis on non-public Census microdata. The ARDC, established in 2011, is 1 of 8 centers in the United States and is a partnership between the U.S. Census Bureau and a consortium that includes Georgia State University, the Federal Reserve Bank of Atlanta, the Centers for Disease Control and Prevention (CDC), Emory University, Georgia Tech, the University of Alabama at Birmingham, and the University of Georgia. There are four general categories of data on which qualified researchers may perform statistical analysis inside the secure ARDC: 1) Economic Data; 2) Demographic Data; 3) Mixed Data; and 4) Health data. The ARDC is part of a network of secure Research Data Centers located across the United States, collectively known as the Federal Statistical Research Data Centers (FSRDCs). The ARDC is managed by the Census Bureau's Center for Enterprise Dissemination (CED). Funding for the ARDC is provided in part by the member institutions.

16. OsteoArthritis Initiative (OAI)

The Osteoarthritis Initiative (OAI) is a nationwide, multi-center, longitudinal, prospective observational research study of men and women. The OAI is a public-private partnership between the NIH and private industry which has an overall aim to develop a public domain research resource to facilitate the

scientific evaluation of biomarkers for osteoarthritis as potential surrogate endpoints for disease onset and progression. Osteoarthritis (OA) is the most common form of arthritis and the major cause of activity limitation and physical disability in older people. Four clinical centers and a data coordinating center conducted the Osteoarthritis Initiative (OAI), a public-private partnership that brought together new resources and commitment to help find biochemical, genetic, and imaging biomarkers for development and progression of OA. The OAI established and maintain a natural history database for osteoarthritis that will include clinical evaluation data, radiological (x-ray and magnetic resonance) images, and a biospecimen repository from 4,796 men and women ages 45-79. The seven-year project enrolled participants who have, and those who were at high risk for developing, symptomatic knee osteoarthritis. All data and images collected is available to researchers worldwide to help quicken the pace of biomarker identification, scientific investigation, and OA drug development. Access to biospecimens is by application to the National Institute of Arthritis, Musculoskeletal and Skin Diseases (NIAMS).

17. Cohort Study of Medication Adherence among Older Adults (CoSMO)

The mission of the Tulane-led Cohort Study of Medication Adherence among Older Adults (CoSMO) is to lay the groundwork for interventions to improve medication adherence and clinical outcomes in older adults with hypertension and will increase our understanding of factors contributing to therapeutic outcomes in the use of medications by these patients. The adverse impact of Hurricane Katrina led to hypertension medications and care to not be accessible, which led to PTSD and untreated hypertension patients in Katrina ravaged area codes. The CoSMO was initiated to observe the Katrina recovery and effects on untreated hypertension. The goal of Cohort Study of Medication Adherence among Older Adults (CoSMO) with essential hypertension (HTN) in a managed care setting is to investigate the multiple factors that influence antihypertensive medication adherence (via validated self-report and pharmacy fill measures). The specific aims of this cohort study are as follows:

- to assess the impact of psychosocial, behavioral, health, quality of life, sexual function, medication class, and clinical factors measured at baseline on subsequent change in antihypertensive medication adherence over 2 years of follow-up
- to assess health care system issues (perception of primary care provider, satisfaction with access and communication), use of prescribed and over-the-counter and unconventional medications and lifestyle modifications on anti-hypertensive medication adherence and change in adherence
- to determine the relationship of antihypertensive medication adherence at baseline with future medical and psychosocial outcomes such as blood pressure control, cardiovascular disease incidence and all-cause mortality, quality of life, utilization
- to explore differences in aims 1-3 with regards to gender and race.
- to address these specific aims, a random, race-and gender-diverse sample of 2194 HTN patients > 65 years of age who met the study eligibility requirements from the pool of all hypertensive patients enrolled in a large southern managed care organization. Study participant's medication adherence, demographic, behavioral, treatment (i.e., medication class), quality of life, duration of hypertension, psycho-social factors and perceptions of primary care provider, and satisfaction with access to care were assessed at baseline and after 1 and 2 years of follow-up via telephone-administered surveys.
- Rigorous quality control procedures have been implemented to assure high quality data. Blood pressure control, severity of hypertension, cardiovascular outcomes, healthcare utilization at baseline and follow-up have been collected. Models predicting change in medication adherence, blood pressure control, utilization, and cardiovascular events are under development. Krousel-Wood and Muntner have experience mentoring trainees using this cohort.

18. Cooperative Human Tissue Network (CHTN) – Southern Division

The CHTN was initiated in 1987 by the National Cancer Institute (NCI) Cancer Diagnosis Program to provide increased access to human tissue for basic and applied science from academia and industry to accelerate the advancement of discoveries in cancer diagnosis and treatment. The CHTN –Southern Division at the CCTS Hub is one of six member institutions funded by the National Cancer Institute to

prospectively collect, process, and distribute remnant human tissue specimens to IRB-approved biomedical researchers. The CHTN operates through a shared networking system which allows investigators greater access to available research specimens. CHTN offers a variety of preparation and preservation techniques to ensure investigators are receiving the quality specimens needed for research. The CHTN operates on a unique prospective procurement model rather than a banking model and focuses on being user friendly. While a bank collects, processes, and stores specimens in a "one-shoe-fits all" approach, the CHTN staff work closely with each investigator to tailor the collection, processing, temporary storage, and distribution of tissues in order to meet his/her exact needs and to support his/her research in a timely manner. A diagnostic pathologist reviews each request and can help investigators select the proper tissues and protocols to support their research. All tissues distributed must meet quality assurance/control standards, ensuring investigators a high quality product. Remnant human tissue specimens (including normal, benign, malignant, or diseased) from routine surgical resections and autopsies are procured to the specifications of the investigator. Frozen aliquots of fluid (serum, plasma, buffy coat, urine, saliva) as well as paraffin blocks and/or slides may also be made available. Although the CHTN operates as a network, each CHTN division is responsible for primary coordination and intake of applications from investigators based upon the investigator's geographic location. The Southern Division encompasses Kentucky and all states south and west from the Carolinas to Texas.

19. Veterans Affairs (VA) Administrative Databases (inpatient, outpatient, and pharmacy datasets)

- **VA administrative databases (inpatient, outpatient, and pharmacy datasets):** VA administrative data documenting utilization of care and patient characteristics are available as computerized VA administrative databases, including patient treatment file (PTF) and outpatient clinic (OPC) tables, through the Austin Automation Center, a national VA data warehouse. These data are reliable for demographics and most common diagnoses, and valid for specific diagnoses. Data are available from fiscal year 1998. The PTF covers four main categories of care: (1) acute (inpatient admissions); (2) extended (domiciliaries, VA nursing homes, or community nursing homes); (3) observation (hospital stays (generally less than 24 hours); and (4) non-VA (care funded by the VA and provided in non-VA hospitals). The OPC files have two components, visit file which contains one day's services for a patient (date, patient demographics, codes for each clinic stop (up to 15) for the day etc.) and event file which contains one ambulatory encounter by a patient (date, appointment type (e.g., regular, employee, research), procedure done (up to 15), surgeries performed (up to 15), provider type etc.). These datasets have been used extensively to perform clinical research in veterans for decades.
- **Veterans Health Information Systems and Technology Architecture (VISTA) / Veterans Affairs Medical Centers (VAMC):** VAMCs use 180 health information systems deployed across all veteran care sites in the United States. VISTA provides clinical, administrative, and financial functions for all of the 1700+ hospitals and clinics of the Veterans Health Administration. VISTA consists of 180 clinical, financial, and administrative applications integrated within a single transactional database. The Veterans Health Administration (VHA) is the largest integrated national healthcare delivery system in the United States, providing care for nearly 9 million veterans by 180,000 medical professionals.
- **Informatics and Computing Infrastructure (VINCI):** As part of the mission of the VA Informatics and Computing Infrastructure (VINCI), data sources collected both locally and nationally through various initiatives are aggregated and prepared for research use. In addition to data available from individual VISTA systems, data from the Regional Data Warehouses for all 4 VA regions, the VA Corporate Data Warehouse, and the VA Health Data Repository are included. Other data sources collected and published from the VHA Decision Support System (DSS), and Inpatient and Outpatient Medical SAS (MedSAS) can be requested through VINCI. VINCI does not grant use of the data but instead facilitates the process through VA National Data Services and other data stewards as needed. VINCI's physical environment is at the VA Automation Center in Austin, Texas. It has 20 high-performance servers and 72 terabytes of fast storage. This environment is a secure enclave within the VA and has multiple technologies and procedures in place to prevent data loss.

- **The VA Pharmacy Benefits Management (PBM) database:** is a national database of information about all prescriptions dispensed within the Veterans Health Administration (VHA) System beginning with fiscal year 1999. The PBM system is a longitudinal database including VA pharmacy data for each individual patient. PBM data have been used more extensively for pharmacy utilization studies, and validation on PBM data is more complete than for other VA data sources, such as the Decision Support System, which only includes data to 2002. The PBM Database is a Microsoft SQL Server™ database maintained by the PBM Service located at Hines, IL. Outpatient prescription orders filled at a VA Pharmacy or Consolidated Mail Outpatient Pharmacy (CMOP) are extracted monthly from each VistA site and loaded into the PBM Database. The data elements available for each prescription order dispensed for a patient include: product name, ordering provider, drug product costs, dosing instructions, National Drug Code (NDC) where applicable, quantity dispensed, formulary status, and VA drug class. Other data elements are available depending on whether the order was an IV, unit dose, or outpatient prescription order. These VA databases will be linked with each other using scrambled Social Security Numbers (SSNs), or in some cases, real SSNs, as has been done in previous VA studies.

20. Arthritis Patient Partnership with Comparative Effectiveness Researchers (AR-PoWER)

In recognition of the importance of filling evidence gaps in inflammatory arthritis-related research, CreakyJoints (CJ) arthritis patient network, a network of approximately 55,000 arthritis patients and caregivers in all 50 U.S. states, and the University of Alabama at Birmingham received funding from the Patient-Centered Outcomes Research Institute (PCORI) to establish the Arthritis Patient Partnership With Comparative Effectiveness Researchers (AR-PoWER) patient-powered research network (PPRN). Partnered with the UAB CCTS, UAB DSAM CERTs, the American College of Rheumatology (ACR), and the Consortium of Rheumatology Researchers of North America, Inc. (CORRONA) the AR-PoWER PPRN is translating a high-impact patient advocacy and education-focused organization into an equally high-impact patient-centered network able to conduct research (additional details of active research provided in the scientific plan).

21. Cancer Care Outcomes Research and Surveillance Consortium (CanCORS)

The CCTS HUB serves as a Primary Data Collection and Research (PDCR) site in the NCI-funded Colorectal and Lung Cancer CanCORS consortium (Fouad, PI). This research consortium of eight grantees measures the quality of cancer care and associated health outcomes in the United States. The project supports prospective research in a cohort of approximately 10,000 patients with newly diagnosed lung cancer or colorectal cancer recruited from geographically diverse populations and health care systems. The CCTS HUB PDCR site is for newly diagnosed cases of both lung and colorectal cancer with special emphasis on African Americans. Fouad is an author of the publication that introduced the goals and methods of the Consortium to the broader community of cancer researchers and clinicians; several manuscripts elucidating the findings of the consortium with regards to ovarian cancer and the recruitment of patients to cancer clinical trials are in the process of being submitted for publication. Fouad has mentored trainees using this cohort.

22. UAB Health System Cancer Community Network (CCN)

The UAB Health System Cancer Community Network, developed by the UAB Comprehensive Cancer Center and UAB Medicine, is a network of hospitals across Alabama, Florida, Georgia, and Mississippi that emphasizes collaboration between UAB and community cancer centers on evidence-based guidelines for cancer treatment to patients in local communities. The UAB Health System Cancer Community Network provides a structured program to support community-based oncology services to foster collaborative physician relationships, provide continuing medical education and offer local patients the opportunity to enroll in clinical trials managed by leading scientists and physicians, and access to UAB's best practices in cancer care at a local level.

23. Alabama Regional Quality Management Group

The Alabama Regional Quality Management Group (ALRQG) initially formed in response to the Ryan White Treatment Modernization Act of 2006, which instructed quality leaders in Part C and D clinics to implement a continuous quality improvement program with activities particularly focused on the HIV

Care Continuum. The ALRQG is comprised of Ryan White Part C and D clinics and represent all 67 counties in Alabama. After UAB CFAR members shared study findings that missed HIV clinic visits are linked to a three-fold increased mortality risk,^{4,5} a risk level equivalent to a CD4 count <200, the ALRQG decided to add missed visits as a quality indicator to quarterly reports. As these missed visit data have now been shared quarterly for several years, a number of participating sites have questioned what can be done in response to the observed high clinic-wide missed visit rates.

24. CFAR Network of Integrated Clinical Systems (CNICs)

This is the first electronic medical records-based network poised to integrate clinical data from the large and diverse population of HIV-infected persons in the modern HAART era. CNICS provides research infrastructure to support HIV clinical outcomes and comparative effectiveness research using data collected at one of 8 Center for AIDS Research (CFARs). As of early 2016, CNICS contained 32,237 patients; 82% male and 18% female. CNICS directly reflects the outcomes of clinical decisions and management options made daily in the care of HIV infected individuals. Unlike data collected in structured interviews or retrospective medical record review, CNICS captures a broader range of information associated with the rapidly changing course of HIV disease management. CNICS is distinguished by its ability to provide peer-reviewed-open access to a rich and rapidly evolving clinical research platform that prospectively collects comprehensive patient data including validated outcomes, longitudinal resistance data, and detailed PROs with readily available biological specimens.

25. National Exercise Clinical Trials Network (NExTNet Clinical Database)

The National Exercise Clinical Trials Network (NExTNet) was established to facilitate multi-site exercise clinical trials to address these knowledge gaps in a disease-specific or population-specific manner. Currently 68 institutions from coast to coast are members of the growing network. Among NExTNet's primary functions is to foster standardization of procedures for rigorous multi-site trials. The University of Alabama at Birmingham (UAB) Center for Exercise Medicine serves as the NExTNet Coordinating Center.

26. Spinal Cord Injury Model Systems Database

Since 1975, the UAB-SCIMS has enrolled more than 2,600 people with acute SCI in our database with 13,041 annual follow-up entries. Combined with the other centers across the country, more than 42,000 people have been enrolled with over 150,000 subsequent annual follow-up visits documented.

27. UAB Pharmacoepidemiology and Economic Research Unit of COERE (PEER)

Offering considerable experience using Medicare and Medicaid data and other large administrative databases including those from large health plans (e.g., United HealthCare, Aetna, Blue Cross Blue Shield, and the General Practice Research Database). Expertise includes: 1) preparing applications to the CMS for permission to obtain claims data; 2) storing and managing large databases securely and efficiently; 3) designing studies to use the data appropriately; 4) processing and analyzing the data; and 5) conducting linkages with the National Death Index (NDI).

28. Treatment Efficacy and Toxicity in Rheumatoid Arthritis Database and Repository (TETRAD)

A sustainable database of treatment-response data and a repository of accompanying samples. Funding for the start-up phase of TETRAD stemmed from a two-year, \$3.3 million Grand Opportunity (GO) grant from the National Institute of Arthritis, Musculoskeletal, and Skin Diseases (NIAMS). The database is headquartered at UAB with the repository of samples residing in New York. UAB will spearhead the undertaking involving 10 sites nationwide. Other sites include Johns Hopkins University, University of California at San Francisco, Stanford University, and Harvard University.

29. UAB 1917 HIV Clinic Cohort

A prospective, observational HIV clinical cohort study established in 1992 through support by UAB Center for AIDS Research (CFAR). It includes extremely well characterized patients (>7,000 overall, 1,700 active). In 1999, the database was expanded to include real-time collection of clinic utilization data, thereby allowing cost / expenditure analyses. In August 2004, the UAB 1917 Clinic deployed a client server-based point-of-care electronic medical record system (1917 EMR) developed within the

clinic to its own specifications. The 1917 EMR system allows for real-time collection of medication, laboratory, clinical, behavioral, and health care utilization data. Over the years numerous clinical and behavioral comparative effectiveness studies have been conducted through the cohort. These include evaluation of the “efficacy vs. effectiveness” of initial ART regimens in patients treated in clinical trials vs. routine care.

CLINICAL CARE AND MEDICAL TRAINING

Facilities

Partnering with UAB and the School of Medicine to provide resources for clinical care and training for medical professionals, the entities listed below highlight the diversity of the UAB network and showcase the advances made since its inception. UAB Medicine unites **UAB Hospital**, The **Kirklin Clinic**, **UAB Health Centers**, the **Callahan Eye Foundation**, **VIVA Health** (a health maintenance organization and subsidiary of Triton Health Systems, LLC, owned by UAB Medicine that provides quality, reliable health care) and a host of other facilities. The entities listed below are part of the broad patient care network on the UAB campus:

UAB Hospital: The centerpiece of UAB's clinical enterprise with 877,036 square feet of building space, UAB Hospital is located in Birmingham's Medical District. In the midst of UAB's major research centers and clinics, the 1,157-licensed-bed hospital is among the 20 largest and best equipped in the nation. It includes the UAB Women & Infants Center, Spain Rehabilitation Center, the Center for Psychiatric Medicine, and the freestanding UAB Hospital-Highlands. As Alabama's only Level 1 Trauma Center (as designated by the American College of Surgeons), UAB Hospital provides care for many of the most serious injuries that occur anywhere in the state through its emergency department, operating rooms, Trauma/Burn Unit, and Spain Rehabilitation Center, which is one of the Southeast's foremost providers of comprehensive rehabilitation care. The Women & Infants Center offers advanced services and the latest medical technology to care for healthy and high-risk pregnant women, healthy and high-risk newborns, and women receiving care for a variety of gynecological problems, including gynecological cancers. It includes UAB's Regional Newborn Intensive Care Unit (RNICU), the state's largest. Together with Children's of Alabama, UAB offers the only Level IV NICU in Alabama – designated by the American Academy of Pediatrics as the highest and most comprehensive level of care available. UAB Hospital-Highlands is a general acute care component adjacent to campus that provides an emergency department for non-traumatic and non-catastrophic cases, comprehensive surgical and nonsurgical treatment for bone and joint disorders, a specialized unit for fragility fractures, and the UAB Sleep-Wake Disorders Center. It also houses the Acute Care for the Elders (ACE) Unit, the region's first model patient unit for coordinated geriatric care, and the UAB Pain Treatment Clinic, which serves patients with acute and chronic conditions including intractable cancer pain.

The Kirklin Clinic: The Kirklin Clinic® (TKC) opened in 1992 as a premier outpatient facility to provide examination and treatment rooms for physicians representing nearly three dozen specialties in adult medicine. The five-story facility covers a full city block with 577,350 square feet, 51 different services for patients, more than 30 distinct clinical units of multidisciplinary teams, and an adjacent covered parking deck that accommodates 1,450 vehicles. The Kirklin Clinic® at Acton Road provides a variety of patient care services south of Birmingham, established in the suburban community. The Whitaker Clinic of UAB Hospital opened in the summer of 2017. The two clinics serve more than 2,000 patients per day. With more than 250 exam rooms and many nationally ranked specialties, The Kirklin Clinic of UAB Hospital and the Whitaker Clinic of UAB Hospital combine the latest in clinical care with teaching and research. TKC staff collaborates and communicates extensively with our patients in order to deliver the ultimate patient experience and the highest quality of health services.

1917 HIV/AIDS Outpatient Clinic: The 1917 Clinic provides care to individuals infected with HIV. The 1917 Clinic is the largest HIV health care unit in Alabama and one of the country's leading HIV clinics. Its mission is to address the needs of patients, their families and significant others, doctors and scientists, and the community in responding to the urgent and unique issues surrounding HIV/AIDS. The Clinic's mission is to provide comprehensive and compassionate health care for people with HIV infection by: 1) delivering world-class, state-of-the-art primary HIV treatment; 2) offering specialty clinics for HIV patients with needs in dermatology, oncology, neurology, addiction recovery, and palliative care; 3) providing social service support; 4) offering chaplain services; 5) facilitating interactions between laboratory scientists and the Clinic by providing clinical specimens from well-characterized patients; 6) providing ongoing medical education; 7) establishing a vital link between the activities of the Clinic and the community; and 8) conducting clinical trials of new approaches to treatment

Spain Rehabilitation Center: As one of the Southeast's premier providers of comprehensive rehabilitation care, the nationally recognized programs available at Spain Rehabilitation Center are designed to address every aspect of a patient's rehabilitation, including physical, social, and psychological health. Spain Rehab is

the hub for UAB Medicine's Traumatic Brain Injury Model Systems, Spinal Cord Injury Model Systems, and the National Spinal Cord Injury Statistical Data Center. Specialists are devoted exclusively to the practice of rehabilitation medicine, utilizing advanced research, technology, and expertise to provide the highest level of patient care. Spain Rehab specialists and staff provide the highest level service across the SRC spectrum with services that include Physician Services, Neuropsychology and Rehabilitation Psychology, Orthotists and Prosthetists, Rehabilitation Case Management, and Therapeutic Recreation Specialists. In addition, Spain Rehab offers stellar therapeutic services which include Occupational, Physical, Music, Speech-Language, and Outpatient Therapy Services. Interdisciplinary treatment integrates specialists from all areas of the UAB Health System to bring together unique skills and expertise to form care teams that evaluate and treat each patient. These efforts result in a comprehensive care plan that coordinates treatment to meet each patient's individual needs. To further expand the Spain Rehab network, in May 2022, UAB Medicine opened a replacement inpatient rehabilitation facility on 7th Avenue South, behind the UAB Sparks Building. The 106-bed, 11-story facility is expected to open in 2025. It will feature the most advanced design and the latest technology, and each floor will be dedicated to caring for specific types of patients, including those being treated for stroke, traumatic brain injury, spinal cord injury, and epilepsy. Each room will have an overhead lift, and patients will have access to a therapy gym, private therapy suites, and speech therapy suites. The new facility also will include a putting green, basketball court, and many other areas and features designed to enhance the rehabilitation experience and provide proper support for physical, mental, and emotional recovery.

UAB Women and Infants Center: UAB's newest facility, the UAB Women and Infants Center is a world-class health care facility dedicated solely to the care of women and infants. Whether it is inpatient surgical care or a routine outpatient office visit, the Center provides complete care, all under one roof. The 400,000-square-foot hospital is one of the first in the Southeast with all private neonatal intensive care nursery and continuing care nursery rooms. It also offers private labor, antepartum, postpartum, and gynecology patient rooms. The department of obstetrics and gynecology has a regional, national, and international reputation for clinical excellence and innovation, and in 2020, it was ranked #15 by US News and World Report. UAB Hospital is the third largest public hospital in the USA. The UAB Women & Infants Center houses one of the largest neonatal ICUs in the United States. In 2019, UAB was honored with the America's Best Hospital designation by the Women's Choice Award for obstetrics, bariatric surgery, heart care, cancer care, and as a best breast center practice. After surpassing more than 10,000 robotic surgeries in 2018, UAB also became one of the nation's leading hospitals in robotic surgery volume. In addition, the Department of Obstetrics and Gynecology provides subspecialty expertise in gynecologic oncology, maternal-fetal medicine, prenatal genetic and structural diagnosis, pelvic floor and urogynecologic disorders, reproductive endocrinology and infertility, in vitro fertilization and human reproductive genetics, adolescent gynecology and primary care in obstetrics and gynecology. The private room design enhances maternal, family, and infant bonding. Specialized isolation rooms and rooms designed for twins and triplets further enhance the family atmosphere. UAB's highly-trained and compassionate physicians, nurses and other health professionals utilize advanced services and sophisticated state-of-the-art medical technology dedicated to the care of healthy and high-risk pregnant women, healthy and high-risk newborns, and women receiving care for a variety of gynecological challenges, including gynecological cancers.

UAB Medicine Urgent Care: UAB Medicine Urgent Care offers convenient access to both UAB Medicine physicians and Advanced Practice Providers when a provider needs to be seen quickly for non-life-threatening illnesses and injuries. UAB Urgent Care offers walk-in appointments seven days a week, with lab and x-ray services available onsite. The 2,756-square-foot clinic features seven exam rooms, a digital X-ray machine and a moderate complexity lab, and it will employ the UAB electronic health record, which will enable seamless follow-up and communication with other UAB providers. Clinic physicians will not refill or change narcotic or other controlled substance prescriptions. Patients must have those requests handled by their primary-care physician.

UAB Eye Care: At UAB Eye Care, comprehensive eye care services is provided to the community as well as training and education for optometry students and resident optometrists. UAB Eye Care's state-of-the-art, multidisciplinary clinic is outfitted with the latest optometric equipment necessary for the accurate diagnosis and treatment of most eye problems. UAB Eye Care clinicians provide comprehensive services for both pediatric and adult patients in a number of optometric subspecialties. Exemplary patient care is provided in the recently renovated clinic "UAB Eye Care," a 34,000 square foot state-of-the-art facility that covers everything

from primary eye care, including the dispensing of glasses and contacts, to the treatment of ocular disease, as well as low vision rehabilitation and pediatric vision care.

Callahan Eye Foundation Hospital: The UAB Callahan Eye Hospital (CEH) is the state's only facility dedicated to providing quality medical and surgical eye care to the people of Alabama and the Southeast. Callahan's primary business consists of outpatient ophthalmology and ambulatory surgery, making it one of the busiest ophthalmology surgery centers in the country. To meet the growing demand for eye care in Alabama, UAB Callahan Eye Hospital Clinics operates numerous convenient locations across central Alabama. These satellite clinics are backed by the knowledge and expertise of Callahan Eye Hospital, which for over 50 years has focused on delivering innovative eye care and pioneering breakthroughs in preserving and restoring eyesight. Callahan Eye Hospital Clinics provide that same level of vision care within the community. Moreover, the hospital offers a 24-hour, 7 day a week eye emergency room and is the region's only Level I Ocular Trauma Center. With exceptional healthcare professionals, dedicated surgery suites, and state-of-the-art equipment, more than 11,000 surgeries per year. The hospital offers nine superbly equipped ophthalmology operating rooms and provides the full spectrum of specialized eye care. UAB Callahan Eye Hospital is also home to a comprehensive eye research program via partnership with the UAB Department of Ophthalmology and provides the state's only accredited (Accreditation Council for Graduate Medical Education, ACGME) ophthalmology training program.

University of Alabama Health Services Foundation: UA Health Services Foundation is a nonprofit, group physician practice including The Kirklin Clinic and The Kirklin Clinic at Acton Road. The UAHSF was founded by pioneering heart surgeon John W. Kirklin, M.D., in 1973. UAHSF comprises multiple clinics and a network of community based clinics that offer medical services in over 35 specialties, as well as administrative, technical, and support departments. Since its inception, the UAHSF has achieved national prominence for high quality patient care services and the unique knowledge, dedication, excellence, and compassion of its employees.

- **HSF General Endowment Fund:** The University of Alabama Health Services Foundation (UAHSF) General Endowment Fund (GEF) provides capital on a competitive, peer-reviewed basis, to enhance the infrastructure of the UAB academic health center for laboratory research, patient-oriented efforts, clinical care program development, and medical education initiatives. In general, funds from the HSF-GEF are invested in research, educational, and clinical programs that are deemed in the best interest of the UAB Medical Center and for UAB university-wide projects which are consistent with institutional priorities.

Affiliated Hospitals Involving UAB Faculty, Campus, and Resources

In addition to the UAB Medicine facilities listed above, two additional hospitals are physically part of UAB's main campus in Birmingham along with three affiliated off-campus hospitals. In addition, the use of UAB faculty and an extensive network of affiliated faculty and staff provides both clinical and investigative expertise to the greater Birmingham area and beyond.

Children's Hospital of Alabama: Since 1911, Children's of Alabama has provided specialized medical care for ill and injured children. Ranked among the best pediatric medical centers in the nation by U.S. News & World Report, Children's provided care for youngsters from every county in Alabama, 45 other states and six foreign countries last year, representing more than 677,000 outpatient visits and more than 15,000 inpatient admissions. With more than 2 million square feet, including dedicated space for the Center for Clinical and Translational Science (CCTS) Child Health Research Unit, it is the third largest pediatric medical facility in the U.S. In 2012, Children's opened two additional facilities, strengthening its ability to serve pediatric patients statewide. The Benjamin Russell Hospital for Children, a 12-story, 760,000-square-foot, \$400 million expansion allowed Children's to increase its licensed beds from 275 to 332, ranking Children's in the top 10 pediatric medical centers based on bed count. The hospital also opened the Joseph S. Bruno Pediatric Heart Center, which includes a 20-room cardiovascular intensive care unit, two dedicated surgical suites, three heart and vascular catheterization labs and four dedicated extracorporeal membrane oxygenation (ECMO) rooms. The floor connects directly via skywalk to the University of Alabama at Birmingham (UAB) Women and Infants Center to provide quick and efficient access for physicians and surgeons to pediatric patients, as well as immediate transport of newborns requiring specialized care for congenital heart ailments. At the cornerstone of

the Bruno Heart Center is its innovative pediatric hybrid catheterization suite, the only one of its kind in the state of Alabama. The hybrid cath lab is equipped with \$3 million worth of state-of-the-art technology that allows it to be immediately converted to a cardiovascular surgical suite, eliminating the need to bring children out of anesthesia for a second procedure in a different room.

Birmingham VA Medical Center: Also situated in the heart of the UAB academic research center and interconnected with UAB research and health care delivery facilities since 1975, the Birmingham Veterans Affairs Medical Center (BVAMC) is an acute care facility with 313 beds currently in operation. The Birmingham VA Health Care System also provides health care services at 11 locations in Alabama. Facilities include the Birmingham VA Medical Center and 9 community-based outpatient clinics in Bessemer, Birmingham, Childersburg, Gadsden, Guntersville, Huntsville, Jasper, Shoals, and Anniston-Oxford. The medical center provides Veterans with comprehensive primary and specialty health care in medicine, surgery, psychiatry, physical medicine and rehabilitation, neurology, oncology, dentistry, and geriatrics. BVAMC also provides specialty care for Veterans referred from other VA facilities, including eligible veterans in the VA Southeast Network Veterans Integrated Service Network. The facility provides acute tertiary medical and surgical care to veterans of Alabama and surrounding states. Recent construction provides state-of-the-art facilities and equipment in all clinical programs. Research at the BVAMC is conducted by the University of Alabama at Birmingham faculty from the School of Medicine and the School of Nursing. Grants funded through the VA support those research projects. Most staff physicians have joint appointments with VA and its primary affiliation, UAB.

Baptist Health: Baptist Health, a proud UAB affiliate located in Montgomery, AL, is the largest healthcare system serving central Alabama, providing comprehensive hospital-based and outpatient services to residents in Central Alabama. With over 600 highly respected and experienced physicians on the medical staff, Baptist Health provides residents of Central Alabama with access to advanced treatments, technologies, and cutting-edge medical care close to home. The 775-bed health system has a regional service area of 14 counties with approximately 700,000 people. Baptist Health's family of health care services includes three acute care hospitals, a regional cancer center, a free standing psychiatric hospital, a joint venture surgical center, a network of ambulatory clinics, outpatient imaging centers, urgent care facilities, wound care services, rehabilitation, and home care services. Baptist Health also proudly supports medical education and teaching through support of the UAB School of Medicine Montgomery Regional Campus, physician and nurse residency programs and clinical rotations offered through numerous allied health programs. In addition, the Institute for Patient Safety and Medical Simulation provides medical education for practicing professionals and clinicians in training with real-time simulation exercises to advance learning, improve the quality of health care delivery and reduce the likelihood of medical errors. Baptist Health makes a commitment to providing compassionate care and advanced technology offerings that are relevant today and in the future for each and every patient they serve. Baptist Health has placed a strong emphasis on teaching community members to reduce their risks of illness and disease while encouraging them to live healthier lives. Baptist Health providers know that wellness conversations are not the wave of the future, but instead, life-changing conversations for today. The Baptist Health focus on preventive care began well ahead of its time and continues today because prioritizing the health of the community is their primary goal.

Cooper Green Health Services: Cooper Green Mercy Health Services is owned by Jefferson County, Alabama and is an affiliate of UAB. It first opened as Mercy Hospital in 1972 as a 319-bed acute care facility and in 2012, the facility was transitioned to a multi-specialty outpatient health service organization. The health service organization offers both primary and specialty care, behavioral health, and urgent care. In addition, it offers an onsite pharmacy, radiology, and clinical laboratory, as well as OT, PT, Speech, and Respiratory Therapy. Consistent with its mission, the health service organization continues to offer healthcare to the citizens of Jefferson County regardless of their ability to pay. As a county-owned health service organization, Cooper Green Mercy provides healthcare services to all Jefferson County residents with fees based on family size and income. The health service organization coordinates with the University of Alabama at Birmingham (UAB) Health System, one of the nation's leading academic medical centers, as a training site for medical residents and to provide patients with diagnostic tests and procedures not provided onsite. In addition, many of the specialty clinics are staffed by UAB faculty who practice part-time at the facility. Through this partnership, Cooper Green Mercy Health Services' patients, most of whom are low income or economically-challenged, are able to receive not just comprehensive healthcare services, but world class healthcare.

UAB Medical West: UAB Medical West offers outstanding health care in and around Bessemer, Alabama. Our 13 health center locations offer a combination of emergency care, orthopedics, rehabilitation, medical imaging, and more. Medical West provides 310 licensed beds for primary and specialty care, plus a 21-bed emergency room and new professional office building with surgical center. In November of 2021, Medical West Hospital Authority, broke ground on its replacement facility in Bessemer, slated to be opened in 2024. The new building will include a 412,000 square foot, 9-story hospital with 200 beds and a 127,000 square foot, 5-story medical office building. The facility, a full-service hospital, will feature a new surgical and endoscopy suite, state-of-the-art imaging technology and more intensive care beds.

Ascension St. Vincent's: The University of Alabama at Birmingham Health System and Ascension St. Vincent's have entered into a strategic alliance that will increase access to high-quality, innovative medical care through multiple outlets and health programs. In January 2020, the health systems announced their intention to form a strategic alliance and began a period of due diligence. The formal alliance began July 1, 2020. St. Vincent's Health System, based in Birmingham, Alabama, United States is an operator of acute care hospitals located in the Birmingham area and a health ministry of Ascension Health. St. Vincent's Health System is made up of six facilities: St. Vincent's Birmingham, St. Vincent's Blount, St. Vincent's Chilton, St. Vincent's East, St. Vincent's St. Clair, and St. Vincent's One Nineteen. The company employs over 4,700 people throughout its six facilities.

Lakeshore Foundation: The Lakeshore Foundation is a non-profit 501c3 organization that promotes independence for persons with physically disabling conditions and provides opportunities to pursue active, healthy lifestyles. Lakeshore Foundation offers a wide range of rehabilitation, fitness, recreation, athletic and education programs to children and adults who experience diagnostic conditions including spinal cord injuries, cerebral palsy, multiple sclerosis, stroke, amputation, and visual impairment. The Foundation also serves persons who have been diagnosed with arthritis, diabetes, chronic pain, cardiac conditions, and many other related disorders. The University of Alabama at Birmingham (UAB) and Lakeshore Foundation established a formal collaboration in 2011 to advance research and training in promoting the health of people with disabilities. The primary aim of the Collaborative is to create a unique and focused research program that capitalizes on Lakeshore Foundation's success in promoting the health of people with physical disabilities, with UAB's advanced research expertise in exercise, nutrition, disease prevention and health promotion. The Collaborative explores research topics on exercise, physical activity, sport, recreation, and rehabilitation science. Interventions examine the dose-response relationship between exercise and obesity, health and function, secondary conditions, quality of life and health care expenditures across the lifespan. The UAB-Lakeshore Research Collaborative began with a \$10 million research investment funded by the Lakeshore Foundation with additional support from UAB for startup costs. Two million dollars funded an Endowed Chair's position in the School of Health Professions, and the remaining funds will be used to support UAB researchers interested in disability, exercise, nutrition, and rehabilitation science. James H. Rimmer, Ph.D., is the first Lakeshore Foundation Endowed Chair in Health Promotion and Rehabilitation Sciences and Director of the Research Collaborative.

- Lakeshore is located on a 45-acre campus in Homewood, Alabama. In 2001, due to growing community need, Lakeshore opened one of the nation's world-class fitness, recreation, and education facilities for persons with physically disabling conditions. A highly trained and experienced staff of more than 100 full and part-time employees provide programs in this state of the art facility which includes: Aquatics Center with two heated pools; Fieldhouse with three hardwood courts and a 200-meter Mondo surface track; 7-lane Marksmanship Range; 6,000 sq-ft. Fitness Center; Research Laboratory; Climbing Wall; The Cottages of Lakeshore; and Athletic Dormitory. These facilities serve the fitness, recreation, and athletic needs of youth and adults with physically disabling conditions from across the Southeast. Since 2003, Lakeshore has also served as an official U.S. Olympic & Paralympic Training Site and is the official home of USA Wheelchair Rugby. In addition to these amenities, the Lakeshore campus is home to an outdoor tennis facility with eight championship lighted hard courts, the Birmingham office of the Alabama Department of Rehabilitation Services (ADRS), and the HealthSouth Lakeshore Rehabilitation Hospital.

- Lakeshore Foundation has more than 30 years of experience as a community-based service provider of fitness, recreation, sport, and health promotion programs for approximately 3,500 people with disabilities, chronic health conditions and aging-related health issues. Lakeshore staff play key leadership roles in local, national, and international organizations that are important assets to the Research Collaborative.
- The UAB/Lakeshore Research Collaborative is home to two federally funded Centers, the National Center on Health, Physical Activity and Disability (NCHPAD) and the Rehabilitation Engineering Research Center on Exercise and Recreational Technologies for People with Disabilities (J. Rimmer is PI of these centers). Both Centers focus on improving the health and wellness of adults and seniors with disabilities including MS through the medium of physical activity, technology, and lifestyle health promotion. The opportunities are provided to individuals with disabilities residing in Alabama and across the country through information, programs, services, and research interventions that target improvements in healthy lifestyles and reduction of secondary conditions. The Collaborative receives federal funding from the National Institutes of Health (NIH), Centers for Disease Control and Prevention (CDC), Department of Defense (DOD), Patient-Centered Outcomes Research Institute (PCORI), and the National Institute on Disability, Independent Living, and Rehabilitation Research (NIDILRR).

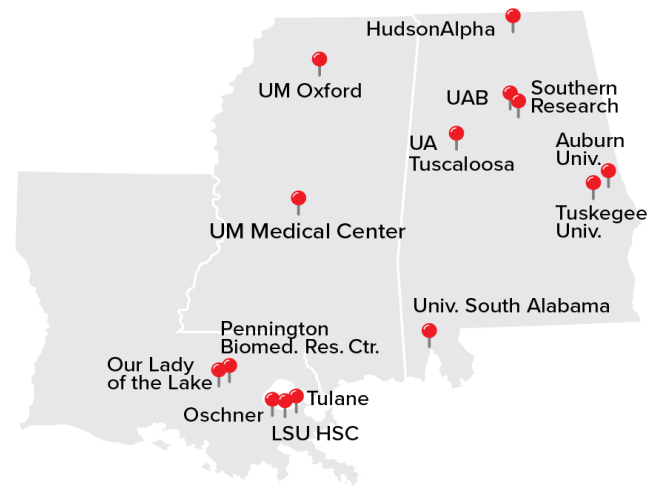
Lakeshore Foundation Facilities: Lakeshore Foundation maintains one of the nation's premier fitness, recreation, and research facilities for people with physically disabling conditions. The Foundation provides a state-of-the-art universally designed community health and fitness facility to address numerous barriers associated with physical activity participation for people with disabilities. Lakeshore offers more than 60 ongoing inclusive activities and classes each week for children and adults with disabilities, including classes in aquatics, fitness, dance, competitive athletics, general recreation, and transition support. Facility support for these various activities include three hardwood courts, a 200-meter Mondo surface track made of soft materials to ease the impact on joints, an outdoor tennis center, a seven lane archery and marksmanship range, a 23-foot indoor climbing wall, an Aquatics center that houses an accessible warm water therapy and 8-lane 25-yard lap pool, and a 6,000 square foot fitness center.

Information and Communication Technology (ICT) Support: ICT manages 40 desktops and 12 laptops, which are connected to a central administrative server run by the School of Health Professions at the University of Alabama at Birmingham or at Lakeshore Foundation, enabling a very secure and stable environment. All computers run on a minimum of a dual core processor and have a minimum of 4 gigabytes of memory and Windows 7 operating system. The computers and the network receive a double layered support mechanism with UAB's AskIT providing the highest level of network routing, AD authentication, policy administration and a secure file server support. ICT staff provides application level and basic tech support. All files are saved to a secure file server. The collaborative also houses several Linux-based servers where the IT team performs all development operations for the various applications. All production level applications are then hosted from an 8 Gig Ram cloud-based server with a 99.99% SLA, enabling our applications to be able to handle any spike in network and hardware requirements. In addition to regular desktops, ICT also employs professional video processing workstations (Macs) with Adobe Master Collection CS6, which is used by the graphics staff in the collaborative to produce high quality videos

Regional Networks of Clinical and Translational Research

Dental Practice-based Research Network: The UAB-led Dental Practice-Based Research Network (DPBRN) is a consortium of participating practices and dental organizations committed to advancing knowledge of dental practice and ways to improve it. The Network strives to improve oral health by conducting dental practice-based research and by serving dental professionals and their patients through education and collegiality. It assists in the translation of scientific discovery into clinical practice. DPBRN's major source of funding is the National Institute of Dental and Craniofacial Research (NIH/NIDCR). Clinical studies embrace four approaches: studies that may involve practitioners and/or their patients: retrospective studies using dental records; observational studies of routine care activities, case-control studies, and clinical trials comparing alternative treatment strategies. Practitioner-investigators help design clinical studies, assess the implications of study results for practitioners and patients in different practice settings, and disseminate research results.

Deep South Network for Cancer Control (DSN): Mindful of the elevated risk of cancer and lower outcomes in the African American community, UAB has established the Deep South Network for Cancer Control, which builds on an established community and institutional capacity in order to eliminate cancer health disparities by conducting community-based participatory education, training, and research. The goals of the DSN are to improve access to and utilization of proven beneficial cancer interventions. DSN serves two underserved rural areas - the Black Belt of Alabama and the Delta of Mississippi - and two urban underserved areas - Jefferson County, Alabama, and Hattiesburg/Laurel Metro, Mississippi.



CCTS Partner Network Institutions

AUBURN UNIVERSITY

HUDSONALPHA INSTITUTE FOR BIOTECHNOLOGY (HAIB)

LOUISIANA STATE UNIVERSITY HEALTH SCIENCES CENTER

PENNINGTON BIOMEDICAL RESEARCH CENTER

SOUTHERN RESEARCH

TULANE UNIVERSITY

TUSKEGEE UNIVERSITY

UNIVERSITY OF ALABAMA AT TUSCALOOSA

UNIVERSITY OF MISSISSIPPI MEDICAL CENTER

UNIVERSITY OF SOUTH ALABAMA

CCTS Network Partnerships

In synergy with the resource strengths available at UAB, the CCTS has established Institutional Partnerships to improve and accelerate translational research. The CCTS Partner Network is a Tri-State collaborative effort that includes 12 total institutions. The CCTS Partner Network crosses institutional boundaries to improve human health and health care delivery. This innovative partnership provides the foundation for addressing health disparities through collaborative research and training efforts. Building on some initial relationships from the Deep South Network for Translational Research, UAB has significantly expanded the Partner Network to create new and more formal partnerships with regional institutions for mutual benefit. Regional partners are working together to facilitate and promote unique opportunities, including drug discovery and development (with UAB, Southern Research, Auburn University and University of South Alabama), integrative genomics (with HudsonAlpha Institute for Biotechnology), advanced magnetic resonance imaging (with Auburn) and substantial experience with participant populations having disparities in clinical outcomes (Louisiana State

University Health Sciences Center, University of Mississippi, Pennington Biomedical Research Center, University of South Alabama, Tulane University, University of Alabama, Tuskegee University, and UAB).

CCTS Affiliations

The CCTS also has established several collaborative relationships across the region to advance clinical and translational science. The CCTS has engaged leadership of NIGMS-sponsored Institutional Development Award Program Infrastructure for Clinical and Translational Research (IDeA-CTR) initiatives in Louisiana and Mississippi as well as Research Centers in Minority Institutions (RCMI) at Tuskegee, Jackson State and Xavier Universities ([CTR/RCMI Affiliates](#)) to provide important, mission-oriented guidance and to identify and pursue programmatic synergies that can bring further value to our region. Similarly, the CCTS' Southeast Health Alliance for Research (SHARe) has engaged Ochsner Health System in New Orleans to advance the translation of discovery to improve health and health care delivery via multi-site studies and clinical trials.

AUBURN UNIVERSITY (Auburn)

The first land-grant college in the South, Auburn University was established in 1856. Over 200 years since its founding, the University has developed into one of the largest institutions in the region with an enrollment over 25,000 selecting from 140 degree options in 12 schools and colleges at the undergraduate, graduate, and professional levels.

INSTITUTIONAL RESEARCH ENVIRONMENT & EXPERTISE IN CLINICAL AND TRANSLATIONAL SCIENCE

Facilities and Resources

Auburn MRI Research Center: The Auburn University MRI Research Center (AUMRIRC) is located in the Auburn University Research Park. The AU MRI Research Center focuses on the broad application of magnetic resonance imaging (MRI) in basic science research, technology development, and clinical applications in both humans and animals. The AUMRIRC has a 3 Tesla (T) open-bore whole-body MRI scanner and a 7T whole-body MRI scanner with multi-nuclear imaging capability. Faculty and staff at the AUMRIRC have expertise in cardiovascular MRI, image analysis, brain imaging, magnetic resonance spectroscopy, and pulse sequence development. In addition to humans, the AUMRIRC has infrastructure and experience to image animals from rodents to larger animals such as dogs, pigs, and sheep.

Auburn University College of Veterinary Medicine (AU-CVM): Auburn University College of Veterinary Medicine (AU-CVM) is now in its 132nd year of service to animal health in the state, region, and nation. In fall semester 2022, more than 500 students were enrolled in the Doctor of Veterinary Medicine (DVM) degree program. Additionally, the college has approximately 100 graduate students pursuing Master of Science (MS) and Doctor of Philosophy (PhD) degrees through the AU-CVM Biomedical Sciences (BMS) graduate program. The College also offers an undergraduate minor in Public Health and is in the process of creating an undergraduate major in that field. In 2014, Auburn opened the Wilford and Kate Bailey Small Animal Teaching Hospital. The 208,000 square-foot complex is one of the most technologically advanced and largest teaching and referral hospitals in the country. Caseloads for the College average in excess of 20,000 animal patients each year.

The AU-CVM is fully accredited by the AVMA Council on Education and AAALAC, International. Details of physical facilities available at the AU-CVM can be provided upon request.

Auburn University Research Initiative in Cancer (AURIC): The AURIC was established to improve both human and animal health by fostering an environment of excellence in cancer research. An interdisciplinary program, AURIC promotes research that enhances competitiveness in order to advance the understanding of the biology of cancer, and to foster the translation of novel technologies from the laboratory to the clinic.

Boshell Diabetes and Metabolic Diseases Research Program: The Boshell Diabetes and Metabolic Disease Research Program at Auburn seeks to enhance opportunities for diabetes research at Auburn University by facilitating cross-disciplinary scientific discussion, supporting the study of new ideas, fostering the development of investigators new to the field of diabetes, and expanding, the overall base of diabetes investigation at the University. More than 50 investigators from across the AU campus are members of the program and actively involved in diabetes research. Specifically, these investigators are addressing many facets of both type 1 and 2 diabetes, with particular focus on the cardiac, neurological, and metabolic aspects of the disease.

Auburn University Harrison College of Pharmacy: Established in 1885, the Harrison College of Pharmacy (HCOP) is Alabama's only public institution charged to educate pharmacists in the appropriate drug treatment of human disease. The HCOP's primary role is the preparation of competent primary care clinicians who can provide patient-focused, pharmaceutical care. The HCOP's curriculum is grounded in service-based, community practice that is collaborative with other health disciplines. The HCOP is actively engaged in research programs designed to stimulate scientific discovery and to develop new knowledge and applications

in the pharmaceutical sciences and to translate those findings to pharmacy practice. With its state-of-the-art facilities, the HCOP is well positioned to drive novel drug and protein products from discovery to development to clinical trials.

Capabilities and expertise available in the HCOP include high-throughput screening infrastructure (robotics and plate readers) as well as clinical pharmacology resources (operated in collaboration with AU-CVM) that feature a state-of-the-art ultra-performance liquid chromatograph linked to a triple-quad mass spectrometer (UPLC-QQQ-MS), a system ideal for performing PK-PD analyses of experimental agents in pre-clinical and clinical settings. Translational research efforts are led by cancer and neuro drug discovery research groups and a dedicated vivarium housed within our Pharmaceutical Research Building provides support for development of small-animal models used for pre-clinical testing. AU-HCOP also possesses a health care outcomes research group that possesses rich experience in using electronic medical records and payer claims data to evaluate the effectiveness and cost of health care strategies and systems. Finally, AU-HCOP clinical faculty are embedded in practice sites in Columbus, GA and throughout Alabama, making them ideal for participating in multi-site clinical trials.

Auburn Pharmacy Health Services and the Community Pharmacy Research Network: The Auburn University Harrison College of Pharmacy operates two ambulatory clinics and three pharmacies to serve the Auburn, AL and Montgomery, AL communities. These facilities are connected to more than 40 full-time clinical pharmacists practicing in regional hubs throughout Alabama, Mississippi, and Georgia. Training is the core mission of these clinics. This Community Pharmacy Research network consists of over 120 community pharmacies in 7 southeastern states and provides a large regional footprint of community research sites that is supplemented by formal agreements with pharmacies. The network provides an extensive cohort of community sites to conduct research providing a unique laboratory for K12 Scholars.

HCOP Translational Research Acceleration Cooperative (TR_xAC): The HCOP-TR_xAC is housed within the Division of Research (DoR) and serves as an organizational hub connecting the efforts of stakeholders engaged in academic-based, drug discovery. The TR_xAC integrates pre-IND activities with early clinical/translational research opportunities. The operational paradigm allows for “bench-to-bedside” and “bedside-to-bench” flow of research activities and projects. The TR_xAC can catalyze new drug treatment discoveries by connecting the right people with the right projects at the right time. TR_xAC fosters commercial opportunities, development of new academic and/or training programs, new extramural grants and contracts opportunities and awards, new partnerships with external pharmaceutical research entities, and enhances existing partnerships in translational research. Areas that are particularly attractive for stakeholder investment and partnering include our in silico/high throughput screening (HTS) operations, our academic program in pharmacogenomic research, and the availability of a clinical-translational research (CTR) support laboratory.

Center for Pharmacogenomics and Single-Cell Omics (AUPharmGx): The Center for Pharmacogenomics and Single-Cell Omics Initiative (AUPharmGx) was created in 2019 to facilitate collaborative research in Pharmacogenomics and place Auburn on the cutting-edge of personalized medicine. AUPharmGx offers a broad range of facilities under one roof aimed at -omics research. It is a full-service stop that facilitates collaborative research covering a vast area of -omics research, including free consultation for -Omics-based research studies, high-quality Nucleic acid (DNA/RNA) isolation, Next-generation sequencing - genomics (ExomeSeq and whole-genome sequencing), transcriptomics (mRNAseq), epigenomics (ATACseq), Sanger DNA sequencing, Quantitative Real-Time PCR (qPCR) for mRNA/Gene expression analysis, MicroBiome analysis/Metagenomics; epigenomics (ATACseq, MethylSeq, EPIC), SNP genotyping, and most importantly, Single-Cell multi-omics (scATACseq and scATACseq), in addition to Cell line authentication and access to CRISPR-edited Knockout Cell Pools and data analysis. AUPharmGx currently houses several state-of-the-art technologies, including 10X Genomics Chromium single-cell analysis system, Illumina NGS system, QuantStudio 12k Flex high-throughput RT-PCR system, SeqStudio Sanger DNA sequencer, Bio-rad CFX96 Touch real-time qPCR system, and Agilent 2100 BioAnalyzer.

Auburn Laboratory for Imaging Animal Systems (Project ALIAS): ALIAS contains a surgical suite and instrumentation for proof-of-concept experiments using small animal models. ALIAS consists of an animal preparation area for complex small animal surgery, anesthesia, and monitoring (~160 sq. ft.) and an adjacent imaging and holding room (~140 sq. ft.). The front surgery room contains a surgical bench and two large

stainless steel sinks. The backroom contains the IVIS Lumina XRMS and Multispectral Optoacoustic Tomography (MSOT) model 256-TF systems. There is a dedicated Nikon AZ100 with a motorized Z-stage for automated scanning equipped with a Multi-Spectral Nuance FX Camera (PerkinElmer).

The IVIS Lumina XR can perform photographic, bioluminescent, fluorescent, X-ray, and Cherenkov imaging. Our system has the standard, mid-high and high filter sets for near-infrared imaging and spectral un-mixing applications. Our system has been upgraded to simultaneously image the sides of subject animal and either the front or back of the animal using specialized 45° angle mirrors platform and accompanying Dynamic Contrast Enhancement (DyCE™) software using CRi-based technology. This upgrade will reduce the overall required for imaging of a given animal as a dataset containing three-sides is collected at once. The software can also calculate a pseudo-3D volume for the given region of interest. The X-ray stage has also been upgraded to accommodate multiple species including rats, so called IVIS Lumina XRMS platform.

The Multispectral Optoacoustic Tomography MSOT-256-TF (iThera Medical) offers the only optoacoustic imaging system with real-time whole-body imaging capability. Biological processes and the effect of pharmacological substances can be observed in vivo, in deep tissue, in real time, and in high resolution. Endogenous chromophores, such as oxygenated and deoxygenated hemoglobin, as well as extrinsically administered probes can be differentiated from tissue background by tuning the excitation laser wavelength. The collected optoacoustic signal acquired at multiple wavelengths is spectral un-mixing and based on the absorbance spectrum of the agent or species.

HUDSONALPHA INSTITUTE FOR BIOTECHNOLOGY (HAIB)

HudsonAlpha Institute for Biotechnology is a nonprofit research institute committed to improving human health and quality of life by bringing genomic medicine into clinical care, developing genomic resources for bioenergy and sustainable agriculture, fostering life sciences entrepreneurship and business growth, and creating a genomics-literate workforce and society. Located in Huntsville, Alabama's Cummings Research Park, the 152-acre HudsonAlpha campus is home to the nonprofit research institute and more than forty-seven life science biotech companies involved in research, development, or production. Designed to be a hothouse of life science research and innovation, HudsonAlpha's state-of-the-art facilities co-locate nonprofit scientific researchers with entrepreneurs and educators to bring discoveries to market faster. HudsonAlpha is home to the Genome Sequencing Center (formerly the Stanford Human Genome Center), one of few centers in the world that specializes in *de novo* eukaryotic whole-genome sequencing, assembly, and analysis. The CAP-accredited and CLIA-licensed Clinical Services Laboratory, the HudsonAlpha Health Alliance, and the Smith Family Clinic for Genomic Medicine are three limited liability companies wholly owned by the Institute and located on the same campus. HudsonAlpha faculty does cutting-edge and innovative research in human and plant genetics and genomics, and have extensive experience in sequencing and interpreting genomes from people and many species, understanding unexplained diseases in children and adults, and understanding the functions of our genomes at many levels, including understanding the "readout" of the genome for the regulation of gene expression, epigenetic regulation and responses to environmental agents, including drugs. HudsonAlpha's researchers have worked in collaboration with scientists all over the world, and have special relationships and multiple projects with the University of Alabama at Birmingham School of Medicine. HudsonAlpha has been contributors to the CCTS network, led by Dr. Bob Kimberly since inception.

INSTITUTIONAL RESEARCH ENVIRONMENT & EXPERTISE IN CLINICAL AND TRANSLATIONAL SCIENCE

Expertise

In mid-2022, Neil Lamb, Ph.D., former Vice President for Educational Outreach, became the new President of the Institute. During his tenure as Vice President, he led HudsonAlpha's educational outreach from conception, creating innovative teacher training and toolkits, student experiences, public enrichment, and digital resources that shaped how education is delivered. As President, Dr. Lamb drives the strategic vision of the organization. Richard M. Myers, Ph.D., who led the Institute for its first 14 years as its President and Science Director, transitioned to HudsonAlpha's new Chief Scientific Officer and President Emeritus. His laboratory contributed more than 10% of the results to the original Human Genome Project and pioneered fundamental genomic techniques that continue to yield insights into human health and disease. Under his direction, the Institute has become a national and international leader in genetics and genomics research and assembled a diverse and highly regarded faculty. Faculty research interests include the genetics of biodiversity, the genetic and epigenetic basis of human diseases such as cancer and neurodegenerative and rare diseases, bioinformatics to correlate genotype to phenotype, immunogenetics, and bioethics. The faculty's experience includes participation in large-scale projects such as The Human Genome Project, The Cancer Genome Atlas (TCGA), the Encyclopedia of DNA Elements (ENCODE) Project, the Clinical Sequencing Evidence-Generating Research (CSER) consortium, The Alabama Genomic Health Initiative (AGHI), and extensive studies of the genetics of Alzheimer disease, Parkinson disease, Huntington disease, ALS and neuropsychiatric disorders such as schizophrenia, bipolar disorder, and major depression, as well as numerous other consortia.

The HudsonAlpha Center for Plant Genomics and Sustainable Agriculture contributes to and expands genomic resources (genome assemblies, transcriptomes, catalogs of population variation) and research in plant biology with a focus on applications to food, bioenergy, and sustainable agriculture. Center contributions include improving knowledge of how plant genes function, developing new computational approaches to genomic analysis, and carrying out extensive target discovery studies to identify useful agronomic genes. Furthermore, the Center is committed to educating future scientists on applying genomics to plants. The program includes HudsonAlpha's Genome Sequencing Center (GSC), led by Jane Grimwood, Ph.D., and Jeremy Schmutz, which has produced most of the *de novo* plant reference genome assemblies. The team has collaborated extensively with plant researchers worldwide and contributed significantly to Gene Atlas v1.0, Gene Atlas v2.0,

Switchgrass Common Gardens, and Open Green Genomes. The program also includes the research laboratories of Drs. Kankshita Swaminathan, Josh Clevenger, and Alex Harkess.

The HudsonAlpha Center for Genomic Health combines the talent and capabilities of several of HudsonAlpha's research programs and faculty. The Center includes the Clinical Services Laboratory (CSL), the Smith Family Clinic for Genomic Medicine (SFC), the HudsonAlpha Health Alliance, and support from Educational Outreach and Economic Development. The program provides an integrated suite of clinical services to healthcare systems, self-insured employers, and healthcare providers. The suite includes patient education and engagement, physician education and clinical decision support, genetic counseling, peer-to-peer support, and access to the Clinical Services Laboratory for clinical whole genome sequencing and genotyping and the Smith Family Clinic for diagnostic genomic medicine. Genomic Health activities focus on rare disease diagnosis, population health and screening, pharmacogenomics, and precision oncology.

The Educational Outreach team, led by Kelly East, MS, CGC, since mid-2022, cultivates a genetically literate citizenry by creating engaging activities that connect scientific concepts to their application in our changing world. The team leverages science and business activities to design innovative experiences, products, and digital applications that educate society and prepare the workforce. These activities include school projects, camps and internship programs, HudsonAlpha-led college courses with university collaborators, online educational resources and apps, and an ongoing series of presentations, tours, and workshops for the adult life-long learning audience. Physicians and nurse practitioners benefit from a series of continuing medical education (CME) Medical Association of the State of Alabama (MASA) approved courses offered by the team. Students enrolled in masters or Ph.D. programs may pursue their thesis work at HudsonAlpha under the direction of research faculty, who hold adjunct faculty appointments at collaborating universities.

HudsonAlpha's faculty maintain a vibrant network of collaborations around the globe with academia, industry, and medical centers. Examples are the Center for Genomic Medicine and the Alabama Cancer Consortium, both with The University of Alabama at Birmingham and a research center focused on comparative genomics and translational research in plant and animal genomics with Auburn University.

Under the leadership of Dr. Darrell Ezell, HudsonAlpha's Office of Diversity, Equity, and Inclusion (DEI) provides strategic support of the Institute's efforts to engage our diverse community and diversify the workforce. A DEI task force supports programs within the Institute and helps create a more welcoming and inclusive workplace that meets the needs of our employees and the diverse communities we serve. HudsonAlpha offers several training opportunities for underrepresented populations in the STEM field. The Summer Undergraduate Research Experience in Genomic Medicine, funded by the National Institutes of Health (NIH), and an internship program with the Alabama HBCU Cooperative, supported by the Governor's Office of Minority Affairs, are just two examples of these ongoing efforts. The NIH-funded SouthSeq project to diagnose newborns with rare diseases and the Information is Power Initiative are two examples of efforts to lower barriers to access and diversify the representation of minority populations in genetic research and clinical trials.

A dedicated IT team supports the research endeavors with computing resources that include shared software and hardware infrastructure, the necessary support for high-performance parallel and distributed computing, numerical tools, and computing environments. The team operates essential equipment, including servers, storage systems, clouds (private, public, & hybrid), workstations, laptops, and peripherals for research and production workloads. It ensures high-speed network connectivity and security for the HudsonAlpha campus.

Facilities and Resources

The Institute provides an exceptionally high-quality research environment. The main four-story, 270,000 square foot building can serve 500-600 scientists and staff and houses well-equipped state-of-the-art laboratories, numerous small- and medium-sized conference rooms, as well as a library, auditorium, and cafeteria. The flagship building has nine large laboratories with space for 12 to 16 faculty investigators, and the labs have all the standard equipment for molecular biology, genetics, and genomics work, including refrigerators, freezers, centrifuges, incubators, water baths, microscopes, and more. The labs share five tissue culture rooms that house eight laminar flow sterile hoods, sixteen CO2 incubators, two CO2/N2 hypoxic incubators, four Countess FL II automated cell counters, four microscopy workstations and a Nikon AXR Confocal equipped with an Andor iXon 888 EMCCD camera. There is a cold room, a darkroom, computational resources, and conference rooms. One large laboratory, equipped for clinical sequencing and genotyping, is designated to the CAP-

accredited and CLIA-certified Clinical Services Laboratory, LLC. A 14,000 square foot space houses the Genome Sequencing Center.

The third addition to the HudsonAlpha campus, an 88,000 square foot facility, houses growth chambers for plant research, the diagnostic Smith Family Clinic for Genomic Medicine, LLC, and tenant companies. The Clinic includes a waiting room, triage room, exam and consulting rooms, lab, classroom, and conference room with telemedicine capabilities.

The Paul Propst Center, a 105,000 square foot facility, houses HudsonAlpha's Educational Outreach and Economic Development missions and several tenant biotech companies. More than 20,000 square feet of space and substantial resources and personnel are devoted to the educational outreach program. The education space includes three teaching/training labs (each holding up to 32 students), several classroom and presentation rooms, a dedicated auditorium, and multiple areas for student group collaboration. Distance learning equipment facilitates access to HudsonAlpha's experts, and high-definition video conferencing throughout the buildings connects scientists and educators with collaborators, colleagues, teachers, and students around the world.

The newest addition to HudsonAlpha's campus is a glasshouse that includes a headhouse, two laboratory spaces, seed storage, workstations, and nearly 6,000 square feet of growing space across seven rooms. Additional facilities for plant growth include two 480 square foot biosafety level-2 growth houses for controlled plant growth and three A1000 Conviron growth chambers. These are equipped with PDS-1000/He biolistic transformation system, Genogrinder 2010, freezer mill, and three fluorescence microscopes: a Nikon SMZ1500, an EVOS, and a Lionheart.

The Jackson Center, a conference facility on campus, has 13,000 square feet of meeting space.

In addition to the nonprofit Institute, the HudsonAlpha campus is home to 48 tenant companies and their 900+ employees. These tenant companies are all involved in biotechnology research, development, or production. Laboratories and offices of various sizes, ranging from a cubicle to thousands of square feet of space, are available throughout the buildings on the campus. Tenant companies can take advantage of the business expertise of their for-profit biotech neighbors, as well as the proximity of Institute scientists, educators, and other valuable resources. Likewise, the Institute benefits from collaborations and professional exchange with the tenant companies.

Genome Technologies: In addition to its extensive DNA and RNA sequencing facilities (including upstream and downstream experimental and analytical equipment), HudsonAlpha has invested in other cutting-edge technologies, which require both equipment and specialized expertise to use these facilities effectively. These include multiple types of robotics, large-scale gene editing, iPS cells and their differentiated cell types, ChIP-seq, single-cell multiomics (RNA-seq and ATAC-seq), confocal microscopy, extensive cell culture facilities and equipment, FACS and others.

Clinical Services Lab: The HudsonAlpha Clinical Service Lab, LLC (CSL) was established in 2015 to provide genomic data and analysis to physicians, healthcare providers, and patients to improve healthcare through diagnostic and prevention. The CSL is accredited by the College of American Pathologists (CAP) and certified through the Clinical Laboratory Improvement Amendments (CLIA). It offers whole genome sequencing and genotyping for rare disease diagnostics, precision oncology, and population screening and clinical interpretation by a team of board-certified clinical and molecular geneticists. The CSL is continuously working on expanding its clinical tests.

Genome Sequencing Center: The HudsonAlpha Genome Sequencing Center (GSC) has a dedicated 14,000 square foot combined laboratory and office space facility. Led by co-directors Jane Grimwood, Ph.D., and Jeremy Schmutz, a staff of about 25 laboratory and computational professionals generates genome sequence data and creates resources for researchers worldwide. The GSC includes one large laboratory for the library and production groups, a large informatics suite, several storage rooms, freezer rooms, a dishwashing and autoclave facility, several robotics rooms, three dedicated sequencing rooms, and a conference room. The sequencing platforms and data collection pipelines include Illumina (NovaSeq 6000), Pacific Biosciences (Sequel II), and one ABI 3730XL, supported by substantial automated robotic and IT infrastructure.

Information Technology and Computation

HudsonAlpha Information Technology (IT) delivers exceptional technology solutions to help further the missions of HudsonAlpha. We drive technology modernization activities to optimize research and institute productivity. We serve as trusted advisors to our institute partners and develop innovative solutions to help advance human health. HudsonAlpha IT ensures the optimization, growth, reliability, and security of not just institute-wide but campus-wide research. HudsonAlpha itself has 227 employees, but IT also supports the life sciences missions of 48 associate companies and their 900+ employees across the HudsonAlpha campus. The systems supporting these missions are monitored and maintained 24x7 and spread across two campus data centers, various colocation facilities, and private/public cloud resources. HudsonAlpha IT maintains an array of technology platforms across its core teams of Research Computing, Infrastructure Services, Enterprise Applications, End User Support, and Cybersecurity.

Research Computing – High-Performance Computing (HPC): HudsonAlpha IT provides institute labs and associate companies with dedicated and shared resources to perform their research. These resources are spread across an HPC cluster with 2016 hyperthreaded CPU cores (15.2 teraflops), 17TB RAM, 4 petabytes (PB) of block storage, and 7 PB of object storage. These resources are constantly growing at 20% each year to meet the demand of nearly two million research jobs (10,000,000+ core hours) annually and over 6 petabytes of research data. Furthermore, HudsonAlpha IT maintains the lifecycle of its research computing hardware with hardware refreshes every 3 to 5 years, phasing in new technology to optimize research computing capabilities and evaluate innovative vendors. The current vendors and technologies comprising HudsonAlpha's HPC cluster include:

- **HPE Synergy and C7000 blades:**
 - HPE BL460c Gen 9: 6 dual 14 core (336 HT cores), 18 dual 16 core (1152 HT cores) 744 total physical cores 2.30 GHz Intel E5-2695v3 compute nodes with 512/384 GB RAM per node, 2x20 GigE to a high-performance General Parallel File System (GPFS) running disk arrays totaling 3.6PB usable.
 - HPE SY480 Gen 9: 3 dual 22 core, (264 HT cores) 2.20 GHz Intel E5-2698v4 compute nodes with 1 TB RAM per node, 2x20 GigE to a high-performance GPFS.
 - HPE SY480 Gen 10: 3 dual 22 core, (264 HT) 2.10 GHz Intel Gold 6152 compute nodes with 1 TB RAM per node, 2x20 GigE to a high-performance GPFS.
- **Block (Cluster) and Object Storage:** Two DDN 12KEX storage arrays running IBM Spectrum Scale (GPFS) with 4 petabytes (PB). Scalable object storage for off-site archival of research data over 7 PB.
- **Scheduler and other software:** IBM Load Sharing Facility (LSF) for scheduling, Bright orchestration for provisioning, and a suite of bioinformatics tools.
- **Network Infrastructure:** HudsonAlpha supports a collaborative campus with the combined research of our non-profit institute and for-profit life science mission of associate companies. The HudsonAlpha campus has three buildings with 80 Gigabit long-range optics. Core switches (Cisco Nexus 9500 series) with 40 Gigabit connections connect the systems within each building. The campus internet service has multiple fiber paths onto the campus, and redundant network connections provide highly available 20 Gigabit connectivity to a colocation data center in Atlanta. This collocated data center provides private and public peering with cloud providers and federal research networks like Internet2, Amazon/AWS direct connect, Southern Crossroads (SOX), Amazon, CenturyLink, and Cogent. A second collocated data center resides locally in Huntsville, AL hosting archival storage and future burstable resources with 2x40 Gigabit connectivity to the campus.
- **Network Security:** Access to the HudsonAlpha network is strictly controlled. As a general policy, all inbound connections are explicitly denied with specific exceptions. Exceptions are handled by IT staff and are only allowed for hosts located in DMZ networks directly connected to a pair of redundant Palo Alto firewalls. Outbound connections are allowed with specific restrictions (i.e., outbound SMTP is controlled). External access to HudsonAlpha networks is allowed via IPsec client or L2L (LAN-to-LAN) IPsec tunnel. Internal VLANs logically separate functional groups and tenant companies in the building.

VLAN to VLAN access is strictly controlled, with exceptions allowed via layer 3 ACLs (access control lists). Certain sensitive network segments with Protected Health Information (PHI) have additional safeguards to limit access to only personnel with a demonstrated business need. Wireless access to HudsonAlpha networks is controlled by 802.1x authentication. Public Wi-Fi access is controlled via a pre-shared key and is restricted to the internet only. Critical core network equipment is centrally located in controlled access (badge reader) data centers that are UPS/generator protected. Access to IDF closets is controlled by lock and key and is limited to IT staff and facilities. Login access to critical network equipment is controlled and logged with TACACs. Access to shared data is managed through AD (active directory) authentication. Multiple automated systems regularly scan all devices on the network, reporting vulnerabilities, misconfigurations, missing patches, etc., to our cybersecurity team for remediation.

- **Office:** The Faculty Investigators' laboratories have multiple offices and "dry-lab" spaces in addition to "wet-lab" benches. Each Faculty Investigator has an office suite that includes a secondary office and cubical and open space for 5-20 personnel. Office and computer space are available for visiting scientists to work at HudsonAlpha. The campus layout encourages interactions throughout the Institute. Each building has multiple conference rooms and informal meeting areas. The flagship building has a large auditorium, library, lounge, and cafeteria used by all campus occupants. The Paul Propst Center building also has an open concept atrium with a snack area, meeting spaces, and an auditorium. There are additional conference rooms of varying sizes throughout the building.

LOUISIANA STATE UNIVERSITY HEALTH SCIENCES CENTER (LSUHSC)

The Louisiana State University Health Sciences Center – New Orleans includes the Schools of Medicine, Public Health, Dentistry, Nursing, Allied Health Sciences and the Graduate School. The downtown New Orleans campus trains 70% of state's health care professionals. The School of Medicine, which was just re-accredited by LCME, manages multiple residency and fellowship programs in New Orleans, Baton Rouge, Bogalusa, Lafayette and Lake Charles. LSUHSC – NO serves patients throughout Southern Louisiana and surrounding areas through the LSUHSC Health Sciences Network of outpatient clinics and its public-private partnership with University Medical Center, a newly opened 446-bed academic hospital located across the street from the main campus, where LSUHSC physicians and staff see patients in a hospital setting. LSUHSC physicians also see patients at other hospitals in the same system, Louisiana Children Medical Center.

INSTITUTIONAL RESEARCH ENVIRONMENT & EXPERTISE IN CLINICAL AND TRANSLATIONAL SCIENCE

Facilities and Resources

All LSUHSC Schools have active research programs, with the most active being in the Schools of Medicine and Public Health. Specific to LSUHSC, the Clinical/Translational research environment includes:

Clinical and Translational Research Center (CTRC) and the Core Laboratory: Located in the Seton Building and in the LSUHSC campus. The CTRC provides staffing for conduct of research protocols, including nursing staff, nutritional support, administrative assistance, and biostatistician support. The Core Laboratory develops and performs laboratory assays for clinical research projects.

GS-MU-NCORP: Separate from the CTRC, The Gulf South-Minority Underserved-NCI Community Oncology Research Program (GS-MU-NCORP) is the largest and only state-wide cancer clinical trials research consortium encompassing the state of Louisiana and southern Mississippi. The GS-MU-NCORP has three major component sites, LSU Health Sciences Center – New Orleans (which includes the only Children's Hospital in the state), LSU Health Sciences Center – Shreveport and Mary Bird Perkins Cancer Center (Baton Rouge), each with several subcomponent sites for a total of 26 clinical centers participating in this clinical trials consortium. The major goal of this public-private partnership is to bring cutting edge cancer clinical trials to patients in our state. The integrated leadership team works closely with clinical investigators to ensure a coordinated selection of clinical trials and the implementation of these trials at multiple sites. All sites recognize the NCI's central IRB as the IRB of record, and for non-CIRB protocols, all sites are under the LSUHSC IRB. This structure allows for the rapid selection and deployment of clinical trials throughout the various clinical sites of this NCORP. This program also discusses and selects investigator initiated trials and pharmaceutical trials. Its ultimate goal is to provide a closely integrated cancer clinical trials program throughout state of Louisiana, in close association with academic and community physicians dedicated to bringing cutting edge trials to their patients. Currently, the NCORP has over 60 cancer-related studies open.

LCRC Tissue/Biospecimen Repository: The mission of the Biospecimen Core is to collect high quality samples of fluids (i.e., whole blood, cellular blood components, plasma, serum, urine) and tissue from patients with tumors, with the tissue's corresponding pathological variables. This material is available to qualified researchers at the Louisiana Cancer research Consortium (LCRC) and LSU Health Sciences Center and will enable them to reduce costs and minimize risks associated with alternative banking practices. High quality refers not only to the biological quality of tissue and accompanying pathological data, but also to the ethical and legal status under which donors are enrolled and consented. This core is the primary interface with the clinical sites at which donors are enrolled and tissue samples and clinical data are collected. The core utilizes caBIG's Tissue Suite for biospecimen inventory, tracking, and basic annotation. This database permits researchers to track the collection, storage, quality assurance, and distribution of specimens as well as the derivation and aliquotting of new specimens from existing ones. LCRC joins a collaborative effort to construct a clinically annotated "virtual biorepository" from LCRC Biospecimen Repository data in close partnership with the CCTS Hub, with the ultimate goal of developing a regional virtual biorepository with shared data ontology.

The Louisiana Tumor Registry: The Louisiana Tumor Registry has high-quality data covering the entire State of Louisiana including This cancer types (morphology, grade, and behavior), anatomic location, stage at the

time of diagnosis, treatment, and outcomes (survival and mortality). This data along with EHR-derived clinical information from the PCORI-funded REACHnet clinical data repository (for which Dr. Miele serves as LSUHSC coPI).

Clinical Informatics Resources: The LSU Health Sciences Campus uses EPIC throughout its clinical operations within the University Medical Center. EPIC is also used to manage non-cancer clinical trials. EPIC is one of the most commonly used EHR systems in academic medical centers, and readily amenable to health information exchange in the context of clinical/translational research. The LSU Health Care Network of outpatient clinics use Allscripts. Inter-operability with EPIC to match patients is under development. The Minority-Based NCI Community Oncology Research Program led by LSUHSC (A. Ochoa, PI), uses CREDIT a web-based CTMS, which is more amenable to collaborative clinical research in the context of multiple community hospitals. LSU as a whole and LSUHSC New Orleans maintain a comprehensive privacy and information security program that protects the confidentiality, availability, and integrity of all information assets (i.e., patient, research, customer, business data). The LSU System Information Security Policy is [PM-36](#), the LSUHSC-NO Information Technology Infrastructure policy is [CM-42](#), our Information Security policy is [EIS-100](#), and the LSUHSC-NO HIPAA policy is [CM-53](#). Our health system follows HIPAA policies and undergoes review by the Joint Commission on Accreditation of Healthcare Organizations. LSU and LSUHSC-NO comply with Family Educational Rights and Privacy Act controls for student information. Our security policies are overseen by an appointed HIPAA Entity Security and Privacy Officer. Compliance with IT Security policies and local and federal laws and regulations is further ensured through review by our institutional health system internal audit organization. The [Office of Compliance website](#) has additional information on HIPAA and FERPA compliance SOPs.

Bioinformatics Resources

Louisiana State University Health Sciences Center's Bioinformatics and Genomics (BIG) Program is a research and academic component of LSUHSC-School of Medicine in New Orleans that is an integral part of research efforts. The BIG program was established as a multidisciplinary program in 2016. Currently the program has three full time bioinformaticians, two PhD level, one MS level and one PhD student with extensive experience in multi-scale multi-platform omics data analysis and integration and computer programming skills in various languages. The program is Directed by Dr. Hicks, Co-Director of the Informatics Resource for the CCTS). It is a highly interdisciplinary program, covering all the six schools and all departments and centers across the LSUHSC campus and partner institutions across the Southeast. The program has also established the Bioinformatics and Data Science Service Center to support the research community. In addition the BIG program has launched a MS Biomedical Sciences Bioinformatics-Track degree program to train the next generation of bioinformaticians and data scientists. BIG is home to the following small to large-scale computational resources, which will be available to support the proposed projects and training of junior faculty and students. Among the services provided by the program staff include but are not limited to:

- Bioinformatics and computational genomic analysis of “omics”, genotype, sequence, methylation, and other biological data
- Data analytics with application to analysis of big data in a biomedical setting
- Software development and deployment with application to database design and management of large-scale research data
- Providing education and training seminars on bioinformatics to students, medical professionals, and biomedical investigators
- Integration of multiplatform-multiscale biological data with clinical information
- Development and application of novel methods and software tools to emerging biological questions and technologies
- Support in planning and design of grant applications, manuscript, and abstracts
- Pathway prediction and modeling gene regulatory networks driving human diseases
- Quantitative modelling and prediction of disease progression and outcomes
- Maintenance of large-scale genomics and other biological databases
- Drug discovery and repositioning

Research Action for Health Network (REACHNet): LSU has access to a vast clinical informatics data warehouse through the PCORI-funded Research Action for Health Network (REACHNet). The REACHnet clinical data repository includes 1.7 million active records, soon to increase to 2.3 million with the inclusion of the UMC clinical data warehouse. These data can be accessed through LSU's Biomedical Informatics (BMI) or REACHnet teams. The data are currently in the PCORnet Common Data Model 4.0. Data elements not included in CDM 4.0 can be added for specific projects. Both REACHnet and the BMI maintain interconnected i2b2 instances, where research datasets are created. Queries can be submitted through the BMI Core, which has a process for prioritization and optimization of data science projects through the formation of Project Development Teams, including at least a biomedical informatician, a biostatistician and a subject matter clinical research expert. The BMI Core is tasked with creating "virtual biorepositories", including active records specific to conditions that disproportionately affect Louisiana patients. To date, it has created Diabetes and Breast Cancer virtual cohorts, with 8 more (4 cancer and 4 non-oncologic conditions) virtual cohorts planned. The timetable and prioritization will depend on the needs of new projects, including CCTS projects. In order to harmonize data resources, the BMI Core and the CCTS hub are sharing data ontologies. The BMI Core, also in collaboration with the CCTS hub, is also creating "virtual biorepositories" for at least 3 biospecimen collections: the LCRC Biospecimen repository, the Ochsner Biorepository and the Pennington biobank including biospecimens, anthropometric measurements and laboratory values for several thousand participants in diabetes/obesity registries.

Small and Medium scale computing and data storage: BIG is home to small and medium scale computing. For small scale computing, the BCG lab is equipped with 4 Dell Precision Workstations, Tower 5810 XCTO Base (210-ACQM) 32GB (4x8GB) 2133MHz DDR4 RDIMM ECC (370-ABUP) 3.5 inch 2TB SATA 7.2k RPM HDD, FPWS (400-AIJK). Each workstation has 8TB of storage space. In addition, the BCG is home to 3 newly acquired Mac Pros. Each Mac pro is powered by a 12-Core and Dual GPU 3.5GHz 6-Core Intel Xeon E5 processor 64GB 1866MHz DDR3 ECC memory Dual AMD FirePro D500 with 3GB GDDR5 VRAM each with 30TB data storage. These systems are used for small scale and medium scale computing. For medium scale computing, The BIG Program is equipped with 10 Dell Precision LINUX Workstations 7000 Series (7910). Each workstation has 25TB of Storage capacity and 512 GB RAM. They are powered by the Ubuntu operating system. Together they have a combined computing of 250TB of storage capacity and 5.6TB RAM. In addition, the BDSSC is home to 5 Dell precision windows workstations with Tower 5810 XCTO Base (210-ACQM) 32GB (4x8GB) 2133MHz DDR4 RDIMM ECC (370-ABUP) 3.5-inch 2TB SATA 7.2k RPM HDD, FPWS (400-AIJK). Each workstation has 8TB of storage space. Bioinformaticians are available for technical support.

Large-scale DELTA supercomputer in the Center for Computation & Technology: BIG also have access to Delta. LSU has collaborated with IBM to deploy a powerful supercomputer to advance big data research in Louisiana. The new computer has been named DELTA, referencing both the Mississippi delta region. The supercomputer is housed at the LSU Center for Computation & Technology. DELTA is the IBM Power8 cluster system that comprises the 16-computer node cluster and the IBM GPFS storage server with the capacity of more than 400TB. The 16-node compute cluster provides the total of 320 cores and enables end users to experience a high-end cluster environment with the IBM Platform software, i.e., Platform Application Center (PAC), Platform Process Manager (PPM), and Platform LSF. All nodes in the cluster system have Power8 822Ls with 2 Fat Nodes, consisting of 1TB memory and 14 regular nodes, consisting of 256GB memory. DELTA primarily aims to support Big Data research across bioinformatics and translational research, and various data analytics including machine learning for science and engineering domains. Hadoop applications are fully supported with its integration with LSF and GPFS-based storage system. Unlike the traditional HPC cluster system, DELTA encourages end users to utilize web-based services developed with PAC, which are accessible via a user-friendly web interface using web browsers like Firefox, Safari, or Internet Explorer. A user-friendly web interface allows a research to upload and download data from the Delta Cluster using WinSCP, or the Java interface in PAC. Delta is utilized to expand research capabilities in the life sciences and equipped with the IBM Reference Architecture for Genomics, increasing scale and speed for genomics computing.

Data Transfer and Sharing Platform: LSUHSC- Bioinformatics and Genomics (BIG) Program is home to the Globus Data Transfer Sharing Platform, which is supported by the NCI, with Dr. Hicks serving as the Site PI. Globus provides a secure, unified interface to research data. Investigators can use Globus to 'fire and forget'

high-performance data transfers between systems within and across CCTS Partner Institutions as well as other collaborative institutions nationally and internationally. All LSUHSC computing platforms are connected to the Globus platform. LSUHSC-BIG has installed Globus because research often requires sophisticated data management capabilities across CCTS systems and network partner institutions. Globus provides these capabilities and creates an environment to support data sharing and collaborative scientific computing. The Globus system can be connected to Laptops, supercomputers, tape archives, cloud storage, HPC clusters, and scientific instruments, and supports cloud storage like Google Drive and Amazon. With the 'fire and forget' model researchers can concentrate on their research while Globus handles the mundane (but important) details of successful large-scale data transfers, even for protected data like HIPAA-regulated data. The data is transferred directly between the source and destination systems while Globus tunes performance parameters, maintains security, monitors progress, and validates correctness. Investigators can check the transfer status at any time via the Globus activity page and will receive email when the transfer completes. If a network or system involved in the transfer goes down, Globus automatically resumes the transfer when the component comes back online. If an issue requires action, such as an expired credential or exceeded disk quota, Globus resumes the transfer after you remedy the problem. If a transfer has not made progress after a period of time (usually 3 days), the transfer will expire, and researchers will be notified.

Software and data analysis pipelines: BIG is home to various software packages. Available software include but are not limited to SAMtools, Novoalign, BWA, STAR, Bowtie/Tophat, RS_IsoSeq, GMAP, Paraclu, Abyss, Velvet, SOAP, FushionSEQ, TopHat-Fusion, IGV, SAMMate, Cufflinks, CummeRbund, RSEM, EBSeq, miRNAkey, VarScan, GATK, Snape-pooled, Annovar, CNVnator, Variation Hunter, SnoopCGH, HOMER, SeedFinder, SeedAnnotate, VAAST and VAAST 2.0, DSeq, ContTEst, VarScan 2, SNV-PPILP, MapReduce, Polyphen-2, Sift, GERP++, SNVSniffer, SGI, with most workstations additionally loaded with specialized algorithms as well as in-house programming in perl, python and R scripts. In addition, BIG is also home to Ingenuity Pathway Analysis (IPA) for network and pathway analysis. Big is also home to the following data analysis pipelines: Microarray data analysis; RNA-Seq data analysis; DNA Methylation data analysis; Whole exome Seq data analysis; Whole genome mapping; Single-cell data analysis pipelines.

Innovation and Entrepreneurship Resources: The LSUHSC Office of Technology Management offers comprehensive support to LSUHSC investigators, including negotiating Material Transfer Agreements, Non-disclosure Agreements, Inter-institutional Agreements, licensing agreements etc. The OTM also offers training sessions for investigators planning to commercialize their findings and/or to collaborate with industry partners.

Bioinnovation Center: The Bioinnovation Center is a state of the art incubator facility for startup companies in Louisiana, most of which are spinoffs from LSUHSC or Tulane discoveries. The Center, located on Canal Street within walking distance of LSUHSC, Tulane and University Medical Center, provides space and licensing assistance to startup companies. To date, it has raised approximately \$93 million in private funding for health care product and technology development.

TRANSLATIONAL RESEARCH INFRASTRUCTURE

University Medical Center (UMC) Clinical Trials Unit: In addition to the CTTC described above, which primarily serves outpatient clinical studies and trials, UMC supports a broad searchable portfolio of clinical trials and includes a clinical trials unit where LSUHSC physicians can enroll participants for inpatient clinical trials.

Centers of Excellence: LSUHSC New Orleans houses 7 dedicated Centers of Excellence in translational research. These include:

- The Alcohol and Drug Abuse Center
- The Cardiovascular Center
- The Epilepsy Center
- The Eye Center
- The Neuroscience Center
- The Oral and Craniofacial Biology Center
- The Stanley S. Scott Cancer Center

CLINICAL CARE

The health care enterprise at LSUHSC consists of the LSU Healthcare Network, the LSUHSC partnership with UMC and other Louisiana Children Medical Center (LCMC) hospitals and additional clinical locations throughout Southern Louisiana where LSUHSC providers treat patients.

The LSU Healthcare Network: The LSU Healthcare Network includes 175 providers and 9 clinics in the Greater New Orleans area, offering services for over 30 specialties. Appointments can be made through a web-based patient portal, which also allows for secure communication between patients and providers and the creation of easy to access health summaries for LSUHN patients. LSUHN uses Allscripts as its EHR. The University Medical Center New Orleans (UMC-NO). UMC-NO is a 3-years old, 1.1 billion dollar, 2.3 million square foot hospital. Its facilities cover 37 acres across the street from LSUHSC, and include three patient towers with 446-acute care beds including 60 behavioral health beds, 19 operation rooms, 76 pre-op and post-op bays, 56 emergency department exam rooms, nine acute treatment rooms and five trauma rooms. UMC also features a state of the art Conference Center where CME events and research conferences take place. Its patient population is approximately 43% European-American, 40% African-American and 10% Hispanic/Latino, with other minorities such as Vietnamese-Americans also prominently represented. Outlying clinical locations served by LSUHSC providers including family medicine clinics and residency programs include Baton Rouge Our Lady of the Lake Hospital, the Bogalusa rural family medicine clinic, Lafayette General Hospital and the Lake Charles family medicine clinic.

GRADUATE EDUCATION AND POSTGRADUATE TRAINING

The LSUHSC School of Graduate Studies, directed by Dr. Joseph Moerschbaecheer, III, includes the following Ph.D. Graduate Programs:

- Biochemistry and Molecular Biology
- Cell Biology and Anatomy
- Genetics
- Microbiology, Immunology and Parasitology
- Neuroscience
- Pharmacology and Experimental Therapeutics
- Physiology
- Interdisciplinary Studies (consisting of a one-year integrated curriculum for students who will then choose a specific doctoral program)
- MD/PhD Program, which accepts 6 new applicants per year

Additionally, a M.S. program in Biomedical Sciences is offered, and a new M.S. Program in Bioinformatics will be offered in the fall. Applicants are recruited from the U.S. and other countries through a competitive admissions program that involves a pre-screening followed by in-person or electronic interviews. Incoming Graduate students participate in an orientation program that includes descriptions of each Graduate Program by individual Graduate Program Directors and/or Department Heads.

Two levels of Postdoctoral training are offered at LSUHSC. Postdoctoral fellows must have less than 2 years of post-graduation experience, while Postdoctoral Research Associates require more than 2 years of post-graduation experience. A specific training plan must be prepared and submitted by primary mentors for each postdoctoral scientist. Mentoring committees are highly encouraged.

LSUHSC INSTITUTIONAL CORE FACILITIES

LSU Health Sciences Center in New Orleans has numerous core facilities that are available to our investigators. Operationally, they can be divided into Cores that are run by the School of Medicine and those that are administered through Departments/Centers. Regardless of their organization, these core facilities are available to all LSUHSC faculty and staff on a fee per use basis. These services are also available to outside institutions. A searchable database of faculty scientific interests is available on the SOM research portal. The Cores include:

Animal Care (Dr. Leslie Birke DVM, Associate Director & Clinical Veterinarian): The Division of Animal Care (DAC) supports the research activities of LSUHSC faculty, staff, postdoctoral fellows, residents, and students by fostering a comprehensive program of quality animal care. The DAC provides high quality laboratory animals, ensures humane care and use of all laboratory animals, provides expert technical knowledge, and provides training of all faculty and staff in accordance with related laws and guidelines of all federal and state agencies. LSUHSC and the DAC are committed to supporting continued advancements in biomedical research. Mission is to promote the health and well-being of people and animals everywhere by providing quality care of animals and support for scientists at the Louisiana State University Health Sciences Center. The LSUHSC Dental School Annex is a 9,000 ft² facility which features 8 animal rooms, 4 procedure rooms, a large animal OR suite, and a necropsy room, that will replace Dental School facilities lost during Hurricane Katrina. Construction is completed and a move in date is projected for July 2022. Enhanced allergen protection will be provided with Lab Products individually ventilated cages which are connected to the building exhaust. All animals will be maintained in sterilized caging and changed using aseptic technique.

Biostatistics and Bioinformatics (Dr. Chindo Hicks PhD, Director): The Biostatistics and Bioinformatics Core provides support to investigators in traditional experimental planning and design, power analysis, statistical analysis, and data interpretation. Dr. Claudia Leonardi from the School of Public Health, LSUHSC, will facilitate access to an extended Louisiana State network of computational resources. In addition, Dr. Chindo Hicks, bioinformatician, and Professor of the Department of Genetics, LSUHSC, will support bioinformatics component of the Core.

Biospecimen Core Laboratory (BCL) (Dr. Arnold Zea PhD, Co-Director): The BCL is a part of the Louisiana Cancer Research Center (LCRC) infrastructure with mission to collect high quality samples of normal and diseased human material (e.g., whole blood, cellular blood components, bone marrow, plasma, serum, urine, benign and malignant tissue) with appropriate pathological data. The material collected is available to qualified researchers at the LCRC while ensuring ethical informed consent, safety, donor anonymity, and all regulatory safeguards are in place. BCL staff will also provide access to the unique clinical samples to support translational aspects of the research programs that are crucial to investigate how molecular and cellular pathways identified in vitro or in experimental animals correlate with human disease. Since its creation in 2008, the BCL has become a vital resource for researchers from LSUHSC, Tulane, Xavier and Dillard Universities conducting cancer research. The BCL core provides leadership, tools and resources to investigators, to enable translational research and precision medicine for patients.

Cellular Immunology and Immune Metabolism Core (CIMC) (Dr. Dorota Wyczzechowska PhD, Director): This core currently provides state-of-the-art instrumentation and expertise in flow cytometry and cell sorting, and immune cell function. In addition to the BD FACSAria sorter, the core houses advanced analyzers such as BD LSR II, Auto MACS cell sorter, BioRad Bio-plex system, Elispot reader and Luminoscan. It will provide consulting services on experimental design technical assistance, trouble shooting, and data analysis. This core also will provide services to PJs from other participating institutions to facilitate the collaborative efforts of this proposal.

Clinical Trials and Translational Research Core (Dr. Steve Nelson, MD, CM, FCCP, Director): The LSUHSC Clinical and Translational Research Center (CTRC) is approximately 2,000 square feet. This space is located in the LSUHSC Seton Building at 2025 Gravier Street, Room 652. It includes five exam rooms, two interview rooms, two offices, medical records room, core lab, lobby, and a nurse's station. Any LSU investigator or their affiliates conducting an Institutional Review Board (IRB) approved clinical research project may apply to use the LSU CTRC on a fee-for-service basis. The cost for using the CTRC and its services for a pharmaceutical or investigator-initiated study will vary according to the services utilized and available funding. The CTRC will provide a cost analysis for study implementation, which is subject to review and approval prior to study initiation. CTRC has the following equipment for use: KoKo Spirometry, Bod Pod (Total Body Composition), Welch Allyn Spot Vital Signs machines with pulse oximetry, Interview rooms equipped with computers for questionnaire and data input, EKG, Hemocu, Glucometer, and Indirect Calorimetry.

The Epidemiology Data Center (EDC) (Dr. Edward Peters, DMD, ScD, Director): The Epidemiology Data Center (EDC) provides biostatistical, epidemiological, and study design support for health-related research projects sponsored by federal agencies, industry, and other funding sources. The staff at the EDC can assist with questionnaire and data collection form design, implementation of study protocols, data management, data entry, and statistical, database programming. The EDC hosts and provides research support for an LSU Health REDCap (Research Electronic Data Capture) installation. This secure, web-based software was first developed by researchers at Vanderbilt University, and is currently supported by an international consortium of users. Using REDCap, the research team can design web-based surveys and engage potential respondents using a variety of notification methods, including email survey invitations and text messages. REDCap provides flexible features that can be used for a variety of research projects and provides an intuitive interface to enter data with real time validation (automated data type and range checks). The system offers easy data manipulation with audit trails, reports for monitoring and querying participant records, and an automated export mechanism to common statistical packages (SPSS, SAS, Stata, R/S-Plus). For those conducting clinical trials, the EDC designs and manages data management projects using REDCap Cloud, a HIPAA compliant, web-based software ideal for early phase trials requiring FDA compliant electronic data management systems. In addition, The EDC designs high-quality scannable paper forms using OpenText Teleform v10.7 software. Once data has been verified as accurate and complete, it is exported to any standard format for data analysis purposes. The EDC also creates electronic online forms and surveys using SurveyGizmo® software. Additionally, the center can provide epidemiologic methodologic and statistical support for all phases of study design, execution and analyses.

Genomics Core (Dr. Judy Crabtree PhD, Director, or Dr. Christopher Taylor PhD, Co-Director): The Genomics Core Facility is a core resource of LSU Health Sciences Center, sponsored jointly by the Cancer Center and Gene Therapy Program. The Facility is committed to providing quality service by fulfilling the needs of the research community in a consistently rapid, dependable, and economical fashion. Services include automated DNA sequencing, using state-of-the-art instrumentation (ABI PRISM 3130XL Genetic Analyzers) and the latest protocols to ensure high quality results at reasonable prices. The Facility also houses an ABI Prism 7900 HT (a high throughput real-time PCR system) and a Biomek2000 liquid handling robot. The Genomics Core Facility is located in the CSRB, room 738D.

HIV-Clinical/Tumor Biorepository Core (Dr. Sukanthini Subbiah MD, Director): This Core was initially created to support clinical trials; however, it will be expanded with this new addition of new program projects to assist Private Junior Investigators (PJIs) with patient enrollment and subsequent collection, storage, and retrieval of linked clinical data and biospecimens for laboratory analyses. Personnel servicing this Core will be positioned within assigned space at the LSUHSC HIV Outpatient (HOP) Clinic. Clinical data and biospecimens will be linked through established alpha-numeric coding procedures and routine interactions between clinic-based data managers and research associates performing patient enrollment, as well as repository technicians who receive and store biospecimens within the nearby Louisiana Cancer Research Center. The Core will also assist PJIs with creation of IRB protocols and sample shipment to collaborators off campus through interface with clinic-based regulatory personnel. Dr. Subbiah's close ties to the HOP Clinic and his role as an active HIV clinical provider will facilitate these interactions and support for PJIs.

Molecular Histopathology and Analytical Microscopy Core (MHAM) (Dr. Luis Del Valle MD, Director): This core was established in response to high-demands for pathology expertise and laboratory analyses of a large number of clinical and animal tumor samples. This core is critical for Center for Translational Viral Oncology (CTVO) and is/will be heavily utilized by all investigators involved in this project. The core will assist PJIs and their mentors with histopathological evaluation of clinical materials, and will determine how different molecular pathways are altered in the context of carcinogenesis. The highly trained core staff will perform routine tissue processing for paraffin and frozen section preparation, H&E staining, immuno-histochemistry, immune-histofluorescence, in-situ hybridization, and will assist PJIs in all technical challenges and pathological evaluation of the obtained results. In addition, small animal Imaging based on optical imaging (Xenogen IVIS 200), and laser-capture micro-dissection will be available to scientists as a collaborative effort between MHAM and Morphology/Imaging Core.

Morphology and Imaging Core (Dr. Luis Marrero PhD, Core Manager): The Morphology and Imaging Core (MIC) is a comprehensive histopathology and specialized imaging center. The purpose of this core laboratory is to assist investigators requiring detection, imaging, and morphometric analysis of gene and protein expression in any type of cell and tissue. The facility will provide services for sample preparation and analysis as well as training to users. One of the goals is to assure high quality, consistent reproducibility, and technical expertise to produce valid microscopy studies for presentation, publications, and grant proposals to investigators throughout the LSUHSC, Tulane, and neighboring/national academic communities. MIC is located on the 5th floor of the Clinical Sciences Research Building.

Proteomics Core (Dr. Arthur Haas PhD, Director): The Proteomics Core Facility is a resource of LSU Health Science Center New Orleans, sponsored by the SOM. It is located on the 3rd floor of the CSRB. The mission of The LSUHSC Proteomics Core Facility is to support investigators in their biomedical research programs at the Louisiana State University Health Sciences Center and the surrounding New Orleans area. The central focus of The LSUHSC Proteomics Core Facility is in the identification of unknown proteins, the characterization of potential post-translational modifications (phosphorylation, ubiquitination, etc.) resulting from targeted proteomic screens arising from immunoprecipitation, protein interaction studies, or similar approaches, and the implementation of quantitative proteomics analysis approaches. The LSUHSC Proteomics Core Facility houses a nano-flow 2D liquid chromatography coupled to an Electrospray Ionization Linear Ion Trap (LC-MS) instrument for sensitive analyses of samples for which protein identification is required. In addition, a newly acquired Thermo Fusion Orbitrap mass spectrometer facilitates discovery-based quantitative proteomic workflow and is also coupled to nano flow 2D liquid chromatography. The bulk of experimentation in The Core includes protein mass spectrometry for the identification of unknown protein targets. Increasingly more complex samples are being subjected to the quantitative proteomics workflow and analysis. Other applications available in The Core include studies of protein expression profiling, posttranslational modifications, and partial sequencing of novel proteins. In addition, the Core provides access to HPLC methodologies on a case-by-case basis. The staff members also consult with researchers about their particular research interests and assist with development of novel scientific protocols

Translational Genomics Core (TGC) (Dr. Jovanny Zabaleta PhD, Director): The LSUHSC, Stanley S. Scott Cancer Center's Translational Genomics Core (TGC) TGC is committed to our research community through service, training, teaching and organizing seminars to keep our community informed of recent development in specific topics concerning genomics. To fulfill this goal, we follow these Specific Aims:

- To provide expert training in the different genomic techniques used in the TGC to any interested researcher. LSUHMC policy is to help people understand the technologies in the TGC for a better use of them and to obtain the best results possible. To do this, TGC invite researchers from time to time to come and work with us in the processing of their own samples. In this way they could better understand the procedures used in the TGC and would improve the way to handle their samples, improving the chances of better results.
- To provide a high quality service to our genomic users. In order to accomplish this, TGC is always learning about the techniques used in the TGC and keep a close contact with our providers to look for new improvements, way to reduce cost, implementation of new techniques and troubleshooting.
- To keep TGC equipment up-to-date in terms of service and software update to better serve users. To accomplish this, the Stanley S. Scott Cancer Center has been instrumental in the establishment of service contracts with Illumina and Life Technologies (now Thermo Scientific), vendors from three major instruments. These contracts are renewed annually and include visits to TGC for preventive maintenance of the equipment. In addition, both companies have remote assistance and the "Share Desktop" option, so that specialized technicians can access TGC equipment remotely for diagnostics, software upgrades and assistance.
- To help in the generation of preliminary data for the scientific community, TGC has been instrumental in helping the New Orleans scientific community generate high quality data to be included as preliminary information in grant proposals as well providing letters of support to researchers submitting grant proposals.

Located on the 9th Floor of the LCRC Building, the TGC is a core resource of LSU Health Science Center, currently sponsored by COBRE III (P30GM114732, A. Ochoa PI) and COBRE I (1P20GM121288-01, K. Reiss PI) grants. The Facility is committed to providing quality service by fulfilling the needs of the research community in a consistently rapid, dependable, and economical fashion. Services include automated DNA sequencing, using state-of-the-art instrumentation and the latest protocols to ensure high quality results at reasonable prices. The Facility houses an Illumina NextSeq500, a MiSeq (both for next generation sequencing), and an Illumina iScan for the analysis of microarray-based analyses including methylation, GWAS, microarray-based exome analysis, and several focused arrays, among others. The Core also has a 7900HT and QuantStudio 12K real-time PCR systems from ThermoScientific for gene expression validation, a Covaris DNA fragmentation instrument for the preparation of DNA for exome sequencing, a ddSingle cell isolator from Biorad, a 3'-based sequencing technology for the analysis of mRNA levels in single cell suspensions.

Vector Core (Dr. Alistair Ramsay PhD, Director) - The Vector Core is based at LSUHSC in the MEB and facilitates research through the preparation of stocks of pre-existing vaccine delivery vectors, and the provision of facilities for vector preparation. Current core services include large-scale preparation and quality control of replication-defective poxvirus vectors, including recombinant MVA (modified vaccinia Ankara strain) vectors and FPV (fowlpox virus) vectors. Dedicated space, including biohazard hoods, incubators and centrifuges, is also available for qualified investigators to prepare and grow their recombinant adenovirus stocks under Core supervision. The Core also maintains an inventory of plasmids and cell lines that are useful in the development of recombinant vectors. For more information, contact Olga Nichols.

PENNINGTON BIOMEDICAL RESEARCH CENTER (PBRC)

The Pennington Biomedical Research Center (Pennington Biomedical) is a 234 acre campus located in Baton Rouge, Louisiana containing more than 570,000 square feet (ft²) of building space dedicated to research and education in nutrition and preventive medicine. This total square footage houses basic research, comparative biology, clinical research, population science, education, and administration.

INSTITUTIONAL RESEARCH ENVIRONMENT & EXPERTISE IN CLINICAL AND TRANSLATIONAL SCIENCE

Facilities and Resources

Clinical Research Building: The outpatient-based clinical research of PBRC is conducted in Clinical Research Building No. 1. Clinical Research Building No. 1 is a four-story, 90,000-square-foot building that connects to Clinical Research Building No. 2. The facilities are primarily dedicated to clinical research trials for PBRC. The unit is designed for easy access and convenience of research volunteers. PBRC's central location in Baton Rouge, covered drive-up entry and spacious free parking are assets encouraging research subject participation. Accommodations for on-site dining and convenient take-out food service and a food delivery service facilitate feeding studies. The activity of the Clinic over the years 1992-2021 is summarized below in Table A.

The ground floor of Clinical Research Building No. 1 includes 15 general examination rooms; two EKG procedure rooms; one room equipped for determination of height, weight, and anthropometrics; three private interview rooms; and a secured pharmacy storage room. Also on the ground floor is the phlebotomy area. This area includes six phlebotomy chairs with four connecting specimen collection facilities. The medical records library houses three offices and a secured storage space for medical records. The clinical unit also contains administrative office space, reception and waiting areas, six recruiting offices and three offices for physician personnel. Three exam rooms are dedicated to the Pennington Biomedical Diabetes Clinic.

An Imaging Core Laboratory with DXA instrumentation, an ECHO MRI, Ultrasound and BodPod testing rooms are also located on the ground floor. In the Imaging Laboratory, there is also office space for two technicians. In addition, a state-of-the-art exercise lab for conducting ECG-monitored maximal exercise testing (i.e., VO₂ Max) and strength testing in adults and children is found on the ground floor. The exercise lab has men's and women's locker rooms and facilities.

The second floor of Clinical Research Building No. 1 has a psychology/behavioral area that accommodates five eating monitors and offices for the personnel. Since the second floor connects directly to the first and second floors of Clinical Research Building No. 2 at the Metabolic Kitchen area, all participant dining and monitored eating is conducted adjacent to the Metabolic Kitchen. There is a participant dining area on the second floor (close to our Metabolic Kitchen) that accommodates approximately 30 people.

The Clinical Research Building No. 1 also contains the following:

- One floor for additional support personnel for expanded clinical activities
- Housing for the home office of the Louisiana Clinical and Translational Science Center (LA CaTS)
- Housing for up to 40 study coordinators
- Office space for five physicians and 15 faculty members and their support staff

The second floor of Clinical Research Building No. 2 contains the following:

- Metabolic Kitchen (described in more detail below)
- Four indirect room-size calorimeters for the Metabolic Chamber Core (described in more detail below)
- Indirect calorimetry suite (seven stations total)
- Inpatient dining area
- 10 inpatient rooms (each with two beds/room)

- Nurses station
- Satellite pharmacy
- Specimen processing room
- Sunroom for participant utilization
- Three rooms for euglycemic and hyperglycemic clamp procedures
- IV procedure room (seven chairs) for FSIGTT, oral glucose tolerance testing and meal tests
- Biopsy room for skeletal muscle and adipose biopsies

Translational Research Clinic for Children (TReCC): TReCC is a 14,150-square-foot research facility located on the first floor of Clinical Research Building No. 2 and is dedicated for pediatric clinic visits and exercise testing. This outpatient pediatric research unit includes exam and treatment areas, procedure rooms, a metabolic cart room, meeting room and demo kitchen, indoor play and observation area, outdoor play area, exercise room, medical records storage for pediatric charts only, lab and phlebotomy area, administrative and other office support. The exercise and activity rooms are arranged and stocked according to active study trials. Exercise equipment sized appropriately for children are available and on-site including treadmills, stationary bicycles and cybercycles. Metabolic testing equipment for both adults and children is set up in the specialized procedure rooms.

Imaging Center: A 30,000-square-foot Imaging Center connects to Clinical Research Building No. 1. This Imaging Center accommodates Magnetic Resonance Imaging, X-ray, and other imaging equipment as well as faculty offices and support space.

Exercise Training Facility: Clinical research is also conducted within a 2,300-square-foot Exercise Training Facility on the PBRC campus. The facility offers state-of-the-art equipment, professional intervention technicians and optimal training data-capturing capabilities. Staff have the ability to collect and enter data in real time via a standing desk with dual monitors to operate the heart rate software, databases and drive files as needed. The cardiorespiratory fitness training room contains 12 treadmills, six stationary bikes, and two elliptical machines, while the strength training room has an extensive set of machines and free weights. There are three private rooms for intervention-related counseling in a one-on-one or small-group setting. For measurements, there's a private exam room complete with scale, stadiometer, and computer. In addition, there's a meeting room space capable of outfitting group exercise classes, group presentations, study orientations or introductory sessions, or a childcare facility for study participants. The Exercise Training Facility is supported by a trained staff composed of full-time exercise interventionists and students working on exercise-related degrees. The facility is participant-friendly and includes televisions. Further, there are locker rooms with lockers and showers available exclusively for the use of study participants. The facility has a defibrillator, electronic scales, and multiple heart rate monitoring systems (Polar and Zephyr BioHarness). There is an outdoor walking track, as well. The scenic walking track is 12 feet wide, paved, lighted and well-maintained. While the track is over half a mile in length, there are three intermediate circle turn-outs that can be used to create shorter walking courses.

Experience in Pediatric Research: Pennington Biomedical is well known for its excellent basic, clinical and population research programs in obesity, diabetes, and metabolism. Pennington Biomedical houses the Childhood Obesity and Diabetes Research Program. The pediatric research studies that have been conducted at Pennington Biomedical are summarized in the table below.

The following units act as Clinical Research Core Services at Pennington Biomedical Research Center:

- | | |
|--------------------------------------|---|
| • Clinical Trials Unit | • Dietary Assessment Core |
| • Recruiting Core | • Ingestive Behavior, Weight Management & Health Promotion Laboratory |
| • Communications and Marketing | • Metabolic Kitchen Core |
| • Biostatistics | • Energy Metabolism Core Laboratory |
| • Data Management Core | • Imaging Core |
| • Clinical Chemistry Core Laboratory | • Exercise Testing |
| • Mass Spectrometry Core | |
| • Core | |

Clinical Trials Unit: The Clinical Trials Unit is directed by Robert Leonhard, MBA. The unit's Chief Medical Officer is Frank Greenway, M.D., and the Medical Director is Kishore Gadde, M.D. The unit is staffed with two additional medical doctors, a physician's assistant, three nurse practitioners, registered nurses, licensed practical nurses, registered dietitians, project managers, research specialists and study coordinators. The unit is responsible for the oversight and coordination of all clinical trials performed at the center and within the community for both adult and pediatric studies.

Outpatient Clinic: The Outpatient Clinic of the Clinical Trials Unit is open Monday through Friday from 7 a.m. until 4:30 p.m. The Outpatient Clinic provides the following services but is not limited to: screening of potential study participants, completion of protocol-specific clinic visits, regulatory oversight for all studies, study-specific coordinators, and backup coordinators, dispensing of study medications, completion of case report forms and quality assurance of source documentation. The unit includes the general examination rooms, interview rooms, phlebotomy area and pharmacy previously mentioned.

Inpatient Unit: The Inpatient Unit of the Clinical Trials Unit is open seven days a week including holidays, with the exception of the Christmas break. Under the direction of Celeste Waguespack, FNP-C, APRN, the Inpatient Unit provides the following services but is not limited to: euglycemic hyperinsulinemic clamps, hyperglycemic clamps, and hypoglycemic clamps; oral glucose tolerance tests (OGTT); lumbar punctures; frequently sampled insulin glucose testing (FSIGTT); meal tolerance testing; feeding studies; pharmacokinetic testing (including phase I-IV medication trials); muscle and fat biopsies; and overnight stays. The unit can perform extended inpatient testing as necessary. All licensed medical personnel are BLS certified, with MD, NP, and PA staff also ACLS certified. The unit has ten inpatient rooms (twenty-subject capacity), three glucose clamp rooms, a large procedure room, biopsy room, satellite pharmacy, blood specimen processing room, and functional nurses station equipped with a telemetry system. The procedure statistics by year are listed above.

Interventional Resources: The Interventional Resources (IR) department of the Clinical Trials Unit is under the direction of Melissa Harris, MPA, CCRP, and provides services seven days a week as required by specific research studies. This department is responsible for providing project management; conducting prescreening assessments, orientations and consenting; collecting assessment data, physical activity, or other devices; completing run-ins; and assigning randomization. Additionally, IR is involved in designing and conducting behavioral (nutrition, weight loss, behavior change, app delivery, etc.) and exercise interventions for intervention-based trials. IR also has experience in formative and qualitative research including but not limited to lab and field usability of apps, qualitative interviews and focus groups. The work of IR is performed both on the campus of PBRC and offsite in community-based settings.

Pharmacy: The pharmacy is operated by Claire Hazlett, RPh. When a study medication arrives at the center, the shipment is verified by the pharmacist and all records are kept according to each specific study protocol. If a study medication arrives in bulk form, the pharmacist is responsible for counting and labeling the medication in the study-appropriate fashion before it is dispensed to study subjects. An accountability form is completed when a study medication is packaged to keep a record of which subjects received placebo or active. This form records the amount of medication remaining in the pharmacy as well as expiration dates. Accurate accounting for the dispensing of a study drug is maintained by the pharmacist. When a drug leaves the pharmacy for dispensing to a subject, the study coordinator is required to complete a dispensing log. This record requires documentation of the subject identification number, subject initials, coordinator who dispensed, number of bottles/tablets dispensed, date dispensed and if application, the amount of drug returned. If sponsors require drug accountability and dispensing be kept electronically via an IRT/IWRS system specifically for their study, paper logs are not utilized. When study medication is ready for distribution, it is transported by the pharmacist to the locked pharmacy storage area on the ground floor of Clinic Building No. 1. The pharmacy can compound non-sterile products into different dosage forms including capsules, liquids, and nasal sprays. The pharmacy is equipped with a clean room where sterile compounds can be prepared.

Recruiting Core: Recruitment services for clinical trials and other human research studies conducted at PBRC are coordinated by the Recruitment Core and directed by Alison Carville. The Recruitment Core manages all community outreach and recruitment services for human research studies at PBRC, such as screening all

incoming calls to determine study eligibility; assisting in partnership development, specifically with local community groups, physicians, and healthcare facilities; and serving as the first line of contact for all human research study participation. Incoming calls are directed to a call center that is operated by two full-time recruiters and is equipped with a Uniform Call Distributor (UCD) system. A UCD system expands the capability of a traditional phone system and allows multiple individuals to call simultaneously and be directed to the next available recruiter. The core utilizes an electronic message tracking application that tracks the outgoing phone call activity and a “smart” electronic phone screen system that screens potential participants upon initial phone contact and seamlessly matches them to alternative studies when deemed ineligible for the original study that they called about. In 2012, the core launched a new web screener for screeners to be able to go online, choose a study they are interested in and complete a preliminary screening. The system can tell the screener upon completion whether they are eligible at that point in the screening process, and if they are ineligible, it will alert them to other studies they may be eligible for; at that point, they could continue to screen for those studies. If the screener is eligible, they are then contacted by a live recruiter to complete the screening process and schedule their first screening appointment. In 2021, an average of 984 web screens were completed each month with over 6,500 total phone screeners for the year.

Communications and Clinical Trials Marketing: The Communications Department supports the recruiting and marketing functions for clinical research. The communications team consists of web manager Timothy Elder and media relations manager Ted Griggs. The team supports the Recruitment Core’s marketing efforts by creating media assets and pursuing earned media opportunities on the local and national level that focus on research studies currently underway. Through earned (unpaid) media placements (such as newspaper, magazines, radio, television and more), the Communications Department garnered a potential reach of over 250 million impressions with stories focused on research studies currently underway or results of research studies done at the center.

The Clinical Trials Marketing function, led by Aryelle Stafford, secures and places paid advertisements for clinical trials, based upon study budgets and regulatory guidelines, and aligned with central marketing strategies. The marketing function also uses social media such as Facebook, Twitter, Instagram, and strategic email campaigns to aid the Recruiting Department in targeting the 34,000+ subscribers who have requested regular information and updates regarding clinical trials and research at Pennington Biomedical.

Biostatistics and Analysis Capabilities: The PBRC Biostatistics Core is headed by William Johnson, Ph.D. This core resides in the Population and Public Health Sciences research program at PBRC, which is headed by Peter Katzmarzyk, Ph.D. In addition to Johnson and Katzmarzyk, there are two Ph.D. and four masters-level biostatisticians. Together, this team serves the research design and analysis needs for all faculty members at PBRC. The core is housed in Clinical Research Building No. 1, and there are spacious offices for faculty and adjacent cubicles for support personnel. The core is equipped with Pentium computers, and the email and data transfer needs are supported by the PBRC Technology Services Group. The standard software used for statistical analysis is the most recent version of SAS, presently Version 9.4. Other software, such as spreadsheets and word processing packages, are used routinely. All computers used by statisticians are connected to a HP 990Cse color printer. The Biostatistics Core seeks collaborations that lead to smooth transition from hypothesis formulation to efficient power analysis and sample size estimation, study design and execution through quality-controlled data management, statistical analysis, and summary presentations. Our overarching goals are to create electronic datasets that accurately describe research outcomes, provide state-of-the-art statistical techniques for the objective interpretation of our research discoveries, and invoke transparency in our methods to enhance reproducibility of our findings.

Data Management Core: The Data Management Core is directed by Aimee Ellender Stewart and resides in the department of Computing Services. The team includes six full-time employees and three part-time employees with extensive experience working with Pennington Biomedical clinical trials. The data management team serves as a comprehensive clinical data coordinating facility. Their primary responsibility is maintaining the clinical research database and bespoke applications that interface with that database. The team works with researchers to ensure the efficient and accurate transfer of data from observation to electronic files for storage and analysis; monitors the data processing throughout each study’s duration; and provides investigators with study-specific data sets via web-based desktop data access. The team has developed

custom applications for expedited creation of study-specific data sets that may contain both PBRC data and non-PBRC data. This development and data storage paradigm allows the team to work with both intramural and extramural researchers. In addition to supporting and maintaining custom applications, the core administers three local installs of REDCap (Research Electronic Data Capture). REDCap is a secured web-based application created at Vanderbilt University. REDCap development and support services are also provided by the core.

Guidelines for Good Clinical Practices as they relate to data handling have been documented and implemented in daily tasks. The group maintains current HIPAA Security Rule training and works closely with the Director of Intellectual Property, Legal and Regulatory Affairs. Programmers are provided with the latest software and hardware, which allows them to perform their work efficiently.

Clinical Chemistry Core Laboratory

The Clinical Chemistry Core Laboratory is directed by Jennifer Rood, Ph.D., DABCC, FAACC. It is accredited by the Centers for Medicare and Medicaid Services (CMS/CLIA) and the College of American Pathologists (CAP) and operates within the guidelines of Good Clinical Practices. In addition to proficiency testing programs required for accreditation, the laboratory also participates in the Lipid Standardization Program offered by the Centers for Disease Control and Prevention. The Clinical Chemistry Core Laboratory performs analyses for PBRC clinical trials, for basic researchers at the center, for the US Army Institute of Environmental Medicine (USARIEM) and for other contracting clients. The laboratory is staffed by medical technologists and phlebotomists licensed by the Louisiana State Board of Medical Examiners, and by research project assistants. Departments within the Clinical Chemistry Core Laboratory include Phlebotomy, Accessioning, Chemistry, Hematology, Urinalysis, Special Chemistry (RIA, HPLC, Immunochemistry, Automated Immunochemistry) and Point-of-Care Testing. The laboratory currently offers more than 350 different assays and is well equipped to perform both routine and specialized testing, including the development of new methodologies when required.

The following is a complete listing of instrumentation in the laboratory. Examples of the types of assays for each instrument are also listed. The complete test menu can be obtained from the laboratory.

Clinical Chemistry Instruments at Pennington Biomedical

DEPARTMENT	INSTRUMENT	EXAMPLES OF ASSAYS
Chemistry	Beckman Coulter DXC 700AU	general chemistry profiles, free fatty acids, HbA1C, Vitamin C
	NOVA Biomedical NOVA 1 Electrolyte Analyzer	potassium
Hematology	Beckman Coulter Unicel DxH 690T	complete blood cell counts and analysis, and reticulocyte counts
Urinalysis	Siemens Clinitek 50	urine microalbumin
	Siemens Clinitek 500	routine urinalysis
	Microscopic analyses (urine and blood)	routine blood cell morphology and urine microscopic exams
	BiositeTriage Meter Pro	urine screen for drugs of abuse
Special Chemistry	Bio Rad Plate Reader	ELISA assays
	BIOTEK 405 LS Plate Washer	ELISA assays
	Spectramax Plus 384	enzyme kinetic and ELISA-based assays
	Luminex Labmap 200	cytokines and other biomarkers
	Agilent Technologies HPLC 1100	amino acids, carotenoid profiles, vitamins, urine sugars
	Multitek	nitrogen (urine, fecal, sweat and saliva)
	Siemens Immulite 2000	automated immunoassays including insulin, thyroids and hormones
	IDS-iSYS	vitamin D assays

	Perkin Elmer Wizard 2470 gamma counter	radioimmunoassays including gut hormones
	Varian 240Z Atomic Absorption	metals
	WESCOR VAPRO 5600	osmolality
POCT	Alco Scan	breath alcohol
	Breath Tracker	breath hydrogen and methane gases
	Cholestech LDX	cholesterol (total, HDL, LDL) triglycerides
	DCA 2000	HbA1C
	HemoCue 201 System	glucose
	Manual Procedures	HCG (urine or blood), occult blood
	YSI 2900	glucose

Mass Spectrometry Core: The core is directed by Jennifer Rood, Ph.D., DABCC, FAACC, and is divided into two sections: Energy Expenditure/Body Composition and Metabolism.

Energy Expenditure/Body Composition: This section focuses on the measurement of energy expenditure using the doubly labeled water technique. Additionally, measurements of total body water are performed using either deuterium or oxygen 18. This section has three Finnigan isotope ratio mass spectrometers (a Delta XP and two Delta Vs). The laboratory also has automated sample preparation devices interfaced to the mass spectrometers. Three gas benches are used for ¹⁸O sample preparation, and four H devices are used for the sample preparation of deuterium (²H). With these instruments, we can accurately and precisely measure the amount of heavy isotopes, such as ¹⁸O and deuterium, in relation to the common isotopes, ¹⁶O and ¹H, for the measurement of energy expenditure in studies of obesity. The instruments are also used to measure ¹⁸O and deuterium as measures of total body water. The Delta XP is also used for analysis of ¹³C in breath samples as a marker of gastric motility.

Metabolism: This section focuses on the measurement of stable isotopes that are used to examine lipid, protein, and carbohydrate metabolism. This section has three gas chromatograph/mass spectrometers (Agilent 6890 GC/5975 MS, Agilent 6890 GC/5975b MS and an Agilent 7890GC/5975c MS). All three mass spectrometers have EI and CI capabilities, and positive or negative ion monitoring, for measurement of any stable-isotope-labeled (e.g., ²H, ¹⁵N, ¹³C) organic compound. This equipment is used to examine cholesterol metabolism in studies of cardiovascular disease, and glucose, amino acid, and fatty acid metabolism in studies of obesity and diabetes.

Nutritional Epidemiology, Dietary Assessment and Counseling Core: Directed by Catherine M. Champagne, Ph.D., RDN, LDN, FADA, the Nutritional Epidemiology, Dietary Assessment and Counseling Core serves two main needs at PBRC: 1) processing of dietary data collected via food frequency questionnaires, 24-hour dietary recalls or food records; and 2) delivery of lifestyle interventions that follow defined protocols via single-site or multicenter trials. The MENU Database is overseen by Catherine Champagne. The MENU database was donated to the Pennington Biomedical Research Foundation in October 1992 by its owner and developer, Dr. Margaret C. Moore. The Extended Table of Nutrient Values was renamed to honor the name of its developer. The Moore Extended Nutrient Database, now known as the MENU Database, is an appropriate reflection of one of its current uses in analyzing menus and recipes for the PBRC Metabolic Kitchen, for school lunches in Louisiana and for multicenter feeding trials. The MENU Database was selected for use in the National Heart, Lung and Blood Institute multicenter study of diet and lipoproteins and for the DASH and DASH-Sodium Trials. When compared to analytical laboratory values obtained from an outside Food Composition Laboratory, the MENU Database was closer to actual values than the three other databases used to calculate the same menus. Current data from additional menus analyzed still indicates good agreement between values from the MENU Database and the laboratory assays.

Diet Assessment Activities: The current version of Moore's Extended Nutrient Database is MENU 6. Primary datasets used are from USDA. The total count of foods and recipes contained within the MENU food composition files comes from the following data sources:

- USDA Nutrient Database for Standard Reference, Legacy (2018). US Department of Agriculture, Agriculture Research Service, Nutrient Data Laboratory. USDA National Nutrient Database for Standard Reference, Legacy. Version Current: April 2018.
- The Food and Nutrient Database for Dietary Studies (FNDDS 2015-2016). US Department of Agriculture, Agricultural Research Service. 2018). USDA Food and Nutrient Database for Dietary Studies 2015-2016. Food Surveys Research Group Home Page, Released July 2018.
- Food Patterns Equivalents Database (FPED 2015-2016) Released May 2017. Bowman SA, Clemens JC, Shimizu M, Friday JE and Moshfegh AJ 2018. Food Patterns Equivalents Database 2015-2016: Methodology and User Guide [Online]. Food Surveys Research Group, Beltsville Human Nutritional Research Center, Agricultural Research Service, US Department of Agriculture, Beltsville, Maryland. September 2018..
- Healthy Eating Index (HEI) 2015 can be computed from dietary intake data that is referenced to the FNDDS and FPED to determine whether or not the individual is consuming a healthy diet. References for HEI-2015 can be found at the following link:
- Supplementary information from the scientific literature or other reliable food composition tables.
- User-defined foods, allowing the input of nutrient data for foods needed in menus or recipes for which an appropriate food match cannot be found otherwise.
- Recipes input by users of the system at PBRC, using a unique recipe calculation system.

Analysis of dietary intakes of individuals using the Food Diary Program: While menu and recipe analysis is an important activity using the MENU system, several current research protocols use the Food Diary Program. Food Diary utilizes the MENU 6 Food Composition Files to analyze dietary intakes of individuals in research studies, including the most recent food composition files from the USDA. Often these are dietary records kept by participants in various trials or 24-hour recalls collected by the nutrition staff in the Dietary Assessment Center.

24-Hour Dietary Recall Collection Using the USDA Automated Multiple Pass Method. Catherine Champagne and her staff of dietary assessment personnel have been trained by USDA in the use of the Automated Multiple Pass Method (AMPM) and have used this in a number of trials, e.g., the POUNDS LOST Clinical Trial, which was a macronutrient-based weight-loss study involving PBRC and Harvard. AMPM is a computerized method for collecting interviewer-administered 24-hour dietary recalls either in person or by telephone. It is a research-based, multiple-pass approach employing five steps designed to enhance complete and accurate food recall and reduce respondent burden. This method is currently used in "What We Eat in America," the dietary interview component of the National Health and Nutrition Examination Survey, and other research studies nationally.

Diet History Questionnaire from the National Cancer Institute. DHQ II is the current version of the questionnaire distributed by the NCI. PBRC has developed an online version of this questionnaire and with the Diet*Calc software developed by NCI can analyze files to interpret the DHQ data to provide nutrient and food group estimates. This food frequency questionnaire is available in two versions, one that accounts for foods consumed over the past month and one that accounts for food consumed over the last year. The printed version of the DHQ II can be used but it is lengthy at 36 pages and the data can be entered by core staff.

Dietary Counseling Activities: A number of projects at PBRC have involved dietary counseling efforts. The Diabetes Prevention Project Outcomes Study (DPPOS) is following individuals from DPP who have successfully made lifestyle changes. The Look AHEAD trial also focused on lifestyle changes in a population of diabetic individuals. The Weight Loss Maintenance (WLM) trial was designed to determine how weight loss achieved in an intensive six-month initial phase of lifestyle change sessions was best sustained through a second phase, a 30-month period of either personal contact or internet efforts. The POUNDS LOST trial utilized four different diet treatments varying in protein and fat to scientifically test these diets for weight-loss effects. Subjects were asked to follow structured meal plans or exchange options in order to adhere to the dietary targets. The research dietitians/interventionists played a key role in working with these participants by conducting both group and individual sessions utilizing nutrition information and behavior-change messages (a landmark paper was published in the New England Journal of Medicine on February 26, 2009). Additional

projects included a lifestyle program for weight loss in cancer survivors, studies on a variety of low-fat and higher-fat Mediterranean diet regimens, and community interventions focused on weight control and diabetes care. Past activities also involved a weight-loss program in very obese individuals called Heads Up – a behavioral intervention that was being compared to an intervention with individuals who opt for bariatric surgery. The dietary counseling activities were extensive, and the interventionists involved had a breadth of experience in dietary interventions that include lifestyle/behavioral change. These interventionists received significant training in motivational interviewing and theories of behavioral change. Initially the groups were in-person, but since this project was statewide, the latter groups were web-based. Currently, our dietary counseling team is involved in several studies: 1) one study funded by Weight Watchers called POINTS where a person's genetic code is believed to affect weight loss from diets that vary in carbohydrate and fat content; 2) another project funded by industry called EXPEND is a weight-loss study patterned after the CALERIE project completed some years ago in which a person is reducing calories by approximately 25% and is counseled to stay within a zone of weight loss; and 3) the third study (EAT-2) is an overfeeding study designed to provide new insights into mechanisms that regulate human adipose tissue expansion, distribution and function, which can greatly influence health and metabolism – the individuals are offered a weight-loss program following the short-term overfeeding. In addition to these, our team is involved in a study called PREMO that is evaluating if reducing meat in meals and replacing it with either potato or pulses (beans, lentils, etc.) can improve blood sugar and fats, which have been shown to prevent diabetes and heart disease.

Ingestive Behavior, Weight Management & Health Promotion Laboratory

Assessment of Ingestive Behaviors: The Ingestive Behavior, Weight Management & Health Promotion Laboratory is under the direction of Corby K. Martin, Ph.D., a Licensed Clinical Psychologist in the State of Louisiana. The laboratory specializes in the development and evaluation of lifestyle change interventions, as well as the assessment of ingestive behaviors, namely food intake, and other food-related behavior and subjective states. The lab has developed and validated assessment methods for use in free-living conditions and controlled laboratory settings. The laboratory assesses subjective ratings of appetite using Visual Analogue Scales (VAS), and other appetite-related constructs (e.g., dietary restraint food craving) are assessed with self-report inventories. These subjective assessments complement objective measures of food intake that occur in the laboratory. The laboratory regularly uses VAS to assess changes in appetite and satiety due to feeding paradigms, pharmaceutical compounds or behavioral (lifestyle) interventions. The laboratory also empirically evaluates the effect of behavioral (lifestyle) and pharmacological interventions on energy intake and energy expenditure. The laboratory includes three separate eating rooms that are each equipped with Universal Eating Monitors (Kissileff, Klingsberg, & Van Itallie, 1980). Universal Eating Monitors consist of a scale that is concealed in a table and connected to a computer that automatically records the weight of food removed (eaten) from a plate on top of the scale. Each table is covered with a tablecloth, and the participant is not acutely aware that food intake is being monitored. Universal Eating Monitors allow analyses of cumulative food intake throughout the course of the meal, and each of the eating rooms includes a desktop computer that participants use to rate their subjective levels of appetite with VAS. The laboratory also includes a monitoring room that houses desktop computers and closed-circuit video equipment to record food intake behavior in the adjacent eating rooms. Lastly, the laboratory includes a taste-testing area and prep kitchen area, which allows food intake to be quantified by weighing food before and after participants' meals. In addition to laboratory-based endpoint assessment, energy/food intake can be measured on an individual level in free-living or in cafeteria settings (e.g., school cafeterias, Head Start) using food photography methods. The laboratory developed and validated the Remote Food Photography Method© (RFPM) and SmartIntake© smartphone app, which accurately measures energy and nutrient intake in near-real-time as participants live in their natural environment. The RFPM and SmartIntake© app assess food intake based on food images, which are captured by participants and transmitted by the app to the laboratory's server for analysis. SmartIntake allows food intake data to be collected with very little user burden. Additionally, SmartIntake© can provide ecologically valid subjective data surrounding food intake via the integration of ecologically momentary assessment questions into the app.

The laboratory and its colleagues expanded its smartphone-based assessment platforms by developing the PortionSize™ app. PortionSize™ is built around the food photography methods of SmartIntake©, but the laboratory developed and integrated innovative PortionSize™ features that provide users with real-time feedback about their food intake and adherence to specific diets. The laboratory also developed the

FoodImage™ app with colleagues at Pennington Biomedical and The Ohio State University. FoodImage™ uses food photography to quantify household-level food waste and how it is discarded (e.g., landfill, compost). The app quantifies and categorizes food waste that occurs when preparing food, cleaning out the refrigerator/freezer and eating. FoodImage™ also quantifies what and how much food enters the household, as well as the cost of those foods. Further, FoodImage™ quantifies the amount of food selected and how much food is consumed, allowing researchers to examine the relationship between food selection, food waste, food and nutrient intake, and changes in body mass. Lastly, via a collaboration with colleagues from Virginia Commonwealth University and East Carolina University, the laboratory developed an app called eCigTracker to quantify e-cigarette users' device and liquid characteristics remotely and in real time. These data can be used to calculate nicotine flux and exposure (ingestion) and will serve as the basis for future studies on 1) the effect of vaping on energy balance behaviors (e.g., food intake), and 2) mobile health interventions to reduce and stop vaping while preventing weight gain that can occur subsequent to nicotine cessation.

Behavioral Counseling: The Ingestive Behavior, Weight Management & Health Promotion Laboratory includes an intervention team that has designed and implemented numerous lifestyle interventions that modify food intake and exercise. The team has extensive experience with clinic-based (face-to-face) interventions. The team also performs translational research and disseminates population-based interventions that are evaluated in studies that rely on cluster randomized designs. Moreover, the laboratory is on the cutting edge of developing and testing the efficacy of mobile or m-Health interventions that are delivered via communication technologies such as smartphones. The laboratory and its colleagues have also developed methods to objectively quantify adherence to dietary interventions based on observed body weight. These methods have been used successfully in NIH trials. Finally, the laboratory has developed screening paradigms and retention strategies to minimize attrition during randomized controlled trials.

Metabolic Kitchen and Food Preparation: The PBRC Metabolic Kitchen is located on the second floor of Clinical Research Building No. 1 and has 2,622 square feet of working space. The kitchen area is divided into four fully-equipped individual kitchen areas of 130 square feet each. These individual kitchens are ideal for simultaneously conducting various protocols. Each individual kitchen area is equipped with a refrigerator, freezer, microwave, cooktop, one-quart blender, toaster, and electronic balances. There are several different models of electronic balances to accommodate weighing demands. One kitchen area is set up as a bake area, containing a 20-quart mixer. The 440-square-foot large-quantity food preparation area contains state-of-the-art convection ovens, steam ovens and kettle, bake ovens and cooktops, microwave, food warmers, food chopper, slicer, food processor, one-gallon blender and a large-capacity electronic balance. There is a tray service area, a dish room and approximately 800 square feet for receiving and storage including dry storage, a walk-in refrigerator, and a walk-in freezer. Located just outside of the Metabolic Kitchen is the participant dining space. This includes a reception desk where meal trays can be requested by phone or buzzer. Meals that are taken for later consumption are stored in the refrigerator/freezer room. An additional food storage area with space for dry storage, refrigeration and freezer storage is located adjacent to the service road. Approximately 225 meals per day can be prepared in the facility. Study participants consume their meals in the 850-square-foot dining area, and meals may be provided for take-out.

The PBRC Metabolic Kitchen is under the direction and supervision of Renee Puyau, RD, LDN. The Metabolic Kitchen has the capability of providing participants with all of their meals, seven days a week, in both inpatient and outpatient studies. The total number of inpatient meals prepared per year is shown in Table E. Menus consisting of specific macronutrient and micronutrient composition or incorporating study-specific food products are developed to meet the needs of each study. The Metabolic Kitchen has the infrastructure to observe and document consumption of study foods by participants seven days a week, improving adherence to study regimens.

The Metabolic Kitchen employs a director who oversees menu planning, food production and daily management of the operation. The Metabolic Kitchen manager is responsible for procuring foods, equipment, paper supplies and other products necessary for study-specific criteria. The research dietitians are responsible for managing the dietary component of specific study protocols. Research specialists and a food service worker prepare and serve the research-designated diets. Meal monitors and hostesses sit with participants during mealtime to ensure that participants are being compliant. Specified food products, if needed, are developed by the Metabolic Kitchen staff. Recipes are selected to include regional food preferences to

increase dietary adherence. After taste-testing, the food products can be analyzed for nutrient content and then included in the database for menu planning. The research dietitian reviews the finalized menu with each potential participant before the research project begins. The participant's food likes, dislikes and intolerances, including food allergies, are discussed. Food purchases are based on specifications outlined during menu development to meet nutrient content requirements. Upon receiving, the product is inspected by the manager to ensure proper quality and weight specifications. When possible, foods to be used throughout the research study are purchased at one time from a single lot to ensure minimum variation and are stored properly. Bulk food deliveries are stored in adjacent cold, dry or freezer space. Standardized recipes outlining specific ingredients and gram weights, correct mixing and cooking procedures, timing and use of equipment are meticulously followed under sanitary procedures. All ingredients are weighed to 0.1 gram on electronic balances. Mixed foods are prepared in batch quantities. Those foods then are individually portioned, weighed, sealed, labeled and frozen until ready to use. The nutrient composition of study diets may be verified by chemical analysis of aliquots of each menu cycle to ensure that the designed menus achieve the target nutrient values predicted by the nutrient database. Menus of all types, including high and low fat, saturated fat, and protein; high, moderate, and low sodium; DASH diets; and Standard or Average American diets, have been validated by chemical analysis. A continuous quality assurance program is followed to check food item weights, recipe procedures, packed meal and tray assembly, and food temperatures. Documentation is maintained for each study. Furthermore, operational problems are documented with an appropriate plan of action and follow-up. All Metabolic Kitchen staff members receive training in food sanitation and in research diet preparation.

Daily food production sheets for each participant are used when preparing the meals, listing day, menu cycle, food items required with portion weights and special dietary requirements. Foods are labeled for participant identification. Foods are placed on individual meal trays until service, or are individually packaged for take-out, following tray assembly forms. Meals are served to the participant on test days only after all study procedures have been completed. Additionally, Metabolic Kitchen staff obtains daily checklists from participants that contain information on the participant's consumption of meals provided. Potential problems with meal acceptance are identified and resolved. Personal attention and encouragement to continue on the diets are provided by all staff members throughout the study.

Energy Metabolism Core Laboratory: The energy metabolism core consists of four Metabolic Chambers (whole-room indirect calorimeters) for the assessment of 12- and 24-hour energy expenditure and substrate oxidation, and three portable ventilated hood systems (Deltatrac Metabolic Monitors, Sensoredics and Q-NRG Metabolic Monitors, Cosmed) for the assessment of resting energy expenditure and substrate oxidation and the thermic effect of feeding. The respiration chambers are located in the inpatient area of Clinical Research Building No. 2. Three of the chambers measure approximately 12' x 10' with 8' ceilings, corresponding to a total volume of about 27,000 liters. The fourth chamber is approximately 7' x 9' for a total volume of about 16,000 liters (including sealed ductwork). Each chamber is provided with furnishings and equipment necessary to perform metabolic studies on research volunteers over extended time periods in a precisely controlled environment. The three large chambers are comfortable enough for individuals to live for periods up to one week. They are equipped with a bed, chair, desk, toilet, sink, refrigerator, TV, VCR/DVD, computer with internet access, and motion sensors. The smaller chamber is equipped with a treadmill, roll-away bed, and chair, and is used for short-term energy expenditure testing. The respiration chambers and the ventilated hood systems utilize air that is drawn through the unit at a known flow rate. The small, 16,000-liter chamber can be used for exercise studies or studies with sudden change in environmental conditions (temperature and humidity) as well as sleeping studies. The oxygen and carbon dioxide concentrations of incoming and outgoing air are measured for the calculation of oxygen consumption and carbon dioxide production, from which energy expenditure is calculated from the Weir equation. If nitrogen excretion in urine is also measured, substrate oxidation rate can be calculated, as well. Eric Ravussin, Ph.D., is the scientific director and Leanne Redman, Ph.D., oversees the data integrity. In addition, the unit employs a biomedical engineer to ensure accurate data collection and ongoing maintenance and calibration of the equipment. Volunteer testing is performed by trained staff members.

Current services include but are not limited to:

- 12- and 24-hour energy expenditure and substrate oxidation

- Resting energy expenditure and substrate oxidation under basal conditions and during a euglycemic hyperinsulinemic clamp
- Data analysis with correction for urinary nitrogen
- Thermic effect of food

Imaging Core: The Imaging Core is designed to provide in vivo measurements of anatomy, biochemistry, metabolism, and tissue function for clinical research. Researchers also have access to PET scanners through a collaborative agreement with Mary Bird Perkins Cancer Center.

MRI systems have full multinuclear spectroscopy capabilities (^{31}P , ^{13}C and ^1H). A spectrum of coils is available for spectroscopy, as well as standard pulse sequences. Spectroscopy analysis software (jMRUI) is installed on workstations in the scanner suites.

An array of coils is also available on both systems for volumetric imaging including head, head-neck, body, spine, and knee coils. A 32-channel phased array head coil is also available on the Discovery system for brain applications. A number of peripheral devices for functional MRI scans are also available. These include but are not limited to a gustometer, foot tappers, finger tappers, a joystick and a BIOPAC system with electrical stimulation capabilities.

A set of volumetric imaging sequences are available for body composition including the IDEAL-IQ water-fat sequence on the Discovery and LAVA on both systems. The increased bore size (70 cm) of the Discovery system and the resulting increased field of view (50cm x 50cm x 50cm) allows the core to accommodate larger subjects for all scan types. Standard T1-, T2-, T2*-weighted, perfusion- and diffusion-weighted sequences are available for brain applications. Specific state-of-the-art sequences of interest include high-angular-resolution diffusion imaging (HARDI), echo planar imaging with blood oxygenation level dependent contrast (EPI-BOLD), partial continuous arterial spin labeling (PCASL) for perfusion imaging and fluid attenuated inversion recovery (FLAIR). Visual and audio stimulus presentation hardware and software are available for fMRI studies. Image analysis software includes Analyze (Analyze Direct), a suite of structural brain imaging tools originally developed in the IDEA Lab at UC Davis, and SPM and FSL for structural and functional MRI analysis.

Active, optimized research protocols include the following:

- ^1H (proton) spectroscopy for the measurement of hepatic lipid
- ^1H (proton) spectroscopy for the measurement of intramyocellular lipid
- LAVA and IDEAL-IQ imaging for measurement of adipose tissue, muscle, and bone abdominally and throughout the body
- ^{31}P for measuring maximal mitochondrial capacity (PCr resynthesis rate)
- ^{31}P for measuring PCr resynthesis rate pre-post lower leg ischemia
- LAVA-based measurement of internal organ volumes
- Brain tissue structure using T1-weighted, FLAIR and diffusion MRI
- Cerebral blood flow and brain activation by PCASL
- EPI-BOLD for brain activation during cognitive, sensory, and motor tasks, including food photography viewing, gustometry, risk-taking, stress, aggression, and executive control paradigms
- ^{13}C spectroscopy for measuring glial acetate metabolism
- Long-TE ^1H spectroscopy for measuring muscle acetyl carnitine concentration
- Magnetic resonance elastography for measuring liver fibrosis
- EPI-BOLD during motor skill learning and distracted foot-tapping using specialized joystick and foot-tapper devices.

The Biomedical Imaging Center includes a subject waiting room, a subject dressing room and a subject preparation room. The center also contains office space for researchers and administrative staff, a conference room, a large medical records storage room, and a computer and data closet.

Core personnel currently includes three licensed radiological technologists, an ultrasound technologist, and a biomedical engineer and core manager (M.S.). Each of these individuals is cross-trained to perform analyses

of MRI data; ultrasound data analyses are performed in-house by the ultrasound technologist, as well. Baton Rouge Radiology Group serves as a consultant for interpretation of scans as needed. Analyzed data is entered into a centralized database where it is fused with other participant records analyzed on-site and is directly transferred to the PBRC clinical database when possible.

The following is a complete listing of instrumentation in the Imaging Core:

- 70cm-bore GE Discovery 750 3T MRI System
- 60cm-bore GE Signa HDxT 3T MRI System
- GE Lunar iDXA
- Hologic Discovery DXA
- ECHO MRI [ultra-low field strength NMR]
- Cosmed BodPod system
- Cosmed PeaPod system
- GE Logiq E9 ultrasound system
- X-ray system
- Echosens FibroScan
- Thornhill Scientific RespirAct™ gas control system
- Itamar Medical EndoPAT 2000
- Tiba Ambulo 2400 ambulatory blood pressure monitors
- Multigon Transcranial Doppler System (TCD)
- GE diagnostic

Exercise Testing Core: The Exercise Testing Core is directed by Jennifer Rood, Ph.D., and is equipped to perform electrocardiogram (ECG) monitored submaximal and maximal cardiopulmonary exercise performance testing and musculoskeletal strength and endurance assessments. The ergometers are capable of singular wattage increments ranging from 0-1,000 W.

The core also includes an isokinetic strength dynamometer to perform constant velocity muscular strength and endurance testing. The system interfaces with computer microprocessors to measure torque, power, and endurance for resistance throughout a joint's range of motion (ROM) of most musculoskeletal joint areas. Resistance is provided using a servo-controlled mechanism and a user-defined constant velocity.

The following is a complete listing of instrumentation in the Exercise Testing Core:

- Four Parvomedics True One™ metabolic carts
- Two Trackmaster treadmills TMX425C
- Lode Excalibur Sport™ bicycle ergometer
- Lode Corival Pediatric bicycle ergometer
- Two Quinton Q-Stress EKG systems
- Mortara X-Scribe EKG system
- Biodex™ System 4 isokinetic dynamometers
- Two Suntech Tango+ blood pressure monitor systems

SOUTHERN RESEARCH (SR)

Southern Research (SR) (prior to 2015 referred to as Southern Research Institute or SRI) is a not-for-profit research organization that has been in operation since 1941. In terms of drug discovery and development, SR has a proven record of success such as seven FDA-approved anticancer drugs as well as pioneered works in other therapeutic areas including infectious diseases, neurology, rare diseases, metabolic disorders, *etc.* SR is located in Birmingham, Alabama and employs approximately 210 research scientists, technical staff, and support staff, and has a long-standing record of productivity in conducting governmental and industrial research grants and contracts. SR is internationally recognized for its outstanding track record in the discovery and development of antiviral drugs and small molecule cancer therapeutics. For example, six FDA-approved anticancer drugs (lomustine, carmustine, dacarbazine, fludarabine, clofarabine, and pralatrexate) and one cytoprotective agent (ethyol) were all discovered and developed at SR. SR is also a major contributor to the NCI's Chemical Biological Consortium and was a past member of the Molecular Libraries Probe Production Centers Network, a collaborative research initiative to identify small molecule chemical probes for the biomedical research community.



INSTITUTIONAL RESEARCH ENVIRONMENT & EXPERTISE IN CLINICAL AND TRANSLATIONAL SCIENCE

Facilities and Resources

Information Technology: Aligned with the NIST Risk Management Framework (RMF), the Information Technology Systems Support Group provides PC and network services to the staff of SR. Services include procuring, maintaining, and repairing all servers, network equipment, desktop and laptop computers, and printers as well as providing secure file, print, and email services and supporting various applications for the administrative and technical staff. The Facilities and Maintenance Department provides maintenance and repairs for all SR facilities. The Institution has excellent secretarial support services and lab maintenance services. SR's Human Resources, Contracts, Procurement and Accounting offices, provide administrative support through their implied functions. The facilities described in this proposal are currently active and available, as needed, for the proposed research.

Library Resources: Literature searches for the development of proposals and creation of manuscripts for dissemination of research findings is supported by a highly-developed library system. As an affiliate of the University of Alabama at Birmingham (UAB), located within walking distance, SR scientists have reciprocal privileges at UAB libraries, and our staff scientists regularly make use of the Lister Hill Health Sciences Library and the Mervyn Sterne Library of UAB, located a few blocks away. SR researchers also have access to an extensive list of online journals under the subscription list of the Lister Hill Health Sciences Library, Alabama's largest biomedical library, inclusive of the important chemical, biochemical, and biological journals that publish relevant research, searchable using SciFinder[®]. The Birmingham Public Library, as well as the libraries of Samford University and Birmingham Southern College, are also available to SR faculty. Complete access to the library resources, including use of photocopying facilities, are available through each of these libraries. In addition, full-time library personnel are available to research and retrieve information through the facility to access online several electronic databases of publications and patents. All library information is available online and accessible from faculty and staff offices as well as from outside the university through the internet. Additionally, UAB Lister Hill Library has an interlibrary loan system that links us to multiple other universities both nationally and internationally.

Scientific Platforms Division (SP): SP laboratories and offices include more than 450,000ft² of office and laboratory space and are located within close proximity to allow ease of communication between various disciplines, departments, and staff. SP is home to scientists working in a variety of fields including Biological Sciences (Oncology, Infectious Diseases, Neuroscience), Chemistry, and High-Throughput Screening (HTS). A number of core facilities are available for use by the faculty, including BSL-1, -2 and -3 laboratories.

Core equipment available across the Division includes an IntelliCyte iQue screener PLUS flow cytometer equipped with 3 lasers (405, 488 and 561nm) that can detect up to 13 fluorescent parameters, Nikon A1 confocal microscope with image acquisition and analysis software (Harmony, Velocity and Columbus), Thermoscientific Nanodrop 2000 spectrophotometer for RNA quantitation and quality control, HPLC and FPLC systems, Beckman RC2B high speed centrifuge with SS34, GSA and HB-4 rotors, Illumina MiSeq Sequencing System (to be upgraded to a NextSeq 500 instrument in 2017), GE ImageQuant gel documentation system, Operetta high-content imaging system (Perkin-Elmer), two Evos epifluorescence microscopes with 4-color digital image acquisition capability, and an Octet RED96 System.

Chemistry Department: The Chemistry Department within the SP division houses a team of 20 chemists with extensive experience in both medicinal chemistry and synthetic organic chemistry. Drug discovery programs within the Department cover a large range of various disease areas including oncology, infectious diseases (e.g., HIV, SARS-CoV-2, and antibiotics), neurology (e.g., Parkinson's disease, Alzheimer's disease, analgesic, and substance use disorder treatment), rare diseases (e.g., cystic fibrosis), and other areas (e.g., diabetes and antidotes). One of the Chemistry Department's main goals is to identify and bring forth compounds that can be classified as potential preclinical candidates and then collaborate with partners to advance these compounds into human clinical trials. Additionally, compounds are used as tools to investigate novel targets. The Department has collaborative relationships with not only other SR research departments but also external partners, such as universities, research centers, and the National Institutes of Health (NIH). This includes access to the Central Alabama High-field NMR facility housed at UAB. The Department encompasses various disciplines in addition to synthetic chemistry, including computer-aided drug discovery (CADD), bioanalysis, structural biology and protein crystallography, high-throughput synthesis and purification capabilities. Moreover, the Department has data platforms for efficient data management and artificial intelligence (AI)/machine learning (ML) model development. Synthetic chemistry is performed in laboratories of three contiguous buildings, Kettering-Meyer I (KM-I), KM-II, and Daniel Laboratories which are within close walking distance to the Bioanalytical Drug Discovery (BDD) Laboratory (in the Ingalls Central Building) on SR Campus, and the University of Alabama at Birmingham (UAB). The Department houses 18 fully-equipped chemistry laboratories, as well as two laboratories for microwave-assisted synthesis, one laboratory for parallel synthesis, one laboratory containing two walkup LC-MS, one laboratory with a PrepHPLC (Teledyne AccuPrep) and two walkup HPLC, and one laboratory that houses two NMR spectrometers. State-of-the-art CADD facility, a protein X-ray Crystallography Laboratory and associated crystallographic software and workstations, several protein crystallization laboratories, two walk-in cold rooms, a notebook/records archive, three Repository laboratories for long-term sample storage, and a glassware washing laboratory, all of which are described below. In addition, there are sufficient offices proximate to the laboratory space to accommodate all senior staff, other offices dedicated to specialized project uses, general conference and meeting rooms, and ample storage space. Other units of SP division have facilities reciprocally available to the Chemistry Department as needed. As an aggregate, SR has superb facilities for the design, synthesis, isolation, purification, identification, characterization, scale-up, modeling, and assay of synthetic compounds.

- **Parallel Synthesis Laboratory:** The KMII Building houses a large laboratory dedicated to automated combinatorial chemistry and chemical library synthesis. These systems permit the implementation of most conceivable chemistry protocols. Analogs can be rapidly and efficiently prepared using any established parallel synthesis methodology (solid-phase, solution-phase, liquid-phase) on a variety of scales and in high purity. A Waters AutoPurification System equipped with a 3100 Mass Detector is available for high-throughput purification of chemical libraries in the BDD Laboratory.
- **Microwave-Assisted Synthesis Laboratory:** There are three microwave synthesis instruments: The first is a CEM Discover Labmate System with Intelligent Technology for Focused™ Microwave Synthesis that is capable of running stirred reactions with operating limits of 250 °C, 300 psi and 300 Watts irradiation. In addition we have an 80ml Vessel Option (to run larger scale) with accompanying Fiber-optic Temperature Control System. The second system is an Explorer 48 with autosampler which

is available to run robotically 48 reactions sequentially. The third is a Biotage Initiator Robot Eight which is capable of automatic vial-handling with a temperature range of 40–300°C and a pressure range of 0–435 psi. Two separate racks can accommodate up to eight process vials of up to 5 mL volume or four large, 10–20 mL, process vials.

- **BDD Laboratory:** The Laboratory is currently comprised of three individuals and is housed in a 3000 sq ft, air-conditioned laboratory located in the Ingalls Central Building. This laboratory has the capabilities to do specialized NMR experiments and mass spectrometry. This laboratory is also capable of evaluating the pharmacokinetic properties of compounds, such as microsomal stability, LogD and solubility determinations, permeability determinations, metabolite identification, P450 interactions, and plasma protein binding, and bioanalysis of plasma and tissue samples. The equipment and the background, experience and flexibility of the personnel make this group suitable for a wide variety of special services.
- **CADD Laboratory:** A dedicated CADD Laboratory currently located in the KM-I building houses all of the terminal computers (both Windows and Linux operation systems) for performing computer-aided drug discovery and design. Those terminal computers connect to the CADD servers mounted in the server room in Ingalls Central Building which has uninterruptible power supply, security control, and special climate control. The CADD server cluster consists of Schrödinger Small Molecule and Biomacromolecule Drug Discovery server, GPU-accelerated molecular dynamics simulation server, AI/ML server, Optibrium StarDrop cheminformatics server, Dotmatics data/compound management server, and data storage server. Cloud computing utilizing external computing resources is also enabled per project need. Besides specialized CADD computers, office computers in the Chemistry Department are installed with research-related software such as client version of Optibrium StarDrop, electronic notebook system, PerkinElmer ChemDraw, software to view CADD and analytical results, EndNote, and have access to SciFinder, digital library, and Dotmatics database (shared across the division). Lastly, the computational chemists have individual office spaces in the same building in close proximity to the CADD laboratory.

High Throughput Screening Department: The SR HTS Center houses technologies and resources enabling research activities to support investigators in the identification and investigation of pharmacologically active compounds to support basic research and drug discovery efforts. This is achieved through services that include compound distribution, tissue culture resources, assay development, screening, and data management. Along with individual workstations allowing walk-up usage (e.g. plate readers, liquid handlers, incubators), the HTS Center utilizes two integrated robotic platforms for fully automated screening in 384 and 1536 well formats. Various detectors are incorporated into these systems to enable multimodal optical readouts, laser scanning cytometry and qPCR for primary endpoint measurements (Table 1). Non-contact and tip-based liquid handlers capable of low nanoliter through milliliter dispense volumes further support the wide array of assay formats (Table 2). An informatics infrastructure with a dedicated data analysis team is key for rapid turnaround of results and ensuring data are fully captured and tracked. The SR HTS group has access to both BSL-2 and BSL-3 containment, allowing work with agents such as SARS-CoV-2. Our capabilities support a wide array of assay types for both biochemical and cell-based assays (Table 1).

Table 1: Key Detection Technologies

Instrument	Type	Signal Detection	Assay Technologies
BMG PHERAstar BMG CLARIOstar BMG CLARIOstar	Multimodal reader	Colorimetric, fluorescence, luminescence	Absorbance, proximity (FRET, TR-FRET, AlphaScreen), light intensity, fluorescence intensity, fluorescence polarization
SPT Labtech Mirrorball	Laser scanning cytometer	Fluorescence	Low resolution imaging, fluorescence intensity (multiplexing), object recognition (cells or beads)
Roche LightCycler 384/1536	Fluorescence detection with thermal cycling	Fluorescence (dual color)	PCR, RT-PCR, qPCR

Table 2: Liquid Handling Capabilities

Instrument	Description	Volume Range
Beckman Echo 550 and 555	Non-contact acoustic liquid transfer supporting plate-to-plate transfers including stamping and random well access	2.5 – 1000nL
Beckman BioRaptr	Fixed tip dispenser providing rapid dispensing in multiple formats for up to 8 different solutions	100 nL – 60 μ L
Beckman Biomek FX, i7	Fixed 96 or 384 well head enabling full plate transfers and serial dilutions	0.5 – 60 μ L
Beckman NX Span-8	8 spanning channels and plate mover allowing independent operations such as cherry-picking	5 – 1200 μ L
Integra ViaFlo	96 well head transfer station with semi-automatic capabilities.	2.5 – 125 μ L
Various bulk dispensers (Wellmate, Combi, ViaFill)	Bulk dispensing on a per-column basis	Low μ L – mL

Automation Platforms: HTS maintains two automation systems to facilitate our assay process: the Thermo Fisher BenchTrak and a VAL cabinet. The BenchTrak utilizes an Orbitor on a rail in combination with a CatEx multi-directional arm. These two robotic plate movers work in conjunction with multiple liquid dispensers and plate readers to execute a complete assay set up. The VAL works in a similar method, also with a CatEx arm as its primary mover, and also exists within a HEPA-filtered containment cabinet that can be sealed and allows for the safe handling of BSL-2+ biological material. Both systems operate off of the Thermo Fisher Momentum scheduling software platform.

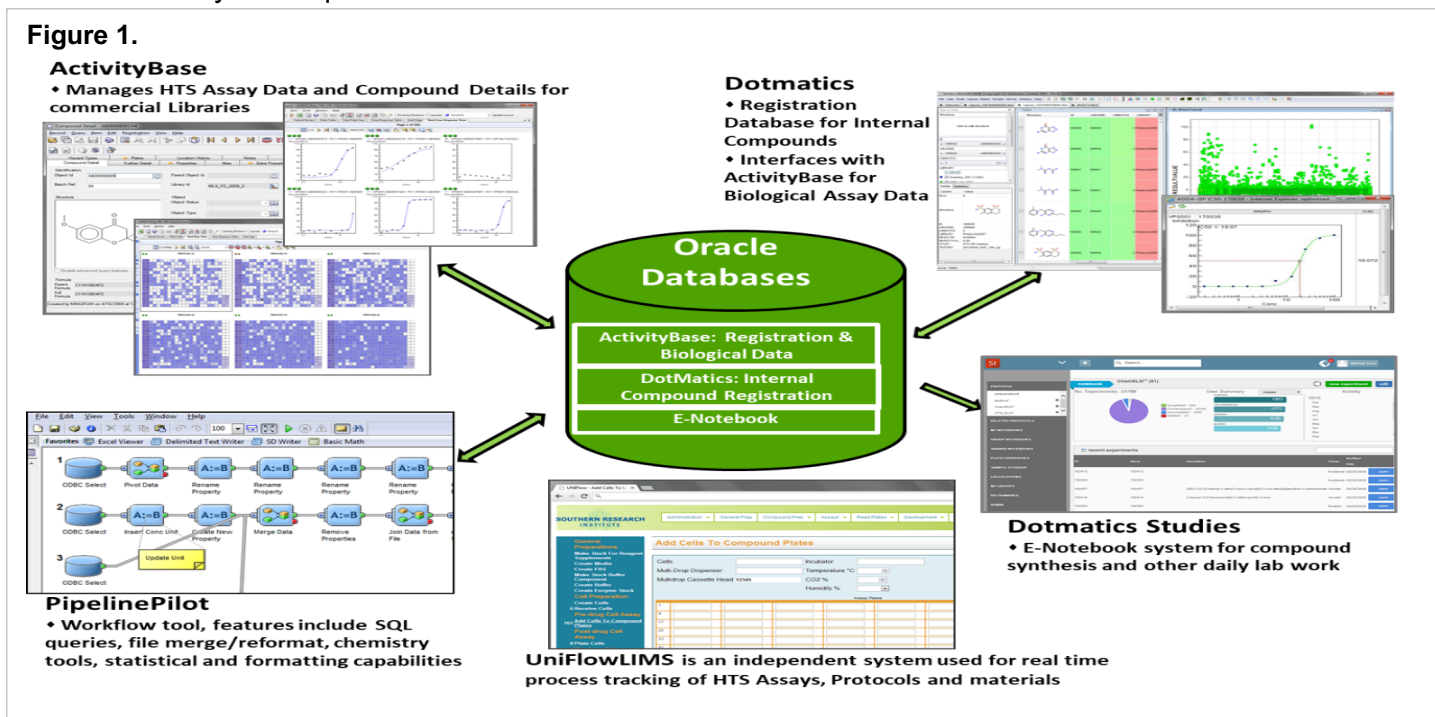
Compound Management and Library Collections: Our dedicated Compound Management group provides support for assay plate creation and general compound management. We maintain a collection of over 750,000 drug-like small molecules that may be used in campaigns ranging from small pilot screens to full library screens. The collections consist of focused (e.g. FDA approved drugs) and diverse libraries. By applying the liquid handling technologies in Table 2, our Compound Management group can support an array of assay formats and designs including 96-well, 384-well, and 1536-well plates.

HTS Informatics

The SR HTS Informatics group has established a robust system for tracking experimental conditions, analyzing, and viewing data, and producing reports. Oracle databases are the central repository for the critical data management systems used by HTS and Scientific Platforms. Both ActivityBase and Dotmatics systems provide front end (user) interfaces that rely on the Oracle databases to store the information gathered and generated by the respective systems.

- IDBS ActivityBase data management suite includes components for Chemistry, Biology, XE (for HTS), and peripheral tools for querying and reporting. Experimental data is imported from plate readers into this system where protocols and templates are created to normalize and calculate appropriate results based on the requirements and best practice for each assay. Biologists use this system to evaluate assay quality and to review plate and compound level data for anomalous patterns or outliers. Data meeting quality standards is verified and made available for internal review in Dotmatics and for reporting to internal and external clients. IDBS provides query tools that are used to generate most reports, supplemented by Biovia Pipeline Pilot when a more powerful tool is needed for complex queries and export of large SD files. Additionally, Pipeline Pilot allows query workflows to be designed for large reports, specifically those needed for compliance with Data Management and Sharing policies.
- Dotmatics Browser is the primary tool used by Chemists to assess how well internal compounds perform in Biological, ADME and other assays. Chemical structures are registered in the Registration module, then distributed to various internal and external sources for testing. While results from HTS/ActivityBase are uploaded through automated means noted above, other types of results can be uploaded to the system using the Nucleus component. Display pages in Browser are flexible and may be edited to include various relevant results.

- Dotmatics Studies functions as our electronic lab notebook systems. Both Chemistry and HTS use this system to retain details and metadata associated with each experiment.
- The SR HTS LIMS software is an in-house process tracking system grown from our pre-existing UNIFlow LIMS. It uses a mySQL server and does not house any proprietary data. It is used to record equipment, consumables, plates and personnel involved in each step of the laboratory process. The system provides a database of information supporting our quality control and assurance efforts including equipment maintenance, reagent lots and expiration dates, and assay protocols. This system is used by compound management to track compound plate genealogy as assay plates are created and follows those plates as they progress through their designated assay's workflow. This system architecture (Figure 1) was designed to enable flexibility to accommodate the constant evolution of laboratory techniques and workflows.



Computer: All associated offices are fully networked and equipped with multiple computers. Dell PCs, along with multiple printers and scanners, are available to all staff. The PIs have Dell laptop computers with a Pentium processor. In addition, laboratory computers are used to interface with the Alpha Innotech FluorChem HD2 Imager, the BioRad IQ5 RT PCR system, MagPix Multiplex Instrument and the Leica DMLB Epifluorescence microscope. All of the computers and printers are connected to the SR LAN, and all of the computers have access to the internet through this network. Computer core services use an Ethernet board network to printers and provide institutional file servers and extensive back-up capacities. The computers have ample storage space with which to enter, process, and analyze all data gathered from this project. In addition, assorted software is available for data analysis and statistical informatics.

Office: The PIs have standard, secure offices located in close proximity to their respective labs. Standard, secure offices are also available for postdoctoral fellows, graduate students and technical support staff, and are located in close proximity. There is additional office space for administrative and secretarial support staff.

Other: In addition to miscellaneous small equipment, larger and/or specialized equipment includes: multiple class II A/B biological safety cabinets, Milli-Q water purification system, gradient and non-gradient PCR thermocyclers, BioRad IQ5 RT PCR system, PCR clean room, sonic dismembrator, Qiagen TissueLyser-LT, Leica DMLB Epifluorescence microscope, Nikon SMZ800N Stereomicroscope, laser capture microdissection system, Invitrogen Countess Cell Counter, Alpha Innotech FluorChem HD2 Imager, GE 2-D gel electrophoresis system, BioRad I-Mark Microplate Reader, a BioTek 405LS Microplate Washer, MagPix Multiplex Instrument, and an Eppendorf Biophotometer.

TULANE UNIVERSITY (Tulane)

Tulane is a proud member of the prestigious Association of American Universities, a select group of 62 universities with “pre-eminent programs of graduate and professional education and scholarly research.” Tulane is ranked by the Carnegie Foundation as a university with “very high research activity”, a classification shared by only 2 percent of more than 4,300 higher educational institutions rated by the foundation nationwide. Tulane was ranked among the top 50 national universities for 2016 by U.S. News and World Report.

INSTITUTIONAL RESEARCH ENVIRONMENT & EXPERTISE IN CLINICAL AND TRANSLATIONAL SCIENCE

This program will build on the research expertise within the Tulane health sciences. The health sciences at Tulane include several main components, i.e., the School of Public Health and Tropical Medicine-SPH and the School of Medicine-SOM (including the Tulane National Primate Research Center). Together, these units provide a broad array of opportunities for education and research from the bench sciences to the population sciences. Tulane SPH is the only school of public health and tropical medicine in the United States, with approximately 125,000 square feet of floor space comprising large classrooms, small conference seminar rooms, newly renovated computer and research laboratories and classrooms, almost all of which are equipped for state-of-the-art distance education. Tulane SOM is the 15th oldest medical school in the nation and was the first medical school in the Deep South. It has a rich tradition of research excellence, including two Nobel Laureates. The SOM facilities are physically located on the Tulane health sciences downtown campus adjacent to the Tulane University Hospital and Clinic and provide more than 550,000 square feet of floor space. Included in the medical school complex are research and teaching laboratories, the medical library, a large auditorium, various conference rooms and classrooms, and administrative offices.

Facilities and Resources

Tulane Office of Research. Tulane University is committed to the support and growth of the research enterprise via its institutionally funded Office of Research. The Vice President for Research (VPR) is the University-wide senior research officer tasked with growing the research effort by facilitating the development of new interdisciplinary collaborations, supporting promising research initiatives, overseeing and facilitating compliance with federal research regulations, and resolving institutional and administrative barriers to progress. The Office of Research is institutionally funded to provide high-quality research support services. A University Research Compliance Officer serves to support the research compliance agenda. *The following research support offices report to the VPR and have been expanded to meet the needs of a research-active faculty:*

- **Human Research Protection Program:** The Tulane University Biomedical Institutional Review Board (IRB) and Social/Behavioral IRB are administered by the Human Research Protection Office as part of Tulane’s Human Research Protection Program. The Program is fully accredited by the Association for the Accreditation of Human Research Protection Programs (AAHRPP). It maintains a comprehensive set of Standard Operating Procedures that incorporate federal and state human subject protection regulations and AAHRPP accreditation standards. Compliance with applicable regulations, policies, and accreditation standards is accomplished through a rigorous initial review process for all proposed research projects and through the continuing review process, which must occur prior to the expiration date of the IRB approval. Initial and continuing reviews are conducted in accordance with federal guidelines. Additionally, compliance is ensured through for-cause and not-for-cause auditing conducted by the Research Compliance Office.
- **Research Compliance:** The Research Compliance Office assists researchers to ensure compliance with applicable regulations, university policies, and accreditation standards. These include the use of human and animal subjects in research, biological safety, pre-award grants administration, export controls, research misconduct, responsible conduct of research training, responding to Freedom of Information Act requests, registering and posting research, and using controlled substances.
- **Office of Research Proposal Development (ORPD):** ORPD assists faculty in the preparation and submission of complex grant proposals, in the areas of physical and biological sciences, medicine, public health, engineering, information and computer sciences, and social sciences. The services

offered by the ORPD are broad, including convening meetings of researchers for multi-investigator funding opportunities, working with investigators and sponsors to understand proposal requirements, developing proposal preparation schedules, creating proposal templates, gathering and formatting commonly required proposal elements, and vetting and editing technical sections of the proposal. Biostatistical support is also available through ORPD.

- **Sponsored Projects Administration (SPA):** SPA assists faculty in identifying sponsors for research funding, provides advice on proposal development, assists in preparing proposal budgets, serves as the Authorized Organizational Representative for proposal submissions and develops and implements policies and procedures involving the post-award aspects of sponsored projects. SPA is also responsible for issuing and monitoring subcontracts and reviewing and approving grant expenditures as needed. The Office of Grants and Contracts Accounting provides both pre- and post-award services to faculty members. Staff members aid investigators in the development of budgets for grant and contract proposals and in filing required compliance documents.
- **Technology Transfer and Intellectual Property Development:** The Office of Technology Transfer and Intellectual Property Development translates research and knowledge from the laboratory and classroom into technologies that benefit the public and provides superior services to the university, its faculty, and students, enabling all aspects of the research mission to strengthen the economy of southeast Louisiana through the creative use of Tulane's intellectual property.
- **Office of Equity, Diversity, and Inclusion (EDI):** The Tulane Office of EDI coordinates University-wide EDIA and anti-racism efforts and collaborates with university leaders to create, implement, and evaluate programs designed to ensure every single community member can grow and thrive together. The Office partners with campus schools and units to craft a vision for EDIA and anti-racism that is unique to the Tulane community and accountable to our place in New Orleans, the Gulf South Region, and the world. In doing so, the Office of EDI engages the Tulane community in crucial, brave conversations about the most challenging issues of our times — including the impacts of racism, sexism, heterosexism, ableism, classism, xenophobia, and other intersectional societal inequities — to identify social change efforts we can make now and in the future. Areas of focus in the EDIA Office include driving cultural change, sustaining racial equity, promoting EDIA excellence, inclusive environments, equity-minded research, and community partnership.

Tulane Center for Cardiovascular Health: The Tulane Center for Cardiovascular Health is located within the Department of Epidemiology, SPH. A main component of this center is the widely recognized “Bogalusa Heart Study”. The Bogalusa Heart Study has been a long-term epidemiologic study. The investigators have identified and followed Black and white children for nearly 35 years, and have described the incidence and prevalence of biologic and behavioral cardiovascular disease risk factors in these children. Their population has enabled them to not only document differences between males and females, but also between Blacks and whites. The results from the Bogalusa Heart Study have clearly documented that the genesis of atherosclerosis has its basis in childhood, and that prevention can and must begin at the early ages. The data available from this study are unique, and several protocols on Women's Health perspectives on CVD, hypertension and diabetes are under development.

Tulane Hypertension and Renal Center of Excellence (THRCE): Tulane Hypertension and Renal Center of Excellence (THRCE) grew out of the significant research in hypertension and renal disease being performed on the basic and clinical levels in the Departments of Medicine, Pediatrics, Physiology and Epidemiology in both the Tulane SOM and the Tulane SPH. This multidisciplinary Hypertension and Renal Center of Excellence is under the leadership of Dr. Lee Hamm, SVP and Dean of the SOM and Dr. L. Gabriel Navar, chairman of the Department of Physiology another BIRCWH mentor. Dr. Jiang He is Chairman of the Department of Epidemiology in the SPH and is Director of its hypertension research program.

The Tulane and Xavier Universities Center for Bioenvironmental Research (CBR): The Tulane and Xavier Universities Center for Bioenvironmental Research (CBR) began in 1989 with a \$33 million grant from the U.S. Department of Defense to establish a program of basic and applied scientific and policy research in bioenvironmental research. Under the auspices of the CBR, a wide variety of disciplines (medical, scientific, legal, economic and managerial) work together to better understand how human, industrial and agricultural processes affect the environment with a focus on human health. Featured in the CBR space and occupying 3 floors in the J. Bennet Johnston Health and Environmental Research Building, are state-of-the-art laboratories

used for core areas of research, including environmental and occupational diseases, toxicology, environmental health sciences and experimental pathology. The CBR represents a solidly established and well-developed collaboration between a major research university and one of the nation's leading historically black universities. The CBR's faculty and students are drawn from disciplines as diverse as anthropology, biochemistry, computer science, disease prevention, ecology, economics, engineering, English, epidemiology, geology, mathematics, molecular biology, philosophy, pharmacology and toxicology, for multidisciplinary basic and applied environmental research and education. Strength of the partnership between Tulane and Xavier Universities is its ability to leverage funds and optimize investments in minority institutions by combining the research capabilities of Tulane University with educational resources at Xavier University. The value of this partnership has been recognized through numerous grants and cooperative agreements funded by many federal agencies including the U.S. Departments of Energy, Defense, and Agriculture; the National Institute of Environmental Health Sciences; the National Science Foundation; and the national Aeronautics and Space Administration. Current priority areas in research focus on women's health, ecosystem research, biomonitoring/bioremediation program and a laboratory dedicated to environmental endocrinology.

Prevention Research Center: Prevention Research Center is funded by CDC and conducts prevention research, develops partnerships with the local community, communicates research insights within the local community and among communities, and provides training for future prevention researchers and community members. The theme of the Tulane University Prevention Research Center is the Impact of the Physical and Social Environment on Obesity. The PRC has been actively engaged in trying to rebuild New Orleans in ways that promote physical activity and healthy eating. PRC projects are planned jointly with a Community Advisory Board consisting of representatives of health-related, environmental, and community organizations in New Orleans.

Center for Evidence Based Global Health (CEBGH): The mission of the Center for Evidence Based Global Health (CEBGH) is to promote and support evidence-based research addressing today's most critical global health issues. The center supports this goal by providing methodological expertise to Tulane faculty in designing, conducting and analyzing cluster randomization and practical trials, as well as by offering administrative and logistical support to faculty in preparing grant proposals and in coordinating international trials. Research projects under the center's auspices have included: the Latin American Perinatal Health Training Program, which is funded by the John E. Fogarty International Health Center; a Trial for Improving Perinatal Care in Latin America, funded by the National Institute of Child Health and Human Development; the Tulane-Xavier Minority Training in International Health program, funded by the National Center on Minority Health and Health Disparities; and Increasing the Impact of Maternal and Neonatal Health Systematic Reviews, a grant funded by the Agency for Healthcare Research and Quality.

Tulane Center for Aging: Tulane Center for Aging, established in 2007, is a NIH-funded, university-wide center, physically located at the downtown health sciences campus. Its goal is to harness the multidisciplinary resources at the three campuses of Tulane University on behalf of the aging population. This is achieved through innovative research, education, and service. The purpose of the Tulane Center for Aging is to enhance existing programs and to create new ones where the need and opportunity arises. A Distinguished Lecture in Aging series was instituted, and this was followed by a seminar program. The Center for Aging hosts a monthly Aging Interest Group meeting that alternate between the uptown and downtown campuses. These gatherings have fostered the development of several interdisciplinary research groups and new funding possibilities. The Tulane Center for Aging is dedicated to the strengthening of training and service in the areas of geriatric medicine and gerontology in cooperation with the Section of General Internal Medicine and Geriatrics in the Department of Medicine and the School of Social Work, respectively.

The Center for Medical Informatics (CMI): The Center for Medical Informatics (CMI) helps the Tulane Medical Center plan, develop, and implement computer/communications systems to support its missions in medical education, clinical practice, and research. It provides expertise in technologies important in education, electronic publishing, and research and clinical data management. It also provides consultative support, expert assessment of commercial hardware and software, training opportunities, internal software development, and shared equipment and software resources.

Tulane Stress and Environment Research Collaborative on Health Disparities (SERCH): The Tulane Stress and Environment Research Collaborative on Health Disparities (SERCH) focuses on Preventing Health Disparities: from genes to neighborhoods. Basic, biomedical and social science research methods are applied to increase mechanistic understanding of the pathways through which stress, defined at multiple socioecological levels and across the life course, is biologically and behaviorally embedded to affect health in women and men and girls and boys. The goal is to foster novel prevention programs that build on psychosocial strengths of individuals and communities with an aim is to alter these negative trajectories with a focus on sustainable implementation and successful dissemination of such programs, using community-based participatory research (CBPR) and ownership as a key ingredient to successful sustainable programs. The interdisciplinary team brings select skill sets and experiences that are highly synergistic. Specifically, the team has expertise in social epidemiology, environmental epidemiology, reproductive epidemiology, genetics and epigenetics, allergy and immunology, sociocultural psychology, social work and community health sciences, with a focus on violence prevention. This new collaborative was made possible through an NIH Interdisciplinary Infrastructure Development grant (NIH 1C06RR029949-01) that supports renovation for interdisciplinary research. This specific collaborative includes 19 faculty representing Tulane University Schools of Public Health and Tropical Medicine, Social Work, Medicine, Science and Engineering. The SERCH collaborative is housed in the J. Bennett Johnston Building on Tulane's downtown campus. The J. Bennett Johnston Health and Environmental Research (JBJ) Building, located on Tulane Avenue, is a seven story, state-of-the-art facility which houses the Center for Bioenvironmental Research and other Tulane research activities. The 184,000 square foot building is designed to encourage interdisciplinary collaboration. The laboratories are configured in 360 square foot modules. Modular design permits economical reconfiguration of the lab space as research activities and needs change. The SERCH research space, located on the first floor and with approximately 1500 square feet of space, includes a biophysiology lab, observation and interview rooms, focus group room, and a GIS computing lab.

Tulane Brain Institute: Tulane Brain Institute represents a new of era of discovery, learning, and public influence in the brain sciences at Tulane. Researchers are working to understand sex differences in the brain and how hormones such as estrogens and androgens impact the brain across the lifespan. Such work has implications for understanding mechanisms by which males and females have different biological vulnerabilities to brain disorders. The Tulane Brain Institute, founded in 2016, builds upon the over 30 years of success of the Tulane Neuroscience Program. The University-wide Brain Institute, created as a transdisciplinary entity to coordinate and oversee neuroscience-related endeavors at Tulane, brings together over 400 faculty and students from across the University including from the Main Campus, the Health Sciences Campus, and the Tulane National Primate Research Center. The three pillars of the Brain Institute are research, education and training, and community outreach and engagement.

Tulane Building Interdisciplinary Careers in Women's Health (BIRCWH K12): The BIRCWH Program provides mentored career development for junior faculty to increase the number of highly trained independent investigators in sex/ gender differences and women's health in the field of cardiovascular and related diseases. The program is dedicated to promoting research and the transfer of findings related to Women's Health by promoting research independence among junior investigators. In order to improve the quality and increase the quantity of Women's Health research, Tulane BIRCWH bridges the period between advanced training and research independence, as well as links professions, scientific disciplines, and areas of interest for selected scholars. The common theme running throughout the various research areas is interdisciplinary research on cardiovascular disease, hypertension, and renal disease. In addition to our long-term goal of increasing the number of skilled, independent interdisciplinary investigators, we are also committed to promoting, through the BIRCWH Program's illustration, the awareness of the need to ensure a strong pipeline when fostering entities; establishing institutional and individual renown both nationally and internationally for the BIRCWH Program's findings on CVD and Women's Health and improving the cardiovascular health of Louisiana women across the lifespan, particularly African American women, by effectively training the next generation of conscientious, culturally competent and independent academic Women's Health researchers.

Women's Health Resource Laboratory (WHRL): The WHRL It provides technical support, guidance and mentoring in the areas of study design, data collection instruments, maintaining and updating study databases and statistical analyses. Lydia Bazzano MD, PhD, Associate Professor of Epidemiology and Medicine directs

the WHRL. WHRL is housed at the SPH and has space that includes a data training “laboratory” with computers and fosters interdisciplinary interactions of Tulane and other investigators. The WHRL serves not only as a service laboratory for Women’s Health research at Tulane, but also a nexus of integration of sciences such as epidemiology, biostatistics, economics, and behavioral and basic sciences.

Tulane Center of Biomedical Research Excellence (COBRE) in Hypertension and Renal Biology:

Tulane Center of Biomedical Research Excellence (COBRE) in Hypertension and Renal Biology was established by a COBRE grant of more than \$10 million, in the third phase of funding that supports the core laboratory and facilities. Dr. Navar is PI and Director of the COBRE. Current investigators represent departments in SOM and SPH. The current junior investigators supported by this program include basic scientists, clinician/scientists and population scientists. The Center is a multidisciplinary and interdisciplinary research center for which the foundation is basic science research. Over the last few years there has been a rapid growth in clinical research and epidemiological collaborative studies in hypertension related areas. Ongoing projects that use the COBRE resources include studies investigating health care delivery in hypertension, lifestyle factors, including dietary nutrients (high sodium, low potassium, low vegetable protein, low carbohydrate and low water-soluble fiber), overweight, physical inactivity, hypertension in minority populations and alcohol consumption as risk factors for hypertension in over 20,000 study participants living in Southwestern China. Another key example is the CRIC study (chronic renal insufficiency cohort), which is a seven-center, NIH-funded, multi-year project exploring the relationship between kidney disease and cardiovascular disease. The two principal investigators (Drs. He and Hamm) also serve as leaders of the Tulane Hypertension and Renal Center.

Animal (Department of Comparative Medicine): The Department of Comparative Medicine ensures high-quality, humane care and use of all laboratory animals at the vivarium located on the 9th floor of the Building for Environmental Research, accredited by AAALAC and under the supervision of veterinarians and trained staff. All faculty and staff with access to the vivarium are trained in accordance with related laws and guidelines of all federal and state agencies. All precautions are taken regarding the safety of animals and staff, and to maintain the integrity of scientific experiments. Appropriate transportation regulations and quarantines are strictly observed, and import/export and anesthesia/euthanasia procedures are performed according to the specific guidelines approved by the Institutional Animal Care and Use Committee (IACUC). In addition, animal care practices are based on the NIH Guide for Care and Use of Laboratory Animals. Access to the vivarium is restricted to qualified personnel, each with a unique security entrance code in the Edstrom Watchdog system. Codes are not shared by departments, and each individual’s code is restricted to those areas in which he or she has documented expertise.

Shared Facilities and Research Cores

Clinical Laboratory: The clinical laboratory in the Tulane University Office of Health Research is approximately 500 square feet and is equipped with a chair for phlebotomy work, facilities, and supplies for the appropriate storage of blood and urine specimens, a protected disposal for sharps, and two refrigerated centrifuges for processing blood and urine specimens. It occupies 800 square feet of space in the Tulane SPH building (23rd floor). The laboratory is equipped with an Olympus AU400e Chemistry-Immuno Analyzer (Olympus America Inc. Melville, NY), a Perkin Elmer 1470 Automatic Gamma Counter (PerkinElmer, Waltham, MA), an ASYS Expert Plus Microplate Reader (Biochrom, UK), Dionex Ultimate 3000 HPLC Systems (Thermo Fisher Scientific Inc., Sunnyvale, CA), an Abbott Laboratories IMX Automated Immunoassay Analyzer (Abbott Laboratories, Abbott Park, IL), a Hitachi 902 Chemistry Analyzer (Roche Diagnostics, Holliston, MA), an Abbott AxSYM® System (Abbott Laboratories, Abbott Park, IL), a Helena QuickScan 2000 (Helena Laboratories, Beaumont, TX), Beckman L5-75 and 1-2-60 Ultracentrifuges (Biostad™, Québec, Canada) and regular centrifuges. In addition, a TM Analytical Gamma Counter, a Tecam Microplate Washer and Reader, an electrophoresis apparatus, a colorimeter, and analytic balances are available.

Available laboratory services include sample processing, storage, shipping, molecular analyses, and multiplex biomarker assays. The laboratory also uses radioimmunoassays (RIA), enzyme-linked immunosorbent assays (ELISA), and high performance liquid chromatography (HPLC) analysis for many special assays, such as cytokines, hormones, and adipokines. The Biochemical Laboratory routinely measures complete chemistry

panels, blood and urine electrolytes, IgG, IgM, urine micro-albumin, cystatin C, HbA1C, CRP, endocrinology panels (estradiol, FSH, hCG, LH, progesterone, prolactin, testosterone, anti-Tg, anti-TPO, free T3, free-T4, T-uptake, total-T3, total-T4, ultrasensitive hTSHII), hepatitis panels, metabolic panels (active-B12, anti-ccp, B12, cortisol, ferritin, folate, glycated hemoglobin), homocysteine, troponin-I, PSA, BNP, CK-MB; protein and amino acids, ADMA, Larginine; insulin, C-peptide, adiponectin, leptin, e-selectin, SHBG, ICAM-1, vCAM-1, IL-6, 8-Isoprostane, TNF- α , and other traditional and novel CVD risk factors. The laboratory has served the Bogalusa Heart Study and other large-scale epidemiology and clinical research projects. As part of the clinical laboratory that supports storage of samples, Tulane also has a Freezer Farm with 12 ultra-low freezers (-85°C) for biological sample storage are available at the Tulane SPH. After Hurricane Katrina, the school invested sufficient funds to set up this freezer farm, which is located at the Tulane National Primate Research Center, an inland research facility which is protected from hurricane damage. All freezers have 24hour emergency power support, as well as CO₂ back up.

Molecular Genetics Laboratory: There are several faculty mentors at Tulane University with molecular genetics laboratories. These laboratories are usually 300-500 square feet and used for molecular genomic studies and high-throughput genotyping. Some laboratories are also conducting studies in functional genomics and epigenetics.

Molecular, Imaging, and Analytical Core Facility: The Molecular, Imaging, and Analytical Core Facility was developed to provide cell, molecular and biochemical services to researchers of the Tulane Hypertension and Renal Center (THRCE) that would make the performance of their research programs more efficient, convenient, and cost effective. It is a state-of-the-art facility that provides research infrastructure support to all Center investigators encompassing molecular biology, semi quantitative imaging, immunohistochemistry, genomics, HPLC, and RIA of angiotensin peptides. The Molecular, Imaging, and Analytical Core Facility has three separate components:

- **Molecular component:** DNA, RNA, protein, and tissue culture work are primarily performed in this laboratory. These include DNA and RNA extractions, purification, concentration, quantification, amplification, cloning, and detection procedures using PCR and real time qRT-PCR. Protein analyses include extraction, quantification and detection of target protein expression and activity using Western blot, EMSA and ELISA. Tissue culture work includes primary cultures and cultures of cell lines, transfection using RNA silencing technology and analyses of specific cells using microscopy and flow cytometry.
- **Imaging component:** This facility provides support for immunohistochemistry and immunofluorescence using an automatic robot immunostainer or manual immunoperoxidase techniques. High resolution upright light and fluorescent microscopes including an inverted microscope with an imaging capturing system and time-lapsed and chamber-incubator functionality to facilitate the evaluation of specific changes in protein expression in live cells, fixed tissues, and the evaluation of histopathological alterations.
- **Analytical component:** This facility provides assistance with the harvesting and collecting of tissues, including plasma, urine, and tissues such as heart, kidney, and brain, among others. This core performs the partial purification of samples by solid phase extraction along with HPLC separation with a major focus on the measurement of different angiotensin peptides and proteins by radioimmunoassay (RIA). In addition, it provides instrumentation support for measuring other fundamental parameters such as hematocrit, Na⁺ and K⁺ concentrations and osmolality in plasma and urine, various ELISAs and Luciferase assays.

TRANSLATIONAL RESEARCH INFRASTRUCTURE

Clinical and Translational Unit (CTU): Clinical and Translational Unit (CTU): provides research facilities with equipment, exam rooms, and support areas; regulatory, monitoring, and audit support for protocols; research nursing support for recruitment and protocol implementation; financial and contract support for negotiations with industry-supported studies; and core laboratory support for specimen processing, shipping, and/or analysis for investigators at Tulane University conducting clinical research. The CTU staff maintains credentials and a collaborative relationship with the Louisiana State University Health Sciences Center-New

Orleans' Clinical and Translational Research Center (CTRC) at the University Medical Center (UMC), sharing facility and nursing staff as needed and the core laboratory at Tulane and LSUHSC-NO protocols. The core laboratory functions play a major role in providing assistance for routine and special processing, storage, and shipping of all cellular and serologic samples; performing molecular assays including DNA, RNA isolations and genotyping, and gene expression analyses for various protocols; assisting investigators in identifying new methods that will support their research as well as in the proper validation of these new methods; training investigators, fellows, residents, medical students, and technical staff in molecular techniques, which includes both theoretical and practical training in molecular techniques in the lab.

Clinical Neurosciences Research Unit (CNRC): The CNRC is a translational and clinical research enterprise with educational and community science components. The CNRC works to develop novel therapies for stroke, dementia, and traumatic brain injury and to translate these therapies from bench to bedside to improve patient outcomes. The CNRC plans to serve as the integrating point and driving force behind the development of cutting-edge multidisciplinary science, state-of-the-art clinical services, innovative community outreach improving health and care, and engagement with hospital partners. The CNRC also partners with other institutes and departments at Tulane University to develop innovative multidisciplinary neuroscience programs and to achieve international recognition as a top-tier neuroscience research center.

Tulane University Office of Health Research: Tulane University Office of Health Research is a community-based research clinic and home to the COBRE Clinical Research Core in the SPH. Dr. Jiang He and Dr. Jing Chen are co-directors of the Core and also BIRCWH mentors. The Tulane University Office of Health Research includes a reception/patient waiting area, six participant examination rooms, a clinical laboratory, two conference rooms, a dietary interview room, an intervention room, mail and copy rooms, a kitchen, secured data storage rooms, a freezer room, and offices for study staff and research coordinators. The reception/patient waiting area is approximately 350 square feet and equipped with a reception desk, telephone, magazine rack, and couches and chairs for participant comfort. Each clinical exam room is approximately 150 square feet and is equipped with an examination table, supplies, desk, a mobile stool and chairs for participants. In addition, stadiometers, digital scales, and aneroid sphygmomanometers are present for use during participant clinical visits. The Office of Health Research also has a ACUSON SC2000 ultrasound system (Siemens Medical Solutions USA, Inc., Malvern, PA), Non-Invasive Blood Pressure Monitors with AI (HEM 9000, Omron HealthCare CO, LTD, Kyoto Japan), a HDI/Pulsewave CR2000 Research Cardiovascular Profiling System (Hypertension Diagnostic Inc., Egan, MN), a SphygmoCor® CPV System (AtCor Medical Inc North America, Itasca, IL), two GE MAC 1200 STs (GE Medical Systems Information Technologies GmbH, Germany), two Nicolet Elite 100 Non-Display Dopplers (CareFusion Corporation, San Diego, CA), a Noninvasive instrument (DynaPulse 2000A) and a Non-Invasive Automatic Oscillometric Device (BP-203 RPE: Colin, Komati, Japan). The two conference rooms each include a table and chairs for seating 10 to 20 persons. Two copy machines, two fax machines, and multiple network printers are available to the staff and coordinators in the clinic. A small kitchen and a food storage room are accessible for feeding study participants who have completed fasting blood draws. The remainder of the complex is occupied by staff offices and secured data storage rooms. Each office is equipped with a desk, chair and hutch and serviced by a fast access internet connection and telephone connections. All study staff have PC computers. Two secure data storage rooms (approximately 250 square feet in size for one and 150 square feet in size for another) are furnished with file cabinets and racks for participant binders and paper forms. These rooms remain locked unless study staff must access the participant information for study visits.

DATA RESOURCES AVAILABLE TO CCTS INVESTIGATORS AND TRAINEES

The Bogalusa Heart Study (BHS) Clinic: The BHS Research Clinic is a 7,000 square foot clinical research facility located in the community of Bogalusa, LA. This 7,000 square foot clinical research facility is organized into 4 clinical suites arranged around a large central reception area with a waiting room, laboratory, and storage area. Each clinical suite consists of a separate administrative/reception area of 150 square feet equipped with a reception desk, task chair, telephone and computer for study personnel, and a waiting area of 200 square feet featuring local art and equipped with magazines, a coffee table, and upholstered chairs for participant comfort. Each clinical suite contains several exam rooms of 75 to 100 square feet in area, a kitchen equipped with refrigerator, a staff lavatory, and a private office space of 115 square feet. Each clinical exam

room is equipped with an examination table, supplies, a desk, a mobile stool and chairs for participants. In addition, stadiometers, digital scales, and sphygmomanometers are present for use during participant clinical visits. Each office is equipped with a desk, chair and hutch and serviced by a fast access internet connection and telephone connections and shares access to a private fenced courtyard. A variety of non-invasive cardiovascular measurement instruments are available including a Toshiba Digital Ultrasound instrument (Toshiba Xario, SSA-660A, America Medical Systems) with multiple probes (Toshiba PSK25AT, 2.5 mHz, Toshiba PCK703AT, 7.5 mHz), a SphygmoCor® XCEL system (AtCor Medical Inc North America, Itasca, IL), multiple Non-Invasive Blood Pressure Monitors (Omron HEM907XL, Omron HealthCare CO, LTD, Kyoto, Japan), and a HDI/Pulsewave CR2000 Research Cardiovascular Profiling System (Hypertension Diagnostic Inc., Egan, MN). The 290 square foot laboratory and freezer space is equipped with a phlebotomy chair, facilities and supplies for the appropriate storage of blood and urine specimens, a protected disposal for sharps, a centrifuge for processing blood and urine specimens (Eppendorf 5810R, Eppendorf AG, Hamburg, Germany), and includes a lavatory for obtaining urine specimens. The common central waiting area, of approximately 260 square feet in size, includes chairs and can be converted to a meeting/conference area with tables and seating for approximately 20-25 persons. Two copy machines, two fax machines, and multiple network and PC printers are available to the staff in the clinic. All study staff have PC computers. The remainder of the complex consists of storage areas. Secure information storage rooms are approximately 250 square feet in size and furnished with cabinets and racks for participant binders and paper forms. These rooms remain locked unless study staff must access the participant information for study visits. Eight staff members currently work in the BHS clinic complex, including a registered nurse coordinator, experienced and certified phlebotomists, a laboratory technician, and field research assistants. The attached in-front parking area has 45 available parking spots with an additional 17 in the rear of the clinic complex. The Bogalusa Heart Study, an NHLBI/NIA/AHA funded study, was initiated in 1972 and continues to be funded by NIH.

CLINICAL CARE

Tulane Medical Center. The Tulane Medical Center (TMC) is one of New Orleans' most comprehensive health care facilities. The hospital is a 300+ bed acute care center, including an ambulatory care teaching facility, housed in a seven-story building adjacent to Tulane SOM, and nearby UMC and Southeast Louisiana Veterans Healthcare System. Opened in 1976, the TMC is the main practice location and teaching center for the Tulane SOM and operates principally as a multispecialty regional tertiary care center, providing both inpatient and outpatient facilities for clinical faculty. Extensive state-of-the-art diagnostic facilities are housed in the hospital/clinic, including advanced radiological facilities, nuclear medicine and ultrasound units, blood flow laboratory, and sleep center. The hospital offers primary patient care in all specialties, as well as critical care facilities including a medical intensive care unit, cardiac catheterization laboratory, chronic hemodialysis unit, and a state-of-the art organ transplantation program.

- ***Tulane Research Pharmacy:*** Located on the first floor of the TMC, is a licensed pharmacy that provides Tulane faculty with support and guidance for the safe and efficient conduct of clinical drug trials. The Lead Research Pharmacist on staff is specially trained in the research process to ensure the delivery of high-quality pharmaceutical care by adhering to federal and state regulations, accreditation standards and institutional policies for investigational drug control.

Tulane University Hospital and Clinic (TUHC): Tulane University Hospital and Clinic (TUHC) is one of New Orleans' most comprehensive health care facilities. The hospital is a 300+ bed acute care center, including a Children's Hospital as a "hospital within a hospital," and an ambulatory care teaching facility, housed in a seven-story building adjacent to the medical school, and nearby to the Medical Center of Louisiana, New Orleans, and the New Orleans Veterans Affairs Medical Center. It operated principally as a multi-specialty regional tertiary care center, providing both inpatient and outpatient facilities for the Tulane University School of Medicine clinical faculty. TUHC attracts patients from throughout Louisiana, the Gulf South area and Latin America. Extensive state-of-the-art diagnostic facilities are housed in the hospital/clinic, including advanced radiological facilities, nuclear medicine and ultrasound units, blood flow laboratory and sleep center. The hospital offers primary patient care in all specialties, critical care facilities including a medical intensive care unit, a cardiac catheterization laboratory, a chronic hemodialysis unit and a state-of-the art organ transplantation program including a bone marrow transplantation unit.

Lakeview Regional Medical Center: Established in 1977, Lakeview Regional Medical Center is a 167-bed, full service, acute care hospital. It offers the most advanced medical and surgical technologies in state-of-the-art facilities available to St. Tammany Parish residents, including Lacombe, Abita Springs, Mandeville, Madisonville, and Slidell. The Lakeview Regional Physician Group employs over 30 physicians who see patients at 11 convenient locations on the Northshore providing care in family medicine, general surgery, heart care, internal medicine, orthopedics, and vascular care. Lakeview Regional Medical Center's emergency department is the only level II trauma center in St. Tammany Parish and the only local ER staffed with all board-certified physicians. Lakeview Regional Medical Center continues to reinvest in its facilities and staff to better meet the needs of the growing community and provide the latest in medical innovations in diagnostic and treatment services and state-of-the-art medical equipment.

Tulane Lakeside Hospital: Tulane Lakeside Hospital has a bed capacity of 119 and is home to over 600 physicians and 450 employees. The Tulane-Lakeside specialized healthcare team concentrates on awareness, prevention, diagnosis and treatment to meet the health challenges of women from general gynecology to robotic surgery for Hysterectomy. Lakeside Hospital has delivered over 100,000 babies and treated well over 300,000 patients. Tulane-Lakeside Hospital's commitment to treating women and their babies has grown by expanding services and offering a wider range of healthcare options for the entire family.

GRADUATE EDUCATION AND POSTGRADUATE TRAINING

Masters of Science in Clinical Research: The School of Medicine has a structured program leading to either a Master of Science in Clinical Research degree or a Certificate in Clinical Research. The MSCR program includes: 1) formal didactic training providing tools to conduct modern clinical and translational research; 2) a clinical research and molecular medicine seminar series, providing peer interaction and mentor guidance on research topics; 3) a mentored clinical research project; and 4) an annual MSCR retreat. The goal of the program is to identify, recruit, and train the best possible candidates from diverse academic backgrounds for sustainable careers in clinical research (academia, industry, foundations, etc.)

Tulane Inter-American Training for Innovations in Emerging Infectious Diseases: This post-doctoral training program funded by the Fogarty International Center provides post-doctoral trainees with mentored training experiences and opportunities to work together as a team to identify problems in the diagnosis, management, or control of infectious diseases in the Americas. The program effectively integrates the four distinct disciplines of public health, science and engineering, social sciences, and medicine to provide interdisciplinary training in innovative approaches to infectious diseases for eight post-doctoral level participants from consortium institutions. The dissemination of activities associated with this program will provide broad perspectives to the PCOR/LHS trainees.

Masters in Clinical Investigation. The SPHTM Epidemiology Department offers the MS in Clinical Investigation to prepare students for advanced research careers solving patient-centered health concerns. During the Program, students become grounded in biostatistical and epidemiological methods to be successfully able to work with medical researchers and practitioners to address contemporary health problems. The Program emphasizes the understanding of clinical issues and prepares student to apply epidemiological methods in clinical and translational research settings. All students complete a research internship as well as a thesis, both of which will help them to employ skills learned in academic settings.

Certificate in Clinical and Translational Research. The Tulane SPHTM offers a Certificate in Clinical and Translational Research to prepare master's level students (including MD/MPH students) for research readiness in conducting clinical and translational research. The program, led by Dr. Lydia Bazzano, provides epidemiology or biostatistics students with an in-depth exploration of epidemiologic methods within the context of clinical research. Students learn clinical research methods, clinical trials, and meta-analysis, and the program is useful both to those with a clinical background and to those without prior clinical training.

TUSKEGEE UNIVERSITY (Tuskegee)

Tuskegee attained University status in 1985. Tuskegee University's academic programs are organized into five Colleges and three Schools: (1) The College of Agriculture, Environmental and Nutrition Sciences; (2) The College of Business and Information Science; (3) The College of Engineering; (4) The College of Veterinary Medicine (TUCVM), (5) The College of Art and Sciences (6) The School of Education, (7) The Taylor School of Architecture and Construction Sciences and (8) The School of Nursing and Allied Health. The colleges and schools offer 49 degrees: 35 Bachelor's, 11 Master's, Doctor of Philosophy in Engineering and Materials Science, Doctor of Philosophy in Integrative Biosciences, Doctor of Veterinary Medicine, and a Doctor of Philosophy in Interdisciplinary Pathobiology.

INSTITUTIONAL RESEARCH ENVIRONMENT & EXPERTISE IN CLINICAL AND TRANSLATIONAL SCIENCE

Facilities and Resources

TU CBR/RCMI Research Infrastructure Core: The National Institutes of Health established the Research Centers in Minority Institutions (RCMI) Program in 1985 after Congress noted stark health disparities between minority and white Americans. TU is one of eighteen institutions that receive funding from this program, to increase not only the presence of minority researchers in biomedicine but also studies in minority health. At TU, this funding has been used in multiple ways, most notably was the establishment of The Center for Biomedical Research (CBR)/RCMI Research Infrastructure Core (RIC). RIC enhances multidisciplinary research infrastructure for TU faculty by making available capital-intensive resources, and by providing the services and technical support required for research. This is helping the researchers at TU not only to stay on the cutting-edge of biomedical research but also establish cross-disciplinary and multi-institutional collaborations that are essential in the current increasingly multidisciplinary research environment our faculty find themselves in. This primary goal is achieved by providing researchers access to 1) an inventory of major capital instrumentation, 2) basic laboratory equipment and spec for routine experimental needs, 3) professional development in the areas of bioethics and responsible conduct in research, and 4) experienced and knowledgeable research support personnel that can assist with experimental design, instrument training, data analysis, bioinformatics, and data visualization. Core Goals are:

- To provide **instrumentation, technical, methodological, and personnel support** for faculty-led research supported by the TU CBR/RCMI, under Research Project or Pilot Project categories. Here, we plan to support the design, execution, analysis, and reporting of specific projects proposed in this application by providing support and by identification of appropriate resources through collaborative networks such as the RTRN and the CTSA/CCTS.
- To maintain a modern and reliable **shared instrumentation facility** for biomedical research at TU that enhances the competitiveness of the TU research faculty and to provide opportunities for collaborations. Here, we consider the maintenance and extended usage of shared major research equipment utilized by the biomedical research faculty.
- To provide project-specific mentoring and service on **Bioethics and Responsible Conduct of Research (RCR)**.
- To encourage and improve **access to and utilization of TU RIC resources** by the broader community by providing services, training, and informational sessions. This aim is expected to enhance the visibility of our RCMI program and to increase the overall research activity and collaborations across the TU campus and beyond.

Williams-Bowie Research Building (WBRB): Resources within WBRB offer the following capabilities: Digital Wide-field Microscopy (Inverted and Upright), Gene Expression Analysis, Flow Cytometry, Absorbance and Luminescence Plate-Reading, Gel Imaging, Tissue Culture, HPLC, GC/MS, Pulsed Field Gel Electrophoresis, Electroporation, Ultra-High-Speed Centrifugation, Film Processing, Western Blot Scanner, and InVivo Imaging. Supplementary equipment includes two large capacity autoclaves, two 4°C walk-in cold rooms, two refrigerators, two -80°C freezers, one liquid N₂ tank, three incubators, two incubator/shakers, two centrifuges,

one reagent-grade water system, one ice machine, one pH meter, two spectrophotometers, and other common lab items. WBRB also has a Small Animal Facility and Pathobiology department, which provide access to diagnostics and board-certified veterinarians and pathologists.

- **Microscopy:** Two Olympus microscopes (BX53F and IX71) with fluorescent lamps and digital cameras are used for wide-field fluorescent microscopy. CellSens software, installed on a Dell Precision TX500 computer, is used to acquire and manipulate microscope images. Additionally, a second BX53 (also running CellSens) is set up for the quantification and sorting of immunohistochemical staining. Three extra visible light microscopes (Olympus, Meji, and Omano) are also available for visible light microscopy.
- **Gene/Protein expression:** Researchers needing to investigate gene expression have several systems at their disposal within WBRB. These systems include two Stratagene QPCR systems (Mx3000P and Mx3005P), two Eppendorf thermocyclers (Mastercycler Pro and Mastercycler Gradient), one Alphamager HP (Innotech), and one CHEF Mapper system (Bio-Rad). The Mx3000P system is connected to a Dell Optiplex 380 PC and the Mx3005P system is connected to an HP Compaq 8000 Elite SFF PC. Both systems use MXPro software. Lastly, a Li-Cor Digiblot scanner is available to image and quantitate western blots.
- **Flow Cytometry:** A FACSCalibur and an ec800 cytometer are available. Both platforms offer robust analytical capabilities. On the FACSCalibur, FloJo CE is used to manage data acquisition and FlowJo for data analysis. The ec800 system uses proprietary software called ec800 1.3.1. Additionally, the ec800 software allows users to acquire sample data successively without handling samples individually.
- **Plate-reading:** Two Bio-Tek readers provide absorbance and luminescence plate-reading capabilities. The Powerwave XS is used for absorbance and the Synergy 2 is used for luminescence. Both units are controlled using a Gateway E-4500D computer and Gen5 software.
- **Chromatography:** A Beckman Coulter HPLC System Gold and Perkin Elmer Autosystem XL Gas Chromatograph/Turbo Mass Spectrometer with headspace sampler are utilized for chromatography. The HPLC is controlled with an IBM PC 300PL using 32 Karat. The GC/MS is controlled using Turbo Mass on a Dell Optiplex GX110.
- **InVivo Imaging:** Housed inside the TU Animal Facility, the IVIS Lumina XR (Caliper LifeSciences) provides InVivo imaging capabilities. This system can provide small animal imaging using fluorescence, bioluminescence, and/or X-ray. Living Image software on a Dell Precision T3500 computer is used to operate the imager.
- **Tissue Culture:** A dedicated tissue culture room contains a Nuair Class 2 biosafety cabinet, two water-jacketed incubators, and one inverted visible light microscope (Olympus).
- **Electroporation, Film Processing, and Ultra High-Speed Centrifugation:** A Bio-rad Gene Pulser 2 is available for electroporation; film processing can be done using a Konica Minolta processor and a Sorvall RC2-B ultracentrifuge (with multiple rotor options) is on-hand for applications that require ultra-high-speed centrifugation.

Carver Research Building (CRB): Resources within CRB offer the following resources: Digital Pathology Scanning, Multiplex Spatial Immunofluorescent Imaging, Cell Sorting, Digital Wide-field, and Confocal Microscopy, Time-Lapse Microscopy, Dark-field Microscopy, Molecular Modeling, Gene Expression Analysis, Absorbance, Fluorescent and Luminescent Plate Reading, Gel Imaging, Tissue Culture, Liquid Nitrogen Storage, Ultra-High-Speed Centrifugation and Film Processing. Supplementary equipment includes one large capacity autoclave, one 4°C walk-in cold room, two -80°C freezers, one -130°C freezer, ten incubators, one incubator/shaker, thirteen centrifuges, one ice machine, a transfection system, a sonicator, distilled/deionized water system, three pH meters three spectrophotometers and other basic lab devices.

- **Microscopy:** Two Leica microscopes (DM5000B and DMIRE2) with fluorescent lamps and digital cameras are used for wide-field microscopy. The DMIRE2 is an inverted microscope and the DM5000B is an upright microscope. CellSens, installed on a Lenovo Thinkcentre M72e computer, is used to acquire and manipulate microscope images. Additionally, two confocal microscopes are available to users. An Olympus IX81 with a Fluoview FV 1000 accessory provides confocal laser scanning microscopy, using a DDI computer running Fluoview 10 software to acquire and analyze

images. A second Olympus IXB1 with an IX2-DSU accessory provides confocal spinning disk microscopy. MetaMorph software run on a Velocity Micro ProMagix computer is used to acquire and analyze images. Additionally, confocal setups allow for darkfield and time-lapse microscopy. Five extra visible light microscopes are also available for visible light microscopy.

- **Gene expression:** Available systems for gene expression include two Applied Biosystems RTPCR systems (StepOne and 7500 Fast), an Eppendorf Mastercycler, one Alphasampler 2000 (Innotech), and a FluorChem E unit (Cell Biosciences). The StepOne system is connected to a Dell Latitude D520 with StepOne™ and the 7500 Fast RTPCR system is connected to a Dell Latitude E-6500 using 7500 software.
- **Plate-reading:** One Bio-Tek and two Molecular Devices (MD) readers provide absorbance, fluorescence, and luminescence plate-reading capabilities. The ThermoMax (MD) is used for absorbance, the SpectraMax Gemini EM (MD) is used for fluorescence and the Synergy HT (Bio-Tek) can provide multimodal functionality. The MD systems are controlled using a Lenovo Thinkcentre M72e computer and SoftMax software. A Gateway Pentium 4, with Gen5 software, is used to control the Synergy HT.
- **Digital Pathology Scanner:** The Leica Aperio CS2 can be used to identify, scan, and digitize entire slides for downstream staining quantification and pathological scoring. The scanner digitizes images up to 40x magnification. ImageScope software provides quantification algorithms that can identify staining intensities by cellular location (membrane, nuclear, and cytoplasmic). Using the cloud-based eSlide Manager service, users can remotely analyze and/or share all server stored images with collaborators.
- **Tissue Culture:** A dedicated tissue culture room contains two Nuair Class 2 biosafety cabinets, four Thermo Scientific water-jacketed CO₂ incubators, and a Labovert microscope.
- **Transfection System and Ultra-High-Speed Centrifugation:** The Lonza 4D-Nucleofector facilitates reproducible cell transfections and a Beckman L7-55 ultracentrifuge (with multiple rotor options) is on-hand for applications that require ultra-high-speed centrifugation.
- **Molecular Modeling:** Two dedicated workstations provide molecular modeling capabilities. Utilizing Chimera, Schrodinger, PyMol, Discovery Studio, and other software packages, researchers can investigate known molecules, generate novel molecules, and investigate molecular interactions. Both workstations have Xeon E5 processors, at least 10MB Cache, run at 3.10-3.90 GHz, and have high capacity TB HDDs, this provides all of the computational power necessary to perform in-depth investigations.
- **Cell Sorting:** The BD FACSAria IIu provides ~98% pure 4-way event sorting capability, using 3 excitation lasers (violet, blue and red) and 14 fluorescent detectors. Event detection sensitivities range from 0.5 to 100um with a maximum collection rate of 70,000 events/second. DIVA 8 software is used for data acquisition and FlowJo X is used for data analysis.
- **Multiplex Spatial Immunofluorescent Imaging:** Using 40+ marker panels the Akoya Codex allows core users the ability to spatially resolve cell populations in fixed tissue slides. The system is incorporated into a Keyence BZ-X800 microscope which provides automated image acquisition across 4 excitation filters (DAPI, GFP, TxRed, and CY5). Codex Instrument Manager software allows users to design and run Codex experiments.

Computer IT and Statistical Support: Tuskegee University has a strong IT support team. In addition, two units in the CVMNAH supplement the institution-wide IT support. CCEBRA research team is supported by the Biomedical Information Management Systems IT team (BIMS). The expertise of the team members includes network engineering, tele-media conferencing, database development, and website design which empower researchers for both on-campus and off-campus support. The BIMS team is also responsible for all IT and statistical needs at Tuskegee University's College of Veterinary Medicine (TUCVM). This includes technical support and training for both hardware and software as well as troubleshooting. Moreover, as the college is in the RCMI network, computing support is also available from other institutions and RTRN, if necessary.

Genomics/Bioinformatics Support: All Genomic sequencing, Whole Genome, Whole Exosome, Whole Transcriptome, and 850K methylation ChIP is performed at Hudson Alpha Genomic Institute. The RIC staff also provide bioinformatics support services. These services include sequencing project design, primary data analysis, secondary data analysis, data visualization, statistical analysis, and training seminars in R, online

data repositories, HPC resources, and command-line navigation. Core staff has extensive knowledge across multiple omics platforms, including RNA-seq, ChIP-seq, WES, miRNA-seq, and microarray.

Complementary Non-RCMI Resources at TU

NMR Spectrometer: A 400 MHz Bruker BioSpin Avance III with a 5mm BBFO 400 MHz Z-gradient high-resolution probe with automatic tuning and matching. The probe is capable of performing H^1 , C^{13} , F^{19} , and P^{31} . The 400 MHz magnet provides the ability to perform complex 1D and 2D experiments that are necessary for structure elucidation. The range of disciplines and applications include organic chemistry, polymer chemistry, physical/biochemistry, biology, agricultural sciences, and engineering. The NMR is housed in Samuel C. Armstrong Hall, Room 101, and managed by Mohamed A. Abdala, Ph.D.

Agilent Q-TOF HPLC-MS: An ultra-high pressure HPLC system with a binary pump, autosampler, two-column modules, and a diode array detector. The mass spectrometer is capable of being operated in either MS mode or MS-MS mode. Compounds can be run by Electrospray or APCI, in both positive and negative ion mode, with a mass measurement accuracy within 2 ppm. This unit is located in Samuel C. Armstrong Hall, Room 101, and managed by Marilyn Tourne, Ph.D.

Animal Facility and Pathology Services: The Veterinary College (located on the 1st floor of Williams-Bowie Hall) has a modern animal facility capable of accommodating from rodents to large animals and a well-organized Comparative Medicine Resource Center (CMRC) for research involving laboratory animals and small ruminants. The facility provides all services to researchers who have projects approved for animal use. The animal facility serves the biomedical research community in the university and is fully equipped with, among others, offices, garment changing areas, animal isolation/quarantine, housing rooms (for both conventional and special accommodations), and rooms for feed storage, cold holding, and necropsy. A designated attending veterinarian, a facility manager, a center director, and adequate non-technical support personnel are available. Facility usage can be coordinated through Benjamin Datiri, Ph.D.

Pathology services are provided to the clinical and research community on a fee-for-service basis. A fully equipped and man-powered tissue processing service facility is located in the Williams-Bowie building. One board-certified veterinary pathologist and three faculty (with a Doctorate degree in Anatomical Pathology) are available for consultation. Interested users can contact Thomas Graham, Ph.D., DVM.

Tuskegee Partner in the UAB Center for Clinical and Translational Science (CCTS)

The CCTS moves scientific discoveries into practical applications that enhance health by increasing interaction between UAB researchers and the community and researchers at UAB and other health centers to provide advanced medical treatments to patients. CCTS offers many resources and support for faculty, clinician-scientists, trainees, students, staff, and community members.

UNIVERSITY OF ALABAMA AT TUSCALOOSA (UA-Tuscaloosa)

The University of Alabama (UA), founded in 1831, was the first public college in Alabama and is the state's premier academic institution. UA's mission is to advance the intellectual and social condition of the people of the state, the nation, and the world through the creation, translation, and dissemination of knowledge with an emphasis on quality programs for teaching, research, and service. UA has been ranked among the top 50 public universities in the nation by *U.S. News and World Report's* annual college rankings for more than a decade—ranking 51st in 2017. The cooperative atmosphere of the campus and proximity of departments fosters the integration of research across schools and programs of study, thus ensuring assistance with project interventions are readily available and encouraging the academic/community partnerships that will be created through this project. UA supplies each investigator with a personal computer of sufficient capability to perform all tasks necessary for this project. These computers are connected through a network to all other University networks, the internet, and the University's mainframe systems. UA has a fleet of vehicles available for travel to visit rural communities. UA employees more than 6,000 faculty and staff.

INSTITUTIONAL RESEARCH ENVIRONMENT & EXPERTISE IN CLINICAL AND TRANSLATIONAL SCIENCE

Facilities and Resources

Alabama Life Research Institute (ALRI) Directed by Dr. Sharlene Newman: The ALRI is committed to providing research support for the project on equipment usage, supplies, human resources, and laboratory space. The ALRI is one of four leading university-wide institutes at the University of Alabama. It provides support for interdisciplinary research related to the human condition and offers research training and funding for pilot data collection and statistical analysis consultancy. The scientific environment of the ALRI not only greatly facilitates the implementation of the project, increases the probability of its successful completion, but also contributes significantly to the research and professional development of undergraduate trainees.

- **Office Space:** The ALRI in the UA Northeast Medical Building has ~5,000 sq. ft. of office space, housing twelve private offices, each equipped with a computer, Wi-Fi access, a network-connected printer, office furniture and other supplies. The PI's office is a part of the open floor plan of about ~150 sq. ft. The institute has three conference/workshop rooms with a video conference function, ~ 550 sq. ft. student workspace with 16 booths and one meeting space. The space is dedicated to student research assistants to make material preparations, data entry and management, and hold group discussions on research projects. Each booth has four secure locked filing cabinets to store study materials.
- **Faculty and Staff:** The ALRI has seven inaugural research faculties from different UA colleges and departments (Department of Communicative Disorders, Psychology, Community Medicine and Population Health, Human Nutrition and Hospitality Management, Electrical and Computer Engineering, Mechanical Engineering and Business Management), two neuroscience research scientists, a statistician, a project coordinator and two program assistants. The ALRI also includes interdisciplinary research scholars from across the University, other research affiliates, centers, and universities across the U. S. on multiple large-scale federally funded projects focusing on neurodevelopment and intervention, cancer prevention and community health. The institute holds both local and national scientific seminars and symposia on cognitive and computational neuroscience to facilitate the dissemination of new scientific research.
- **Computational resources:** The ALRI provides local and remote computational resources for the proposed project. A local password-protected Dell workstation (4.9 GHz 12th Gen Intel Core i7-12700) is used for basic data management to ensure the confidentiality of the data. This computer has a high-speed internet connection and has access to the analytic software used in the project (MATLAB, R, SPSS). The ALRI also supports the project for using UA high-performance computer clusters and purchasing Panasas Ultra as additional data storage nodes. UAHPC (formerly RC2) is an 87 node (1660 core) cluster featuring Dell PowerEdge M610s, M620s, and M630s with over 40 Teraflops of theoretical sustained performance. Eighteen nodes contain two Intel 6-Core Nehalem Xeon X5650 processors, 48GB of SDRAM, and the newer nodes contain two Intel 8-Core E5-2650, E5-2640v2, or 10-core E5-2640v3 processors and at least 64GB of RAM per node. The newest nodes have 20-cores

with 96 GB of memory. Our research jobs requiring only a single node can reach up to 88 cores controlled by a Dell PowerEdge M830 master node, which can ensure our analytical work can complete timely based on the research schedule. In addition, two dedicated storage nodes allow for efficient handling of data between nodes and the data storage devices. The storage nodes have 10G connectivity to the internet.

- **Recruitment resources:** The project collaborates with the UA Chinese program to ensure that (1) our L2 sample population is representative and more than sufficient to implement the proposed analytic methods; (2) scientific evaluations of students' language proficiency and their progress over time are obtained. The UA Chinese program has been enjoying an increasing enrollment in the past five years, reaching a maximum of 200 students per academic year. Program students come from diverse racial backgrounds and different majors across the University. The course level is determined by a composite set of indices, including the number of high school units completed, language placement examination scores and faculty evaluations. Fine-grained course stratifications from CH101 to CH401+ provide an essential reference for our project to keep track of the effect of language exposure with different levels of language proficiency on neural plasticity. A variety of university and community organizations are available in Tuscaloosa and Jefferson counties to provide support for us to recruit L1 speakers. UA Intercultural Diversity Center, Capstone International Center, Alabama Asian Cultures Foundation and Chinese Sisterhood of Tuscaloosa serving international students and local families will help us to post flyers and distribute brochures.

University of Alabama MRI Research Facility (Managed by ALRI): The new magnetic resonance imaging (MRI) research center (funded by NSF FAIN201920), located adjunct to the University Medical Center with a spacious parking lot accessible to visitors with disabilities, houses a Siemen's Prisma 3T scanner. The facility is more than 9,500 sq. ft. (see floor plan below) designed to host two MRI scanners, a mock scanner, an EEG system, and bio-specimen storage.

- **MRI:** The core MRI area in operation now consists of the MRI suite, a control room, an equipment room and two preparation rooms. The magnet room contains the MR magnet, supporting footings, enclosure, and a patient table. The room has magnetic and radiofrequency shielding to confine the fringe field and electromagnetic noise. The acoustic shielding is to reduce noise transmission to the control room. The scanner is installed with an InRoom Viewing 40" LCD Monitor (Nordic Neurlabs) to present visual stimuli, MRI compatible BOLDfonic headphones (Cambridge Research Systems Ltd.) to provide audio stimuli isolated from scanner noise, an fMRI-III + NC microphone system (Optoacoustics Ltd.) to collect vocal responses of participants and a fORP response recording system (Current Designs Inc.) to record the participants' responses via 1 x 2, 1 x 4, or 2 x 2 button boxes. The magnet room also contains two closets to store MRI accessories, including head (64, 32 and 20 channels) / body (body matrix, flex, wrist, foot, ankle, knee, and shoulder) coils, straps, cushions, wedges, sponges, towels, blankets, and phantoms. The control room contains the operator console with the Siemen's Prisma XA interface, a keyboard, a Siemen's intercom to communicate with participants, a Mac workstation for data storage, transfer and management, and a shielded window through which experimenters can observe the participants. The facility is also equipped with a Fully Integrated Real time MRI Monitoring system (FIRMM, Nous Imaging Inc.) to monitor the participant motion during the course of data collection using f(MRI), T1/T2 and DWI sequences and an MRI-compatible EyeLink 1000 Plus Eyetracker (SR Research, Ottawa, Canada). The equipment room adjacent to the magnet room contains gradient, radiofrequency and power cabinets, the cooling system (a helium pump and a water pump/chiller) and electrical devices. The whole-body 3T scanner includes the latest acquisition sequences for human neuro and body MR research, such as functional MRI (fMRI), advanced diffusion imaging (dMRI), spectroscopy (MRI/S) and whole-body scanning, etc. These offer the system the capability of investigating healthy populations and clinical populations with various developmental and neuropsychiatric disorders. They align the compatibility with other MRI facilities at other institutions for multi-site studies like the NIH Healthy Brain and Child Development Study (HBCD) study. The whole-body scanning provides the possibility for correlational studies like aging (Alzheimer's disease, Parkinson's disease, and stroke), diabetes and osteoarthritis. The 3T scanner is outfitted with an MRI-EEG compatible EyeLink 1000 Plus Eyetracker (SR Research, Ottawa, Canada) and Etymotics MR-compatible ER-30 sound isolating insert earphones to deliver sound stimuli.

- **EEG:** The core EEG area consists of three sections: a testing room, a control room, and a supply storage room. The testing room is equipped with a Dell Optiplex 7010 (IntelCore i7) computer installed with E-prime (version 3.0) to present experimental stimuli and collect behavioral data, an EGI NetAmps400 amplifier, an ethernet cable, a video camera mounted on top of the presentation computer and testing furniture. The control room contains a Power Macintosh iMac computer (3.2 GHz Quad-Core Intel Xeon) installed with Net Station (version 4.5.6) (Acquisition, Viewer and Waveform Tools) to collect and process EEG data. A 2-Port High- Resolution VGA Video Splitter is installed to enable the switch between the Macintosh iMac and Dell Optiplex. The storage room keeps the EEG experimental supplies and is used to make net preparations. The equipment includes 10 high-density 128-channel Hydrocel Geodesic sensor nets for infants (42-43cm, 44-47cm, 47- 51cm) and adults (55-58cm) and testing supplies like potassium chloride, pipets, distilled water, disinfectant, buckets, towels, baby shampoo, a ruler, an amplifier supporting arm and timing devices. The complete EEG hardware and software portfolio facilitates the electrophysiological studies of populations on a broad age spectrum with ecologically friendly, noninvasive, and direct measurement of brain electrical activity for a longer time span.
- **Behavioral assessment and others:** The center contains two testing rooms designated for conducting various behavioral assessments/prescreening, a conference room, a break room and a ~150 sq. ft. open office space for research personnel to discuss their projects. Each area is equipped with comfortable modern furniture with Wi-Fi access for visitors.

Majeti Lab Research: The Majeti lab research is centered on the interface of polymers and therapeutics at the nano-micro or macro-scale to prevent, manage or treat diseases using drugs or drug-like compounds or their combinations. We apply innovative delivery strategies to existing small or large molecules improving the risk vs benefit ratio; realize new indications or apply the innovative delivery technologies early on in the drug discovery program to minimize the attrition rates. The laboratories of Dr. Majeti are on the second floor of AIME building. The labs of are spread in an area of over 8000 sq.ft. and are well equipped. The following are some of the major equipment in Majeti labs. We also have designated BSL-2 approved labs to work with human cells, CO₂ incubators. In addition to the facility, we also have a satellite small animal facility in the AIME building that can house 50 cages and a surgical suite (Rooms 239/240) consist of approximately 1500 square feet of space on level 2 in the AIME Building.

Bioanalytical and Polymer Suite	Molecular Biology & Experimental Therapeutics Suite
<ul style="list-style-type: none"> • 6470B Triple quadrupole LC/MS • 1260 Infinity HPLC • 1260 Infinity II GPC • 630 FTIR • Circular dichroism Chirascan V100 • EmulsiFlex-C5 High Pressure Homogenizer • Environmental Test Chambers • FreeZone Triad Benchtop Freeze Dryer • MCR 302 Rheometer • UNHT³ Bio Bioindenter • Zetasizer Nano ZS 	<ul style="list-style-type: none"> • Attune NxT Flow Cytometer • Axio Vert.A1-Inverted Microscope • BeadBlaster 24R Refrigerated Microtube Homogenizer • Bio-Plex® 200 System with High-Throughput Fluidics • C1000 Touch Thermal Cycler • CFX Opus 384 Real-Time PCR System • CFX Opus 96 Real-Time PCR Detection System • ChemiDoc MP Imaging System • Cytation 5 Multi-Mode Reader • GentleMACS™ Octo Dissociator • Noninvasive Blood Pressure System for rats/mice • Pictor plus full hit handheld camera retina, anterior, derma • QIAcube Connect System • ZEISS LSM 900 Confocal

Histology Suite

- ASP6025 S - Advanced Smart Tissue Processor
- BioGenex Xmatrx® Infinity-IHC Station
- HistoCore Arcadia H Modular Tissue Embedding System
- HistoCore Arcadia C Cold Plate for Embedding System
- HistoCore MULTICUT R - Rotary Microtome
- HistoCore PERMA S Slide Printer
- HistoCore SPECTRA CV Coverslipper
- HistoCore SPECTRA ST Automated H&E Slide Stainer
- Leica CM1860 UV Cryomicrotome
- Leica IP C Cassette Printer
- Vet Axcel Chemistry Analyzer
- ZEISS Axiolab 5
- ZEISS Axioscan 7 Slide Scanner
- ZEISS Primostar 3
- Zoetis VETSCAN HM5

College of Community Health Sciences (CCHS): CCHS was established in 1972 to meet the critical demand for primary care physicians and quality healthcare in Alabama's medically underserved rural areas. CCHS was founded on the principle that community inclusion is essential to the health profession. The College serves as a model for community-oriented medical education and clinical training, offering rural medicine clerkships, novel curriculums that increase students' exposure to rural medical practice, and programs that guide rural Alabama high school and college students into health careers. CCHS is dedicated to promoting and improving the health of individuals and communities in Alabama and the region through leadership in medical education and primary care, the provision of high quality accessible health care services, and scholarship. Engaging communities as partners, particularly in rural and underserved areas, and fostering innovative, community-oriented research to inform population health and support community providers central to the CCHS mission. The College is located in a state-of-the-art 77,000 square foot facility that houses 48 physicians in training, 75 medical students, 25 graduate students, 50 faculty, and 300 staff. CCHS provides the Institute for Rural Health Research (IRHR) space for current staff and allows for growth in personnel and programs. CCHS has classrooms and space for lectures, seminars, and training workshops/activities. The College's Health Sciences Library maintains the Clinical Digital Library, which provides professional digital library services to off-site users. Nearly 800 students have completed their third and fourth years of medical school at the Tuscaloosa Regional campus and 456 residents have graduated from the Family Medicine residency as of 2016. One in 7 Alabama family physicians graduated from the Family Medicine residency at CCHS.

The Institute for Rural Health Research (IRHR): Established in 2001, IRHR seeks to raise standards of attainable health status and quality of life for rural citizens. IRHR's efforts to reduce health disparities in rural communities is exercised through research, clinical trials, screenings, and health education that is participatory and mutually beneficial to communities. IRHR partners with UA colleges/schools and rural communities, and has participated in federal and state grants totaling more than \$25 million. IRHR investigators have access to an outstanding research infrastructure including: office space, research lab space, conference rooms, state-of-the-art computers, specialized research software (NVivo, SPSS, SAS etc.), printing and reproduction capabilities, administrative support, etc. IRHR desktop and laptop computers are configured for key personnel to work with large data sets, conduct advanced research analysis, and have adequate processing and graphic capabilities. Specialized software and software licenses allow for statistical, data management, and GIS applications. IRHR's desktop and larger computers utilize SAS, SPSS, and SUDAAN software packages. IRHR has its own password-protected server that allows for complex study and GIS mapping. Cameras, dictation devices, and other supplies can aid in the dissemination of data and instructional materials. IRHR has web-conference capabilities that enable efficient communication between IRHR and its partners around Alabama. Additionally, IRHR has multi-point video-conferencing capability for up to 15 sites using Internet 2. Distance conference is also available using the ITBA System. IRHR has use of UA's Center for Business and Economic Research, Alabama State Data Center (a U.S. Census Bureau repository), and the Cartographic and Geographical Information Systems Lab. IRHR also provides a wealth of resources and infrastructure to support faculty research in the form of four 4 full-time staff in the following roles, respectively: (1) Proposal

development administrator; (2) Editor and writer; and (3) Data analyst; and (4) Administrative assistant. Additionally, IRHR is closely affiliated to UAB's CCTS as part of the CCTS partner network. IRHR hosts an annual Rural Health Conference that provides a platform for academic researchers and community members to partner and share research ideas.

University of Alabama, Tuscaloosa, Alabama Life Research Institute (PI: J. Lochman): The Alabama Life Research Institute is a newly-formed consortium catalyzing inter-disciplinary biopsychosocial research by uniting several existing research centers (Aging, Prevention of Youth Behavior Problems, Rural Health, and Social Science Research), the Institute synergizes the existing research protocols with new resources for data management and analysis, grant development, and results dissemination. This new Institute cultivates, supports, sponsors, and conducts cutting-edge translational research that will be useful for KL2 Scholars.

UNIVERSITY OF MISSISSIPPI MEDICAL CENTER

The University of Mississippi School of Pharmacy (UMSOP) is home to the Center for Clinical and Translational Science (CCTS). With a presence on the University of Mississippi's main campus in Oxford and on the University of Mississippi Medical Center campus (UMMC) in Jackson, UMSOP is uniquely positioned to facilitate translational research through its extensive network of pharmaceutical researchers and clinical pharmacists.

INSTITUTIONAL RESEARCH ENVIRONMENT & EXPERTISE IN CLINICAL AND TRANSLATIONAL SCIENCE

The UMSOP is home to the Research Institute of Pharmaceutical Sciences (RIPS), which was established to discover and disseminate knowledge of natural drug products, develop, and commercialize new products, and improve public health. There are currently four centers within RIPS: The National Center for Natural Products Research (NCNPR), the Pii Center for Pharmaceutical Technology, the Center for Pharmaceutical Marketing and Management (CPMM), and the Center for Clinical and Translational Science (CCTS). The recent addition of the CCTS creates the infrastructure, not currently available in Mississippi, to transition drug discoveries to clinical trials, then to practice and community settings.

The CCTS is structured to bridge research on the UM campus in Oxford and the UMMC campus in Jackson and to assist in the commercialization of new discoveries. This new Center provides a progressive infrastructure and additional core competencies in Oxford and Jackson to support the expansion of clinical and translational research at both sites. The strategic goals, objectives, and priority areas for the CCTS have been aligned with the broader organizational strategic priorities identified in the UMSOP 2012 visioning process and the current UMMC strategic plan, *UMMC 2020*, which include the development of translational science capacity to strengthen the already significant national leadership in pharmaceutical research, aligning across missions by creating synergies between clinical, educational and research activities and demonstrating institutional effectiveness through removing operational and infrastructure barriers. The establishment of the CCTS supports the achievement of these institutional priorities. The environment in the School of Pharmacy is highly collaborative and provides full support to scholarly activities. Personnel freely share ideas, technical expertise, and brainstorm and work towards solutions, when needed, to ensure success of research projects undertaken. Additionally, personnel often work with other departments to solve formulation and drug delivery issues. The UMSOP has acquired all the necessary instruments and equipment necessary to support research and the research infrastructure is in place.

Additionally, the Institution supports continuous learning and scholarly activities and provides financial support for attending workshops and courses geared towards facilitating research activities. Financial support is also provided for attending international and national meetings which facilitates dissemination of research findings as well as provides a venue for the exchange of ideas and establishment of collaboration. Furthermore, the School of Pharmacy has an ongoing "mentoring" program, wherein identified senior researchers guide junior investigators in various aspects of research.

The Office of Research and Sponsored Programs at The University of Mississippi provides support in various aspects of research including training in protocols, procedures and regulations; responsible conduct in research; grant writing, management and budgetary aspects; and laboratory safety. A Clinical Research Unit (CRU) on the Oxford campus provides suitable facilities, equipment and basic personnel support to allow low-risk studies to be performed in a Good Clinical Practice (GCP) environment. Examples of these studies are:

- Phase-0 Exploratory Study involving very limited human exposure to a drug or dietary supplement.
- Phase-1 Interventional Study normally conducted with healthy volunteers in the earliest clinical stage of drug development to explore drug tolerability and safety, and to determine how it is metabolized and excreted.
- Drug/drug or drug/herb interaction studies determining effects on drug metabolism or kinetics.
- Physical Exercise Study to measure physiological benefits of exercise.
- Study of dietary supplement products already widely utilized, in order to evaluate pharmacokinetics or impact on physiological parameters.

TRANSLATIONAL RESEARCH INFRASTRUCTURE

In 2016, the UMSOP completed the addition of a new building on the Oxford campus (West Wing of the Thad Cochran Research Center; TCRC-West), which includes more than 95,000 sf of additional laboratory space. The addition of this LEED-certified building almost doubles the school's research space. The construction of this facility was made, in part, through a grant award from NIH (C06RR030081) and cost \$40 million. The new addition will foster translation of basic research into clinical studies and commercial development as follows: 1) provide laboratories for scaling up extraction and isolation of bulk natural products in quantities that will support advanced development activities; 2) provide laboratories for scale-up synthesis and analog development; 3) provide Good Laboratory Practice-compliant (GLP) analytical facilities that will support bioanalytical research, product and regulatory package development; 4) provide Good Manufacturing Practice-compliant (GMP) facilities for production of active pharmaceutical ingredient (API); 5) provide laboratories for pre-formulation, formulation and stability studies to characterize APIs; 6) provide laboratories for cellular and molecular mechanism of action and toxicity studies; 7) provide laboratories for expansion of discovery efforts with greater emphasis on microbial and marine natural products; 8) provide Biosafety Level 3 (BSL-3) laboratories; and 9) provide a 10-bed Clinical Research Unit (CRU), which includes a procedure room, drug room, private bathrooms, sample preparation lab, an analytical lab, and a bioanalytical lab.

The CSF comprises the suite of rooms in which a clinical study is conducted (104H, 104J, 104K, 106A) and the adjoining laboratories where clinical specimens are processed and analyzed (106B, 107A). These six rooms are dedicated to the conduct of clinical studies. Adjoining areas that support the CSF but are also used for other UMSOP activities include the reception area (104), records storage (104F), conference (105C), kitchen (105A), restroom (105B), and clinical staff offices (104B&C). A Clinical Research Unit (CRU) is located within the CSF operations in the rooms 106B and 107A, where specimens are processed and analyzed. These facilities are equipped with emergency power generators to provide electrical power in case of an interruption in electrical service to the building. Although emergency power is not provided to the entire building, the clinical facilities are provided adequate power to continue study operations. In January 2012, a new UMSOP instructional and research facility opened on the UMMC campus which provides a state-of-the-art building in the heart of UMMC's academic corridor. The facility houses the SOP administrative offices and UMSOP faculty/staff. The building includes 17 PBL rooms and approximately 635 sf of student common space and student organization office space. There is approximately 2,000 sf devoted to clinical and basic research.

DATA RESOURCES AVAILABLE TO CCTS INVESTIGATORS AND TRAINEES

The SOP works closely with two libraries, the Science Library in the TCRC on the Oxford campus and the Rowland Medical Library in the Learning Resource Building on the UMMC campus. The Science Library, a branch of the University of Mississippi Libraries, maintains a chemistry/pharmacy collection which contains over 69,000 volumes and receives approximately 450 journals and standing order serials, including online subscriptions to Medline, Lexi Pals Drug Guide, International Pharmaceutical Abstracts, SciFinder Scholar, Web of Science, ScienceDirect selected titles, Biological Abstracts, Agricola, and ACS Web editions full text journals. The library has study carrels, study tables and three group meeting rooms with a total seating capacity of 161. Hard wired and wireless access to the internet is provided as are PCs and one networked printer. The Science Library has access to nearly 100 electronic databases, 3,000 electronic journals and over 25,000 electronic books via the Main University Library. All offices are connected to the library via Ethernet connections.

Rowland Medical Library at UMMC provides and supports access to biomedical and health sciences resources for students, faculty, and researchers in the Schools of Dentistry, Graduate Studies in the Health Sciences, Health Related Professions, Medicine, Nursing, Population Health, and Pharmacy. The library acquires, preserves, and manages these resources and provides services on campus and through the library's website. At Rowland, the Library Faculty Advisory Committee advises the library director on the selection and provision of library resource services and materials, and assists with strategic planning and goals. The collection development policy ensures a balanced, quality collection to meet the needs of students and faculty. Core lists, recommendations, interlibrary loan requests, and usage statistics support the scope and focus of the institution and SOP.

University of Mississippi (UM) Historically Black Colleges and Universities (HBCU) Programs to Increase Diversity among Individuals Engaged in Health-Related Research (PRIDE) (PI: B. Beech): The HBCU PRIDE program trains and mentors URM early career faculty interested in obesity disparities and chronic diseases related to obesity. The program provides skills training in research, grant writing, and scientific writing with a focus on community-based interventions to address disparities in obesity and related chronic diseases. By collaboration with the CCTS network, PRIDE participants are exposed to current challenges and cutting-edge research methods. Participants and alumni of the program will be ideal candidates for transitioning to a comprehensive, full-scale research training in the KL2. Since its inception, 26 early career faculty from HBCUs have been trained or employed through PRIDE. Of note, KL2 co-Director Lucio Miele serves as a PRIDE program mentor. The PRIDE program does not overlap with the KL2 and does not provide stipends or salary support.

CLINICAL CARE

The CCTS has a 10-bed CRU on the Oxford campus that provides the infrastructure and laboratory capabilities to administer Phase I and other low-risk clinical trials. With an initial focus in neuroscience and cancer, the translation of natural products discoveries into clinical trials will be a priority. The Community/Population arm of the CCTS builds upon the work of the SOP Community-Based Research Program which has provided pharmacist support in underserved areas since 2008. This program provides increased access to care and evaluates care delivery models targeting improved utilization, and adherence to medications. Areas of focus for this arm of the CCTS include: Comprehensive Medication Management (CMM); integrating Health Information Technology (HIT); improving transitions of care; and addressing health disparities. The CCTS is currently partnered with the UMMC National Telehealth Center of Excellence, the Mississippi State Department of Health, and the Centers for Disease Control and Prevention. The CCTS will continue to build collaborations with the UMMC School of Population Health and other community-focused initiatives.

GRADUATE EDUCATION AND POSTGRADUATE TRAINING INFRASTRUCTURE

The UMSOP offers the Master of Science in pharmaceutical sciences and Doctor of Philosophy in pharmaceutical sciences with emphases in environmental toxicology, medicinal chemistry, pharmaceuticals, pharmacognosy, pharmacology and pharmacy administration. All of these programs offer opportunities to study with nationally and internationally recognized research scientists. The programs prepare students for teaching and research positions in academia, or administrative and research positions in the pharmaceutical, chemical, agrochemical, food and health care industries, as well as government agencies. The University of Mississippi is recognized as a major research institution and is a part of the R-1: Doctoral Universities (Highest Research Activity by the Carnegie Classification of Institutions of Higher Education) group. Comprehensive in scope but relatively small in size, both provide excellent opportunities for advanced studies in a supportive and nurturing environment. Our diverse graduate community includes outstanding faculty and students from around the globe, and their cutting-edge research and scholarship reflect tremendous vitality, impact and significance.

UNIVERSITY OF SOUTH ALABAMA (USA)

The University of South Alabama (USA), the only major public institution of higher learning on the upper Gulf Coast, was created by an act of the Alabama State Legislature in May of 1963. The University is strategically located in the greater Mobile area, which has a population of more than a million within a 100-mile radius. USA offers high-quality academic, research and medical programs that create, communicate, preserve and apply knowledge in service to Alabama and the region. In pursuit of establishing a preeminent, comprehensive university, recognized for its intellectual, cultural and economic impact on the health and well-being of its community, USA thrives by promoting research innovation, stimulating academic engagement, and maintaining the highest standards of clinical practice.

INSTITUTIONAL RESEARCH ENVIRONMENT & EXPERTISE IN CLINICAL AND TRANSLATIONAL SCIENCE

Facilities and Resources

USA Mitchell Cancer Institute (USA MCI): The USA MCI is a state-of-the-art facility with approximately 50% of the total assignable square footage devoted to basic and translational research and the other 50% devoted to clinical activities. There are 13 principal investigators leading research groups (consisting of graduate students, postdoctoral fellows, undergraduate research students, visiting scientists, and technical staff) focused on cancer genomics, cancer proteomics, biomarker discovery and validation, cancer stem cells, cancer metabolism, cancer metastasis, and the development of novel therapeutics. The USA-MCI has been nationally recognized for its unique design and open architecture that facilitates interactions between clinicians, clinical scientists, and basic/translational scientists. In keeping with the spirit and intent of the building, clinical and basic/translational scientists jointly participate in multidisciplinary working groups, tumor board, and clinical trial meetings. In addition, disease-specific working groups (pancreatic cancer, ovarian cancer, etc.) involving multiple investigators and clinicians meet weekly to discuss shared research projects, clinical trials, and translational studies.

USA Health Clinical Trails Office (USA-CTO): The Clinical Trails Office (CTO) is a USA Health system wide office providing support to investigators conduction clinical studies, including industry-sponsored, investigator-initiated, and federally funded trials. Managed by a Director with budgetary, regulatory and research coordinator teams, it assists with all steps in clinical trial pathway, including an initial feasibility analysis, trial startup, management of active trials and trial closeout.

Information Technology

USA researchers will participate in projects utilizing protected health information. Along these lines, the USA Health System maintains a unified and comprehensive privacy and information security program that protects the confidentiality, availability, and integrity of all information assets (i.e., patient, research, customer, and business data). Our health system follows HIPAA policies and undergoes review by the Joint Commission on Accreditation of Healthcare Organizations. Our security policies are overseen by an appointed HIPAA Entity Security and Privacy Officer. Further, we comply with Family Educational Rights and Privacy Act controls for student information. Our security policies are overseen by an appointed HIPAA Entity Security and Privacy Officer, and compliance with IT Security policies and local and federal laws and regulations is further ensured through review by our expert security consultants, Security Risk Solutions Inc.

USA Information Technology Operations: USA's security policies, IT infrastructure and connectivity are highly compatible with those of UAB and other partner institutions. The University Computer Services Center (CSC), under the direction of the University Executive Director for Information Technology, provides IT support for all University networks and core services, as well as end-user support for most main campus and general division locations. The Health Systems Chief Information Officer, reporting to senior hospital administration, leads the HS Information Technology group, which supports Hospital and Clinical systems and end users. The TRSC utilizes services and resources provided by both CSC and a third party data host, FireHost. Key components of these services and resources are described below.

Offices and Data Centers: TRSC and supporting personnel are located in offices in the Technology and Research Park building III (11,576 sq. ft.). Additional offices are located in the College of Medicine Basic Medical Sciences Building, the USAMC, USACW, the USA MCI, and elsewhere on the main campus. The network core and primary data center is located at the University CSC. A secondary disaster recovery site is located across campus, housing redundant network connections, directory services, virtual systems, and mirrored Network Addressable Storage. The USAMC, USACW, the USA MCI, and the CSC are connected in a metropolitan ring using leased dark fiber. There are multiple paths to the facilities, and the main campus core includes dual paths to the CSC and the disaster recovery site. The data center currently supports 10Gbps switching. The metropolitan ring and main campus distribution fiber networks currently operate at 10Gbps link speeds. The main campus distribution will remain primarily at 1Gbps per building, with upgrades to 10Gbps as required by building traffic. The copper network wiring plant is Ethernet Category 5 or above. Edge switch ports are primarily 100Mbps, but in general, desktop gigabit could be deployed where required through an edge switch upgrade.

Network protection/security and access control: The University networks are protected by Cisco Adaptive Security Appliances (ASA), providing firewall, intrusion prevention, and botnet detection services. Various monitoring tools are in place to detect and isolate network threats. Public facilities, such as “guest” wireless and student computer labs, are contained in separate firewall zones from internal resources. Access to internal, secured resources requires internal physical wired connection or secure wireless authentication under control of Active Directory. VPN services, also controlled by Active Directory, are provided for vendor and employee remote access.

Directory Services and Access Control: The HS Information Technology department manages a Microsoft Active Directory system for authentication and access control to a range of services, including Windows desktops and servers, Network Addressable Storage, secure wireless and VPN, and other internal applications. Redundant Domain Controllers and other key components are distributed through the University network system on main campus and in health care locations. The Active Directory is populated primarily with employee and vendor accounts. Domain Name Services (DNS) are provided by a hybrid ISC BIND/Microsoft DNS configuration. The BIND servers are the authoritative source for the registered University domains and respond to DNS queries from external sources. The Alabama Supercomputer Center in Huntsville, Alabama, also hosts secondary authoritative DNS servers for these domains. The Microsoft DNS service supports internal clients and Dynamic DNS registrations. The CSC also manages a Red Hat Directory (LDAP) system in support of a range of systems, including Google Apps and the University’s externally hosted Learning Management System. Student accounts are primarily populated here. Redundant servers are located across campus and at the Alabama Supercomputer Center.

Animal Research: Translational research often begins with pre-clinical laboratory studies. In this regard, USA has state-of-the-art animal care facilities located on the first floor of the Medical Sciences Building’s. These facilities are approved for Biosafety Level-2 approved, possess full accreditation by the Association for Assessment and Accreditation of Laboratory Animal Care International (AAALAC International), and meet NIH guidelines for the care and use of laboratory animals. Surgical and animal manipulation rooms are available within this facility.

Core Facilities

Multiple research core facilities available to CTSA investigators include but are not limited to: biomedical imaging, proteomics and metabolomics, flow cytometry, gene vector development and delivery. These and other aspects of research support are provided to investigators at institutionally approved recharge center rates.

Flow Cytometry Shared Resource Laboratory: The Flow Cytometry Laboratory has locations in both the MCI and MSB, and provides cell counting and cell sorting services to researchers. Instrumentation includes Becton-Dickinson FACSAria and FACSCanto II instruments, as well as a Microfluidic Cell Sorter. The facility also houses a Nexcelom CeligoS microplate-based imaging cytometer, Agilent Seahorse XFe24 and XFe96

Analyzers and a ZetaView® TWIN - NTA Nanoparticle Tracking Analyzer. Each Flow Cytometry laboratory also has on-site tissue culture facilities.

Bioimaging Cores: The Bioimaging Cores, located in the USA CoM and MCI, provide imaging and microscopy services to investigators. Equipment in the facilities includes wide-field, line-scanning confocal, and spinning disk confocal microscopes, as well as spectrofluorimetry and laser dissection capabilities. Systems provide multi-label high-resolution fluorescent imaging for both fixed and live-cell preparations, and allow for specialized applications, including high-speed, time-lapse and spectral unmixing. The flagship instrument in the core is a **Zeiss LSM 980 Airyscan2 spectral confocal microscope purchased via an NIH S10 award** that enables extended time lapse imaging of cells and tissues, with minimal photobleaching or photodamage, and enhanced/super resolution imaging of live cell preparations.

Mass Spectrometry Core Facility: USA Mass Spectrometry Core Facility, located in the Mitchell Cancer Institute, provides mass spectrometry services, include protein profiling, targeted and untargeted proteomics, lipidomics, and metabolomics. The facility is equipped with two state-of-the-art mass spectrometers: a Thermo LTQ Orbitrap XL and Thermo Q-Exactive Plus. Also available is a Thermo MSQ Plus mass spectrometer and an Agilent 1200 HPLC (equipped with UV detection). . The facility assists with development of a total proteomics approach for evaluating major proteins in a cell system or gel, and similarly for detecting metabolites in whole cell lysates or cell media. Additional goals of the core are to contribute to the development of methodology for proteomics and metabolomics, and to provide training in state-of-the-art mass spectrometry methodologies.

Biobank and Histology Core Facility: Located in the Mitchell Cancer Center, the biobank and histology core facility provides biobanking services, including biospecimen collection, processing, and storage, data repository, and molecular analyses, as well as complete histology services, including embedding, H&E, special stains, and immunohistochemistry. The core also provides general pathology services in support of clinical research.

Electrophysiology Core: This core has approximately 250 square feet of dedicated space with two independent patch-clamp systems fully integrated for use. These systems are capable of combining ion channel measurements with fluorescent measurements of cytosolic calcium, perfusion studies, single channel analysis, and whole cell and perforated patch clamp.

Cell Culture Core: This core isolates, cultures, and characterizes lung macro- (artery and vein) and microvascular endothelial cells available for use by independent investigators.

Gene Delivery Core: This core has approximately 400 square feet of dedicated space used for a full complement of gene isolation and production techniques, and also provides expertise for various methods of gene delivery. Among the services offered by the Core are: plasmid construction, protein expression and purification and generation of recombinant adenovirus and adeno-associated virus vectors.

Translational Biostatistics and Bio / Medical informatics Consulting Services

Biostatistical services are available to USA faculty through the Statistical Consulting Center, directed by Dr. Madhuri Mulekar, Chair of the Department of Mathematics and Statistics. The Statistical Consulting Center also serves investigators across the CCTS network as a component of the Biostatistics, Epidemiology and Research Design (BERD) unit.

Scientific Environment: Patient engagement and subject recruitment are important contributions of the USA Health System to the UAB CTSA program. These activities will be facilitated by several highly active administrative units in the USA Health Sciences Division, including the NIH-supported Center for Health Communities, the USA Family Practice Center, and the Center for Strategic Health Innovation. Engagement of patients and subject recruitment will occur primarily in Mobile County. Mobile County is located in the southwest corner of Alabama and is the second most populous county in the state with a population of 413,073 (2020 US Census). It is a large county (over 1600 square miles or larger than the state of Rhode Island) but the majority of the population lies within 16-mile radius surrounding the USAMC. The population immediately

surrounding the Center is 66% African American (2010 US Census) with an average per-capita income of \$26,778. Of these, 17.7% live below the poverty level (2020 US Census estimate). The county itself is a primary care physician shortage area with an HPSA Score of 14 for Mobile County and is designated a low income population HPSA.

Mobile County has a poor health status when compared to peer counties and the United States as a whole (following data from 2009, Department of Health and Human Services, Community Health Status Indicators Project). Life expectancy is below the peer counties at 75.42 years. County residents regard themselves as unhealthier than those people living in the “peer counties” (counties selected because of similar age/sex/urban demographics). 23% of all Mobile residents rate their health status as fair or poor as compared to 21% of all AL peers and 17 % of the best peer. Mobilians report an average of 4.8 unhealthy days / month. A number of risk factors for premature death are prominent in the USAMC service area. One chief factor is obesity, which is prominent despite a weather pattern that allows outdoor activity on most days of the year and 73% of the population reporting having access to locations for physical exercise. Mobilians report a diet lacking in fresh fruits and vegetables and the obesity rate of 36% is reflective of the first two observations. Mobilians continue to smoke at a rate higher than the national average. Mobilians report a high rate of diabetes as well. Collectively, these patient demographics present unusual opportunities for a wide range of high impact translational research.

CLINICAL CARE

University of South Alabama University Hospital (USAUH): The University of South Alabama University Hospital serves as the region’s safety-net hospital and is the primary site for the clinical educational programs for USA College of Medicine students. The USAUH is a major referral center for southern Alabama, southeast Mississippi and portions of northwest Florida. It is home to the region’s only Level I Trauma Center and one of only four such designated centers in Alabama. Highly trained clinicians and staff manage trauma and critical care, surgical and medical intensive care, and neurotrauma intensive care. USAUH Trauma Center houses two trauma resuscitation bays that are fully equipped and staffed with professionals from nursing, respiratory care, and radiology. The Emergency Department, expanded and renovated in 2021, includes a designated major operating room in the surgical suite. Support services include the Radiology Department, which houses two state of the art 64-slice, high resolution CT scanners and interventional radiology, the Clinical Laboratory, and the Blood Bank. The USAUH Burn Center is the only burn center serving the central Gulf Coast region. USAUH is noted for its remarkable stroke, cardiovascular and sickle cell disease centers. USAUH averages more than 30,000 Emergency Room (ER) encounters and more than 11,000 hospital discharges per year. The acuity of the patient population at the USAUH has been rated among the top 10% of the nation’s hospitals.

USA Children’s and Women’s Hospital (USACW): The USA Children’s and Women’s Hospital provides neonatal and pediatric intensive care services, high risk obstetrics services as well as routine pediatrics and OB/GYN services, and pediatric oncology services. The Evaluation Center provides emergency medical services for pediatric and OB/GYN patients. An expanded Pediatric Emergency Department is under construction and is expected to be completed in 2023. Currently, USACW sees more than 30,000 pediatric emergency visits each year. The USACW Hospital is the only designated children’s hospital in South Alabama. The hospital also includes South Alabama’s only level 3 neonatal intensive care unit. USACW provides pediatric intensive care service as well as obstetrics and gynecology. A Ronald McDonald house for families of pediatric cancer patients is now affiliated with the hospital. USACW treats more than 6,500 children each year in an inpatient setting.

GRADUATE EDUCATION AND POSTGRADUATE TRAINING INFRASTRUCTURE

Responsible Conduct of Research (RCR) program: The USA Frederick P. Whiddon College of Medicine’s (CoM) RCR training program satisfies the NIH requirement for training in the ethical conduct of research in the following nine areas: research misconduct, human participants, research involving animals, data acquisition, management, sharing, and ownership, mentor/trainee responsibilities, publication practices and responsible authorship, peer review, collaborative science, and conflict of interests. Instruction in our RCR program utilizes a combination of lectures, on-line tutorials, and small group discussions.

Selected additional courses / active learning experiences: The USA Whiddon COM offers a variety of additional learning experiences for students at all stages of pre- and post-graduate training. A partial list of such activities with particular relevance to trainees engaged in patient-centered, clinical, and/or translational research includes: Effective Scientific Writing, Presentation Skills, and Statistics & Experimental Design, and Introduction to Research Methods.

- **Computer:** All mentors, residents, prospective trainees, and members of the research teams have dedicated personal computers with internet and email access networked through the University. An interactive computer laboratory is also located in the Medical Sciences Building.
- **Office:** All mentors, prospective trainees, and members of research teams have adequate personal office located in close proximity to the clinics, specialized care units or laboratories. Multiple large and small rooms are available for seminars, laboratory meeting, didactic instruction, etc.