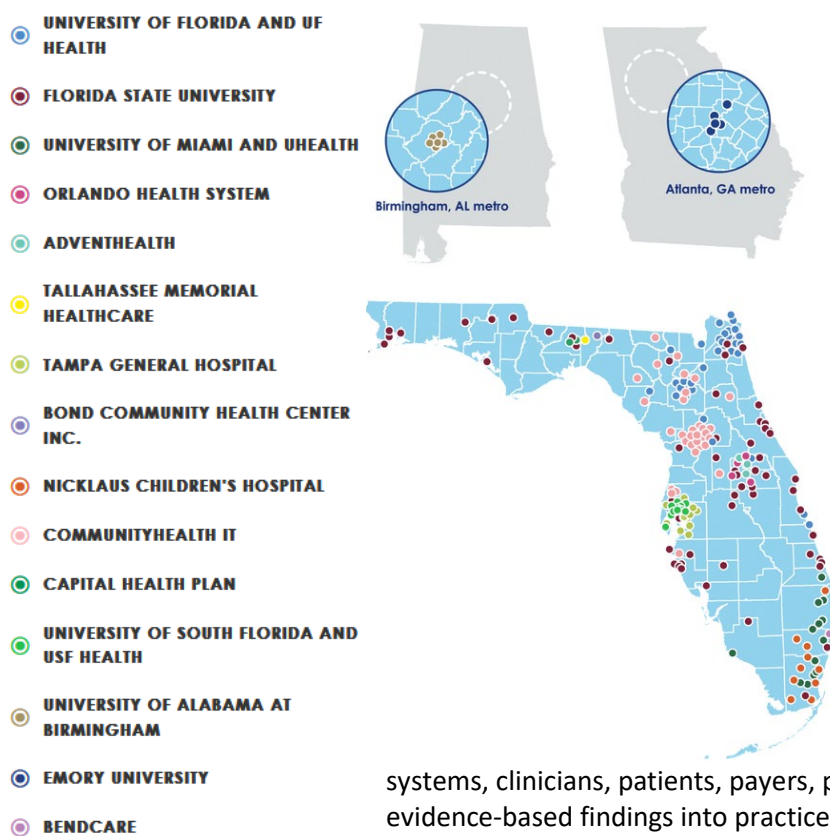


Overview of OneFlorida+ Clinical Research Network

The OneFlorida+ Partner Engagement Network, led by the NCATS-funded University of Florida Clinical and Translational Science Institute, includes 10 health system and clinical partners in Florida and also metropolitan sites in Atlanta, Georgia and Birmingham, Alabama. The University of Florida (UF) serves as the Coordinating Center. The patient population in the OneFlorida+ of today looks like the population of the United States of tomorrow: older and more diverse in race, ethnicity, and socioeconomic vulnerability. Ongoing demographic transformations will make the US of 2030 look like our current network participants. By 2030, for the first time in US history, people 65 and older are expected to outnumber children. Florida leads the way with 21% of the population 65 or older in 2020, with an increase to 30% expected in the next 10 years. The US population percentage of Non-Hispanic White (NHW) will continue to shrink. OneFlorida+ currently reflects the shift with NHWs comprising 45% of the network's patient population in Florida, 43% in Georgia and 59% in Alabama. Our diverse health settings include academic health centers, statewide and regional health systems, federally qualified health centers and safety-net behavioral health providers. With 16.8M patients in Florida, 2.1M patients in Georgia and 1M patients in Alabama (19.1M total), OneFlorida+'s strengths lie in the diversity of its patient populations and settings.

Figure 1. OneFlorida+ Partnership Network



OneFlorida+ is a collaboration among researchers, clinicians and patients that provides a venue for pragmatic clinical trials, comparative effectiveness research, implementation science studies, observational research, and cohort discovery for a wide range of research. Consortium partners include the University of Florida, Florida State University, the University of Miami, the University of South Florida, Emory University, University of Alabama at Birmingham, Orlando Health, AdventHealth, Tallahassee Memorial HealthCare, Tampa General Hospital, Nicklaus Children's Health System, CommunityHealth IT, Bond Community Health Center, Inc., Bendcare, Florida Agency for Health Care Administration, Florida Department of Health and Capital Health Plan, creating a network that extends to all of Florida's 67 counties and metro areas of Atlanta and Birmingham (Figure 1). OneFlorida+ is committed to conducting stakeholder-engaged research in partnership with health

systems, clinicians, patients, payers, policymakers and communities and to translating evidence-based findings into practice. The OneFlorida+ partners are focused on ensuring that the lessons from research conducted in its diverse settings are systematically captured and translated back into improved health, health care and health policy for Floridians.

Governance and Organizational Structure. OneFlorida+ shares governance among patients, clinicians, healthcare system leaders, researchers and state agency directors, as both leaders and members of the Executive Committee (the main governing body) and its four programs (Data Trust, Clinical Research, Patient and Stakeholder Engagement, and Outreach and Dissemination). OneFlorida+ Front Door staff link researchers to resources including the Design Studio, where patients, clinicians and researchers jointly discuss ideas and study designs and form partnerships for proposal submissions. A Multisite Study Team and a OneFlorida+ IRB work in collaboration with PCORnet, site PIs, patients and collaborators to ensure efficient study onboarding.

Centralized IRB. The OneFlorida+ partners have all signed agreements to be part of the OneFlorida+ Institutional Review Board (IRB) to facilitate the review and approval of multisite protocols and to oversee the OneFlorida+ Data Trust. Peter lafrate, PharmD is the Director for the OneFlorida+ IRB. The OneFlorida+ IRB was designed to streamline the submission

process and facilitate the conduct of observational studies, comparative effectiveness research (CER), pragmatic clinical trials (PCTs) and implementation science studies in multiple sites. Signed agreements are in place with all OneFlorida+ partners. The OneFlorida+ IRB's expertise and experience with streamlining the approval processes facilitates study approvals and positions OneFlorida+ favorably to participate in any national agreements. The OneFlorida+ IRB serves as the IRB of record. In addition, all OneFlorida+ partners have executed the SMART IRB reliance agreement.

The University of Florida Health Science Center Institutional Review Board (IRB-01) has substantial experience to provide leadership for the OneFlorida+ IRB. In total, the IRBs at UF oversee 3,500 research protocols. There are three on-campus IRBs and one contracted IRB. IRB-01, the largest IRB in the UF system, reviews and oversees biomedical research conducted on the Gainesville, Florida campus, for the North Florida/South Georgia Veteran's Health System (NF/SG VHS), and for all of the hospitals and facilities owned by UF Health. IRB-03 reviews and oversees biomedical research on the Jacksonville, Florida campus. IRB-02 reviews and oversees social and behavioral research on the Gainesville, Florida campus. Several years ago, UF contracted with the Western IRB (WIRB) to offset some of the workload for IRB-01. UF faculty conducting multicenter drug or device protocols sponsored by industry may submit their protocols for review by the WIRB. Annually, WIRB reviews an average of 110 protocols a year, allowing the investigators who conduct industry-sponsored protocols to compete nationally due to faster review times. Seventeen staff members at the three on-campus IRB offices provide investigator education, protocol design consultation as it relates to regulatory considerations, and compliance monitoring. No human subject protection issues have been identified during recent FDA audits, UF Clinical and Translational Science Institute (UF-CTSI) competitive grant renewal reviews, or Florida Agency for Health Care Administration VA licensure accreditation surveys.

IRB-01 has experience serving as the central IRB for the United States' portion of a 150-site, multinational, and 23K-subject research protocol. All IRB-01 new study submissions are made through the electronic myIRB program. The electronic submission program will be implemented in the IRB-02 and -03 offices in the near future. IRB-01 meets twice a month and investigators are encouraged to attend so that changes can be made by the investigator during the meetings to facilitate rapid turnaround time. A robust IRB-01 website is available for investigators, which provides them with all current forms, educational bulletins, required standard language, IRB position papers on common topics, and links to frequently used websites. IRB-01 also serves as the Privacy Board for the UF Gainesville campus and the NF/SG VHS in accordance with the Health Insurance Portability and Accountability Act (HIPAA) and implementation of its regulations.

Data Trust. The OneFlorida+ Data Trust is the centerpiece of the OneFlorida+ Partner Engagement Network and is the informatics infrastructure that supports pragmatic clinical trials, comparative effectiveness research, implementation science studies and other research in the network. The OneFlorida+ Data Trust contains electronic health record data for 16.8M patients in Florida, 2.1M patients in Georgia and 1M patients in Alabama (19.1M total). The data are confined to a HIPAA Limited Data Set (LDS), which restricts the types of protected health information (PHI) to only dates (e.g., birthdates and dates of service) and location (to the ZIP code level). The Data Trust includes links to: Medicaid, Medicare, and selected commercial claims; geospatial data; linked mother-baby records; early childhood (0 to 3 years) education records; and tumor registry data. OneFlorida+ has experts in natural language processing, who use technology provided to UF (GatorTron™) to remove protected health information from over 300M clinical notes for later use in the Data Trust. With the knowledge gained, GatorTron™ will be able to detect and identify critical clinical concepts, such as disease states and social determinants of health. The tools will be shared throughout PCORnet.

All healthcare data in the Data Trust are standardized to the most current PCORnet Common Data Model (CDM). Electronic health record data are submitted to the Data Trust in two formats: 1) the Patient Centered Outcomes Research Institute's (PCORI) Common Data Model (CDM), and 2) as close to raw files as possible. In both cases, the OneFlorida+ Data Trust does not request any contact information for patients (i.e., only an LDS). Data for the Texas and Florida Medicaid and CHIP programs are submitted as enrollment files and claims data with fully identified information. These data are stored at the UF Health Science Center Data Center as part of contractual arrangements and data sharing agreements between UF and the Florida Agency for Health Care Administration.

In addition, OneFlorida+ is part of a national PCORI workgroup to develop linkage strategies within each of the Clinical

Data Research Networks. The linkage uses a mechanism that does not enable UF honest brokers to see or learn the names, addresses, or other identifying information of the contributors' patients. Each site's honest broker must undergo honest broker training. UF has honest broker training available for sites that do not have their own training program.

The key research functions supported by the Data Trust include but are not limited to:

- Hypothesis generation
- Cohort discovery
- Participant enrollment
- Observational studies
- Research workflow, including but not limited to electronic informed consent and eligibility determination
- Study data collection, including repurposing the EHR and healthcare claims as study data collection tools for common data such as diagnoses, clinical labs, medications, vital signs, etc.
- Patient-reported outcomes collection and use

OneFlorida⁺ has extensive query capability and responds to over 100 data queries a year. Our average query response time is 2-3 weeks. We have staff with extensive expertise in SAS, SQL, and other query-development technologies for writing study-specific queries. We have also been at the forefront of computable phenotype development, having worked on computable phenotypes in the areas of hypertension, resistant hypertension, diabetes, Duchenne Muscular Dystrophy, bone fracture, acute kidney injury, Hepatitis C, cirrhosis, at-risk-for-cirrhosis, and Zika and related complications/sequelae.

Data Sharing. OneFlorida⁺ has a data-sharing agreement with PCORnet, the network that comprises the national clinical data research network sites coordinated through Duke University, which facilitates data sharing across the PCORnet network. OneFlorida⁺ also provides data access to researchers after approval of the research study by the OneFlorida⁺ Data Trust. OneFlorida⁺ has Business Associate Agreements and Data Sharing Agreements with the Florida Agency for Health Care Administration for child-level health care claims, dental claims, pharmacy, enrollment, and provider data.

Data Security. The UF IT Security Office is responsible for the development and maintenance of the HSC Information Security Program. The UF-HSC IT Department is responsible for adapting, supplementing as necessary and implementing the Information Security Program for OneFlorida⁺. Each component is reviewed internally at least biannually (every two years) or as necessary due to environmental, operational, or Information Security Program changes. OneFlorida⁺ maintains optimal security practices through the use of the services and expertise of the UF-HSC IT Department. Specifically, the UF-HSC IT Department has experts on protection of health data and HIPAA compliance across multiple platforms, systems and applications. The servers supporting the OneFlorida⁺ computing environment are connected to a Cisco-based IP network and protected by a high-performance firewall that provides both application- and port-based security. The firewall provides connectivity to the AHC enterprise network. The UF-HSC IT Security Office and the overall UF IT Security Office conduct audits and perform network and vulnerability scanning and alerting. The University of Florida has a campus-wide Intrusion Detection Service that monitors all traffic leaving the university. Network sweeps look for vulnerabilities in cooperation with AHC system administrators. Ongoing routine and scheduled risk assessments follow a process outlined in the IS Audit Methodology document. Each server is individually protected by a host-based firewall that provides local-port based access control. The configuration of all host-based firewalls is managed centrally through either Active Directory GPOs or through a third-party security console. A VPN encrypts data between remote devices and the secure network. A site-to-site VPN and secure FTP architecture provide security for bulk data transfers.

A video recording security system monitors physical access to the AHC Data Center 24/7. Full motion video for all data center cameras is retained for 15 days. Data Center personnel administer and audit physical access using the University of Florida's enterprise access management system. Wiring closets have key-specific locks and all equipment is protected by software that only allows devices approved and maintained by the institution to access the network. Professional IT security products protect OneFlorida⁺ Windows servers from viruses and spyware. Remote security agents protect workstations from viruses and malware. Additional software provides automated deployment of

Windows Security updates and auditing of server patch compliance. The Linux server patching process utilizes a combination of Puppet configuration management software and shell scripts to download a list of pending patches per system. The UF IT Security Office provides continuing and updated training for end users and IT personnel. Training includes topics related to protected health information, viruses, spyware, and password protection. All new employees must obtain this security certification prior to being issued user accounts. All employees must re-test and sign updated security agreements annually. Employees who do not complete their security certifications as required and on time immediately lose computer access. In addition, any security and/or privacy breaches can result in termination and civil and criminal penalties. Each UF-HSC department and institute has an Information Security Manager. The OneFlorida+ Information Security Manager is responsible for coordinating all information security policies, procedures, standards, training and communications for the unit. This includes serving as a liaison to the UF-HSC IT Department and providing local support to OneFlorida+.

User account access is granted on a need-to-know basis. All user accounts are unique and assigned to an individual. Privileged accounts are not shared whenever possible; users with appropriate need for privileged access are given individual logins. Database access is controlled with a combination of Active Directory integration and SQL authentication. Data is classified in one of three categories: 'restricted', 'sensitive', and 'open', based on the UF Data Classification policy (www.it.ufl.edu/policies/information-security-andcompliance/data-classification/). This and the UF-HSC security policies include general guidelines on how to effectively manage the different classes of data, including access, authentication, inactivity timeouts, access logging, and intrusion detection requirements. All data related to Medicaid members are treated as 'restricted' unless de-identified for research purposes. These de-identified Medicaid data would still be treated as 'sensitive.' Output data and reports from Medicaid data are treated as 'restricted' if they fall under HIPAA or privacy protection and are otherwise treated as 'sensitive.'

Compliance with HIPAA and HITECH 2: These central resources are supplemented with numerous end-user computing and productivity tools to facilitate constant communications and collaboration across multi-university research teams. All investigators have the latest generation Mac or Windows desktop PCs with multiple monitors, webcams, headsets, etc., with numerous collaboration tools installed. All investigators also have secure Wi-Fi-connected laptops and mobile devices, permitting immediate online access to all project documents during on-site project meetings, and facilitating easy participation in weekly project team meetings when traveling. All University of Florida employees are required to complete annual HIPAA training. The completion of this training is carefully monitored by the UF Privacy Office. Individuals who fail to complete their training as scheduled have their computer access terminated and are no longer allowed to conduct their projects until they have completed the required training. The UF Privacy Office monitors compliance with all aspects of the HITECH Act. In addition, external contractors requiring access to UF system components that permit access to personal data directly or through any application do so under governance of a Business Associate Agreement (BAA) compliant with the HITECH Act. The required BAAs govern third-party compliance with the university's established security and confidentiality policies.

Data Infrastructure. The UF-HSC Data Center, which houses the OneFlorida+ HP Proliant enterprise-level server equipment, is a state-of-the-art facility. The Network Operations Center is staffed 24/7 to monitor physical security of the Data Center and system health and availability. The UF-HSC IT staff manage OneFlorida+ equipment throughout its lifecycle, thus maintenance and replacement are addressed efficiently and as needed. The Data Center facility provides the following:

- Raised floor – 1664 SF capacity with 12-inch raised floor
- Multiple redundant CRAC/CRAH cooling units
- Chilled water primary design with DX backup CRAH units
- Pre-action charged fire suppression system
- HALOTRON hand-held gas fire extinguishers (entire facility – no ABC allowed)
- Overhead cable tray management
- N+1 True Dual Pathway Dual Source Liebert 130kVA UPS Systems (generator connected) and Liebert Street Conditioner providing A/B power bus design
- JT Packard – UPS system support contract with one semi-Annual (non-bypass mode) Inspection and one yearly full inspection (bypass mode)

- N+1 Data Center generator backup power provided by a PPD UF generator plant (3 x 1 megawatt N+1 generator plant)
- 24/7 monitoring, alerting, escalation and trending for temperature, humidity, HVAC, and UPS systems
- 24/7 monitoring of the NMS centralized tree of dashboards that display the health of critical applications and core systems
- 24/7 video recording security system; full motion video for all cameras is retained for 15 days
- Physical access administered and audited by Data Center personnel using the University of Florida's enterprise LENEL access management system

OneFlorida+ servers run the Windows Server Operating System or RedHat Linux. The UFHSC uses current management software to maintain and service systems including Trend OfficeScan, Lumension Endpoint Management and Security Suite, Nimsoft Monitoring Solution, Tivoli Storage Manager (TSM), Idera SQL Safe, and Idera Diagnostic Manager. The primary data warehousing and analysis functions at OneFlorida+ are carried out using Microsoft SQL Server and SAS®. Clinical Risk Groups (CRG) and Diagnosis Related Groups (DRG) needed for analysis are obtained using 3M™ CRG and Core Grouping Software (CGS) suites. Quality-of-care measures for the EQRO work in Texas and Florida are calculated using three primary software systems: QSI© software (Inovalon) for National Committee for Quality Assurance (NCQA) Healthcare Effectiveness Data and Information Set (HEDIS®) measures; adapted software from The Department of Health and Human Services (DHHS) Agency for Healthcare Research and Quality (AHRQ) for Pediatric Quality Indicators (PDI) and Prevention Quality Indicators (PQI); and 3M™ CGS modules for potentially preventable events (PPE).

Data Quality. Maintaining a high standard of data quality to enable health research is a central concern of the OneFlorida+ Data Trust team. An appointed member of the team is responsible for ensuring established data quality standards are followed. These standards include procedural guidelines, technical protocols, and a system of recurring quality-checking phases. Proper quality procedures include ensuring no unauthorized private health information is included in a data set. Before submitting data to the OneFlorida+ Data Trust team, partner healthcare institutions must complete an honest broker review of the data and provide formal sign-off via an approved form attesting that the data set meets HIPAA requirements and the current approved IRB protocol (IRB201500466). The form is submitted along with a data set each time changes are made to the parameters or process for data extraction on the partner side. The OneFlorida+ Data Trust team has built a software package to track changes in data file headers and compare them to canonical historical headers to verify no unauthorized data elements are added to the data feed.

Additionally, an appointed member of the OneFlorida+ Data Trust team reviews the new data sets before releasing them to the team for processing. Data received from partner health care institutions comes from a heterogeneous mix of electronic health record systems and in a mixture of formats, but it is all transformed to the PCORI Common Data Model (CDM) via OneFlorida+'s custom extract/transform/load (ETL) software. Raw fields are included in the final output data as a cross-check to verify the accuracy of transformed data. In addition, data coded using external data standards such as ICD-9, ICD-10, LOINC, and CPT are validated by the ETL software and corrected where necessary. Dates and test values are standardized. The data set must maintain referential integrity and this is enforced by disallowing orphaned keys or replication errors in replicated fields.

Quality checking phases occur at every step of the data pipeline. While performing the ETL process, team members verify correct data counts and track deltas in row counts across data refreshes against historical counts to verify data has been loaded correctly. Once the data is loaded, it must be curated to the current standards established by PCORnet and submitted for review and certification on a quarterly basis. In order to submit a data set, the OneFlorida+ Data Trust team runs SAS software that produces an Empirical Data Characterization (EDC) report, once per refresh cycle per partner and for the data set as a whole. These reports are reviewed to find exceptions or investigative issues for PCORnet's curation checks, which are then resolved by the Data Trust team. The reports investigate internal consistency in the data set, real-world consistency (prescribing dates before birth date, for example), adherence to the CDM (no values outside the allowed CDM values), and display changes in the data set over time. No exceptions to the EDC are allowed before submission of the data set. Once the data set is successfully submitted and certified, the database is set to read-only, ensuring no further changes will be made, and the database

is ready for authorized research staff to run queries against it.

In addition to internal quality phases, the OneFlorida+ Data Trust team meets regularly with data producers (partner health care institutions) and data consumers (researchers, staff running queries on the data, and those who utilize the data in secondary systems) to correct issues and answer questions regarding how results are represented in the data set. The EDCs for each partner are delivered to the authorized technical and leadership staff at each site, as well as summary statistics and deviations noted while processing the data. This bi-directional link with those who produce and utilize the data ensures the successive resolution of data quality issues in every data refresh cycle. Ensuring data quality is a part of every step of the data life cycle, and through continuous monitoring, feedback, and improvement the OneFlorida+ team maintains its high standards.

PCORnet Linkage through Datavant. The patient data in the OneFlorida+ Data Trust are linked securely and anonymously to the data across the PCORnet network of CDRNs via the use of the Datavant de-identification and linkage software. This privacy-preserving record linkage (PPRL) solution allows a patient's data within OneFlorida+ to be linked to any data they have at other healthcare sites within the PCORnet network. This linkage is accomplished using secure and de-identified tokens created for every patient seen at each of the participating PCORnet health systems. Unique HIPAA-certified tokens are created for the same patient at each of the PCORnet health systems they visited, thus preventing a security breach at one network from compromising the data in another network. The Datavant De-ID tool used to generate the tokens is installed directly into each health system's data-secure environment so the identifiable patient information used to generate the tokens does not have to leave the health system. The PCORnet Coordinating Center receives the unique tokens generated for each patient across all the sites in the PCORnet network and runs the Datavant Link tool. This tool matches the unique tokens from the sites that represent the same patient and transforms those tokens into a new de-identified token that ties the patient's data together.

Engagement. OneFlorida+ is highly successful in engaging diverse stakeholders throughout the research process. The Citizen Scientist Program enrolls patients and community members as a key engagement strategy to empower patients as research partners. They participate in every aspect of OneFlorida+'s governance and are compensated for their time. Design Studios and Front Door referrals link Citizen Scientists with researchers and PCORnet-wide governance and study committees. OneFlorida+ works with HealthStreet, a community engagement program offered through the University of Florida (UF) Clinical and Translational Science Institute that focuses on building community trust in research. The UF/IFAS County Extension Program, a particularly trusted resource in rural areas, also provides sustaining infrastructure to engage community members. OneFlorida+ uses a clinical champion model in addition to personal outreach to engage clinicians. Clinicians participating in studies have access to the OneFlorida+ Maintenance of Certification Program, where OneFlorida+ research coordinators assist clinicians in translating study findings into quality improvement programs in their practices. Personal outreach, newsletters and issue briefs are used to engage health system leaders and researchers.

Scientific Resources. OneFlorida+ provides an enduring infrastructure for comparative effectiveness research, pragmatic clinical trials, and implementation science studies through strategic integration and expansion of clinical and research partnerships across the state. The network includes two main levels of infrastructure: (1) a statewide practice network presenting opportunities to engage clinicians and patients in diverse healthcare settings in interventional studies, and (2) the Data Trust, a central repository of patient-level, HIPAA-limited electronic health record and health insurance data transformed into a common data model. The common data model enables the creation of analysis-ready standardized data to support both observational studies and pragmatic randomized clinical trials. It also provides the opportunity for cohort discovery, analyses for study optimization as preparation for research, and augmentation of data streams during interventional trials. The Front Door Policy was developed to enhance investigator access to, and support the timely conduct of research within OneFlorida+. The Front Door supports three types of inquiries with three application forms: (1) OneFlorida+ information/consultation requests; (2) preparatory-to-research queries; and (3) infrastructure support.

Facilities. The academic institution and health systems participating in OneFlorida+ include:

PRIMARY RESEARCH FACILITY

Name: **University of Florida/UF Health**

Street address: 1600 Southwest Archer Road

City, county, state, and zip code: Gainesville, Alachua County, Florida 32608

Name: **UF Health Jacksonville**

Street address: 655 8th St. W.

City, county, state, and zip code: Jacksonville, FL 32209

Name: **UF Health Central Florida – Leesburg and Villages**

Street address: 600 E. Dixie Ave.

City, county, state, and zip code: Leesburg, FL 34748

Street address: 1451 El Camino Real

City, county, state, and zip code: The Villages, FL 32159

The OneFlorida+ Partner Engagement Network (OPEN) is led out of the NCATS-funded University of Florida Clinical and Translational Science Institute. The University of Florida serves as the coordinating center and all OneFlorida+ data are housed at the University of Florida.

The University of Florida (UF) is a top 10 public university and home to 16 colleges located on one campus. Faculty garner over \$700M in total research dollars annually with \$180 M from the National Institutes of Health (NIH). **UF Health** serves a variety of inpatients and outpatients, including those receiving diagnostic and therapeutic oncology care and emergency and trauma services. The primary clinical facilities for **UF Health** are located in Gainesville, Jacksonville, Starke, and Lake City, Florida. There are nine hospitals at these sites with 2,200 licensed beds. UF Health's clinical strengths are in cancer, neurosciences, aging, gene therapy, psychiatry, addiction medicine, transplantation, and children's services. UF Health at the University of Florida in Gainesville is the primary on-site teaching hospital for the Health Science Center. The Jacksonville campus has a 528-bed University Medical Center. UF and UF Health also have an inpatient physical rehabilitation facility, an inpatient behavioral health facility, and 12 home health care agencies. Together, the facilities and physician network under the University of Florida Health System have created the Southeast's largest and most comprehensive academic medical center. In 2017, approximately 1,300 UF College of Medicine faculty provided care in more than 100 specialty and subspecialty areas, including heart care, women's and children's services, neuromedicine, and transplant services. The **UF College of Medicine** has attained national leadership in research related to the brain and spine, cancer, diabetes, drug design, genetics, and organ transplantation. Collectively, the faculty are responsible for nearly half of UF's total extramural research awards. The college has more than 350K square feet of research laboratory space in more than 20 buildings on campus, including the Cancer & Genetics Research Complex (2006), one of the largest research buildings in Florida. The college is home to the **Clinical and Translational Science Institute (CTSI)**, which operates with funding from the National Institutes of Health and provides an interdisciplinary hub for generating cutting edge clinical and translational research as well as support and infrastructure to carry out major grant-based initiatives. UF is located in North Florida, which is characterized by urban and rural areas, and high rates of current smokers, obesity, adults over 65 years, cardiovascular disease, and late stage cancer diagnoses relative to Florida and the US.

The **Jacksonville Aging Studies Center (JAX-ASCENT)** is located in a stand-alone building on the UF Health Jacksonville campus with an attached parking garage that includes dedicated parking spaces for our research participants. The 5,000-square-foot space includes five interview, assessment and examination rooms and a corridor specifically dedicated to performing walking tests; a biological specimens processing laboratory, data-entry stations, study coordinators' offices, a phlebotomy room, a study-drugs storage room and several secured storage areas for study documents. JAX-ASCENT

also has a DEXA scanner and a Biodex Isokinetic Strength System 4 Pro, each in its own examination room. A conference room with teleconference capabilities is available for teaching, community health education needs, or conferencing for multi-centered trials. Our biological specimens processing room is equipped with a centrifuge, an ice machine, a refrigerator and -20°C freezer, autoclave and an ultra-low freezer for storage of biological specimens. The space is set up for patient recruitment and ongoing enrollment activities. Participants enter our second-floor space through a welcoming reception and waiting area. An iPad with access to the university's wireless network is available for patient consent, questionnaires and other measurements needing electronic capture.

JAX-ASCENT has seven offices for use by faculty, research managers and research coordinators. Each office is equipped with color printers, phones and desktop computers hardwired to the university's server and high-speed internet. These computers have software critical for inter-investigator communication and data analysis including programs such as Microsoft Office, Adobe Acrobat Professional, STATA, SAS, Skype and FaceTime (iPad). The research coordinators have dedicated office space in the building adjacent to the data collection laboratories that is readily accessible to investigators. The investigators' proximity to the data collection, staff and facilities assures that they have the necessary space and accessibility to formulate experiments, hold team meetings, analyze results and prepare manuscripts for publication.

UF Health Central Florida provides inpatient acute hospital services at UF Health Leesburg Hospital and UF Health The Villages® Hospital, inpatient rehabilitation services at UF Health The Villages® Rehabilitation Hospital, adult inpatient psychiatric services at UF Health Leesburg Hospital Senior Behavioral Health Center and diagnostic laboratory services at several locations. Approximately 1,800 College of Medicine faculty and community physicians, along with 17,905 employees, provide care in more than 100 specialty and subspecialty medical areas, from primary care to highly complex care, including cancer specialties, heart care, women and children's services, neuromedicine specialties and transplant services. All care providers and staff contribute to UF Health's reputation for quality care and service.

The Villages Health (TVH) is a combined family and multi-specialty medical group that delivers patient-centered healthcare in The Villages community. TVH currently operates six primary care and two specialty care centers, including the Center for Advanced Healthcare at Brownwood, a 240,000-square-foot, bedless hospital connected to a full-service hotel on a 31-acre campus near Brownwood Town Square in The Villages. TVH cares for over 55,000 patients and is ranked the number 1 physician group in North and Central Florida for patient satisfaction and care quality, and in the top 1 percent of the nation's health systems. TVH has over 500 employees, including 80 physicians with a vast scope of expertise across primary and 15 specialty practice focus areas and offers care through in-person and telehealth visits. Healthcare education is a critical component of patient well-being, which is why TVH sponsors over 1,500 health and wellness classes annually. Classes are open to everyone in The Villages and cover a variety of topics, including nutrition, exercise, brain health, and management of chronic conditions such as diabetes. Each of the health system's six primary care centers dedicates thousands of square feet to clinical exam rooms, procedure rooms, x-ray, phlebotomy, audiology and behavioral health services.

The Villages is home to **The UFHealth: Precision Health Research Center (PHRC)**. In collaboration with UF Health, The Villages Health, and The Villages community, the **PHRC** focuses on advancing science that facilitates our ability to predict, prevent, and cure health problems that impact health and wellness in late-life in a customized and personal way - at the individual and community levels. The **PHRC** is rooted in community-based participatory research engagement principles and conducts social-behavioral and clinical trial research across various areas ranging from brain health to smart technologies. In collaboration with scientists across the UF system, The **PHRC** provides an interdisciplinary hub for generating cutting-edge clinical and translational research as well as support and infrastructure to carry out large, interdisciplinary research initiatives. The 3,700-square-foot **PHRC** includes 11 interview, assessment, and exam rooms, 2 phlebotomy rooms, a study drug storage room, secured areas for study documents, study coordinator offices, and offices for the center's leadership team. Two conference rooms with teleconference capabilities are available for teaching, community education needs, or conferencing multicenter trials. The **PHRC** provides a large educational training space for community members, industry partners, and academic professionals.

FACILITY 2

Name: **Emory University (1836)**

Street address: 1599 Clifton RD, NE, 4th Floor

City, county, state, and zip code: Atlanta, GA 30322-4250

For more than a decade, Emory University has ranked among the top 25 universities nationwide by U.S. News and World Report. Its overall objectives stress research, patient care, and education with a strong commitment to research. For ten consecutive years Emory has received over \$500 million in external funding.

The **Emory University School of Medicine** (1854) has 3,100 full- and part-time faculty. The school has 556 medical students and trains 1,311 residents and fellows in 106 accredited programs including 53 programs unique in the state of Georgia. The school has five dual degree programs including a joint program with Georgia Tech, with which the medical school shares a biomedical engineering department ranked second in the country by U.S. News & World Report. Medical school faculty received \$443.8 million in external research funding in fiscal year 2019 including 290.7 million from the NIH. The school is best known for its research and treatment in infectious disease, neurosciences, heart disease, cancer, transplantation, orthopaedics, pediatrics, renal disease, ophthalmology and geriatrics. Alumni totals included 6,033 from the medical school, 11,844 residents/fellows, and 6,453 health professionals. Approximately 25 percent of the doctors in Georgia have trained at Emory.

The **Emory University School of Medicine Health Services Research Center** (2018) is a cooperative initiative between the Department of Surgery and Department of Medicine within Emory University's School of Medicine. The Center's mission is to advance healthcare access, quality, value, and outcomes of all patients and populations through scientific inquiry and innovative solutions. The Health Services Research Center is designed to deliver patient-centered outcomes through the promotion of health services research and aligns academic research with clinical care delivery.

Emory Healthcare (1905) is the largest service provider in Georgia comprising 2,691 inpatient beds across 11 campuses and 250 outpatient clinics throughout the state supporting more than 4.6 million annual outpatient visits. Emory Healthcare provided \$151.5 million in charity care in fiscal year 2018-2019 and serves as an exceptional environment for patient-oriented research.

The **Georgia Clinical & Translational Science Alliance** ([Georgia CTSA](#)) is a statewide partnership between Emory University, Morehouse School of Medicine, Georgia Institute of Technology, and University of Georgia and is one of over 50 in a national consortium striving to improve the way biomedical research is conducted across the country. Georgia CTSA's partnerships with research centers and healthcare networks contribute to clinical and translational science advances in Georgia. A key component of the Georgia CTSA is the Integrating Special Populations (ISP) program, which focuses on access, study inclusion, minimizing barriers to participation, and characterizing and promoting high priority special populations such as underserved, rural and geriatric populations.

FACILITY 3

Name: **University of Alabama at Birmingham**

Street address: 1720 2nd Ave. South, AB 1170

City, county, state, and zip code: Birmingham, Jefferson County, AL 35294

The **University of Alabama at Birmingham (UAB)** is located in Birmingham, Alabama, in the heart of the southeastern United States, a region disproportionately impacted by HIV/AIDS. UAB is a publicly funded institution encompassing 11 schools and spanning more than 100 city blocks in downtown Birmingham. Founded in 1969, UAB is an urban university with a major medical center, which has an annual economic impact exceeding \$7 billion.

The **UAB School of Medicine** is one of the leading public medical schools in the US. It ranks 7th among public medical schools and 18th among all US medical schools in NIH funding. The Department of Medicine is the largest department within the UAB School of Medicine. It encompasses 11 divisions and over 400 faculty members. The Department had total research funding of over \$230 million in FY2016. Faculty attend on the internal medicine service four to six weeks

per year, and the infectious diseases consult service four weeks per year.

The **UAB Division of Infectious Diseases** includes more than 130 support staff and 48 full-time faculty members. The faculty are active in teaching, patient care, and research. The Division provides clinical care for a statewide catchment area and consult services for the UAB Hospital, the largest comprehensive medical facility in Alabama, and the Birmingham Veteran's Administration (VA) Hospital. Major clinical trials units within the division include: 1) the AIDS Clinical Trials Group (Dr. Michael Saag, PI); 2) the STD Clinical Research Center (Dr. Edward Hook III, PI); 3) the AIDS Vaccine Research Center (Dr. Paul Goepfert, PI); and 4) the Mycosis Study Group (Dr. Peter Pappas, PI).

The UAB HIV Research and Informatics Service Center (RISC) provides a collaborative infrastructure to conduct HIV clinical and behavioral studies through a combination of research and informatics expertise. Research core services include study coordination, recruitment and tracking, consultation on study design, logistics, and implementation. Informatics core services include software development, database design and management, study eligibility queries, generation of analysis-ready data sets, desktop support, network security services, graphic design, and health informatics consultation. Also offered is biostatistical and epidemiologic analysis. Founding RISC leadership includes Michael Mugavero, MD MHSc, and James Willig, MD MSPH, both of whom are also 1917 HIV Clinic providers. The RISC team includes six faculty members, data analysts, programmers, information systems specialists, biostatisticians, research coordinators, research recruiters/study specialists, interventionists/ health coaches, research and informatics managers, and a program manager. Several of these staff have expertise in qualitative data collection, including conduct of in-depth interviews and focus groups, and in qualitative data coding and analysis.

Bendcare. Headquartered in South Florida, Bendcare supports the business aspects of the American Arthritis and Rheumatology Associates (AARA) and is the largest U.S. rheumatology “supergroup” comprised of more than 750 community rheumatology practitioners. Bendcare connects and collaborates with multiple stakeholders to design innovative models of specialty care, provide best-in-class services, and delivers superlative outcomes for rheumatology patients. Bendcare has created multiple technology-based, practical solutions to help rheumatologists standardize and simplify their practices, improve quality, and generate real-world evidence. It is committed to a ‘learning healthcare system’ model of delivery, with a particular emphasis on vulnerable and at-risk patients. Starting in 2018, Bendcare’s Chief Information Officer (Brian Owens) and other Bendcare physicians have collaborated with multiple UAB faculty, particularly Dr. Curtis, on a variety of research, telehealth-related, and quality improvement projects.

FACILITY 4

Name: **University of South Florida Health**

Street address: 13330 USF Laurel Drive

City, county, state, and zip code: Tampa, Hillsborough County, FL 33612

Name: **Tampa General Hospital**

Street address: 1 Tampa General Circle

City, county, state, and zip code: Tampa, Hillsborough County, FL

USF Health (USF) and Tampa General Hospital (TGH) operate as a distinctively robust, research-based, academic medical center committed to improving the health of the Tampa Bay community through world class research, evidence-based clinical practice, and measurable quality of care. Within this enterprise, clinical research is well supported in a number of important ways. First, all USF and TGH clinical departments directly employ clinical research coordinators who can be made available to support subject recruitment and enrollment, ongoing study activities, specimen collection and data abstraction. Geographically, these teams work in close proximity to the clinicians for their home Department. In addition, both USF and TGH have elected to further support clinical research by developing additional, dedicated facilities designed to support all phases of clinical trials at each of the primary sites at which USF or TGH clinicians see patients. These include a dedicated clinical research facility on the 3rd floor of the Morsani Center for Advanced Health Care on USF’s main Temple Terrace campus, the 4th floor of USF’s South Tampa Campus on Davis Islands and at the TGH HealthPark in Seminole Heights, Tampa. Each of these facilities consists of multiple fully-equipped clinical examination

rooms, a dedicated phlebotomy station, -80C and -20C freezers, Sorvall table-top clinical centrifuges and 4C refrigerators dedicated to specimen processing and storage. Additional clinical research capacity is available at TGH's 409 Bayshore Building, immediately adjacent to the clinical workspaces for the Tampa General Transplant program, a short walk from TGH's primary clinical campus on Davis Islands. Similar to other USF/TGH clinical research facilities, 409 Bayshore contains multiple fully equipped clinical examination rooms (n=4), dedicated facility for phlebotomy, -80C, -20C freezers and a refrigerator dedicated to specimen storage. Commercial drop boxes allowing specimens for routine clinical laboratories performed both by the TGH Clinical Laboratory and outside commercial providers (Quest, others) are available at each research site. Access to oncology-certified infusion nurses is available within TGH Cancer Center's Infusion Center, which contains 20 bays equipped with reclining chairs and/or stretchers, reception/check-in and a patient refreshment center and a dedicated Infusion pharmacy. Lastly, space has been made available to support ongoing biorepository activities immediately adjacent to the primary operating rooms for TGH (within the Department of Pathology's frozen section room) as well as Room H012. Of note, the space in H012 is equipped with a tabletop Sorvall centrifuge, a monitored and alarmed -80C freezer, liquid nitrogen, and ample storage space for supplies.

Most recently, in response to the ongoing COVID-19 pandemic, TGH and USF have collaboratively established the Global Emerging Diseases Institute (GEDI), which has been designed as a dedicated state-of-the-art facility to support not only the care of COVID-19 patients requiring hospitalization but also subsequent outpatient follow-up and evaluation. Seeded by a \$10 million donation by local philanthropists, GEDI facilities contain dedicated single-occupant isolation rooms equipped with negative pressure ventilation, -a dedicated outpatient clinical facility and more than 2,000 square feet of dedicated research space with fully equipped patient evaluation room, and space dedicated for the preparation of high-quality bio analytes (e.g. gDNA, RNA, whole blood, serum). Of note, GEDI has been equipped with a dedicated MiSeq Next Generation genomic sequencer which will be used, at least in part, to support ongoing community surveillance activities. It is anticipated that these latter resources will also be made available to the broader USF/TGH research community.

FACILITY 5

Name: **University of Miami/University of Miami Health System (UHealth)**

Street address: 3312 South Dixie Highway

City, county, state, and zip code: Coral Gables, Dade County, FL 33146

University of Miami Miller School of Medicine (MSOM): The University of Miami (UM) MSOM is an academic medical center with extensive clinical facilities. Research is a top priority, with more than 1,300 ongoing projects funded by more than \$380 million in extramural grants and contracts. The school ranks in the top third among U.S. medical schools in terms of research funding awarded. With more than 1,400 faculty members, MSOM is dedicated to generating major advances in medical research and converting these discoveries into enhanced patient care. The medical center includes three University-owned hospitals: UHealth Tower, Sylvester Comprehensive Cancer Center, and Anne Bates Leach Eye Hospital. UM affiliates include Jackson Health System, Holtz Children's Hospital, and the Miami VA Healthcare System.

Miami CTSI: In 2012, UM was awarded a Clinical and Translational Science Award, becoming part of a national consortium of medical research institutions working together to improve the way clinical and translational research is conducted nationwide. The Miami Clinical and Translational Science Institute (CTSI) focuses on culturalized health sciences, minority health and health disparities. The Community and Stakeholder Engagement program, co-led by Dr. Olveen Carrasquillo, seeks to transform research at UM and the CTSI Hub to be responsive and inclusive of community/key stakeholder participants. Our CTSI community engagement framework is a multi-faceted approach that a) engages other organizations having a wealth of experience in the target communities, b) engages and activates the informal leadership of ethnic communities, and c) engages health care systems, providers and patients.

Sylvester Comprehensive Cancer Center (SCCC): All SCCC physicians are on the faculty of the Miller School of Medicine, South Florida's only academic medical center. SCCC physicians annually handle 1,500 inpatient admissions, perform more than 2,400 surgical procedures, and treat 6,000 newly diagnosed cancer patients. In addition, SCCC supervises the care of more than 2,500 new cancer patients at Jackson Memorial Hospital. This represents the largest experience of any

hospital or health system in the counties that make up South Florida. SCCC physicians and scientists are engaged in approximately 112 therapeutic clinical trials and receive more than \$28 million annually in research grants. Research is organized around three multidisciplinary research programs and multiple shared resources, ensuring access to the most innovative techniques across a range of cancer specialties.

UM operates shared resources that facilitate research, including: **Behavior & Community Research Shared Resource (BCSR)**: Led by Dr. Carrasquillo and Natasha Schaefer Solle, PhD, RN, the BCSR provides services to support community-based and disparities-focused research. The BCSR works with researchers from a wide range of academic disciplines including epidemiology, genetics, gynecology, medicine, oncology, psychology and sociology/anthropology. UM also provides services that assist researchers in identifying communities at increased risk of adverse health outcomes and in networking effectively with these communities toward mutually beneficial research aims. Services include consultation on research design and study implementation, development of community research partnerships, and project coordination and management.

FACILITY 6

Name: **Florida State University**

Street address: 600 West College Avenue

City, county, state, and zip code: Tallahassee, Leon County, FL 32306

Florida State University (FSU) is affiliated with practice partners at its six regional campuses (Daytona, Fort Pierce, Orlando, Pensacola, Sarasota, and Tallahassee) throughout Florida, along with small to medium size physician practices located throughout each of the regional campuses. Our regional campuses, as well as our two rural training sites in Immokalee and Marianna, give us a statewide presence in Florida. We also have a clinical training site in Thomasville, Georgia. Florida State University brings 20 years of experience working with hundreds of small, medium, and large practices across the state of Florida.

The FSU College of Medicine has a distributed medical student and residency training program in which medical students and residents are paired with practicing clinicians across the state. Its training program is particularly focused on training physicians to work in primary care in rural and underserved areas. FSU formed its regional campuses to support medical student training and for College of Medicine-sponsored residency programs in family and internal medicine. The FSU College of Medicine currently sponsors residency programs in Dermatology (Tallahassee), Emergency Medicine (Sarasota), Family Medicine (Fort Myers and Winter Haven), General Surgery (Tallahassee), and Internal Medicine (Tallahassee and Sarasota). It also sponsors fellowship programs in Global Health (Fort Myers), Hospice and Palliative Medicine (Sarasota), and Micrographic Surgery and Dermatologic Oncology (Tallahassee).

The FSU College of Medicine has built an extensive Network for Clinical Research and Training (NCRT), which has access to over 2,100 community physicians who serve as community clinical faculty at our regional campuses. NCRT supports the statewide, collaborative research network of our faculty, community-based healthcare professionals, and researchers. It enhances and promotes research collaboration; strengthens partnerships between multidisciplinary professionals who work with patients in the community via a formalized, structured, and integrated network; and builds capacity for community-based research through education, collaboration, and access to diverse and underserved patient populations.

UF and FSU formed a partnership in 2009 that was the beginning of OneFlorida⁺. FSU contributes its research strengths as well as those related to its statewide practice infrastructure, and UF contributes its research strengths as well as its clinical expertise in Gainesville and Jacksonville. The FSU College of Medicine regional deans at all six campuses have agreed to work with the OneFlorida⁺ to recruit practices and physicians they have pre-existing relationships with for clinical trials and other comparative effectiveness, pragmatic, and implementation science studies as part of PCORnet.

FACILITY 7

Name: **Tallahassee Memorial HealthCare**

Street address: 1300 Miccosukee Road

City, county, state, and zip code: Tallahassee, Leon County, FL 32308

Tallahassee Memorial HealthCare (TMH) is a private, nonprofit healthcare system serving the surrounding 17 counties in North Florida and South Georgia. With 772 beds, 3,500 employees and over 500 medical staff members, TMH is the seventh largest hospital in Florida. TMH is home to the area's only state-designated Level II Trauma Center and the Big Bend's only accredited community hospital cancer program. It has been accredited since 1951 by the American College of Surgeons' Commission on Cancer — making it the longest continuously accredited community cancer program in the state of Florida. TMH has the only state-designated Brain & Spinal Cord Injury Center. It is the Panhandle's most advanced neurosurgery program, including stroke and aneurysm treatments without opening the skull. Additionally, TMH is recognized by the Society of Chest Pain Centers as an Accredited Chest Pain Center with PCI, the highest designation available for heart attack care. TMH has the only Comprehensive Stroke Center, as well as the only Neurological and Level III Neonatal Intensive Care Units in the Big Bend. It is the only center in the region to be a designated ACR Breast Center for Excellence and accredited by the National Accreditation Program for Breast Centers.

OUTPATIENT TMH DATA FACILITY

Name: **Capital Health Plan**

Address: 1545 Raymond Diehl Road

Tallahassee, Florida 32308

Capital Health Plan (CHP) is a federally qualified, local non-profit health maintenance organization created in 1982 to provide comprehensive and coordinated medical care for a fixed, prepaid fee with predictable copayments and no deductibles. This prepaid fee covers members' health care needs from routine physicals to hospitalization. CHP is a local HMO focused solely on serving the area surrounding Tallahassee, providing coverage to more than 135,000 members. It is the highest-ranked Medicare and commercial plan in Florida and the 6th ranked commercial plan in the nation by the National Committee for Quality Assurance (NCQA) in "NCQA's Health Insurance Plan Ratings 2019-2020". NCQA uses comprehensive categories such as clinical performance (treatment), access to care, prevention and member satisfaction to determine accreditation levels. Among important findings from Consumer Assessment of Healthcare Providers and Systems (CAHPS) data, Capital Health Plan is rated highest in the nation for Colorectal Cancer Screenings; highest in the Southeast Region for Members Rating of Health Plan; and highest in the Southeast Region for Access to Necessary and Routine Care.

FACILITY 8

Name: **Adventist Health System/Sunbelt, Inc. dba AdventHealth Orlando**

Street address: 601 E. Rollins Street

City, county, state, and zip code: Orlando, Orange County, FL 32803-1248

AdventHealth is part of the Adventist Health System, one of the country's largest not-for-profit health care providers. AdventHealth Orlando is the flagship hospital of the Central Florida Division (CFD). It is an acute-care medical facility with multiple affiliated outpatient practices. CFD includes over 20 central Florida hospitals and has more than 3.4 million patient visits annually. It includes 176 different specialties, such as cancer, orthopedics, gynecology, cardiac, rehab, pediatric medicine and more. CFD includes over 3,400 staff physicians. CFD outpatient services include over 300 AdventHealth Medical Group practices, 35 urgent care centers, over 30 sports medicine and rehabilitation centers, and 35 imaging and diagnostic centers.

AdventHealth for Children's care network includes 292 pediatric beds in Central Florida. The Children's care network includes an acute care medical hospital, primary care pediatricians, specialty clinics, emergency departments, and Centra Care Kids pediatric urgent care centers. AdventHealth for Women provides dedicated, full spectrum services including prenatal care, well care and specialty services including a heart program for women.

AdventHealth Research Institute (AHRI) supports over 250 investigators with over 560 active clinical studies.

AdventHealth Orlando's Research Services department consists of the Office of Sponsored Programs (OSP) and the Office of Research Integrity (ORI). The OSP has dedicated staff that assists and manages grant-funded studies. OSP also includes personnel who support and manage clinical trials, sponsored program budgets, and clinical trial applications. The ORI consists of staff who oversee the IRB, research compliance and regulatory services. In addition, AHRI has a research information systems department, research finance department, and a research legal unit. Collectively, these units provide support and safeguards for investigators, research team members, and research subjects to ensure the integrity of research at AdventHealth Orlando. AHRI works closely with AH clinical investigators and sponsors to evaluate innovations in health care delivery and patient outcomes. Utilizing sound scientific principles and the latest technologies of electronic data collection, management, and analysis, this team specializes in the big data analyses that are key to generating real-world evidence in healthcare system settings.

AdventHealth has a research-specific information technology department called Research Information Systems (ResIS). ResIS will be integral to the success of this project by providing limited data sets on a recurring basis and addressing any technical requirements and issues.

FACILITY 9

Name: **Nicklaus Children's Health System**

Street address: 3100 Southwest 62nd Avenue

City, county, state, and zip code: Miami, Dade County, FL 33155

Founded in 1950 by Variety Clubs International, Nicklaus Children's Hospital ("Nicklaus"), formerly Miami Children's Hospital, is South Florida's only licensed specialty hospital exclusively for children, with over 650 attending physicians and 130 sub-specialists, and more than 3,500 employees. The 289-bed hospital is renowned for excellence in all aspects of pediatric medicine with several specialty programs ranked among the best in the nation since 2008 by the U.S. News & World Report. Nicklaus is also home to the largest pediatric teaching program in the southeastern United States and was the fifth pediatric hospital in the nation to be designated an American Nurses Credentialing Center ("ANCC") Magnet facility, the nursing profession's most prestigious institutional honor. Nicklaus represents the leading edge of children's medicine by participating in research that helps bring the latest technology to children in need. In fact, the Nicklaus Children's Hospital Research Institute is one of the largest providers of pediatric research in the region and has earned full accreditation from the Association for the Accreditation of Human Research Protection Programs ("AAHRPP"), and the Comprehensive Epilepsy Center is the first center in the world to directly map the brains of infants and children as a first step toward successful pediatric brain surgery.

Over the past 20 years, Nicklaus Children's Hospital Research Institute has grown to become one of the largest providers of clinical research services to children in the southeastern United States. As a leading provider of clinical research studies involving children of Latin and Hispanic origin, Nicklaus Children's Hospital Research Institute is ideally positioned to become a Center of Excellence in the field of personalized medicine, providing groundbreaking treatment protocols and improving clinical effectiveness and outcomes for diverse communities on a national and international scale. Nicklaus Children's Hospital Research Institute coordinates all research activities, and provides research infrastructure and clinical research services to support and streamline clinical and translational research activities within the hospital and health system. Nicklaus Children's Hospital Research Institute is accredited by the Association for the Accreditation of Human Research Protection Programs (AAHRPP) and strives to promote efficiency, standardization, compliance, and responsible clinical and translational research conduct through education, quality assurance visits, positive influence, and guided internal and community leadership. The Nicklaus Children's Hospital Research Institute ensures that human subject research is conducted according to the highest ethical standards. Additionally, the Nicklaus Children's Hospital Research Institute engages the community by increasing awareness of Nicklaus Children's Hospital research initiatives and providing training for clinical research teams. The Nicklaus Children's Hospital Research Institute's mission is to 1) provide leadership, education, expertise, and guidance to clinical research professionals at Nicklaus and its affiliates; 2)

serve as a centralized resource within Nicklaus to support the conduct of patient-oriented research focusing on clinical trials; 3) provide a primary point of contact for sponsors and investigators; 4) serve as an educational resource to investigators and research staff; and 5) provide an interface with the research participant community.

Nicklaus Children's Hospital Research Institute also offers research outcome support through the Research Institute Outcomes Team to expand organizational research capabilities by: providing support to physician/investigator-initiated research projects, using increasingly complex methodologies; improve efficiency by decreasing physician/investigator time for intensive chart review; support data stewardship and management by supporting RedCap and best practices for research information management; collaborate with external research partners; and increase extramural funding for research and other data-intensive initiatives and programs.

FACILITY 10

Name: **Orlando Health System**

Street address: 52 West Underwood Street

City, county, state, and zip code: Orlando, FL 32806

Orlando Health is a not-for-profit healthcare organization with more than 3,200-beds that includes 15 wholly-owned hospitals and emergency departments; rehabilitation services, cancer institutes, heart institutes, imaging and laboratory services, wound care centers, physician offices for adults and pediatrics, skilled nursing facilities, an in-patient behavioral health facility, home healthcare services in partnership with LHC Group, and urgent care centers in partnership with CareSpot Urgent Care. Nearly 4,200 physicians, representing more than 80 medical specialties and subspecialties have privileges across the Orlando Health system, which employs nearly 22,000 team members. Areas of clinical excellence are orthopedics, heart and vascular, cancer care, neurosciences, surgery, pediatric specialties, neonatology, women's health and trauma.

Orlando Health hospitals are: Bayfront Health St. Petersburg, Orlando Health Arnold Palmer Hospital for Children, Orlando Health Dr. P. Phillips Hospital, Orlando Health – Health Central Hospital, Orlando Health Horizon West Hospital, Orlando Health Orlando Regional Medical Center; Orlando Health South Lake Hospital; Orlando Health South Seminole Hospital, Orlando Health St. Cloud Hospital and Orlando Health Winnie Palmer Hospital for Women & Babies.

In FY20, Orlando Health served nearly 150,000 inpatients and nearly 3.1 million outpatients. During that same time period, Orlando Health provided approximately \$760 million in total value to the communities it serves in the form of charity care, community benefit programs and services, community building activities and more.

FACILITY 11

Name: **Bond Community Health Center, Inc.**

Street address: 1720 South Gadsden Street

City, county, state, and zip code: Tallahassee, Leon County, FL 32301

Bond Community Health Center, Inc. (CHC) is a 501(c) (3) community health center deemed as a federally qualified health center for greater than 35 years. Bond provides a patient-centered approach to quality primary and preventive healthcare services for residents of Leon and surrounding counties. Support services range from eligibility assistance and transportation to nutrition and cooking classes. Providing access to quality health care for all people in our community is our mission. Bond CHC serves a predominantly African-American, yet diverse, patient population with a wide range of primary care, dental, and behavioral health services. Bond CHC is committed to serving underserved communities and promotes access to care at its three sites and through mobile clinics. Bond CHC has collaborated with OneFlorida+ since 2009, contributing to everything from data collection and recruitment on multisite clinical trials to the concept of the OneFlorida+ Clinical Research Consortium. Bond CHC has collaborated on several grant applications in the last twelve months and is currently receiving OneFlorida+ funding in addition to funding allocated from the CDRN, to support other activities related to successful grant applications. Dr. Temple Robinson, MD, is the Chief Executive Officer of Bond CHC and has attended OneFlorida+ Steering Committee meetings for several years. In addition, she has continually supported

research and innovative information dissemination strategies. The Accreditation Association for Ambulatory Health Care, Inc. (AAAHC) awarded full accreditation to Bond Community Health Center, Inc. and deemed it a Patient-Centered Medical and Dental Home.

FACILITY 12

Name: **CommunityHealth IT, Inc.**

Street address: Astronaut Memorial Foundation Building M6-306 SR 405

City, county, state, and zip code: Kennedy Space Center, Brevard County, FL 32899

CommunityHealth IT (CommHIT), a 501(c)(6) at the Kennedy Space Center, has a network of community mental health facilities, federally qualified health centers (FQHCs), rural and community hospitals, and rural health clinics (RHCs) primarily located in several rural and underserved Florida areas. Medical sites are in the following counties Alachua, Baker, Bradford, Citrus, Columbia, Miami-Dade, DeSoto, Dixie, Duval, Escambia, Gadsden, Gilchrist, Hamilton, Hernando, Hillsborough, Lafayette, Lake, Levy, Marion, Putnam, Sumter, Suwannee, and Union. CommHIT's primary role is assisting these facilities to recoup funds from the Federal Communications Commission for their broadband expenses, receive funds and resources for needed telehealth services, safely and effectively adopt health information technologies, and participate in clinical research—particularly patient-centered research. CommHIT works very closely with the Department of Health and Human Services (HHS), Department of Homeland Security (DHS), Information Sharing and Analysis Organizations and Centers (ISAOs/ISACs), and Computer Emergency Response Teams (CERTs) worldwide to reduce the risk of a data breach and improve our network's cybersecurity and privacy postures.