# Welcome!

Receive the CCTS Newsletter: **go.uab.edu/JoinTheCCTS**

Follow us on Twitter: **@cctsnetwork**

Check out upcoming events: **go.uab.edu/cctsevents**

Catch past events anytime: **go.uab.edu/cctsvideochannel**

CCTS

Center for Clinical and Translational Science

CCTS
Center for Clinical and Translational Science

# Robert P. Kimberly, MD
# Senior Associate Dean
# *Center for Clinical and Translational Science*

ACCELERATE. INNOVATE. DISSEMINATE. **WITH YOUR CCTS.**

# Zoom Etiquette

- Everyone will be muted.
- To ask a question, please use the Zoom chat box.
- Questions will be answered **after** the last speaker as time permits.
- In chat box, please include question, your name and email address.
- If your question is not answered, you will be emailed an answer by one of our speakers after the Lunch and Learn.
- We appreciate your patience and cooperation.
- Slides and recording link will be emailed after Lunch and Learn.

# AGENDA

- Meredith Fitz-Gerald -Welcome
- Dr. Robert Kimberly
- Poll Questions
- Kimberly McCall – Biotechnology Regulatory Affairs
- Mark Marchant – Updates on Clinical Trials Initiative
- Debbie Graves- Office of Sponsored Programs
- Jereme Logan – Office of Compliance and Risk Assurance
- Mackenzie Roberts - OnCore
- Christina Blackmon – IRB
- Nick Ciancio/Emily Colpack – UAB Green Labs
- Alicia Gunter - PowerTrials
- Rebecca Hardin – UAHSF Travelers Badge

# *Upcoming Events*

***Research Seminar Series***

- **January 5, 2023 -** Overview to Initial and Ongoing Steps for Travelers Badge
- **January 19, 2023 -** Benefits of the UAB Green Labs Program

***Research Orientation Program***

- ***January 26, 2023 (Register using link below)***

***Clinical Investigator Training Program***

- ***February 7, 2023 (Now accepting applications until 1/27/23)***

***Research Training Program***

- ***April 18, 2023 (Register using link below)***

*https://www.uab.edu/ccts/clinical-research/trainings*

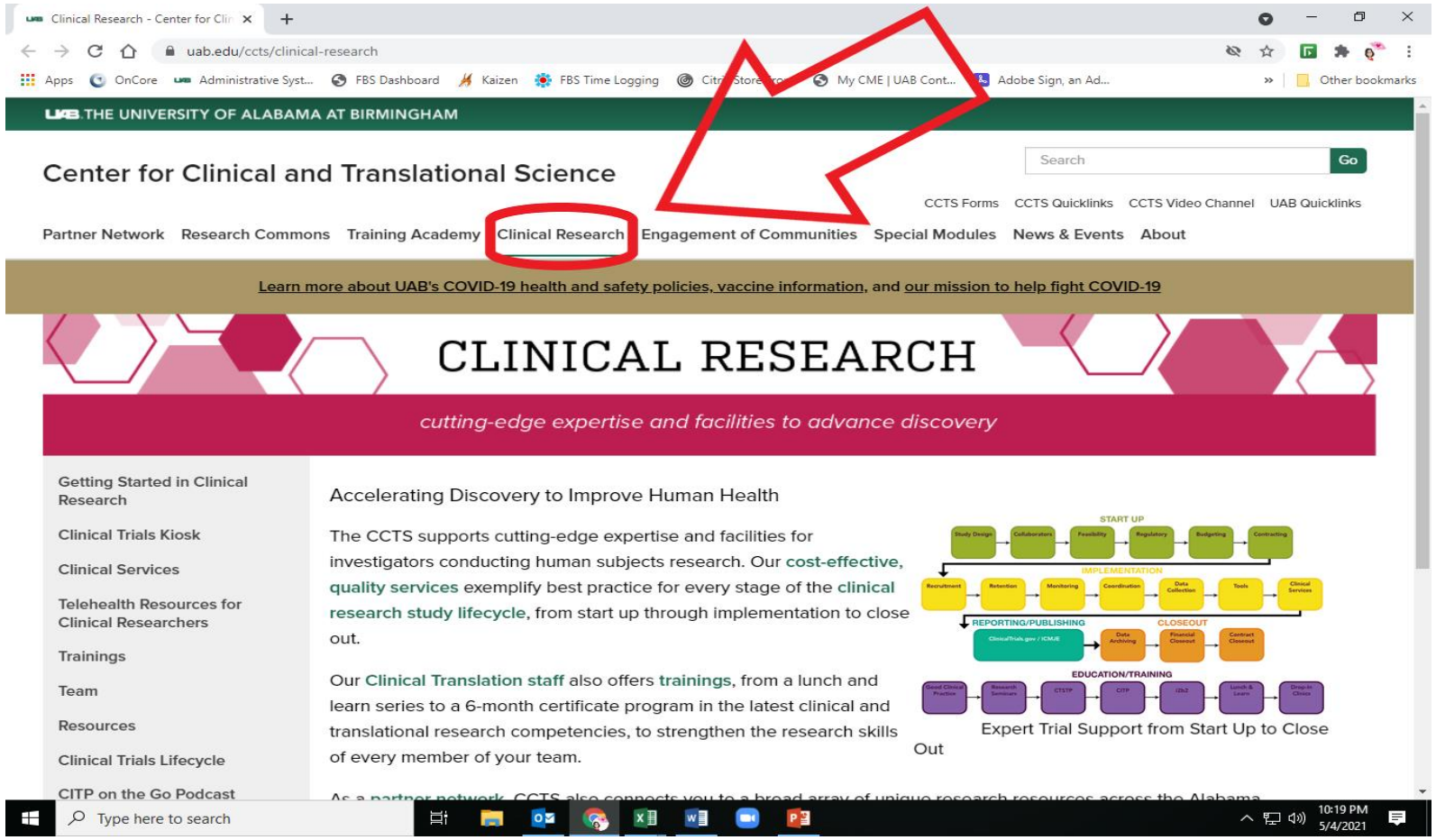
# CCTS Clinical Research Support Program
# RECRUITMENT AND RETENTION

We offer consultations during the protocol development stage to help **improve your clinical trial enrollment** and keep participants engaged throughout the duration of the trial.

Our **Recruitment and Retention Consultation Team** include a Clinical Coordinator, Regulatory Coordinator, and Clinical Research Administrator experienced in clinical trials budgets to help you develop a comprehensive Recruitment and Retention plan.

Questions? Contact CRSPrecruitment@uabmc.edu or 205-934-9360

# https://www.uab.edu/ccts/clinical-research/clinical-trial-kiosk



# And the winner is…….

**Team members –** Nehal Vekariya, M.S., Naman Shetty, M.D., Nirav Patel, M.D., Vibhu Parcha, M.D.

**Department-** Division of Cardiovascular Disease

**PI –** Pankaj Arora, M.D

# Poll Questions

UAB SCHOOL OF HEALTH PROFESSIONS

Knowledge that will change your world

# Biotechnology Regulatory Affairs (BTR)


**Dr. Kimberly McCall**

**Assistant Professor & Regulatory Affairs Specialist**

205-934-3378

kmccall@uab.edu

# FAST FACT

**The demand for regulatory affairs knowledge is becoming increasingly more important in health care, in particular for those working as medical professionals, scientists, biomedical engineers, clinical researchers/coordinators, entrepreneurs, and quality assurance experts.**

# Purpose of Regulatory Affairs

- Ensure regulatory compliance and stay up-to-date with government regulations at each phase of development.
  - These phases include research & development, clinical trials, regulatory submissions, manufacturing, marketing, and post market surveillance.
- Navigate the regulations for marketing approval for a biologic, pharmaceutical or medical device product

# BTR Program Overview

## 100% Online. Learn it here. Use it everywhere

- **REQUIREMENTS**
  - BS degree with min. 3.0 GPA
  - Meet UAB Graduate School requirements
  - TOEFL, IELTS AND TWE scores (international students)

- **CURRICULUM (Earn your certificate in only 5 Courses)**
  - BTR 605: Biotechnology Regulatory & Quality Systems
  - BTR 615: Applications of Biological Processes in Drug Development
  - BTR 620: Food and Drug Law
  - BTR 640: Clinical Development of Drugs, Biologics, Diagnostics, and Medical Devices
  - BTR 690: Clinical Trial Implementation

- **UNDERGRADUATES**
  - Must have at least 60 undergraduate hours
  - 36 hours completed at UAB
  - 3.0 GPA

# CERTIFICATE BENEFITS

- Distinguish Yourself
- Demonstrate Regulatory Knowledge
- Sharpen Critical Thinking Skills
- Career Advancement

# Want to Learn More?

Website: Biotechnology Regulatory Affairs Certificate - SHP - Department of Clinical And Diagnostic Sciences | UAB

Phone: (205) 934-3378

AskCDS@uab.edu

# Updates on Clinical Trials Initiatives

Mark Marchant, MPH, MBA, CCRP
Director
Clinical Trials Administrative Office

# Pending Accounts

**Reminder:**

- Accounts automatically generated for industry-funded clinical trials
- Both PI and Staff effort should be applied
- Effort only has to reflect period for which work expended to start-up trial
- Hold placed on contract at OSP if no effort applied

# Patient Privacy

**Reminder:**

- Don’t forget to move away from crowds/waiting areas when speaking with patients about potential clinical trial opportunities in order to maintain confidentiality.

# Research Business Operations (RBO) Updates OSP/MTO/RTC

Debbie Graves
Manager Research Training & Development, OSP

# NIH Federal Submission Updates/Reminders

- New “FORMS-H” required on or after January 25, 2023
- Primary change: **2023 NIH Data Management and Sharing Policy (DMSP)**: competing applications submitted for activities subject to DMS Policy required to submit DMS Plan when applying for NIH grants or cooperative agreements – see **NOT-OD-22-189**
- See recent webinar, FAQs, draft template, additional resources on NIH DMSP on UAB libraries website: https://guides.library.uab.edu/c.php?g=1239636&p=9074311&preview=bb23e68e40f3fdcd9c2edf1befa061d4

# NIH Federal Submission Updates/Reminders

UAB LIBRARIES
The University of Alabama at Birmingham

UAB Libraries / Research Guides / Research Data Management / NIH Data Management and Sharing Policy

## Research Data Management: NIH Data Management and Sharing Policy

Search this Guide | Search

- Home
- NIH Data Management and Sharing Policy
  - NIH Policy for Data Management and Sharing
  - Webinar on the NIH DMSP
  - FAQ
  - The 6 elements of a DMSP
  - (Draft) Template DMSP
  - Example Plans
  - DMPTool
  - Additional Resources
- How to select a data repository

### What's in the new policy?

NIH grants submitted on or after January 25, 2023 must adhere to the new Data Management and Sharing (DMS) Policy. The policy applies to all UAB grant submissions to the NIH that will generate scientific data. Applicants will be required to submit a two-page data management and sharing plan.

There are notable differences from earlier NIH policies:

- Changes in format and broader in scope
- Required for all NIH grant submissions if the grant will generate scientific data
- Defines what *is* and *is not* data (see below)
- Asks PI to maximize appropriate data sharing
- Data must be made available at the time of publication or at the conclusion of the granting period, whichever comes first

NIH Data Management and Sharing Plan

"The final DMS Policy **defines Scientific Data as**: *"The recorded factual material commonly accepted in the scientific community as of sufficient quality to validate and replicate research findings, regardless of whether the data are used to support scholarly publications. Scientific data do not include laboratory notebooks, preliminary analyses, completed case report forms, drafts of scientific papers, plans for future research, peer reviews, communications with colleagues, or physical objects, such as laboratory specimens."* "

**1-Page summary of the 2023 policy change**

- 2023DMSP_summary

### Watch our latest training webinar on the new NIH DMSP

Click here to access the video

Click here to download the slides from the presentation (pdf)

# NSF Federal Submission Updates/Reminders

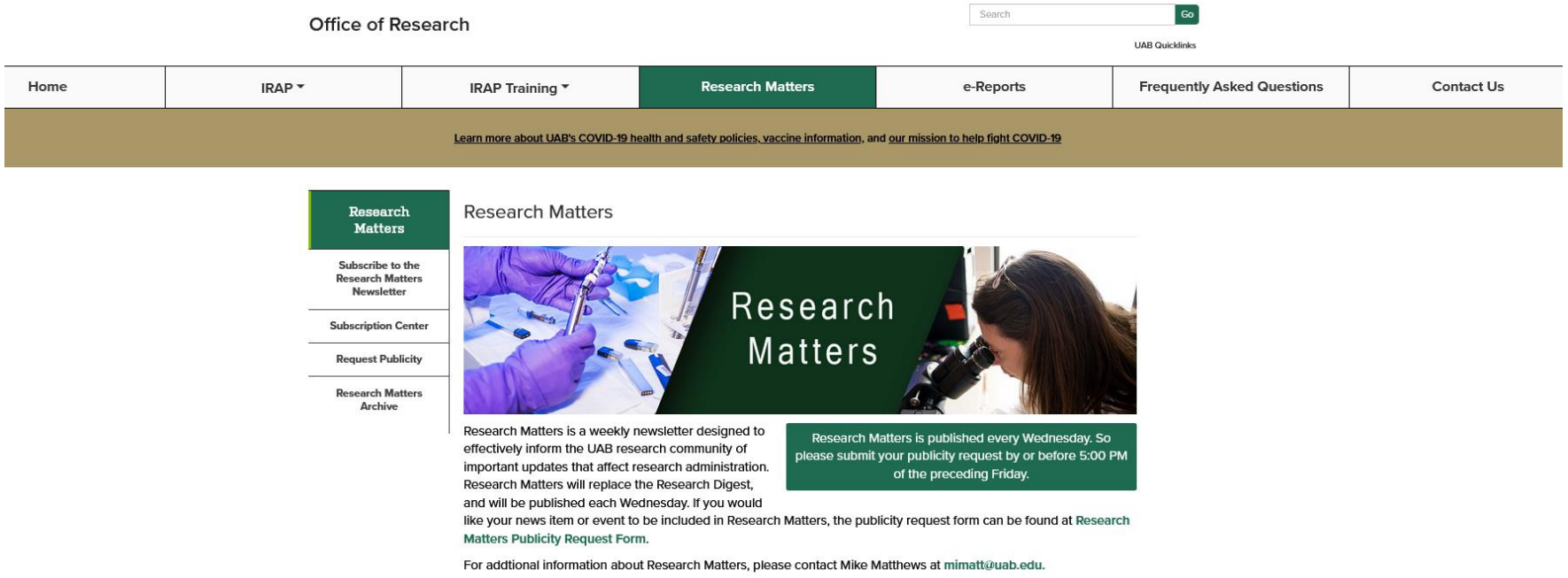
- NSF transitioning all preparation and submission functionality for **new** proposals from FastLane to Research.gov when *Proposal & Award Policies & Procedures Guide* (PAPPG) (NSF 23-1) is effective in late January 2023
- Upcoming OSP training opportunities available for Research.gov:
  - Wednesday, January 18 – 9:30 to 10:30

# General RTC Reminders

- IRAP Basics Training course available
- Provides general information about IRAP, instructs users on how to navigate self-configurable IRAP EnAble portal, and explains how to correctly search and navigate IRAP module records
- Available in Campus Learning LMS and takes about 30 minutes

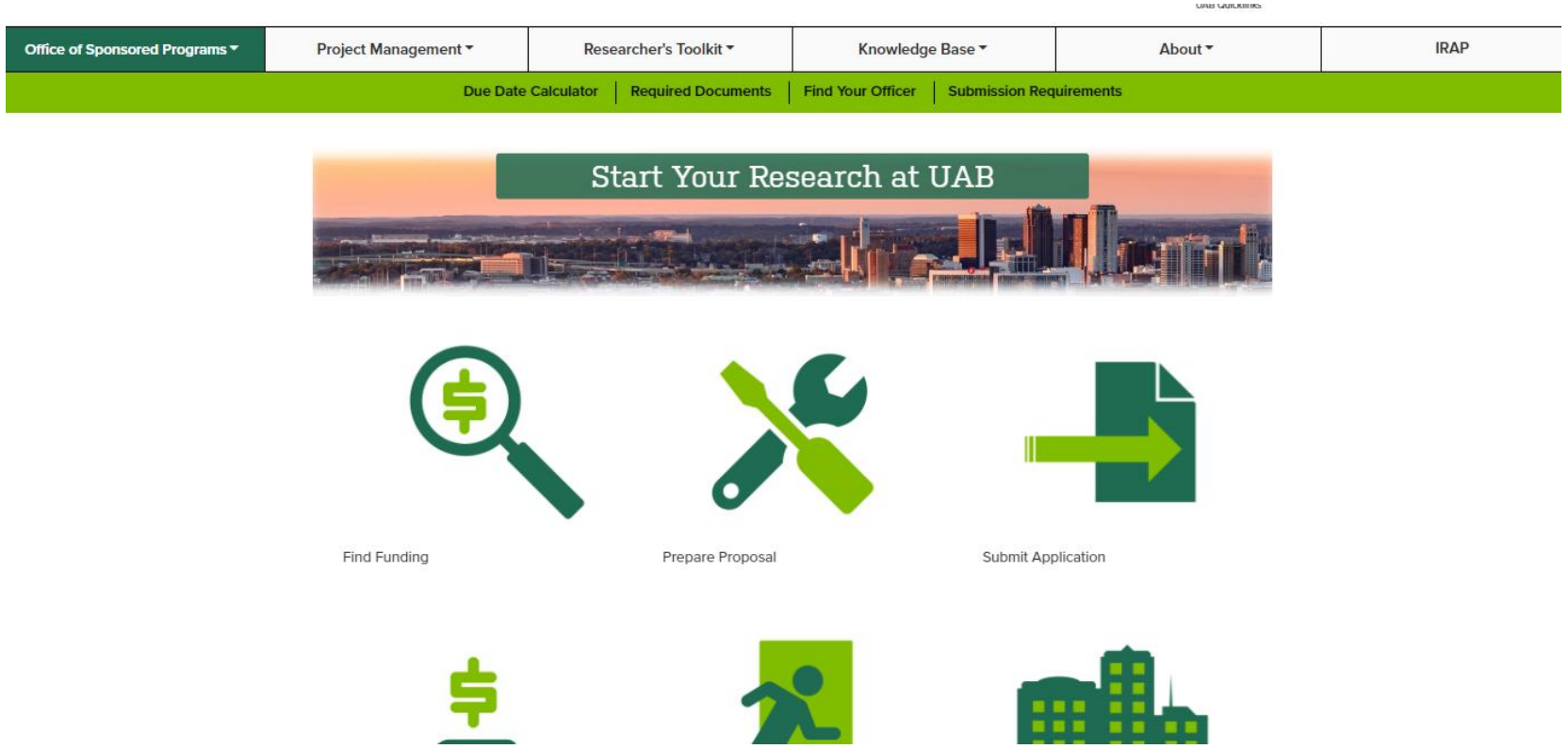
# General RTC Reminders

- Sign up for Research Matters newsletter
- Submit news items and events to be published



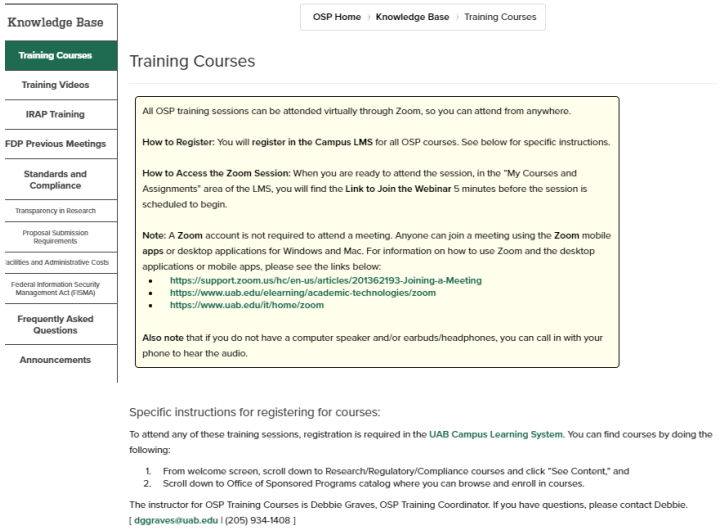
# General OSP Reminders

- OSP website tools, training and videos available regarding OSP processes



# General OSP Reminders

- See training courses and videos available in Knowledge Base area of website
- OSP training is ongoing through Zoom – register through Campus Learning LMS



Knowledge Base

- Training Courses
- Training Videos
- IRAP Training
- FDP Previous Meetings
- Standards and Compliance
- Transparency in Research
- Proposal Submission Requirements
- acilities and Administrative Costs
- Federal Information Security Management Act (FISMA)
- Frequently Asked Questions
- Announcements

OSP Home › Knowledge Base › Training Courses

Training Courses

All OSP training sessions can be attended virtually through Zoom, so you can attend from anywhere.

**How to Register:** You will **register in the Campus LMS** for all OSP courses. See below for specific instructions.

**How to Access the Zoom Session:** When you are ready to attend the session, in the "My Courses and Assignments" area of the LMS, you will find the **Link to Join the Webinar** 5 minutes before the session is scheduled to begin.

**Note:** A **Zoom** account is not required to attend a meeting. Anyone can join a meeting using the **Zoom** mobile **apps** or desktop applications for Windows and Mac. For information on how to use Zoom and the desktop applications or mobile apps, please see the links below:

- https://support.zoom.us/hc/en-us/articles/201362193-Joining-a-Meeting
- https://www.uab.edu/elearning/academic-technologies/zoom
- https://www.uab.edu/it/home/zoom

**Also note** that if you do not have a computer speaker and/or earbuds/headphones, you can call in with your phone to hear the audio.

Specific instructions for registering for courses:

To attend any of these training sessions, registration is required in the UAB Campus Learning System. You can find courses by doing the following:

1. From welcome screen, scroll down to Research/Regulatory/Compliance courses and click "See Content," and
2. Scroll down to Office of Sponsored Programs catalog where you can browse and enroll in courses.

The instructor for OSP Training Courses is Debbie Graves, OSP Training Coordinator. If you have questions, please contact Debbie.
[ dggraves@uab.edu | (205) 934-1408 ]

THE UNIVERSITY OF ALABAMA AT BIRMINGHAM

# Compliance Updates:

## Annual Disclosures, NIH DMS Policy … and more!

Jereme C. Logan, JD, CHRC

Associate Risk & Compliance Officer

Office of Compliance & Risk Assurance

December 13, 2022

# I. Annual COI Disclosures

## New Policy

- UAB Enterprise Conflict of Interest and Conflict of Commitment Policy

- Why New Policy?
  - Changing regulatory environment

  - *Foreign influence*

## Who?

- The annual disclosure requirement applies to:
  - Institutional Officials
  - Faculty
  - Investigators
  - Designated Staff


© UAB. All Rights Reserved.

# Federal Focus on Transparency

GAO Releases Review of Federal Agency Policies on Foreign Interference in Research

January 5, 2021 | Executive Branch News

NIH grantees often fail to report foreign interests

A survey showed that many institutions don't ask about foreign funding sources

by Andrea Widener

June 9, 2022 | A version of this story appeared in Volume 100, Issue 21

POLICY

U.S. scientific research agencies tighten foreign affiliation rules

NEWS | 18 January 2022

What Charles Lieber's conviction means for science

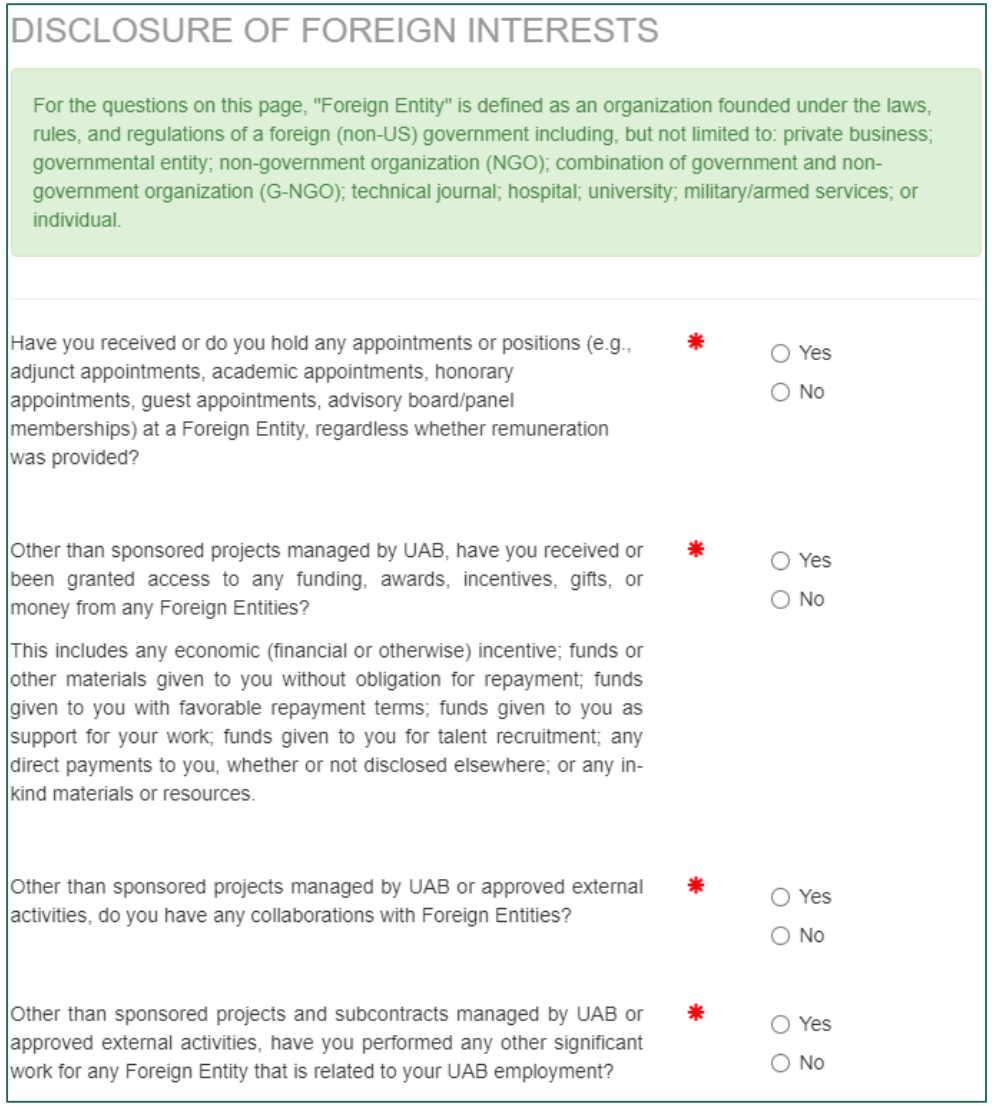
**After Harvard chemist's trial, scientists report ripple effects for federal funding and research itself.**



© UAB. All Rights Reserved.

# New Disclosure Questions

- Responsive to federal funding agency priorities
- Helps provide assurance of expected transparency.
- Affirmative answers prompt reminders about other possible required disclosures (e.g., Other Support, biographical sketch, external activity request).



DISCLOSURE OF FOREIGN INTERESTS

For the questions on this page, "Foreign Entity" is defined as an organization founded under the laws, rules, and regulations of a foreign (non-US) government including, but not limited to: private business; governmental entity; non-government organization (NGO); combination of government and non-government organization (G-NGO); technical journal; hospital; university; military/armed services; or individual.

Have you received or do you hold any appointments or positions (e.g., adjunct appointments, academic appointments, honorary appointments, guest appointments, advisory board/panel memberships) at a Foreign Entity, regardless whether remuneration was provided? * ○ Yes ○ No

Other than sponsored projects managed by UAB, have you received or been granted access to any funding, awards, incentives, gifts, or money from any Foreign Entities? * ○ Yes ○ No

This includes any economic (financial or otherwise) incentive; funds or other materials given to you without obligation for repayment; funds given to you with favorable repayment terms; funds given to you as support for your work; funds given to you for talent recruitment; any direct payments to you, whether or not disclosed elsewhere; or any in-kind materials or resources.

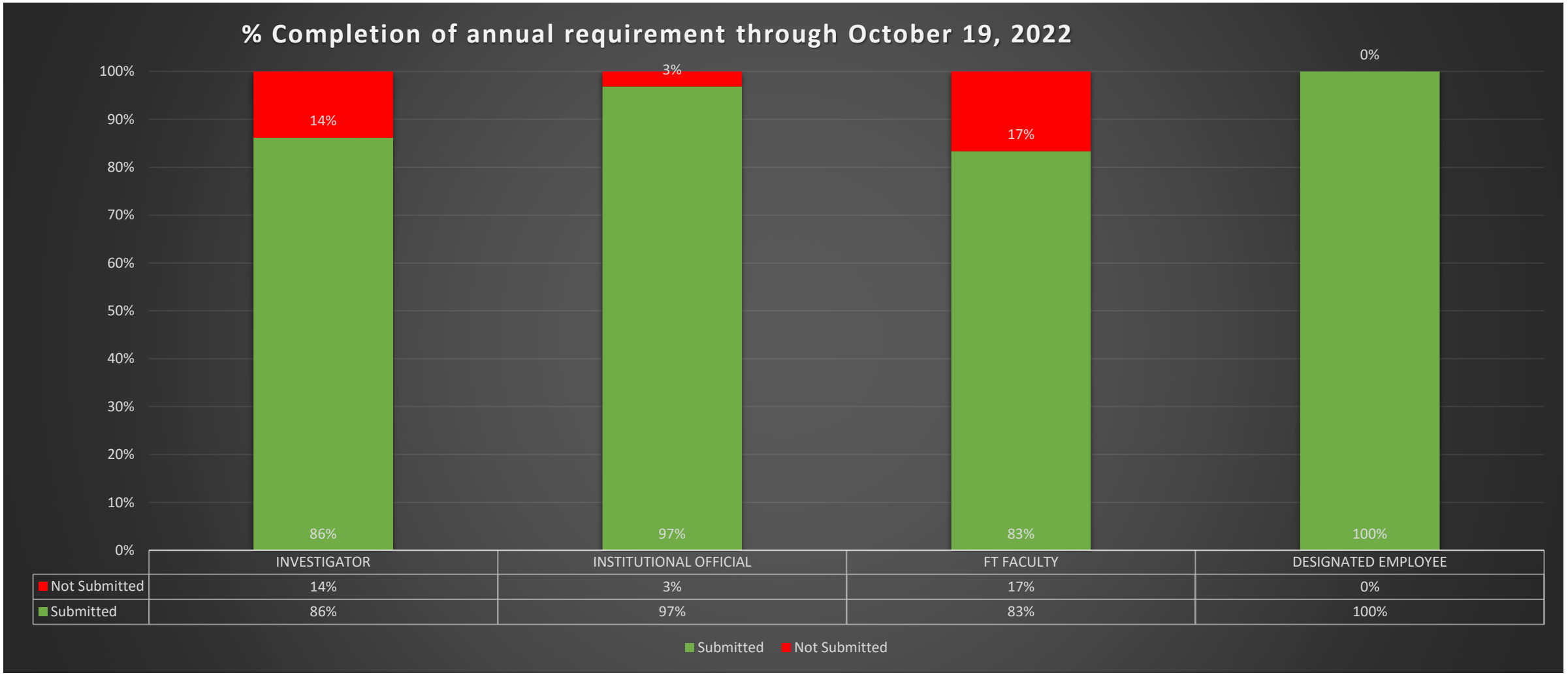
Other than sponsored projects managed by UAB or approved external activities, do you have any collaborations with Foreign Entities? * ○ Yes ○ No

Other than sponsored projects and subcontracts managed by UAB or approved external activities, have you performed any other significant work for any Foreign Entity that is related to your UAB employment? * ○ Yes ○ No


© UAB. All Rights Reserved.

# Disclosure by the Numbers






| | INVESTIGATOR | INSTITUTIONAL OFFICIAL | FT FACULTY | DESIGNATED EMPLOYEE |
|---|---|---|---|---|
| Not Submitted | 14% | 3% | 17% | 0% |
| Submitted | 86% | 97% | 83% | 100% |


© UAB. All Rights Reserved.

# II. NIH Data Management & Sharing Policy



## Why?

- **To promote the sharing of scientific data**
  - Increased rigor, transparency and reproducibility in research
  - Facilitate the development of treatments and products that improve human health
- **To ensure research data management begins in the planning stages**

## When?

**The new NIH policy becomes effective on January 25, 2023.**


© UAB. All Rights Reserved.

# Policy Scope – Does this apply to my grant?

All research funded by NIH that **generates scientific data,** including:

- ❑Extramural grants
- ❑Contracts
- ❑Intramural research projects
- ❑All other NIH funding mechanisms

Research Projects (Rs)
Some Career Development Awards (Ks)
Small Business SBIR/STTR
Research Centers

Policy does not apply to funding that does not generate data

Training (T)
Fellowships (Fs)
Construction (C06)
Conference Grants (R13)
Resource (Gs)
Research-Related Infrastructure Programs (e.g., S06)

# NIH DMSP Task Force formed by VPR office

Directive: Raise awareness, oversee implementation, and assess impact of the policy on UAB campus

**Jonathan Miller,** Associate VP for Research Regulatory Oversight, Office of Research (Task Force Chair)

**Peggy Biga, PhD,** Associate Professor Department of Biology, Chair of the Faculty Senate Research Committee

**Victor Darley-Usmar, PhD,** HSOM Senior Associate Dean For Research Compliance and Administration

**Marla Hertz, PhD,** Associate Professor and Research Data Management Librarian, UAB Libraries

**Jereme Logan, JD,** Associate Risk and Compliance Officer, Office of Compliance and Risk Assurance

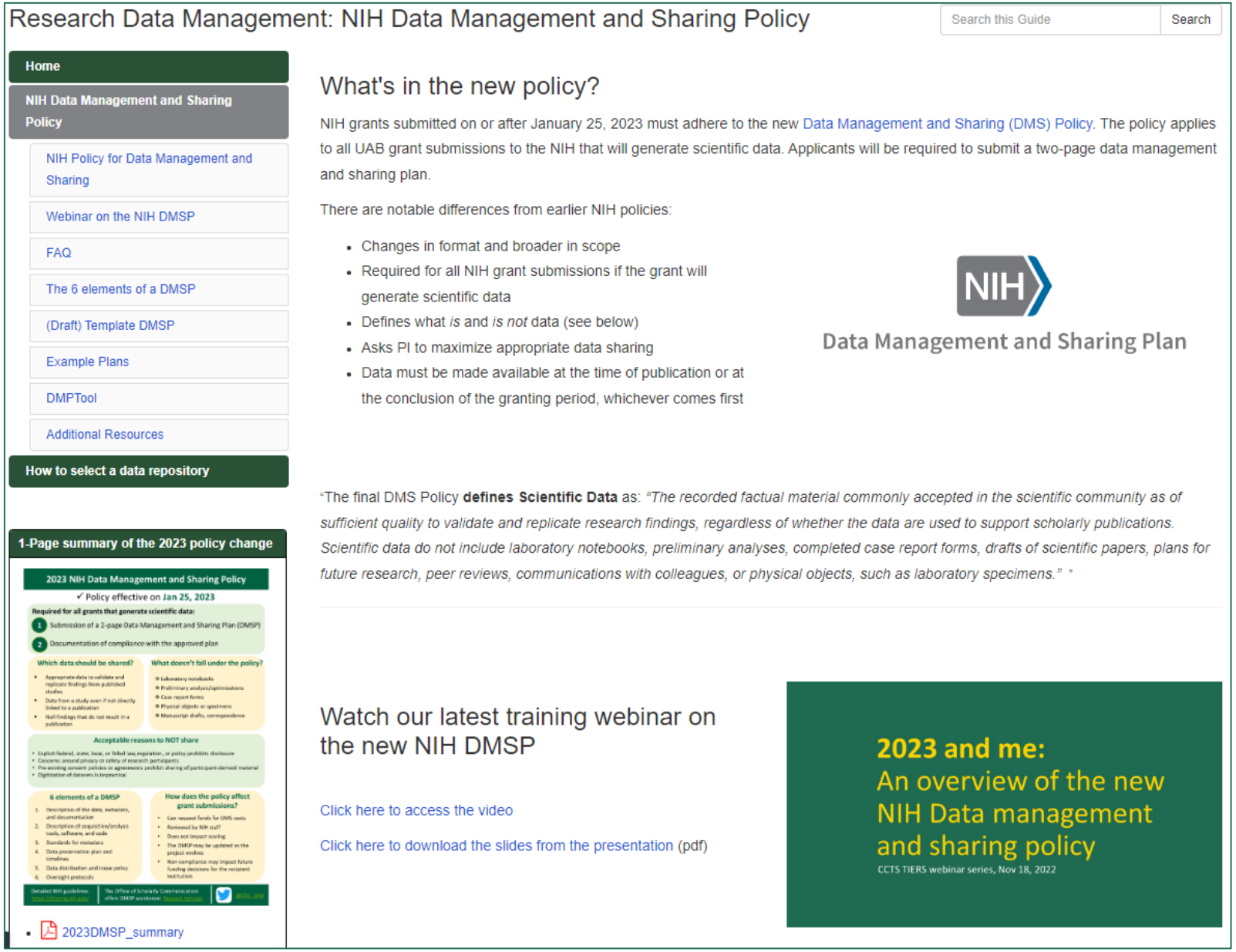
**Mike Matthews,** Interim AVP for Research Business Operations, Office of Research

**Ralph Zottola, PhD,** Assistant Vice President, Research Computing

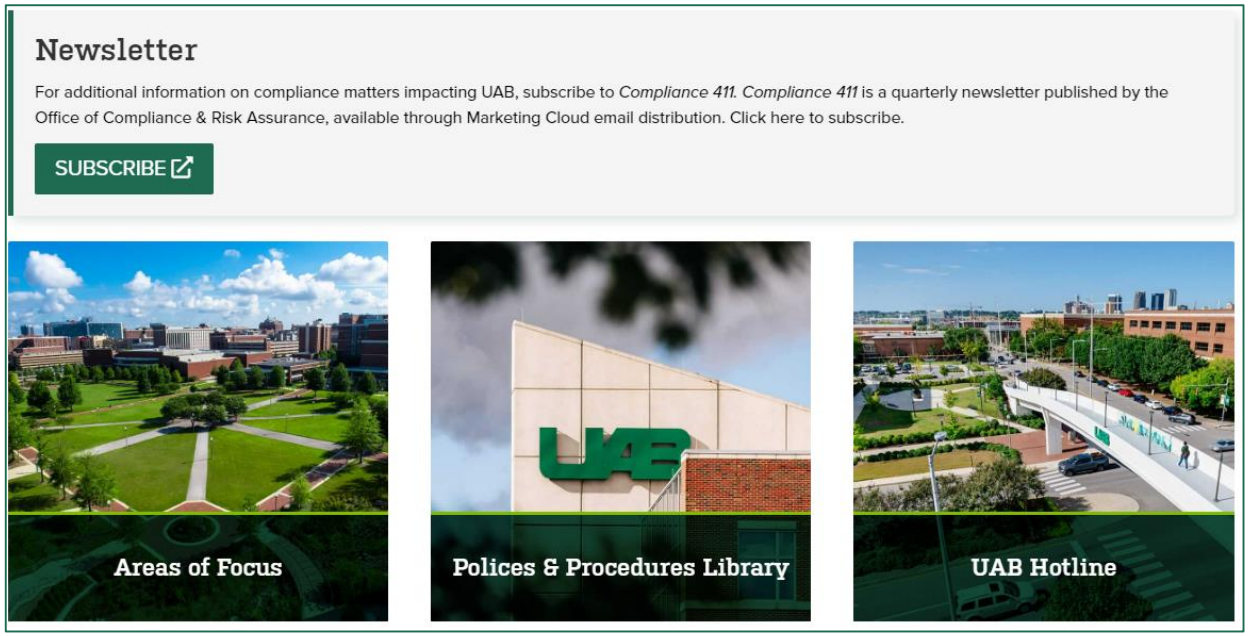
# UAB Resources

# UAB Resources

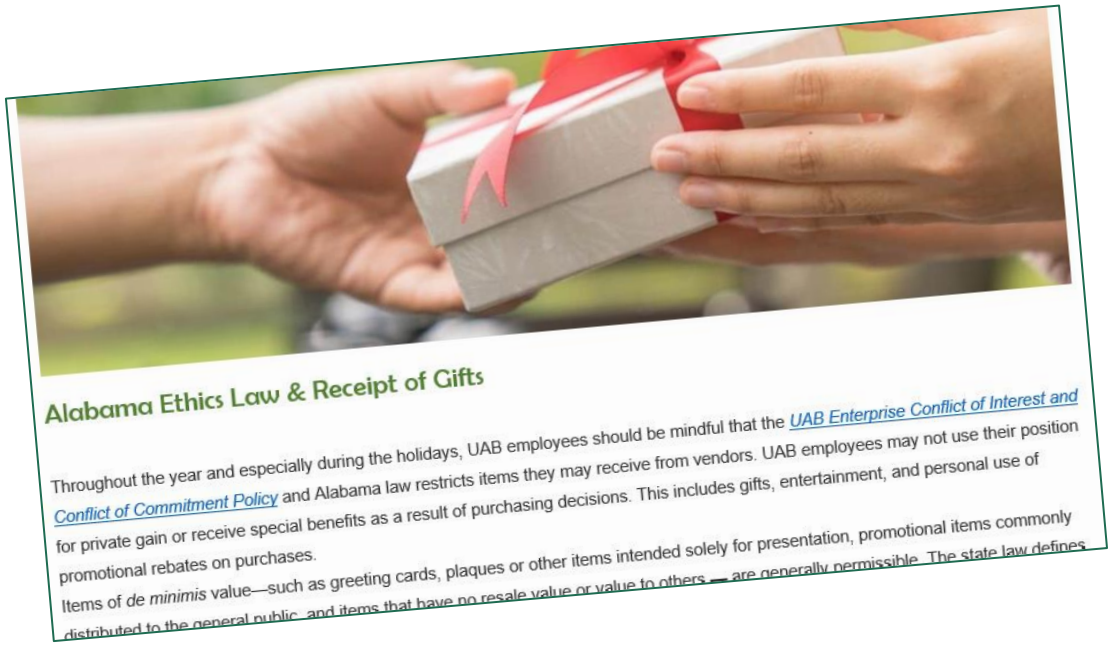
- Contact the Office of Scholarly Communication to request instruction or consultations on
  - Preparing a DMSP
  - Finding an appropriate data repository
- UAB Libraries' online guide to the policy and example DMSPs
- Central NIH website and AAMC resources on data sharing policies
- OSF resource toolkit



# III. Compliance 411




**Subscribe at uab.edu/compliance**



# Office of Compliance & Risk Assurance


**Phone: 205.996.6540**

**Address: 701 20th Street South, AB990**

**Email: jcl@uab.edu**

**Website: www.uab.edu/compliance**





© UAB. All Rights Reserved.

# Oncore Team Updates

Mackenzie Roberts

OnCore System Administrator

# OnCore Updates

- OnCore Financials
  - Introducing Lauren Bryant
  - New email address for OnCore Financials: oncorefinancials@uabmc.edu
- OnCore Weekly Q & A Sessions
  - Include Shay Chambless (OnCore Trainer), Mackenzie Roberts (System Administrator/Billing Liaison) and Lauren Bryant (Financial Analyst)
  - Tuesdays
  - 11:00 AM – 1:00 PM
  - Zoom link: https://uab.zoom.us/j/81006916371

# OnCore Updates

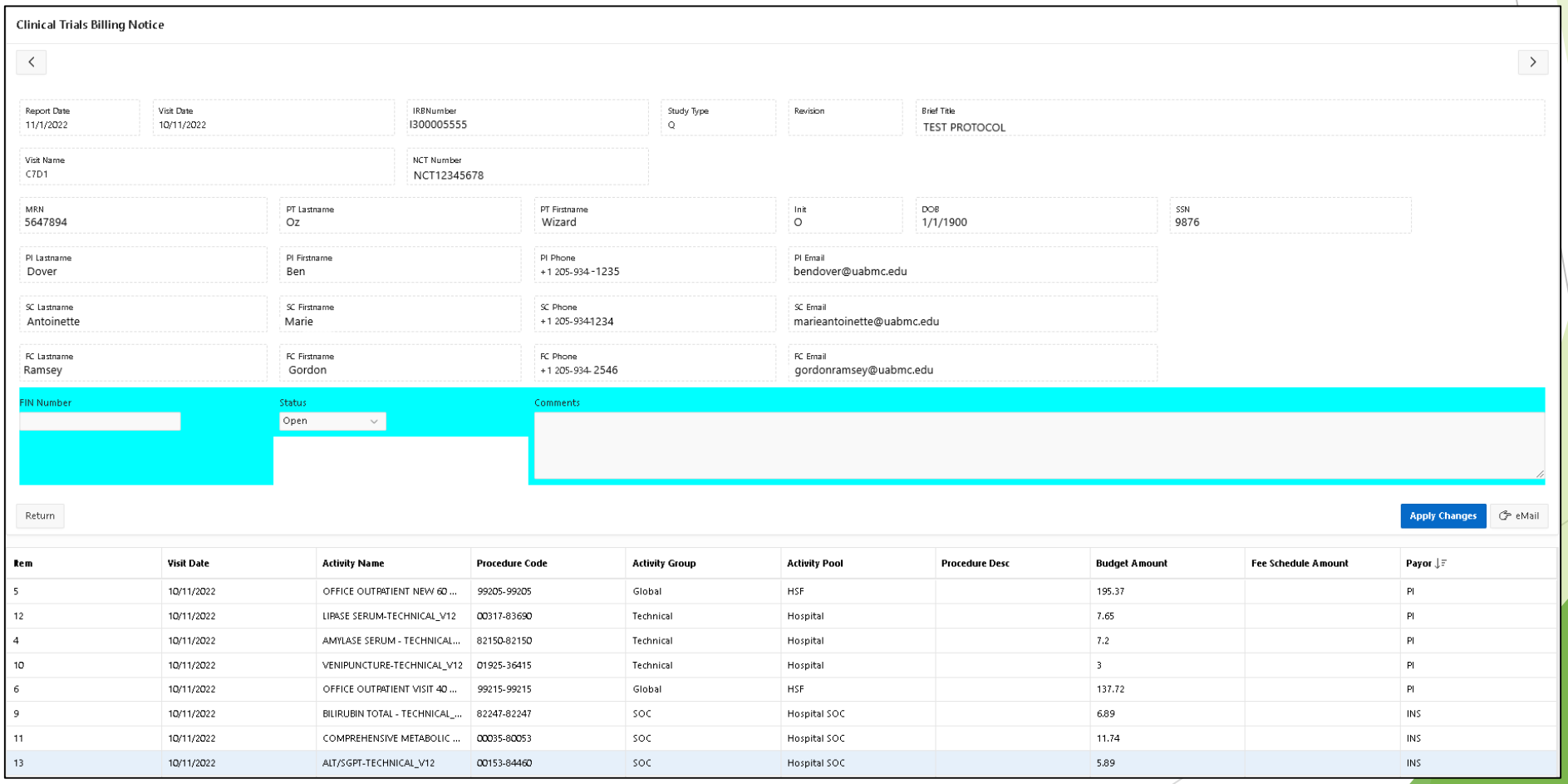
- Updates and Reminders:
  - Investigational Pharmacy
    - Added to OnCore as a Management Group
    - IDS Pharmacy Management Group will be added to all studies which noted use of the Research Pharmacy in REDCap submission
    - Allows pharmacy to run reports from OnCore on studies that are marked active or have been closed out - ***Please remember to update your study status in the system***
  - IRB Study Closure Status
    - If the study status = "IRB STUDY CLOSURE," the study team needs to move the subjects to “Off Study.” This does not happen automatically - ***Please note that if the subjects are not moved to “Off Study” they will show up in IMPACT as participants in an active trial.***

# OnCore Updates

- Updates and Reminders:
  - Study Abandoned/Terminated
    - Please let OCS know if the study has been abandoned or terminated during the start-up process. This allows for more focus on higher priority studies.
  - OnCore Visit Management
    - Visits should be occurred within 48 hours from time of service
    - ECGs, ECHOs, and hospital labs are services can bill out in 48 hours or less
    - If you know you will have to occur a visit late, please email the billing offices so that they can hold the charges
      - MSO/Professional Services
        - ctbillingquestions@uabmc.edu
      - PFS/Hospital Services
        - Donna Simpson dsimpson@uabmc.edu (Team Supervisor)

# OnCore Updates

- Updates and Reminders:
  - New CTBN Database (CTBN Central) available to coordinators!



Clinical Trials Billing Notice

| | |
|---|---|
| Report Date | 11/1/2022 |
| Visit Date | 10/11/2022 |
| IRBNumber | I300005555 |
| Study Type | Q |
| Revision | |
| Brief Title | TEST PROTOCOL |
| Visit Name | C7D1 |
| NCT Number | NCT12345678 |
| MRN | 5647894 |
| PT Lastname | Oz |
| PT Firstname | Wizard |
| Init | O |
| DOB | 1/1/1900 |
| SSN | 9876 |
| PI Lastname | Dover |
| PI Firstname | Ben |
| PI Phone | +1 205-934-1235 |
| PI Email | bendover@uabmc.edu |
| SC Lastname | Antoinette |
| SC Firstname | Marie |
| SC Phone | +1 205-934-1234 |
| SC Email | marieantoinette@uabmc.edu |
| FC Lastname | Ramsey |
| FC Firstname | Gordon |
| FC Phone | +1 205-934- 2546 |
| FC Email | gordonramsey@uabmc.edu |

FIN Number | Status: Open | Comments

Return | Apply Changes | eMail

| Item | Visit Date | Activity Name | Procedure Code | Activity Group | Activity Pool | Procedure Desc | Budget Amount | Fee Schedule Amount | Payor |
|---|---|---|---|---|---|---|---|---|---|
| 5 | 10/11/2022 | OFFICE OUTPATIENT NEW 60 ... | 99205-99205 | Global | HSF | | 195.37 | | PI |
| 12 | 10/11/2022 | LIPASE SERUM-TECHNICAL_V12 | 00317-83690 | Technical | Hospital | | 7.65 | | PI |
| 4 | 10/11/2022 | AMYLASE SERUM - TECHNICAL... | 82150-82150 | Technical | Hospital | | 7.2 | | PI |
| 10 | 10/11/2022 | VENIPUNCTURE-TECHNICAL_V12 | 01925-36415 | Technical | Hospital | | 3 | | PI |
| 6 | 10/11/2022 | OFFICE OUTPATIENT VISIT 40 ... | 99215-99215 | Global | HSF | | 137.72 | | PI |
| 9 | 10/11/2022 | BILIRUBIN TOTAL - TECHNICAL_... | 82247-82247 | SOC | Hospital SOC | | 6.89 | | INS |
| 11 | 10/11/2022 | COMPREHENSIVE METABOLIC ... | 00035-80053 | SOC | Hospital SOC | | 11.74 | | INS |
| 13 | 10/11/2022 | ALT/SGPT-TECHNICAL_V12 | 00153-84460 | SOC | Hospital SOC | | 5.89 | | INS |

# OnCore Updates

- If you would like access, please contact Mackenzie Roberts mstanford@uabmc.edu for training. Access will be requested following training.
- Training will be offered during the Oncore Q & A session
  - If you cannot make it during that time, we can do a one-on-one session
- SMR will run concurrently with CTBN Central until January 9, 2023 before officially becoming the CTBN database

# IRB Updates & Current Events
*CCTS Lunch & Learn*

Christina R. Blackmon | Education and Outreach Specialist
Office of the Institutional Review Board

# IRB Update Topics

1. New resources
    - New IRB Policies and Procedures resource document
    - CCTS Video: “Common IRB Submission Problems to Avoid”
2. Virtual Office Hours

# IRB Policies and Procedure

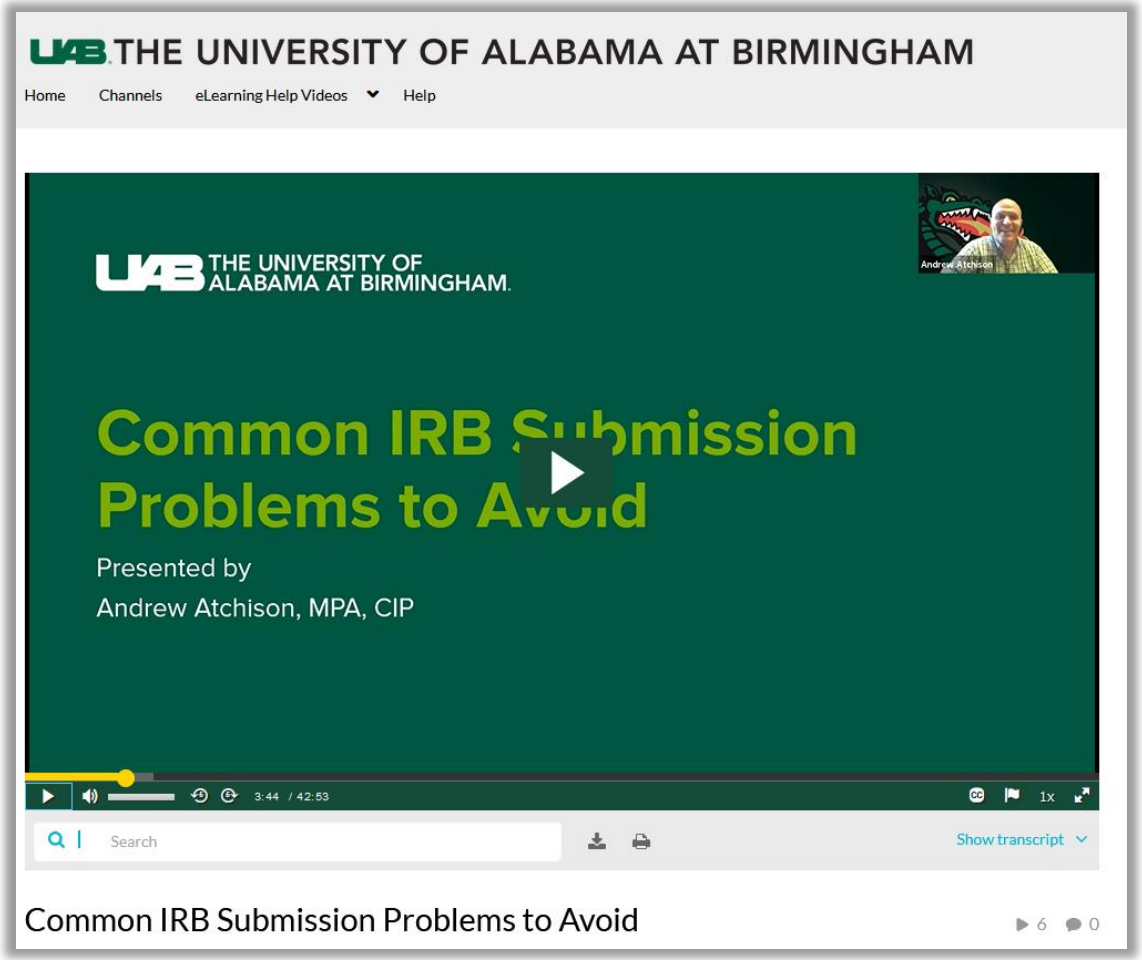
New compilation PDF document of the IRB Policies and Procedures

- Created to be a helpful resource for the UAB research community
- Organized based on common IRB topics
- Formatted with hyperlinks to easily take you to the topic, policy or procedure you are looking for
- Will be posted on the IRB website beginning January 1, 2023

# “Common IRB Submission Problems to Avoid” Video

Training on common submission errors that we see in the Office of the IRB when reviewing applications.

- CCTS Video Channel
  - https://mediaspace.uab.edu
  - Search “Common IRB Submission Problems to Avoid”



# OIRB Virtual Office Hours

The Office of the Institutional Review Board (IRB) is holding virtual office hours to augment current services as an opportunity for members of the UAB research community to have direct access to an experienced OIRB staff member.

- Held bi-weekly on Thursdays.
- 11:00 AM to 1:00 PM
- Next session will be Thursday, January 19, 2023
- For Zoom meeting information, search UAB Campus Calendar for "**Office of the IRB Virtual Office Hours"** or join the OIRB Listserv for Zoom information

CCTS
Center for Clinical and Translational Science

# Center for Clinical and Translational Science

## Benefits of the UAB Green Labs Program

**Nick Ciancio, Sustainability Coordinator**
**Emily Colpack, Green Labs Coordinator**

ACCELERATE. INNOVATE. DISSEMINATE. **WITH YOUR CCTS.**

# What is a ‘Green Lab’?

- A “Green Lab” is a lab dedicated to sustainable research methods, achieved by reducing energy, water, and waste while not compromising research safety or integrity.
- UAB is the first major institution in the state of Alabama to implement a Green Labs Program.
- The Green Labs Program is UAB’s first comprehensive initiative to reduce waste and energy in labs. UAB has joined many universities to implement waste and energy consumption in labs, including:
  - Harvard University
  - University of California-Berkeley
  - Emory University
  - University of Georgia
  - University of Colorado-Boulder

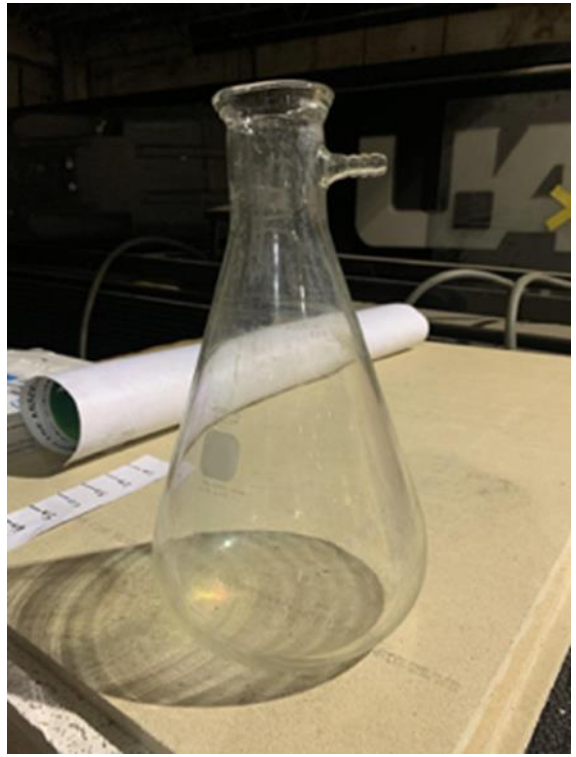
UAB GREEN LABS

# Freezers

- UAB won International Laboratory Freezer Challenge two consecutive years in the academic sector
- Green Labs will clean and replace freezer filter *for free*! Our team will also clean freezer coils for free!
- Five floating freezers across campus for labs to defrost individual lab freezers— Reserve using the link below!

# Glass Free Shelf

- Thousands of pieces of lab-grade glassware
- Valued at tens of thousands of dollars
- Free for all labs at UAB!
- No limit to amount of glass requested!
- Make an appointment to pick up glass below (link in notes)



Email greenlabs@uab.edu to get involved!

Thank you for joining!

CCTS

# PowerTrials Updates

## 12/13/2022

# SmartZone: Research: On Study

Released on
November 10!!!

**WHAT?**

- **An alert for Providers that displays noncritical, patient-relevant notifications**

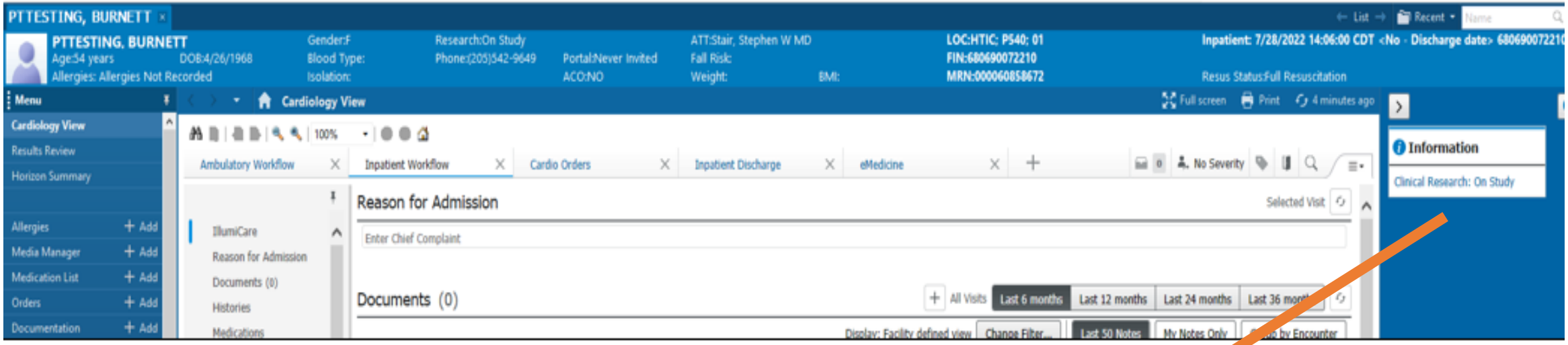
**WHEN?**

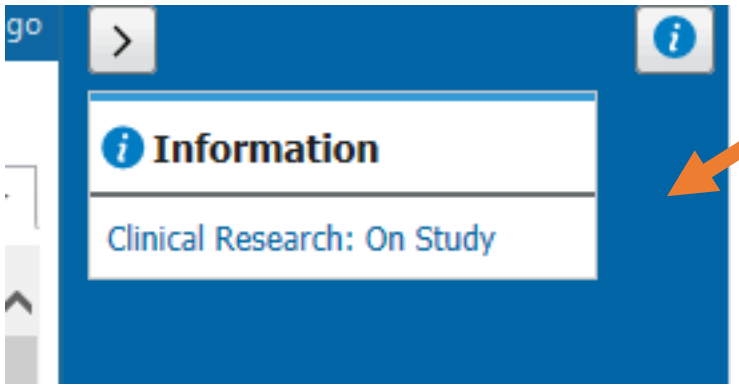
- **When a Research: On Study patient is seen at UAB Hospital or Clinics.**

**WHY?**

- **With this alert, we hope to improve provider utilization of the Research Summary (a short summary of the clinical trial that includes potential Toxicities/Side Effects, Cautions for treatment, and research team contact details) PRIOR to a patient's treatment.**

# SmartZone: Research: On Study



## Clinical Trial Summary

**Title of Protocol:**
A Phase 1 Study of SC-011 as a Single-Agent and in Combination with ABBV-181 in Subjects with Relapsed or Refractory Small Cell Lung Cancer

**Purpose/Objective of Study:**
This study will evaluate the safety, tolerability, toxicity and phase 2 dose of SC-011 alone or in combination with ABBV-181 in patients with small cell lung cancer.

**Study Agent(s) and Mechanism of Drug Action/Device Description:**

**SC-011** – This is an antibody drug conjugate consisting of antibody targeting SC17 and calicheamicin DNA cross-linking agent bound to a linker. This will bind to Seizure related homolog 6 (SRH6) receptor and lead double strand breaks in DNA and apoptosis and cell death.
**ABBV-181** – This is a Program Death – 1 receptor antibody (anti PD-1) which activates T cells in the tumor microenvironment which releases cytokines that act against tumor cells.

**Toxicities/Side Effects:**
**SC-011** - Possible side effects are liver injury, cytopenias, kidney injury, neuropathies, ocular damage, pneumonitis, QTc prolongation and infusion related reaction.
**ABBV-181** is expected to have autoimmune toxicities like other immunotherapy drugs and these include pneumonitis, dermatitis, colitis, hypothyroidism, hepatitis, sciatica, adrenalitis, pancreatitis, and anemia.

**Caution:**

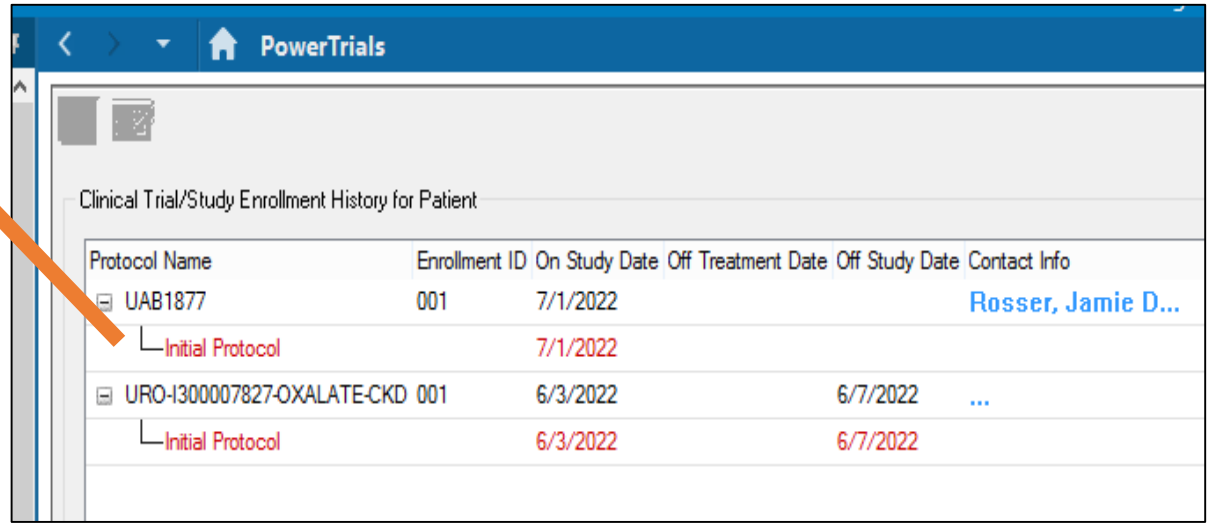
As with any autoimmune condition, treatment of choice for such agent associated autoimmune toxicities is JUDICIOUS USE OF CORTICOSTEROIDS. Steroid administration may potentially abrogate the therapeutic effect of the study agent, and potentially exclude the patient from the study.
Myeloid growth factor and transfusion support is discouraged in the DLT period (within Cycle 1 = 28 days from start of treatment) unless it is medically indicated. After Cycle 1, growth factors or transfusions may be administered according to institutional standards

***In cases of serious medical conditions, including study agent related toxicity, all patients should be treated as per Standard of Care guidelines***

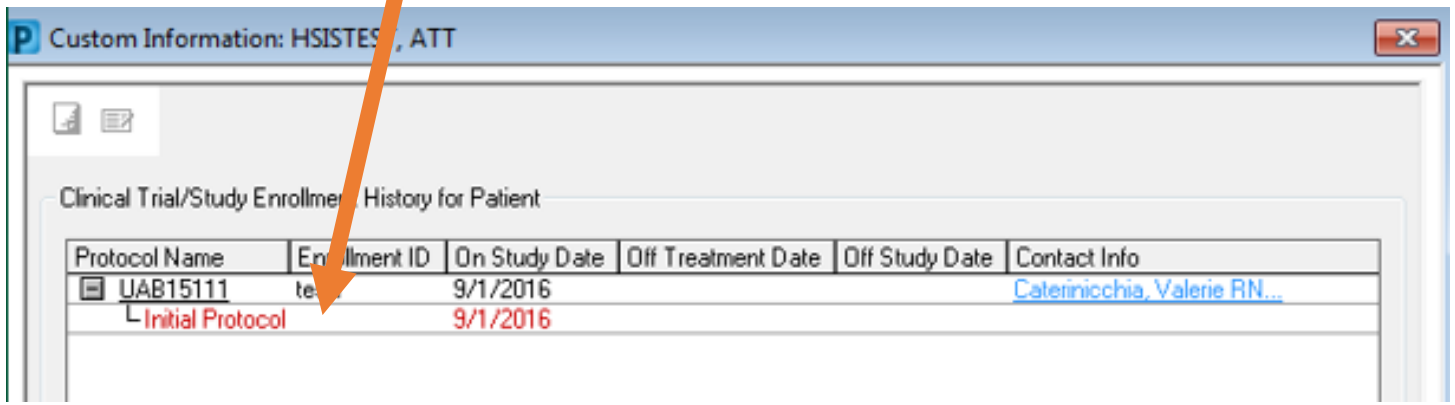
***Please contact PI or study team ASAP.***

**PI name: Francisco Robert, MD**

**PI contact number:205-934-3411 (pager #8193)**



# Banner Bar: Research: On Study




Email to confirm your study has a research summary: powertrials@uabmc.edu

# PROXY MESSAGE CENTER

- **Are you going to be out of the office for an extended amount of time?**
- **Is your coworker/staff out of the office suddenly for an extended amount of time?**

**How will you know when a research patient is admitted for AE reporting?!**

- **Proxy Message Center!**
- **Contact hsispowertrials@uabmc.edu for detailed instructions**

# Oncore Staff Updates

**New Coordinator or PI taking over a study?**

1. **Enter a stop date for previous staff or change to Study Coordinator-Secondary.**
2. **Add new Study Coordinator (there can only be 1!)**
3. **Email oncore@uabmc.edu and powertrials@uabmc.edu**

**Additional steps have to be performed manually by the Oncore and PowerTrials admins.**

**Cerner will not be updated unless these functions are performed.**

**Contact oncore@uabmc.edu if you have further questions about updating staff in Oncore.**

# DON'T FORGET!!!!!!

**VALIDATE THE ONCORE CALENDAR** **(check for send out labs!!)**

**OFF STUDY** Patients in Oncore and **DISCONTINUE** the PowerPlan. Why does it matter?

- As long as the patient is On Study, the study coordinator and PI will continue to receive the admission notifications.
- Tracking billing and charges correctly.
- Amendments and updates.

**UPDATING STAFF IN ONCORE**

- If you need to change the study coordinator or PI for any reason, email oncore@uabmc.edu and powertrials@uabmc.edu to alert both teams of the changes
- Ensuring that the correct study team member receives the admission notifications

**GREEN SHEETS** for labs if **not** using PowerTrials PowerPlan

CCTS

# PowerTrials Updates
## 4/12/22

Alicia Martin-Gunter, RHIA
PowerTrials Administrator
(205) 504-5579 office
abmartin@uabmc.edu

Angel Elliott, MSN, RN
PowerTrials Administrator
(205) 346-3013 office
ansanders@uabmc.edu

Shannon Roper, BSN, RN
PowerTrials Administrator
(205) 542-9649 office
sroper@uabmc.edu

hsispowertrials@uabmc.edu

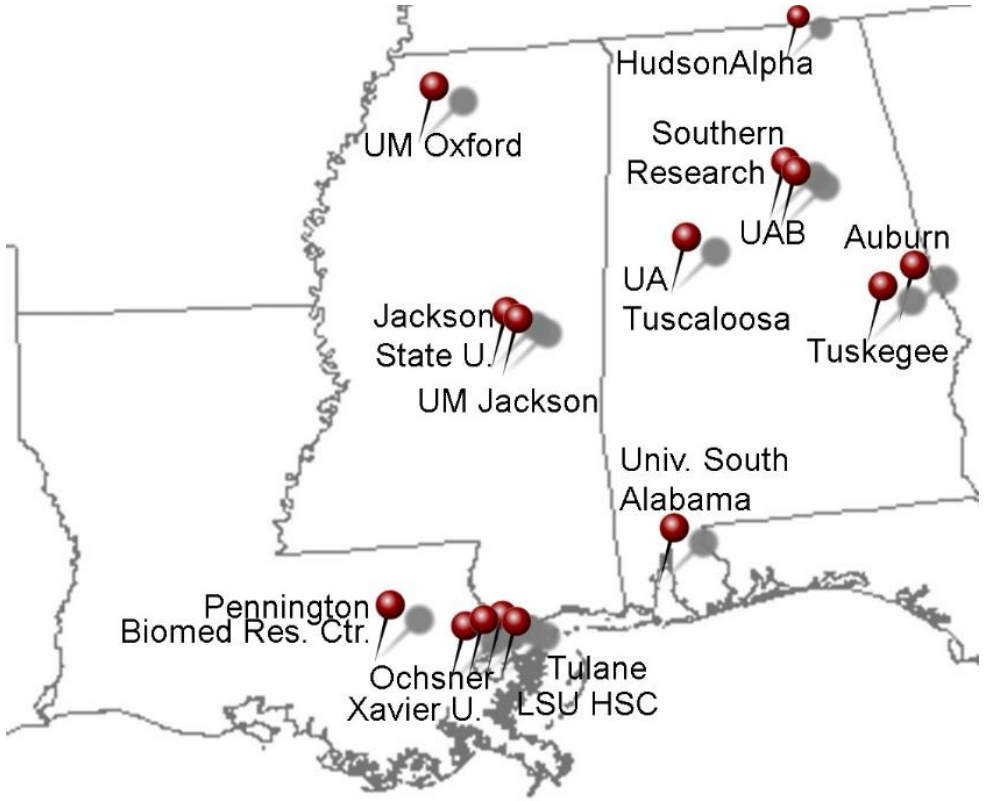
powertrials@uabmc.edu

# Travelers Badge


Rebecca Hardin

HSF Education Specialist

# *Questions & Discussion*




CCTS

Center for Clinical and Translational Science