



## *CCTS Lunch and Learn* *April 13, 2021*



*Science through Synergy*



# 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.





## Upcoming Events

- **Research Seminar Series**

*April 15, 2021: Staying Engaged and Motivated, Morale Boosters, Managing Burnout*

*May 6, 2021: Recruitment and Retention*

*May 20, 2021: IRB e-Portfolio*

*June 3, 2021: CCTS Website Navigation with CCTS Staff/Brainstorming Topics for Fall 2021*

- **Research Training Program**

*April 13, 2021-May 18, 2021*

- **Research Orientation Program**

*May 20, 2021*





# Agenda

## Lunch And Learn

- ***Upcoming Events/CCTS Website Navigation*** – Meredith Fitz-Gerald
- ***Introduction-*** Dr. Robert Kimberly
- ***OSP -*** Debbie Graves
- ***IRB*** – Christina Blackmon
- ***CTAO -*** Mark Marchant
- ***CTAO/CBR-*** Ashley Knight Specht
- ***CBO -*** Mackenzie Roberts
- ***OnCore-*** John Sandefur
- ***PowerTrials-***Alicia Martin-Gunter





# Clinical Trials Initiative

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

---

## **CENTER FOR CLINICAL & TRANSLATIONAL SCIENCE**

AUBURN UNIVERSITY | HUDSONALPHA INSTITUTE FOR BIOTECHNOLOGY | LOUISIANA STATE UNIVERSITY HEALTH SCIENCES CENTER | PENNINGTON BIOMEDICAL RESEARCH CENTER | SOUTHERN RESEARCH  
TULANE UNIVERSITY | TUSKEGEE UNIVERSITY | UNIVERSITY OF ALABAMA | UNIVERSITY OF ALABAMA AT BIRMINGHAM | UNIVERSITY OF MISSISSIPPI MEDICAL CENTER | UNIVERSITY OF SOUTH ALABAMA



# Clinical Trials Initiative

Service Level Expectations for PowerPlan development and production

- Document approved by the OnCore/PowerTrials Oversight Committee, 4/9/21

Timeliness of “occurring” visits in OnCore

- 48 hr expectation (Sandy Peterson’s office); Oversight Committee, 4/9/21

Recruitment working group initiative (CTAC mtg, 4/7/21))

- Recruitment plans/people/tools

Update on Hospital LOA for device trials (scheduled for 4/23/21)

- Updated Chargemaster, anticipated by the end of April





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

Debbie Graves  
Training Coordinator, OSP

---

## CENTER FOR CLINICAL & TRANSLATIONAL SCIENCE

AUBURN UNIVERSITY | HUDSONALPHA INSTITUTE FOR BIOTECHNOLOGY | LOUISIANA STATE UNIVERSITY HEALTH SCIENCES CENTER | PENNINGTON BIOMEDICAL RESEARCH CENTER | SOUTHERN RESEARCH  
TULANE UNIVERSITY | TUSKEGEE UNIVERSITY | UNIVERSITY OF ALABAMA | UNIVERSITY OF ALABAMA AT BIRMINGHAM | UNIVERSITY OF MISSISSIPPI MEDICAL CENTER | UNIVERSITY OF SOUTH ALABAMA



## UAB Proposed Composite Fringe Benefit Rates for FY 2021-2022

- UAB Financial Affairs released new rates for 2021-2022
- Can be used currently for all proposal submissions except federal contracts
- Once approved by DHHS, will be incorporated into our F&A rate agreement
- Can find the rates on FA website:

<https://www.uab.edu/financialaffairs/paying/compensation/composite-fringe-benefits>





## **30-Day Notification Required if Submitting SBIR/STTR Proposal**

- PIs participating as sub in SBIR/STTR proposal with small business concern (SBC) should submit notification of intent to submit e-form 30 days prior to due date of proposal
- E-form allows central administrative units to perform due diligence in regard to SBC partner and ensure appropriate agreements are in place related to UAB IP
- Draft proposal (and other required documents) still due 5 business days prior to SBC's anticipated submission date



## Federal Submission Updates: NIH Other Support and Biosketch Updates

- NIH updated templates for Other Support and Biosketches
- Updated forms will be required for applications and RPPRs for due dates on or after May 25, 2021
- New **Biosketch form** – can use immediately (see NIH Biosketch page for form and instructions)
- New **Other Support form** – can begin using May 3, 2021 or use current UAB form until May 25, 2021 (current UAB template and instructions on UAB Transparency in Research website)
- Upcoming announcement and town hall(s) forthcoming regarding new form
- Transparency in Research website will be updated soon to reflect changes



# General OSP Reminders

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

Office of Research

[Home](#) [IRAP](#) [IRAP Training](#) **[Research Matters](#)** [e-Reports](#) [Frequently Asked Questions](#) [Contact Us](#)

[Learn more about UAB's COVID-19 health and safety policies, vaccine information, and our mission to help fight COVID-19](#)

**Research Matters**

- [Subscribe to the Research Matters Newsletter](#)
- [Subscription Center](#)
- [Request Publicity](#)
- [Research Matters Archive](#)

**Research Matters**



Research Matters is a weekly newsletter designed to effectively inform the UAB research community of important updates that affect research administration. Research Matters will replace the Research Digest, and will be published each Wednesday. If you would like your news item or event to be included in Research Matters, the publicity request form can be found at [Research Matters Publicity Request Form](#).

Research Matters is published every Wednesday. So please submit your publicity request by or before 5:00 PM of the preceding Friday.

For additional information about Research Matters, please contact Mike Matthews at [mimatti@uab.edu](mailto:mimatti@uab.edu).



# General OSP Reminders

- OSP training is ongoing through Zoom – register through Campus LMS; current schedule and registration instructions on OSP Training webpage

Knowledge Base

OSP Home | Knowledge Base | Training Courses

**Training Courses**

Training Videos

IRAP Training

FDP Previous Meetings

Standards and Compliance

Transparency in Research

Proposal Submission Requirements

Facilities and Administrative Costs

Federal Information Security Management Act (FISMA)

Frequently Asked Questions

Announcements

### Training Courses

With the recent announcement of UAB's cancellation of in-person classes and non-essential university meetings, gatherings and events on campus, all OSP training sessions (except computer lab sessions) will be held virtually until further notice.

You will register in the Campus LMS for all OSP courses. See below for specific instructions. Then, in the "My Courses and Assignments" area, you will find the [Link to Join the Webinar](#).

Computer lab sessions will be postponed until further notice.

**Note:** A Zoom account isn't 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. The phone number(s) will be included in the email invitation.

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.

[ [dgraves@uab.edu](mailto:dgraves@uab.edu) | (205) 934-1408 ]



# IRB Updates & Current Events

## *CCTS Lunch & Learn*

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

---

### **CENTER FOR CLINICAL & TRANSLATIONAL SCIENCE**

AUBURN UNIVERSITY | HUDSONALPHA INSTITUTE FOR BIOTECHNOLOGY | LOUISIANA STATE UNIVERSITY HEALTH SCIENCES CENTER | PENNINGTON BIOMEDICAL RESEARCH CENTER | SOUTHERN RESEARCH  
TULANE UNIVERSITY | TUSKEGEE UNIVERSITY | UNIVERSITY OF ALABAMA | UNIVERSITY OF ALABAMA AT BIRMINGHAM | UNIVERSITY OF MISSISSIPPI MEDICAL CENTER | UNIVERSITY OF SOUTH ALABAMA

# What Is The IRB Up To?

1. Issuing Revisions to the IRB Smart Forms
2. Continuous Improvement
3. Building Training Resources





# Revisions to IRB Smart Forms



- Based on survey feedback received by the Office of the IRB
- Revisions are in process for the following smart forms:
  - IRB ePortfolio
  - Continuing Review
  - Revision/Amendment,
  - SIRB Site Addition Amendments
  - Personnel eForm
- Highlights of form revisions include:
  - Enhanced formatting capabilities on several free text questions in the ePortfolio
  - Revised instructions for submitting amendments within the ePortfolio
  - Addition of an inclusion/exclusion criteria question in the ePortfolio
  - Clarification of several questions across all revised forms





# Revisions to IRB Smart Forms



## Things to Keep in Mind

- Revisions to the smart form may mean that any form changes will populate when you re-open the form for further revision.
  - Please review the entire form for unanswered questions before submitting your revisions.
- The ePortfolio is a “single threaded” application.
  - Processes must be completed in succession. (Example: An Amendment must be completed before a Continuing Review, so the information from one can be carried on to the next submission.)
- Users are not permitted to submit a Personnel Amendment, Continuing Review, or Revision/Amendment if a submission of the same type is still active.
  - Open submissions include those that have not received a terminal status (i.e., Approved, Exempt, Disapproved, Withdrawn)







# Continuous Improvement



## Future state

- Regular updates to the forms and system on at least a quarterly basis
  - Based on your ongoing input, feedback and suggestions
- Fully utilizing technology for other workflow and procedural improvements

## Future Smart Forms updates will include:

- Problem reports
- Requests to rely on an external IRB
- Humanitarian use devices (HUDs)
- Other expanded access requests





# Training Resources for IRB Smart Forms

IRB Smart Forms Resource Hub: <https://go.uab.edu/eportfolio>

- Types of Resources Available
  - Step-by-step how to documents
  - Frequently asked questions (FAQs)
- Future Resources
  - Video-based how-to resources
  - Learning libraries for stakeholder groups
  - Other resources based on community needs





## Helpful Tips/Reminders

- The Office of Research updated it's "Guidance for the Resumption of Human Subjects Research Activities" document.
- When creating a response, to edit the smart form, uncheck the "complete" checkbox in the upper right corner.





# Updates on Clinical Trials Initiatives

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

---

## CENTER FOR CLINICAL & TRANSLATIONAL SCIENCE

AUBURN UNIVERSITY | HUDSONALPHA INSTITUTE FOR BIOTECHNOLOGY | LOUISIANA STATE UNIVERSITY HEALTH SCIENCES CENTER | PENNINGTON BIOMEDICAL RESEARCH CENTER | SOUTHERN RESEARCH  
TULANE UNIVERSITY | TUSKEGEE UNIVERSITY | UNIVERSITY OF ALABAMA | UNIVERSITY OF ALABAMA AT BIRMINGHAM | UNIVERSITY OF MISSISSIPPI MEDICAL CENTER | UNIVERSITY OF SOUTH ALABAMA



## Uber Health

- New process being expanded from UAB Medicine to research participants
- Provides rides to qualifying participants to/from research visits
- Utilizes P-Cards to schedule and pay for rides
- Contact Mark at 934-2098 for account creation or questions
- More Information: <https://www.uab.edu/medicine/ctao/investigators/uber-rides>





## Monitor Access to Cerner

- Monitors able to gain remote access to defined patient list during pre-determined monitoring days to review source docs
- Process should be initiated at least 30 days prior to visit to ensure access
- Be sure to clearly communicate the process to the Monitor and set expectations relative to steps and timing
- <https://www.uab.edu/medicine/ctao/investigators/monitor-access-to-ehr>





# Shared Investigator Platform (SIP)

- Collaborative industry platform created by Transcelerate
  - Operational efficiency
  - Accelerate timelines
- Single Sign-on, Documents (site, study, lab, CVs), Safety Notifications, Training
- Pharma Companies: Amgen, Eli Lilly, Merck, Pfizer, Roche, et al
- Sites:
  - 97 Countries
  - 23,000+ Institutions
  - 100,000+ Users





## Shared Investigator Platform

- Cognizant: Vendor responsible for managing SIP
- UAB began working with Cognizant to create an institutional profile last year.
- Implementing therapeutic areas in a staged process based on industry priorities.
- Feel free to direct a Sponsor/CRO to the CTAO if contacted about registering.
- Profile registration ongoing with Anesthesiology, Cardiology, Endocrinology, Gastroenterology, Ophthalmology, Orthopedics, Psychiatry, & Surgery up next.





# CBR-CCTS-OCS

## Intake and Workflow

# Current Intake Process

Three different submissions with three different formats:

- **CBR** – download and complete a multi-tab Adobe PDF workbook, upload documents, email to [FAP@uab.edu](mailto:FAP@uab.edu)
- **CCTS** – download and complete a PDF document, send documents, email to [CCTSclinical@uab.edu](mailto:CCTSclinical@uab.edu)
- **OCS** – complete a REDCap request and upload documents

Study Teams may submit these request forms in any order, but work cannot begin in any order.

# New Intake Process

- One submission via REDCap using the survey queue feature.
- Multiple forms appear as one continuous submission; submitter only sees forms relevant to the particular submission, including:
  - Protocol and Administrative Information
  - Lab Questionnaire
  - Device Form
  - Flow Cytometry Form
  - CCTS Clinical Support Registration Form
- Users upload documents to forms.

*Exploring additional workflow changes to reduce the amount of administrative burden on study team.*

# New Intake Process

- Pilot underway
- We hope to have training dates available for the research community in the coming months.

# New Intake Process

- Pilot underway
- We hope to have training dates available for the research community in the coming months.

**UAB** THE UNIVERSITY OF  
ALABAMA AT BIRMINGHAM.

# Clinic Billing Office (CBO)

CBO Clinical Trials Manager: Mackenzie Roberts, CPC

## Reminders:

- Please make sure that your study staff is up to date and accurate in OnCore
- If you get an inquiry from the billing office about verifying a charge and the charge is standard of care, please specify as to whether that is conventional standard of care or protocol-driven standard of care.
- Validation of both PowerPlans and OnCore Calendar correctly and accurately will prevent billing issues in the future
- CBO has limited OnCore access and cannot assist in OnCore related questions

# Contact Info

- Clinical Billing Office (CBO):
  - Mackenzie Roberts, CPC
    - [mstanford@uabmc.edu](mailto:mstanford@uabmc.edu)
    - 205-731-5629
- PFS (Hospital):
  - [pfsctbillinginquiries@uabmc.edu](mailto:pfsctbillinginquiries@uabmc.edu)
- MSO (Professional):
  - [ctbillingquestions@uabmc.edu](mailto:ctbillingquestions@uabmc.edu)
- Customer service number for none clinical trials related billing inquiries:
  - 205-731-6055





# OnCore Updates

John Sandefur, MBA, MSHI  
OnCore Team Leader

---

## CENTER FOR CLINICAL & TRANSLATIONAL SCIENCE

AUBURN UNIVERSITY | HUDSONALPHA INSTITUTE FOR BIOTECHNOLOGY | LOUISIANA STATE UNIVERSITY HEALTH SCIENCES CENTER | PENNINGTON BIOMEDICAL RESEARCH CENTER | SOUTHERN RESEARCH  
TULANE UNIVERSITY | TUSKEGEE UNIVERSITY | UNIVERSITY OF ALABAMA | UNIVERSITY OF ALABAMA AT BIRMINGHAM | UNIVERSITY OF MISSISSIPPI MEDICAL CENTER | UNIVERSITY OF SOUTH ALABAMA



## OnCore Financials

**OnCore Financials** – Completion of training target is 7/1/2021.

Completed OnCore Financials Training	
# of Areas	# of Staff
29	58
as of April 6, 2021	





## OnCore Phase 2

**Phase 2** management groups –13 management groups listed below make up the Wave 2 rollout that will go live on May 1<sup>st</sup>. Wave 3 will go live August 1<sup>st</sup> and will complete the rollout to existing OnCore users.

Neuro-Oncology	URO/GYN
Dermatology-Clinical Research	Dermatology-Grants
OB/GYN-MFM	Nephrology Transplant
Neurosurgery-MC	Otolaryngology-MC
Urology-MC	Oral and Maxillofacial Surgery
Anesthesiology	Clinical Nutrition
Emergency Medicine	





# Billable Visits by Scheduled Visit Date Enterprise Studies

**08/01/2020 - 02/28/2021**

SCHEDULED MONTH	OUTSTANDING VISITS	OUTSTANDING BILLABLE VISITS	ALL VISITS	% OUTSTANDING VISITS	% OUTSTANDING BILLABLE VISITS
2020-8	65	42	1140	5.70%	3.68%
2020-9	106	72	1334	7.95%	5.40%
2020-10	175	106	1487	11.77%	7.13%
2020-11	146	65	1303	11.20%	4.99%
2020-12	175	113	1029	17.01%	10.98%
2021-1	151	102	796	18.97%	12.81%
2021-2	161	89	703	22.90%	12.66%
<b>Total</b>	<b>979</b>	<b>589</b>	<b>7792</b>	<b>12.56%</b>	<b>7.56%</b>





## QUESTIONS?

- Thank you! The OnCore Team appreciates the way in which individual study teams have worked with us to improve data quality and correct issues surrounding study visits in OnCore.
- If you have a question or require support, email [oncore@uabmc.edu](mailto:oncore@uabmc.edu). 3 OnCore Administrators monitor the inbox and will respond to requests.





## PowerTrials Updates 12/8/2020

Alicia Martin-Gunter, RHIA  
Power Trials Administrator  
(205) 996-8763 office  
[abmartin@uabmc.edu](mailto:abmartin@uabmc.edu)

Angel Elliott, MSN, RN  
PowerTrials Administrator  
(205) 996-3146 office  
[ansanders@uabmc.edu](mailto:ansanders@uabmc.edu)

*Science through Synergy*



# Amendments & the Research Summary

All treatment trials should have a research summary that is accessible through clicking the **Research: On Study** in the banner bar.

HSISTEST, ATT

Isolation:

Allergies: Latex, Paper, Sulfamag

Age:65 years

Portal:Active Account

Blood Type:O POS

Research:On Study

If you have an amendment that affects the **Toxicities/Side Effects** or **Cautions**, please submit an updated Research Summary to [powertrials@uabmc.edu](mailto:powertrials@uabmc.edu)





# Keeping OnCore Visit Workaid

**To ensure research charges are billed correctly, the OnCore calendar visit must be kept 24 – 48 hours post visit activity AND reflects the study procedures that were actually performed.**

**PowerTrials now offers a ‘Reviewing Completed Orders in Impact’ workaid with 2 options for checking the orders performed.**

**Great for non licensed coordinators that the PI is ordering through the PowerTrials PowerPlan.**







## POWERTRIALS PROCESS!!!!!!

1. **Research Coordinator** checks that the Oncore calendar is **correct** per the protocol's schedule of events
2. RC responds to the OnCore Calendar builders validation request email
3. When the OnCore Calendar team sends the OCS Calendar Marked Complete email, the PowerTrials team will be cc'd
4. PowerTrials team will evaluate if the study meets PowerTrials criteria (>3 orders, visits, and patients) and will email the RC

***If you delay in validating the Oncore calendar, you will experience delays in receiving your PowerTrials PowerPlan.***





## POWERTRIALS PROCESS!!!!!!

1. **Research Coordinator** checks that the Oncore calendar is **correct** per the protocol's schedule of events
2. RC responds to the OnCore Calendar builders validation request email
3. When the OnCore Calendar team sends the OCS Calendar Marked Complete email, the PowerTrials team will be cc'd
4. PowerTrials team will evaluate if the study meets PowerTrials criteria (>3 orders, visits, and patients) and will email the RC

***If you delay in validating the Oncore calendar, you will experience delays in receiving your PowerTrials PowerPlan.***





# DON'T FORGET!!!!!!

## VALIDATE THE ONCORE CALENDAR

### 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.

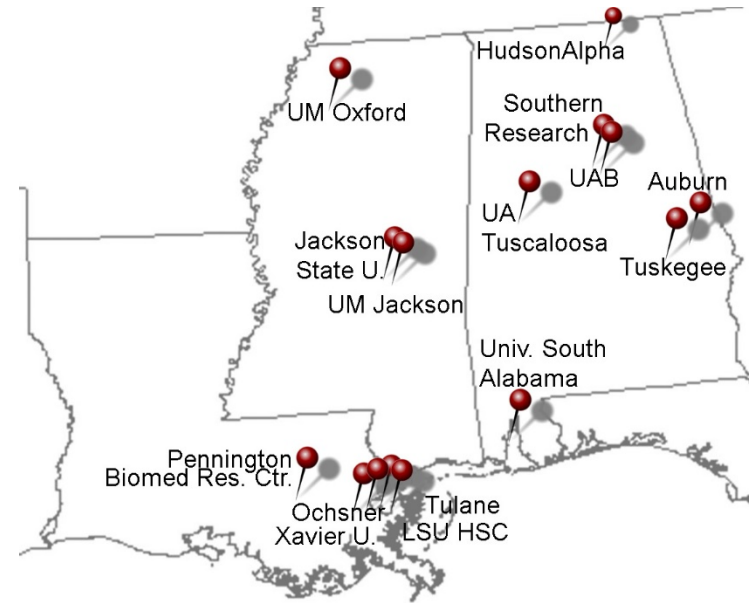
## UPDATING STAFF IN ONCORE

- If you need to change the study coordinator or PI for any reason, email [oncore@uabmc.edu](mailto:oncore@uabmc.edu) and [powertrials@uabmc.edu](mailto: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



# Questions & Discussion

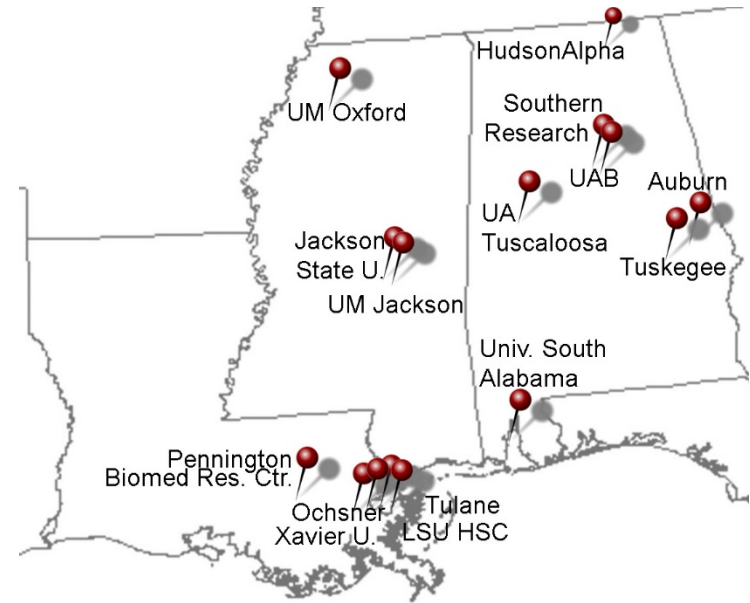


# CCTS

Center for Clinical and Translational Science



# Questions & Discussion



# Stay Connected



# CCTS

Center for Clinical and Translational Science

Search [Go]

CCTS Forms CCTS Quicklinks UAB Quicklinks

Partner Network Research Commons Training Academy Clinical Translation Engagement of Communities Special Modules News & Events About

**CCTS**  
Center for Clinical and Translational Science

### CCTS Opportunities at a Glance

Learning	Collaborations	Research
<ul style="list-style-type: none"><li>Clinical Data/2b2</li><li>I-Corps@NCATS</li><li>Drop-in Clinics</li><li>Friday Fellows</li></ul>	<ul style="list-style-type: none"><li>Partner Network</li><li>TriNetX</li><li>SHARe</li><li>SE SHRINE</li></ul>	<ul style="list-style-type: none"><li>Panels</li><li>Grant Library</li><li>Protocol Implementation</li><li>Find a Clinical Trial</li></ul>
Funding	Innovation	Impact
<ul style="list-style-type: none"><li>CCTS Pilots</li><li>Research Vouchers</li><li>Mini-Sabbaticals</li><li>Drug Discovery</li></ul>	<ul style="list-style-type: none"><li>Informatics Gateway</li><li>Kaizen Platform</li><li>Drugs/Devices (AD4)</li><li>I-Corps@NCATS</li></ul>	<ul style="list-style-type: none"><li>CCTS Achievements</li><li>Undiagnosed Diseases</li><li>Community Health</li><li>OnCore</li></ul>



[www.uab.edu/ccts](http://www.uab.edu/ccts)



205-934-7442



[ccts@uab.edu](mailto:ccts@uab.edu)



PCAMS – 1924 7<sup>th</sup> Ave South



[@cctsnetwork](https://twitter.com/cctsnetwork)



Search YouTube: [cctsnetwork](https://www.youtube.com/cctsnetwork)

*Science through Synergy*