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**

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Center for Clinical and Translational Science

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

- ***Upcoming Events***– *Meredith Fitz-Gerald*
- ***Introduction-*** *Dr. Robert Kimberly*
- ***Research Administration-*** *Jonathan Miller*
- ***Research Administration (Research Integrity Officer)****- Matt Ronning*
- ***OSP -*** *Debbie Graves*
- ***IRB –*** *Adam McClintock*
- ***CTAO*** *- Mark Marchant*
- ***PowerTrials****-Alicia Martin-Gunter*
- ***OnCore****- Lisa Williams*
- ***CTAO/CBR/CBO-*** *Ashley Knight Specht/Emily Bruer*
- ***ClinicalTrials.gov****- Tamara Howard*

Upcoming Events

- ***Research Seminar Series***

  January 6, 2022- COVID Updates with Dr. Michael Saag
- ***Research Training Program***

  April 18- May 24, 2022
- **Research Orientation Program**

  January 27, 2022
- **Clinical Investigator Training Program**

  February 22-March 29, 2022
- ***Lunch and Learn***

  April 11, 2022

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

THE CLINICAL TRIALS KIOSK:

EVERYTHING YOU NEED FOR CLINICAL TRIALS RESEARCH

Clinical research teams!

Get to know the Clinical Trials Kiosk, which provides vital information for investigators and study teams, including tools, guidelines, and resources for conducting clinical research.

The Kiosk hosts budgeting tools and guidelines, a collection of templates that can be modified for your area of expertise, and your specific clinical trial's needs, in order to aid in **Feasibility Assessment, Recruitment and Retention, Source Document creation**, and access to templates for **Standard Operating Procedures** for your department or division, and so much more!

VISIT GO.UAB.EDU/KIOSK

Questions about the Kiosk? Email **ccts@uab.edu** for more information.

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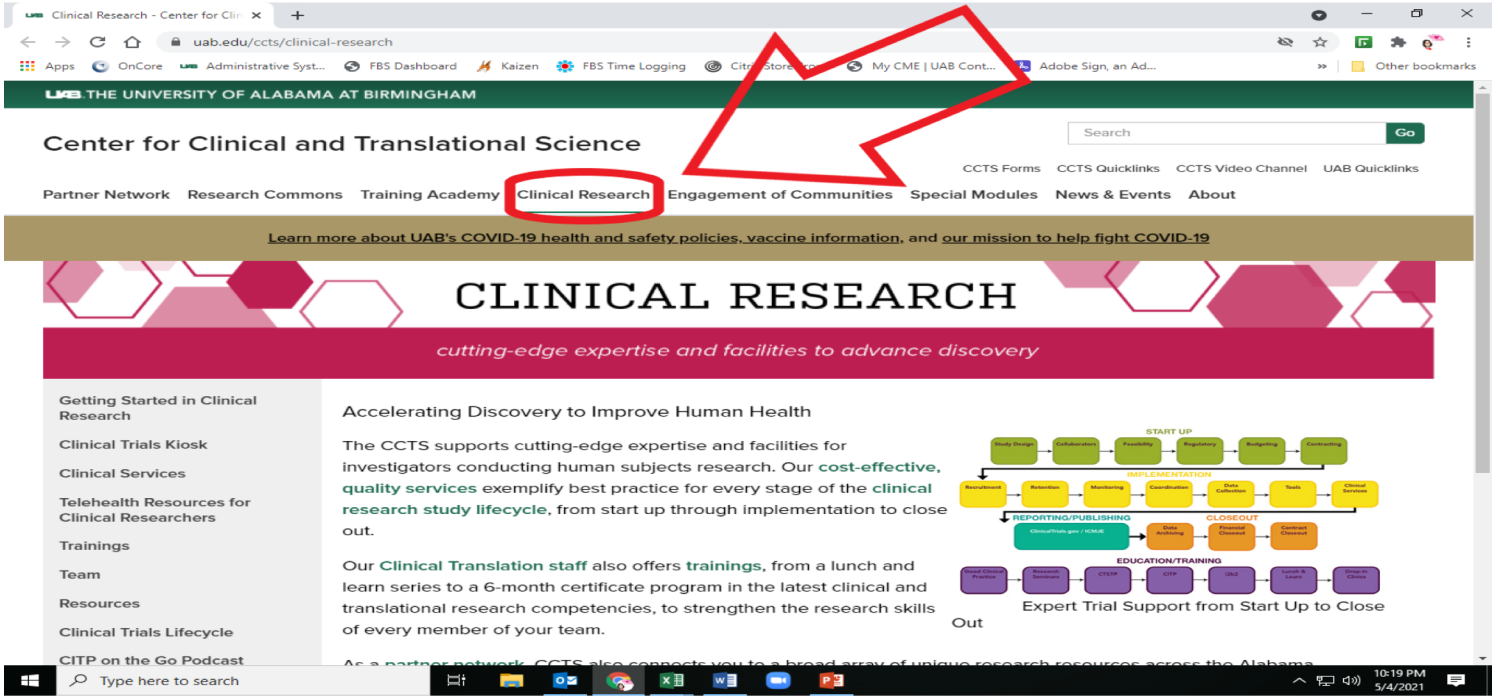
https://www.uab.edu/ccts/clinical-research/clinical-trials-kiosk



Contact

Meredith Fitz-Gerald, MSN
Director, Clinical Research Support Program
mfitzgerald@uabmc.edu
205-975-2758

Rhonda Corvalan
Nurse Research Manager, Clinical Research Support Program

WELCOME TO THE CLINICAL TRIALS KIOSK:

EVERYTHING YOU NEED FOR CLINICAL TRIALS RESEARCH

- UAB Research Administration Offices
- COVID-19 Support Documents & Resources
- Resources for Conducting Clinical Research
- Source Documents, Tools & Templates
- Investigator Toolkit
- Budget Toolkit
- Corrective Action and Preventative Plan (CAPA)
- Standard Operating Procedures (SOPs) Templates
- UAB Clinical Research Onboarding
- Seminar Archive (CRSP Education Videos)
- IND/IDE Consultation Team

Website Information:

Use the Clinical Research Tab on the webpage and find the following:

- **Getting Started in Clinical Research** includes links to training websites and training information
- **Clinical Trial Kiosk** includes sample source documents and logs, budget tools, SOP templates, onboarding, Research Seminar Archive Videos
- **Trainings** : links and information about CRSP trainings
- **Recruitment and Retention:** Investigator Toolkit tab- Recruitment and Retention Plan worksheet

are you reading?

Trending in Trials is an **e-newsletter** for Clinical Trialists at UAB.

This 60-second read from the UAB Clinical Trials Administration Committee (CTAC) supplies tools and information that reduce barriers to clinical trial success.

Subscribe Today @ forms.uab.edu/255

TRENDING IN TRIALS

Essential Information for Principal Investigators at UAB

LATEST UPDATES

Don't Miss Important Research Updates & Information: The UAB Research Administrators Forum is today, December 1st at 3pm and the

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CCTS Lunch & Learn

December, 2021

Robert P. Kimberly, MD

Professor of Medicine

Director, Center for Clinical and Translation Science

Senior Associate Dean for Clinical and Translational Research

Vice President for Medicine and Biomedical Research

Clinical Trials Initiative

- Hospital LOA process for device trials, implemented
  - Approval time ~70 days (target: 60 days)
- Managing scheduled visits in OnCore
  - Unmanaged visits, which can trigger errant billing, continue to decline
- IRB Advarra engagement
  - Re-engineering workflows, reduction in backlog, target metrics met
- ClinicalTrials.gov expectations have been updated
  - Number of records with flags ~steady over the last several months

Clinical Trials Initiative

Accrual Working Group (CTAC subcommittee)

- Accrual reports based on data in OnCore
  - Individual study level, and management group level
- Recruitment specialist in CRSP
  - Recruitment plans/people/tools/budget; CCTS Clinical Trials Kiosk
- Pilot study of an app within Cerner to identify patients at POC
  - Practical utility to be assessed

NEW CRSP SERVICE
Coming JANUARY 2022

Need help with recruiting and/or retaining participants?

- CRSP will provide consultation services on how to recruit participants and how to keep them engaged throughout the duration of the trial.
- We will have regulatory, coordinator and budget help available.
- We will use the UAB Recruitment and Retention Plan Worksheet.

For help or more information, please contact 205-975-2758 or email: CRSPtraining@uabmc.edu

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Clinical Research Support Program (CRSP)

UAB Recruitment/Retention Plan Worksheet

Protocol Title: _____
Protocol Number: _____
PI: _____
Protocol Synopsis: _____
Sponsor/CRO: _____

As part of the pre-study activities for the upcoming protocol, please provide the following information regarding your access to the required population and your site's initial plan for recruiting participants in this trial.

1. Based upon review/search of available databases, document the number of participants who fit protocol criteria and would be contacted for participation in trial: _____

On what sources are you basing this number?

- ☐ Medical Record Chart Review (i2b2, ICD-10 code search)
- ☐ Community Database
- ☐ Research Database
- ☐ Other: _____

2. Please list the potential challenges you see to enrolling participants and what you would implement to overcome these issues: _____

- ☐ Inclusion /Exclusion criteria too strict
- ☐ Distance/ Participant lives too far away/Participant Travel or Transportation Issues/Participant does not want to drive to UAB due to traffic/Parking
- ☐ Protocol requires too much from participant: procedures/frequency of visits/ duration of protocol (lasts for years)
- ☐ Study/Protocol will not pay participant for time to participate
- ☐ Age of participant population
- ☐ Investigational Product (IP) administration route/ requirements (multiple doses, injections, refrigeration)
- ☐ Randomization deterrent
- ☐ Seasonal illness/ Time of year for enrollment

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Clinical Research Support Program (CRSP)

UAB Recruitment/Retention Plan Worksheet

3. Based on your past performance and considering this protocol, please provide details on how the following resources would be used in your recruitment efforts:

- ☐ Social Media (Facebook, Twitter, Snapchat, Instagram, Google Ads)
- ☐ Newspaper/ Magazines/written advertising outlets
- ☐ Community Outreach (Navigators, Health Advisors)
- ☐ Television (local affiliates such as ABC, CBS, NBC, FOX)
- ☐ Electronic Signage (local advertisers provide billboard space)
- ☐ Radio
- ☐ Video Recordings in waiting areas
- ☐ Other Print Materials & Mailings (Flyers, Brochures, pamphlets)
- ☐ MD/Outside Community referrals (engage professional networks)
- ☐ Clinical Faculty Engagement through Faculty meetings or listservs
- ☐ ClinicalTrials.gov
- ☐ Research Match
- ☐ NCATS (Recruitment Innovation Center)
- ☐ Other _____

4. If source(s) other than those noted above will be used, please provide details and number of participants who could be contacted for participation in this trial:

_____

5. Are the costs for the above resources included in your budget? Yes or No

6. What are your plans to pay for the resources and who will provide the services?

_____

_____

7. Based on questions above, should protocol be aborted? Yes or No

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Clinical Research Support Program (CRSP)

UAB Recruitment/Retention Plan Worksheet

TIER ONE

Based upon the above data, please provide a written description of your site's Recruitment Plan for the study.

- Include details of the number of participants that will be scheduled for screening within 4 weeks of the study opening at your site:
- What is the goal for the number of participants to be enrolled per month until target enrollment has been reached? _____
- What is your initial plan for recruiting participants (what tactics will you use):

TIER TWO

5. What are your contingency plans for recruitment if your recruitment plan is not yielding enrollment goals, document the triggers or timelines for implementation should they be required?

   First Contingency Plan

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Office of Research

Jonathan Miller, MPPA, CIP

Assistant VP for Research Regulatory Oversight

December 14, 2021

Topics

- Office of Research Senior Leadership
- R2Ops updates - https://www.uab.edu/research/home/r2ops
- Research Matters
- myUABresearch

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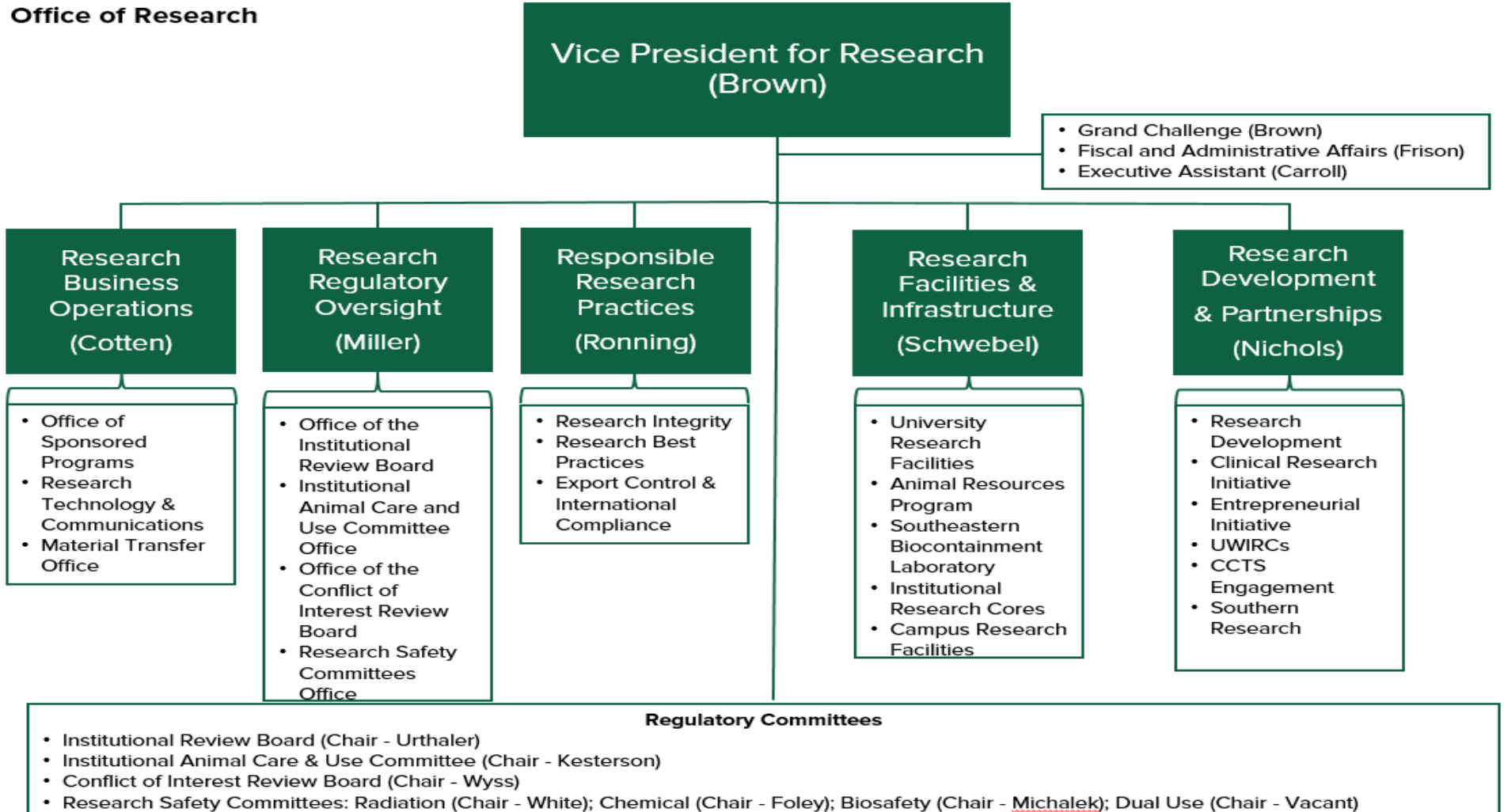
Office of Research



General Announcements

- Resumption of Research Operations (R2Ops)
  - Guidance related to the COVID-19 pandemic as it relates to research at UAB
  - Updates communicated via website (https://www.uab.edu/research/home/r2ops) and OoR weekly newsletter Research Matters
- Research Matters
  - Subscribe at https://forms.uab.edu/177
- UAB's next electronic research administration system (eRA) – myUABresearch
  - For updates – see https://www.uab.edu/research/home/project-era

THE UNIVERSITY OF ALABAMA AT BIRMINGHAM

Office of the Vice President for Research

Responsible Conduct of Research (RCR) Training for Faculty & Staff

Matt Ronning
Assistant Vice President for
Responsible Research Practices
Research Integrity Officer

Lisa Schwiebert, PhD
Interim Dean
Graduate School
RCR Training Coordinator

uabrcr@uab.edu

Executive Summary of RCR Training at UAB

Introduction

- In 2015, the President's Risk Cabinet identified a **need for required RCR training** across the UAB Research Enterprise
- To date, RCR training requirements have been implemented for all UAB trainees engaged in research, **but not for faculty and staff**

Objectives

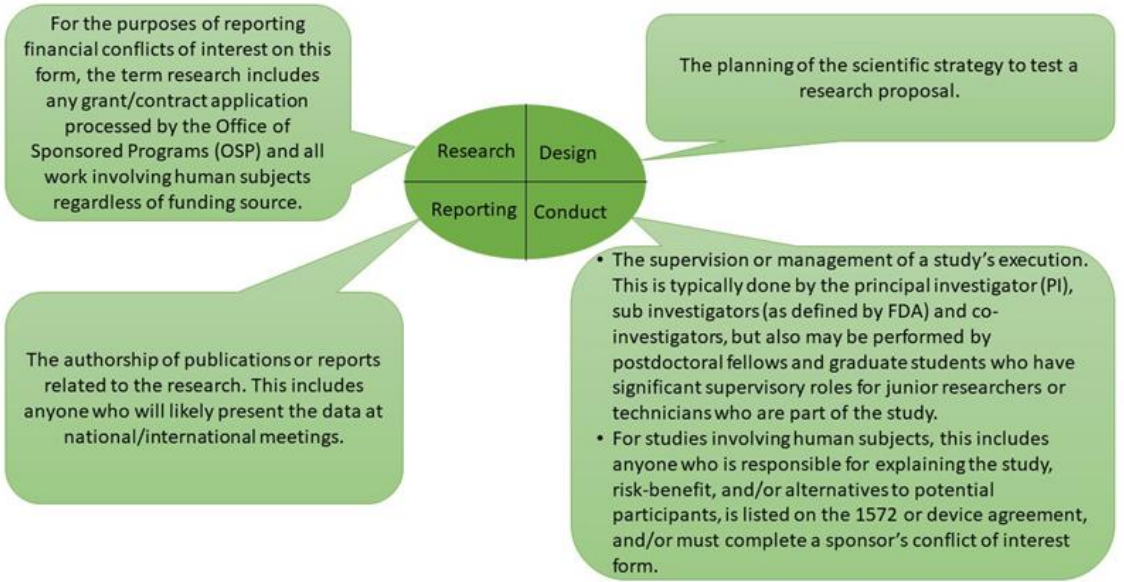
- Define **RCR training requirements for faculty and staff** engaged in research
- Describe oversight process to ensure **training compliance**
- Announce **date of launch** for these RCR training requirements

RCR Training Components

- **CITI RCR Modules**
  - Set of 6 online modules; can complete in approximately 90min
  - Each module has a quiz; must achieve 80% accuracy
  - Renew every 4 years
- **Faculty & Staff Course**
  - authorship
  - data management
  - export control
  - peer review
  - Plagiarism
  - reproducibility

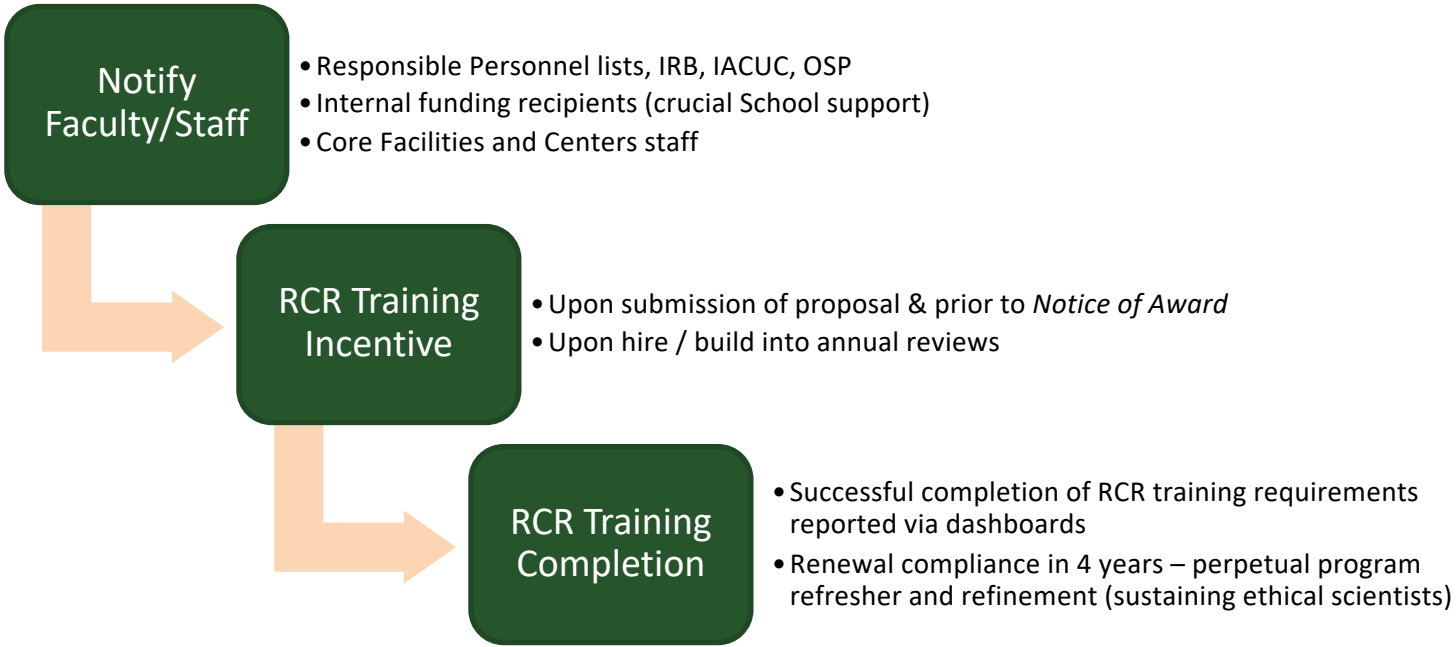
Definition of Faculty and Staff Engaged in Research

- Listed as **key personnel** on an active, sponsored research project, IRB or IACUC protocol
- Supported via **internal** start up, pilot or bridge funding mechanism
- Staff working in **UAB Core Facilities**



https://www.uab.edu/research/home/responsible-personnel-list

Oversight Plan: Support for Faculty & Staff RCR Training Engagement –Effective 10.01.2021



FAQs: Responding to Concerns…

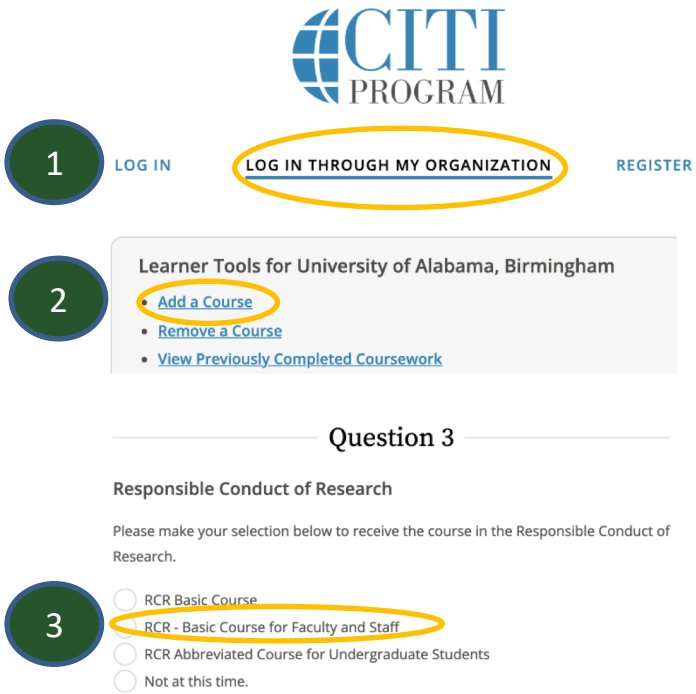
https://www.uab.edu/research/home/uab-rcr-training

- “Why do I need to do this?”
- “Do I have to pay for this?”
- “I can’t register with CITI”
- “I’ve already completed IRB training – isn’t that the same?”
- “I’ve already completed this training at a previous institution – do I have to do this again?”

How to Enroll

1. Login in using your BlazerID and Password,
2. follow the prompts to “Add a Course,”
3. find and select the “RCR – Basic Course for Faculty and Staff” and complete the course at your convenience.

https://citiprogram.org/



Trouble? Contact uabrcr@uab.edu for assistance.

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Office of the Vice President for Research

Questions? Thank you!

Matt Ronning **Lisa Schwiebert, PhD**

uabrcr@uab.edu

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

Debbie Graves
Training Coordinator, OSP

Federal Submission Updates – NIH Changes coming January 25, 2022

- NIH FORMS-G Grant Application Forms required - new grant application instructions available
- Applications submitted using incorrect application package may be withdrawn and removed from funding consideration
- Applicants are encouraged to submit early to allow time to work through any unforeseen issues
- NIH will require eRA Commons IDs in credential field of Sr/Key Person Profile form for all individuals listed
- Reminder: eRA Commons ID required on biosketches

Federal Submission Updates – NIH
Enhanced checks regarding clinical trials

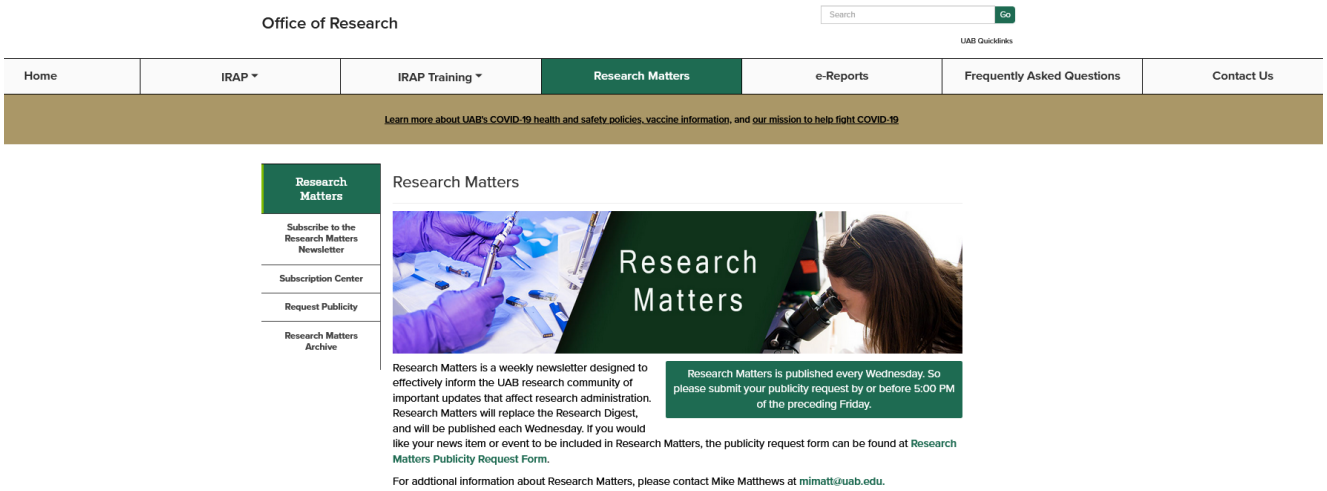
- October 1, 2021 - NIH enhanced checks for compliance with clinical trial registration and reporting in Human Subjects System (HSS) that could delay RPPR submission if late (clinical trial registration and/or results reporting)
- Reminder: All NIH-funded clinical trials are expected to register and submit results information to ClinicalTrials.gov per the "NIH Policy on Dissemination of NIH-Funded Clinical Trial Information" for competing applications and contract proposals

Federal Submission Updates – NIH
Enhanced checks regarding clinical trials

- The new checks will now result in errors for grant recipients upon submission of Research Performance Progress Report (RPPR) when clinical trial registration (required 21 days after enrollment of first participant) and/or results reporting (required 12 months after trial actual primary completion date) is overdue
- In other words, errors will appear in ASSIST rather than warnings (which will be resolved when requirements are met or exception document is submitted if in progress)
- Additional information: https://nexus.od.nih.gov/all/2021/11/09/enhanced-checks-for-compliance-with-clinical-trial-registration-and-reporting-in-rppr/

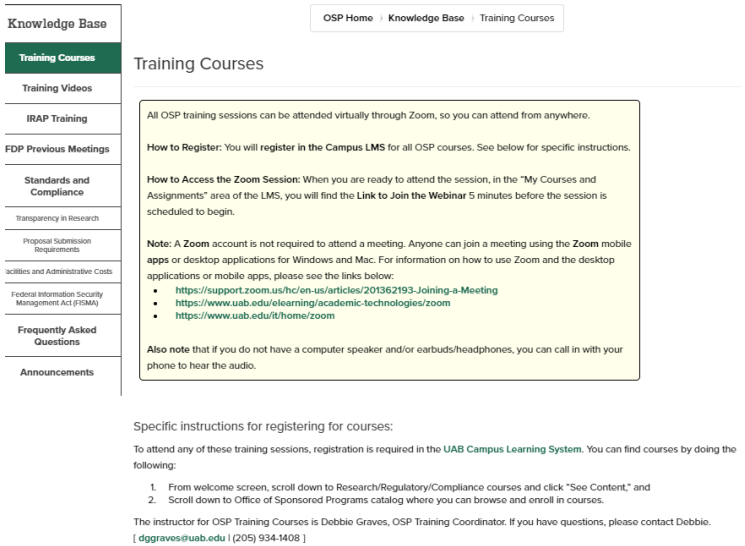
General OSP Reminders

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



General OSP Reminders

- OSP training is ongoing through Zoom – register through Campus LMS
- Link to OSP catalog: https://uab.docebosaas.com/learn/catalog/view/18



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]

IRB Updates & Current Events

CCTS Lunch & Learn

Adam J. McClintock | Director

Office of the Institutional Review Board

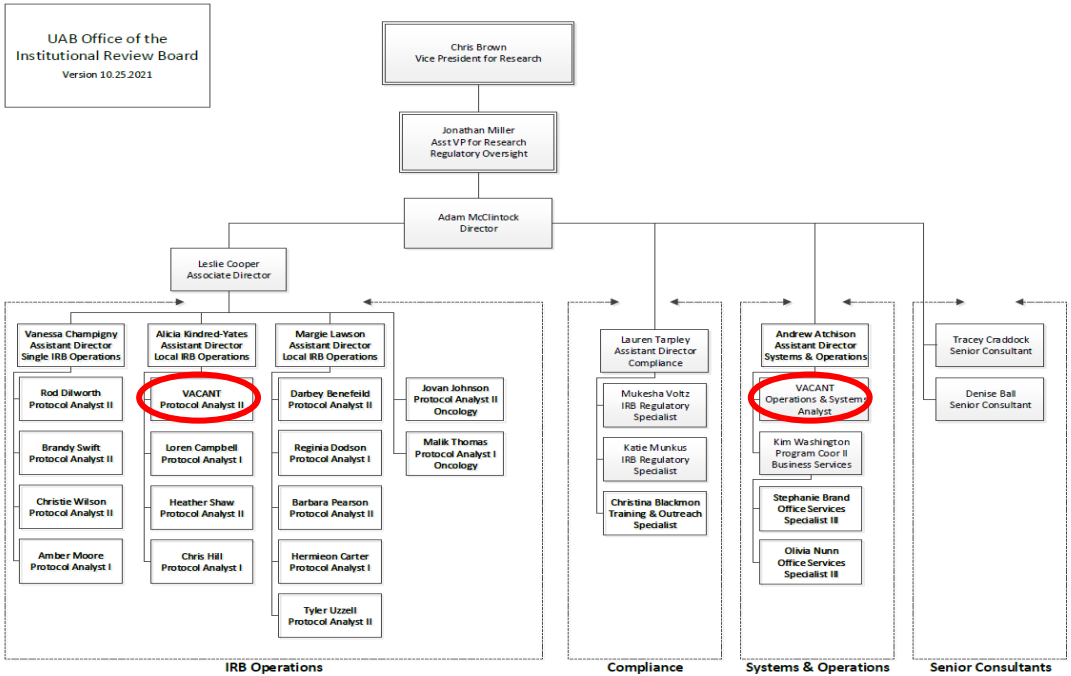
Office of the Institutional Review Board (OIRB)

Overview of OIRB Staffing/Vacancies

Outline Recent Improvement Initiatives

Review Results & Progress

OIRB Staffing (current vacancies)

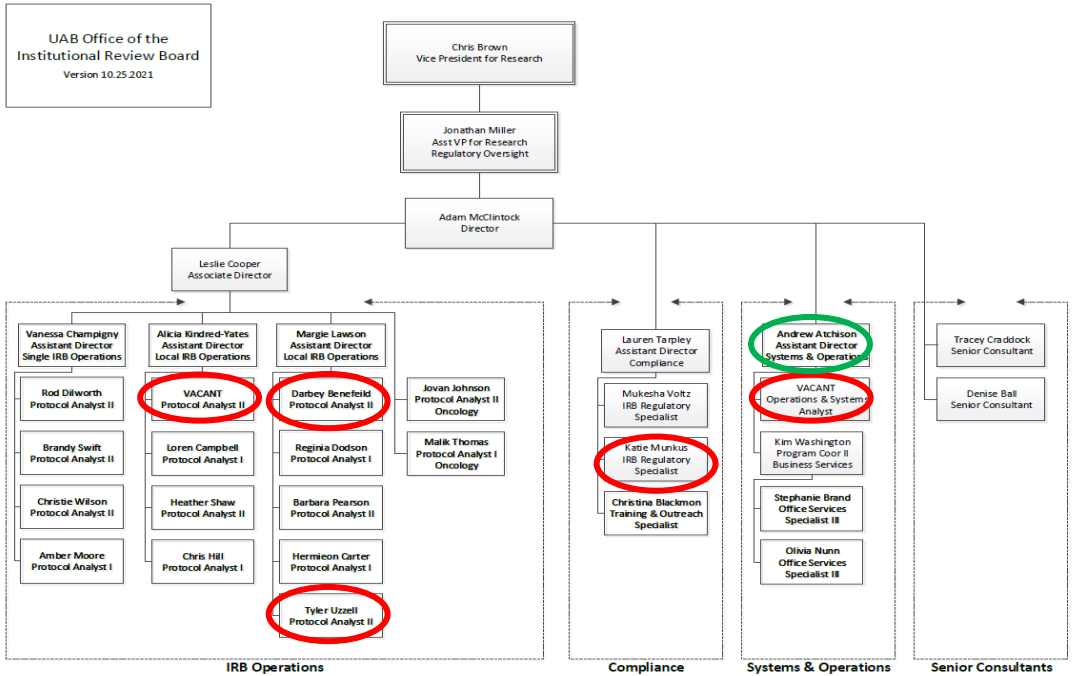


Legend

New to Office

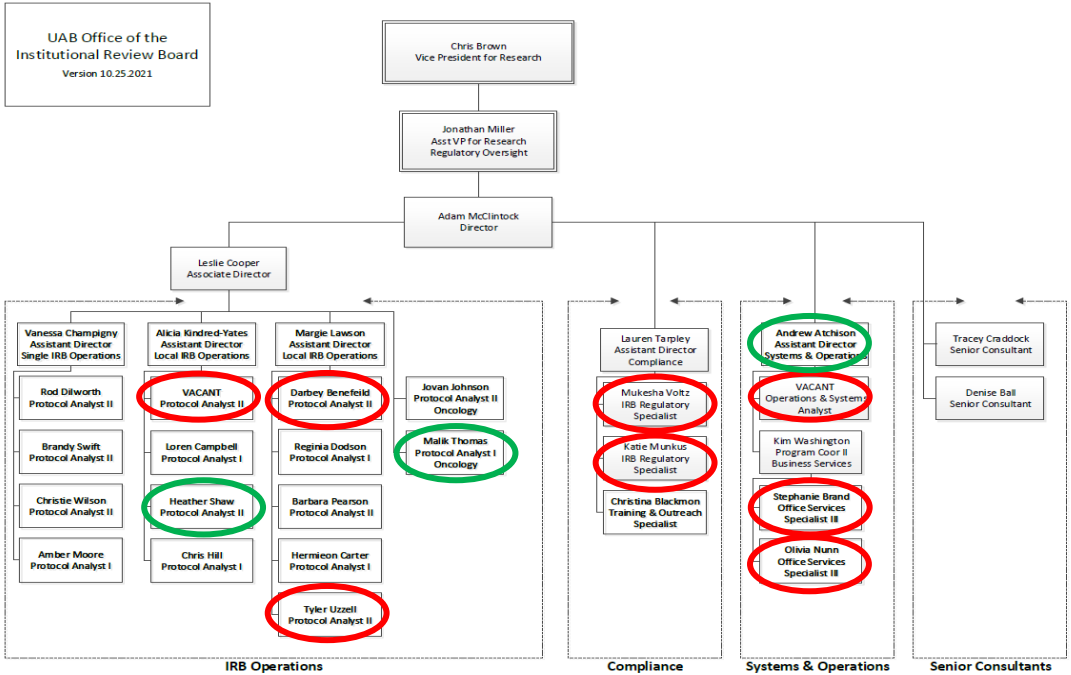
New to Role

OIRB Staffing (plus new staff in October)



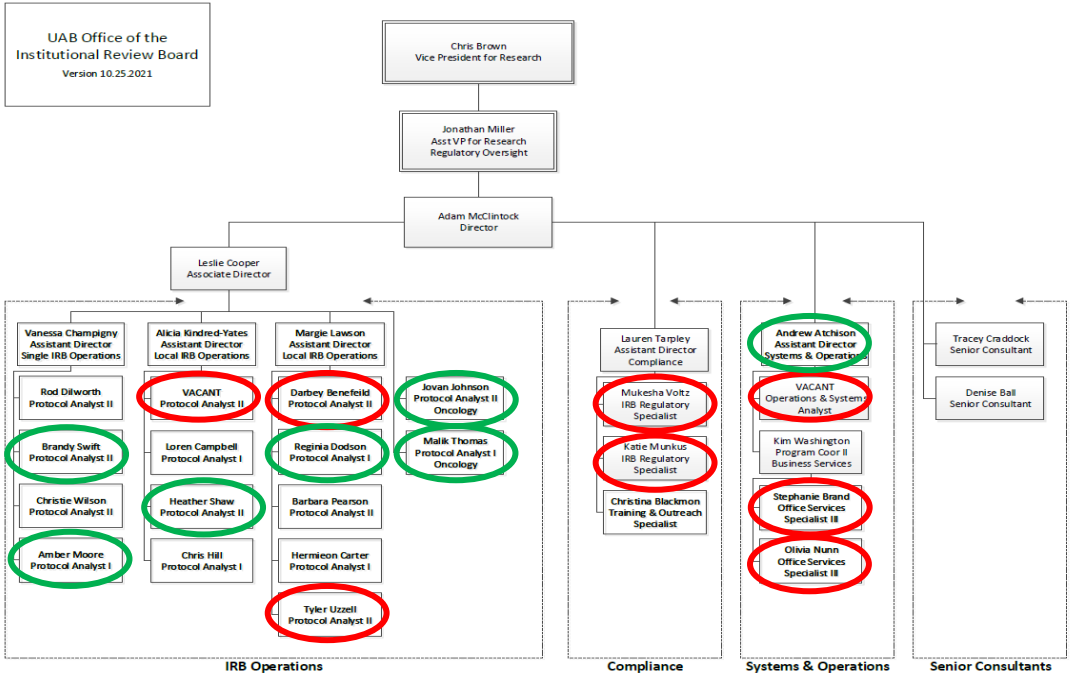
Legend
New to Office
New to Role

OIRB Staffing (plus new staff in past year)



Legend
New to Office
New to Role

OIRB Staffing (plus new staff in past 15 months)

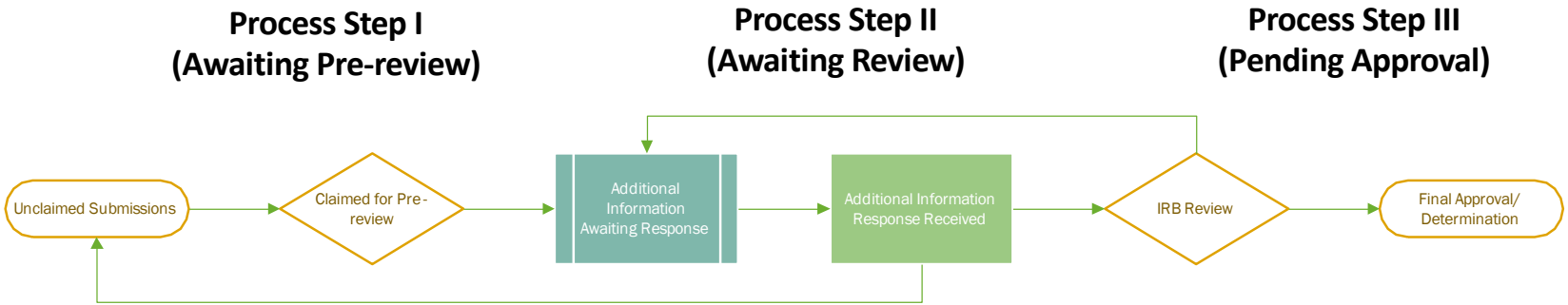


Legend
New to Office
New to Role

Changes & Initiatives

- Engaged Advarra Consulting to Assist with Backlog
- Process Changes & Improvements
  - Implemented Cross-Training & Workload Balancing
  - Identified & Removed Bottlenecks from Review Processes
  - Put an Emphasis on Interim Steps/Investigator Reminder Notices
- Summer 2021: Introduced Virtual IRB Office Hours to Augment Services

Results: Reduction in Backlog



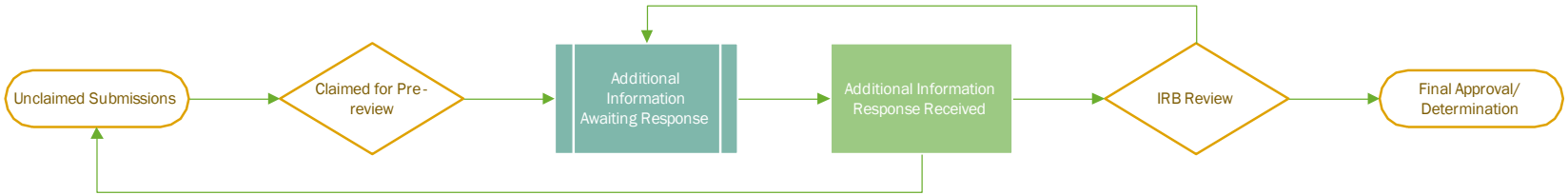
More than a 50% reduction in submissions in Process Steps I or Process Steps II since beginning to measure in March 2021 (i.e., applications awaiting pre-review or formal review/determination).

Results: Reduction in Backlog

Process Step I (Awaiting Pre-review)

Process Step II (Awaiting Review)

Process Step III (Pending Approval)



Overall throughput of final approvals and determinations is up 30% from FY2021 Q2 when improvement initiatives began.

Results: Median Turnaround Times FY22 Q1 to Date

- Expedited IRB Reviews: 36 days is approaching target (target 30 days)
- Exemption Determinations: 32 days is approaching target (target 25 days)
- Revision/Amendments: 5 days is approaching target (target 4 days)
- Personnel Amendments: 1 days is on target (target 2 days)

- sIRB Convened IRB Reviews: 63 days is approaching target (target 60 days)
- NCI CIRB Reviews: 12 days is on target (target 19 days)

- Research Administration Process Improvement and Design (RAPID) Historical Data: https://uab365.sharepoint.com/sites/research/rapid/SitePages/IRB-Metrics.aspx

Updates on Clinical Trials Initiatives

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

Monitor Access to Cerner

Reminder:

- When walking through the process outlined at the below link, be sure to provide a complete unique identifier (SSN, DL #, or Employee ID) for the ‘user’ in step 5a.
- https://www.uab.edu/medicine/ctao/investigators/monitor-access-to-ehr

Clinical Research Career Ladder

Reminder:

Send an Org Chart to marchant@uab.edu for any positions that are expected to have supervisory oversight of personnel in addition to the REDCap assessment.

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PowerTrials Updates

Alicia Gunter

12/14/2021

Science through Synergy

Banner Bar: Research: On Study

WHAT?

- **Research: On Study indicator in the patient's banner bar in Cerner IMPACT PowerChart.**

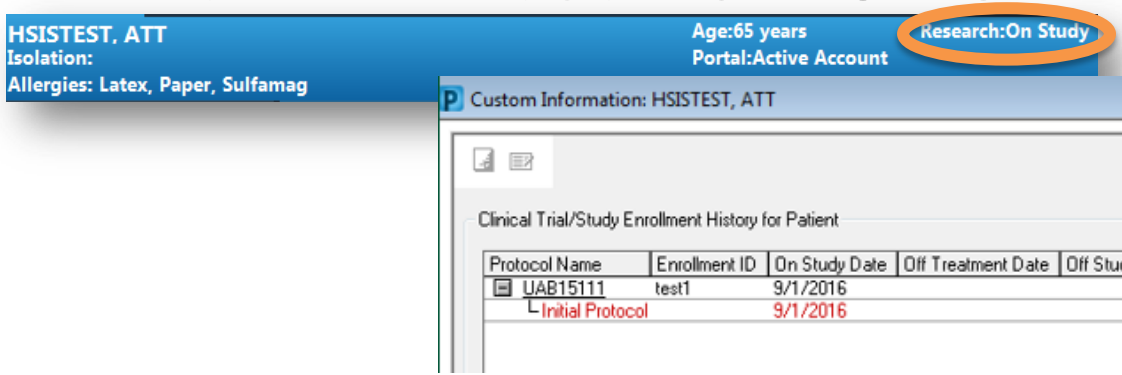
WHEN?

- **When a patient's status is updated to 'On Study' in Oncore, this info crosses over to Cerner.**

WHY?

- **This is a patient safety feature that alerts providers to click on the banner bar and review the research summary for toxicities or cautions related to clinical trial. Linked to admissions notifications.**

Banner Bar: Research: On Study



IS IT CORRECT?

- The first time you put a patient On Study, go into PowerChart and confirm the On Study flag.
- Left click on the Research: On Study and confirm that you and the PI are listed.
- Contact powertrials@uabmc.edu to confirm that are listed on your study before enrolling.

WHY DOES IT MATTER?

- Admission message for ER and inpatient admissions linked to the staff listed in the On Study flag.

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.

Research Enhanced Impact Training

What can HSIS do to help you use Cerner IMPACT PowerChart more efficiently?

Looking to develop quick enhancement trainings.

Suggestions welcome!!

hsispowertrials@uabmc.edu

PowerTrials Order Catalog

- **NEW!!! Ultrasound!!**
- **What's next?**
  - **Infusion**
  - **PFT**
  - **Leukapheresis**
- **PowerTrials order catalog now has: lab, rad, echo, ECG, dexa scan, mammogram, ultrasound, research prescriptions**
- **What's needed? Please contact hsispowertrials@uabmc.edu with any suggestions**

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 **(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
9/14/21

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

CCTS

Highlights of the OnCore Upgrade

System Upgrade Coming Soon

Lisa Williams MSHI

Enterprise OnCore Administrator

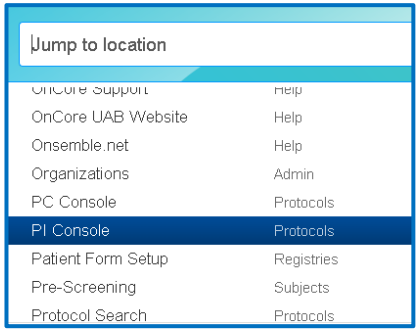
14 DEC 2021

Highlights of the OnCore Upgrade

"Jump To" rocket on landing page

Or use keyboard shortcut Ctrl+K (Cmd+K on a Mac)

To navigate to other pages you select or type in



Updated logo to reflect Advarra as the new owner;

you will no longer see "Forte"

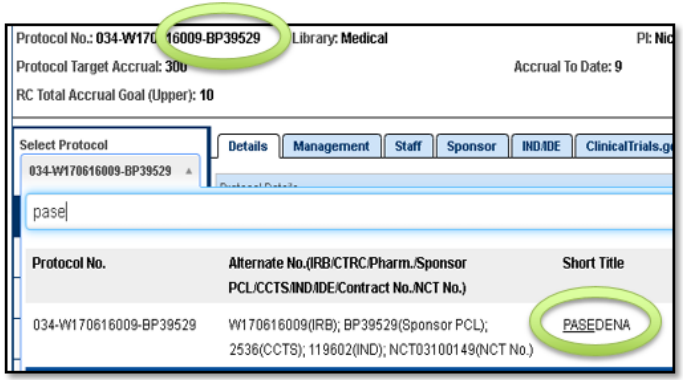
Microsoft Edge browser is now supported (not just Chrome)

(Edge Version 79 and newer)

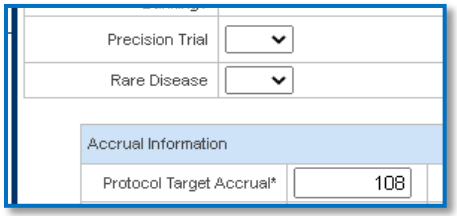
Highlights of the OnCore Upgrade

Can now search by Short Title

Previously, the Short Title could not be used as a keyword when searching in “Select Protocol” fields.



Rare Disease flag on the PC Console >Main > Details tab for ease of tracking/reporting e.g. Rare Disease Clinical Research Network protocols. Calendar builders will set this field when creating the protocol.



Highlights of the OnCore Upgrade

Users can no longer manually set an MRN when registering a new subject.
(Prevents one from creating or duplicating an MRN)

"Find Subject" fields must be used to pull demographics from EMMI

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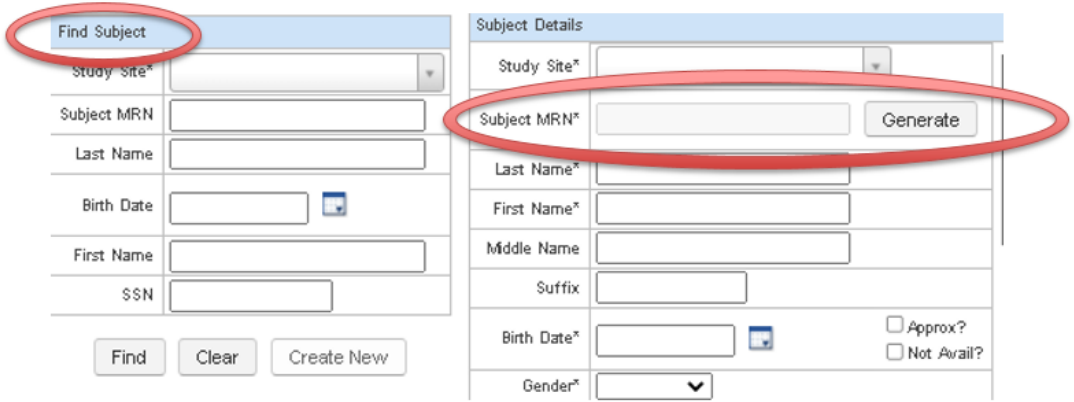
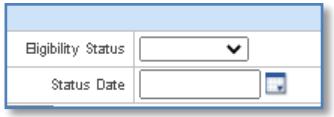
"Generate" button allows system to create unique "99-MRN." (Use is limited to specific types of protocols & cohorts. OCS will provide direction.)



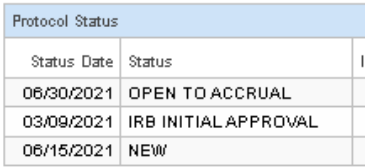
Highlights of the OnCore Upgrade

Subject Console Date Rule Changes

Consent Signed Date AND Eligibility Status Date



can only be entered in OnCore when those dates fall ON or AFTER the protocol's Open to Accrual date.



New error message:

This is a hard stop – no overriding this one.

Highlights of the OnCore Upgrade

Financials Module Changes for Financials Users

Communications from our OnCore Financials Analyst, Renarda Lane, regarding changes to the Financials Console will be forthcoming.

Contact the OnCore Team with Questions

Thank You!

OnCore Administrators

oncore@uabmc.edu

OnCore Website

https://www.uab.edu/ccts/research-commons/oncore/resources

New Minimum Footprint (required fields); How-Tos; Forms; Calendar Requests; Training Information

How does Santa stay healthy during the holidays?

He practices elf-care.

Hang in there, Everyone, and Stay Safe

CBR-CCTS-OCS
New Submission and Workflow

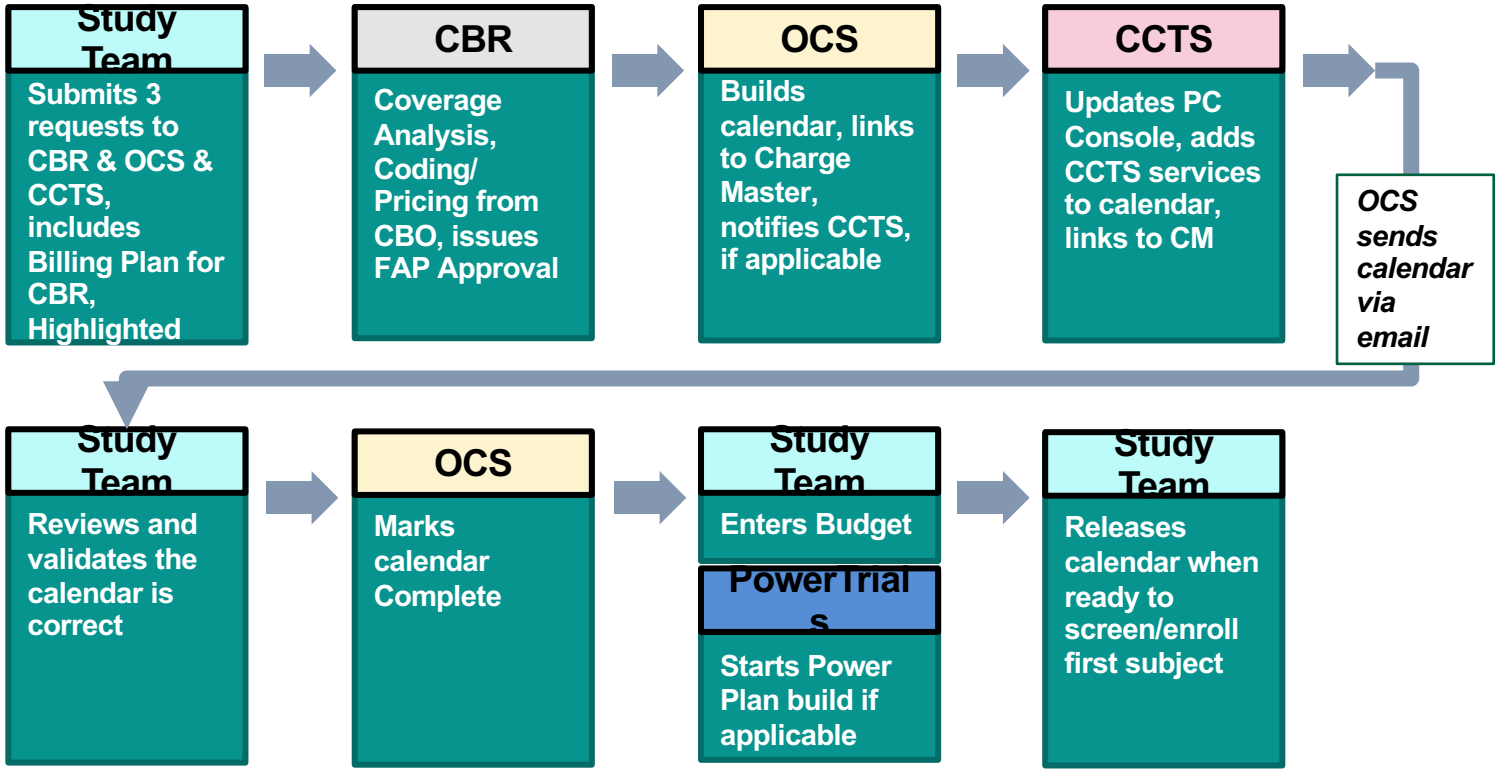
Emily Bruer, Ashley Specht

Implementation and Transition Period

- After receiving feedback from study teams, CBR, OCS, and CCTS engaged in a process improvement project. This resulted in a new **unified submission** for our teams and **updated workflow**
- Go-live for our new process took place on **November 15**
- Training has been completed for most therapeutic areas. If you have not had training, please reach out and we will set something up for your team.
- **Transition Period**
  - Due to significant workflow changes, studies that were immediately submitted prior to go-live must be reviewed in the old process. This has resulted in delays with review of the newer submissions.
  - Straddling two processes has caused confusion. If you have questions about the status of a submission, or need assistance with a study that was submitted close to the go-live date, please reach out.

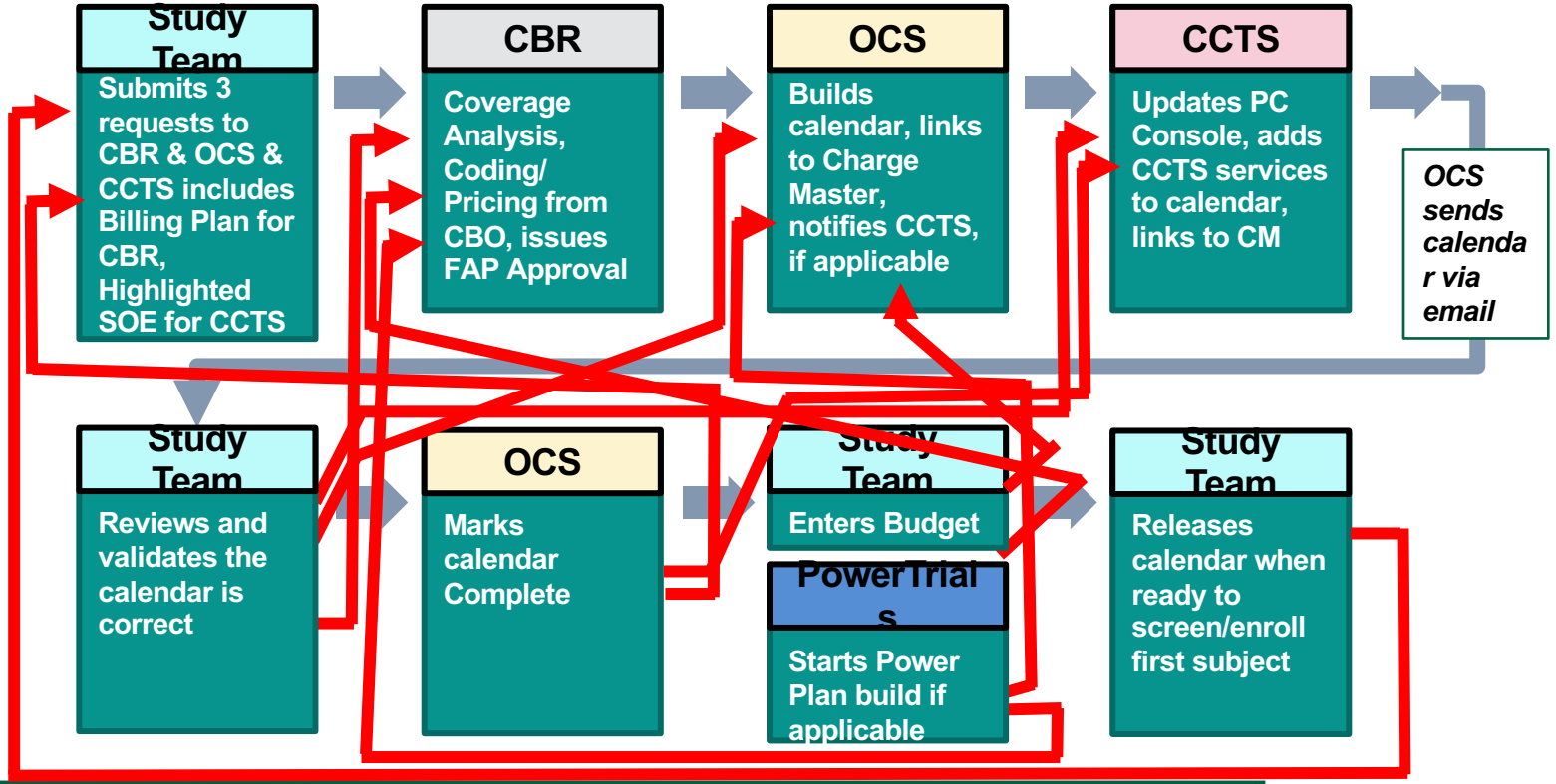
Previous Process for New Calendar Requests

(when all goes according to plan)

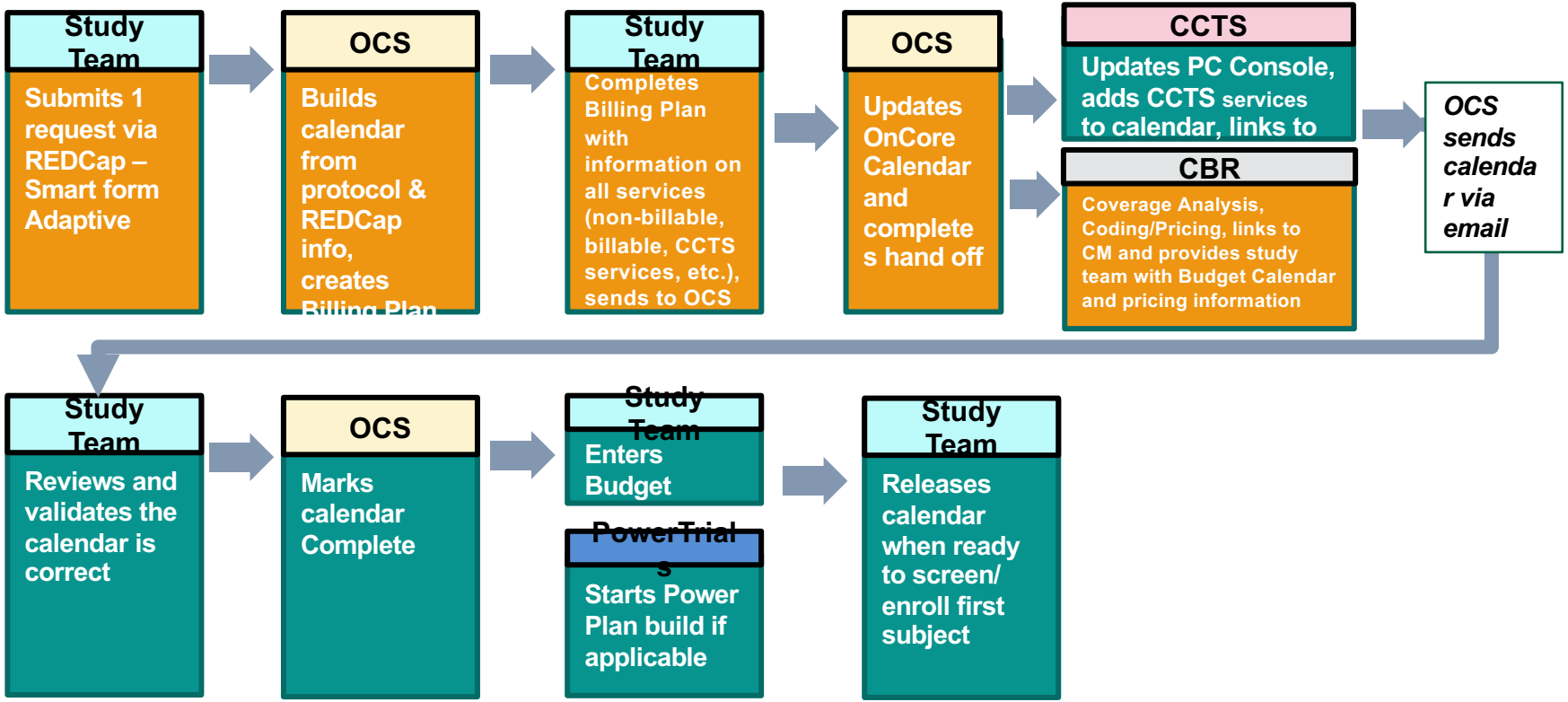


Deviations for Previous Process

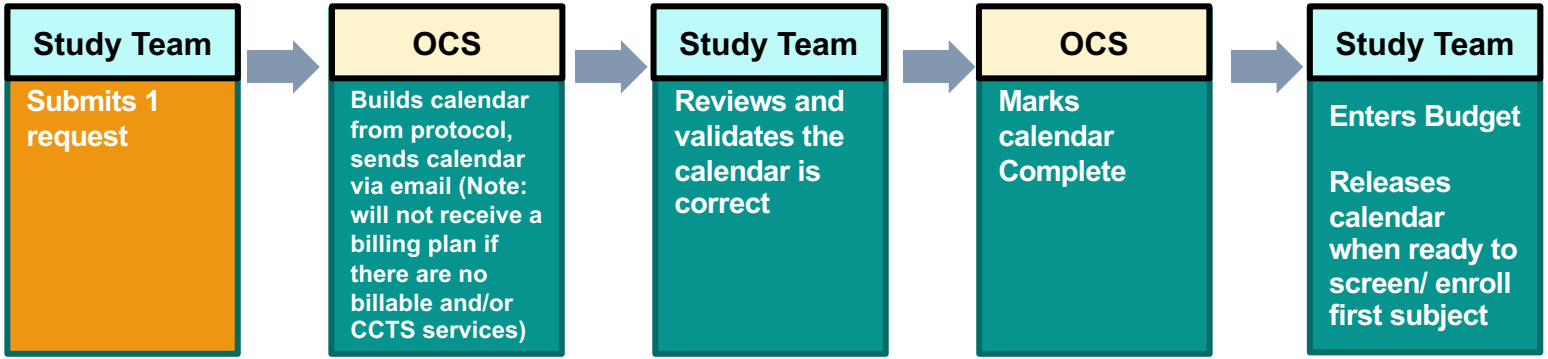
(often things did not go according to plan)



New Workflow



New Workflow: protocols without HS billables or CCTS services



Biggest Workflow Changes for Med Enterprise Protocols

- OCS will build calendar in OnCore ***before*** CBR or CCTS review
- You will not need to create a billing plan when submitting through Redcap. You will simply submit for the amendment and wait for further contact from OCS. OCS will export OnCore calendar, reformat into the billing plan template, and send to the study team to complete.
- CCTS services will also need to be included in the billing plan (this will replace the highlighted schedule of events)
- CBR will link procedures to the Charge Master instead of OCS.
- Exported Budget Calendar from OnCore will serve as the FAP approved billing plan, and will be sent to study team by OCS for validation.
- Study team will see the linked codes in the calendar during validation.
- If there are CCTS services, OnCore Calendar will not be marked complete until services have been confirmed during the in service (in service is complete)

Points to Consider

- New process was designed to help Study Team prepare to manage study.
- Study Team will need to have all required information on hand before submission. A checklist is provided in the submission so that study teams may prepare in advance.
- If pricing is needed quickly for UAB Health System clinical billable services, it is recommended to submit a Feasibility Fee Request. This can be done by going to *this link* and entering in the requested information.
- Though the *submission* process is consolidated, review continues to include three separate groups with individual processes. Workflow changes should help make things more efficient. However, overall process time (from OCS-CBR-CCTS) may not be faster, initially.

Revisions

- If you have ever submitted to OCS, CBR, or CCTS for the study, then you will check “Revision” when you’re submitting through Redcap.

- You will ***not*** need to create a revised billing plan or highlight changes when submitting through Redcap. You will simply submit for the amendment and wait for further contact from OCS.

- OCS will export the OnCore Calendar and create a revised billing plan Template which will be sent to the study team for completion.

Conclusion and Questions?

- Link to Redcap Submission: https://redcap.dom.uab.edu/surveys/?s=ELDN9LW9YP
- Link to Feasibility Fee Request: https://redcap.dom.uab.edu/surveys/?s=YJFR3EJKE7KFKY98

We are here to help! Please contact us with questions or to set up a Zoom meeting.

- CBR: FAP@uab.edu
- CCTS: CCTSclinical@uab.edu
- OCS: OncoreCalendars@uabmc.edu

CBO Reminders

- Please make sure that your study staff is up to date and accurate in OnCore.
- Please include the group email address if you are emailing CBO. If someone is out unexpectedly, some else from the team can address the question or issue if we all are included.
  - PFS (Hospital):
    - pfsctbillinginquiries@uabmc.edu
  - MSO (Professional):
    - ctbillingquestions@uabmc.edu
- Please contact the billing office if you have questions regarding how to pay a bill from CBO. We are happy to help you through the process.

CCTS

Update: Non-Compliance with ClinicalTrials.gov

ClinicalTrials.gov

Tamara Howard

Clinical Research Regulatory Coordinator II, ClinicalTrials.gov Administrator

Dunia Ritchey

FDA Submission Specialist, DSMB Administrator, ClinicalTrials.gov Administrator

New Errors for Non-Compliance

“Enhancements to clinical trial registration and reporting checks are to be released today, October 1, in the Human Subjects System (HSS). The new checks will now result in an error for grant recipients upon submission of a Research Performance Progress Report (RPPR) when clinical trial registration (required 21 days after enrollment of first participant) and/or results reporting (required 12 months after trial actual primary completion date) is overdue.”

https://era.nih.gov/news/era-enhancements-new-errors-non-compliance-clinical-trial-registration-and-reporting-time

New Errors for Non-Compliance
Cont.

Warning: If the enrollment of the first participant was more than 21 days and less than or equal to 30 days ago and no NCT number was provided.

Error: If the actual primary completion date was more than 12 months ago and the results have not been reported to Clinicaltrials.gov.

Error: If the first participant was enrolled more than 30 days ago and no NCT number has been provided.

https://era.nih.gov/news/era-enhancements-new-errors-non-compliance-clinical-trial-registration-and-reporting-time

New Errors for Non-Compliance

Cont.

- **ClinicalTrials.gov, ASSIST and eRA Commons material must match.**

- **Non-Compliance can negatively impact you being able to publish your research.**

ClinicalTrials.gov New Beta Site

- Public Site – available now to preview

- PRS Site – coming soon in early 2022
  - More user friendly format
  - Simply data entry and stream line review
  - More customizable features

Need Help?

Contact Us:

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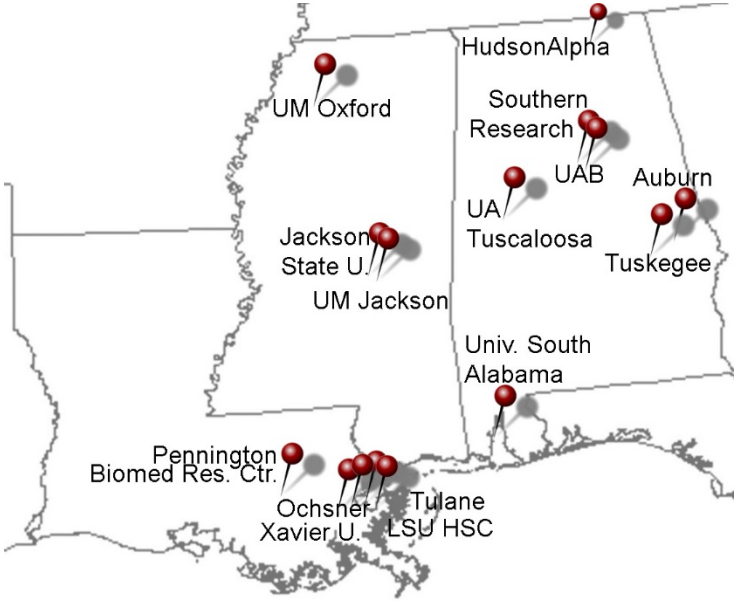
Questions & Discussion



CCTS

Center for Clinical and Translational Science