Upcoming Education Events:

January:

*Research Seminar Series/ Special Topics in Clinical Trials*

**January 17**\(^{th}\) Clinical Trials.gov Results Reporting Workshop (11:30a- 1:00p)
**January 31**\(^{st}\) UAB Research Pharmacy (12:00p- 1:00p)

*Research Orientation Program*
**January 24**\(^{th}\) (8:00a- 12:00p)
Clinical Trials Initiative

Robert P. Kimberly, MD
Senior Associate Dean
Clinical and Translational Science
Clinical Trials Initiative

Key elements (in 2018):
- OnCore implementation
- Clinical trials w clinical billables
- Siteminder sunsetting

Key elements (upcoming):
- OnCore financials project
- Standardized budgeting
- Clinical trials w/o clinical billables

Accomplishments (in 2018):
- Expenditures up >10% over 2017
- Increased >2X over 2018

Thank you
Clinical Trials Initiative

Messages heard (in 2018):
Process improvement
(more to come)

More messages (in 2018):
Coordination
Specialization
Desire for greater expertise

Key initiatives (in 2019):
Professional career ladder
Training opportunities

Your suggestions for 2019
Clinical Trials Initiative

Research Commons
https://www.uab.edu/ccts/research-commons

Training Academy
https://www.uab.edu/ccts/training-academy

Clinical Research Support Program
https://www.uab.edu/ccts/clinical-translation/clinical-services

Solution Studios
https://www.uab.edu/solutionstudios/
OSP Updates

Debbie Graves
Training Coordinator- OSP

dggraves@uab.edu   (205) 934-1408
OSP Updates

CDA Submission Changes
• Confidentiality Disclosure Agreement (CDA) processing moved to Office of Sponsored Programs (OSP) from Office of Industry Engagement (OIE)
• Submit CDAs to new mailbox: cdas@uab.edu
• For documentation questions, see OSP CDA webpage

New Research Administration Network Group (RANG)
• Pillars: Process Improvement, Metrics, Communications, Training
• Representatives from every school
• May be reaching out to you regarding best practices

• Industry officers on leave during December and first few months of 2019
Research Administration Updates

Jonathan Miller
Research Administration Updates

New OIRB Director
• Adam McClintock, MBA, CIP
• Starts January 28, 2019
UAB Office of the IRB

Who review my IRB submission in IRAP?
UAB Office of the IRB- Find your IRB Reviewer

• Log into IRAP
• Search for your project
• Click on the yellow folder

<table>
<thead>
<tr>
<th>Actions</th>
<th>Number</th>
<th>Title</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>IRB-200001461</td>
<td>Retirement versus Working Forever: A Randomized Trial</td>
</tr>
</tbody>
</table>
UAB Office of the IRB- Find your IRB Reviewer

• Select the submission

<table>
<thead>
<tr>
<th>Type</th>
<th>Investigator Submitted On Date</th>
<th>Determination</th>
<th>Determination Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>Revision/Amendment</td>
<td>04-Dec-2018</td>
<td>Under review</td>
<td>N/A</td>
</tr>
<tr>
<td>Revision/Amendment</td>
<td>08-Nov-2018</td>
<td>Approved</td>
<td>10-Nov-2018</td>
</tr>
</tbody>
</table>

• Click on Reviews
UAB Office of the IRB- Find your IRB Reviewer

IRAP General Screen
UAB Office of the IRB

NEW IRB FORMS
UAB Office of the IRB- New IRB Forms

NEW! Project Revision/Amendment Form
No PI signature needed
Institution Review Form Relying on Outside IRB

- Used in Single IRB studies
- Previous version will no longer be accepted in 2019

### Institution Review Form Relying on Outside IRB

<table>
<thead>
<tr>
<th>1. UAB IRB Protocol Number:*</th>
<th>IRB-</th>
</tr>
</thead>
<tbody>
<tr>
<td>2. UAB Principal Investigator (PI)</td>
<td></td>
</tr>
<tr>
<td>Name (with degree)</td>
<td>Blazer ID</td>
</tr>
<tr>
<td>Department/Division</td>
<td>Email</td>
</tr>
<tr>
<td>Phone</td>
<td></td>
</tr>
<tr>
<td>PI Contact (Optional)</td>
<td></td>
</tr>
<tr>
<td>Name</td>
<td>Email</td>
</tr>
<tr>
<td>Phone</td>
<td></td>
</tr>
<tr>
<td>UAB Billing Contact (if applicable)</td>
<td></td>
</tr>
<tr>
<td>Name</td>
<td>Email</td>
</tr>
<tr>
<td>Phone</td>
<td></td>
</tr>
</tbody>
</table>
UAB Office of the IRB

Revised Common Rule
UAB Office of the IRB – Revised Common Rule

What is the Common Rule???
- Federal regulations governing human subjects research
- Criteria used by IRBs to review research
- Last updated in 1991

Revised Common Rule
- Effective: January 21, 2019
- Allows some changes to be implemented early
UAB Office of the IRB – Revised Common Rule

Information & updates available on the IRB website

The UAB Institutional Review Board for Human Use (IRB) is a committee established under federal regulations for the protection of human subjects in research (45 CFR 46). Its purpose is to help protect the rights and welfare of human participants in research conducted under the auspices of the University of Alabama at Birmingham.
UAB Office of the IRB – Revised Common Rule

IRB Webpage:
- Major areas of change
- Revised Common Rule Training
- Guidance Documents

Revised Common Rule

The Federal Policy for the Protection of Human Subjects, known as the Common Rule has undergone substantive revisions for the first time since its publication in 1991.

- The revised Common Rule was published in the Federal Register on January 19, 2017.
- An interim final rule delaying the implementation was published on January 22, 2018.
- The current final rule published on June 19, 2018. The effective date for the revised Common Rule is January 21, 2019.
UAB Office of the IRB – Revised Common Rule

How will the Revised Common Rule affect me?

<table>
<thead>
<tr>
<th>Topic</th>
<th>Change</th>
</tr>
</thead>
<tbody>
<tr>
<td>Informed Consent</td>
<td>All consent forms will now contain a concise summary on the first page</td>
</tr>
<tr>
<td>Exempt Categories</td>
<td>New categories and changes to some existing categories</td>
</tr>
<tr>
<td>Continuing Review</td>
<td>Expedited studies will no longer require continuing review (there will be some exceptions)</td>
</tr>
</tbody>
</table>
UAB Office of the IRB – Revised Common Rule

Informed Consent Changes

- **Concise Summary**
  - Consent forms must begin with a “concise and focused presentation of the key information”
  
  - A summary that will help a potential participant understand whether or not to participate in the research

- IRB will develop samples/templates of concise summaries
### UAB Office of the IRB – Revised Common Rule

Consent Form Changes: Concise Summary

---

**CONSENT FORM**

<table>
<thead>
<tr>
<th>Title of Research:</th>
<th>Retirement versus Working Forever: A Randomized Trial</th>
</tr>
</thead>
<tbody>
<tr>
<td>UAB IRB Protocol #:</td>
<td>IRB-300001461</td>
</tr>
<tr>
<td>Principal Investigator:</td>
<td>John Doe, M.D.</td>
</tr>
<tr>
<td>Sponsor:</td>
<td>University of Alabama at Birmingham</td>
</tr>
</tbody>
</table>

**General Information**

You are being asked to take part in a research study. This research study is voluntary, meaning you do not have to take part in it. The procedures, risks, and benefits are fully described further in the consent form.

**Purpose**

The purpose of the study is to compare the good and bad effects of two study arms, either retirement or working forever.

**Duration & Visits**

You will be in this study for 2 years, including 4 visits to UAB.

**Overview of Procedures**

You will come to a screening visit that includes an interview and completion of quality-of-life surveys. If you are eligible and enroll in the study, you will complete surveys twice a year and be asked to come to a focus group twice a year to discuss information we learn from reviewing the surveys.

**Risks**

The most likely risks are fatigue, headaches, and depression.

**Benefits**

You may or may not have a direct benefit from being in the study.

**Alternatives**

The alternative is to not participate in this study.

---

**Purpose of the Research**

We are asking you to take part in a research study. The purpose of this research study is to determine...
UAB Office of the IRB – Revised Common Rule

Continuing Review for Expedited Studies
- Continuing reviews are **no longer required** for *(most)* expedited studies
- Some studies have already been transitioned
- Email notifications to PI and Delegates
- If you have not received an email from the IRB...
  - **Keep sending in your Continuing Review submissions!**
  - **We will let you know when to stop!**
UAB Office of the IRB – Revised Common Rule

Expedited Review Studies

• Still **required** to submit amendments and problem reports to the IRB, as necessary
  o IRB will send you email reminders annually
  o Must check in at least **every 3 years**
  o The check in (amendment or problem report) will be considered an **Expedited Status Update (ESU)**
    ➢ Each time an ESU is submitted, the 3 year date will reset
UAB Office of the IRB – Revised Common Rule

NEW! Project Revision/Amendment Form

Expedited Status Update (ESU) section

Complete this section:

- If it has been 3 years since the last approval
- To close an expedited study

4. Types of Change

Check all types of change that apply, and describe the changes in Item 5.c. or 5.d. as applicable. To help avoid delay in IRB review, please ensure that you provide the required materials and/or information for each type of change checked.

- Expedited Status Update (ESU) ONLY
  - For protocols under the 2018 Revised Common Rule, reviewed via the expedited procedure, any change to the protocol will be considered an ESU. Expedited studies are required to submit an ESU at least every 3 years to remain in compliance with UAB IRB POL020 & PRO150. Indicate one of the following:
  - Continuing (Item 3 indicates current study status)
  - Completed (all protocol-related data analysis is complete and no further work is being conducted)

Total number of participants entered: [ ]

In Item 5.c., (a) include any findings or publications resulting from the research; (b) describe the storage plan: (1) how will data records be stored, (2) how will they be protected, (3) how long will data be stored, (4) where will data be stored, and (5) following storage will records be destroyed, archived, or transferred?
UAB Office of the IRB – Contact Us

Office of the IRB
AB470
934-3789
irb@uab.edu
Updates on Clinical Trials Initiatives

Mark Marchant, MPH, MBA, CCRP
Director, CTAO
greenphire

- Electronic Subject Payment System
- Utilizes ClinCards
- Replaces Visa Debit Cards and Petty Cash
- Web Portal for Subject Entry and Visit Keeping
- Cards have no value until study visits kept in system
- Reporting capabilities
• Phased Roll-out
• Test Sites: Lung Health Center & Psychiatry (October 2017)
• Wave 1:
  • Q1 2018
  • Anesthesiology; Cell, Developmental & Integrative Biology; Dermatology; Emergency Medicine; Genetics; OB/GYN; Ophthalmology; Oral & Maxillofacial Surgery; Pathology; Pediatrics
• Wave 2:
  • Q2 2018
  • School of Public Health; Medical Education; College of Arts & Sciences
• Wave 3:
  • Q1 2019
  • Dept. of Medicine
Phased Roll-out Continued

Wave 4:

School of Optometry; Neurology;
Neurosurgery; Otolaryngology; Urology;
Radiology; Psychiatry; Surgery
• HIPAA Training Requirement for Non-Covered Entities
• SSN Requirement Exemption
• Cost
  • Cards: $3.70 paid by University
  • Loads: $1.15 paid by University
• Reminder:
  • Review language in ICF to ensure silent on payment type
Pending Accounts

• Be sure to apply appropriate expenses (fees and faculty/staff salary) to pending accounts upon receipt for industry-sponsored clinical trials.
• Reminders continue monthly with individual orgs.
• Notify us if CTA won’t be executed prior to End Date.
Career Ladder

• Create a professional model to outline the career path for those in Clinical Research
  • Boosts Staff Recruitment & Retention
  • Proficiency Standards Elevate Profession
• 5 Tracks
  • Coordinator, Nurse Coordinator, Regulatory, Data, Administration
• 5 Levels
  • I, II, III, Manager, Director (Entry, Intermediate, Senior)
Career Ladder

• Mapping
  • Proficiency-based Assessment
  • Person to Position
• Timeline
  • Completion of Ladder
  • CCC Pilot
  • Departmental Meetings
Questions

???
Institutional Lab Billing Statement Changes

UPDATE

Nicole Halbrooks
Hospital / Facility Clinical Trial Statements

Objective:

• Implementation of PowerTrials has presented an opportunity to consolidate hospital study charges into one statement.

• Format statement to facilitate reconciliation between the statement and budget
Hospital / Facility Clinical Trial Statements

**Current State:**
- Lab charges on institutional account
- Other charges on encounter specific UB04

**Short Term**
- Proposal is to include Radiology charges with Lab charges on the Institutional statement which will still be unique by IRB number.
Hospital / Facility Clinical Trial Statements

Statement Feedback

• Statement format currently sorts by date of service. Would another format be preferred for the mixed services?

• Sorting options: Patient, Service Type, DOS or a combination of these. What is the best sort to help you reconcile with budget?

• Are there any issues from a payment perspective? Would the Radiology services be paid by a different person/area than the Lab charges?
Hospital Institutional Account Statement Customization

<table>
<thead>
<tr>
<th>SERVICE DATE</th>
<th>DESCRIPTION</th>
<th>PT. NAME</th>
<th>CPT</th>
<th>REF</th>
<th>AMOUNT</th>
</tr>
</thead>
<tbody>
<tr>
<td>07/03/18</td>
<td>SPECIMEN PROCESSING C</td>
<td></td>
<td></td>
<td></td>
<td>30.00</td>
</tr>
<tr>
<td>07/10/18</td>
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<td></td>
<td>30.00</td>
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<tr>
<td>07/10/18</td>
<td>SPECIMEN PROCESSING C</td>
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<td>30.00</td>
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<tr>
<td>07/17/18</td>
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<td>SPECIMEN PROCESSING C</td>
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<td></td>
<td>30.00</td>
</tr>
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<td></td>
<td></td>
<td></td>
<td>30.00</td>
</tr>
</tbody>
</table>

SUB-TOTAL OF CHARGES: 210.00
Hospital Institutional Account Statement Customization

Next Steps
• Present statement design recommendations to HQ.
• Bring back recommendations to group for second review and share potential implementation timeframe.

• Contact Information:
  • Clinical Trial Billing ctbillingquestions@uabmc.edu

• Questions?
CBR UPDATES

Dawn Matthews, MPA, CCRC, CPC, CNM
Manager, Clinical Billing Review
CBR Annual Meetings With Research Departments

✓ Completed - conducted during September and October

✓ Great feedback and interaction with the departments

✓ Successful research community outreach effort
New CBR Submission Workbook

- Expected to be piloted in January 2019
- Anticipated distribution to campus is February 2019
OnCore Updates

John Sandefur
Lisa Williams
OnCore implementation overview

- 274 protocols were migrated from SiteMinder to OnCore in 3 waves. As part of the data migration process, data was scrubbed and updated.

SiteMinder has been retired.

OnCore training:

- OnCore Overview-58 attendees
- Protocol Management-272 attendees
- OnCore Calendars-246 attendees
- Subject Management-267 attendees
- OnCore Financials Overview-42 attendees
OnCore Financials Project

• In early 2018, the need to break out the OnCore financials implementation as a separate project was identified. This was due to several dependencies that require a great deal of effort and coordination between various units to implement.
  • Development of a new universal chargemaster that will streamline the building of study calendars and greatly simplify the ability of study teams to identify pricing for labs and procedures. The billing offices have agreed to use the same chargemaster and pricing structure at 100% of Medicare reimbursements.
  • Development of processes and code to replace the current CTBN. The current code is not compatible with version 15.x of OnCore. Replacing the code will also greatly reduce the chances of breaking the code when future patches and upgrades are implemented.
  • Upgrade to OnCore version 15.4 or above. This version provides significant enhancements to financials functionality. This requires upgrades to Oracle and other technical changes.

• Implementation planned to begin in April 2019

OnCore Expansion

• In the second half of 2019, OnCore will be expanded to allow use of the application to manage protocols without clinical billables.
Helpful OnCore Hints

1. In the *PC Console* the Duplicate Enrollment button allows subjects to be added the protocol multiple times. Use the same MRN but each enrollment must have a unique sequence number.
Helpful OnCore Hints

2. A report that shows the reason subject were marked “Ineligible” for a protocol is available in REPORTS > Reports > Accrual Monitoring > Custom Reports > Subject Not Eligible.

3. In the REVIEWS tab: The CTMC Console is a very informative summary of various protocol data points: Protocol Accrual; Arms; IRB History; Subject Demographics; Accrual by month; year; subject demographics, and more! EXTREMELY beneficial for REG Managers for IRB renewals or to show as a protocol summary to a principle investigator.
Helpful OnCore Hints

4. The date that populates the Visit Date field when you occur a visit applies to all the procedures within that visit. One does not need to re-enter the visit date in the individual Procedure Date field. A blank procedure date field does not mean the procedure did not happen.

If the procedure occurred on a date that is different from the “all encompassing” Visit Date then that procedure-specific date must be entered in the Procedure Date field.
Notes from the Calendar Builders (aka OCS)

1. A **new** calendar requires both CBR submission and OCS request.
   (Assumes trial has clinical billables.)

2. A **calendar revision** *always* requires an OCS request and *sometimes*
   requires a CBR submission if the requested changes affect clinical
   billables.

3. Please do not click the New Version button in the *Specifications* tab when
   viewing the calendar. *(Stop at the Release button.)*

   “New Version” STOP! Calendar Builders Only
If you have Questions…

Try the “?” first.

Ask a Super User.

Call the HelpDesk at 4-8888

Email OnCore@uabmc.edu

Website https://www.uab.edu/medicine/ctao/investigators/oncore-enterprise
PowerTrials:
Quick Overview and Updates
PowerTrials is the IMPACT module that uses the information from OnCore for research study management within the electronic health record. This includes:

- **Banner Bar indicator:** Research: On Study displays on the banner bar, with an attached research summary

- **PowerPlans:** an electronic protocol order set built specifically for each research study that drives clinical billing to the research study or the patient’s insurance as determined by the Clinical Billing Review office (CBR)
Q1: billed to the patient’s insurance as Standard of Care

IRB number: billed to the Clinical Trial
Check out the PowerTrials website! There are Updates! Resources! FAQs!

https://www.uab.edu/medicine/ctao/investigators/powertrials
ER Admission Automated Notification
As of 5/24/18, the Study Team listed in OnCore (Principal Investigator and Research Coordinator) will receive a Message, in the Impact PowerChart Message Center, when a patient that is listed as enrolled in the study is admitted to the Emergency Room.

PowerTrials needs your feedback!
  Do you love it?
  Do you hate it?
  Email powertrials@uabmc.edu
New PowerPlan Ordering Icon!!

As of 10/18/18, if a patient is listed as On Study in Oncore, and you have a PowerTrials PowerPlan released in Production, you can select the icon below and the PowerPlan will automatically generate.
New Orderables!!!

Now Offering:

• **Echo**

• **Research Pharmacy Outpatient Prescriptions**
PowerTrials PowerPlans should be **discontinued** in any of the following situations:

- The study is closed and no more visits will take place
- The patient is no longer on the study
- The PowerTrials PowerPlan has been placed on the patient more than once.
  - There should only be 1 PowerTrials PowerPlan per patient.

Email powertrials@uabmc.edu for detailed instructions

**Research Summaries**
- Document should be titled the ‘Protocol No.:’ listed in OnCore
- Should be in PDF format
Questions?

For further questions or concerns:

Alicia Gunter
PowerTrials Administrator (HSIS)
(205) 996 - 8763 office
abmartin@uabmc.edu