CCTS Lunch and Learn:
21 February 2017
UPDATES
Clinical Billing Review

Updates

Dawn Matthews, BS, CCRC, CPC, CNM
Manager, Office of Clinical Billing Review
CLINICAL BILLING REVIEW UPDATES

• CBR has released the CBR Submission Workbook to campus which is now required for **ALL** FAP Submissions.

• The FAQ sheet for the CBR Submission Workbook to be released soon and sent out via the CBR Email listing.

• If you have any questions you would like to have addressed in the FAQ sheet, please send them to the following link:

  FAQ Questions for CBR Submission Workbook
CLINICAL BILLING REVIEW UPDATES

• Since we now have our fourth staff member processing FAP submissions, the therapeutic area workloads have been re-distributed.

• Research units may have a new FAP/SiteMinder contact for their therapeutic area.
Questions?
Updates

- Office of the IRB Org Chart
- GCP Training Requirement
- Definition of Clinical Trial
- Revised IRB Forms
- Witness Signature on Consent Form
- Genomic Data Sharing
- Revised Common Rule
GCP Training Requirement

• NIH policy effective January 1, 2017
  – Basic GCP training
  – Refresher GCP training every three years

• All UAB investigators and staff involved in clinical trials, regardless of funding source

• Training requirement must be met for new protocols submitted as of January 1, 2017

• Training requirement must be met for ongoing protocols by February 28, 2017
Definition of Clinical Trial

• A research study in which one or more human subjects are prospectively assigned to one or more interventions (which may include placebo or other control) to evaluate the effects of those interventions on health-related biomedical or behavioral outcomes.
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A research study in which one or more human subjects are prospectively assigned to one or more interventions (which may include placebo or other control) to evaluate the effects of those interventions on health-related biomedical or behavioral outcomes.

- Prospectively assigned -- a pre-defined process specified in an approved protocol that stipulates the assignment of research subjects to one or more arms
Definition of Clinical Trial

A research study in which one or more human subjects are prospectively assigned to one or more *interventions* (which may include placebo or other control) to evaluate the effects of those interventions on health-related biomedical or behavioral outcomes.

- Intervention -- manipulation of the subject or subject’s environment for the purpose of modifying one or more health-related biomedical or behavioral processes and/or endpoints.
Definition of Clinical Trial

A research study in which one or more human subjects are prospectively assigned to one or more interventions (which may include placebo or other control) to evaluate the effects of those interventions on health-related biomedical or behavioral outcomes.

- Health-related biomedical or behavioral outcomes -- the pre-specified goal(s) or condition(s) that reflect the effect of one or more interventions on human subjects’ biomedical or behavioral status or quality of life.
Is this a “Clinical Trial” per the NIH definition?

No

No human subjects research per the Common Rule?

Yes

Are subjects prospectively assigned?

Yes

Interventions may include placebo or other control.

Intervention - a manipulation of the subject or subject's environment for the purpose of modifying one or more health-related biomedical or behavioral processes and/or endpoints. Examples include:
- Drugs/direct molecules/compounds
- Biologics
- Devices
- Procedures (e.g. surgical techniques)
- Delivery systems (e.g. tattoos, face-to-face interviews)
- Interventions to change health-related behavior (e.g. diet, cognitive therapy, exercise, development of new habits)
- Treatment strategies
- Prevention strategies
- Diagnostic strategies

No

Does the study evaluate the effects of those interventions on health-related biomedical or behavioral outcomes?

Yes

This is a Clinical Trial.

No

This is not a Clinical Trial.

Does the study involve one or more interventions?

Health-related biomedical or behavioral outcome is defined as the pre-specified goal(s) or condition(s) that reflect the effect of one or more interventions on human subjects' biomedical or behavioral status or quality of life. Examples include: positive or negative changes to physiological or biological parameters (e.g. improvement of lung capacity, gene expression), positive or negative changes to psychological or neuropsychological parameters (e.g., mood management intervention for adolescents, reading comprehension and/or information retention), positive or negative changes to disease process, positive or negative changes to health-related behaviors, and positive or negative changes to quality of life.
Revised IRB Forms

- Human Subjects Protocol & Sample Consent Form
  - Reflect updated guidance and necessary corrections throughout
  - Begin using these forms immediately
    - Outdated version of Human Subjects Protocol will no longer be accepted as of March 1, 2017
    - Use new sample consent form for consent forms submitted as of March 1, 2017
Witness Signature on Consent Form

- Witness signature is not always required by IRB
  - Required by IRB if enrolling illiterate participants
  - Required by IRB if using a Short Form
  - Sponsor may require the witness signature
  - PI may request witness signature for other reasons

- If witness signature line included on the consent form, provide rationale in the HSP (Item 21)
- IRB may request a witness signature based on the nature of the study
Genomic Data Sharing

• NIH issued the *Genomic Data Sharing Policy* (GDS Policy) effective January 25, 2015

• Applies to all NIH-funded research that generates large-scale human or non-human genomic data, as well as the future use of the data.

• For IRB submission to obtain Institutional Certification
  – HSP with new question (Item 24) regarding GDS answered -or- Project Revision/Amendment Form if protocol is already approved
  – Data Sharing Plan
  – Consent Form with appropriate information
  – Completed Institutional Certification
Revised “Common Rule”

- Department of Health and Human Services (DHHS) issued revisions to the Federal Policy for the Protection of Human Subjects (the “Common Rule”)
- Effective January 19, 2018, with the exception of the requirements for cooperative research, which are effective January 20, 2020
- Office of the IRB is working through the revisions and will provide updates through the year
IRB Forum: Revised HSP and Sample Consent Form

Thursday 3/02/17 from 9:00am - 10:30am
Finley Conference Center, Kaul Building

Monday, 3/06/17 from 1:30pm - 3:00pm
Finley Conference Center, Kaul Building

Forum held to describe in the detail revisions to the Human Subjects Protocol and Sample Consent Form. The same information will be presented at both forums.
Contact Us

Administration Building 470
701 20th Street South
Birmingham, AL 35294

www.uab.edu/irb
irb@uab.edu
205.934.3789
205.934.1301 (fax)
Goals of OnCore Enterprise

• OnCore will be replacing SiteMinder
• Improve patient safety by enhancing information sharing across UAB
• Creating consistent tracking of clinical trial activity
  ✓ Protocol accrual
  ✓ Visit tracking
  ✓ Financial management
What’s Been Happening?

• Survey
  ✓ 60 responses returned!! Thank you for participating.

• Research Site Interviews
  ✓ Providing a comprehensive view of your site. (staff details, clinical trial demographics, systems used). Very enlightening!
  ✓ Many, many methods being used to collect information and manage trials.

• Enterprise Kick Off - This Week
  ✓ Discussion between Forte (Vendor) and UAB leadership about current clinical trial processes and UAB’s plan to move forward.
Next Steps

• Continuing to conduct interviews
  • Why interview?
    ✓ Helps determine OnCore phase-in approach.
    ✓ Identifies needs of sites when transitioning to OnCore

• Creation of work groups to assist in defining usage (e.g. drop lists)

• Configuration of and Interfacing with other UAB systems
Rollout Target Date

4th Quarter of 2017
PowerTrials Update

Teresa Alexander
What is PowerTrials?
A module within the IMPACT EHR

PowerTrials Relation to OnCore?
“Bridge” (interface) links the two systems
“Push” will happen behind-the-scenes
Goals of Power Trials

- Enhance patient safety
- Automate research billing
- Enhance research billing compliance

- On/Off Study in IMPACT
- Protocol and Contact Info
- Research PowerPlans
- Pre-coded PowerPlans delineate SOC & Research charges
What’s Been Happening?

• Trials that **are Open to Accrual**, have human subjects, have clinical billables:
  - ✓ 100+ active Cancer Center trials being sent to PowerTrials
  - ✓ ~ 900 patient charts will display **On Study** and have contact information available

• Trials that **will soon Open to Accrual**:
  - ✓ Building & Testing Research PowerPlans

• PowerTrials education materials in development
Next Steps

- Education sessions with research staff
- **Open to Accrual** trials in OnCore
  - ✔ Research PowerPlan will be used to place research lab/rad orders in IMPACT

**Rollout Target Date:**
The first PowerPlans are scheduled for testing in PROD
OnCore Questions or Comments

OnCore@uabmc.edu
CCTS Lunch and Learn: 21 February 2017
UPDATES from the CCTS
Topics

• **At Risk Accounts/Pending Accounts:** where we stand

• **Drop in Clinics:** getting more information on critical issues

• **ClinicalTrials.gov:** what to expect

• **Other Education efforts**
At Risk Accounts/Pending Accounts: where we stand

- As of January 1, 2017, all contracts that have gone through OSP have been assigned at Risk Accounts/Pending Accounts.
- Audits will soon begin
Overview

Purpose: At Risk accounts or Pending accounts are used to assist in timely assigning and tracking the actual costs (e.g., pre-contract award/study start-up costs) of conducting a clinical trial (especially pharmaceutical trials); setting accounts up early in the process allows charges to be allocated to appropriate cost center at the time the work is being done.

General Process: Applies to all Industry sponsored trials beginning January 1, 2017. The process will be AUTOMATIC – no additional effort for the site.
Site responsibility

• Promptly submit the Extramural Checklist to OSP as soon as the determination has been made to participate in the study. The submission is NOT predicated on the status of or the receipt of the IRB, budget, protocol, CTA or CDA.

• Contact OSP if you do not receive your account number within two (2) weeks.

• Once you receive the account number:
  • Use the account to apply all study related pre-contract award/study start-up expenses, including effort and IRB. Project activities need to be assigned to the project that benefited from the work. This includes expenses and revenue.
  • Know if your unit uses a combined clinical trials account for personnel costs and process ACT documents accordingly.
  • If project activities started before you received the account number process the appropriate cost transfers as soon as possible.
  • Review and reconcile your account monthly.

• Do NOT worry if project expenses are applied to the account before any revenue is received or if project costs exceed revenue.
OSP’s responsibility

- Receives Extramural Checklist for a new Industry sponsored clinical trial.

- Notifies Accounting of the need for a new pending/at risk account.

- Once an actual award is executed, OSP notifies Accounting to change account from pending to active.
Accounting’s responsibility

- Sets up pending account *
- Notifies PI/Site of pending account (System Generated Email sent to award manager and PI of account number setup)
- Changes account to active upon execution of contract or closes account if a contract is not executed 1 year after account is set up

* The start date of the pending/at risk account will be 1 year prior to the receipt date of the checklist by OSP to enable sites to charge activities related to study start up. And the account will remain ‘pending’ status for 1 year after creation unless the account is either activated or terminated.
SITE: Receive CTA

SITE: Submit to OSP with Extramural Checklist

OSP: Contacts Accounting to request *At Risk/ Pending Accounts*

ACCOUNTING: Creates *At Risk/ Pending Accounts*; notifies site (Note: Allow 2 weeks for receipt of account notification)

ACCOUNTING: Activates account

SITE: Begins using *At Risk/ Pending Accounts*

OSP: Contract executed, notifies Accounting to make account active

SITE: Keep on going!
DO NOT PANIC!!!

• THIS ACCOUNT IS EXPECTED TO GO INTO THE RED – ESPECIALLY IN THE BEGINNING

• Goal is to appropriately accumulate/assign ALL study costs and revenue to the study account throughout the entire study period from start-up to closeout.
ClinicalTrials.gov: what to expect

- Final Rule: key changes are
  - Penalties
  - Uploading documents
  - A few additional data fields
Clinicaltrials.gov: penalties

• When: no penalties between now and April 17 – catch up delinquent reporting

• April 17, 2017 is expected to be the start of the penalties
Uploading documents to ClinicalTrials.gov

- URL ???
- Documents: protocol, IRB approval, approved unsigned consent forms, Statistical Analysis Plan
- Still evolving
Required protocols

Per the FDAAA

• Trials of drugs and biologics: Controlled clinical investigations, other than phase 1 clinical investigations, of drugs or biological products subject to Food and Drug Administration (FDA) regulation

• Trials of devices: 1) Controlled trials with health outcomes of devices subject to FDA regulation, other than small feasibility studies, and 2) pediatric post market surveillance required by FDA

Per the NIH

• The policy applies to all NIH-funded awardees and investigators conducting clinical trials funded in whole or in part by the NIH regardless of study phase, type of intervention, or whether they are subject to the statute and to the rule. (including phase I)
And the penalties

• Per the FDAAA (not new, but will now be enforced due to the Final Rule)
  • $10,000 (increasing – to $11,383) per infraction
  • If not corrected within 30 days, $10,000 (increasing – to $11,383) per day thereafter

• Per the NIH
  • Loss of NIH funding for the investigator
  • Loss of NIH funding for the institution
  • Public listing of non-compliant investigators, clinical trial and institutions on the ClinicalTrials.gov website
University Strategy due to the possibility of penalties

UAB establish an expectation that results are to be reported by the \textit{tenth} month, studies not reported by that time are considered at risk. Additionally, Departments will be responsible for penalties.

- CCTS will remind the investigators whose studies meet the reporting requirement along with offering of education and support.

- A communication plan with staged escalation through the 10th month will be used to provide the PI, Department, and School leadership opportunity to ensure the reporting requirements are effectively managed. Including a notice that any penalties resulting from delinquent reporting will be the \textit{responsibility of the Department}. 
University Strategy due to the possibility of penalties (con’t)

• If study results have not been reported by the 10th month, the School and Department leadership will meet with the PI, VP for Research, and the University Compliance Officer to determine a plan to provide the PI the time to devote to completing the reporting. For example, if the circumstances warrant there may be a suspension proposal.

• The Compliance Office will provide a summary to the President’s Risk Cabinet of studies beyond the 10 month standard, studies beyond the 12 month federal requirement and any penalties assessed.
What services we can provide

• Obtain password access to enter a new protocol or update one already registered (or regenerate a new one if needed!)
• One on one training with research teams
• Presentations for large groups
• Assistance with entering information
• Assistance with interpreting review comments
• Suggestions on completing data fields.
• Assistance with finding assistance!
Contact ccts@uab.edu for training and support

- One to one (at your office)
- Group sessions
  - Overview
  - Registration
  - Results reporting
Drop in Clinics at PCAMS: getting more information on critical issues

- Wednesdays – 11:30 – 1, PCAMS
  - Biostats (Every Wed.)
  - Clinicaltrials.gov (2\textsuperscript{nd} Wed., 4\textsuperscript{th} Wed.)
  - CRU (1\textsuperscript{st} Wed.)
  - Biorepository (1\textsuperscript{st} Wed.)
  - Bionutrition (1\textsuperscript{st} Wed.)
- COMING SOON: IRB
Education efforts

• Clinical Investigator Training Program
  • Next session to be announced – will start in late summer or fall

• Research Training Program
  • Next session: Starts Friday April 7 (7 sessions)

• Research Orientation Program
  • Next session: Monday Feb 27
Education efforts (con’t)

• Research Seminars
  • Career Development: how do you get there? (March 2, 12 -1)
  • ClinicalTrials.gov: the ‘how to’ of registration and results reporting (March 16, 11 -1)
  • Watch for a repeat of Budget Workshop and the IRB HSP Completion Workshop
  • Adding a Part 2: Negotiating a Clinical Trials Budget

• CCTS Lunch and Learn
  • May: xxxxxx
News

• Building a comprehensive mailing list: if you have attended anything, you will be on the list!

• Tracking everything you have attended…..so you can have the information.
Who to contact with Education questions?

- ccts@uab.edu
- dpatel@uab.edu
- chauser@uab.edu
- sadavis@uab.edu
Also – check out CCTS website for education opportunities

https://www.uab.edu/ccts

Go to ‘Events’ in banner bar
How can the CCTS help achieve your goals?

The CCTS and our partner network are here to sharpen your science and build vital collaborations by helping to facilitate all of the processes that make up research and innovation. As needs arise—for a program, resource, collaboration, or conversation—we facilitate solutions to help meet them.

The mission of the Center for Clinical and Translational Science (CCTS) is to address disparities and diseases disproportionately represented within the Deep South as we accelerate discovery to improve human health.
Events

Upcoming Events:

Feb. 21    Accessing Clinical Data for Research with i2b2
Feb. 21    CCTS Clinical Trials Lunch and Learn
Feb. 21    ADDA Lecture Series: Introduction to Drug Discovery
Feb. 21    UAB Exercise Clinical Trials Facility Open House
Feb. 23    CCTS: Accelerating the Translational Process
Feb. 24    Translational Science 2017: Early Bird Deadline
Feb. 25    Alabama Brain Bee
Feb. 27    UAB Research Orientation Program
Feb. 28    ADDA Lecture Series: What is a Valid and Druggable Target?
March 1    CHIA Innovation Workshop Deadline
March 1    UAB-HudsonAlpha Center for Genomic Medicine Seminar
March 1    CCTS Forum: New Paradigms for Scientist to CEO Transition and New Biotechnology Startup Creation
March 2    CCTS Research Seminar Series: Career Growth for Clinical Research Professionals
March 2    Research Methods and Secondary Data Analysis Seminar Series
March 2    Accessing Clinical Data for Research with i2b2
March 3    Genetics and Genomics in Day to Day Medical Practice
March 8    UAB-HudsonAlpha Center for Genomic Medicine Bioethics Seminar Series
March 15   UAB-HudsonAlpha Center for Genomic Medicine Seminar
March 16   CCTS Research Seminar Series: How to Register a Protocol in ClinicalTrials.gov
March 16-17 SfRBM Regional Redox Symposium: Translational Redox Biology
March 21   Accessing Clinical Data for Research with i2b2
Where are the recordings of the CCTS offerings?

• Training academy
• Events Archive
  • (CCTS YouTube channel)