CCTS Lunch and Learn
25 October 2016

WELCOME!!!!!!!!!!!!!!!!!!!!!!!!!!!!!!!!!!!
Agenda

• **Introductions:** P Jester
• **CTAO:** Mark Marchant
  •  **Oncore/Powertrials:** Lisa Williams
  •  **Clinical Billing Review:** Dawn Bryant Matthews
• **Update on IRAP:** Jonathan Miller
• **Update from the IRB:** Leslie Cooper
• **I2B2/recruiting:** Matt Wyatt
• **Compliance/Effort Reporting:** Jeremy Logan
• **RPL and new training:** Brenda Cox
• **Education Initiatives:** Penny Jester
Clinical Trials Administrative Office

School of Medicine Dean’s Office

Clinical Trials Administrative Office
- Mark Marchant (Director)
- Mansoor Saleh, MD (Med Director)
- Coverage Analysis (CBR)
- Policy & Procedures
- Implementation of Information Systems Billing Compliance
- Performance Measurement
- Operations Improvement
- Liaison for Investigators w/Central Admin

CTAO Advisory Board
- Robert Kimberly, MD (Chair)
- Anupam Agarwal, MD
- Mansoor Saleh, MD (Med Dir)
- Burt Nabors, MD
- Mike Mugavero, MD
- Mark Dransfield, MD
- Lauretta Gerrity, DVM
- Brian Bates
- Teresa Bragg
- Raheel Farough
- Geoff Gordon
- Penny Jester
- Mark Marchant

UAB THE UNIVERSITY OF ALABAMA AT BIRMINGHAM
Knowledge that will change your world
CTAO’s Charge

• Ensure appropriate 3rd party billing and enhance financial management processes that improve internal controls in research-related activities

• Enhance use of clinical research management systems and support an integrated approach to capturing research data throughout UAB
Introduction to

Lisa Williams MSHI
OnCore Enterprise Administrator
What IS *OnCore Enterprise Research System?*  
**On-line Collaborative Research Environment**

- Clinical Trial Management System (CTMS)
  - Comprehensive, internet-based system manages day-to-day operational activities of clinical trials
  - Forte Research Systems based in Madison, Wisconsin
  - Utilized in nearly 100 academic medical centers, cancer centers, and health care systems
  - Well-established community of experienced users with whom to share best practices
- Provides support throughout the protocol lifecycle continuum, from trial activation to study closure
OnCore’s Customer Base

- **48 Cancer Centers (36 NCI-designated)**
- **31 Academic Medical Centers (18 CTSAs)**
- **12 Health Care Systems & Hospitals**

Courtesy of forte Academy Systems
Why are We Expanding OnCore to the Whole Campus?

✓ Provides more streamlined workflows and information collection across teams/departments
✓ Improves operational efficiency by providing visibility of protocol management, subject enrollment, regulatory status, and budget information
✓ OnCore’s abilities align with leadership and sponsor reporting needs – Tools to track and evaluate site/institutional performance
✓ Communicates with IMPACT through PowerTrials – linking protocol and subject information with the electronic medical record
✓ SiteMinder - older system, limited functionality, and no longer supported by the vendor
What benefits will I see by using OnCore?

✓ Advanced feature set provides more functionality for several areas of research
  • Protocol and subject management – set up protocol visits and procedures
  • Financial – create study budgets; tracks research and negotiated rates
  • Regulatory – upload protocol documents; renewal reminders; safety data tracking

✓ Create CRFs and use them with Electronic Data Capture

✓ Gain immediate insight into activities across all your protocols

✓ Flexible Do-It Yourself Reporting Tool
  • Protocol Accrual Reports e.g. by Gender, Age, Race, Ethnicity
  • Expiring Staff Credentials (training, license, CVs)
  • Subject Visit Invoicing
Will I be able to be involved?

Absolutely! Successful projects need user input.

Working Groups Help make configuration decisions (i.e. choosing options for various drop lists)

Super Users First-line of support for the sites. Smaller units may have a shared super user resource.

Provide Feedback Via future OnCore website
What is PowerTrials and What does it have to do with OnCore?

✓ A set of new features in UAB’s electronic health record, IMPACT
✓ Protocol and Subject Information from OnCore to IMPACT
✓ Current efforts are focused on

1. Patient Safety – An On/Off Study indicator displays in chart’s banner bar
2. Simplify ordering of clinical services - Research PowerPlans
   • similar to ordering method used for patient care orders
   • will direct the flow of charges to the proper payer, either the participant’s health insurance or institutional research account
So what happens now?

✓ Research Survey
  • Emailed to research personnel
  • If you prefer, pool your responses to respond to survey

✓ Follow-up Interviews
  • Post receipt and review of surveys

LIKE DR. SEUSS’S HORTON THE ELEPHANT,
WHETHER LARGE OR SMALL
WE WANT TO HEAR FROM YOU ALL!
✓ Phased implementation
✓ Training schedule
Future State of OnCore

- Biminate duplicate entry of administrative data
- Tools to efficiently manage conduct of trials
- Improve fiscal reporting and regulatory tracking
- Visibility of clinical research portfolio

- Patient safety
- Appropriate billing

- Pre-Study Start Up Activities
- Clinical Trials Management
- Electronic Health Record
Thank You

from the OnCore Enterprise Team

OnCore@uabmc.edu
Clinical Billing Review

Dawn Bryant Matthews, BS, CCRC, CPC, CNM
Manager-Office of Clinical Billing Review

dbryant@uab.edu
996-7573
NEW FAP SUBMISSION PROCESS

• CBR will soon have a new campus-wide FAP submission process using a FAP Submission Workbook.

• A meeting to discuss FAP submission changes is being scheduled for November. Additional information will be provided as details are finalized.

• Representation by all departments who submit to FAP will be required.
CLINICAL BILLING REVIEW STAFF GROWTH
Clinical Research Analysts

• Ashley Specht
• Kristi Oliver
• Isha Moore (beginning 10/31/16)
• Dawn Matthews

===========================================
• Kimberly Lowery (New Part-Time Administrative Support)
CLINICAL BILLING REVIEW

For FAP/SiteMinder questions, please Email fap@uab.edu.
Integrated Research Administration Portal (IRAP)

Jonathan E. Miller, MPPA, CIP
Assistant VP for Research Administration
Operations and Systems
October 25, 2016

Powered by Software from InfoEd Global, Inc.
Implementation Status

• Modules Implemented
  • SPIN, SMARTS
  • My External Interests (CIRB)
  • My Proposals (OSP)
  • My Technology Transfer-MTA (MTO)
  • My Lab Animal Research (IACUC)

• Next Steps – Modules to support
  • Online submission to OSP
  • Submission of IPDs to IIE, IP management
  • IRB
  • OH&S Safety Committees
IRAP Human Subjects Module Rollout

• Step 1 – Legacy data conversion

• Step 2 – OIRB utilization and existing form uploads

• Step 3 – eForm for full electronic submission
Step 1 – Legacy data conversion

- Status – first data loaded earlier this month
- >14K protocols loaded
- “Rinse and repeat”
Step 2 – OIRB utilization and existing form uploads

InfoEd

Logged in User: Joe Investigator

$ Find Funding CV Database

Exit Help

My Projects
My Proposals
External Interests
Human Subjects
Lab Animal Research
Technology Transfer
My Profile
Administrative Notes...
V14 eReports

My Open Action Items

- Under Review
  Lab Animal Research Protocol - IACUC-20004
  PI: Investigator, Joe (UAB root node)
  Title: Test Protocol
  Open Action Items: 0
  Outstanding Reviews: 1
  Reviewer

- Under Review
  Lab Animal Research Protocol - IACUC-20004
  PI: Investigator, Joe (UAB root node)
  Title: Test Protocol
Step 2 – OIRB utilization and existing form uploads
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Step 3 – eForm for full electronic submission

• Focus group of experienced campus users already meeting regularly
• eForm will combine all forms for initial submission into one – regardless of level of review
• Branching logic will solicit all of the information – and only the information - needed for your project
  • Waivers of consent, authorization, documentation
  • Special population information
  • Drug and device information
Questions?

Jonathan Miller
975-0699
jonathanm@uab.edu

• If you have questions about IRAP please contact IRAP@uab.edu or see our IRAP Project website at www.uab.edu/irap

• If you have any problems with the system please contact AskIT at 996-5555 or askit@uab.edu

• IRAP Help is available during Tuesday help sessions or by contacting us to set up date/time. Information can be found at http://www.uab.edu/era/News/Pages/IRAPHelpSessions.aspx.
IRB Update

Leslie Cooper, CIP
Interim Director, Office of the IRB
University of Alabama at Birmingham
IRB Update Topics

• Single IRB
• Human Subjects Protocol
• Sample Consent Form
Single IRB

• One IRB reviews the research study for multiple sites/institutions.

• That IRB is the IRB of record for all of the sites/institutions.
Goals of Single IRB

- to streamline the process of IRB review
- to improve efficiency and consistency
- to reduce administrative burdens/inefficiencies
In September 2015, the DHHS published its NPRM for Revisions to the Common Rule.

- "...to modernize, strengthen, and make more effective" the Federal Policy for the Protection of Human Subjects, aka the Common Rule
- one of the proposals is for U.S. institutions engaged in cooperative research to rely on a single IRB for that portion of the research that takes place within the U.S.
- The rules have not yet been finalized.
In June 2016, the Final NIH Policy on the Use of a Single IRB of Record for all Multi-site Research was issued.

• “...all sites participating in multi-site studies involving nonexempt human subjects research funded by the NIH will use a single Institutional Review Board to conduct the ethical review required.”

• The policy applies to all competing grant applications (new, renewal, revision, or resubmission) with receipt dates on or after May 25, 2017.
NIH Policy - Details

• Domestic sites of NIH-funded multi-site studies where each site will conduct the same protocol

• “Multi-site” is defined as two or more sites

• Foreign sites are not expected to follow the policy
NIH Policy - Details

- Research supported through
  - Grants
  - Cooperative Agreements
  - Contracts
  - NIH Intramural Research Program
- Does not apply to career development, research training or fellowship awards
NIH Policy - Applicant Responsibilities

• Applicant of the funding includes in the application/proposal to NIH:
  • Description of use of the single IRB that will be selected to serve as the IRB of record for all study sites
  • Statement confirming that all participating sites will adhere to NIH Single IRB Policy
  • Description of how sites and single IRB will communicate
NIH Policy – Applicant Responsibilities

• If delayed-onset research (single IRB not yet identified), applicant of the funding includes in the application/proposal to NIH:
  • Statement that awardee will follow the NIH Single IRB Policy
  • Statement that awardee will inform the funding NIH Institute/Center of plan to use a registered IRB of record before initiating a multi-site study
NIH Policy – Applicant Responsibilities

• Applicant may request direct cost funding
  • Costs of establishment and review of the multi-site study by the single IRB
  • Requires appropriate justification
  • Must be reasonable and consistent with cost principles
    • NIH Grants Policy Statement
    • Federal Acquisition Regulation
NIH Policy - Exceptions

- Exceptions made when single IRB reviewed prohibited by federal, tribal, or state laws, regulations or policies

- Other requests for exceptions can be made to NIH
Issues with Single IRB

• Reliance Agreements
• Institution Responsibilities vs. IRB Responsibilities
• Varying policies & procedures
• Varying state laws
• Communication between Single IRB and all sites/institutions
• Costs
UAB Office of the IRB’s To Do List

• Update and refine handbook
• Update and refine template reliance agreement
• Educate research community & IRB members
• Create Single IRB section of website
Human Subjects Protocol & Consent Form

• Revised HSP & Consent Form to come out next couple of weeks
• Will host session to go over revisions to documents
• To include Spanish Consent Form
• To include Boilerplate Language document
Questions

Office of the Institutional Review Board
470 Administration Building
701 20th Street South
Birmingham, AL 35294

http://www.uab.edu/irb
irb@uab.edu
Phone: 205-934-3789
Fax: 205-934-1301
What is i2b2

- Any faculty or staff can log in with BlazerID
- Aggregate and De-Identified Data (LDS) data
- Self service query for patient populations
- Easy Drag-and-Drop user Interface
- IRB Approved

When to use i2b2

- Feasibility assessment and cohort estimation
- Proposal preparation and population characterization
- Study initiation
  - Determining patients for recruitment
- Hypothesis Exploration

What if i2b2 isn’t sufficient

Consultations can be initiated within i2b2

- More detailed Feasibility Assessment
- More Detailed Proposal Preparation
- Study Initiation
  - Identify patients for recruitment
- Study Data Collection (or acquisition)
- Targeting chart review

Included Organizations:
- UAB Hospital
- The Kirklin Clinic
- Other UAB Clinics
- UAB Highlands
- Women & Infants

Organizations Not Included:
- UAB Affiliates
- Callahan Eye Children’s
- Veterans Adm
- CCTS Partners
- CTSA Southeast Consortium

Data Currently Available:
- Patient Demographics
- Visits/Encounter Details
- Clinical Diagnoses and Problems
- Labs
- Medications
- Procedures
- Vital Signs
  - BMI, Height, Weight
  - Waist, Blood Pressure
- Cancer/Tumor Registry
- DRGs
- Allergies
  - Drugs / Non-drugs / NKA
- Other project specific
  - Rheumatology, Microbiology
How to get more information

https://www.uab.edu/ccts/researchcommons/research-data-requests

https://www.uab.edu/ccts/research-commons/informatics/i2b2

Or Google “i2b2 UAB”
Effort Reporting Update

CCTS Lunch and Learn
October 25, 2016
## Effort Reporting Changes

<table>
<thead>
<tr>
<th>Previous</th>
<th>Effective with effort reports for periods beginning October 1, 2016</th>
</tr>
</thead>
<tbody>
<tr>
<td>Exempt employee <em>approves his/her effort</em>; PI <em>certifies employee’s effort</em></td>
<td>Each exempt employee will <em>certify his/her own effort</em></td>
</tr>
<tr>
<td>Effort recorded to within two decimals</td>
<td>Effort rounded to integer (no decimals)</td>
</tr>
<tr>
<td>Effort reporting by object code group</td>
<td>Effort summarized by account</td>
</tr>
<tr>
<td>Uncertified effort reports considered <em>past due at 60 days after end of quarter; delinquent upon generation of next quarter’s effort reports</em></td>
<td>Uncertified effort reports considered <em>delinquent 60 days after end of effort reporting period</em> (No distinction between <em>past due vs. delinquent</em>)</td>
</tr>
<tr>
<td>Effort reporting period by quarter</td>
<td>Effort reporting period semi-annually beginning with October 1, 2016 reporting period (Oct-March, April-Sept)</td>
</tr>
<tr>
<td>Training must be completed before effort can be allocated to extramurally sponsored projects</td>
<td>New training required by all investigators and DEOs, then refresher training every three years</td>
</tr>
</tbody>
</table>
Compliance 411 Newsletter

Published quarterly by the UCO to help:
• Raise awareness
• Communicate important developments, and
• Foster transparency

To subscribe, email compliance@uab.edu or join the newsletter distribution list.
OFFICE OF CONFLICT OF INTEREST (OCIRB)

Helpful Tips
Disclosure Process

- Anyone involved with the Design, Conduct or Reporting of research regardless of title, position or employment status

- Anyone named by the PI on the Responsible Personnel List (RPL) or Human Subject Protocol (HSP)
  - Consenting, listed on 1572, device agreement, or sponsor’s form

- Must include any significant interest of spouse/prominent partner and minor children
Financial Disclosure

- **Financial Interest Disclosure**
  - Required prior to OSP submission of the grant application
  - All new significant financial interests or modification of existing financial interest must be submitted within 30 days

- **External Activity Form (EA)**
  - Required prior to any activity related to institutional responsibilities
  - Must be approved by School/College Dean/VP

[www.uab.edu/uabforms](http://www.uab.edu/uabforms)
Financial Conflict of Interest in Research Training Course

- Required by federal regulations and UAB Conflict of Interest and Conflict of Commitment Policy

- Required for all RPL individuals prior to OSP releasing the grant

- Required prior to beginning internally funded research activity

- Required re-training every four years
Financial Conflict of Interest in Research Training Course

- Courses taken through UAB Learning System

- Financial Conflict of Interest (FCOI) training courses
  - “Financial Conflict of Interest in Research – CIRB_FCOI (Initial course)"
  - “Financial Conflict of Interest in Research – 4\textsuperscript{th} Yr Refresher – CIRB_FCOI_Refresher”
Responsible Personnel List (RPL)

- Required for all new applications
- Required any time there is a change in responsible personnel
  - Addition/removal of individuals
- Submitted to the Office of Sponsored Programs (OSP).
- Note HSP responsible personnel must match RPL.
OCIRB

- Phone number: (205) 975-9691
- Email: cirb@uab.edu
- Campus address: AB 719, zip 0111
- http://www.uab.edu/cirb
General Updates

Penelope M Jester BSN RN MPH
Program Director CRSP/CCTS
University of Alabama at Birmingham, Birmingham, Alabama
1 November 2016
Miami CITI
GCP and HSP Course

UAB Research Orientation Program:
Operationalizing GCPs: a primer

Research Training Program (staff)

Clinical Investigator Training Program

Continuous training:
Research Seminar

Within 2 weeks of employment
Within 2 months of employment
Within 6 months of employment
Offered 2 times each month

Content driven by Competencies / GCPs
Where is the training and how will we know we are compliant?

- **Basic course:** Miami CITI ICH-GCP training
  http://www.uab.edu/research/administration/offices/IRB/Training/Pages/ICHGCP-Training.aspx

- **Enhanced courses:**
  - Research Orientation Program (monthly – everyone)
  - Research Coordinator Training Program (twice a year – staff)
  - Clinical Investigator Training Program (in development)
  - Research Seminar (2 offerings monthly)
  - Others to come
Overview of At Risk Accounts

Purpose: At Risk accounts or Pending accounts are used to assist in tracking the actual cost of conducting a clinical trial (especially industry trials)

Goal: To facilitate appropriate accounting for expenditures associated with study activation including, study start-up fees and personnel expenses

General Process: For Industry sponsored trials, the process will be AUTOMATIC – no additional effort for the site
OSP’s responsibility

1. Receives Extramural Checklist for a new industry trial
2. Notifies Accounting of the need for a new pending/at risk account
3. Once an actual award is executed, OSP notifies Accounting to change account from pending to active
Accounting’s responsibility

1. Sets up pending account *
2. Notifies PI/Site of pending account (oracle string sent to site)
3. Changes account to active upon execution of contract

* 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

- Applies start up charges to pending/at risk account and then continues to use when becomes active.

This includes start-up fees for IRB, Pharmacy, Radiology, etc., as well as personnel expenses associated with the time required for study activation procedures.
SITE: Receive CDA

SITE: Submit to OSP with Extramural Checklist

OSP: Contacts Accounting to request At Risk/Pending Accounts

ACCOUNTING: Creates At Risk/Pending Accounts; notifies site

ACCOUNTING: Activates account

SITE: Begins using At Risk/Pending Accounts

OSP: Contract executed, notifies Accounting to make account active

SITE: KEEP ON GOING!

Schematic – quite simple!

ACCOUNTING: Activates account

SITE: Begins using At Risk/Pending Accounts

OSP: Contract executed, notifies Accounting to make account active
DO NOT PANIC!!!

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

• Goal is to get it out of the RED by the end of the study or have identified a source to offset the deficit.
Summary:

- The accounts will automatically be set up.
- You will be notified when the account is available.
- Start using immediately
Upcoming

Sept 27 2016 – Research Orientation Program

Nov 3 2016 – Research seminar: Building a Budget (2 hours)

Nov 17 2016 – Research Seminar: Team approach to successful clinical trials implementation: A Case Study

LET US KNOW WHAT YOU NEED!