Agenda

Introduction- Meredith Fitz-Gerald
Clinical Trials Initiative- Dr. Robert Kimberly
OSP- Debbie Graves
IRB- Adam McClintock
Job Ladder- Mike Bertram
Financial Affairs (GreenPhire)- Debbie Snider
CBR- Dawn Matthews
OnCore- John Sandefur/Lisa Williams
i2b2- Matt Wyatt
SAVE THE DATES

Next Lunch and Learn: September 17, 2019

Special Topics in Clinical Research /Research Seminar:

• April 18th OnCore Updates
• May 2nd RTP Continuation: PowerTrials, GreenPhire and OnCore
• May 16th RTP Continuation: Preparing IRB Documents

Research Training Program: Fall- August 20, 2019
Research Orientation: May 23, 2019

Questions on training, please email CRSPtraining@uabmc.edu
Clinical Trials Initiative

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

Debbie Graves
OSP Training Coordinator
dggraves@uab.edu (205) 934-1408
OSP/RBO Updates

- Cathy Tarver - Federal Associate Director, OSP
- Mike Matthews – Director, Research Technology and Communications, RBO
- Coming: IRAP Assessment
IRAP Assessment Timeline

April 30, 2019
- Define Project Scope
- Assessment Plan Finalized & Approved
- Identification of Participants and Focus Groups

June 30, 2019
- Site visit to InfoEd vendor scheduled
- Identify Architecture Stability
- Focus Groups Sessions Scheduled

July 31, 2019
- Perform Gap Analysis
- Focus Groups Sessions Complete

Sept. 30, 2019
- Written Assessment Report Finalized
- Recommendation to Vice President for Research
IRB Updates & Current Events

CCTS Lunch & Learn

Adam J. McClintock | Director
Office of the Institutional Review Board
What are they doing over at the IRB office?

1. Needs Assessments
   1. Stakeholders Meetings
   2. Operational Needs Assessments

2. Assess Processes/Workflows
   1. Level Setting/Stabilizing
   2. Building a Foundation

3. Identify & Prioritize Opportunities
Career Ladder

Michael Bertram, PhD, MBA
Associate Director for Administration
O’Neal Comprehensive Cancer Center
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

- Pilot-CCC
  - Began January 28\textsuperscript{th}
  - Document Collection
    - Resume
    - Experience Credit Form
    - Org Chart
    - Duties Assessment
  - Mapping Process
    - Involves CCC, SOM Dean’s Office, Central HR
- Communication
Greenphire Update

Debbie Snider
Staff Development Officer
Office of Chief Financial Officer
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
- HIPAA Training Requirement for Non-Covered Entities
- SSN Requirement Exemption

**Cost:**
- Cards: $4.80 paid by University
- Loads: $1.15 paid by University
- FY20: Load fees paid by Departments

**Reminder:** Review ICF language to ensure silent on payment type
Greenphire

- Phased Roll-out
  - Pilot: Fall 2017
  - Waves 1 & 2: 2018
  - Wave 3: Q1/2 2019
    - Department of Medicine
  - Wave 4: Q3 2019
    - Optometry, Neurology, Neurosurgery, Otolaryngology, Urology, Radiology, Surgery
  - Wave 5: Q4 2019
    - Orthopedic Surgery, Physical Medicine, Radiation Oncology, Others?
Questions
Clinical Billing Review Updates

Dawn Matthews, MPA, CCRC, CPC, CNM
Manager, Clinical Billing Review
REMINDERS:

• Please send **ONE** CBR study submission per Email.

• Please ensure the chemistry labs on the Billing Plan are listed based on the UAB Hospital Laboratory Panels (i.e. CMP + Magnesium + GGT).

  * Here is a link to the UAB Hospital Laboratory Panel information provided during the CBR Annual Meetings:
• The **new** CBR Submission Workbook in PDF format has been piloted and is ready for use by the research departments. An Email distribution of the PDF Workbook and training session information was sent to the research departments last week.

• CBR will conduct training sessions for the PDF CBR Submission Workbook:
  - April 10\(^{th}\) from 2:00-3:00PM in Margaret Cameron Spain Auditorium
  - April 16\(^{th}\) from 10:00-11:00AM in West Pavilion Conference Room E

• **ALL** CBR submissions **must** include the new PDF Workbook beginning Wednesday, May 1\(^{st}\). Submissions that do not include the new Workbook on or beyond this date will be returned.
CLINICAL BILLING REVIEW QUESTIONS

Questions?

For questions regarding CBR, please Email: fap@uab.edu
OnCore Updates

John Sandefur
Manager II-Application Architect
OnCore Team Leader
The OnCore Road Map

Q2 2019
New (1st update) chargemaster complete

Q3 2019
New CTBN process complete
New (2nd update) chargemaster complete

Q4 2019
OnCore Expansion

Q2 2019
OnCore version 15 upgrade

Q3 2019
OnCore financials goes live-pilot group followed by two waves
What will OnCore version 15 bring?

- A more modern look and feel along with more options for customization to individual tastes. A new favorites bar and drag-and-drop functionality.
What will OnCore version 15 bring?

- Greatly enhanced financials functionality.
- Optional treatment segments. Designate that a segment isn’t necessary for all subjects based on the arm/group to which they are assigned.
- Improved Protocol and Subject Search. Short Title is now available as a search criteria and result column in Protocol Search.
- Protocol level control of blinded treatment and randomization
What will OnCore version 15 bring?

- Updates to Subject Visit Details Report (the current Planned Visit Report)
What will OnCore financials bring?

- The ability to enter a protocol budget so that budget items can be tracked and appear on invoices that can be created and sent to sponsors.
What will OnCore financials bring?

- The ability to track contractual invoiceable items such as monitor visits, SAEs, and screening failures in the CRA Console and invoice for these expenses.
What will OnCore financials bring?

- Leverage the use of triggers such as IRB Approval, IRB Study closure, or CRA Console to identify items that can be included on an invoice.
The addition of protocols that do not contain clinical billables to the portfolio of trials in OnCore.

Expansion into units that do not currently use OnCore.

Challenges (this list is not all-inclusive):

- Determine the impact of the new protocols on the billing feeds that are sent to MSO and PFS. These feeds alert the billing units when new trials/new patients are added to OnCore. We do not need to send them information on trials without billable items.
- Support for forms development for IITs. Curation of forms libraries, use of CDEs, etc.
- Implications for the Cerner interface-trials with UAB patients/MRNs and non-UAB patients without MRNs.
In other news….  

- CCTS calendar events will be built by OnCore Calendar Services (OCS).
  - A unified submission process will be developed and implemented for CCTS and OCS services.
- New chargemaster
  - Single event per procedure
  - Pricing is 100% of Medicare reimbursement (cost to the study team).
  - Removal of duplicate chargemaster items
- A newer, “smarter” CTBN is under development.
- Positions are being added to the OnCore Team to support the increased volume of calendars and to support financials. Research Protocol Analyst, Financial Analyst-OnCore.
- Please join us for a celebration on 04/17 in PCAMS at 4:30.
Reminders for OnCore Users

Lisa L. Williams MSHI
OnCore Administrator
An Adjustment to your Routine

Wave 3
September 2018

Wave 2
April 2018

Wave 1
Dec. 2017 & Jan 2018
An Adjustment to your Routine – Ongoing Maintenance

**STAFF Tab**
- Keep Study Staff list up to date – New staff?
- ESPECIALLY Study Coordinator, Billing Contact, or P.I. These roles have CTBN and billing implications.

**STATUS Tab**
- Move protocols to **Closed to Accrual** when accrual goal is met
- Move protocol status to **IRB Study Closure**

**Reviews/IRB Tab**
- Update IRB reviews at time of renewal or amendment
- Also enter corresponding consent information

WHO is managing these updates?    WHEN are these updates being made?

Do you have a “tickler system” in place to remind you to make updates?
Ongoing Protocol Maintenance     Study Close Out

After the **Closed to Accrual** status:

- All visits have been kept AND all subject statuses are moved to **Off Study**

Then do the following:

- Update **Primary Completion Date** on MAIN/Details tab AND change status to **IRB Study Closure** on the STATUS tab
OnCore is Not Your Momma’s SiteMinder

ALL Visits Should be Managed in OnCore – Not Just Visits with Clinical Billables:

• Calendars are built with all protocol visits. Please Occur, Miss, or NA all visits.
• Use the Planned Visit Report to keep up with un-tracked visits.
  • (Filter by Protocol, Subject Staff, Management Group, or Visit Status.)
  • (The future) Financial module depends on this activity so it can produce items for invoicing the sponsor.

OnCore tracks many additional protocol, sponsor, and study-related details:

• Which allows data to be presented to Study Teams, PIs, and Leadership in a more meaningful way.
QUESTIONS?

If you have Questions…

Try the “?” first.

Ask a Super User.

Call the HelpDesk at 4-8888

Email OnCore@uabmc.edu
Clinical Data & Tools to Support Research

*i2b2 and the Enterprise Data Warehouse*

Matt Wyatt

Director of Clinical Research Informatics
Center for Clinical and Translational Science
UAB Informatics Institute
Health System Enterprise Data Warehouse
mwyatt@uabmc.edu
Support for All Parts of the Research Process

Proposal Development / Preliminary Data

Feasibility Assessment Within UAB

Hypotheses Exploration

External Collaborations?

Additional Data for Participants

IRB Approved Research Datasets (PHI)

Recruitment Datasets

LDS/Aggregate Study/Phenocasts

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How to Get Data and/or Help?

What you can Ask?

What you can get!

EDW Analysts

Researcher

Enterprise Data Warehouse

Cerner impact
What’s in i2b2?

Included Organizations:
- UAB Hospital, TKC, Highlands, WIC
  - i.e. Anyone Using IMPACT

Organizations Not Included:
- CEFH, Children’s, VA, CCTS Partners

Amount of Data:
- ~ 1.07M Patients
- > 1Billion Facts

Major Systems Included:
- IMPACT, OnCore, Metriq, TransChart, TCBF, Census

Date Coverage: Generally, 2010/2011 - Present
More Information – Who to call

i2b2support@uabmc.edu or Google "UAB i2b2"

Informatics Services
  – http://www.uab.edu/ccts/research-commons/informatics

EDW data requests
  – http://www.uab.edu/ccts/research-commons/research-data-requests

Information about i2b2
  – http://www.uab.edu/ccts/research-commons/informatics/i2b2

i2b2 login URL: https://i2b2-uab.hs.uab.edu
Questions & Discussion

Next Lunch and Learn September 17th, 2019