Welcome!

In this session, we will provide an overview of clinical research at Duke from two perspectives—industry (Lindsey) and non-industry (Laura)

Objectives:
- Describe clinical research structure at Duke
- Describe which offices/contacts can assist with various stages of study
- Describe research administrators’ roles in supporting clinical research
Resources/Handouts

- DOCR Clinical Research Resources and Contacts
- DOCR Contract Flowchart for Industry
- DOCR Industry SPS Budget Entry Guide
- Closeout Tasklist Section 6 Quick Reference Guides (Exempt, Campus IRB, Non-Industry, Industry)
- Maestro Care Quick Reference Guide

Duke Medicine

- 3 integrated hospitals using Epic 2014 (16,513 employees)
  - Duke University Hospital: 957 beds
  - Duke Raleigh Hospital: 186 beds
  - Duke Regional Hospital: 369 beds
- 2015 clinical revenue: $2.98B, 1.35m outpatient visits
  - 2015 total research expenditures = $678m (direct & indirect costs)
  - 2014 NIH funding = $293.2m
- 2013 industry-funded research = $177m
- 1462 investigators, 400 coordinators in site-based research
- About 2,100 open, enrolling IRB studies during FY15
- About 300 NEW clinical trial studies/year
- 7% of patients enrolled in clinical studies (17,699 unique patients)
Overview of Players

Central Administration:
• Duke Office of Clinical Research (DOCR)
• School of Medicine – Finance (SOMF)
• Office of Research Administration (ORA)
• Office of Corporate Research Collaborations (OCRC)
• Patient Revenue Management Organization (PRMO)
• Institutional Review Board (IRB)—Medical Center and Campus
• Treasury Billing Services (TBS)
• Office of Sponsored Programs (OSP)
• SOM Implementation Team

Department Administration:
• Clinical Research Unit (CRU)
  – CRU Director
  – Financial Practice Manager (FPM)
  – Research Practice Manager (RPM)
  – Clinical Research Coordinators (CRCs)
  – Other research staff (CTAs, techs, nurses, regulatory)
• Grant Managers/Administrators
• Principal Investigator (PI)
Key Terms

- **Clinical Trial (NIH) Definition**
  - 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.

- **Qualifying Trial**
  - Clinical trials must be deemed “qualifying” in order to bill Medicare for routine costs.

- **Billing Risk vs. orderable/chargeable/scheduleable**
  - Change in terminology with implementation of Maestro Care.

- **IRB Reviews**
  - Full Board
  - Expedites
  - Exempt
  - External

Industry Sponsor

Assumptions:
- Protocols written by pharmaceutical company.
- Multi-site studies.
- Timelines related to site start-up and enrollment.
Industry Sponsor

- Sponsor contacts PI
- Confidential Disclosure Agreement (CDA)
  - Confirm interest in study with PI
  - Normally on sponsor’s template
  - Send to OCRC for review and execution
  - PI should not sign for the institution
  - Protects sponsor’s confidential information
  - Prerequisite to Sponsored Research Agreement (SRA)

Industry Sponsor

Study Documents:
- Protocol (PI, CRC, Regulatory)
- Budget template (FPM and/or RPM)
- Contract (FPM or RPM → OCRC)
- Study manuals and materials (PI, CRC)
- Case Report Forms (PI, CRC)
- Consent Form (FPM, RPM, CRC, PI)
Internal Cost Assessment (ICA)

- Required for all industry-funded studies
- Review with PI/RPM/CRC to determine actual project costs
  - Timeframe/calendar (enrollment, study, analysis)?
  - How many participants?
  - How many visits?
  - Procedures per visit (routine vs. research-specific)?
  - $/visit?
  - Radiology, pharmacy, DCRU involved?
  - Associated costs?
    - Participant Expenses
    - Duke ClinCard (purchase of card must be from non-federal code, reloading fees can be charged to individual study code)

- Obtain prices from PRMO (Grant Manager to go through CRU - FPM/RPM); can take 48 -- 72 hours
- Radiology Review, Investigational Drug Service (IDS), etc. (could take multiple weeks to obtain pricing). See handout for contact information.
- CRU Management Fee
- Determine feasibility
- Obtain CRU approval of ICA
Additional Responsibilities

• Negotiate budget and payment terms with sponsor
• Attend study initiation meeting
  – Another set of eyes to look over budget and provide feedback, as needed
  – Helpful if scheduled prior to budget negotiations (if adjustments needed), but dependent on IRB application progress and schedules of study team

As soon as you receive protocol, contract, and draft budget from industry sponsor, begin...

- Feasibility Assessment
  - Complete Internal Cost Assessment (financial feasibility)
  - Review protocol and related documents for scientific feasibility
  - Consider potential enrollment and available resources

- Contract/Budget Negotiation
  - Send draft of contract to OCRC to begin negotiation of legal language
  - If study found to be feasible, begin negotiating external budget
  - Route SPS entry once external budget negotiated

- IRB Submission
  - Enter study information and documents into IRB
  - Obtain CRU/Departmental approval
  - Work with DOCR to schedule study initiation meeting, if applicable

By following a parallel process, you can avoid delays in institutional approval and begin enrollment earlier
Contract Process

- Work with OCRC to get legal language of contract negotiated
- Enter project into SPS
  - Tip: If open-ended term, consider extra time for data analysis and study closeout
  - Less-detailed budget entry required compared to federal- or foundation-sponsored studies
  - Only 1% effort required for PI (other personnel does not need to be listed)
- Complete and attach WBSE Request Form in Internal Documents at time of SPS submission
- Provide OCRC with CRU approval of budget/payment terms, eIRB and SPS numbers

Non-Industry Sponsor

- NIH National Institutes of Health
- National Science Foundation
- DARPA
- American Heart Assoc
- Susan G. Komen
- Arthritis Foundation
- American Diabetes Association
- Cystic Fibrosis Foundation
Non-Industry Sponsor

- Assumption: Federal cost reimbursement
- PI responds to program announcement (PA), application or request for proposal (RFP)
- Grant Manager reviews submission information:
  - Deadline
  - Application details and requirements
  - Budget restrictions (total award amount, cost considerations)

Budget Development

- Review with PI/RPM/CRC to determine project costs
  - Timeframe/calendar (enrollment, study, analysis)?
  - How many participants?
  - How many visits?
  - Procedures per visit (routine vs. research-specific)?
  - $/visit?
  - Radiology, pharmacy, DCRU involved?
Budget Development and Considerations

• Determining project costs
  – Associated costs?
  – Participant expenses?
    • Duke ClinCard (purchase of card must be from non-federal code, reloading fees can be charged to individual study code)

• ICA not required for foundation- or federally-funded studies

• Depending on costs, may need supplemental funds from PI or Department (e.g., purchase of Duke ClinCards)

• DEADLINE to meet!
• WAIT

Post-Award Shift
Transition to Study Conduct

**Industry**
- Fully executed agreement
- Fund code
- IRB and institutional approval

**Non-Industry**
- Just in Time (JIT)
- IRB and institutional approval
- Notice of Award
- Fund Code

Challenges

- Effort Management
- Maestro Care Reconciliation
- Maintaining Maestro Care Fund Code
- Trial Trackers
- Subject Reimbursement
- Financial Reporting
- Closeout
Effort Management

One of the top challenges in clinical research due to shifting needs on study

• PI, CRCs, research staff
  – On multiple studies
  – Effort changes monthly
  – RPM/FPM or effort manager should meet on monthly basis to confirm effort

Maestro Care Challenges

• Maintaining Maestro Care WBSE
  – Billing risk studies require WBSE -- should be confirmed by FPM via monthly report
  – Make sure eIRB number is tied to correct WBSE

• Reports

• Win: Central Charge Review
  – New initiative to be piloted in early 2016

Please see new Maestro Quick Reference Guide!
Trial Trackers

- Currently manage milestone payments and invoiceable items via trial trackers
- Manual process in Excel
- Will hopefully be replaced by CRMS system

Subject Reimbursement

- Duke ClinCard:
  
  *Duke University is implementing a new system called “ClinCard” that uses a debit card system to compensate study participants for their involvement in clinical studies.*
  
  - Initial card fee not an allowable expense on federal codes ($3.50 per card)
  - Reload fees, including subject reimbursements are an allowable expense on federal codes ($1.00 per load)
  - Include in future budgets (rollout should be complete Spring 2016)
Financial Reporting

Monitor the overall financial performance of the study, identify trends, issue identification and resolution

- Revenue management
- Effort management
- Reconciliation
- Overdraft review

Closeout

- Closeout Tasklist used for both industry and non-industry
- Human Subjects/eIRB section (#6) completed by sponsor type
- Signatures
  - Industry: FPM (or Grants Manager), RPM, business unit specifics
  - Non-industry: Grants Manager, business unit specifics
- Submission
  - Industry: submit via email to DOCR (docr-ctgov@dm.duke.edu)
    - SOMF completes final JV(s)
    - Submit request to close code to TBS (tbsawardsetup@duke.edu) once code is zeroed out
  - Non-industry: submit via email to closeoutdocs@duke.edu
    - Copy DOCR (docr-ctgov@dm.duke.edu)
Questions?