Office of Research Administration: Clinical Research Contracting

Presented to:
Research Administration Professionals Group

Presented by: Patricia Travis and Mont Brownlee
October 22, 2013
Training Agenda

- Contracting Staff at Fells Point
- Types of Agreements
- Overview of Contracting Process for Agreements with Industry Sponsors
- Contracting Issues and Delays
- Resources and Questions
Clinical Research Contracting –
Provide expertise to faculty and staff for clinical research agreements by reviewing academic, business, and legal issues. Negotiates non-disclosure agreements, contracts and other associated agreements with commercial sponsors.
Clinical Research is all research that involves:

- **Patients**, or
- PHI (Protected Health Information), or
- clinical testing or procedures, or
- drug or device trials, or
- planning of clinical/lab services in support of clinical research.
Clinical Research Agreements

- **Confidentiality Agreements** (CDA or NDA)
- **Clinical Trial Agreements** (CTA)
  - Funding, Supply or both
  - Sponsor-initiated or Investigator-initiated
- **“Master” Agreements** and **Work Orders**
- **Amendments** (Supplements, extensions and modifications)
- **Service Agreements** (Lab services; Consulting)
Confidentiality Agreements (CDA’s)

• Also called: *Nondisclosure Agreements* (NDA's)

• A MyRAP record is generated by ORA for each CDA

• No COEUS PD is required for CDA’s

• What do I submit?:

  ➢ Email an editable version of the CDA to your Sponsored Project Specialist;

  ➢ Provide contact information for the Sponsor; and

  ➢ Identify the purpose and your timeline.
Clinical Trial Agreements (CTA's)

• Also called: Clinical Study Agreements (CSA's)

• A MyRAP record is generated by ORA for each CTA.

• Must be submitted via COEUS system with the following:
  
  ➢ Editable version of the contract document (preferably MS Word);
  ➢ Supplemental Information Sheet for Commercial Agreements (the "S/S")
  ➢ Proposed budget (draft is OK; does not need to be final); and
  ➢ Study protocol or Scope of Work (IRB application # may be listed).
Clinical Trial Agreements (CTA's)

- Once all materials are received, ORA will create a contract file and a contract reviewer can be assigned.
- Until ORA has a complete COEUS PD for a CTA, there is no contract file and your contract is *not* in the queue for review.
- Emailing CTA documents to ORA staff does *not* mean ORA has a contract file, and does *not* mean that a reviewer has been assigned.
- The Prospective Reimbursement Analysis (PRA), budget, IRB Review, and contract should be worked on simultaneously.
Clinical Trial Agreements (CTA's)

• ORA does not need an IRB approval to initiate contract review, but we need the approval in order to fully execute the contract.

  ➤ *Contract negotiations and IRB review should proceed in parallel.*

• A draft budget is needed to initiate contract review, but a final sponsor budget and internal budget will be needed to complete the contract negotiation.

  ➤ *Contract and budget negotiations should proceed in parallel.*
Study Startup Process

- Pre-Study Planning
- Prospective Reimbursement Analysis
- Budget Development
- Contracting
- Study approved for startup
- Study Accounts Established
- Institutional Review Board (IRB)
Contracting Lifecycle

- ORA receives required documents – logged in MyRAP
- Assigned to ORA negotiator – PI is notified
- Initial Review; prepare redline draft for sponsor
- Sponsor replies
- Repeat as needed (elevate)
- Resolve ancillary issues (budget; IRB; COI; etc)
- Receive originals, review, obtain signatures (PDF v. hardcopy)
Computer Systems

- **COEUS** – Proposal Development (“PD”) record includes key project data, Research Compliance Questionnaire, Investigator certifications and uploaded documents.

- **MyRAP** – Launched Fall 2011; A “MyRAP record” is created for each agreement to track activity, pending issues, and communications.

- **OCULUS/SAP** – Executed contract is scanned into OCULUS, which triggers Sponsored Shared Services that a new SAP account must be created.
Common Contracting Issues

- HIPAA & Informed Consent Issues
- Publication rights
- Indemnification & Subject Injury
- Intellectual Property (IP)
- Confidentiality
- Duty to Update (tied to JHM IRB’s AAHRPP accreditation)
- Budget, payment schedule, and deposit details
- Biological Samples
Common causes for contracting delays

- Incomplete Paperwork
- Budget not resolved
- CRO or Sponsor contact not authorized to negotiate
- JHU Policy or Sponsor Responsibilities (General Counsel)
- IRB Issue / Outside Interest management (COI)
- Lack of parallel processing
Links to Contracting Resources:

JHU SOM Office of Research Administration
http://www.hopkinsmedicine.org/Research/ora/index.html

"How do I…?" reference sheet for ORA Fells Point contracts:

ORA Information, Model Agreements and Policies:

JHM Policy ORA.1 – Sponsor Responsibilities:
http://www.hopkinsmedicine.org/institutional_review_board/guidelines_policies/organization_policies/ora1.html

Sponsored Projects Handbook:
(Especially Appendix C & Appendix D for key overhead info)
THANKS!

• Any Questions?

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Objectives

• Become familiar with our office staff, roles, and responsibilities.

• Understand a Prospective Reimbursement Analysis, how it can benefit your studies, and other documents related to the PRA process

• Gain tools and information to help in your budget development process
Office Organization

Associate Director:
• Karen Roz, MS

• Sr. Clinical Research Coverage Analysts:
  – Cindy Elliott
  – Tracy McCracken RN BSN
  – Lisa Wallace MT ASCP

• Clinical Research Coverage Analysts:
  – Mario Adrien
  – Genea Smith
  – Linda Wilkins
  – Leslie Wolf
  – Dawn Young
  – Erika Maden Gailunas

• Administrative Assistant
  – TBN
Office of Research Administration
Clinical Research Support Services

• Primary Function
  – Prospective Reimbursement Analysis

• Multiple Secondary Functions
  – Study Budgeting
  – Initiate JHH Research Account through Patient Financial Services (PFS)
  – Patient Financial Responsibility Sheet
  – Clinical Research Insurance Clearance determination
  – Etc. etc. etc…
Prospective Reimbursement Analysis (PRA)

• Complex process
• Simultaneous with
  – IRB review
  – Contract negotiations
• Constantly changing
  – Changes to regulations/coverages/care standards
  – Changes in institutional processes
Prospective Reimbursement Analysis (PRA)

<table>
<thead>
<tr>
<th>Event</th>
<th>Date Details</th>
</tr>
</thead>
<tbody>
<tr>
<td>PRA Initial Review Date</td>
<td>Date Draft Completed</td>
</tr>
<tr>
<td></td>
<td>Date Sent to PI for Review</td>
</tr>
<tr>
<td>Final PRA Date</td>
<td>IRB Approval</td>
</tr>
<tr>
<td></td>
<td>Funding Awarded</td>
</tr>
<tr>
<td>Author</td>
<td>CRSS Analyst</td>
</tr>
</tbody>
</table>
Prospective Reimbursement Analysis (PRA)

PRA Revision # and Date
- Original Application
- Changes in Research

Study Identifying Information

Department:
Principal Investigator (PI):
Protocol Name:
Phase of Study:
Study Location:
eIRB Number:
Oncology CRO#:
Financial Sponsor:
Material Sponsor:
Prospective Reimbursement Analysis (PRA)

Issues Summary

Protocol Related Items:
Informed Consent Form Related Items:
Contract Related Items:
Budget Related Items:

Documents Received for Coverage Analysis Review

• Study Protocol
  • Dated
• The Clinical Trial Agreement Notice of Grant Award
  • Dated
  The following procedures, tests, drugs or devices will be supplied free of charge by the study:
• Informed Consent Document
  • Dated
  • Sponsor template
  The following procedures, tests, drugs or devices are part of this research and will be supplied free of charge by the study:
• Budget Related Items:

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### Qualifying Clinical Trial Analysis

Does the Clinical Trial meet the necessary Requirements?

<table>
<thead>
<tr>
<th>Requirement</th>
<th>Yes</th>
<th>No</th>
<th>Comment</th>
</tr>
</thead>
<tbody>
<tr>
<td>Does investigational item or service fall into a Medicare benefit category?</td>
<td>Yes</td>
<td>No</td>
<td>The investigational product is a member of Medicare benefit category “drugs, biologics, and therapeutics.”</td>
</tr>
<tr>
<td>Does the study have therapeutic intent?</td>
<td></td>
<td></td>
<td>This study is</td>
</tr>
<tr>
<td>Does the study enroll patients with diagnosed diseases?</td>
<td></td>
<td></td>
<td>This protocol enrolls patients that have</td>
</tr>
<tr>
<td>Is the study a deemed trial?</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Is the study a qualifying clinical trial?</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

### Investigational Item or Service Analysis

- What is the investigational item or service?
- What is the FDA status of the investigational item or service?
- Does a CMS benefit policy, NDC, or LCD allow coverage of the investigational item or service?
Prospective Reimbursement Analysis (PRA)

Does investigational item or service fall into a Medicare Benefit Category?
- Drugs, Biologics, Therapeutics
- Non-qualifying include: cosmetic surgeries, dental, etc.

Does the study have therapeutic intent?
- Phase I studies
- Consent form benefit statement

Does the study enroll patients with diagnosed diseases?
- Studies with only normal controls are non-qualifying

Is the study a deemed trial?
- Federal oversight such as FDA monitored, Federally-funded consortium study, NIH funded.
Prospective Reimbursement Analysis (PRA)

Investigational Item or Service Analysis

<table>
<thead>
<tr>
<th>Analysis Questions</th>
<th>Answer</th>
</tr>
</thead>
<tbody>
<tr>
<td>What is the investigational item or service?</td>
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<td>Does a CMS benefit policy, NCD, or LCD allow coverage of the investigational item or service?</td>
<td></td>
</tr>
</tbody>
</table>

Investigational Item/Service

- Documents the investigational item/service
- Documents its FDA status (i.e. IND, IDE, exempt, etc)
- Whether or not CMS allows coverage
Prospective Reimbursement Analysis (PRA)

Items and Services Analysis
Conventional Care Standards Used
Items and Services

These items are routine/standard of care: “S”
  - XXX
  - XXX

These items are research: “R”
  - XXX
  - XXX

These items will be supplied by the sponsor at no charge: “F”
  - XXX
  - XXX

These items are not billable events: “NB”
  - XXX
  - XXX

Additional Comments:

Additional Comments:
Prospective Reimbursement Analysis (PRA)

Conventional Care Standard

- National Guideline Clearing House
- American College of Cardiology
- American College of Radiology
- National Comprehensive Cancer Network (NCCN)

Items and Services

- Standard of Care
- Research
- Free
- Non-billable

Additional Comments
Prospective Reimbursement Analysis (PRA)

Schema

• Can be very simple or very complex
• Details participant timeline
• Details items/services described in protocol
• Details location where items/services are expected to be provided
• Delineates reimbursement analysis (i.e. Standard of Care vs. Research vs. Free vs. Non-billable)
• May include extensive footnotes
Prospective Reimbursement Analysis (PRA)

Simple Schema

<table>
<thead>
<tr>
<th>Items and Services</th>
<th>Purpose</th>
<th>Annual Monitoring Visit</th>
<th>2 Month Visit</th>
</tr>
</thead>
<tbody>
<tr>
<td>Informed Consent</td>
<td>Required per 21 CFR 50 and 40 CFR 25</td>
<td>NB</td>
<td>NB</td>
</tr>
<tr>
<td>Psychophysical Tests and Self-reported Outcome Measures</td>
<td>Research purposes only</td>
<td>NB</td>
<td>Research purposes only (%) effort</td>
</tr>
<tr>
<td>Visual Function Testing (Best-Corrected Visual Acuity, Contrast Sensitivity, Static Perimetry, Kinetic Perimetry, and Color Vision)</td>
<td>Research purposes only</td>
<td>R</td>
<td>R</td>
</tr>
<tr>
<td>Dilated Retinal Exam</td>
<td>Research purposes only</td>
<td>R</td>
<td>R</td>
</tr>
<tr>
<td>Fundus Photography</td>
<td>Research purposes only</td>
<td>R</td>
<td>R</td>
</tr>
</tbody>
</table>

S = Standard of Care  
NB = Non Billable  
R = Research  
F = Provided Free by sponsor
Prospective Reimbursement Analysis (PRA)

Complex Schema
Prospective Reimbursement Analysis (PRA)

**Draft PRA**
- EPIC form
- Draft Budget (if requested)

**Final PRA**
- IRB Approval
- Funding Awarded
- Insurance Clearance status
- Patient Financial Responsibility Sheet
- EPIC Activation
- CRMS

**Further Study Actions**
- Revised accordingly
- PRA used for charge adjudication is the one in effect at the time of participant consent
Prospective Reimbursement Analysis (PRA)

• Highlights
  – Therapeutic Intent
    • Phase I studies
    • Consent form benefit statement
  – Must use
    • Patient Financial Responsibility Sheet
    • CRMS
  – Communicate, Communicate, Communicate
Prospective Reimbursement Analysis (PRA)

• Summary
  – The PRA is the internal tool developed to document how each study meets the NCD criteria for billing routine costs to Medicare.

  – A systematic review of clinical trial related documents to determine the billing status of items and services that are documented within the research protocol.

  – A method for ensuring that all the documents pertaining to a research protocol are consistent with each other.
Budget Development and Negotiations
Budget Development

• Concurrent with PRA development

• How CRSS can help:
  – Identify “hidden” costs
  – Identify and document “routine” vs. “research”
  – Provide completed budget template
  – Negotiate with your sponsor
Budget Development

• Study Team must:
  – Provide salary information
  – Identify amount of effort for all personnel
  – Identify cost amounts (i.e. cost of special labs, radiology procedures)
  – Maintain timely communication with CRSS
  – Process proposal through standard methods
Budget Negotiations

• Service offered by CRSS
• Benefits
  – Maintain rapport with sponsor
  – Removed from “business” aspect of research
  – Institutional backing
• By request only
  – Some PIs prefer to be “hands-on” with the negotiation process
Questions?

Thank you