Successful Pharmaceutical Study Start-Up: Key Steps for Investigators
Learning Objectives

- What contracts are reviewed by ORA?
- How do I submit my contract for review?
- Where is my contract?
Clinical Research Contracting
(a/k/a the “Fell’s Point Office”)

- 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.
What is Clinical Research?

Clinical Research is all research that involves:

Patients,

or

Protected Health Information (PHI),

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
  – Includes “compassionate use” or “expanded access” studies.

• **“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)

- What do I submit?:
  - Email an **editable version** of the CDA to your Sponsored Project Specialist (Jared and Josh);
  - Provide **contact information** (email and phone #) for the Sponsor; and
  - Identify the **purpose** and your **timeline**.

- A MyRAP record is generated by ORA for each CDA

- No COEUS PD is required for CDA’s
Clinical Trial Agreements (CTA's)

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

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

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

Institutional Review Board (IRB)

Study approved for startup

Study Accounts Established
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)
Outgoing Sub-Contracts

- Sub-contracting processes can only begin after the prime agreement has been signed.

- To initiate a sub-contract, you must submit an Outgoing Subcontract Information Sheet via email to ORASUBCONTRACTS@jhmi.edu

- Potential JHUCRN and CAPRES investigators are required to sign a “Participation Agreement” before they can receive the protocol or participate in a study.
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)

Subcontract Information Sheet:
http://www.hopkinsmedicine.org/Research/ora/handbook/appendixh.html
This presentation owes thanks to Patricia Travis and Mont Brownlee for providing slide content.

- Any Questions?

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