JOHNS HOPKINS
MEDICINE

# Office of Research Administration: **Clinical Research Contracting**

Successful Pharmaceutical Study Start-Up: Key Steps for Investigators

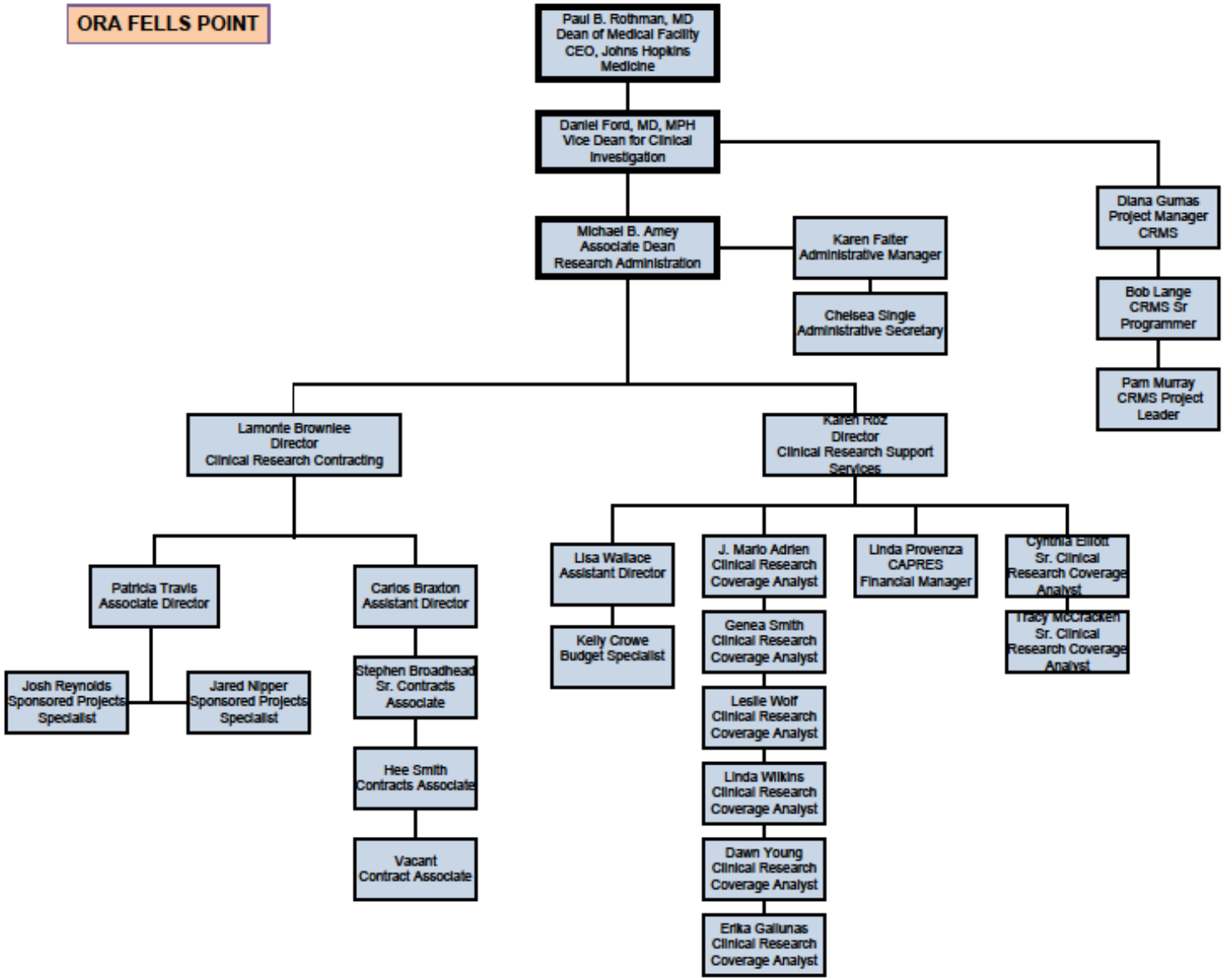
Stephen Broadhead

April 7, 2015

# Learning Objectives

- What contracts are reviewed by ORA?
- How do I submit my contract for review?
- Where is my contract?

**ORA FELLS POINT**



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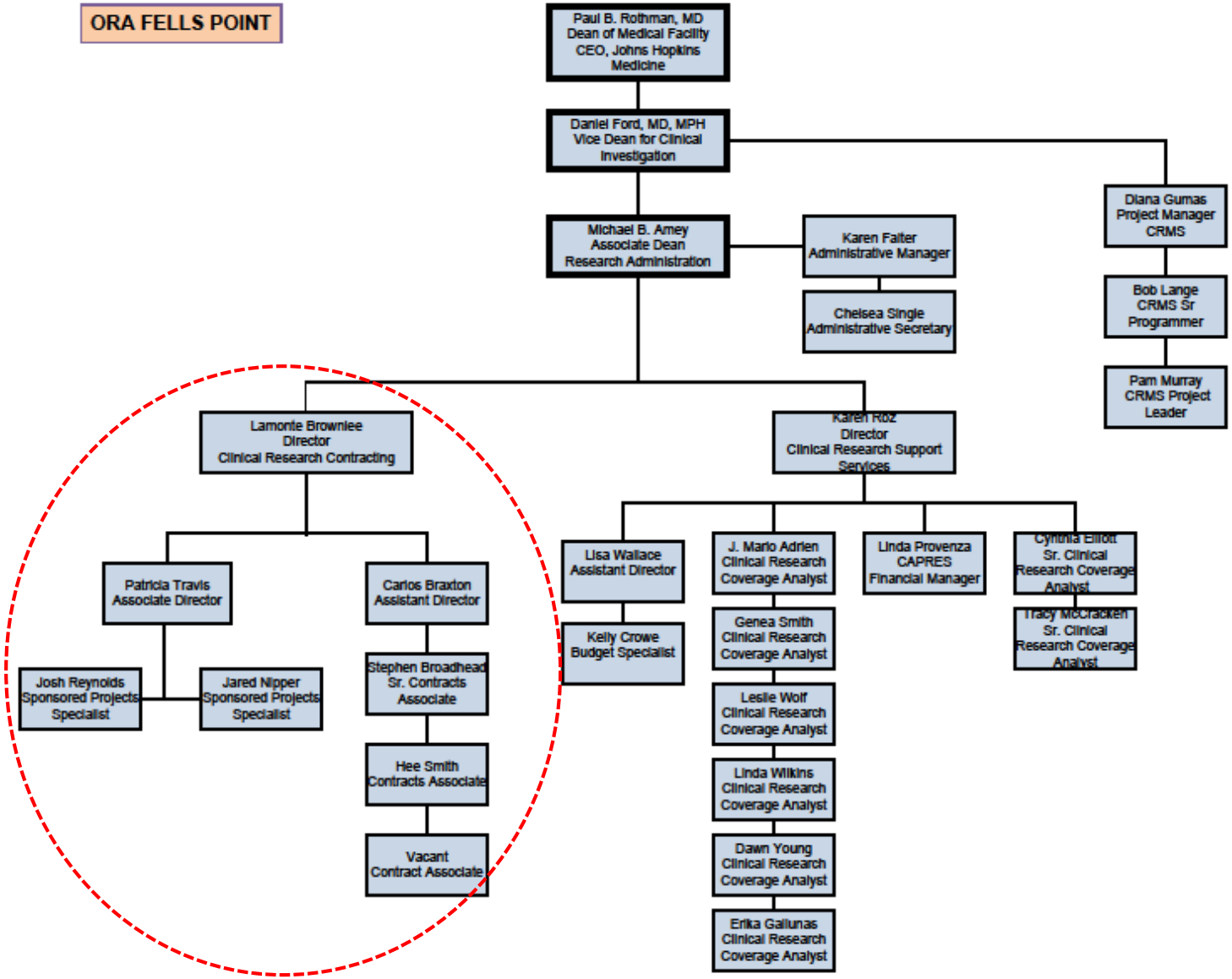

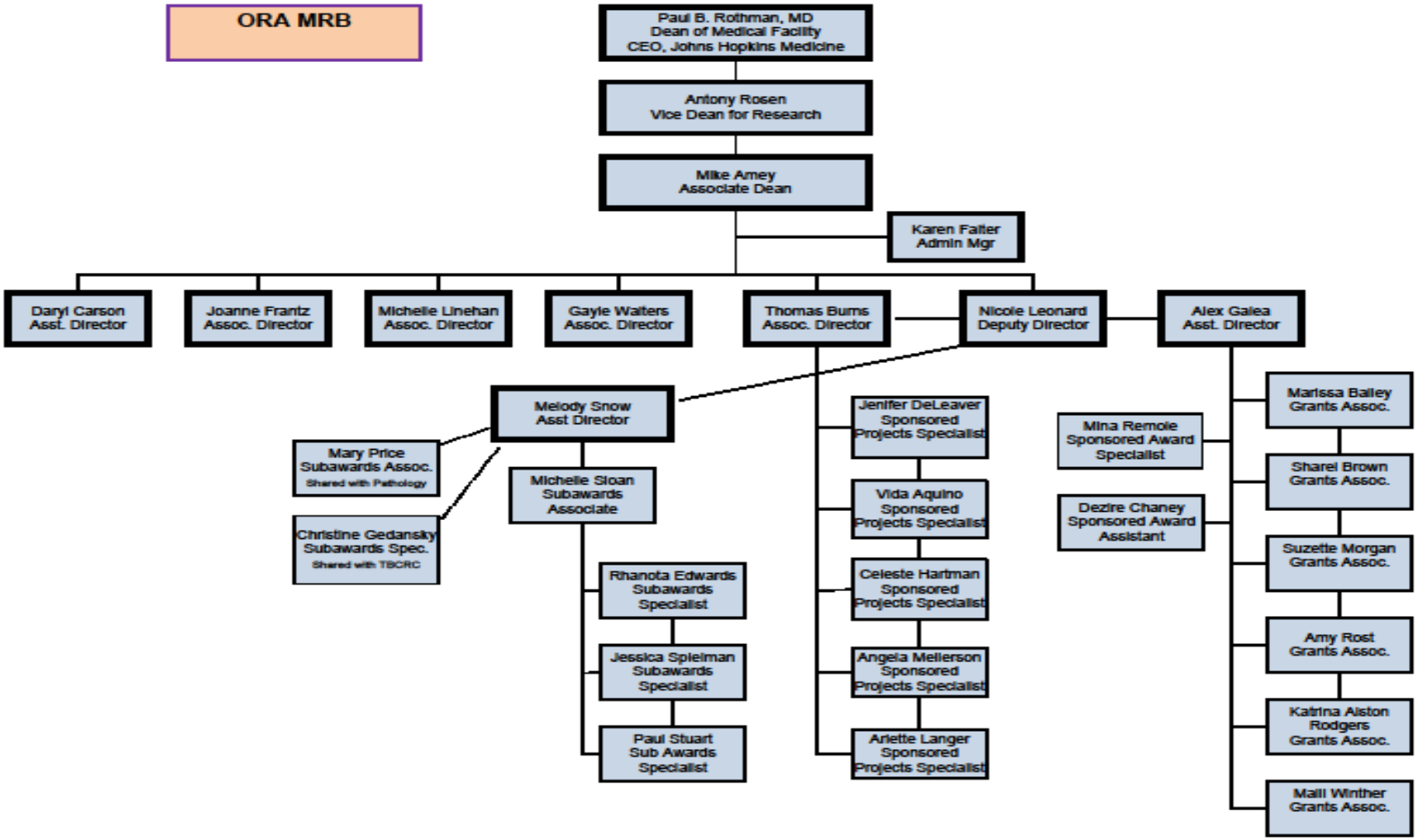
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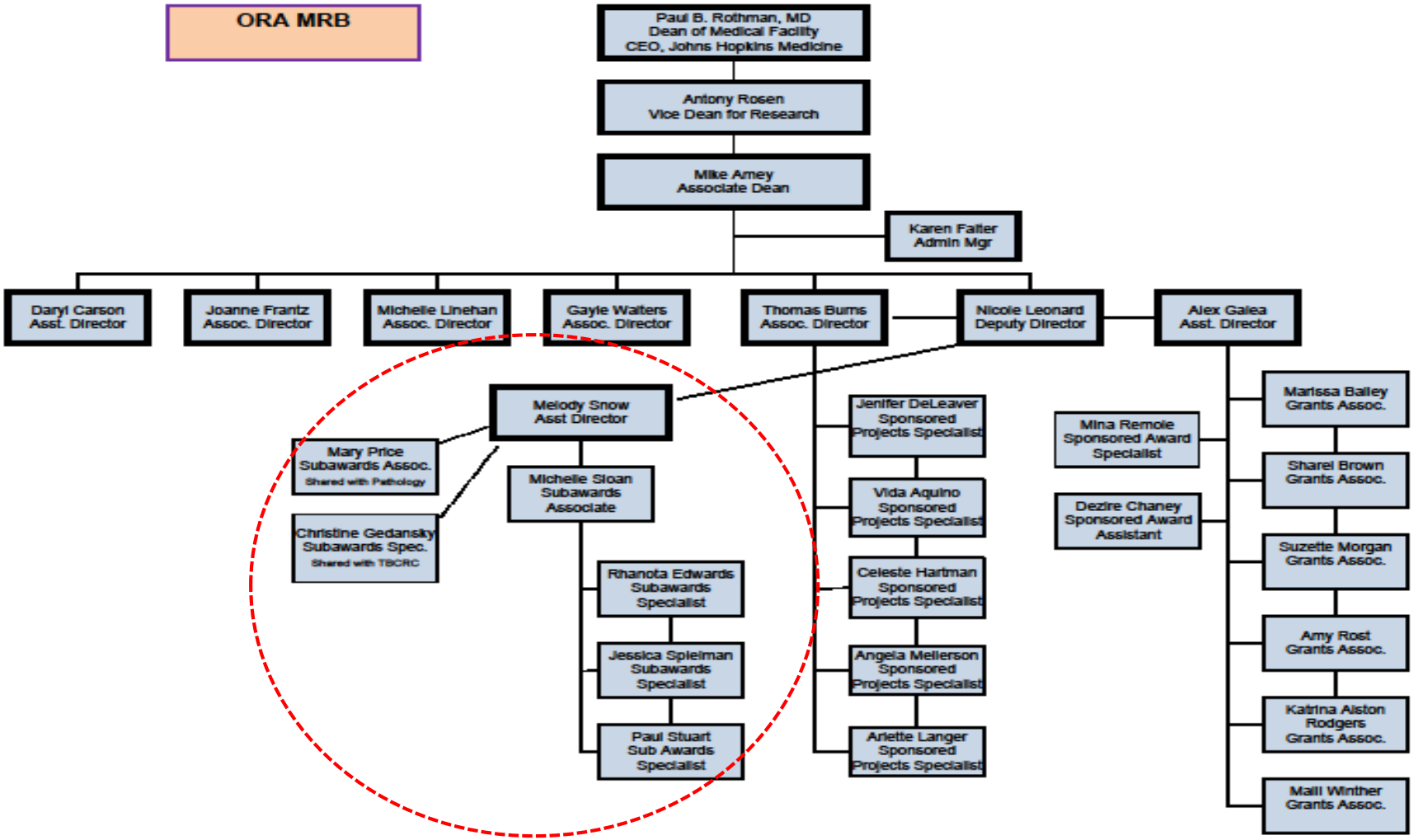
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# Clinical Research Contracting
## (a/k/a the "*Fell's Point Office*")

- **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*

*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
  - 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.

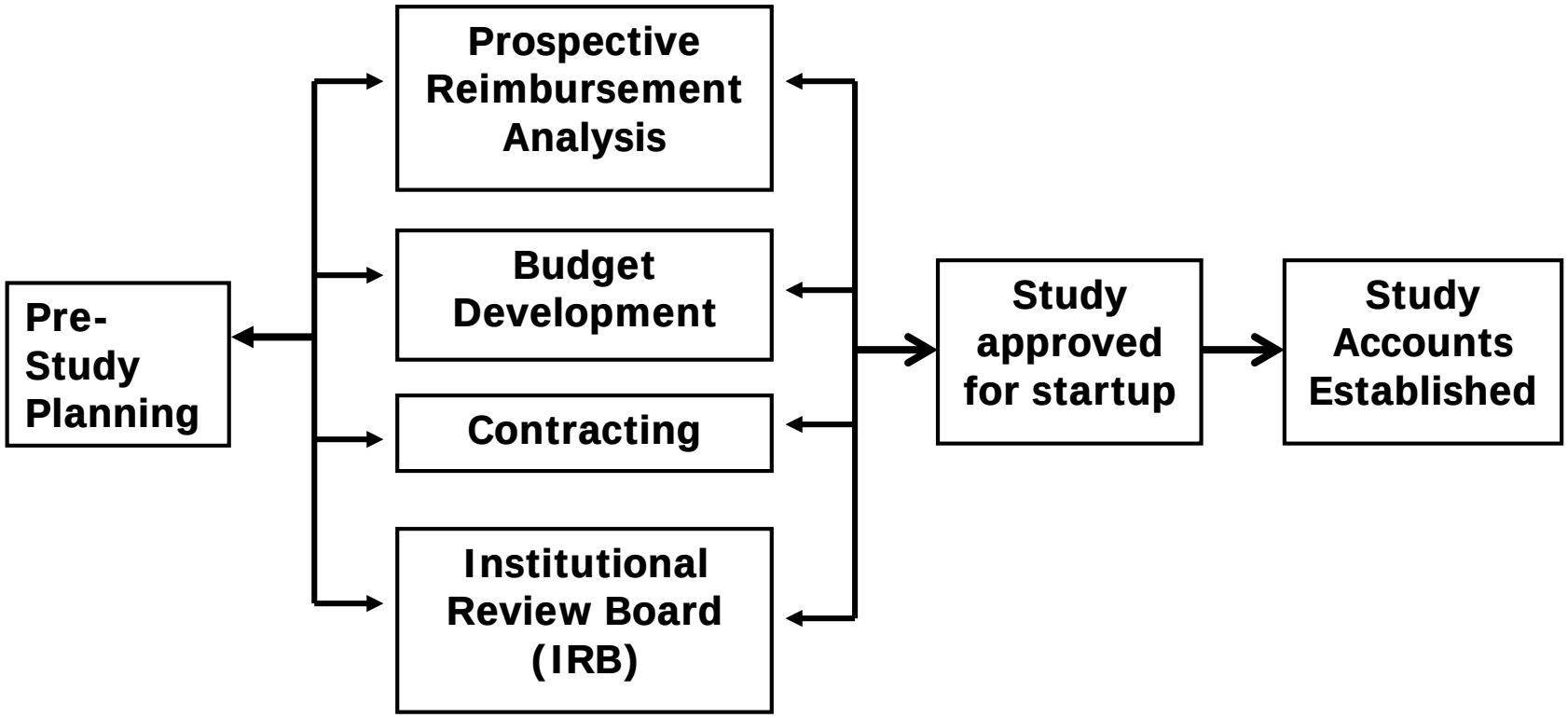
# Clinical Trial Agreements (CTA's)

- 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



# 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:**
http://www.hopkinsmedicine.org/Research/ora/WhatcontrolsroutingofCommercialAgreementstoORA-FP.pdf

**ORA Information, Model Agreements and Policies:**
http://www.hopkinsmedicine.org/Research/ora/agreements/index.html

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

**Sponsored Projects Handbook:**
http://www.hopkinsmedicine.org/Research/ora/handbook/index.html
(*Especially Appendix C & Appendix D for key overhead info*)

**Subcontract Information Sheet:**
http://www.hopkinsmedicine.org/Research/ora/handbook/appendixh.html

# THANKS!

This presentation owes thanks to Patricia Travis and Mont Brownlee for providing slide content.

- **Any Questions?**

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