

Office of Clinical Trials / Clinical Research Contracting Group:

## Overview of Clinical Research Contracting

Presented to: ORA Office Hours
9 May 2024

#### ORA Before mid-2006



Inbound Contracts	Outbound Contracts
ORA Office of Research Administration	ORA Subcontracts Group (Subs)
ORA reviews all sponsored research proposals and awards.	Outbound Subcontracts / Subawards

#### ORA 2006-2022



Inbound Contracts		Outbound Contracts	Support Services
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ORA Clinical Research Contracting Group (CRC)	ORA Office of Research Administration (MRB office)	ORA Subcontracts Group (Subs)	ORA Clinical Research Support Services (CRSS)
CRC reviews and negotiates all commercial clinical research agreements.	ORA-MRB reviews all sponsored research proposals and awards, except commercial clinical research.	Outbound Subcontracts / Subawards	Prospective Reimbursement Analyses
Includes agreements where Prime Sponsor is commercial (such as inbound subawards from another university, where a commercial entity is the upstream sponsor)	All agreements with non-commercial sponsors (federal, foundation, academic)  Commercial pre-clinical/non-clinical research (animal or basic science)		Budgets

#### ORA/OCT 2022-present

Office of Research Administration Office of Clinical Trials



Inbound C	Contracts	Outbound Contracts	Support Services
OCT Clinical Research Contracting Group (CRC)	ORA Office of Research Administration (MRB office)	ORA Subcontracts Group (Subs)	OCT Clinical Research Support Services (CRSS)
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Includes agreements where Prime Sponsor is commercial (such as inbound subawards from another university, where a commercial entity is the upstream sponsor)	All agreements with <u>non-commercial</u> sponsors (federal, foundation, academic)  Commercial pre-clinical/non-clinical research (animal or basic science)		Budgets
* ALL NDA's *	, , , , , , , , , , , , , , , , , , ,		



#### OCT/CRC Portfolio

# The Clinical Research Contracting office negotiates

<u>clinical research</u> agreements with

commercial sponsors.

\* \* \* Must be both \* \* \*

Complex regulatory/policy issues & greater institutional risk

Often less collaborative "zero sum" approach

Greater demand for rights & control



#### **OCT/CRC Stakeholders**

- CRC is part of JHU-SOM's Human Research Protection Program, working closely with the JHM IRB office
- CRC is delegated responsibility from JHHS for commercial research in JHH and other JHHS facilities
- ➤ CRC works closely with both JHU and JHHS legal departments, as well as JHTV, OPC (Conflict of Interest office), Export Controls, and other research compliance offices.

#### Types of 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)

#### **CRC** Organization

**Jared Nipper** 

**Sponsored Projects Associate** 

**Josh Reynolds** 

Sr. Spons. Projects Specialist

**Abigail Logsdon** 

Sr. Spons. Projects Specialist

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Sr. Associate Director

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> **Curstie Miller NDA Paralegal**



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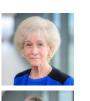


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## **Clinical Trial Agreements (CTA's)**



#### Also called:

- Clinical Study Agreements (CSA's),
- > Sponsored Research Agreements (SRA's),
- > Research Collaboration Agreements (RSA's), etc.

#### Must be submitted via FIBI system with the following:

- <u>Editable version</u> of the contract document (preferably MS Word);
- ➤ <u>Supplemental Information Sheet</u> for Commercial Agreements (the "SIS")
- Proposed <u>budget</u> (draft is OK; does not need to be final); and
- > Study protocol or <a>Scope of Work</a> (IRB application # may be listed).
- A MyRAP record is generated for each CTA.

## Contracting Lifecycle



- ORA receives required documents logged in MyRAP [Specialist]
- Triaged and Assigned to ORA negotiator PI is notified [Specialist] [K Manager]
- Initial Review; prepare redline draft for sponsor [ Negotiator ]
- Sponsor replies [ Negotiator ]
- Repeat as needed (elevate) [ Negotiator ]
- Resolve ancillary issues (budget; IRB; COI; etc) [ Negotiator ] [ Specialist ]
- Receive originals, review, obtain signatures (DocuSign) [ Specialist ]

#### New for 2023!

## SOMNDA@jh.edu



#### **Nondisclosure Agreements (NDA's)**

A new, dedicated team has been created to handle all SOM research NDA's – just <u>forward all NDA requests</u> to <u>SOMNDA@jh.edu</u> for processing. They will acknowledge receipt, set up a file and work with the sponsor to negotiate and finalize the NDA.

No COEUS/FIBI record is required for review of an NDA; a **MyRAP** record will be generated for the agreement and the PI will be contacted upon review.

Once the NDA is finalized, it will be sent to the PI for their signature; once the PI signs, it will be signed on behalf of JHU and sent to the sponsor for their signature.

\* NDA's are sometimes called Confidential Disclosure Agreements (CDA's)

## **New for 2023**



#### **FIBI system** rolled out in Fall 2023

- Replaces the COEUS system
- Used for routing research proposals / initiating contract review
- Modern interface

#### **Dedicated NDA team** launched in Spring 2023

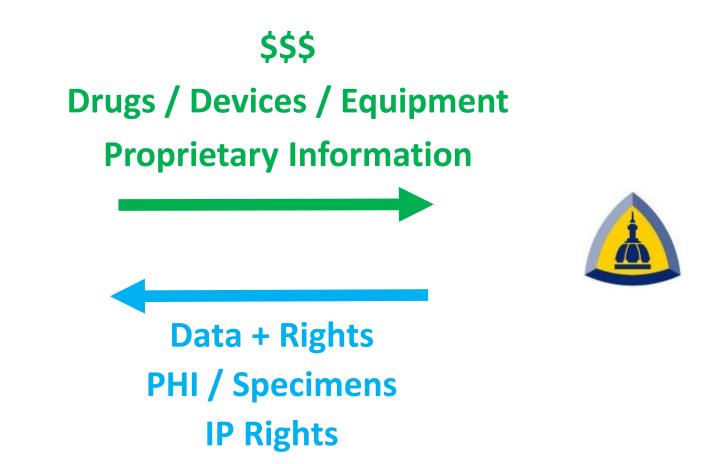
- All research-related NDA's for SOM (no subject matter distinction)
- Painless process: just forward NDA requests to <u>SOMNDA@jh.edu</u>
- No FIBI submission required

New "CRCinquiry" mailbox for general questions and help



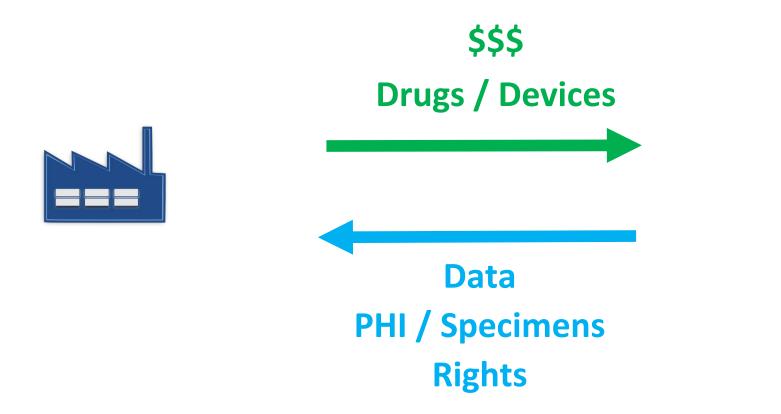
#### **Industry Transactions**

Typical exchanges in Research Agreements





# Industry Transactions CTA for sponsor-initiated study

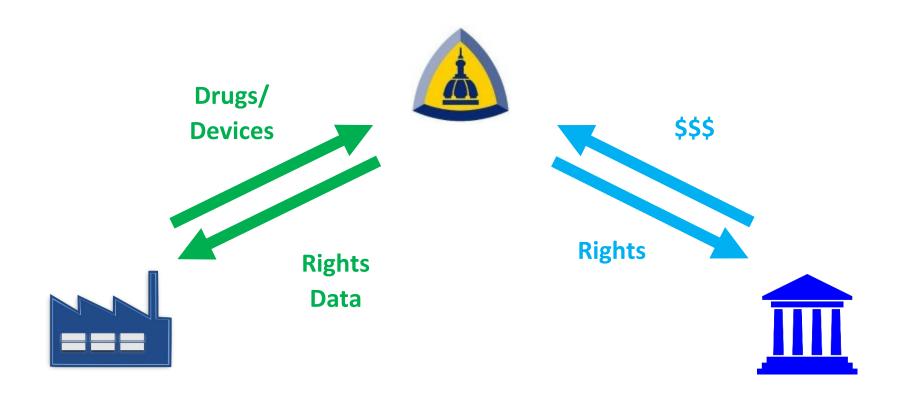






## **Industry Transactions**

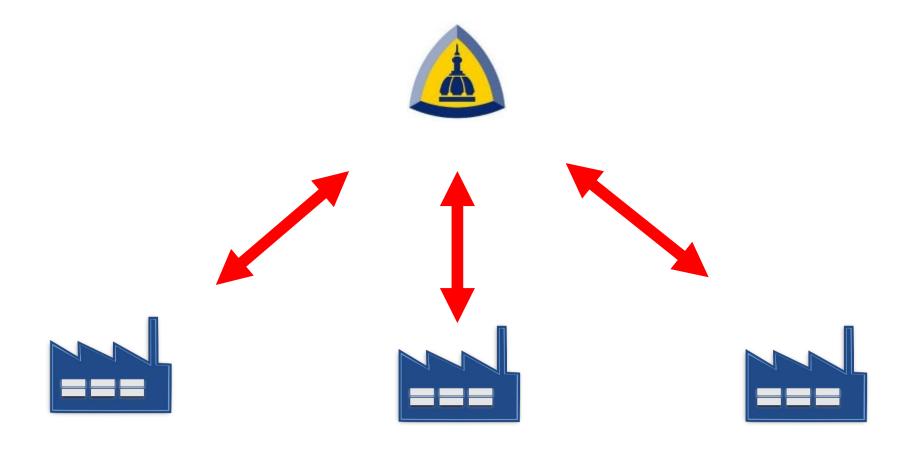
Government-funded, industry supported study





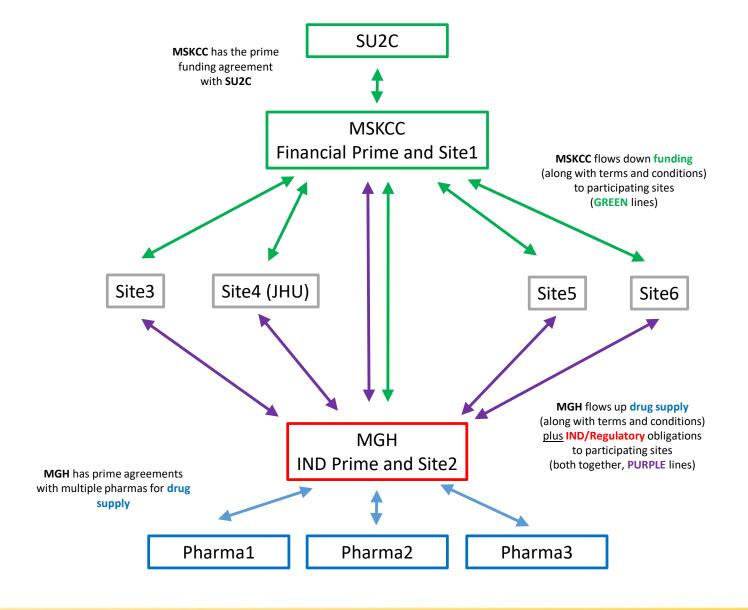
Multiple sponsors





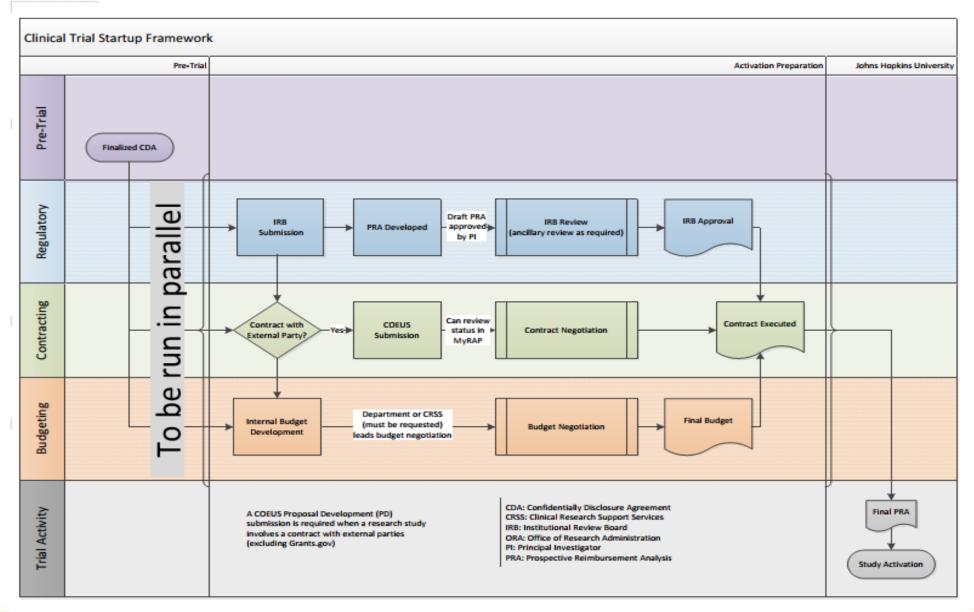
#### Complex Transactions Multi-directional obligations





#### Study Startup Process





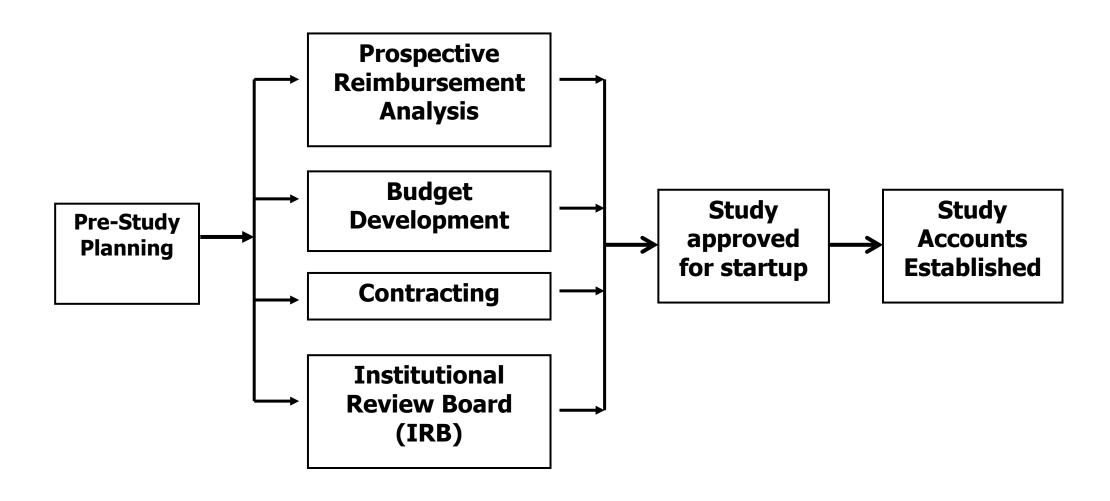
## Parallel Processing & Signature Timing



- IRB review, Contract review & Budget development should proceed in parallel
  - Do not wait for the IRB to approve the study to submit via COEUS.
  - Do not wait for the budget to be finalized to submit the contract request to COEUS.
- General Rule is that contracts are signed <u>after IRB approval</u>
  - But CRC can review/negotiate while IRB is pending, so do not wait to submit
- Exceptions are routinely made under appropriate circumstances
  - Ex: The work scope includes protocol development or related pre-clinical work
  - Ex: Sponsor must commit funds by a certain date
  - Ex: JHU needs to lock in participation or risk losing support

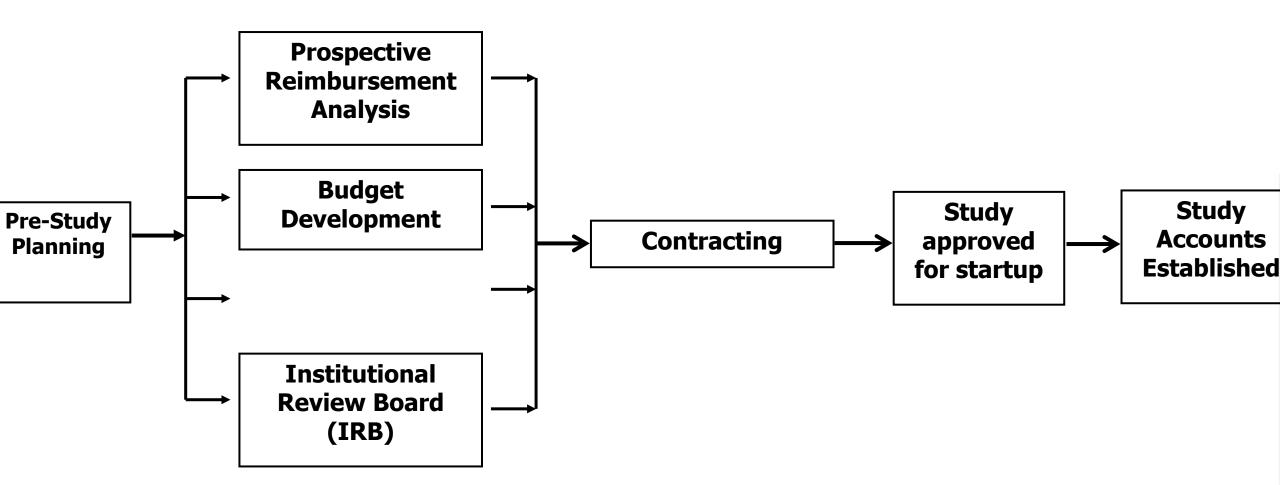


# **Parallel Processing**



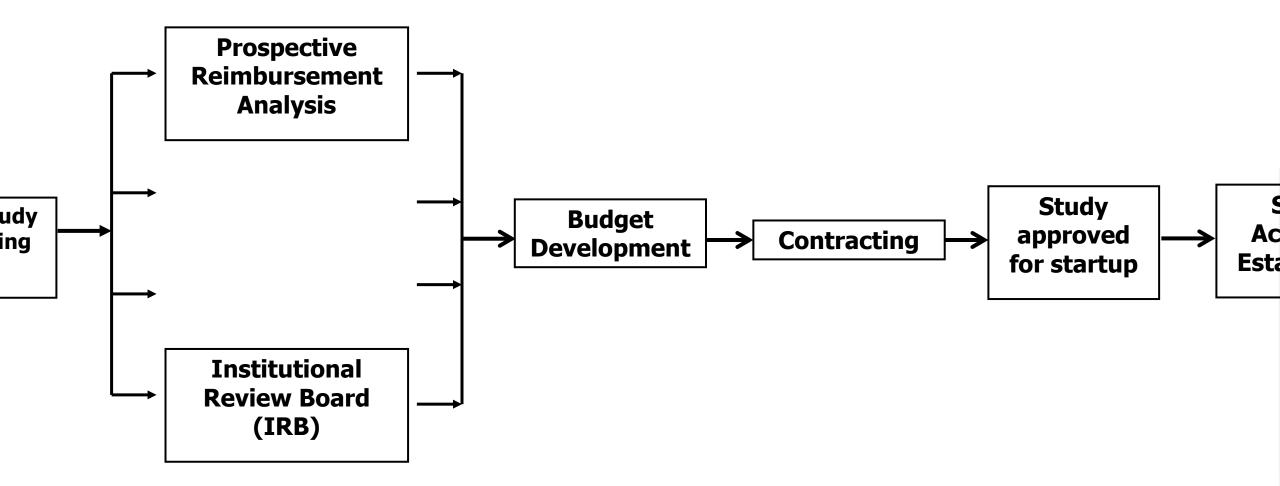


# **Parallel Processing**





# **Parallel Processing**





## THANKS!

## • Any Questions?

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