



JOHNS HOPKINS  
SCHOOL *of* MEDICINE

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



**ORA**  
**Office of Research Administration**

**ORA reviews all sponsored research proposals and awards.**

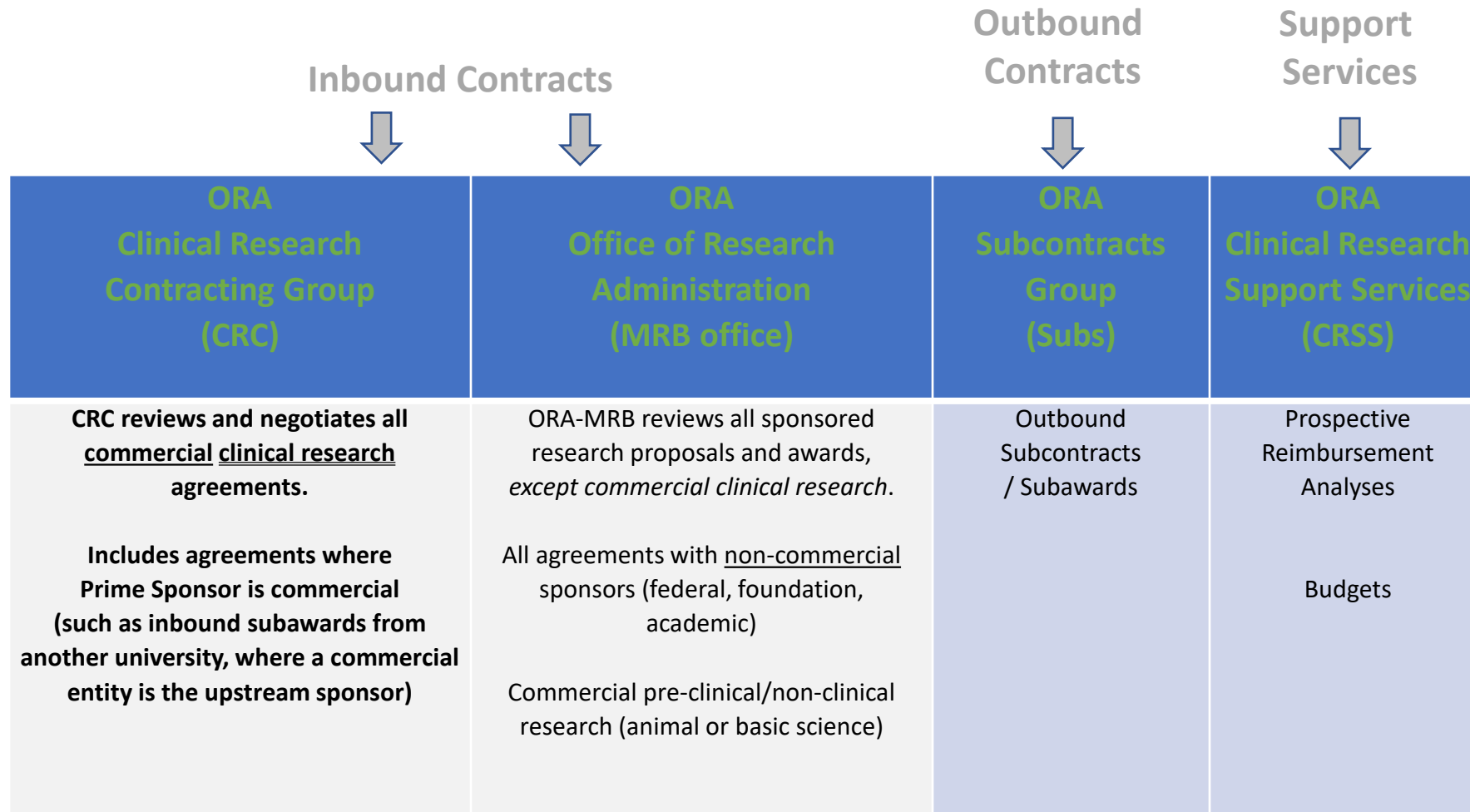
Outbound Contracts



**ORA Subcontracts**  
**Group**  
**(Subs)**

Outbound Subcontracts / Subawards

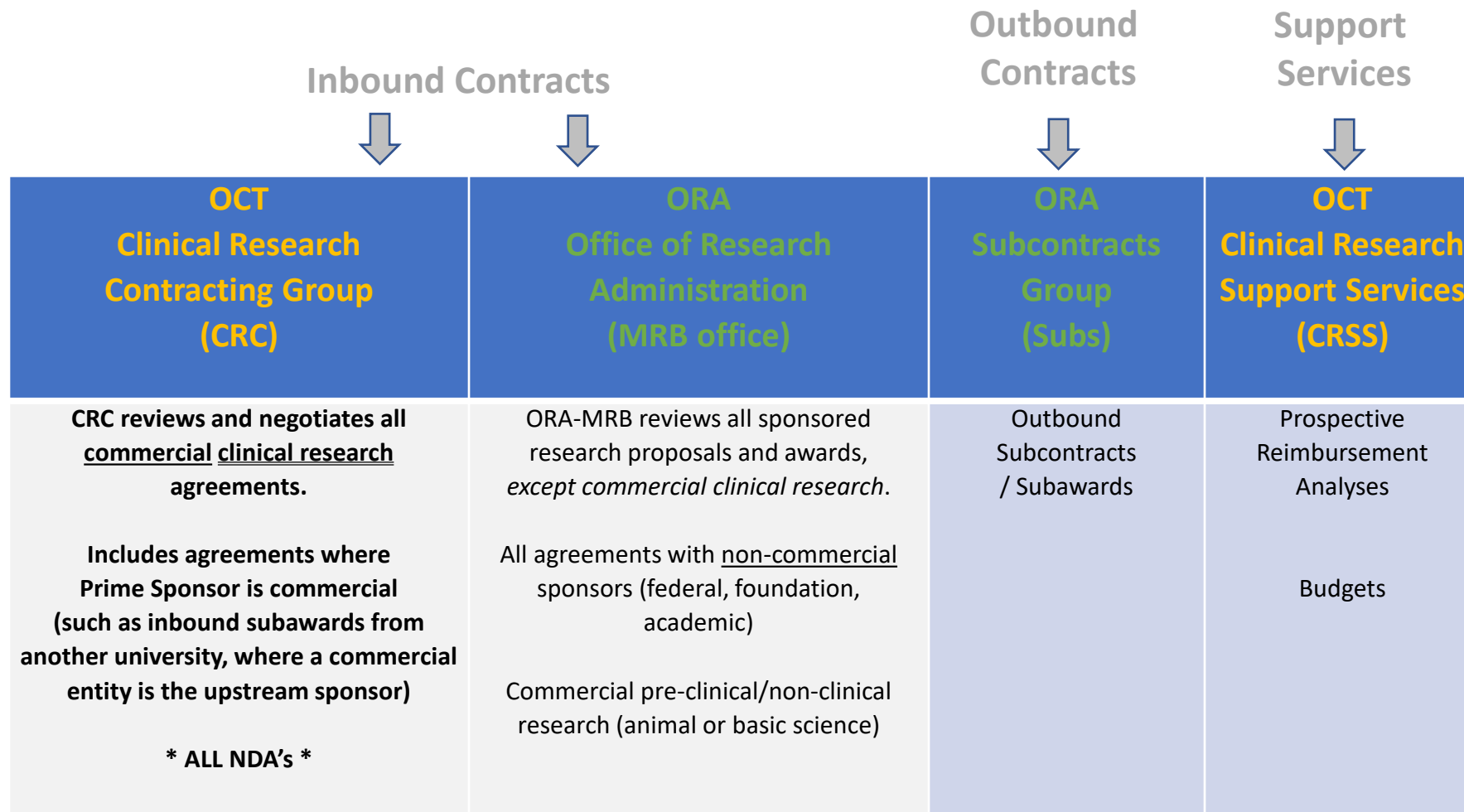
# ORA 2006-2022



# ORA/OCT 2022-present

Office of Research Administration

Office of Clinical Trials



# OCT/CRC Portfolio

The Clinical Research Contracting office  
negotiates

*clinical research* agreements



Complex regulatory/policy issues  
& greater institutional risk

with

*commercial* sponsors.



Often less collaborative  
“zero sum” approach

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

Greater demand for rights &  
control

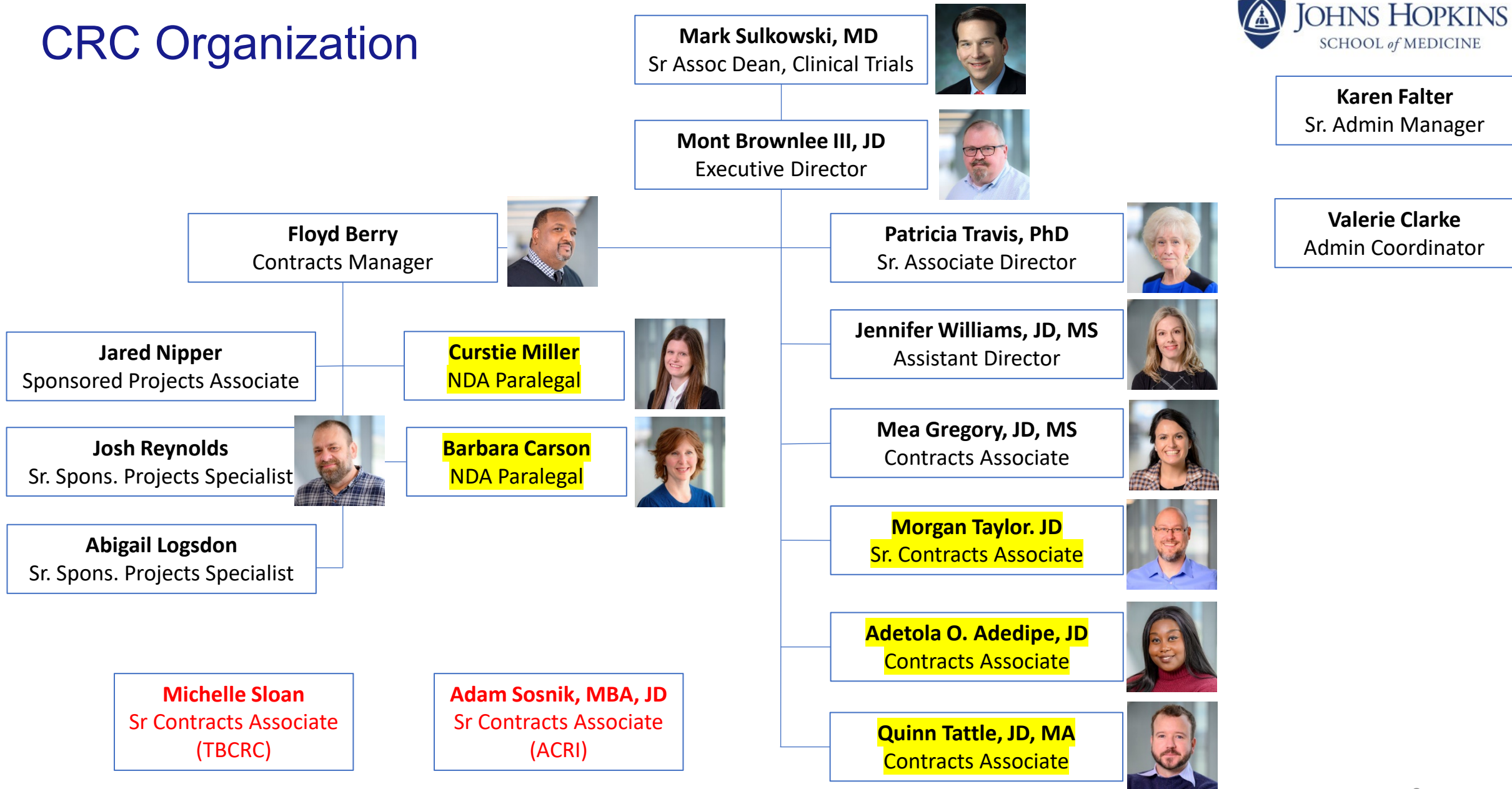
# OCT/CRC Stakeholders

- 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





# 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:
  - Editable version of the contract document (preferably 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 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 forward all NDA requests to [SOMNDA@jh.edu](mailto:SOMNDA@jh.edu) 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

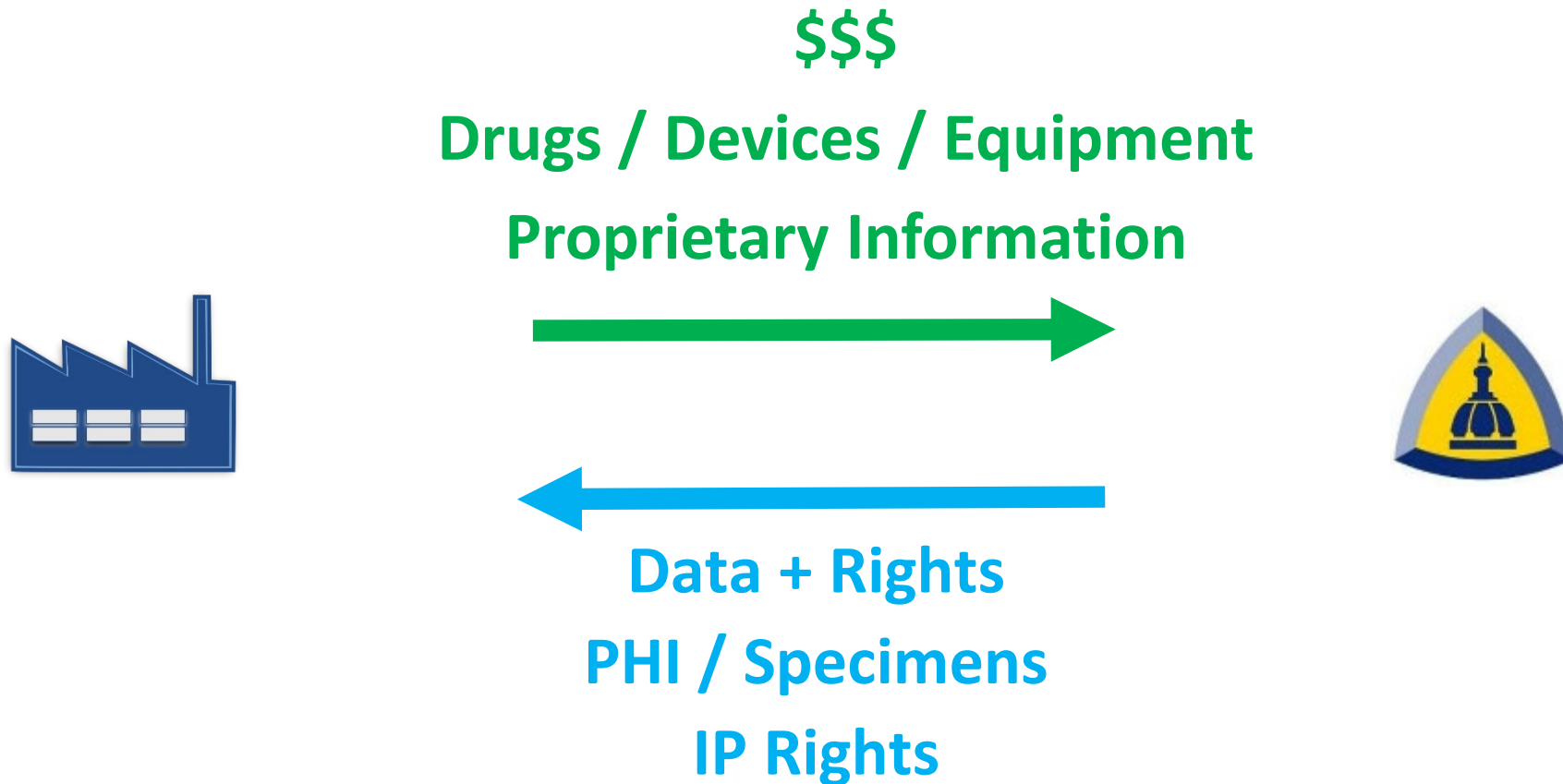
## **Dedicated NDA team** launched in Spring 2023

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

## **New "CRCInquiry" mailbox** for general questions and help

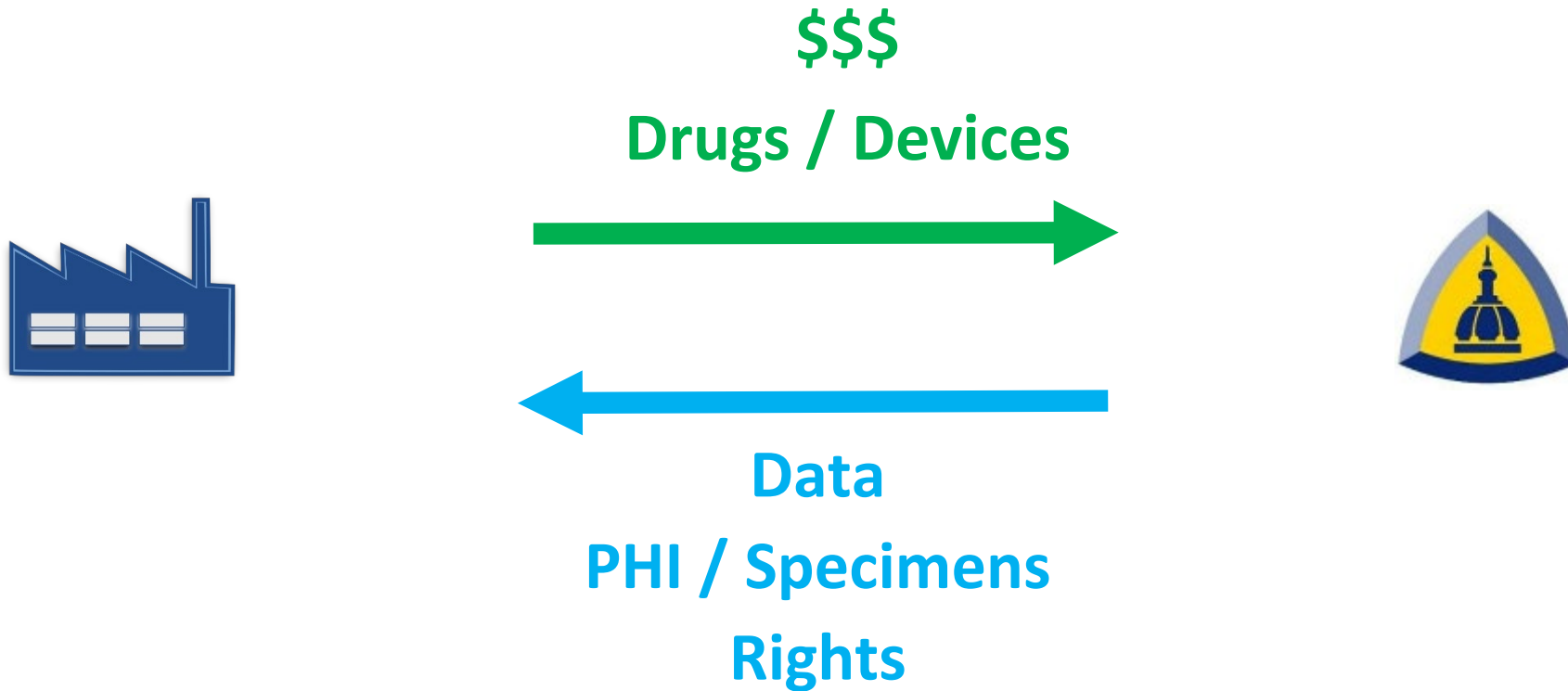
# Industry Transactions

*Typical exchanges in Research Agreements*



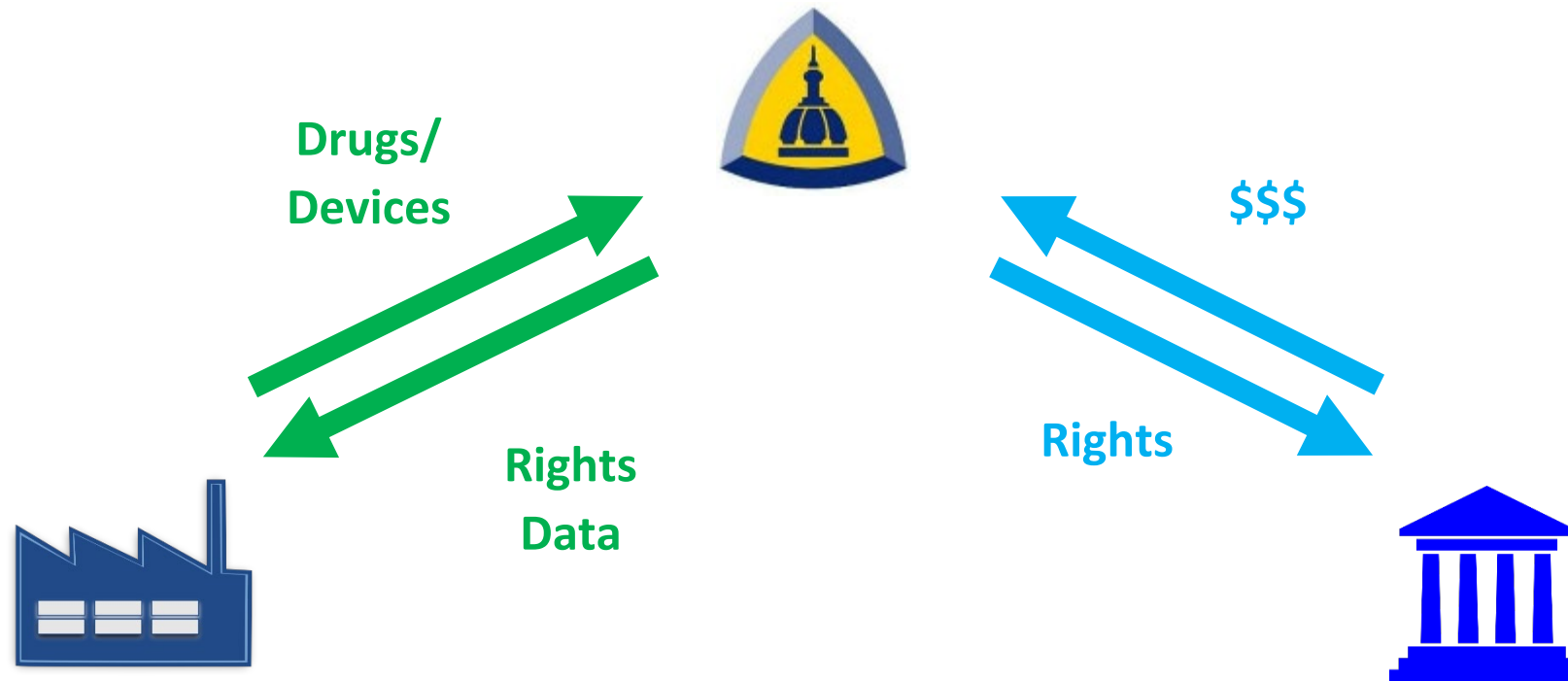
# Industry Transactions

*CTA for sponsor-initiated study*



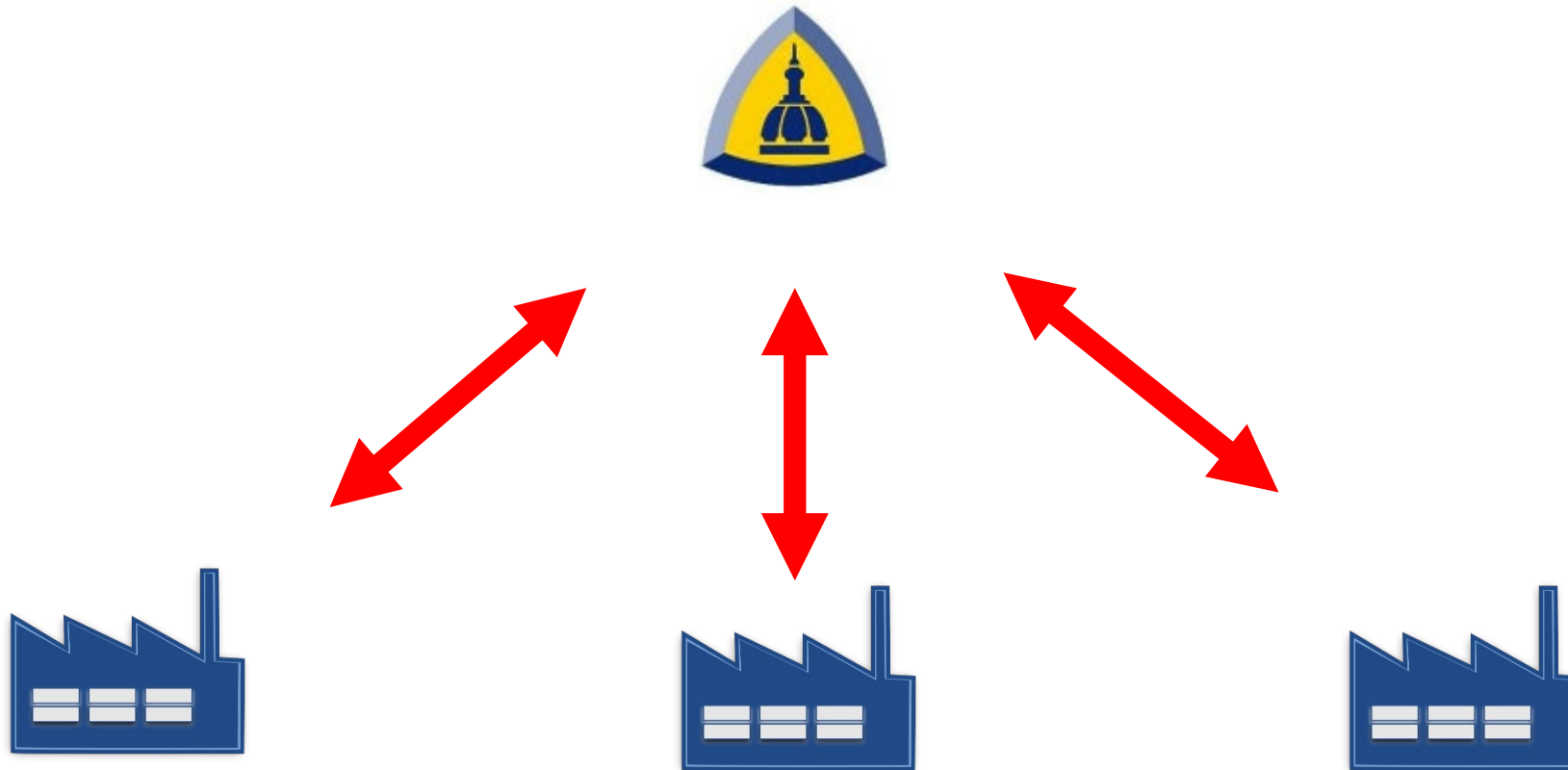
# Industry Transactions

*Government-funded, industry supported study*



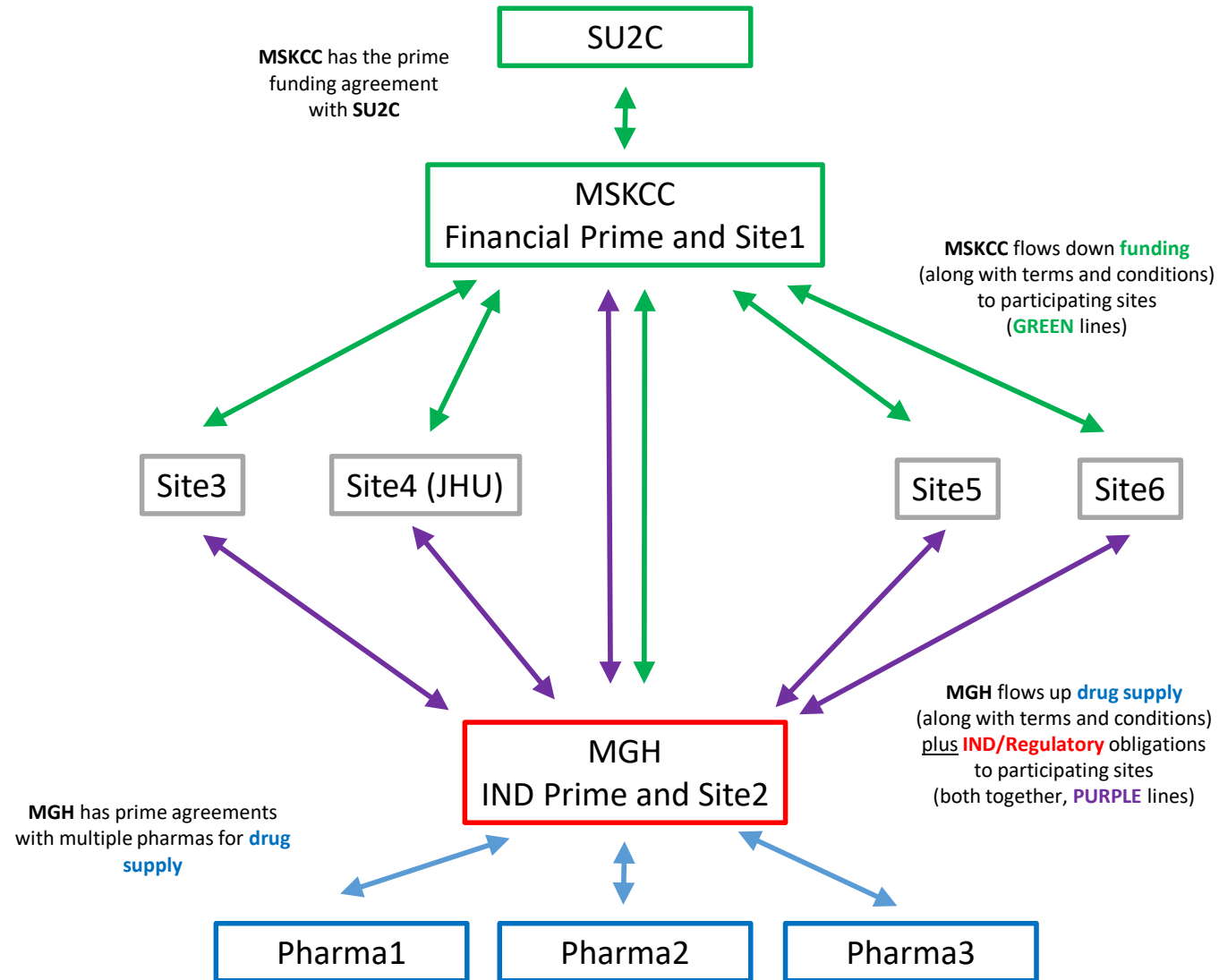
# Industry Transactions

*Multiple sponsors*

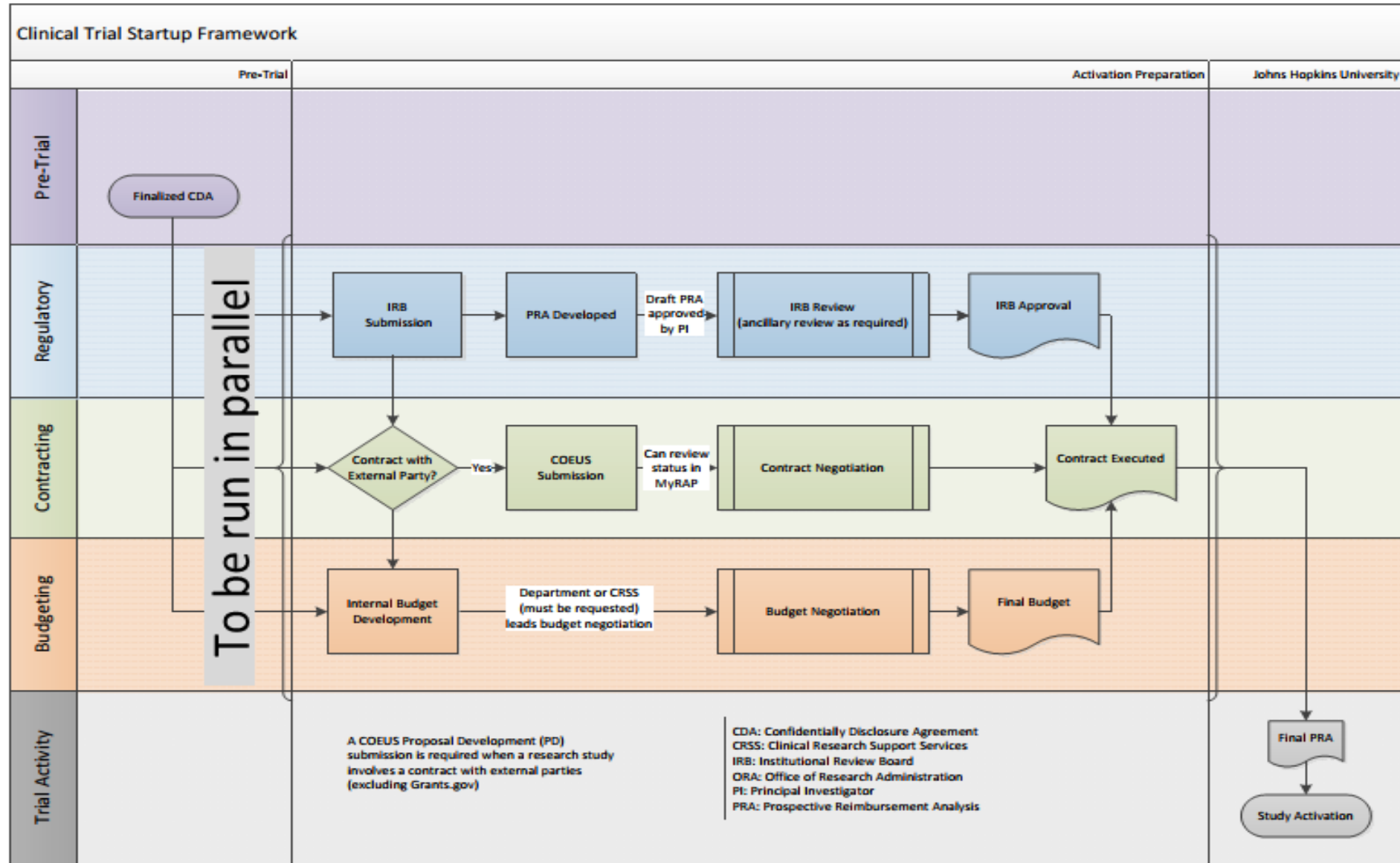




# Complex Transactions *Multi-directional obligations*



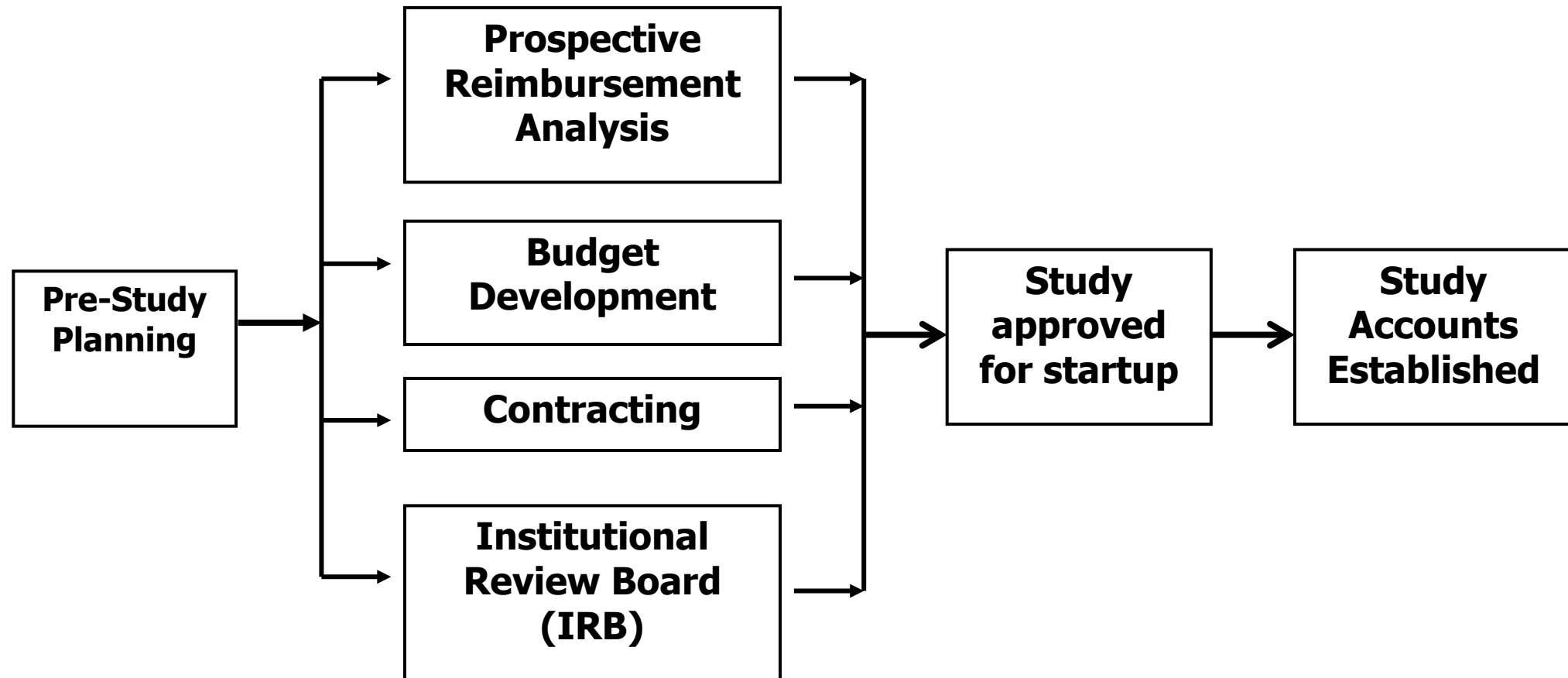
# Study Startup Process



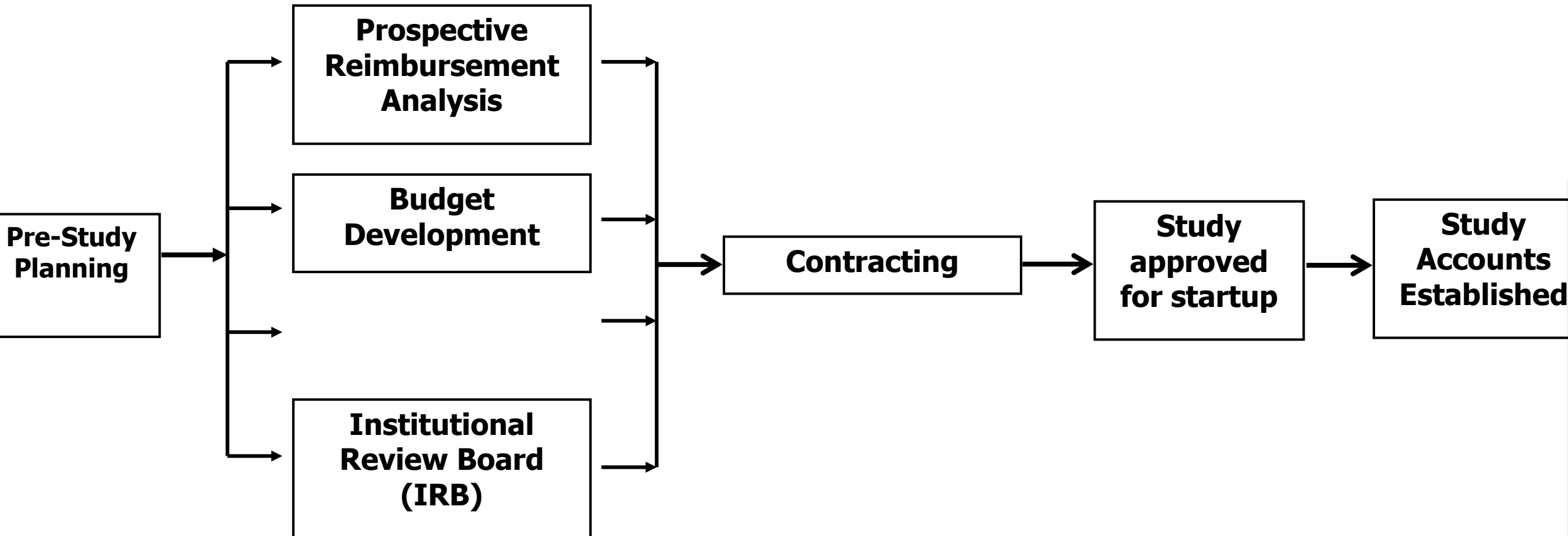
# Parallel Processing & Signature Timing

- **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 after IRB approval
  - 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

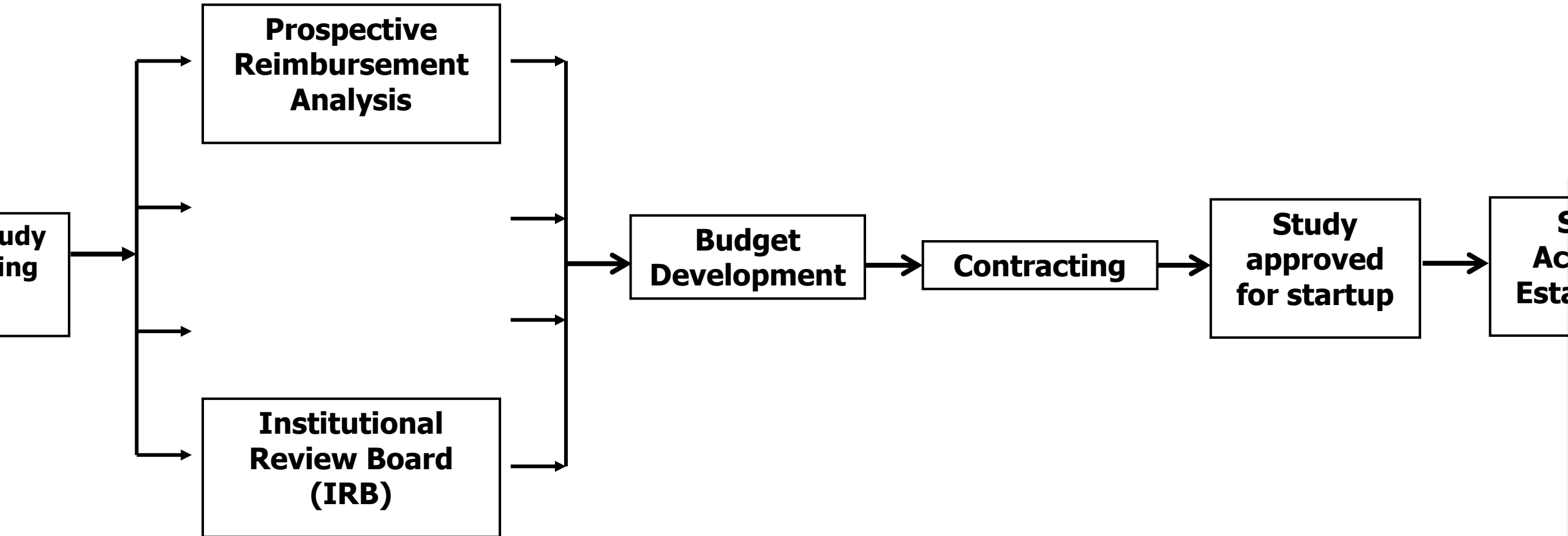
# Parallel Processing



# Parallel Processing



# Parallel Processing



# THANKS!

- **Any Questions?**

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