Overview of Clinical Research Contracting

Presented to: ORA Office Hours
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ORA Before mid-2006

Inbound Contracts

ORA
Office of Research Administration

Outbound Contracts

ORA Subcontracts Group (Subs)

ORA reviews all sponsored research proposals and awards.

Outbound Subcontracts / Subawards
## ORA 2006-2022

### Inbound Contracts

**ORA Clinical Research Contracting Group (CRC)**

CRC reviews and negotiates all commercial clinical research agreements.

Includes agreements where Prime Sponsor is commercial (such as inbound subawards from another university, where a commercial entity is the upstream sponsor).

### Outbound Contracts

**ORA Office of Research Administration (MRB office)**

ORA-MRB reviews all sponsored research proposals and awards, except commercial clinical research.

All agreements with non-commercial sponsors (federal, foundation, academic)

Commercial pre-clinical/non-clinical research (animal or basic science)

### Support Services

**ORA Subcontracts Group (Subs)**

Outbound Subcontracts / Subawards

**ORA Clinical Research Support Services (CRSS)**

Prospective Reimbursement Analyses

Budgets
CRC reviews and negotiates all commercial clinical research agreements.

Includes agreements where Prime Sponsor is commercial (such as inbound subawards from another university, where a commercial entity is the upstream sponsor)

* ALL NDA’s *

ORA-MRB reviews all sponsored research proposals and awards, except commercial clinical research.

All agreements with non-commercial sponsors (federal, foundation, academic)

Commercial pre-clinical/non-clinical research (animal or basic science)

Outbound Subcontracts
Subawards

Prospective Reimbursement Analyses
Budgets
OCT/CRC Portfolio

The Clinical Research Contracting office negotiates

* clinical research agreements
* 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)
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
- Triaged and 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 (DocuSign)
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 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 SOMND@jh.edu
- No FIBI submission required

**New “CRCinquiry” mailbox** for general questions and help
Industry Transactions

*Typical exchanges in Research Agreements*

$$$

Drugs / Devices / Equipment

Proprietary Information

Data + Rights

PHI / Specimens

IP Rights
Industry Transactions

CTA for sponsor-initiated study

$$$  
Drugs / Devices

Data

PHI / Specimens

Rights
Industry Transactions

_Government-funded, industry supported study_

Drugs/Devices

Rights

Data

$$$

Rights

$$$
Industry Transactions

*Multiple sponsors*
Complex Transactions  *Multi-directional obligations*

MSKCC has the prime funding agreement with SU2C

MSKCC flows down funding (along with terms and conditions) to participating sites (GREEN lines)

MGH flows up drug supply (along with terms and conditions) plus IND/Regulatory obligations to participating sites (both together, PURPLE lines)

MGH has prime agreements with multiple pharamas for drug supply
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

- Pre-Study Planning
  - Prospective Reimbursement Analysis
  - Budget Development
  - Contracting
  - Institutional Review Board (IRB)

- Study approved for startup
- Study Accounts Established
Parallel Processing

Pre-Study Planning

- Prospective Reimbursement Analysis
- Budget Development
- Institutional Review Board (IRB)

Contracting

Study approved for startup

Study Accounts Established
Parallel Processing

1. Study Planning
2. Prospective Reimbursement Analysis
3. Institutional Review Board (IRB)
4. Budget Development
5. Contracting
6. Study approved for startup
7. Study Accounts Established

Flowchart:
- Study Planning -> Prospective Reimbursement Analysis
- Institutional Review Board (IRB) -> Budget Development
- Budget Development -> Contracting
- Contracting -> Study approved for startup
- Study approved for startup -> Study Accounts Established
THANKS!

• Any Questions?

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