Office of Research Administration:
Contracting Issues for Clinical Research
Presented to:
JHURA Brown Bag Seminar Series

Presented by: Mont Brownlee
November 4, 2020

ORA Structure

Clinical Research Contracting

ORA-MRB

Subcontracts

Clinical Research Support Services (CRSS)

CRC reviews and negotiates all commercial clinical research agreements. Includes agreements where Prime Sponsor is commercial (such as subawards from another university, where a commercial sponsor is the upstream sponsor).

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

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

Commercial pre-clinical/clinical research (defined or basic science).

Consortium activity

Outbound Subcontracts

Prospective Reimbursement Analyses

Budgets

Clinical Research Contracting
(f/k/a the “Fell’s Point Office” / a/k/a the “Pratt Street Office”)

The Clinical Research Contracting office handles clinical research agreements with commercial sponsors.

*** Must be both ***

November 4, 2020
What is Clinical Research?

Clinical Research is all research that involves:

- Patients,
- PHI (Protected Health Information),
- clinical testing or procedures,
- drug or device trials,
- planning of clinical/lab services in support of clinical research.

November 4, 2020

Study Startup Process

- Pre-Study Planning
- Prospective Reimbursement Analysis
- Budget Development
- Contracting
- Institutional Review Board (IRB)
- Study approved for startup
- Study Accounts Established

November 4, 2020

Clinical Research

- Human Subjects
  - Medical intervention – investigational drugs/devices
  - Outcomes
  - Observational
- Medical Data (Electronic Medical Records) (HIPAA / GDPR)
- Human Specimens

November 4, 2020
Clinical Research Compliance

Complex regulatory and policy compliance issues

- FDA
- Institutional Review Board
- Contracts
- Prospective Reimbursement Analysis

November 4, 2020

Principal Investigator

The Principal Investigator ("PI") has significant regulatory responsibilities associated with the conduct of the research, supervision of study team, and reporting of results

Contracting:

- PI listed with the IRB is "the PI" (even if the award is to a different investigator)
- PI should be identified by name in Clinical Trial Agreement (CTA)
- PI signs the CTA to acknowledge their role (but not as a party)

November 4, 2020

Investigational Drugs/Devices

FDA regulates the use of investigational drugs and devices

Use of drugs/devices may require filing of an:

- "IND" or Investigational New Drug application; or
- "IDE" or Investigational Device Exemption

Per FDA regulations, the person or party that holds the IND/IDE is the "Sponsor" (capital "S")

The (capital "S") Sponsor has the ultimate responsibility to the FDA for the overall study

IRB application will include IND/IDE details

November 4, 2020
IND/IDE Sponsors

Not every study has an IND/IDE
- Companies providing funding/materials are providing support, but are not (capital “S”) Sponsors in the technical sense
- Must be careful not to identify a supporter as a “Sponsor”

Where a commercial entity is the IND/IDE Sponsor, JHU requires:
- More comprehensive indemnity
- Coverage of Subject Injury costs
- Enhanced reporting of adverse results (AAHRPP)

Where a faculty member is the IND/IDE Sponsor:
- They are the “Sponsor-Investigator” / responsible for both roles

Sponsors and Supporters

IRB application lists all entities providing Financial or Material support

Contracting:
- Need to contract with each entity supporting a study
- May be a mix of commercial and non-commercial support
- Need to be careful about inconsistent terms if there are multiple contracts
- Support may change over time
- Note that CRO’s may not be authorized to enter into all terms, so a side agreement with the Sponsor may be needed

Protocol

Studies are performed in accordance with a written protocol, which is on file with the IRB

Contracting:
- Make sure that the work covered by the contract matches is consistent with the IRB-approved protocol
- Note that JHU may not be performing all aspects of the protocol; important that the contract is clear as to what we are undertaking
- Whose protocol is it? May impact IP and data use terms.
Protocol

Contracting:

- Protocols change over time: "...the protocol and any approved amendments thereto, as kept of record by the appropriate Institutional Review Board ("Protocol")."

- Protocols may include hidden terms: "In the event of a conflict between the terms of this Agreement and the Protocol, the terms of this Agreement shall control except as regards Study participant care, in which case the Protocol terms shall control."

November 4, 2020

Study Location

IRB application will identify all locations where the study is being performed

Johns Hopkins University and Johns Hopkins Health System are separate legal entities

- JHHS has delegated to SOM ORA the authority to enter into contracts for research studies performed at JHHS facilities
- JHHS facilities include the Johns Hopkins Hospital, JH Bayview Medical Center, Howard County General Hospital, Suburban Medical Center; Sibley Memorial Hospital, and All Children’s Hospital

November 4, 2020

Study Location

Contracting:

- JHHS entities are not generally included as separate parties to research contracts, but JHU may represent and warrant their compliance with contract terms.
- The study location(s) should be specifically identified in the contract – this is most typically addressed in the indemnity section
- If non-JHHS study locations are used, a separate Facility Use Agreement may be needed; there may also be IRB coverage issues.

November 4, 2020
### Study Location

**Contracting for multi-site studies:**

- If JHU will be issuing subcontracts, care must be taken to draft the prime agreement with flowdowns in mind.
- Must be careful to avoid taking on responsibility/liability for other sites/investigators.
- Privity issues may be problematic for indemnity; a sponsor-issued Indemnity Letter is the gold standard, but many companies will not agree to provide one.

**November 4, 2020**

---

### Consent Form

**IRB application will include copies of all approved Consent Forms**

**Contracting:**

- It is critical that the study contract and consent form are consistent, particularly in regard to:
  - Subject Injury costs
  - Costs to subjects
  - Disposition of data and specimens
- Studies may also be approved under a consent “Waiver”; must be sure that the contract is consistent where this is the case.

**November 4, 2020**

---

### Odds and Ends

- Many studies are required to be registered on ClinicalTrials.gov — this will be indicated in the IRB application; there are financial penalties for noncompliance, so it is important to be clear in the contract who is responsible for registration.
- Investigational **drugs** are typically provided at no charge, but the cost of **investigational devices** are often charged to subjects/patients — where this is the case, there may be need for a separate supply agreement with JHHS.
- The Prospective Reimbursement Analysis (“PRA”) is also included in the IRB application, and is a valuable reference regarding study costs.

**November 4, 2020**
THANKS!

- Any Questions?

Patricia Travis, RN, Ph.D., CCRP
Sr. Associate Director, CRC
Office of Research Administration
Johns Hopkins School of Medicine
730 E. Pratt Street, 14th Floor
Baltimore, MD 21202
Email: ptravis2@jhmi.edu

Mont Brownlee, III, J.D.
Executive Director, CRC
Office of Research Administration
Johns Hopkins School of Medicine
730 E. Pratt Street, 14th Floor
Baltimore, MD 21202
Email: mbrownl1@jhmi.edu

November 4, 2020