Duke's Office of Research Contracts – Why have a contract at all?

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Learning Goals

1) Office of Research Contracts – internal processes; how our group is organized; how we interact with other Duke offices, specifically Office of Regulatory Affairs and Quality (ORAQ)

2) Types of agreements we review and negotiate

3) Examples of agreement types that often require collaboration with our compliance and regulatory offices. Ex) Treatment Agreements, TORO's, Quality Agreements, Manufacturing Agreements

4) Questions?

Office of Research Contracts (ORC)

***Duke Site Based Research**

Marti Salguero, B.A.

Research Program Collaborations/ Data Transfer/Use

Susan Hayden, J.D.

***Non-Clinical Research Group**

Curtis Bradney, Ph.D.

ORC Processes –
Site-Based Research/industry funded clinical trials group

- Acknowledgement email and preliminary questions
- Negotiates and approves the terms and conditions to assure that terms are reasonable, and compliant with Duke's policies and Duke's tax-exempt status;
- Requests Budget and Payment terms from CRUs
- Confirms research related injury language in the ICF is consistent with the contract;
- SPS
- Contract is routed to ORC's signatory for signature.

Study Initiation Process

ORC

* Negotiates the legal terms and conditions;
* Reviews research related injury language in ICF and posts Mods in iRIS;
* Confirms compliance with the SoM policy on budgets and payment terms.

IRB

*Reviews the protocol.

CRU

Scientific and financial feasibility

Once approved, study team can move forward with the study start-up activities.

DOCR – billing review

* DOCR will email study teams to schedule a meeting to discuss their protocol and related study documents. DOCR will gather the information necessary to create the study calendar and order set that will be built in Maestro Care.

ORC – signature process for industry funded clinical research

* Reviews conflict of interest statement
* Reviews budget
* Reviews SPS
* Signs the contract

Types of agreements that ORC handles and signs:

- Confidentiality/Non Disclosure Agreement (CDA or NDA)
- Core Lab Research Agreements
- Clinical Research/Trial Agreements (CRA or CTA, also for DCRI)
- Expanded Access/ Individual and Emergency IND Agreements
- Data Transfer/ Use Agreements (DTA/DUA)
- Material Transfer Agreements (MTA)
- Non-Clinical Research Agreements
- Non-CME and CME Educational Program Agreements
-Surplus Material Transfer Agreements
-TORO's, Quality Agreements, Manufacturing Agreements
- Amendments
- Other

How ORC interacts with other Duke offices

Often a standard CTA or CRA will cover regulatory/compliance, procurement, IP licenses, Data security processes and other issues and timeframes that need input from other offices, such as:

- Procurement
- Office of Licensing and Ventures (OLV)
- Data Security Office
- Duke Office of Clinical Research (DOCR)
- Pharmacy
- Office of Risk Management (insurance waiver requests)
- Office of Regulatory Affairs and Quality (ORAQ)…Just to name a few.

Why a research contract is necessary – Compliance with IRS regulations

501(c)(3) Tax Exempt Organization

- All contract terms must be consistent with institution's tax-exempt mission of research and education.
- Institution must control research done in its tax-exempt facilities.
- Work must be bona fide academic research, not contract services or routine product testing. Also not "secret" research.
- Research contracts must preserve institution's academic freedoms and independence

Why a research contract is necessary – Compliance with IRS regulations

501(c)(3) Tax-exempt Research does not include:

- Activities of a type ordinarily carried on incident to a commercial operation (ex. – CRO)
- Ordinary testing or inspection of materials or products (routine sample analysis)
- Design or construction of equipment
- Research with the primary purpose of commercial application

Compliance and Regulatory Collaboration: Research Types

- Collaboration with university stakeholders varies across agreement types and by project
- Research in humans v. bench/animal research
- Responsibilities of regulatory sponsors and holders of INDs/IDEs
- Technology and intellectual property specific issues
- Data use and transfer
- Compliance with existing grant or contract obligations

Treatment Agreements

- Also called Expanded Access Agreements (more than one patient), Compassionate Use Agreements, IND (single patient) Agreements
- With the help of ORAQ, developed a template Treatment Agreement and CDA.
- Often provided a Company template that is a research agreement
- PHI protection imperative, but often negotiate other check list items.
- Work very closely with ORAQ assigned staff member throughout the process to prioritize and promptly handle – TREATMENT NOT RESEARCH

Thank you!

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