
ORGANIZING REGULATED RESEARCH ACTIVITIES

UNIVERSITY OF TEXAS



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ORGANIZING REGULATED RESEARCH ACTIVITIES

- Research Involving Human Subjects (IRB)
- Research Involving Animals (IACUC)

HUMAN SUBJECT RESEARCH – SINGLE IRB REVIEWS

- HSR requires IRB review
- Options to avoid duplication of effort
 - OHRP: “Institutions may enter into joint review arrangements, rely upon the review of another qualified IRB, or make similar arrangements to avoid duplication of effort”
 - NIH (effective May 2017): “Expectation that a single IRB (sIRB) of record will be used in the ethical review of non-exempt human subjects research protocols funded by the NIH that are carried out at more than one site”

HUMAN SUBJECT RESEARCH – RELIANCE AGREEMENTS

- Determine IRB of record
- IRB Reliance Agreement
 - UT System “Reciprocity” Agreement (UT + Others)
- Acknowledgement Process



HUMAN SUBJECT RESEARCH – DETERMINING IRB OF RECORD

- Where will the work take place? (site requirements – access to facilities or subjects)
- Where are the subjects? (local or institutional policies – patients, employees, etc.)
- Who is the funding recipient? (sponsor obligations)
- Who is engaged? (Determines protocol personnel and perhaps site responsibility – intervention, interaction, or access to/receipt of identifiable data)

ANIMAL RESEARCH – SINGLE IACUC REVIEW

- Work involving live animal vertebrates requires IACUC Review
- Options to avoid duplication
 - OLAW: “The approval of more than one IACUC is not required if the grantee and performance site(s) have Assurances; the institutions may exercise discretion in determining which IACUC reviews research protocols and under which institutional program the research will be conducted.”
- Determine IACUC of Record
- Written agreement, MOU

ANIMAL RESEARCH – DETERMINING IACUC OF RECORD

- Where will the work take place? (site requirements – training, OHS)
- Where are the animals? (local or institutional policies – housing space, animal care)
- Who is the funding recipient? (sponsor obligations)
- Who is engaged? (Determines protocol personnel and perhaps site responsibility – work with live vertebrate animals)

REGULATORY SERVICES

We are here to help!!!

Center for Innovation

202 E. Border St., Suite 300

817-272-3723

regulatoryservices@uta.edu

Open Office Hours: Every Thursday, 9:00am – 11:00am

RESEARCH COLLABORATION – BASIC CONSIDERATIONS

- What is the purpose of the collaboration?
 - Sponsored / Funding
 - Generate Pilot Data
 - Partnership
 - Data sharing
 - Internal or external

RESEARCH COLLABORATION – BASIC CONSIDERATIONS

- Who is collaborating?
 - Individuals
 - Organizations
- What is being shared?
 - Data
 - Ideas
 - Materials
- How will it be shared?

RESEARCH COLLABORATION – BASIC CONSIDERATIONS

- Authority and Process
 - Approval to perform activity (supervisor)
 - Use or commitment of University resources (institutional approval)
 - Space, renovations, or access to special equipment (what is required for success)
- Sustainment of commitments
- Regulatory Requirements

RESEARCH COLLABORATION – AGREEMENT TYPES

- Sponsored Research Agreement
 - Statement of Work
 - Subcontractors / Subrecipients / Vendors / Consultants
- Memorandum of Understanding
- Non Disclosure Agreements
- Collaborative Research Agreements
- Material Transfer

RESEARCH COLLABORATION – AGREEMENT TERMS

- Publication Rights
- Confidentiality
- Intellectual Property
- Data Ownership
- Deliverables
- Financial Management
- Liability / Indemnification
- Use of Results

RESEARCH COLLABORATION – AGREEMENT CONTACTS

- Sponsored Funding (Proposals and Awards)
 - Office of Grant and Contract Management (ogcs@uta.edu)
- Intellectual Property (License Agreements)
 - Office of Technology Management (otm@uta.edu)
- Other Research Collaboration Agreements
 - Agreement Manager – Dan Vincenzo (vincenzo@uta.edu)
- THANK YOU – Jeremy Forsberg, Assistant Vice President for Research (j.forsberg@uta.edu)