ORGANIZING REGULATED RESEARCH ACTIVITIES
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- 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”
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)
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
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)
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
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)