Institutional Handbook of Operating Procedures Policy 11.01.07	
Section: Research Policies	Responsible Vice President: Executive Vice President and Provost
Subject: General Research	Responsible Entity: Research Services

I. Title

Principal Investigator Roles and Responsibilities

II. Policy

A. Overview

The Principal Investigator (PI) is responsible for the overall conduct, direction, and oversight of a sponsored or unsponsored project, including but not limited to, all technical, programmatic, financial, compliance, and administrative aspects, management and integrity of the design, conduct, and reporting of the sponsored or unsponsored project; and managing, monitoring, and ensuring the integrity of any collaborative relationships. The PI is responsible for being knowledgeable of and ensuring the project is conducted in accordance with state and federal laws, federal regulations, UTMB institutional policies and procedures, and sponsoring agency rules and regulations. While the PI may involve personnel from their school, department, or central administration, the PI remains ultimately responsible even when some aspects of the research are delegated to other members of the study team.

B. General Areas of Responsibility

Principal Investigator responsibilities include, but are not limited to, the following:

1. Preparation of the scientific proposal
2. Development of the research budget
3. Protocol preparation and review
4. Award acceptance (i.e., sign agreement, complies with terms of award/contract, etc.)
5. Coordination with department for space management, facilities and administrative cost application, and equipment management
6. Conduct of the research as agreed to in the grant, contract, and/or study protocol(s)
7. Compliance with applicable laws, regulations, and institutional policies.
8. Financial Management
    a. Monthly expense monitoring
    b. Cost Transfers and budget adjustments, where applicable
    c. Cost Sharing, where applicable
    d. Financial reporting to Institution, Sponsor, or government in concurrence with other UTMB department(s)
    e. No cost extension and prior approval requests submissions to central administration
9. Effort Reporting or Salary Administration according to institutional policy
10. Conflict of Interest
    a. Ensure all personnel comply with COI training and disclosure requirements, per IHOP 6.5.1, *Research Conflicts of Interest*
    b. Disclose personal interests, as required under IHOP 6.5.3
    c. Cooperate with Office of Institutional Compliance to implement any necessary COI Management Plans

   d. Ensure compliance with any COI Management Plans of project personnel when applicable
11. Ensure personnel compliance with all Export Controls policies and laws
12. Reporting of research (e.g., reporting to Sponsor, ClinicalTrials.gov, etc.)
13. Project Closeout

D. Responsibilities Specific to Human Subjects Research

Principal Investigator responsibilities relating specifically to Human Subjects Research include, but are not limited to, the following:

1. Protocol and Informed Consent Form preparation and review
2. Submission of all necessary Institutional Review Board ("IRB") documentation and forms
3. Ensure proper Informed Consent Process
   a. Informed consent is not a single event or document, but an ongoing process that takes place between the Principal Investigator (or other key personnel, as appropriate) and the research subject.
   b. Informed consent requires full disclosure of the nature of the research and the subject's participation, adequate understanding on the part of the subject (or the subject's legally authorized representative), and the subject's voluntary decision to participate.
4. Ensure patient privacy of Protected Health Information
5. Prompt reporting to IRB, including reporting of unanticipated problems, adverse events, etc.
6. Ensure compliance with all IRB Policies and Procedures
7. Ensure duties are delegated to appropriately licensed/trained study staff
8. Conduct the study according to the Sponsor and/or institutional guidelines

E. Responsibilities Specific to Animal Research

Principal Investigator responsibilities relating specifically to Animal Research include, but are not limited to, the following:

1. Protocol and Informed Consent Form preparation and review
2. Submission of all necessary Institutional Animal Care and Use Committee ("IACUC") documentation and forms
3. Ensure all personnel are adequately trained and certified regarding policies and procedures for humane care and use of animals
4. Ensure all personnel are adequately trained and knowledgeable of the protocol(s)
5. Prompt reporting to IACUC, particularly any event that may affect animal safety
6. Ensure compliance with all IACUC Policies and Procedures

F. Responsibilities Relating to Environmental Health and Safety

Principal Investigator responsibilities relating specifically to Environmental Health and Safety include, but are not limited to, the following:

1. Ensure all staff have met the occupational health requirements related to their job function

G. Responsibilities Relating to Intellectual Property

Principal Investigator responsibilities relating specifically to Intellectual Property include, but are not limited to, the following:

1. Coordinate with the Office of Technology Transfer ("OTT") to disclose and report patent and invention information

2. Promptly report all inventions to OTT
3. Coordinate with OTT on the preparation and prosecution of patents

III. Definitions

Principal Investigator: A Principal Investigator (PI) is responsible for the overall conduct of a sponsored or unsponsored project, including all technical, programmatic, financial, compliance, and administrative aspects, and for the management and integrity of the design, conduct, and reporting of the project as well as assurance with applicable laws, regulations, and institutional policies governing the project.

Co-Principal Investigator and Co-Investigator: A Co-Principal Investigator (Co-PI) is person that shares responsibility and accountability for the conduct of the study with the PI. For example, a Co-PI can sign study documents in the investigator's absence, but may not request study changes through the IRB. A Co-Investigator (Co-I), is key personnel that collaborates on the study along with the PI, but does not share any responsibility or accountability for the conduct of the study.

IV. Relevant System Policies and Procedures

UTS 175, Disclosure of Significant Financial Interests and Management and Reporting of Financial Conflicts of Interest in Research
UTS 180, Conflicts of Interest, Conflicts of Commitment, and Outside Activities

V. Related UTMB Policies and Procedures

IHOP - 06.05.01 - Research Conflicts of Interest
IHOP - 06.05.03 - Individual Conflicts of Interest

VI. Dates Approved or Amended

Originated: 10/02/2018	
Reviewed with Changes	*Reviewed without Changes*

VII. Contact Information

Research Services
(409) 266-9400