DIVISION OF RESEARCH & INNOVATION Research Integrity & Compliance	**Institutional Review Board Standard Operating Procedures**

Title: Pre-IRB Spending Requests

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Approval/Date:

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REVISION HISTORY

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PURPOSE

The purpose of this Standard Operating Procedure (SOP) is to define Research Integrity and Compliance (RIC) and Researcher procedures for the review and approval of Pre-IRB spending requests for Non-human Subject Research-Related Activities prior to IRB approval.

SCOPE

This SOP delineates systematic process activities and functions for compliance with the US Department of Health and Human Service, Office for Human Research Protections (OHRP) and Common Rule requirements, and University of North Texas (UNT) requirements for the management, coordination, and operation of the Institutional Review Board (IRB) program. It applies to sponsored projects involving human subject research activities reviewed by the UNT IRB.

DEFINITIONS/ ABBREVIATIONS

1. Definitions

1.1 Non-human Subject Research-Related Activities: Activities performed on a research study that do not involve human subject research. This may include, but is not limited to, protocol development, administrative duties, purchasing equipment, setting up the research location, and hiring of support staff.

1.2 *Principal Investigator:* The primary individual responsible for the preparation and conduct of a research grant, sponsored project, or human subjects research study, in compliance with applicable laws, regulations, and institutional policy governing the conduct of research.

1.3 Researcher: Any individual performing various tasks related to the conduct of human subjects research activities, including but not limited to obtaining informed consent from subjects, collecting and analyzing data, interacting with subjects, and communicating with the IRB.

1.4 Sponsored Projects Involving Human Subjects Research: Externally funded projects that contain research activities requiring IRB review and approval.

2. Abbreviations

2.1 GCA: Grants and Contracts Administration
2.2 IRB: Institutional Review Board
2.3 OHRP: Office for Human Research Protections
2.4 PI: Principal Investigator
2.5 RIC: Research Integrity and Compliance
2.6 SOP/SOPs: Standard Operating Procedure(s)

RESPONSIBILITIES

This SOP is applicable to all members of Research Integrity and Compliance and Institutional Review Board members who are involved in record keeping, reviewing, or approving research studies for the Institutional Review Board program. This SOP is also applicable to all UNT Principal Investigators and Researchers performing human subjects research under the oversight of the UNT Institutional Review Board.

PROCEDURE

1. Prior to IRB approval, and when the award period has begun, Pre-IRB spending that is deemed necessary and essential to the protocol development may be approved. The work done prior to IRB approval is limited to activities such as protocol development, IRB submissions, setting up research location, ordering equipment, hiring study support staff, and training study staff. This is assessed on a case by case basis and infrequently determined to be the best course of action.
2. Principal Investigator Responsibilities
   - 2.1 Contact Research Integrity and Compliance at untirb@unt.edu to request an assessment to determine if the project is eligible for Pre-IRB spending. Provide a copy of the Scope of Work or other Proposal document that contains a description of activities.
   - 2.2 If the project is deemed eligible for Pre-IRB spending, the Principal Investigator must complete the request form and submit the form to untirb@unt.edu.
     - 2.2.1 All fields on the form must be completed, including the explanation of what spending will occur.
     - 2.2.2 The form must be signed by:
       - 2.2.2.1 The Principal Investigator
       - 2.2.2.2 The Department Administrator (The faculty/staff member working within the Principal Investigator's department with oversight over the funds of the department)
       - 2.2.2.3 RIC staff member, as determined by the Assistant Vice President of Research Integrity and Compliance.
       - 2.2.2.4 GCA staff member, as determined by the Director of Pre-Award.
   - 2.3 Once all signatures are obtained, the Principal Investigator must send a fully-executed copy of the form to untirb@unt.edu. The Principal Investigator is responsible for providing a copy of this form to the GCA staff member that is the point of contact for the Sponsored Project involving human subjects research.

2.4 Once the study receives IRB approval, the Principal Investigator will share a copy of the approval letter with the GCA staff member.

3. RIC Staff Responsibilities
   3.1 Once an email request for Pre-IRB spending is received, the request will be evaluated by the Assistant Vice President of RIC, or designee, to determine if the Pre-IRB Spending Request corresponds to Non-human Subject Research-Related Activities only.
   3.2 Once the determination is made, the Assistant Vice President of RIC, or designee, will email the Principal Investigator explaining the determination.
   3.3 If Pre-IRB spending is approved, the Assistant Vice President of RIC, or designee, will request the Principal Investigator to complete the Pre-IRB Spending Request Form.
      3.3.1 Once the form is received back, the Assistant Vice President of RIC, or designee, will assess the form for completeness and to determine if the Pre-IRB Spending Request corresponds to Non-human Subject Research-Related Activities only.
      3.3.2 If changes are needed, the Assistant Vice President of RIC, or designee, will request changes from the Principal Investigator via email. Correspondence will continue until the form has been determined to be complete and the Pre-IRB Spending Request is approved.
   3.4 The Assistant Vice President of RIC, or designee, will sign the form and send the form back to the Principal Investigator.
   3.5 Once a fully executed copy of the form has been received from the Principal Investigator, the Assistant Vice President of RIC, or designee, will save the form in the shared drive for reference.
   3.6 Once the study receives IRB approval, the IRB approval letter will be issued to the Principal Investigator by the IRB.

REFERENCES

1. US Department of Health and Human Service, Office for Human Research Protections (OHRP)

APPENDICES

1. UNT System Procurement Guide
2. Pre-IRB Spending Request Form