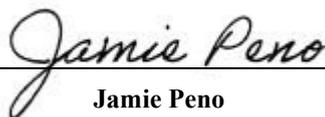


 DIVISION OF RESEARCH & INNOVATION Research Integrity & Compliance		Institutional Review Board Standard Operating Procedures	
Title: Funded Research Studies			
Effective Date:	4/1/2021	Document Number:	IRB-SOP-14-0.1
Approval/Date: <div style="display: flex; justify-content: space-around; align-items: center;"> <div style="text-align: center;">  <hr style="width: 100%;"/> Jamie Peno Assistant Vice President, Research Integrity and Compliance </div> <div style="text-align: center;"> <hr style="width: 100%;"/> 4/1/2021 Date </div> </div>			
REVISION HISTORY			
Date	Section	Author	

PURPOSE

This Standard Operating Procedure (SOP) is to define the procedures for review and maintenance of funded research studies within the Institutional Review Board program and to clarify necessary communications between the Office of Grants and Contracts Administration (GCA) and the Research Integrity and Compliance (RIC) Institutional Review Board (IRB) program.

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 requirements for the management, coordination, and operation of the Institutional Review Board program. It applies to the Assistant Vice President and the Research Compliance Team members whom are engaged in the operations and support of the Institutional Review Board.

DEFINITIONS/ ABBREVIATIONS

1. Definitions

- 1.1 *Funded Research Studies*: Studies that have been awarded internal or external funding. Funding sources may include government agencies, private organizations or the University of North Texas.
- 1.2 *IRB Analyst*: Staff member of the Office of Research Integrity and Compliance that perform administrative activities, pre-reviews, reviews, and approvals for the Institutional Review Board program.
- 1.3 *Grants and Contracts Administration*: The coordinating office for proposal

submissions to external funding entities and for administration of externally sponsored project awards received by the university; these include both government agencies (Federal and/or State) and private organizations (not-for-profits, industries).

1.4 *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.

2. Abbreviations

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

RESPONSIBILITIES

This SOP is applicable to all members of the Office of Research Integrity and Compliance who are involved in preparing, reviewing, or approving research studies for the Institutional Review Board program, or those responsible for record keeping for the Institutional Review Board program.

PROCEDURE

1. Funded Study Notification and Review

1.1 Funded Research Studies will be sent to RIC for review and action in several ways:

1.1.1 By Email from GCA

1.1.1.1 If RIC receives email regarding a new funded study notification, an IRB Analyst must review the study proposal, in conjunction with the PI, to provide a determination if the study needs IRB approval.

1.1.1.1.1 If the study does not need IRB approval, The IRB Analyst must email the PI and GCA to state that IRB approval is not needed.

1.1.1.1.2 If the study does need IRB approval prior to beginning study activity, the IRB Analyst must notify the PI and GCA via email. The IRB Analyst will then instruct the PI to submit the study through the electronic IRB system.

1.1.2 By Email from PI:

1.1.2.1 If RIC receives a new funded study notification by email from the PI, an IRB Analyst must review the study proposal with the PI to provide a determination if the study needs IRB approval.

1.1.2.1.1 If the study does not need IRB approval to begin, the PI is emailed and told that IRB approval is not needed.

1.1.2.1.2 If the study does need IRB approval prior to beginning study activity, the IRB Analyst notifies the PI and GCA via email. The IRB Analyst will

then instruct the PI to submit the study through the electronic IRB system.

1.1.3 By electronic IRB system submission:

1.1.3.1 If RIC receives a new funded study notification in the electronic IRB submission, the assigned IRB Analyst must review the study proposal in accordance with IRB-SOP-22.0 titled, "Review Process for IRB Submissions."

1.2 All new Funded Research Study submissions should be reviewed in accordance with all IRB SOPs if it is determined that IRB approval is needed.

1.3 Pre-IRB Spending Requests

1.3.1 When IRB Approval is needed for studies to begin, IRB approval must be received by the PI prior to GCA setting up research accounts. Intermittently, funding is needed prior to the receipt of IRB approval. In this case, a request can be made by the PI by following the IRB SOP related to Pre-IRB Spending Requests.

2. Record Keeping and Follow-up

2.1 The Assistant Vice President, or Research Compliance Team member as delegated, must keep an accessible record of all funded projects on file in RIC. The record must be updated on a monthly basis.

2.2 All Funded Research Studies requiring IRB approval, must have accurate information reflected on the in the electronic IRB submission portal. All information in the electronic IRB system must match the proposal information provided by GCA, if available. This is the responsibility of the PI. If inconsistencies are noted, the IRB Analyst may notify the study team upon review of the study.

2.3 Once a study obtains IRB approval, it is the responsibility of the Principal Investigator to notify GCA of the approval.

REFERENCES

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

APPENDICES

1. IRB Guidelines
2. Pre-Award Authorization Form (last updated October 2019)