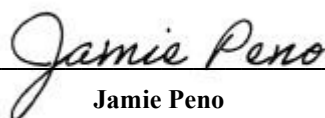
 DIVISION OF RESEARCH & INNOVATION Research Integrity & Compliance		Institutional Review Board Standard Operating Procedures	
Title: Collaborative Research Studies			
Effective Date:	1/11/2023	Document Number:	IRB-SOP-18-0.2
Approval/Date:			
 _____ Jamie Peno Assistant Vice President, Research Integrity and Compliance		<u>1/11/2023</u> Date	
REVISION HISTORY			
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1/11/2023	1.8; 2.0; 6.0	Hannah Snowberger	

PURPOSE

The purpose of this Standard Operating Procedure (SOP) is to describe the IRB oversight, to outline the responsibilities of Principal Investigators when participating in or leading multi-site research, and to describe the information that must be provided to the IRB regarding the oversight, operations, and procedures which will be used during the conduct of a multi-site research study.

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 program. It applies to all staff members whom are engaged in the operations and support of the Institutional Review Board, and to all UNT Researchers performing human subjects research.

DEFINITIONS/ ABBREVIATIONS

1. Definitions

1.1 *Lead Site*: The home site of the lead investigator for the entire project. For federally funded and/or FDA-regulated multi-site projects, the “primary awardee” or “grantee institution” will typically be designated as the coordinating or lead site. The lead site is responsible for overall data management, monitoring and communication among all sites, and general oversight of conduct of the project.

1.2 *IRB Analyst*: Staff member of Research Integrity and Compliance that performs

administrative activities, pre-reviews, reviews, and approvals for the Institutional Review Board program.

- 1.3 *IRB Authorization Agreement (IAA)*: An agreement that states an institution agrees to transfer oversight of a project under its jurisdiction to another IRB. UNT IRB requires a signed agreement to be in place prior to final IRB approval of the project. Also known as “defer,” “cede,” or “rely.” If the IRB of Record for non-UNT sites is the UNT IRB, an IAA must be in place.
- 1.4 *IRB of Record*: The IRB responsible for review of research involving a participating site.
- 1.5 *Multi-Site Study*: A human subjects research project that will be initiated at more than one location other than or in addition to UNT.
- 1.6 *Principal Investigator*: The individual who is actively leading and/or supervising the initiation, execution, and completion of a research project in compliance with applicable laws, regulations, and institutional policy governing the conduct of research. It is ultimately the PI’s responsibility to ensure that all personnel actively working on the project and interacting with human subjects are following the guidelines of the approved protocol and are treating subjects in a manner befitting ethical use of human subjects. The PI should be the party responsible for submitting the research protocol, providing the RIC or the IRB with requested changes in order to garner approval, and for following the guidelines stipulated for annual review of the protocol and submission of any modification requests.
- 1.7 *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.
- 1.8 *Site Authorization*: A letter from appropriate leadership within an organization/institution where research is taking place, allowing for research to take place at their organization/institution. This letter should outline the terms to which research is allowable at their site.
- 1.9 *Unaffiliated Investigator*: Any individual proposing to conduct research using any UNT property, facility, population, non-public information, or in collaboration with a UNT faculty, staff or student, who is not employed or affiliated with an institution that has an IRB covered under an FWA.

2. Abbreviations

- 2.1 FWA: Federal Wide Assurance
- 2.2 IAA: IRB Authorization Agreement
- 2.3 IRB: Institutional Review Board
- 2.4 OHRP: Office for Human Research Protections
- 2.5 PI: Principal Investigator
- 2.6 RIC: Research Integrity and Compliance
- 2.7 sIRB: Single Institutional Review Board
- 2.8 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 Researchers performing human subjects research under the oversight of the UNT Institutional Review Board.

PROCEDURE

1. The UNT IRB defines its scope of oversight jurisdiction to include studies falling in the following categories:
 - 1.1 Human subjects research conducted at UNT
 - 1.2 Human subjects research conducted by, collaborating with, or initiated by UNT faculty, staff, or students.
 - 1.3 Human subjects research conducted with the use of UNT resources, including recruitment of UNT faculty, staff, or students.
2. All projects meeting the scope noted above must be submitted to the UNT IRB for review and approval or site authorization.
3. All researchers listed on a UNT IRB Request for Approval, who are not affiliated with UNT, and are affiliated with an institution that has an IRB covered under an FWA must:
 - 3.1 Submit a copy of the IRB approval letter sought from their local IRB; or
 - 3.2 Request that the UNT PI obtain an IAA through Research Integrity and Compliance at UNT.
4. All researchers listed on a UNT IRB request for Approval, who are not affiliated with UNT, and are not affiliated with an institution that has an IRB covered under an FWA must:
 - 4.1 Obtain an Unaffiliated Investigator Agreement from Research Integrity and Compliance, sign the document, request the UNT Principal Investigator sign the document, and submit with study documents in the IRB submission portal. Further instructions are noted below under the section titled, “Unaffiliated Investigator.”
5. All UNT Researchers engaged in research outside of UNT, which has received IRB approval from an institution other than UNT, must submit the study for review to the UNT IRB, and secure approval.
 - 5.1 The external IRB approval letter, consent form, and documents must be submitted through the IRB submission portal as an initial study, reviewed, and approved by the UNT IRB before a UNT researcher can engage in research activities.
 - 5.2 The only exception is if an IAA has been sought and signed to cover activity for this project.
6. All external researchers who wish to recruit UNT faculty, staff, or students and who have received an IRB exemption determination from their local institution must obtain site authorization from UNT before conducting research at UNT.
 - 6.1 The external IRB exemption letter, consent form, and other related documents must be submitted to the UNT IRB for review. If appropriate, an IRB analyst will provide a site authorization letter.
 - 6.2 For exempt studies, UNT may grant a site approval letter to the external research team, allowing them to recruit from the UNT population.
 - 6.3 For expedited or full board studies, a site authorization letter may not be appropriate. Instead of a site authorization, the researcher should identify a UNT researcher willing to serve as PI and obtain UNT IRB approval or enter an IRB Authorization Agreement.
 - 6.4 Site authorizations will only be provided to external researchers if there are no UNT researchers engaged in Human Subjects Research. If a UNT researcher is engaged in Human Subjects Research, the UNT researcher must obtain UNT IRB approval.
 - 6.5 The external researcher must identify a UNT research faculty member to oversee the research activities at UNT and ensure UNT policies and procedures are being followed.
7. UNT IRB is willing and able to both serve as the IRB of Record (Institution A) or the relying institution (Institution B).
 - 7.1 Both engaged institutions must agree on the site that will serve as the IRB of Record

- (Institution A) for the research procedures at all sites as described in the approved IRB study.
- 7.2 This relationship requires the institutions to enter into an Institutional Authorization Agreement (IAA).
 - 7.3 An IAA cannot be initiated with an agency that does not have a federally approved human subjects research program, or Federalwide Assurance approval.
 - 7.3.1 If a UNT researcher wishes to conduct research elsewhere, such as at a privately-owned business or a secondary school which does not have an IRB, they must obtain approval from that agent to conduct research on their premises but must obtain IRB approval from the UNT IRB.
 - 7.4 A full research protocol must be approved by one of the institution's IRB, and the IAA states that Institution A will act as IRB of Record for the proposed project.
 - 7.5 IAAs are executed on a study-by-study basis. An IAA must be signed for each individual study being performed by multi-site collaborators.
8. If a Principal Investigator wishes for UNT research to rely upon a non-UNT IRB for review and approval of a project or for a non-UNT IRB to rely on the UNT IRB for review and approval of a project, known as an IAA request, the Principal Investigator must submit this request to Research Integrity and Compliance.
- 8.1 All IRB IAA requests must be initiated by emailing untirb@unt.edu
 - 8.2 The Principal Investigator, or designee, must provide information related to the research in the format as requested by the UNT IRB staff.
 - 8.3 All IRB IAA requests will be reviewed in the order they are received
 - 8.4 Principal Investigators should be aware that IRB IAA requests are reviewed on a case-by-case basis and the request may be denied.
9. Relying on an External IRB:
- 9.1 When Research Integrity and Compliance is notified of a request to rely on another IRB, an IRB Analyst will log the request, review the information, contact the PI for any additional information needed.
 - 9.1.1 This may include the following documents:
 - 9.1.1.1 Informed Consent/Assent forms
 - 9.1.1.2 Protocol
 - 9.1.1.3 Delegation of activities
 - 9.1.1.4 IRB Approval Letter
 - 9.1.2 Research Integrity and Compliance will contact the appropriate IRB office regarding the proposed reliance request.
 - 9.1.3 Principal Investigators should allow 2 weeks for initial intake and review.
 - 9.1.4 If the outside IRB has agreed to provide IRB review for the project, Research Integrity and Compliance will obtain the appropriate IAA form and route for signature by the Institution Official at UNT and send to the collaborating IRB for signature.
 - 9.1.5 Research activities may not begin until the external IRB grants permission to do so.
10. Relying on UNT IRB:
- 10.1 When Research Integrity and Compliance is notified of a request for UNT IRB to serve as the IRB of Record for multi-site research, an IRB Analyst will log the request, review the information, contact the PI for any additional information needed.
 - 10.1.1 This may include the following documents:
 - 10.1.1.1 Protocol number
 - 10.1.1.2 Informed Consent/Assent forms and any proposed changes
 - 10.1.1.3 Delegation of activities

- 10.1.2 Research Integrity and Compliance will contact the appropriate IRB office regarding the proposed reliance request.
 - 10.1.3 Principal Investigators should allow 2 weeks for initial intake and review.
 - 10.1.4 Principal Investigators should be aware that IRB IAA requests are reviewed on a case-by-case basis and the request may be denied based on a number of factors including, but not limited to, the risk of the study.
 - 10.1.5 If UNT IRB agrees to provide IRB review for the project, Research Integrity and Compliance will obtain the appropriate IAA form and route for signature by the Institution Official at UNT and send to the collaborating IRB for signature.
 - 10.1.6 Research activities may not begin until UNT IRB grants permission to do so.
11. NIH Single IRB Requirement:
- 11.1 All NIH multi-site studies are required to rely on a single IRB (sIRB) to carry out the functions that are required for institutional compliance with IRB review set forth in the HHS regulations at 45 CFR 46.
 - 11.1.1 The NIH Single IRB (sIRB) policy applies to grant applications proposing non-exempt human research which are received for due dates on or after January 25, 2018.
 - 11.1.2 The sIRB must have the necessary infrastructure to support the required activities (e.g., administrative or regulatory staff, policies, procedures, workflows and technology).
 - 11.1.3 In reviewing multi-site research protocols, the sIRB may serve as a Privacy Board, as applicable, to fulfill the requirements of the HIPAA Privacy Rule for use or disclosure of protected health information for research purposes.
 - 11.1.4 The sIRB can delegate to relying institutions the ability to monitor or observe the conduct of the research and/or the consent process.
 - 11.1.5 The sIRB must review and approve proposed management plans for investigators determined to have a financial conflict of interest.
 - 11.1.6 Participating sites are responsible for meeting other regulatory obligations, such as obtaining informed consent, overseeing the implementation of the approved protocol, and reporting unanticipated problems and study progress to the sIRB.
 - 11.1.7 Participating sites must communicate relevant information necessary for the sIRB to consider local context issues and state/local regulatory requirements during its deliberations. Participating sites are expected to rely on the sIRB to satisfy the regulatory requirements relevant to the ethical review.
 - 11.1.8 Participating sites must also:
 - 11.1.8.1 Report incidents of protocol deviations, noncompliance, or unanticipated problems to the sIRB;
 - 11.1.8.2 Monitor the conduct of the research activities if specified in the IAA;
 - 11.1.8.3 Ensure appropriate disclosure and management of any potential related Conflict of Interest and submit documentation to the sIRB for review
 - 11.1.8.4 Report to the sIRB any changes to research implemented to eliminate immediate hazard or risk to participants
 - 11.1.8.5 Ensure any local required reviews (i.e. Biosafety, Radiation Safety) are conducted in accordance with local policies and procedures prior to the implementation of research activity.
 - 11.1.9 The policy does not prohibit any participating site from duplicating the sIRB.

However, IRB ethical review at a participating site would be counter to the intent and goal of this policy.

11.1.9.1 If this approach is taken, NIH funds may not be used to pay for the cost of the duplicate review.

11.2 The UNT Principal Investigator should contact Research Integrity and Compliance as early in the grant writing process as possible to either confirm that UNT IRB can serve as the sIRB for the study, or to assist the Principal Investigator in making alternative arrangements.

12. Unaffiliated Investigators

12.1 An Unaffiliated Investigator is any individual proposing to conduct research using any UNT property, facility, population, non-public information, or in collaboration with a UNT faculty, staff or student who is not employed or affiliated with an institution that has an IRB covered under an FWA. UNT IRB is supportive of human subjects research conducted with Unaffiliated Investigators, while at the same time being mindful of risk/liability concerns and the impact on UNT resources.

12.2 All Unaffiliated Investigators listed on a UNT IRB application must sign an Unaffiliated Investigator Agreement. This agreement must also be signed by the Principal Investigator.

12.3 Unaffiliated Investigators may not serve as Principal Investigator or Co-Principal Investigator on any UNT IRB approved human subjects research study.

12.4 Unaffiliated Investigators are subject to the same education, training, and human subjects research requirements as UNT affiliated Researchers.

12.5 To obtain an Unaffiliated Investigator Agreement, the Principal Investigator must contact Research Integrity and Compliance by emailing untirb@unt.edu.

REFERENCES

1. US Department of Health and Human Service, Office for Human Research Protections (OHRP)
2. 45 CFR 46
3. [NIH Single IRB Policy for Multi-site Research](#)

APPENDICES

1. IRB SOPs