
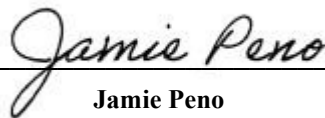


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|  DIVISION OF RESEARCH & INNOVATION Research Integrity & Compliance | | Institutional Review Board Standard Operating Procedures | |
| Title: Roles, Responsibilities, and Composition of the IRB | | | |
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PURPOSE

The purpose of this Standard Operating Procedure (SOP) is to define the roles and responsibilities of the Institutional Review Board (IRB) program at UNT.

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 *IRB*: An appropriately constituted group that has been formally designated to review and monitor research involving human subjects.
- 1.2 *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.

2. Abbreviations

- 2.1 SOP/SOPs: Standard Operating Procedure(s)

- 2.2 OHRP: Office for Human Research Protections
- 2.3 RIC: Research Integrity and Compliance
- 2.4 IRB: Institutional Review Board
- 2.5 PI: Principal Investigator

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. IRB Authority

- 1.1 The University of North Texas Administration through the Vice President of Research and Innovation, and under the Federal Wide Assurance governed and regulated by the US Department of Health and Human Services (HHS) Office for Human Research Protections, grants the IRB authority to approve human subjects research activity, specify modifications required to secure IRB approval, or disapprove any human subjects research activity overseen and conducted by the University of North Texas.
- 1.2 The IRB may suspend or terminate any approval of research that is identified as noncompliant with University policies, University procedures, federal regulations, or that has been associated with unexpected serious harm to participants as determined by the IRB.
- 1.3 The IRB has the authority to observe, or designate a third-party to observe, any research conduct.
- 1.4 Research approved by the IRB may be subject to further review and approval or disapproval by officials of UNT, as appropriate. University officials may not approve research that has not been approved by the IRB.
- 1.5 The IRB Chair, or designee as deemed appropriate by the IRB Chair, has the authority to sign any and all documents in connection with the review and approval of human subjects research studies.

2. Management and Composition of the IRB

2.1 Appointment of Members

- 2.1.1 The IRB Chair, sometimes with recommendations from existing IRB members, can recommend appointment of new members to the Vice President of Research and Innovation. Members can be removed at the discretion of the IRB Chair.

2.2 Regular Members

- 2.2.1 In order to be properly constituted, the IRB shall have no less than five members with varying degrees of expertise and experience. At least one member should be unaffiliated with UNT and represent the larger community. The IRB should also include a member whose primary focus is outside of scientific areas. A member can meet multiple requirements (such as a nonscientific community member) but it is preferred if these are separate individuals. The IRB and the Assistant Vice President of RIC will review the membership of the IRB regularly and will review the qualifications of the current members or any new members as needed.

2.3 Responsibilities

- 2.3.1 IRB members responsibilities include: attending IRB meetings (generally occurring monthly), reviewing protocols that will be discussed at the convened meetings, being prepared to discuss issues related to human subjects research, serving as a designated reviewer/subject matter expert at the request of the IRB Chair, and staying informed about relevant regulations and any changes or current state of the human subjects research program(s).
- 2.4 Compensation of IRB members
 - 2.4.1 IRB members are generally not compensated for service on the IRB. Unaffiliated members may be set up with parking on campus in order to attend meetings, but are not directly compensated for parking costs or mileage. The IRB Chair generally receives compensation for their service as the Chair, but this is at the discretion of the Vice President of Research and Innovation.
- 2.5 Member Liability
 - 2.5.1 IRB members are covered by UNT as they act as a member or representative of the UNT IRB.
- 2.6 Alternate members
 - 2.6.1 Alternate members can be appointed to the IRB and requested to attend meetings as needed in order to obtain a quorum. They can only vote during a convened meeting if the member they are an alternate for is unable to attend and will not be voting during said meeting. Alternate members cannot count towards constitution of a quorum.
- 2.7 Non-voting members
 - 2.7.1 The Vice President of Research and Innovation, at their discretion, may appoint non-voting (ex officio) members. These may be administrative staff, subject matter experts, or otherwise serve as an addition to the discussion of the meetings. Non-voting members may not vote for or against the approval of a protocol, they do not count towards the constitution of the IRB, and are not counted towards quorum of the meeting. IRB meeting minutes will include the presence of non-voting members.
- 2.8 Consultants/ad hoc reviewers
 - 2.8.1 As needed and at their discretion, the UNT IRB may request or allow testimony from outside sources, consultants, or subject matter experts in order to ensure a protocol is properly reviewed and understood. This ad hoc reviewer may review all documentation related to the protocol and offer information and recommendations, but may not vote on the final dispensation of the protocol.
- 2.9 Conflicts of Interest
 - 2.9.1 IRB members, including the Chair, cannot vote on protocols in which they have a conflict of interest, such as protocols in which they are serving as PI or Co-PI. They may offer information to the other voting members and answer any questions related to the protocol, but they may not participate in voting and they must leave the room of the meeting during the final voting. If a member must abstain from voting due to a COI, this will be noted in the meeting minutes and the meeting must still have quorum with the absence of that voting member. Minutes will reflect ongoing quorum throughout the meeting in which a voting member must abstain.
- 2.10 HHS Reporting Requirements
 - 2.10.1 The UNT IRB, as part of the federal welfare assurance, is registered with the Department of Health and Human Services via an online portal, no less than

annually and as needed if any changes to the IRB is made. This process is handled administratively by the Assistant Vice President of the Office of Research Integrity and Compliance.

3. Duties of IRB Members

- 3.1 The task of making the IRB a respected part of the institutional community will fall primarily on the IRB members. IRB members must maintain the IRB's reputation for being fair and impartial, as well as invulnerable to pressure from the institution's administration, research faculty, Principal Investigators, or any other professional and nonprofessional sources.
- 3.2 Unaffiliated members are expected to provide input regarding their knowledge about the local community and be willing to discuss issues and research from that perspective.
- 3.3 Nonscientific members are expected to provide input on areas relevant to their knowledge, expertise and experience, professional and otherwise. Nonscientific members should advise the IRB if additional expertise in a nonscientific area is required to assess if the research proposal adequately protects the rights and welfare of subjects.
- 3.4 Scientific members are expected to contribute to the evaluation of a study on its scientific merits and standards of practice. Additionally, these members may also advise the IRB in a nonscientific area to assess if the research proposal adequately protects the rights and welfare of subjects.
- 3.5 All IRB members are required to perform and maintain their training as stated in the "Training and Education" SOP.

4. Operations of the IRB

4.1 Scheduling of Meetings

- 4.1.1 The IRB normally meets once per calendar month. Meetings may be cancelled if the IRB is unable to meet quorum, if there are no full board applications to review, or other miscellaneous reasons at the discretion of the IRB Chair or RIC staff. In the event of an unplanned cancellation, the RIC staff and IRB Chair will work to reschedule and to notify any affected personnel.

4.2 Submission of New Applications

- 4.2.1 IRB applications are submitted electronically in the online IRB system to be reviewed by RIC staff and the IRB, if necessary.

4.3 Determination of Type of Review

- 4.3.1 The staff of Research Integrity and Compliance conduct an initial review of the submitted protocol application and will make a determination as to the level of review required, based on the categories of review from 45 CFR 46.101. This includes reviewing whether the proposed research meets federal regulations of the definitions of research and human subjects. The RIC staff, under the guidance of the IRB Chair, will determine the level of review required based on the risk to the participants or the use of vulnerable populations. Applications are categorized as needing exempt review, expedited, or full board review.
- 4.3.2 The IRB and the RIC staff may, at their discretion, interpret the federal guidelines related to review level and make changes to the review level as warranted by inclusion of certain populations or the nature of the research. The IRB online application allows the PI to suggest a level of review based on the nature of their procedures, but it is ultimately the job of the RIC and the IRB Chair to confirm the final level of review.

4.4 Exempt Review

- 4.4.1 Exempt means that the study poses no more than minimal risk to subjects and does not require any annual or continued review by the IRB Chair or Full IRB after initial approval. This does not mean an application does not need to be submitted or does not require 'approval' by Research Integrity and Compliance.
- 4.4.2 The following types of studies are examples of those who may qualify for an exempt review:
 - 4.4.2.1 Research involving effectiveness of educational programs, research conducted in commonly accepted educational settings
 - 4.4.2.2 Research involving educational tests, surveys, interviews or observation of public behavior that does not involve identification of participants, and any potential identification of participants would not pose an increased risk of criminal or civil liability, or be damaging to a participant's finances, employability, or reputation.
 - 4.4.2.3 Research involving the collection or study of pre-existing data, documents, or records that are publicly available.
 - 4.4.2.4 Research or demonstrative projects that are designed to study, evaluate, or examine public benefit or service programs.

4.5 Expedited Review

- 4.5.1 A protocol may meet the requirements for expedited review if they still represent no more than a minimal risk to participants and involve procedures listed in categories specified in either 45 CFR 46.110 or 21 CFR 56.110 (FDA). Expedited review does not reference the time frame required for review, and instead indicates that full board review may not be required. Protocols approved through expedited review may require annual renewals to be submitted at the discretion of the IRB Chair. Protocols submitted for expedited review may fall into the following categories, for example:
 - 4.5.1.1 Clinical studies of drugs and medical devices only when one of the following conditions is met:
 - 4.5.1.2 Research on drugs for which an investigational new drug application (per 21 CFR Part 312) is not required (Note that marketed drugs which increase risk are not eligible for expedited review.);
 - 4.5.1.3 Research on medical devices for which an investigational device exemption application is not required, or that the medical device is cleared and approved for marketing and is being used in accordance with its cleared and approved labeling and use.
 - 4.5.1.4 Collection of blood samples through finger stick or venipuncture in healthy participants.
 - 4.5.1.5 Collection of biological specimens or biological data for research purposes through non-invasive means, such as hair samples, x-rays and dexta scans, simple to moderate exercise, body composition, or flexibility testing on healthy individuals.
 - 4.5.1.6 Research involving materials (data, specimens, records) that have been collected or will be collected for non-research purposes
 - 4.5.1.7 Research involving audio or video recording in which the possibility of participant identification is increased.
 - 4.5.1.8 Other interventions or activities not identified in these categories, but that do not qualify for exempt review.
- 4.5.2 Expedited applications are reviewed either by the IRB Chair or a primary

reviewer, in accordance with requirements of 45 CFR 46.110. The IRB Chair may elect to utilize a Primary (designated) reviewer for a submitted research protocol, either in lieu of or prior to full board review. The primary reviewer may be a specialist in a certain field and chosen with respect to their experience to review a certain protocol. The primary reviewer will review all documentation related to the protocol and make their recommendation to either approve with revisions or to suggest full board review. The IRB Chair, along with the administrative staff of RIC, will facilitate the review process and requests for revisions and findings being sent to the IRB and/or to the PI. Any requests for revisions or recommendation to approve will be noted in the online system or in writing, and will be communicated to the IRB Chair, RIC staff, and to the PI.

4.6 Requests for revisions on submitted protocols are submitted to the PI through the online IRB system. The PI will have the opportunity to make any revisions needed to the application or to the associated documentation (such as the informed consent document, recruitment material, survey or interventions, etc.) or to answer any questions needed on the protocol. The PI then completes the submission, recertifies the application in the online IRB system, and the updated application will be sent to RIC staff to restart the review cycle.

4.7 Notification of Meetings and Distribution of Materials

4.7.1 Protocols to be reviewed, meeting agenda, and any other pertinent information will be sent to IRB members with sufficient time to allow their review and preparation in advance of the meeting, at least one week in advance of the meeting.

4.7.2 IRB meetings are scheduled at the beginning of the fiscal year, and meeting notices and information are available publicly on the UNT Research webpage. The deadline for submitting an application for full board review is generally 30 days prior to the next meeting. The IRB will be provided with documentation pertinent to the applications being reviewed or adverse events/non-compliance issues to be discussed, such as the full protocols, informed consent documents, recruitment and survey material, etc. This documentation can be sent in writing either through the online IRB system or by email at the IRB member's request. The meeting documentation will also include any materials on training available or changes to the human subjects research or changes to federal guidelines, and a list of all protocols approved since the last meeting.

4.8 Meeting Procedures

4.8.1 IRB meetings will be called to order by the IRB Chair (or Vice-Chair in the Chair's absence), and quorum will be confirmed before any voting on measures or protocols takes place.

4.8.2 The meeting is officially ended by adjournment of the present Chair.

4.8.3 The IRB may include alternates, who may vote in the place of the IRB member for which they are an alternate.

4.8.4 An IRB member and their alternate may not both count towards constitution of a quorum, or both vote on a protocol. However, alternates are always welcome to attend meetings even if they are not able to vote on measures at the meeting.

4.8.5 If quorum is lost for any reason (due to abstention, sudden absence of a voting member, unforeseen issue, etc.), then further voting on protocols must be tabled until quorum is regained, either at that meeting or the following.

- Loss of quorum should be noted on the meeting minutes.
- 4.8.6 The RIC staff generally attend meetings to assist with administrative tasks, providing copies of agenda and information to be discussed, and to assist with taking meeting minutes.
 - 4.8.7 PIs may also be invited to attend the IRB meeting if their protocol is being voted on and to provide additional information on the research protocol, but they must leave the room for final voting.
 - 4.8.8 Voting on a protocol is by aye, nay, or abstention. All votes of present members must be noted in the meeting minutes.
 - 4.8.9 A member may not vote on their own protocol, cannot count towards quorum of their own protocol's review, and must leave the room for final voting. This information and confirmation of abstention will be noted in the meeting minutes.
- 4.9 Meeting Minutes
- 4.9.1 Minutes are generated following the meeting, taken from notes during the meeting and an audio recording of the meeting. Minutes will include the details of the meeting time, date, and location; names and information of all present at meeting; notes on previous business including approval of the previous meeting's minutes; details of all voting including abstentions; findings of all discussed protocols and any revisions needed; documentation of any dissenting opinions on any IRB business; and notes on any miscellaneous business such as IRB workings, composition, and any adverse events or non-compliance issues discussed.
- 4.10 Approval of Research
- 4.10.1 A protocol may be approved as is, approved with revisions needed, table for future review, or disapproved.
 - 4.10.2 If the IRB approves research with revisions, RIC staff will notify the PI of the revisions needed, generally through the online IRB system. Discussions may also be sent through email as needed, but will always be communicated in writing.
 - 4.10.3 Any major or additional modifications submitted as part of the revisions may require additional primary review or additional full board review.
 - 4.10.4 If the IRB disapproves a research protocol, the PI will be notified in writing of the findings and the reasons for disapproval and will be given the opportunity to resubmit the application or provide additional information for further review.
 - 4.10.5 The PI has the right to appeal, in writing, any findings by the IRB.
- 4.11 Appeal of the IRB Decisions
- 4.11.1 The PI may appeal the decisions of the IRB in writing. The appeal should include the basis of the appeal and any supporting documentation. The Assistant Vice President of RIC, or designee, and the IRB Chair will conduct an initial review of the appeal, and the appeal will then be taken to the next convened IRB Full board meeting for review.
 - 4.11.2 The IRB Chair may hold a closed session without the researcher to discuss the details of the research protocol and the appeal. The PI may be invited to the meeting to discuss the details of the appeal. The PI should leave the room for any voting on the measure of the appeal.
 - 4.11.3 After review, the IRB may grant approval of the research based on the appeal, they may approve with revisions or provide conditional approval, or they may uphold the original determination.

- 4.11.4 Findings of the review of the appeal will be provided to the PI in writing. If the decision to disapprove the protocol is upheld, this decision cannot be reversed by the Vice President of Research and Innovation or any other agency. The PI is allowed one appeal. The decision of the appeal is final.
- 4.12 Length of Approval
 - 4.12.1 Research which involves human subjects must be reviewed on the anniversary of the original approval date if the study has been reviewed at a full board meeting or if deemed to be needed by the IRB Chair. Initial approval is generally given for one year, and if the PI intends to continue the project with no changes, it can be renewed for an additional year.
 - 4.12.2 A research protocol involving human subjects can only be renewed twice. After the third anniversary, if the PI wishes to continue the project, a new protocol must be submitted.
 - 4.12.3 Approval and expiration dates are provided to the PI on their approval letters. PIs also receive an automatic reminder if their protocol is set to expire, along with instructions on how to renew if they choose. If a PI wishes to renew the project, they should submit their renewal at least two weeks prior to the expiration date to ensure no lapse in approval. If no renewal is received by the expiration date, the protocol will expire and no further human subject research can take place under that protocol.
- 4.13 Monitoring Approved Projects
 - 4.13.1 Continuing Review
 - 4.13.1.1 Continuing review is required for all full board applications and any expedited applications at the discretion of the IRB Chair. Continuing review is required to take place, at a minimum, annually, and may be requested more frequently depending on the nature of the project and at the discretion of the IRB. The PI will be advised in writing if their protocol requires more than annual review. More frequent review may be required based on the nature of the interventions of the protocol, the risk level, or other reasons at the discretion of the IRB. The PI receives a reminder through the IRB online system when continuing review/renewal is due on their protocol. Continuing review and renewal on full board protocols require review by the full board to ensure that the interventions of the project are being followed and that no adverse events have taken place.
 - 4.13.2 Additional post-approval monitoring, such as independent review or audit of ongoing data collection and interventions, may be required in cases of PIs with previous history of non-compliance, complex projects which may require a higher amount of detail, or at random to ensure human subjects are being protected and treated ethically, and that projects have not been modified without prior approval. These audits will be communicated to the PI through either the IRB Chair or through RIC staff, and any findings or confirmation post-review will be sent to the PI in writing. Lapse in Approval
- 4.14 The federal regulations of the Department of Health and Human Services in 45 CFR 46 do not provide any grace period after expiry of a research protocol. The only way to continue a research protocol is for an official renewal to be submitted. If a renewal is not received and the expiration date of the protocol passes, then no further human subject participation can take place under that protocol. If a protocol lapses approval and human subjects participation continues, any data obtained after the date of expiry cannot be used. A protocol which has lapsed can be renewed after the date

of expiry, but these are reviewed on a case-by-case basis. PIs are made aware of the expiration dates of their protocols on the approval letters sent at the initial time of approval. Renewals will also include the new expiration dates.

4.15 Modifications-

- 4.15.1 Any changes to an approved protocol must be submitted for review as a modification.
- 4.15.2 Modifications of protocols previously approved via a full board review will also receive full board review.
- 4.15.3 Modification to a protocol may include, but are not limited to, adding or removing a research site, addition of research personnel, changes in funding or compensation, or changes to the planned interventions.
- 4.15.4 Modifications are submitted as part of the study in the IRB online system. Modifications should be minor.
- 4.15.5 Any major changes, such as major changes to the planned interventions or activities, new collaboration with an outside agency, major increases or decreases in the suggested participant numbers may require a new application be submitted.
- 4.15.6 The PI will be notified if a modification is not appropriate and a new application is required.
- 4.15.7 Modification does not change or extend the approval or expiration date of the protocol.
- 4.15.8 Minor administrative changes, such as the addition or change to key personnel or an update to the study title, may be processed administratively by the RIC.
- 4.15.9 Modification requests must be submitted and approved before the PI can proceed with the changes. If changes are proceeded with before a modification is approved, then the protocol is considered out of compliance and may be subject to a non-compliance review.

4.16 The level of review on an approved project can be raised based on the proposed changes. For example:

- 4.16.1 A minimal/exempt protocol can be increased to expedited or full board review and now require continuing review if a proposed change falls outside of the scope of what is eligible for minimal/exempt review.
- 4.16.2 Changes that increase or change the review level may require a new application.
- 4.16.3 This is at the discretion of RIC and the PI will be notified in writing if the changes proposed have increased the level of review required and/or require a new application.

4.17 Study Closure and Protocol Expiration-

- 4.17.1 Once a PI has completed a research project, they can submit their Final Report through the IRB submission portal at any time.
- 4.17.2 If RIC does not receive a renewal on an eligible protocol and the protocol expiration date has been reached, the PI will receive a notice stating that the protocol has expired and that no further human subjects research can be completed under that approved application.
- 4.17.3 If the PI receives a renewal notice and does not plan to renew or continue the project, they can submit a Final Report.
- 4.17.4 If the approved protocol does lapse and is not renewed, if the PI wishes to continue the project, they will be instructed to submit a new application.

REFERENCES

1. US Department of Health and Human Service, Office for Human Research Protections (OHRP)
2. 45CFR46
3. UNT Policy 13.004

APPENDICES

1. IRB SOPs