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

Title: Submission and Review of Requests for Approval

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Approval/Date:

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REVISION HISTORY

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PURPOSE

This Standard Operating Procedure (SOP) is to define the procedures for Research Integrity and Compliance Institutional Review Board (IRB) Program staff member to perform a review on all requests for IRB approval of a human subjects research submissions.

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 (IRB) program. The process begins when the researcher begins a Request for Approval within the electronic IRB system and ends when the post-review process is complete and an approval letter is issued following the determination made by the IRB Committee or an IRB reviewer.

DEFINITIONS/ ABBREVIATIONS

1. Definitions

1.1 *Incident:* Any reported Unanticipated Problem, Serious Adverse Event or Noncompliance.

1.2 *IRB Analyst:* Staff member of Research Integrity and Compliance that perform administrative activities, pre-reviews, reviews, and approvals for the Institutional Review Board program.

1.3 *IRB Committee:* An objective, third party oversight committee at UNT, governed by Federal Regulations and Institutional Policies, with the purpose of protecting and managing risks to human participants involved in research.

1.4 *IRB Submission Portal:* A web-based system for preparing, submitting, and routing research studies for IRB approval. All information is stored in a cloud system and can be accessed securely from any location. Researchers receive electronic notifications whenever an action is required on their part to move the study through the review and approval process.

1.5 *Modification:* Any proposed change to an IRB approved study that may or may not affect an assessment of the risks and benefits of the study and may or may not change the specific aims or design of the study.

1.6 *New Research Study:* A new systematic investigation, meeting the federal definition of both Research and Human Subject, into a particular concern, problem, or idea affecting human subjects, using a scientific method, and performed by UNT faculty, staff, and affiliates.

1.7 *Personally Identifiable Information (PII):* Any data element that can be used to distinguish or trace an individual's identity, such as name, social security number, date and place of birth, mother's maiden name, biometric records, or any data element that is linked or linkable to an individual, such as medical, educational, financial, and employment information.

1.8 *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.

1.9 *Researcher:* An individual performing various tasks related to the conduct of human subjects research activities, such as obtaining informed consent from participants, interacting with participants, collecting data and communicating with the IRB.

1.10 *Request for Approval*: Any New Research Study, Modification, Renewal, or Incident submitted to the IRB through the IRB submission portal for review and approval.

2. Abbreviations

2.1 SOP/SOPs - Standard Operating Procedure(s)
2.2 IRB- Institutional Review Board
2.3 OHRP- Office for Human Research Protections
2.4 RIC- Research Integrity and Compliance

RESPONSIBILITIES

This SOP is applicable to all members of Research Integrity and Compliance who are involved in reviewing Requests for Approval that are submitted to the Institutional Review Board program using the IRB Submission Portal. This SOP also applies to all Researchers and Principal Investigators involved in conducting human subjects research.

PROCEDURE

1. Primary Responsibility:

1.1. The primary responsibility of the Institutional Review Board (IRB) is to protect the rights and welfare of research subjects. Federal regulations require that the IRB ensure that certain criteria for approval of research are met prior to approving a study.

1.2. The Principal Investigator must provide the IRB with the information necessary to permit

an informed decision on whether to approve, disapprove, or to require modifications prior to approval for all Requests for Approval.

1.3. The Principal Investigator, and all Researchers, are responsible for communication with the IRB throughout the research process in order to assure compliance with the regulations and to protect the safety and well-being of study subjects including, but not limited to, any changes to the protocol and any Incidents that may arise during the conduct of the study.

2. Study Details

2.1. The Principal Investigator must provide the IRB with the information necessary to permit an informed decision on whether to approve, disapprove, or to require modifications prior to approval.

2.2. The Principal Investigator and Researchers must review and are responsible for compliance with all IRB SOPs. The RIC staff provide a more detailed guidance for submissions on the UNT IRB website.

2.3. The following is a summary of information that may be required elements contained within a Request for Approval. This list is not to be considered comprehensive, as the study design, data collection methods, recruitment procedures, and participant population may require additional information to be submitted.:

2.3.1. Funding

2.3.1.1. The Principal Investigator must submit all funding sources with the Request for Approval.

2.3.1.2. If funding is received during the conduct of the study, funding sources must be submitted to the IRB through a modification request to an existing approved study.

2.3.1.3. For any internal or external funding, the PI will submit a statement of work or a project summary and provide the Proposal Number or Project ID Number for any external funding or the account number for any internal funding for their project.

2.3.1.4. The Principal Investigator must review the scope of work to ensure the contents match the Request for Approval submitted to the IRB.

2.3.2. Multi-Site Research

2.3.2.1. The Principal Investigator must provide a list of all collaborators and their affiliated sites, locations of each affiliate site, and contact information for each collaborator.

2.3.2.2. The Principal Investigator must provide documentation of IRB approval, as required, (either domestically or internationally) for all Multi-Site Research.

2.3.2.2.1. IRB approval may come in the form of direct IRB approval from a collaborating site or through an IRB Authorization Agreement. All researchers performing multi-site research are encouraged to contact untirb@unt.edu or visit our website to view the requirements for multi-site research approval.

2.3.3. Personnel

2.3.3.1. All personnel working on the project must be listed within the Request for Approval. As the study team is updated throughout the conduct of the project, the researchers are required to submit a modification request and add the team members to the project.

2.3.3.2. Principal Investigator

2.3.3.2.1. The listed PI must be a UNT faculty or staff member who is eligible to serve as the Principal Investigator. In order to serve as Principal (Lead) Investigator, the PI must be a full-time UNT faculty member or a full-time staff employee whose job responsibilities include conducting human subjects research.

2.3.3.2.2. The IRB application must be submitted by the lead PI/supervising investigator (in the case of student projects).

2.3.3.2.3. Adjuncts or lecturers must either submit a letter from the Department Chair acknowledging their approval for the research submission, or a full-time PI eligible faculty or staff member must serve as lead PI of a study for the IRB purposes.

2.3.3.3. Key Personnel

2.3.3.3.1. All persons involved in study procedures must be documented as Key Personnel; this includes study team members who are unaffiliated with UNT.

2.3.4. Training

2.3.4.1. All persons listed on the Request for Approval, including external collaborators, must have current human subjects education. Education certificates will be considered current if they have been completed within the last three years. Human subjects education requirements are posted in the Training and Education SOP and linked in the Appendices.

2.3.5. External or Unaffiliated Investigators

2.3.5.1. External Investigators

2.3.5.1.1. Researchers engaged in UNT research, who are not employees of the university and are agents of an outside entity that can provide IRB review, must obtain IRB approval from their local institution or request an IRB Authorization Agreement (IAA) to be executed between UNT and their local institution.

2.3.5.1.2. To request an IRB Authorization Agreement, the Principal Investigator must contact Research Integrity and Compliance by emailing untirb@unt.edu. Requests for IAAs will be reviewed on a case-by-case basis.

2.3.5.1.3. Copies of the fully-executed IAA or IRB approvals from External Investigators must be uploaded to the Request for Approval within the IRB submission portal.

2.3.5.2. Unaffiliated Investigators

2.3.5.2.1. Researchers engaged in UNT research, who are not employees of the university and not agents of an outside entity that can provide IRB review, must sign an Unaffiliated Investigator Agreement to assure that they understand their obligations as human research personnel.

2.3.5.2.2. The Unaffiliated Investigator Agreement must be co-signed by the Principal Investigator, who agrees to take responsibility for this researcher's actions.

2.3.5.2.3. Unaffiliated investigator Agreements must be uploaded to the Request for Approval submitted within the IRB submission portal.

2.3.5.2.4. To obtain an Unaffiliated Investigator Agreement, the Principal Investigator must contact Research Integrity and Compliance by emailing untirb@unt.edu. These requests are reviewed on a case-by-

case basis.

2.3.5.3. Human subjects education must be provided for all external or unaffiliated researchers working on a study. UNT IRB may accept training provided by external or unaffiliated Co-PI's, as defined by their own institution, if it is equivalent to the requirements set forth for UNT Researchers.

2.3.6. Purpose of the Study

2.3.6.1. The PI must provide a brief summary of the project, in lay language, and must include the research question(s) he/she/they intends to answer.

2.3.7. Previous Research

2.3.7.1. The PI must provide a summary of previous research that lead to the formation of the current study and include citations and references.

2.3.8. Overall Study Design

2.3.8.1. The PI must describe the design of the study.For example, if surveys or focus groups will be used, or if a randomized, controlled approach will be employed. The PI will describe the scientific method for the current submission.

2.3.9. Step-by-step Outline of Study Activity

2.3.9.1. The PI must describe what events will occur and the order in which they will happen. The PI will also detail how information will be presented to subjects.

2.3.10. Number of Subjects

2.3.10.1. The PI must detail the number of subjects to be consented for the study. The PI should include a statistical analysis of the number of subjects needed to achieve statistical power for the study, which will include the number of subjects to be screened to reach the target enrollment number.

2.3.10.2. If the Request for Approval is not directly recruiting subjects, the study should include a detailed number of data records or specimens to be reviewed.

2.3.11. Subject Population

2.3.11.1. The PI must describe the population from which subjects will be recruited (including gender, racial/ethnic composition, and age range).

2.3.11.2. If specific ages, genders, or racial/ethnic compositions are being excluded, an justification as to why should be included.

2.3.12. Recruitment Methods

2.3.12.1. The PI must describe, in detail, how subjects will be recruited for their study.

2.3.12.2. Common recruitment methods include emails, flyers, classroom announcements, social media posts, face-to-face recruitment, among others.

2.3.13. Location of Recruitment

2.3.13.1. The PI must describe where subjects will be recruited. If the PI is recruiting from a private business, office, school, or organization, the PI must provide a consent letter from a person inaposition of authority from all locations. RIC staff will determine if the documentation provided is sufficient or if further documentation is required.

2.3.13.2. If subjects are being recruited on social media, the Principal Investigator

must state if the social media pages being utilized are the personal pages of the Researchers. If the social media pages are private groups, the Principal Investigator must obtain permissions from the group page administrator and attach as documentation to the Request for Approval for review.

2.3.13.3. If subjects are being recruited via an email distribution list, the Principal Investigator must obtain permissions from the email distribution list administrator and attach as documentation to the Request for Approval for review. If the email addresses are publicly available, the Request for Approval should contain a statement describing them as such.

2.3.13.4. If the PI is not directly recruiting subjects, a description of how data or specimens will be obtained must be included. If the data or specimens are collected from a private business, office, school, or organization, the PI must provide a consent letter from a person in a position of authority from all locations

2.3.14. Recruitment Materials

2.3.14.1. The PI must provide all recruitment materials for review. Common documentation to be reviewed will include, but is not limited to, flyers, letters, social media posts, classroom announcements, phone scripts, emails, etc. RIC staff and/or board member(s) will determine if the recruitment material provided is within university guidelines, laws, and regulations for recruitment materials and ensure that the materials are not coercive in nature. If no recruitment materials are presented, the PI must provide a rationale for the exclusion of this documentation.

2.3.14.2. The Principal Investigator and Researchers should refer to the UNT IRB website for a listing of all template documents, including template flyers, to ensure all required elements are contained within these materials.

2.3.14.3. The following should not be included in recruitment materials: coercive language; amount of payment, dollar signs, or the words “free” in large or bold face type; bolded, underlined, or italicized compensation intended to draw attention.

2.3.15. Vulnerable Populations

2.3.15.1. The Principal Investigator must state if any vulnerable populations (children, prisoners, cognitively impaired persons, fetuses) are being enrolled into the study and ensure appropriate protections and regulations are followed with respect to the population.

2.3.16. Location of Study

2.3.16.1. The PI will provide the locations where all study related procedures and recruitment will take place. RIC staff will ensure that the PI has provided adequate permissions from all private businesses, offices, organizations, schools, or any other locations by requesting documentation on company letterhead with those approvals. This should be received from someone within a position of authority from the location.

2.3.17. Foreign Languages

2.3.17.1. Should the PI want to enroll subjects who speak languages other than English, all consent documents, recruitment materials, and study materials must be presented to subjects in the language they are most comfortable speaking.

2.3.17.2. The PI must submit study documents written in the subjects native language for review and provide certification of the translation service used to create those documents. If a certificate of translation cannot be obtained, the Principal Investigator must submit the curriculum vitae or resume of the person who performed the translation, showing they have the training and education to perform translation services.

2.3.18. Methods of Data collection

2.3.18.1. The following are a few examples of methods of data collection, but additional collection methods may be identified. The IRB must review all methods of data collection to be performed by the Principal Investigator and Researchers related to the study conduct, in thorough detail.

2.3.18.1.1. Interviews

2.3.18.1.1.1. The PI must provide details regarding the conduct of interviews.

2.3.18.1.1.2. Additionally, all questions to be asked during an interview must be included. For unstructured interviews, a listing of all potential questions should be included. RIC staff will review the proposed questions to ensure that they are related to the study and determine if they are sensitive in nature. Questions or topics that are considered sensitive may necessitate the study to be reviewed as a "more than minimal risk" study.

2.3.18.1.2. Paper/Survey Questionnaire

2.3.18.1.2.1. The PI must provide details regarding the conduct of paper surveys or questionnaires. The PI will provide all survey questions for review. RIC staff will review the proposed questions to ensure that they are appropriate, follow all guidelines, laws and regulations, and determine if they are sensitive in nature. Questions or topics that are considered sensitive may necessitate additional safeguards or protections for participants.

2.3.18.1.3. Focus Groups

2.3.18.1.3.1. The PI must provide details regarding the conduct of focus group sessions, including but not limited to number of participants, pseudonym use, and topics to be discussed. The PI will provide all questions to be asked during a focus group session. RIC staff will review the proposed questions to ensure that they are appropriate, follow all guidelines, laws and regulations, and determine if they are sensitive in nature. Questions or topics that are considered sensitive may necessitate additional safeguards or protections for participants.

2.3.18.1.4. Internet Surveys/Questionnaires

2.3.18.1.4.1. The Principal Investigator will provide all survey questions for review. The Principal Investigator must upload a copy of the survey instrument in combination with electronic consent notice, if one is being used. RIC staff will review the proposed questions to ensure that they are appropriate, follow all guidelines, laws and

regulations, and determine if they are sensitive in nature. Questions or topics that are considered sensitive may necessitate additional safeguards or protections for participants.

2.3.18.1.5. Review of Existing Records

2.3.18.1.5.1. The PI will detail which records will be reviewed and the content of those records for the proposed study and state whether those records are publicly available. The PI will detail how the data is being obtained and if the data have been de-identified or not. If the data is not deidentified, the PI will explain how and when identifiers will be removed from the dataset.

2.3.18.1.5.2. The IRB Analyst will ensure that the PI has the appropriate approvals to access those records and may request documentation to support the PI's plan.

2.3.18.1.6. Observation

2.3.18.1.6.1. The PI will describe a plan for observations for the protocol and detail how they will be documented.

2.3.18.1.6.2. The PI should state who will be observed, how observations will be recorded, will subjects recorded be identifiable, if the observations could reasonably place the subject at risk for (legal, financial, employment, reputation) if they became known outside the research, and if informed consent will be obtained.

2.3.18.1.6.3. The IRB Analyst will determine if this plan is in line with the proposed study and if all regulations are being followed.

2.3.18.1.7. Exercise Protocol

2.3.18.1.7.1. If the proposed protocol will include an exercise regimen for subjects, the PI will detail what subjects will be doing, the time duration, and safety precautions that will be followed.

2.3.18.1.7.2. The IRB Analyst will ensure that the proposed plan minimizes all risks to subjects.

2.3.18.1.8. Blood Draws

2.3.18.1.8.1. If the proposed protocol will include blood draws, the PI will detail the volume and frequency of the draws.

2.3.18.1.8.2. The PI will also provide information regarding the usage and storage of samples, as well as the long-term plans for discard.

2.3.18.1.8.3. The IRB Analyst will review and assess if the PI is complying with the Biohazard and Biosafety Review processes.

2.3.18.1.9. Saliva

2.3.18.1.9.1. If the proposed protocol will include saliva collected, the PI will detail the technique that will be used to collect samples. The PI will also provide information regarding the usage and storage of samples, as well as the long-term

plans for discard.

2.3.18.1.9.2. The IRB Analyst will review and assess if the PI is complying with the Biohazard and Biosafety Review processes.

2.3.18.1.10. Tissue Samples

2.3.18.1.10.1. If the proposed protocol will include tissue collection, the PI will detail the technique that will be used to collect samples.

2.3.18.1.10.2. The PI will also provide information regarding the usage and storage of samples, as well as the long-term plans for discard.

2.3.18.1.10.3. The IRB Analyst will review and assess if the PI is complying with the Biohazard and Biosafety Review processes.

2.3.18.1.11. DXA, X-ray, or Other Potential Radiation Exposure

2.3.18.1.11.1. If the proposed protocol will include DXA, x-ray, or other imaging technique that included radiation exposure, the PI will detail the type of imaging used, the frequency of scans, the amount of radiation staff and subjects will be exposed to, and if subjects could potentially be co-enrolled in other studies.

2.3.18.1.11.2. If the proposed protocol will include other forms of radiation exposure, the PI will detail the study process, the potential forms of radiation exposure, the amount of radiation staff and subjects will be exposed to, and if subjects could potentially be co-enrolled in other studies.

2.3.18.1.11.3. The IRB Analyst will ensure that the proposed plan meets the requirements of Risk Management procedures and guidelines and complies with the Radiation Safety review processes.

2.3.18.1.12. Audio/Video Recording

2.3.18.1.12.1. The PI will inform the IRB if audio and/or video recording will be utilized in his/her/their protocol. This includes Zoom recordings.

2.3.18.1.12.2. For audio recording:

2.3.18.1.12.2.1. The PI will detail who will be transcribing audio data.

2.3.18.1.12.2.2. If a third-party company is doing transcription, the PI will submit a copy of their non-disclosure agreement to cover this activity. If a non-disclosure agreement is not being sought, a thorough description of the reasons why should be included.

2.3.18.1.12.2.3. If pseudonyms are being utilized, the PI will detail the criteria that will be used to ensure subject's anonymity.

2.3.18.1.12.3. For video recording:

2.3.18.1.12.3.1. The PI will detail the plan to keep subject's anonymity, including but not limited to facial blurring and use of pseudonyms.

2.3.18.1.12.3.2. For all recordings, the PI will verify that subjects'

approval will be obtained before any dissemination of data.

2.3.19. International (Transnational) Research

2.3.19.1. For studies involving international travel, the PI must contact the UNT Risk Management office for their guidance and respond back to the IRB with documentation for the risk assessment and report, if received.

2.3.19.2. When a researcher is conducting research at international sites, the Researcher must comply with all local, federal, and international law as relevant to the research study as well as comply with items as outlined in the International (Transnational) Research SOP, linked in the Appendices.

2.3.20. Third Party Software or Websites

2.3.20.1. Studies utilizing third-party software or websites (for example, Facebook, Twitter, SurveyMonkey, Qualtrics, Zoom, etc.) to recruit or capture data will need to list these software or websites within the Request for Approval.

2.3.20.2. Additionally, the Researcher must provide a link to the privacy practices of the software and websites used in the informed consent form, notice, study summary, or in some format to the research participant unless a waiver to do so is granted.

2.3.21. Medical Records

2.3.21.1. Should a PI need to access medical records for a research study, the Principal Investigator must ensure they follow all HIPAA regulations, procedures, and guidelines.

2.3.21.2. The PI may be required to obtain a HIPAA Authorization from the subject or apply for a Waiver of HIPAA Authorization from the IRB.

2.3.22. Data Security and Storage

2.3.22.1. Anonymous

2.3.22.1.1. For studies to be considered anonymous, there must not be any way for the Researcher to identify the subject at any point in the study.

2.3.22.1.2. The IRB Analyst will ensure that no Personally Identifiable Information (PII) is obtained and that the PI has described a thorough plan to adequately protect data collected. The UNT IRB considers IP addresses to be Personally Identifiable Information.

2.3.22.1.3. The IRB Analyst will also review the consent document to confirm that subjects are informed of types of data collected and procedures to protect data.

2.3.22.2. Confidential

2.3.22.2.1. For studies to be considered confidential, there may be a possibility for the Researcher to identify the subject during the study conduct.

2.3.22.2.2. The PI will provide a plan to protect, de-identify, and store the data collected.

2.3.22.2.3. The IRB Analyst will ensure that any Personally Identifiable Information (PII) that is obtained is stored in such a manner to protect the information from unauthorized access or disclosure.

2.3.22.2.4. The IRB Analyst will also review the consent document to confirm that subjects are informed of types of data collected and

procedures to protect data.

2.3.22.3. Any data that is made accessible outside of UNT, regardless if to collaborators, must detail their specific data sharing plan within their IRB submission. Data shared outside of UNT may require a contract to be in place for the safeguard of this information.

2.3.22.3.1. Researchers determined to potentially require a contract for the sharing of data will be referred to Research Commercial Agreements for review of the study plan. IRB approval may not be granted until confirmation from Research Commercial Agreements is received.

2.3.22.4. The Principal Investigator must also provide specific details for long-term storage, maintenance, and discard of all research data. This plan must comply with local, state, and federal policies, procedures, and regulations.

2.3.22.5. The IRB Analyst will determine if the stated plan is in line with the proposed study and if all regulations, procedures, and policies are being followed.

2.3.23. Devices, Drugs, or Products

2.3.23.1. If the Request for Approval contains study procedures that will test, review, or utilize a drug, device, or product, the PI must provide detailed information about the drug, device, or product. This may include, but is not limited to:

2.3.23.1.1. Drug, device, or product Investigator Brochures

2.3.23.1.2. IND (Investigational New Drug) or IDE (Investigational Device Exemption) numbers or correspondence

2.3.23.1.3. Device schematics

2.3.23.1.4. Drug and Device safety information

2.3.23.2. Investigators are required to first discuss any proposed FDA-related plans with Research Integrity and Compliance prior to communicating directly with the FDA. In addition, all IDE and IND submissions must first be sent to Research Integrity and Compliance for a pre-review prior to formally submitting the application packet(s) to the FDA. Investigators are required to send the IDE/IND documentation via email to untirb@unt.edu.

2.3.23.3. The IRB Analyst will determine if the stated plan is in line with the proposed study and if all regulations, procedures, and policies are being followed.

2.3.24. Potential Risks and Benefits

2.3.24.1. Risks

2.3.24.1.1. The Principal Investigator must include all perceived potential risks, including minimal risks, within the IRB submission portal, as well as within the informed consent form, notice, or study summary document for review by the IRB.

2.3.24.1.2. Risks are the probability of harm or injury (physical, psychological, social, or economic) occurring as a result of participation in a research study. Both the probability and magnitude of possible harm may vary from minimal to significant.

2.3.24.1.3. A risk is minimal where the probability and magnitude of harm or discomfort anticipated in the proposed research are not greater, in and of themselves, than those ordinarily encountered in the daily

lives of the general population or during the performance of routine physical or psychological examinations or tests.

2.3.24.2. Benefits

2.3.24.2.1. The Principal Investigator must include all perceived potential benefits, to both the subject and to the field of study, within the IRB submission portal, as well as within the informed consent form, notice, or study summary document for review by the IRB.

2.3.24.2.2. A benefit is a desired outcome or advantage as a result of the study.

2.3.24.3. Risk:Benefit Ratio Assessment

2.3.24.3.1. According to the DHHS and FDA regulations (45 CFR 46.111 and 21 CFR 56.111), two required criteria for granting IRB approval of human subjects research include the following:

2.3.24.3.1.1. Risks to subjects are minimized by using procedures which are consistent with sound research design and which do not unnecessarily expose subjects to risk, and whenever appropriate, by using procedures already being performed on the subjects for diagnostic or treatment purposes.

2.3.24.3.1.2. Risks to subjects are reasonable in relation to anticipated benefits, if any, to subjects, and the importance of the knowledge that may reasonably be expected to result. In evaluating risks and benefits, the IRB Analyst and IRB Committee will consider only those risks and benefits that may result from the research, as distinguished from risks and benefits of therapies subjects would receive even if not participating in the research.

2.3.24.3.2. The IRB Analyst and IRB Committee are responsible for evaluating the potential risks and weighing the probability of the risk occurring and the magnitude of harm that may result. The IRB Analyst and IRB Committee must then judge whether the anticipated benefit, either of new knowledge or of improved health for the research subjects, justifies inviting any person to undertake the risks.

2.3.24.3.3. The IRB Analyst and IRB Committee cannot approve research in which the risks are judged unreasonable in relation to the anticipated benefits.

2.3.25. Compensation

2.3.25.1. Compensation includes any monetary, cash-equivalent (gift cards, coupons, lotteries, etc.), and non-monetary (extra credit, gifts, course credit, etc.) item offered to a research participant in exchange for their participation in a human subjects research study.

2.3.25.2. Compensation is meant to offset the time and inconvenience of participation, as well as to serve as an incentive to participate. Compensation is not considered a benefit of the study.

2.3.25.3. The Researchers and the IRB are tasked with ensuring that research subjects provide voluntary, informed consent that is free from coercion or undue influence.

2.3.25.4. The Principal Investigator must provide a detailed description of proposed compensation to research participants in the Request for Approval.

2.3.25.4.1. This will include timing of compensation, pro-rating schedule, compensation for participants who withdraw before completion, and completion bonus plans, if applicable.

2.3.25.5. The Internal Revenue Service (IRS) requires that UNT (or whomever is paying the research participants for their participation) report payments in excess of $600 per calendar year on Form 1099-Misc. The participant must be notified of this requirement within the consent form.

2.3.25.6. The IRB Analyst will determine if the stated plan is in line with the proposed study and if all regulations, procedures, and policies are being followed.

2.3.26. Debriefing Statements

2.3.26.1. Debriefing statements are required for studies involving deception and for those in which support resources are necessary to help minimize adverse effects to participants.

2.3.26.2. The UNT IRB additionally recommends debriefing as an educational tool. A debriefing statement may also be used as a way to provide additional information and resources to the research participants, to thank them for their participation, and to give them information for reflection on the study activities at the conclusion of study activities.

2.3.26.3. Debriefing statements may include, but are not limited to, appropriate referrals to counseling services, Researchers' contact information for future questions, withdrawal procedures, and the study purpose.

2.3.27. Conflicts of Interest

2.3.27.1. The Principal Investigator is responsible for assessing and reporting any potential conflicts of interest upon submitting an application for review and approval, throughout the course of conducting that approved study, and for a period thereafter. This includes, but is not limited to, pre-existing relationships with participants, financial or other self-interests by members of the research team, or any potential conflicts of commitment.

2.3.27.2. The Principal Investigator is responsible for disclosing any potential conflict of interest, pre-existing relationships with participants, financial or other self-interests by members of the research team, or any potential conflicts of commitment of the research team to the IRB for review. The Principal Investigator must also disclose this information to the participants during the informed consent process.

2.3.27.3. The IRB Analyst will determine if the stated plan is in line with the proposed study and if all regulations, procedures, and policies are being followed.

2.3.28. Informed Consent and Assent Forms

2.3.28.1. Informed consent is a potential participant's voluntary agreement, based upon comprehensive knowledge and understanding of pertinent information, to participate in a human subjects research study.

2.3.28.2. Informed consent of all subjects is required prior to initiation of study activities, unless it has been waived by the IRB as allowed by the federal regulations.

2.3.28.3. Informed consent should be obtained after the potential participant is provided a sufficient chance to consider whether or not to participate.

2.3.28.4. The potential participant must be informed of all the aspects of the human

subjects research study, including all information relevant to the potential participant's decision to participate, and must have been given the opportunity to ask questions relevant to the research.

2.3.28.5. Informed consent is documented in a written, signed and dated on an Informed Consent Form, unless documentation of consent has been waived by an Institutional Review Board (IRB).

2.3.28.6. The informed consent process should continue beyond the initial discussion and documentation of consent.

2.3.28.6.1. This may take the form of an ongoing conversation between the subject and the study team that includes any new information that could impact the subject's decision to participate and confirmation of the continuing willingness of the subject to participate.

2.3.28.7. Informed consent must be formatted in compliance with all regulations, policies, and procedures.

2.3.28.7.1. Informed consent templates can be located on the UNT IRB website and contain required elements of the informed consent as required by regulations, policies, and procedures. Additional elements may be requested based on the study design, procedures, risks, or participant population.

2.3.28.8. The Principal Investigator is responsible for ensuring consent is obtained from all subjects in compliance with regulations, policies, and procedures, unless waived by the IRB. The Principal Investigator is also responsible for ensuring that vulnerable populations are provided with adequate consenting procedures, including but not limited to, obtaining assent, translated documents, and guardian consent.

2.3.28.9. Original consent documents must be maintained and stored by the Principal Investigator and Researchers with study related data in compliance with all data retention regulations, policies, and procedures.

2.3.29. Principal Investigator Declaration

2.3.29.1. The Principal Investigator must certify all Requests for Approval submitted to the IRB.

2.3.29.2. By certifying all Requests for Approval, the PI is agreeing to assume the overall responsibility for the study conduct. By doing so, they are agreeing to conduct or supervise the research, to ensure that each Researcher to whom a task is delegated, is qualified by virtue of education, training, and experience to perform each of their delegated tasks; and to protect the rights, safety and welfare of all participants.

2.4. All Researchers are required to comply with all laws, regulations, policies, and procedures with respect to the contents of their Request for Approval.

3. Intake:

3.1. Upon receipt of a Request for Approval from a Researcher, an IRB Analyst, will log into the IRB Submission Portal and open the new Request for Approval.

3.2. Based on the workload distribution within RIC, an IRB Analyst will be assigned as the current analyst for the review of the request.

3.3. The assigned IRB Analyst will log into the IRB Submission Portal and pre-review the items listed in the IRB submission portal.

4. Pre-Review:

4.1. The assigned IRB Analyst will log into the IRB Submission Portal and pre-review the

documentation for completeness and accuracy.

4.2. The IRB Analyst will communicate, via the IRB Submission Portal, with the Principal Investigator with comments, requested for completeness, modification, or clarity of the Request for Approval based on local and federal law and guidelines as well as University policies, procedures, and guidelines.

4.3. The Principal Investigator must respond to all comments by the IRB Analyst by making the correction to the Request for Approval submission. The Principal Investigator must also respond to the comments in writing, giving assurance that all IRB Analyst comments have been addressed.

5. Review Category:

5.1. All Human Subjects Research projects conducted by UNT faculty, staff, students, or affiliates must undergo review and approval by the UNT IRB prior to initiation of research activities. Definitions for what is considered "Human Subjects Research" are located at 45CFR46.102.

5.2. All research is required to be closed after 3 years' time and to be resubmitted as a new study submission if continuation is required or desired.

5.3. Once the pre-review process is complete, the IRB Analyst will make a determination, with consultation with the IRB Chair if needed, regarding the risk level of the study.

5.4. Regulated Research

5.4.1. Exempt

5.4.1.1. To qualify for review at the exempt level, the research must not be greater than "minimal risk" (definition found at 45CFR46.102) and must fall into one or more of the exempt categories (45CFR46.104).

5.4.1.2. Exempt reviews are conducted typically by only one reviewer, an IRB Analyst, within the Research Integrity and Compliance Office. This process typically occurs simultaneously with the Pre-Review process.

5.4.1.3. Typically, no annual renewal is required to be submitted.

5.4.1.4. Modifications and Incidents are required to be submitted for review.

5.4.2. Expedited

5.4.2.1. To qualify for review at an "expedited" level, the study must be no more than "minimal risk" (definition found at 45CFR46.102) and fit in one of the federally designated expedited review categories (45CFR46.110 and 21 CFR 56.110).

5.4.2.2. Expedited reviews are conducted by Research Integrity and Compliance staff and a member of the IRB committee.

5.4.2.3. Expedited studies may or may not require annual review. This is determined by the reviewers after a full assessment of the study. The reviewers will take a variety of factors into consideration including the study population and risks. Annual review requirements will be listed on the approval letter that is issued once the study is marked approved.

5.4.2.4. Modifications to study plans must be submitted prior to initiation.

5.4.2.5. Incidents are required to be submitted.

5.4.3. Full Board Review

5.4.3.1. More than minimal risk studies, as determined by the IRB Chair, must be reviewed at monthly Full Board Committee meetings. Additionally, any human subjects research study that does not fit into one of the federal categories for Exempt or Expedited must be reviewed at the monthly Full Board Committee meetings.

5.4.3.2. All Full Board Review submissions must be submitted prior to the first of the month to be reviewed at that month's meeting.

5.4.3.3. Annual reviews are required.

5.4.3.4. Modifications to study plans must be submitted prior to initiation.

5.4.3.5. Incidents are required to be submitted.

5.4.3.6. All submissions associated with a study previously reviewed at the Full Board must be reviewed at the subsequent Full Board meeting.

5.5. Non-Human Subjects Research

5.5.1. Non-human subjects research refers to studies not covered by the HHS Regulations. Activities are non-human subjects research if they do not involve a systematic approach involving a predetermined method for studying a specific topic, answering a specific question, testing a hypothesis, developing theory, or do not meet the federal definitions of human subject or research as defined in 45 CFR 46.

5.5.2. Researchers who believe their project is non-human subjects research must submit a "Proposed Human Subjects Research Assessment" form for review. This should be done prior to submission of the new study in the IRB submission portal.

5.5.3. Research Integrity and Compliance must make the final determination if your proposed project meets this federal definition as outlined in 45 CFR 46.

5.5.4. Research Integrity and Compliance will review these forms and determine if IRB approval is required or if the project is determined to be non-human subjects research.

5.5.5. Research Integrity and Compliance will issue a formal letter to the Researcher with a determination. The Researcher must comply with the Research Integrity and Compliance determination.

5.5.6. If an IRB Analyst receives a new study submission in the IRB submission portal that they believe qualifies as non-human subjects research, the IRB Analyst will reach out to the Principal Investigator to notify them of this determination and to discuss further action. Completion of a Proposed Human Subjects Research Determination form may be requested. The IRB Analyst will also mark the study as "non-human subjects research" within the IRB submission portal and issue a determination letter to the Principal Investigator.

6. Determination:

6.1. A thorough evaluation of all Requests for Approval is conducted by IRB Analysts, and IRB Committee Members as appropriate, allowing the IRB to determine if the study meets the minimum criteria for initial approval and the minimum criteria for continuing approval.

6.2. IRB Analysts, and IRB Committee Members as appropriate, review changes in approved research during the period for which approval has already been given to determine if the study meets minimum criteria for ongoing review.

6.3. IRB Analysts, IRB Chair, and the IRB Committee Members as appropriate review all submitted Incidents to ensure preventative plans are appropriate, risks to participants are minimized, and further action may be requested of the Researcher and Principal Investigator, as needed.

6.4. All members of the IRB panel have access to the submitted documents and may provide comments regarding any proposed research. Any board member or Research Integrity and Compliance staff, at his/her discretion, can request any of the following (but are not limited to):

6.4.1. Ad hoc consultant review;

6.4.2. Any additional necessary information beyond what has been provided by the

investigator;

6.4.3. Third-party verification of information submitted by the Investigator.

6.5. Once the thorough evaluation of the Request for Approval is complete, the IRB Analyst, and IRB Committee Members if needed per the study risk level, will make a determination:

6.5.1. Studies that are "Approved" are given permission to proceed with study activities as defined with the current IRB submission. Depending on the risk level of the study, Approval may be issued for 3 years, 1 year, or for a shorter period of time at the discretion of the IRB.

6.5.2. Studies that are "Approved with Stipulations" are given permission to proceed with study activities after all stipulations are addressed by the Principal Investigator.

6.5.2.1. The Principal Investigator must provide a detailed response to any stipulations by responding to the IRB with any requested corrections.

6.5.2.2. Once the stipulations have been addressed, the IRB Analyst will issue a final approval letter.

6.5.2.3. Study related activity may not commence until all stipulations have been addressed and a final approval letter is received. Depending on the risk level of the study, Approval may be issued for 3 years, 1 year, or for a shorter period of time at the discretion of the IRB.

6.5.3. A study is disapproved if it does not provide adequate protection to human subjects, and it is unlikely that it may be modified to provide such protection.

6.5.3.1. The IRB Analyst will notify the Principal Investigator of the disapproval, as determined by the IRB Committee, in writing, including a statement of the reasons for its decision and providing the opportunity for the investigator to respond to the IRB in person or in writing.

6.5.4. A study may be tabled if the IRB Committee did not have time or the adequate resources to review the application at the convened board meeting. The IRB may table a protocol when there are a number of significant questions and concerns that could not be resolved at the IRB meeting. The application is placed on the agenda for the next convened meeting.

7. Post Review:

7.1. Decisions of the IRB Committee, IRB Analyst, or IRB Chair will be communicated to the Principal Investigators via a letter, memorandum, or email.

7.1.1. If the research protocol is approved, the letter, memorandum, or email will indicate that approval has been granted and that the research may begin. The approval letter will contain the date on which the research was approved and the date the approval expires. If no expiration date is provided, the study expires three years from the approval date.

7.1.2. When stipulations are required to be addressed before IRB approval can be provided, this decision and the specific changes that will be required will be communicated to the PI. Researchers may not initiate a research study or a change to a previously approved protocol until final approval is granted and communicated to the PI.

7.2. Consent Stamping

7.2.1. A UNT IRB approval stamp affixed to consent form indicated that the document has been reviewed and approved by the IRB Committee, IRB Chair, IRB Member, or IRB Analyst. The stamp serves as a reminder of the requirements for renewal and re-approval, if applicable. The UNT IRB approval stamp shows the protocol number, and the protocol expiration date, if less than three years.

7.2.1.1. If no expiration date is listed within the stamp, the protocol expires three

years from the approval date.

7.2.2. The stamp is only applied to finalized, IRB approved consent forms, notices, study summaries, or assent documents and will appear on the bottom right hand corner of the approved document.

7.2.3. Following IRB approval, all informed consent form, notices, study summaries, or assent documents will be affixed with a stamp. The stamped documents are the only documents that should be used for the consenting procedures, as applicable.

7.2.4. Stamped documents will be made available within the IRB submission portal for the Researchers to download for use.

8. Document Retention:

8.1. 45 CFR 46.115(b) and 21 CFR 56.115(b) require that all IRB records be retained for at least 3 years, and records relating to research which is conducted be retained for at least 3 years after completion of the research. All records must be accessible for inspection and copying by authorized representatives of HHS or the FDA at reasonable times and in a reasonable manner.

8.2. The minimum retention period is 3 years after study completion, but individual granting agencies can require longer periods of up to 7 years. Investigators must comply with the requirements of the agency with the longest retention period.

8.3. The regulatory mandated duration for records retention varies depending on which regulations apply to the research in question. In addition, UNT policies may have longer retention requirements than the federal regulations. UNT investigators need to ensure that their document retention plan complies both with the federal regulations and UNT policy.

REFERENCES

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

APPENDICES

1. IRB Guidelines