



Institutional Review Board Standard Operating Procedures

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1) Institutional Authority

The Vice President of Research and Innovation serves as the Institutional Official (IO) for UNT, responsible for oversight of the use of human subjects in research at UNT and acts as signatory official for the assurances with the Office of Health and Human Services and Office of Human Research Protections.

2) Purpose

The purpose of the University of North Texas IRB is to ensure that human subjects are properly and adequately protected and that any proposed or later enacted research is conducted with minimal risk to the subjects, and is conducted within the scope of the approved protocol.

3) Principles

Human subjects research conducted at UNT is governed by the principles set in the Belmont Report and the ethical principles detailed by HHS regulations and the UNT Federal Welfare Assurance covering human subjects research.

4) Scope and authority of the IRB

a) Scope- The UNT IRB, assisted administratively by the Office of Research Integrity and Compliance, reviews protocols which involve human subjects, and which must meet the requirement of both “human subject” and “research” per the regulatory guidelines outlined in 45 CFR 46 and FDA regulations 21 CFR 50. This scope includes research conducted by UNT faculty, staff, and students, or conducted by other institutions or outside personnel requesting to use UNT as a research site.

i) The UNT IRB and human subjects research program of UNT also must follow state and local laws, and per 45 CFR 46.101(f), the HHS policy on human subjects research does not affect any state or local laws or regulations which may otherwise be applicable and which provide additional protections for human subjects. The UNT IRB and ORIC will follow the HHS and FDA regulations, as well as follow the state of Texas laws when reviewing and approving human subjects research protocol.

(1) Some applicable regulations for the state of Texas include:

- (a) Texas Civil Practice & Remedies Code Chapter 129 Age of Majority
- (b) Texas Statutes Health & Safety Code Chapter 313. Consent to Medical Treatment Act
- (c) Texas Statutes Family Code Title 2. Chapter 32 Subchapter A. Consent to Treatment of Child by Non-Parent or Child
- (d) Texas Family Code Chapter 261, Investigation Of Report Of Child Abuse Or Neglect
- (e) *Texas Administrative Code, Chapter 97, Control Of Communicable Diseases*
- (f) Texas Administrative Code Title 25, Health Services Part 1, Department of State Health Services Chapter 91, Cancer Subchapter A, Cancer Registry Effective Date: July 9, 2006
- (g) Human Resources Code Chapter 48. Investigations And Protective Services For Elderly And Disabled Persons

- b) Authority- The authority designated on the UNT IRB per the Institutional Official and the Federal Welfare Assurance includes the following:
 - i) Review and approve new and continuing research protocols which involve human subjects, and which meets the definition of research;
 - ii) Review changes (modification/amendment) being requested on approved protocols prior to the implementation of said changes;
 - iii) Review reports of adverse events and non-compliance, and determining the course of action to rectify such events; and
 - iv) Request restrictions on, or suspend/terminate approval of, protocols due to non-compliance issues.
- c) Authority of Institutional Officials- The Vice President of Research (or another designated IO) has the authority to review decisions of the IRB. The IO will work with the IRB directly, or via the Director of Research Integrity and Compliance, as needed to resolve issues.

5) Relationship of UNT IRB to other agencies, institutions, and committees

- a) Compliance with Federal Regulations- UNT has an approved Federal wide Assurance (FWA) governed and regulated by the US Department of Health and Human Services Office for Human Research Protections which confirms UNT is in compliance with 45 CFR 46, which details regulations related to the use of human subjects in research.
- b) Review of Research Activities by Other University committees- The UNT IRB will coordinate with other UNT committees as needed to ensure that all conditions and the subject protections necessary have been reviewed and are covered by regulations.
 - i) Institutional Animal Care and Use Committee (IACUC) - The IACUC is responsible for ensuring the health and well-being of animals being used in research laboratories or in research settings. The IACUC is regulated by and in compliance with the Animal Welfare Act and Animal Welfare Regulations, the Public Health Service Policy, and Office of Laboratory Animal Welfare (OLAW) guidelines. Protocols involving animals must be reviewed and approved by the IACUC prior to initiation of research. In the event that a research protocol involves both human and animal subjects, the necessary components of the research protocol will be reviewed and must have approval obtained by the relevant committee/board. The IRB and IACUC will share information as needed.
 - ii) Institutional Biosafety Committee (IBC) - The IBC is responsible for ensuring safe usage of biomaterials, such as bio contaminants, and radioactive materials that may be used on or interacted with human subjects. If IBC review is required due to the nature of the research protocol, IBC approval must be obtained before final approval can be given for the human subjects research protocol.
- c) External Requests for Recruitment/Involvement of UNT Students as human subjects- If an external institution or university wishes to have UNT students, faculty, or staff involved as subjects in a research project, they must connect or collaborate with an existing UNT faculty member or other researcher (such as a grad student who may act

as key personnel), and the external institution should have an already approved research protocol from their IRB.

6) Membership of the UNT IRB

- a) Appointment of Members- 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 Chairperson.
- b) Regular Members- 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 Director of ORIC will review the membership of the IRB regularly and will review the qualifications of the current members or any new members as needed.
- c) Responsibilities- 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).
- d) Compensation of IRB members- 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 Chairperson, but this is at the discretion of the Vice President of Research and Innovation.
- e) Member Liability- IRB members are covered by UNT as they act as a member or representative of the UNT IRB.
- f) Alternate members- 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.
- g) Non-voting members- 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.

- h) Consultants/ad hoc reviewers- 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.
- i) Conflicts of Interest- 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.
- j) HHS Reporting Requirements- 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 Director of the Office of Research Integrity and Compliance.

7) Management of the IRB Process

- a) IRB Chair- The Vice President of Research and Innovation will assist with recommendations of potential IRB Chairs and will make the final approval of the appointment. The appointment of the Chair, as well as all other members, will be through an official appointment letter.
 - i) Responsibilities of the IRB Chair include: assisting with the review of non-exempt protocols and the referral of reviews to the full IRB or referral for designated review, reviewing reports of adverse events and reports of non-compliance, conducting the business of the full board meetings, recommending new members and facilitating administration of the membership with the VPR and the Office of Research Integrity and Compliance, serve as a resource for IRB members and faculty/staff who are completing human subjects research, facilitate training for new/existing members, and remaining current on any government regulations or changes.
- b) IRB Administrative Staff- The Office of Research Integrity and Compliance (ORIC) serves as the administrative component for the UNT human subjects research program. ORIC staff generally attend IRB meetings and will take minutes, but act as ex officio (non-voting) members. The ORIC responsibilities include: managing the administration/submission/recordkeeping requirements of the human subjects research program, manages continuing review of non-exempt research protocols, managing the electronic database and paper documentation of submitted human subjects research protocols, coordinates and schedules IRB full board meetings and provides agenda and completion of meeting minutes, coordinates with IRB Chair and full board with any needed future review on approved protocols (such as continuing reviews or

modifications requiring full board approval), organizing training on human subjects research and governmental regulations for any faculty, staff, or research personnel including but not limited to grad students or post-docs, and serves as a centralized repository and point of contact for the human subjects research program.

- c) Principal Investigator- The Principal Investigator (PI) is the individual who is actively leading and/or supervising the initiation, execution, and completion of a research project. 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 ORIC 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. The PI should also be ensuring the all personnel are maintaining confidentiality of subjects and for maintaining data and records related to the project. Qualifications of the lead investigator will be confirmed as part of the review process.
 - i) Student projects (such as PhD dissertations) are allowed to be submitted for IRB review, but a full-time faculty member whose job entails completing research on behalf of UNT must serve as PI and be held responsible for the conduct of the protocol and research.

8) Functions of the IRB

- a) Scope of the Review- The ORIC and the IRB will review all new and continuing applications for the following items:
 - i) Determine if the research proposed meets the requirements of research and the definition of human subjects, as defined in 45 CFR 46.
 - ii) Confirm if funding has been or plans to be obtained, and what additional regulatory bodies/institutions may be involved in the post approval monitoring. ORIC will also work with OGCA to provide confirmation on approved human subjects research protocol as required by the funding agency.
 - iii) Identify level of risk and determine the level of review required.
 - iv) Identify benefits and conduct risk/benefit analysis.
 - v) Evaluate scientific merit for protocols above minimal risk
 - (1) Protocols meriting a full board review may require a more extensive literature review and additional discussion with the PI as to the benefit analysis and the maximum number of subjects required. This may include additional explanation of the research design and planned interventions.
 - vi) Assure that protocol and informed consent documentation explains, at a lay level, the proposed benefits, risks, compensation, etc. so any potential participant can make an informed decision to participate.

- vii) Ensure a system is in place for anticipated adverse events (such as counseling available or medical intervention), and for protection of participant confidential information and any generated project data.
- viii) Determine safeguards in place if research intends to include any vulnerable populations, such as minors or incarcerated persons.
- b) Special Consideration for Projects involving vulnerable populations- Certain groups, such as children, incarcerated persons, pregnant women or fetuses, or cognitively impaired persons, are considered to be vulnerable populations, and proposed research involving these groups are subject to further scrutiny. Regardless of the interventions proposed, they will require, at the very least, review by the IRB Chair, and in many cases full board review. The full board review may require subject matter experts or special advocates, such as a prison advocate in cases involving those incarcerated. The risk/benefit analysis should be clearly stated in the protocol application, and the necessity of including the vulnerable populations should be detailed. The IRB review should include confirmation that additional safeguards have been included to protect the rights and welfare of these subjects.
- c) Suspension or termination of IRB approval- As designated authority by the IO, the IRB has the right to request suspension or immediate termination of an approved or ongoing research project which involves human subjects in cases of extreme adverse events, harm to participants, and/or non-compliance with the approved research protocol. Any activity of suspension or termination will be reported to the PI in writing, and will also be reported to the IO, department heads, and funding agency if applicable.

9) Operations of the IRB

- a) Scheduling of Meetings- 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 administrative staff. In the event of an unplanned cancellation, the IRB and IRB chair will work to reschedule and to notify any affected personnel.
- b) Submission of New Applications- IRB applications are submitted electronically in the Cayuse IRB system to be reviewed by the ORIC staff and the IRB, if necessary.
- c) Determination of Type of Review- The staff of the Office 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 it meets federal regulations of the definition of research and the definition of human subjects, and determining the level of review required based on the risk to the participants or the use of vulnerable populations. Applications are categorized as needing exempt (minimal) review, expedited (level of review, not the time frame of review), or full board review.
 - i) Exempt (Minimal) Review- Exempt (better termed 'minimal' review) means that the study poses no or minimal risk to subjects, and does not require any further or continued review by the IRB Chair or Full IRB. This does not mean an application

does not need to be submitted or does not require 'approval' by the Office of Research Integrity and Compliance.

- ii) The following types of studies are examples of those who may qualify for minimal review:
 - (1) Research involving effectiveness of educational programs, research conducted in commonly accepted educational settings
 - (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.
 - (3) Research involving the collection or study of pre-existing data, documents, or records that are publicly available.
 - (4) Research or demonstrative projects that are designed to study, evaluate, or examine public benefit or service programs.
- iii) The IRB and the ORIC 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 Cayuse 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 ORIC and the IRB Chair to confirm the final level of review.
- iv) Expedited Review- 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 are generally approved for one year and require continuing review to renew the application. Protocols submitted for expedited review may fall into the following categories, for example:
 - (1) Clinical studies of drugs and medical devices only when one of the following conditions is met:
 - (a) 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.);
 - (b) 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.
 - (2) Collection of blood samples through finger stick or venipuncture in healthy participants.
 - (3) 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) Research involving materials (data, specimens, records) that have been collected or will be collected for non-research purposes
 - (5) Research involving audio or video recording in which the possibility of participant identification is increased.
 - (6) Other interventions or activities not identified in these categories, but that do not qualify for exempt review.
- v) Primary Reviewer Review Process- 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 the ORIC, 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 notated in the online system or in writing, and will be communicated to the IRB Chair, ORIC staff, and to the PI.
 - vi) Requests for revisions on submitted protocols are submitted to the PI through the Cayuse IRB online 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 Cayuse system, and the updated application will be sent to the ORIC staff to restart the review cycle.
- d) Notification of Meetings and Distribution of Materials- 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. 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 also available on the website, but 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 Cayuse online 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.

- e) Meeting Procedures- 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. The meeting is officially ended by adjournment of the present Chair. The IRB may include alternates, who may vote in the place of the IRB member for which they are an alternate. 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. 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.
 - i) The Staff of the ORIC generally attend meetings to assist with administrative tasks, providing copies of agenda and information to be discussed, and to assist with taking meeting minutes. 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.
 - ii) Voting on a protocol is by aye, nay, or abstention. All votes of present members must be noted in the meeting minutes. 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.
- f) Meeting Minutes- 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.
- g) Approval of Research- A protocol may be approved as is, approved with revisions needed, table for future review, or disapproved. If the IRB approves research with revisions, the ORIC staff will notify the PI of the revisions needed, generally through the Cayuse online system. Discussions may also be sent through email as needed, but will always be communicated in writing. Any major or additional modifications submitted as part of the revisions may require additional primary review or additional full board review. 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. The PI has the right to appeal, in writing, any findings by the IRB.
- h) Appeal of the IRB Decisions- 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

Director of ORIC 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.

- i) The IRB Chair may hold a closed session without the researcher to discuss the details of the research protocol and the appeal. Then the PI is 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. The IRB may at this time 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.
 - ii) 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 and that decision is final.
- i) Length of Approval- With the exception of exempt (minimal) review studies, research which involves human subjects must be reviewed annually, on the anniversary of the original approval date. Initial approval is given for one year, and if the PI intends to continue the project with no changes, it can be renewed for an additional year. 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. Approval and expiration dates are provide 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, than the protocol will expire and no further human subject research can take place under that protocol.
- i) Lapse in Approval- 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. This information is also available in the Cayuse IRB system and is available anytime.
- j) Monitoring Approved Projects
- i) Continuing Review- Continuing review is required for all expedited and full board applications. 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 Cayuse 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.

- ii) 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 ORIC staff, and any findings or confirmation post-review will be sent to the PI in writing.
- iii) Modifications- Any changes to an approved protocols must be submitted for review as a modification. Modifications of protocols previously approved via a full board review will also receive full board review. Modification to a protocol may include adding or removing a research site, addition of research personnel, changes in funding or compensation, or changes to the planned interventions. Modifications are submitted as part of the study in the Cayuse IRB online system. Modifications should be minor. 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. The PI will be notified if a modification is not appropriate and a new application is required. Modification does not change or extend the approval or expiration date of the protocol. 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 ORIC. 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.
 - (1) The level of review on an approved project can be raised based on the proposed changes. For example, 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. Changes that increase or change the review level may require a new application. This is at the discretion of the ORIC 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.

- k) Study Closure and Protocol Expiration- Once a PI has completed a research project, they can submit their Final Report through the Cayuse IRB system at any time. If the ORIC 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. If the PI receives a renewal notice and does not plan to renew or continue the project, they can submit a Final Report. 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.

10) Notification of IRB Activities

- a) Members of the IRB (including alternates) will receive notification from the ORIC with meeting minutes, meeting agenda, and any notifications or reports of pending or needed IRB business. This information and documentation may be sent through the Cayuse IRB online system or by email. Reports will include any pending IRB full board reviews and any pending adverse events or non-compliance reports.

11) Informed Consent Document

- a) Informed consent is an important part of human subjects research, and certain elements are required to be contained in the informed consent document.
- b) General Requirements- An investigator may not conduct human subjects research on a participant who has not been given the opportunity to consent to being a participant. In the event that the participant is physically or legally unable to properly consent (such as with a minor or someone with impaired judgement), the person's legal guardian must be given the same opportunity to consent. Studies involving children and their legal guardians should also include assent documents along with the main informed consent document. The information should be in a form and language that the participant/guardian is able to understand (e.g. in a lay form and in a language that they speak). An informed consent, whether in writing or verbally, cannot invalidate their right or appear to waive the participant's right to legal intervention or give away liability in the event of negligence on the part of the PI or research team.
- c) The UNT human subjects research program requires the use of the approved UNT informed consent document templates. If the PI requests to make revisions to the approved template, these revisions will be reviewed and approved by the ORIC and IRB as necessary or applicable.
- d) The informed consent document shall include the following:
 - i) A statement that the study involves research, an explanation of the research and what it will entail, and identification of any interventions which are experimental.
 - ii) A description of any foreseeable risks or discomfort.
 - iii) A description of any foreseeable benefits or compensation, or the lack thereof.
 - iv) A statement regarding anonymity or expected confidentiality, whether you are collecting identifiable private information or not.

- v) For more than minimal risk studies, information on 24 hour resources in the event of any negative mental or physical effects.
 - vi) An explanation of whom to contact (being the PI and Co-PI as applicable) in the event of questions or reports of adverse events.
 - vii) HIPAA compliant language in the event that protected medical or health information is being gathered as data.
 - viii) A statement that participation is voluntary, and that refusal to participate or withdrawal from the participation at any time will not involve any loss of benefits that the subject is otherwise entitled.
 - ix) Informed consent should be documented in writing, except in cases where this is not possible, such as with online surveys or phone calls. In those cases, the participant should have the opportunity to either read or be read verbally the full informed consent document and be able to consent verbally or by agreeing to continue with an online survey. Consent should be ongoing and consistently provided to participants.
- e) Special Considerations for users of Mechanical Turk
- i) If you are planning to use Amazon’s Mechanical Turk for recruitment and completion of an online survey, it is recommended to add the following information to the Informed consent:
 - (1) Add a disclaimer that any work performed on mTurk could be linked to the user’s profile page.
 - (2) Add a statement that the mTurk worker ID will not be shared, and that the 14 digit worker ID will not be linked to any data or responses.
 - ii) Amazon has stated that mTurk is not designed to protect participant anonymity, so even if the survey does not intend to gather identifiable data, anonymity cannot be guaranteed.
- f) Waiver of documentation of consent- The IRB may agree to waiver of *documented* (for example, a signed informed consent document) if the signature would increase the principal risk of breach of confidentiality, or the research presents not more than normal minimal risk to participants. Inferred or implied consent, such as commonly found with an online or telephone survey, is not a waiver of consent and a consent document is still required as part of the human subjects research application. Full waiver of consent is rare and is handled on a case by case basis. Any requests for full waiver of consent on a protocol may require full board review.
- i) Waiver of consent may be allowed in certain extreme or emergency circumstances. This must be approved by the full board as the “Emergency Research Consent Waiver”, allowed in some instances such as the need of emergency therapy, and because of the subject’s medical condition or unavailability of legally authorized representatives to consent. The IRB will review these cases to see if they meet the requirements for research subject to FDA regulations, or research not subject to FDA regulations, that meet certain specific criteria. This criteria can be found here:

<https://www.hhs.gov/ohrp/regulations-and-policy/guidance/emergency-research-informed-consent-requirements/index.html>.

- g) Record Retention Policy- Documentation of consent, whether in writing or implied and otherwise documented, is required to be kept on file on campus at UNT for a minimum of three years after the termination of the study. Records may be subpoenaed or subjected to federal Freedom of Information Act requests at any time. Records should be protected either on protected IT servers, or in locked cabinets or offices in the case of paper documentation. The PI is ultimately responsible for the collection and retention of any and all documentation related to the research study, and documentation retention should follow federal guidelines for human subjects research, guidelines for the funding agency as applicable, and should follow UNT policies and procedures for records retention.

12) Non-compliance allegations and handling

- a) Noncompliance investigations and actions- Non-compliance is the failure of any member of the research team (from PI to key personnel) to follow the regulatory guidelines (federal, state, or institutional guidelines related to human subjects research) or the approved structure of the research protocol, including any and all recruitment, planned participant numbers, interventions, or confidentiality protections. Non-compliance may or may not involve an adverse event or unanticipated problem. Serious non-compliance may jeopardize the health and/or welfare of a research participant, and in some cases the research personnel. Continuing non-compliance is evidenced by a trend or history of non-compliance with the protocol or against regulations, regardless of how small or egregious the infraction may be. If non-compliance is alleged, the IRB, ORIC, and IO will review the allegations and determine if non-compliance has occurred. An in-process research project may be immediately suspended pending investigation, if participant health or welfare is at an increased risk, or if the alleged non-compliance has the potential to lead to increased risk.
- b) Non-compliance allegations may come from a number of sources, such as an IRB member, ORIC staff, an investigator or key personnel, a subject or their family members, anonymous complaints or reports, the media, or the public. Non-compliance can be reported on approved IRB protocols, or on situations where proper approval was not sought or given for what is deemed to be human subjects research.
- c) Once the review has been completed, a report will be completed and the findings of the review provided to the PI in writing, within 30 days of the completion of the review. The PI has the right to comment on the findings and ask for justification of the findings.
- d) A report of non-compliance may need no further action in the following instances:
 - i) An unanticipated problem or adverse event was self-reported by the PI, immediately upon discovery or occurrence;
 - ii) It was determined to be neither serious nor continuing;
 - iii) And it was addressed through a corrective action plan to remedy the possibility of repeat incident.

- iv) A report with no action required will be documented in writing and the documentation stored by the ORIC, and will be reported to the IRB and the IO in writing upon completion of review. A copy of the review will also be provided to the PI for their records.
- e) If an allegation of non-compliance warrants further review or action is needed, the allegation will go through full investigation.
 - i) The Director of Research Integrity and Compliance will work to designate a review committee. This may be the IRB Chair, the VPR, or a convened full IRB.
 - ii) Depending on the nature of the allegation, the Office of General Counsel or legal department may be requested to perform an independent review.
 - iii) The committee or designated reviewers will review the allegations through one or all of the following: reviewing available written material, interviewing involved parties such as PIs or key personnel, and collecting relevant documentation of the allegation of non-compliance.
 - iv) If the allegation is found to be valid, but not serious or continuing, the Director of ORIC along with the IRB Chair will confirm that an adequate action plan is in place, and this will be documented in writing and filed, and the PI will be notified in writing.
 - v) If the alleged non-compliance is found to be valid, and serious and/or continuing, the issue will be reviewed with the full IRB at the next convened meeting. The IRB may request any or all of the following in the process of, or at the completion of, their review:
 - (1) Verification that subject selection is appropriate and that the informed consent process is being followed;
 - (2) An increase in ongoing monitoring of data collection in the form of a data safety monitoring board or continued evaluation of the research site;
 - (3) Request a comprehensive audit of the area(s) of concern;
 - (4) Request a status report at each stage of the research project or at the completion of certain interventions;
 - (5) Modification of the continuing review cycle;
 - (6) Notify current subjects, if the existence of confirmed non-compliance may affect their willingness to continue to consent in participation;
 - (7) Suspend or terminate the study;
 - (8) Require modification of the protocol;
 - (9) Require additional information be added to the consent form or processes, and re-consent of all subjects.
 - vi) The IRB will review the circumstances and will determine if the non-compliance appears to either (1) cause injury or other unanticipated problems which may cause increased risk, or (2) constitutes serious non-compliance with federal regulations or IRB determinations.

- vii) If serious or continuing non-compliance is confirmed, the IRB will take appropriate action for the situation, follow the procedures for non-compliance detailed in regulations 45 CFR 46, will notify the IO immediately upon final review and determination of non-compliance, and will notify the funding agency per their guidelines as applicable.
- viii) Corrective Actions for Serious and/or continuing non-compliance- The IRB will seek to correct the non-compliance, attempt to mitigate any effects that have already occurred or may continue to occur, and consider suspension or termination of the research.
 - (1) Per the UNT Policy 13.004 on the Use of Human Subjects in Research, sanctions for non-compliance by the UNT IRB may include but are not limited to: destruction of all data improperly collected; required additional training for the Principal Investigator and key personnel; temporary suspension of the Principal Investigator's eligibility to conduct human subjects research; notification to subjects regarding the non-compliance; and letters of reprimand to persons involved in the non-compliance.
- f) If the allegations also involve research misconduct (such as plagiarism or fabrication), the IRB Chair will report this to the Dean of the PI's school, as well as the Office of Research Integrity and Compliance.
- g) Reporting for Federal Oversight Agencies- The IO or designated official will notify the Office for Human Research Protections of any serious non-compliance issue, and when applicable, will report to the FDA or any relevant funding agencies any serious or continuing non-compliance issues, any unanticipated problems, or suspension or termination of IRB approval, within 30 days of completion of the review.
- h) The IRB has the authority to administratively halt, suspend, or terminate approval of a project which is not being conducted in accordance with the approved human subjects use protocol, UNT policies, or federal guidelines which provide oversight for human subjects research. The IRB authority to halt or terminate research is governed by 45 CFR 46.113. Any suspension or termination of research will include, in writing, the reasons for the IRB's decision and action, and will be reported to the IO, any funding agency or sponsor, and other applicable entities as warranted. The IO does not have the authority to reinstate a terminated or suspended protocol.

13) Coercion and Deception

- a) Deception is occasionally appropriate depending on the nature of the research project. Coercion (or undue influence) can come in many forms and should be avoided as it can negatively affect the university, the faculty researcher, and the research findings.
 - i) Deception
 - (1) Deception occurs in a research project when participants are not given all of the information, or may be given inaccurate information, for the purpose of the research project.

- (2) In the procedures of the protocol application, justification of why deception is being used should be included. Explain all methods and how deception will be handled.
 - (3) Debriefing is required if deception is used in a study. A debriefing statement that will be given or read to participants should be included as part of the application.
 - (4) In order for deception in a research project to be approved, the study must pose no more than minimal risk to participants.
 - (5) Research involving deception cannot be reviewed as “exempt”. It will involve, at the least, review by the IRB chair, and possibly the IRB full board as warranted.
- ii) Coercion
- (1) Per federal regulations, research should “minimize the possibility of coercion or undue influence (45 CFR 46.116).”
 - (2) Coercion occurs when a research participant is either implicitly or explicitly threatened in order to obtain compliance or participation in a research project. Undue influence involves pressure from either a financial gain in order to participate (such as excessive compensation), or influence from a manager or professor (such as ‘encouragement’ from a researcher to their students to participate in their research project).
 - (3) Occasionally excessive compensation is warranted, depending on the nature of the research protocol. Compensation types and amounts should be detailed on the research protocol, and the amount of compensation offered to each participant will be compared to the amount of expected participants. If financial compensation is being offered but no funding is being used for the research project, the protocol application should include how the compensation is being offered to participants, especially if the compensation is excessive based on individual amounts or the amount of expected participants.
 - (4) It is acceptable for professors to offer students extra credit or other non-monetary compensation for research participation. However, if they do they must also offer a non-research option to obtain the same non-monetary compensation, and the other option must be comparable to the amount of time/effort expected for the research project.

14) Class Projects

- a) Some class projects that involve human subjects may fall outside of the purview of the IRB review process, if they are conducted for educational purposes and do not meet the HHS definition of “research”. Educational purposes means the project is done with the intent of instructing students on research methodology. Class projects that involve systematic collection of data for which the design or objective is to develop or contribute to generalizable knowledge is considered research. If the student or the instructor plans to use the data outside of the classroom in any way, then the project is considered research and will require IRB review.
- b) There are some exceptions:

- i) The following project types do require IRB review:
 - (1) Undergraduate theses that may be presented in a professional venue
 - (2) Honor's theses
 - (3) Master's theses
- ii) Class projects that involve protected populations or sensitive information require IRB review and approval
 - (1) Protected populations include pregnant women, children, prisoners, people with mental or physical impairments.
 - (2) Sensitive information includes information related to psychological well-being and mental health, sexual behavior, use of alcohol or drugs, illegal behavior, protected medical information, or information that could place a person at risk for damaging respectability, discrimination, or damaged financial standing.
- c) The faculty instructor is ultimately responsible for overseeing all student projects, whether they require IRB approval or not. For projects that do require IRB review, the faculty member will act as PI and the student listed as a student investigator. In order to act as PI, the instructor must be a full-time faculty member who conducts research as part of their position. (Part-time or adjunct lecturers cannot act as PI.)
- d) If the project meets the definition of research:
 - i) The Faculty member should assist the student in preparing the IRB application.
 - ii) The Faculty member should ensure the student has obtained all necessary permission and documentation prior to the submission of the IRB application.
- e) If the project does not meet the definition of research:
 - i) It is up to the instructor (with the assistance of ORIC if needed) to determine the project does not require IRB review.
 - ii) The project should still be conducted with ethical standards.
 - iii) Personal information of any participants should still be protected. From the participant's perspective, their participation is no different whether it is a research project or a class project. A class project should not be labeled as a research project, as this can be misleading.
 - iv) Students should inform participants that their personal information will not be shared with outside sources and their data will be destroyed after the class project is complete.
- f) A class project, even if it does not meet the definition of 'research', should include a measure of informed consent for potential participants. An informed consent document should include that it is a class project and the purpose of the project, that participants must be 18 years old (minor participants require IRB review), how long the survey/interview, etc. will take, what is entailed with their participation, and the instructor's name and contact information if the participants have questions or concerns.

15) Research involving Tribal/American and Alaskan Native groups

- a) Proposed research which involves tribal or American Indian/Native Alaskan groups involves additional review and is regulated partially by a division of the Department of Health and Human Services called the Indian Health Service (IHS). Tribal sites fall under the IHS FWA and must be approved by the relevant IHS IRB.
- b) A list of the relevant IRBs are available on the IHS website- <https://www.ihs.gov/dper/research/hsrp/instreviewboards/>. Review and approval must be granted by the IRB for any research proposals involving the Native group. The UNT ORIC can provide guidance and assistance through this process if research involves a tribal or Native group. A protocol application should also be submitted for review by the UNT IRB, along with any IHS IRB approval already obtained or confirmation that you are working through the IHS procedures. Research proposals involving these groups will go through either an expedited or full-board review. Regardless of the risk level of the research, exempt review is not available.
- c) If the area or group you plan to research does not have a functioning IRB per the IHS website, the IRB application/research protocol should be emailed to IRB@ihs.gov.

16) Education and Training

- a) The IRB and the Office of Research Integrity and Compliance (ORIC) can provide information and services to the research community on continuing education related to human subjects research. The ORIC offers responsible conduct of research training and workshops on a variety of topics including human subjects research, and UNT subscribes to online training (such as CITI Program) which is offered free of cost to UNT affiliates.
- b) Educational Activities Aimed at Investigators and Research Personnel- The UNT Research webpage contains information on our available workshops and the available online training. As part of the research protocol application, any researcher associated with the study (from PI to key personnel) is required to have completed an online training course on human subjects research every three years. The online program available through CITI provides a certificate of completion as proof, which is required to be submitted as part of the application. The staff of the ORIC is also available to schedule either one on one or group training on submitting human subjects research protocols and the ethics of such research. Any in person or online training is available to all UNT faculty, staff, and students.
- c) Educational Activities Aimed at members of the IRB- At the time of induction of a new member to the IRB, they will be provided with copies of all relevant federal guidelines and UNT policies and procedures by the IRB Chair and the ORIC. The IRB members are welcome to attend any of the ORIC relevant workshops or training classes, as well as explore outside conferences and workshops.

17) Human Subjects Payments

- a) Compensation is often provided to facilitate the participation in and completion of research. If and how a participant is compensated often depends on the source of the funding, whether from a governmental grant or a small amount from the researchers themselves. For payments made to human subjects from UNT funds or from federal,

state, or locally funded grants, compensation received by a participant is considered taxable income, regardless of the amount, and the participants should be made aware that they are required to report any income gained from participant compensation to the IRS for tax purposes.

- b) Special Considerations- Participation through online survey aggregators like Mechanical Turk report earning directly for tax purposes, and this may affect participant privacy. Also, for research studies with larger compensation amounts such as seen with some longitudinal and medical studies, income over \$600 must be reported by UNT to the IRS. Since a participant's information is required in order to make these reports and to provide this compensation, it is important to stress that participants' information will be kept confidential but is not able to be anonymized. It is also suggested to add a statement regarding the IRS reporting requirement to the Informed Consent document.

18) Collaborative Research Projects

- a) The UNT IRB and Office of Research and Innovation is responsible for the oversight of any research which takes place on the UNT campus, which involves UNT students as participants, or involves research conducted elsewhere by UNT faculty and staff. If a researcher from another institution would like to conduct research on the UNT campus, they must partner with a faculty researcher from UNT and enter into an institutional authorization agreement (IAA), but only if the other institution is also governed by their own Federal welfare assurance. A full research protocol must be approved by one of the institution's IRB, and the IAA states that the other institution will act as IRB of Record for the proposed project. 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. An IAA cannot be initiated with an agency that does not have a federally approved human subjects research program.

19) Secondary Data Use and Data Use Agreements

- a) Human subjects research can involve review of already obtained data, either as the primary or secondary data source for a project. Some data is open-access, publicly available, and de-identified. Data use agreements are required for the access and transfer of some data that may or may not be de-identified or publicly available, and has some restriction on its use. Data use agreements (DUAs) are generally required in order to provide obligations to safeguard the data, establish limits as to how the data can be used, and providing liability to the original data holder for the subsequent research use of the data.
- b) If the data is derived from human subjects, an IRB protocol must be submitted for review along with the DUA from the institution providing the data. The protocol and data will be reviewed to determine whether or not data has been or will be properly de-identified, whether informed consent was properly given at the origination of the data collection, and if the proposed research is planning to use the data in the manner(s)

allowed by the DUA and providing institution. Whether or not a DUA is required is generally determined by the original data holder.

- c) Some funding agencies require data generated during a funded project be made publicly available to others, such as with NIH-funded clinical trials. However, some sponsored projects, such as with the DOD or with certain privately-owned sponsors, may have strict limits on who data can be shared with, when, and how. The PI should consult with the funding agency and with the ORIC before any data is released to an outside party.
- d) If any outside party requests data from a UNT PI or from a UNT-conducted human subjects research project, the PI should contact the Office of Research Integrity and Compliance for further guidance on whether or not data can be released or if a DUA is required.

20) Blood Drawing for Human Subjects Research

- a) Per the HHS Guidelines of Expedited review categories, studies with blood draws may be eligible for expedited review if they meet the following limits:
 - i) For healthy, non-pregnant adults who weigh at least 110 pounds. The amount drawn may not exceed 550 ml in an 8 week period and collection cannot occur more often than twice per week.
 - ii) For other adults and children (those under 18 years of age), with consideration of what is the health and relative weight of the subject, the amount drawn may not exceed the lesser amount of 50 ml or 3ml per kg in an eight week period, and collection cannot occur more often than twice per week.
 - iii) Protocols submitted that exceed these allowable time frames or draw limits are not eligible for expedited review and will require full board review.
- b) For full board review of a protocol with blood drawn for research purposes should meet the following limits:
 - i) For an adult, the amount of blood that may be drawn for research purposes should not exceed 5 ml/kg of body weight in any single 24 hour period, and 7 ml/kg of body weight in an eight week period. Any exceptions to these limits must have sufficient justification in the protocol application and the exceptions approved by the convened IRB.
 - ii) For a child, the amount of blood drawn for research purposes must not exceed 3 ml/kg of body weight in any single 24 hour period, and 7ml/kg of body weight in an eight week period. Any exceptions to these limits must have sufficient justification in the protocol application and the exceptions approved by the convened IRB.
- c) A subject with a clinical condition that may be adversely affected by blood draws, such as a person with anemia or a compromised cardiac condition, PIs should limit or restrict the amount of blood drawn in order to minimize harm to the subject. The IRB has the authority to limit the amount of blood drawn for research purposes, or to lower the limits from the upper limits described prior. Any exceptions on blood drawn for research purposes must be approved at a convened meeting of the full IRB.

21) FDA-Regulated Research

- a) Certain clinical research may be regulated by the Food and Drug Administration (FDA) if it involves certain medical devices, drugs, or food products or additives that currently fall under regulations managed or controlled by the FDA.
 - i) Investigational New Drug and Investigational Device Exemption
 - (1) For FDA funded or regulated research, the IRB review will include confirmation if the investigator or the Statement of Work (SOW), which is required as part of the submission for funded studies, states that an investigational new drug (IND) or investigational device exemption (IDE) is required. The study parameters and the SOW will be reviewed with the FDA per regulations 21 CFR 50 for protection of human subjects and 21 CFR Par 312 for INDs, and 21 CFR 817 for IDEs.
 - ii) These studies generally meet the requirements of clinical trials research, and may be subject to further data reviews and plans for clinical trials.
- b) Medical Device Studies
 - i) Proposed medical device studies should include documentation of the determination of whether the device study poses significant or non-significant risk.
 - ii) Per 21 CFR 812.3, a significant risk device is:
 - (1) Intended as an implant and presents a potential health or safety risk for the subject;
 - (2) Purported or represented to be for or used for the sustainment of human life and presents potential health, welfare, or safety risk to the subject;
 - (3) For a use of substantial importance in diagnosing, curing, mitigating, or treating disease or otherwise preventing impairment of human health, and presents potential health, welfare, or safety risk to the subject;
 - (4) Otherwise presenting a potential risk to the health, welfare, or safety of a subject.
 - iii) A non-significant risk device is one that does not meet the definition of a significant risk device.
 - iv) The sponsor is responsible for making the determination of whether the medical device meets the definition of a significant risk device. The FDA can also help make the risk determination.
 - v) These details should be included with the SOW and/or IRB application.
- c) Expanded Access or Treatment Use
 - i) Expanded access involves a medical device or investigational drug (otherwise not in current FDA approval) being provided to a patient or subject who may otherwise not be eligible for a clinical trial or research project inclusion. This is also known as compassionate use. IRB approval, possibly in the form of a modification, and informed consent of the subject are still required for any requests for expanded access, as the subject may fall outside of the normal eligibility parameters.
- d) Emergency Use
 - i) Per regulation 21 CFR 56.104(c), an investigational drug may be used in the event of a human subject experiencing a life-threatening situation for which there is or may

be no available alternative standard treatment. The FDA regulation allows for one use of the investigational drug for emergency use. However, the UNT IRB should be notified immediately prior to the planned use of the drug for emergency use, and any subsequent use must be approved by full board review of the modification request to the study. This notification should take place in writing to the UNT IRB Chair and to the Director of the ORIC.

e) Humanitarian Use Device (HUD)

- i) A HUD is defined by the FDA as a medical device intended to benefit patients in the treatment or diagnosis of a disease or condition that affects or is manifested in not more than 8,000 individuals in the United States per year. To request this determination, the IRB application must include the details and research data showing that the proposed device meet the qualification.
- ii) A device determined to be a HUD may qualify for Humanitarian Device Exemption (HDE). This exemption is defined to create a regulatory pathway for products intended for diseases that affect a small, or rare, population, and may be eligible for exemptions from effectiveness requirements for the marketing of certain devices, and exemptions from some restrictions on marketing and use restrictions.
- iii) If a device planned to be used may qualify as a HUD, this information should be included as part of the IRB application and may require full board review.

22) IRB Contingency Plan

- a) The IRB Contingency Plan is required to be in place in the event that the UNT IRB or the ORIC has been disrupted from normal duties and is unable to provide oversight to the UNT human subjects research program (i.e. if the IRB closes or is disbanded, suffers loss due to natural disaster like a tornado, or suffers loss due to fire). Personnel such as investigators who are unaffected by the disaster (such as a loss of buildings or equipment on campus) are still expected to follow normal processes on items like continuing review and reporting of unanticipated incidents. Once of the scope and duration of the disruption has been determined, a plan will be put in place for the oversight of ongoing projects and the timeline to return to normal operations. Depending on the nature and duration of the disruption, some projects may have to be halted or temporarily suspended if normal oversight is not possible for an extended duration. The IRB and ORIC will work with the IO and/or VPR to communicate timelines to investigators on when normal oversight will resume.
- b) In the event of a disruption that is expected to be extended (disruptions could last weeks or months depending on the nature of the disaster or disruption), the UNT IRB and ORIC may transfer oversight of active protocols due other institutions, such as the UNT Health Science Nature. Any change in oversight will be documented and communicated to investigators as possible and applicable. Any disruptions or change in oversight of the IRB or UNT Human subjects research program will also be communicated to the HHS per the federal welfare assurance.

- c) Personnel changes to the membership of the IRB may be sudden and unexpected. If a member is lost or must leave the IRB without immediate replacement, an alternate may be asked to temporarily fill in for the lost member until they are officially replaced. Any replacement or reconstitution of the IRB, even if temporary, must meet the HHS qualifications for a constituted IRB. If the IRB Chair leaves or is removed from the board, the Vice Chair may be asked to serve in the role of Chair temporarily until the Chair is officially replaced.

23) International Research

- a) Additional review and documentation is required when conducting research outside of the United States.
- b) If human subjects research is being conducted by a faculty, staff, or student from the University of North Texas, regardless of location, an application must be submitted to the IRB for review. This includes locations overseas/outside of the United States, even if those locations or countries do not have a standard human subjects review or process of their own.
- c) If research is conducted outside of the United States, all investigators must comply with both United States regulations on human subjects research, and the regulations of the country within which they are conducting research. It is recommended for the investigator to make themselves familiar with the guidelines of that country, and for the US investigator to work with a local collaborator in the other country. Some countries require an ethics committee or the equivalency of a local ethics board to review and approve research which involves human subjects.
- d) Minimal Risk (Exempt) studies
 - i) If it is determined that the regulations of the foreign country do not require an ethics review of a minimal risk study, a 'memo of cultural appropriateness' should be obtained to ensure that the proposed project does not interfere with or will not be an affront to the local culture's societal norms. The memo should be written by someone who is not associated with the research study but has the knowledge or expertise on the local culture. The memo should include the following:
 - (1) The date
 - (2) The name and title of the author
 - (3) The title of the research project
 - (4) A brief description of the author's expertise and experience
 - (5) A brief description of the research project showing the author's understanding of the protocol
 - (6) A statement that the author attests the appropriateness of the research project and that it is not in conflict of local societal norms
 - (7) A signature of the author
 - ii) In addition to the memo, the protocol application should also include documentation that the country's regulations does not require any official local ethics review. This could be a direct evidence to the local regulations or a letter from

- the proposed foreign research site, provided on a letterhead of the organization/institution which states that further ethics review is not required. The document should be signed and dated, and include the protocol's information and a brief confirmation that the author understands the nature of the proposed research project.
- iii) If the proposed project is minimal risk, but the country DOES require ethics review, a letter of approval from the local ethics committee is required. The letter of approval should include the following:
 - (1) The title of the study
 - (2) A statement describing that the proposed research project was deemed to be minimal risk
 - (3) Clearly state that the research has been approved to commence by the local ethics committee
 - (4) Document should be signed and dated
 - (5) Letter should be on the letterhead of the committee's signatory
 - e) Greater than minimal risk (expedited and full board) studies
 - i) For research than exhibits more than minimal risk (expedited or full board projects), a letter of approval by an ethics committee is required from the foreign agency where the research is taking place. Not all countries have formal ethics review committees, so a review may need to be conducted by a Department of Ministries or alternative government entity. The letter of approval must include the following:
 - (1) The title of the research project
 - (2) Clearly statement(s) that the project has been reviewed and is approved
 - (3) A signature and date
 - (4) Letter on the official letterhead of the signatory.
 - f) Just as with research conducted in the United States, approval letters must be provided for any and all locations where research may take place. The site permission letters should include the title of the study, signature and date, and a statement confirming that the site is approved to be a research location.
 - g) Non-English speaking participants
 - i) Investigators should have a plan for managing communications with non-English speaking participants. All documentation that a participant may see (informed consent document, survey questions, etc.), should be submitted in English and the language of potential participants. Proof should be provided of who completed the translation and their qualifications. The English and translated documents will both need to be approved as part of the IRB application.
 - h) International research guidelines- Since regulations and guidelines on research can vary from country to country, it is important to ensure that you are following the regulations of the county where research will be conducted. The OHRP website contains links and information regarding different foreign research standards-
<https://www.hhs.gov/ohrp/international/index.html>.

- i) Locating a Foreign Ethics Committee
 - i) Research studies which are being funded by US federal funds are required to undergo foreign IRB review by an ethics committee which holds a Federal Welfare Assurance. Registered IRBs and FWAs can be searched for online at <https://ohrp.cit.nih.gov/search/fwasearch.aspx?styp=bsc>.
 - ii) Research studies which are not being funded by US federal funds can search online for a proper oversight committee- <https://ohrp.cit.nih.gov/search/irbsearch.aspx?styp=bsc>.
- j) Processing time for IRB application involving international participants
 - i) IRB approval times can vary and there is no set time frame for a project to be approved. It is up to the investigator(s) to ensure they have submitted their application early as some approvals can take months depending on the review level and the permissions and ethics review required from the international site. Travel plans and airline tickets for investigators traveling to the international site should not be done until permissions and approvals have been obtained.
- k) Items to be included or questions to be answered as part of application relevant to international sites
 - i) Is the research being conducted in a county or at a cultural site (e.g. Native American communities), where the cultural norms and backgrounds are very different to the UNT community surrounding communities?
 - ii) The following information should be included:
 - (1) Name of site
 - (2) Name and title of authorized individual who is acting as signatory or approver for foreign ethics committee
 - (3) Name and information of international site collaborator (as applicable)
 - (4) Anticipated number of subjects
 - (5) FWA number of the international site if the project is federally funded
 - iii) Provide descriptions of the international sites cultural norms and highlight differences from standard U.S. culture. Also include the age of participants (including rules on age limits for minors if it differs from U.S. norms).
 - iv) Describe any aspects of the local culture that may increase the level of risk or increase potential harm for participants or researchers. Describe the steps you will take to minimize these risks.
 - v) Will all individuals be able to read or comprehend English? If not, provide details on how you will manage communication with participants.
 - vi) If translated documents or a translator is to be used, provide proof of credentials for the translator.
 - vii) Explain how rules of confidentiality and privacy differ from U.S. regulations, and how you will manage subject confidentiality.

viii) If research is being conducted by a student investigator, explain the PI's involvement, what their role will be, and how they will manage and oversee the research if being conducted at an international site.

24) Definitions

- a) Research- a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge. Activities that meet this definition as stated in 45 CFR 46.102 are defined as research, whether or not they are conducted in accordance with normally accepted research practices. Generally any plan to disseminate the data or findings outside of the university means that research has taken place and meets the HHS definition of generalizable knowledge and research.
- b) Human subject- a living individual about whom an investigator (whether a professional full-time researcher or student investigator) obtains either: data (including bioinformatics) through intervention or interaction with the individual participant; or identifiable private information.
 - i) The secondary use of previously obtained data which meets this definition requires an IRB application.
- c) Intervention- physical procedures (such as venipuncture) through which data is gathered, or through manipulations of the subject or the subject's environment that are performed and for which the activity meets the requirements and definition of research.
- d) Private Information- information about behavior that occurs in a context where an individual has a normal expectation of privacy, such as a medical record. Private information must be individually identifiable (meaning the identity of the individual could be readily ascertained by the PI or the identity is associated with the data) in order for obtaining this information to constitute research involving human subjects.
- e) IRB- an institutional review board established to meet the requirements of the Federal welfare assurance and to assist with overseeing a human subjects research program.
- f) Human subjects research- any activity that meets the HHS definition both research and human subjects is considered human subjects research.
- g) Unanticipated problem- per the OHRP, an unanticipated problem is an incident, experience or outcome that meets all of the following criteria:
 - i) Unexpected (in terms of the nature or severity) given that research procedures described in the approved IRB protocol and the informed consent, and the characteristics of the subject population in the study;
 - ii) Related to or possibly related to participation in the research (meaning that the incident may have been caused by the interventions or activities of the research project);
 - iii) And suggests that the research places subjects at a greater risk of harm than was previously known or recognized.
- h) Confidentiality- the plan or intention to keep a subject's information (whether data or biological samples) secret and to protect their identity.

- i) Assent- a child's affirmation and agreement to participate in a study. Does not supersede or negate the need for their legal guardian's full informed consent.
- j) Bioinformation- information obtained from a person's physiological or biological characteristics (such as DNA or fingerprints).
- k) Medical device- Technology used to aid participants with certain physical or medical needs (such as wheelchairs, pacemakers).