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| Policies of the University of North Texas at Dallas | Chapter 13 |
| 13.017 Protection of Human Subjects in Research | Research |

Policy Statement. The University of North Texas at Dallas (UNT Dallas) is committed to protecting the rights and welfare of human subjects who participate in research. UNT Dallas has an organized and systematic program in place for the protection of research subjects that includes adherence to the principles and guidelines for protecting research subjects as set forth in the Belmont Report. The National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research created the Belmont Report and published it in the Federal Register on April 18, 1979. The Belmont Report sets the foundational standard regarding ethical principles and guidelines for research involving human subjects. Based on the fundamental principles of the Belmont Report – respect for persons, beneficence, and justice – the over-arching goal of the human subjects research program at UNT Dallas is to protect the rights and welfare of human subjects involved in research conducted at UNT Dallas, funded by UNT Dallas or otherwise associated with UNT Dallas.

Application of Policy.

This policy applies to all faculty, staff, students, and affiliated personnel of UNT Dallas when engaging in research on the UNT Dallas campus, funded by UNT Dallas, or otherwise associated with UNT Dallas. This policy applies to both funded and non-funded human subject research.

Definitions.

1. **Affiliated Personnel.** “Affiliated personnel” are individuals who are not UNT Dallas faculty, employees or students but have a professional relationship with UNT Dallas, such as visiting faculty, visiting postdoctoral fellows, volunteers and other scholars. The North Texas Regional IRB will have oversight of human subject research activities of affiliated personnel when conducting research at UNT Dallas or when funded by UNT Dallas or otherwise associated with UNT Dallas, unless North Texas Regional IRB determines that the research is being appropriately overseen by another IRB.

2. **Clinical Investigation.** “Clinical investigation” has the meaning set forth in 21 C.F.R. § 50.3, and means any experiment that involves a test article and one or more individuals who participate, either as a recipient of the test article or as a control; and that either is subject to requirements for prior submission to the FDA under sections 505(i) or 520(g) of the Food, Drug and Cosmetics Act, or is not subject to requirements for prior submission to the FDA under these sections of the Food, Drug and Cosmetics Act, but the results of which are intended to be submitted later to, or held for inspection by, the FDA as part of an application for a research or marketing permit.

3. DHHS. "DHHS" means the U.S. Department of Health and Human Services.
4. Exempt Research. "Exempt research" means Research exempt from IRB review under Federal Policy or FDA regulations.
5. FDA. "FDA" means the United States Food and Drug Administration.
6. Federal Policy. "Federal policy" means the Federal Policy for the Protection of Human Subjects set forth in the DHHS regulations at 45 CFR Part 46, and corresponding regulations of other federal departments and agencies adopting such policy.
7. Federalwide Assurance. "Federalwide Assurance" or "FWA" means a formal, written, and binding attestation in which UNT Dallas commits to DHHS that it will comply with applicable Federal Policy. The FWA obligates UNT DALLAS to review and approve research involving human subjects in accordance with the ethical principles outlined in the Belmont Report and federal regulations at 45 CFR part 46.
8. HIPAA. "HIPAA" means collectively, the Health Insurance Portability and Accountability Act of 1996, the Health Information Technology for Economic and Clinical Health Act of 2009, and their implementing regulations.
9. Human Subject. "Human subject" has the meaning set forth in 45 C.F.R. §46.102 and means a living individual about whom an investigator (whether professional or student) conducting research obtains: (a) data through intervention or interaction with the individual; or (b) identifiable private information.
10. Institutional Review Board (IRB). "Institutional Review Board" means the committee that is responsible for reviewing research activities involving the use of human subjects to assure the protection of the rights and welfare of human subjects. The function of the IRB is to ensure adherence to all federal, state, local, and institutional regulations concerning the protection of human subjects in research.
11. Interaction. "Interaction" includes communication or interpersonal contact between investigator and subject.
12. Intervention. "Intervention" includes both physical procedures by which data are gathered (e.g., venipuncture) and manipulations of the subject or the subject's environment that are performed for research purposes.
13. IRB of Record. "IRB of Record" means the IRB that assumes responsibility for providing IRB services for a Research project or study, is designated to do so through an approved FWA on file with OHRP (when applicable) and is registered with OHRP.

14. Legal Requirements. “Legal Requirements” means all federal, state and local statutes, ordinances, codes, rules, regulations, restrictions, orders, judgments, writs, injunctions, decrees, determinations or awards of any governmental authority having jurisdiction over UNT Dallas, or UNT Dallas’ assets or operations.
15. North Texas Regional IRB. “North Texas Regional IRB” means the IRB created and operated by the University of North Texas Health Science Center at Fort Worth (“UNTHSC”). UNT Dallas has contracted with UNTHSC for the North Texas Regional IRB to provide the IRB services needed by UNT Dallas.
16. North Texas Regional IRB Principles and Procedures Manual. “North Texas Regional IRB Principles and Procedures Manual” is the document containing the guiding principles and standard operating procedures (SOPs) for North Texas Regional IRB that are required to be followed by faculty, staff, students, and affiliated personnel of UNT Dallas when involved in research.
17. OHRP. “OHRP” means the Office for Human Research Protections of DHHS.
18. Principal Investigator. “Principal Investigator” or “PI” means the person who is faculty, staff or affiliated personnel of UNT Dallas and who has ultimate responsibility for the conduct and integrity of a research project or study.
19. Private information. “Private information” includes information about behavior that occurs in a context in which an individual can reasonably expect that no observation or recording is taking place, and information which has been provided for specific purposes by an individual and which the individual can reasonably expect will not be made public (for example, a medical record). Private information must be individually identifiable (i.e., the identity of the subject is or may readily be ascertained by the investigator or associated with the information) in order for obtaining the information to constitute research involving human subjects.
20. Protocol. “Protocol” is a document (including subsequent amendments) that describes the research design or methodology to be employed, the eligibility requirements for prospective subjects and controls, the treatment regimen(s), and the proposed methods of analysis that will be performed on collected data. A Protocol usually also gives the background and rationale for a human subjects research project or study, but this also could be provided in other protocol reference documents.
21. Research. “Research” means any human subject research within the meaning of the Federal Policy or within the meaning of any other federal human subject research regulations or policies; clinical investigations within the meaning of the FDA IRB regulations; and any other research project or study for which a participating member institution requests IRB review services by North Texas Regional IRB. Research also means a systematic investigation, including research development, testing and

evaluation, designed to develop or contribute to generalizable knowledge (see 45 C.F.R. §46.102); or a Clinical Investigation. Activities which meet this definition constitute research for purposes of this policy, whether or not they are conducted or supported under a program which is considered research for other purposes. For example, some demonstration and service programs may include research activities.

22. Research Personnel. “Research Personnel” means members of the research team for a research project or study (including the PI) engaged or involved in a research project or study and who are at UNT Dallas. These individuals may include, as applicable, physicians, research nurses, coordinators, data managers, lab technicians, postdoctoral fellows, students, volunteers and/or other personnel.

Procedures and Responsibilities.

1. Human subject research conducted at UNT Dallas or with UNT Dallas resources, or otherwise associated with UNT Dallas shall be guided by the principles set forth in the Belmont Report and shall be conducted in accordance with applicable legal requirements, this policy and other applicable UNT Dallas policies, the North Texas Regional IRB Principles and Procedures Manual, and IRB requirements related to a specific research project or study.

Responsible Party: All faculty, staff, students, agents and affiliated personnel of UNT Dallas when engaging in research on the UNT DALLAS campus, funded by UNT Dallas, or otherwise associated with UNT Dallas. This shall include but not be limited to all PIs, Research Personnel, and Office of Sponsored Projects Personnel.

2. The Provost and Executive Vice President for Academic Affairs shall act as the signatory official for UNT Dallas on UNT Dallas’ FWA and for UNT Dallas assurances provided to OHRP, DHHS and other federal agencies.

Responsible Party: Provost and Executive Vice President for Academic Affairs

3. The North Texas Regional IRB shall provide IRB review for all research studies involving human subjects that are conducted on the UNT Dallas campus, that are funded by UNT Dallas, or that otherwise involve UNT Dallas unless the North Texas Regional IRB determines that the research is being appropriately overseen by another IRB. The specific IRB services provided by North Texas Regional IRB include the following:

- Exempt research determinations;
- review and approval or disapproval of new research protocols (a specific protocol shall be developed for each research project or study involving human subjects and must be approved by North Texas Regional IRB prior to the PI or research personnel initiating research);

- review and approval, disapproval or modification of consent forms/parental permission forms/assent forms or waivers or alterations thereof;
- review and approval or disapproval of modifications to research protocols;
- review and approval or disapproval of the PI and other personnel engaged in research and changes in UNT Dallas research;
- collection of reports of unanticipated problems and serious or continuing noncompliance associated with UNT Dallas research and determining whether such reports are required to be reported to appropriate federal agencies, oversight agencies, or funding entities;
- maintenance of required IRB records of UNT Dallas research pursuant to applicable federal policy, governing FDA regulations, and legal requirements;
- continuing review of UNT Dallas research projects and studies appropriate to the degree of risk in such projects and studies. North Texas Regional IRB shall conduct at least an annual review of each UNT Dallas non-exempt research project or study or as specified by federal regulations;
- addressing HIPAA research related considerations that relate to review of UNT Dallas research;
- suspending or terminating IRB approval of UNT Dallas research when research is not being conducted in accordance with IRB requirements or has been associated with unexpected serious harm to subjects and providing notification to applicable federal agencies, oversight agencies or funding entities when required or appropriate;
- review and approve use of humanitarian use devices;
- review and approve emergency use of a test article;
- review and approve requests for compassionate use of a test article;
- observe or have a third party observe the consent process and the research; and
- other services as required by the UNT Dallas Research Office.

Responsible Party: Office of Sponsored Projects shall ensure that IRB services are provided by the North Texas Regional IRB

4. The Principal Investigator is responsible for submitting human subjects research protocols and proposed protocol modifications to North Texas Regional IRB for approval or a determination that the human subject research is exempt from IRB review. Principal Investigators and other research personnel may not make their own determination regarding whether a protocol or proposed modification is exempt from IRB review. All submissions for North Texas Regional IRB approval of a research project or study must be made on the standard form as designated by North Texas Regional IRB and available on the North Texas Regional IRB website. UNT Dallas human subjects research may not be conducted if it has not been approved by North Texas Regional IRB or if North Texas Regional IRB has suspended or terminated its approval of a research project or study.

Responsible Party: All faculty, staff, students, and affiliated personnel of UNT Dallas when engaging in research on the UNT Dallas campus, funded by UNT Dallas, or otherwise associated with UNT Dallas. This shall include but not be limited to all PIs and Research Personnel.

5. The Office of Sponsored Projects and North Texas Regional IRB shall take action to mitigate or eliminate financial conflicts of interest that have the potential to affect the rights and welfare of human subjects in research. Reviews by the Office of Sponsored Projects and the North Texas Regional IRB will be conducted objectively and in a manner that promotes the exercise of independent judgment. All PIs and research personnel shall comply with UNT DALLAS policy No. 13.009, *Professional Commitment and Conflicts of Interest in Research*.

Responsible Party: Office of Sponsored Projects Personnel; PIs and Research Personnel.

6. The North Texas Regional IRB shall approve research protocols or proposed modifications to existing protocols only if a determination is made that the following requirements as set forth in 45 CFR § 46.111 are satisfied:
 - a. Risks to subjects are minimized: (i) by using procedures which are consistent with sound research design and which do not unnecessarily expose subjects to risk, and (ii) whenever appropriate, by using procedures already being performed on the subjects for diagnostic or treatment purposes.
 - b. 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, North Texas Regional IRB 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). North Texas Regional IRB will not consider possible long-range effects of applying knowledge gained from research (for example, the possible effects of the research on public policy) as among those research risks that fall within the purview of its responsibility.
 - c. Selection of subjects is equitable. In making this assessment North Texas Regional IRB will take into account the purposes of the research and the setting in which the research will be conducted and should be particularly cognizant of the special problems of research involving vulnerable populations, such as children, prisoners, pregnant women, mentally disabled persons, or economically or educationally disadvantaged persons.
 - d. Informed consent will be sought from each prospective subject or the subject's legally authorized representative, in accordance with 45 C.F.R. § 46.116.

- e. Informed consent will be appropriately documented on a form approved by North Texas Regional IRB, in accordance with 45 C.F.R. § 46.117.
- f. When appropriate, the research plan shall make adequate provision for monitoring the data collected to ensure the safety of subjects.
- g. When appropriate, there are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data.
- h. When some or all of the subjects are likely to be vulnerable to coercion or undue influence, such as children, prisoners, pregnant women, mentally disabled persons, or economically or educationally disadvantaged persons, North Texas Regional IRB will determine prior to approving the research that additional safeguards have been included in the project or study to protect the rights and welfare of these subjects.

Responsible Party: Office of Sponsored Projects in conjunction with the North Texas Regional IRB

- 7. PIs and research personnel are responsible for ensuring adequate human subject protection in the course of their interactions with human subjects and/or identifiable private information. The PI is the principal point of contact with North Texas Regional IRB and is responsible for overseeing compliance with IRB requirements to maintain IRB approval for the life of a project or study. The PI and research personnel will adhere to an approved protocol except when non-adherence is necessary to eliminate immediate safety hazards to human subject participants. The PI and research personnel are responsible for notifying North Texas Regional IRB and the Office of Sponsored Projects of any deviation from the approved protocol or failure to comply with IRB requirements as soon as they become aware of such deviation or noncompliance. Performing human subjects research in violation of the approved protocol or without IRB approval is a serious breach of conduct and is subject to disciplinary action up to and including termination.

Responsible Party: Principal Investigators and Research Personnel

- 8. Faculty, staff, students, and affiliated personnel of UNT Dallas who wish to conduct human subjects research are responsible for completing training regarding human subjects research as required by North Texas Regional IRB and the Office of Sponsored Projects. For PIs, training shall include but not be limited to education on the protection of human subjects that the National Institutes of Health (NIH) requires for all investigators submitting NIH applications for research involving human subjects.

Responsible Party: Faculty, staff, students and affiliated personnel of UNT

DALLAS; Principal Investigators and Research Personnel

9. North Texas Regional IRB shall maintain appropriate, adequate and informative records of IRB activities, in accordance with the standards set forth in 45 C.F.R. § 46.115, and as required by the Texas Public Information Act, including but not limited to copies of all research protocols reviewed, minutes of IRB meetings, and records of continuing review activities. These records shall be retained for at least 3 years, and records related to conducted research shall be retained for at least 3 years after completion of the research.

Responsible Party: Office of Sponsored Projects in conjunction with NORTH TEXAS REGIONAL IRB; PIs and Research Personnel.

10. Allegations of noncompliance with applicable legal requirements, this policy, the North Texas Regional IRB Principles and Procedures Manual, IRB requirements for a particular research project or study or any safety concern regarding human subject research may be submitted to the North Texas Regional IRB, the Office of Sponsored Projects, the Provost and Executive Vice President for Academic Affairs, or the Executive Director of the Office of Sponsored Projects. Anyone who receives an allegation of noncompliance shall promptly notify the UNT Dallas Executive Director of the Office of Sponsored Projects of such allegation for review and resolution as appropriate. Allegations of noncompliance may be further referred to appropriate and relevant institutional officials to aid in review and resolution or for possible corrective action.

Responsible Party: Office of Sponsored Projects in conjunction with the North Texas Regional IRB; Provost and Executive Vice President for Academic Affairs, and the Executive Director of the Office of Sponsored Projects

References and Cross-references.

- North Texas Regional IRB Principles and Procedures Manual
- The Belmont Report
- Federal Policy for the Protection of Human Subjects (“Common Rule”)
- Department of Health and Human Services, Code of Federal Regulations Title 45 Part 46 (Protection of Human Subjects)
- Food and Drug Administration, Code of Federal Regulations Title 21 Part 50 (Protection of Human Subjects)
- Food and Drug Administration, Code of Federal Regulations Title 21 Part 54 (Financial Disclosure by Clinical Investigators)
- Food and Drug Administration, Code of Federal Regulations Title 21 Part 56 (Institutional Review Boards)
- Public Health Service, Code of Federal Regulations Title 42, Part 50 (Responsibility of Applicants for Promoting Objectivity in Research for which PHS Funding is Sought)

Forms and Tools.

- See North Texas Regional IRB website for latest version of appropriate IRB forms and templates.

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