

The University of North Texas at Dallas Policy Manual	Chapter 13.000
13.001 Use of Human Subjects in Research	Research

Policy Statement. The University of North Texas at Dallas is committed to safeguarding the rights and welfare of human subjects involved in research studies in order to minimize the risks to human subjects, ensure that all human subjects are fully informed about the research and any related risks, and ensure equity in the selection of human subjects. UNT Dallas recognizes and accepts responsibility, which is shared between the institution and its research investigators, for determining that research involving human subjects fulfills the ethical principles set forth in applicable federal regulations, state and local laws, and institutional guidelines.

Application of Policy. All UNT Dallas faculty, staff and students shall comply with this policy. This policy applies to both funded and non-funded human subject research conducted at UNT Dallas, or at any other location if conducted by UNT Dallas faculty, staff or students under the auspices of UNT Dallas. This policy also applies if human subject research is conducted by UNT Dallas faculty, staff or students through a subcontractor or collaborator.

Definitions.

1. **Human Subject.** "Human subject" 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.
2. **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.
3. **Interaction.** "Interaction" includes communication or interpersonal contact between investigator and subject.
4. **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.
5. **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.

6. Research. "Research" means a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge. 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.

Procedures and Responsibilities.

1. Human subject research at UNT Dallas shall comply with applicable federal statutes and regulations. The Provost is the UNT Dallas official with responsibility for oversight of use of human subjects research conducted at or under the auspices of UNT Dallas. The UNT Dallas Provost shall act as the signatory official for assurances with the U.S. Department of Health & Human Services/Office of Human Research Protections.

Responsible Party: UNT Dallas Provost

2. The UNT IRB shall review all UNT Dallas proposals for the use of human subjects in research; notify UNT Dallas investigators in writing of its decision to approve or withhold approval of proposals or modifications of ongoing activities; and direct and review investigations of human subject protection concerns and direct corrective action as necessary.

Responsible Party: UNT IRB

3. When conducting human subject research, faculty, staff and student responsibilities include:
 - i. Completing and submitting an application in accordance with UNT's IRB Guidelines when seeking approval of a proposed human subjects research protocol. IRB approval must be obtained before initiating, modifying, or expanding any research project using human subjects.
 - ii. Obtaining IRB approval prior to implementing any changes to the approved protocol or informed consent form, except in an emergency if necessary to safeguard the well-being of human subjects;
 - iii. Reporting to the IRB any serious or unexpected adverse events related to

human subjects participation or any problems or incidents related to the conduct of an approved protocol or human subjects participation within 10 working days of having become aware of the event. However, any abuse or neglect that adversely affects a minor's physical or mental health or welfare also must be reported immediately to local or state law enforcement authorities or to the Texas Department of Family and Protective Services as provided in UNT Dallas Policy No. 5.032, Reporting Child Abuse and Neglect, and reporting such event to the IRB or any other university official does not fulfill this legal reporting requirement; and

- iv. Considering racial, cultural, and gender diversity among the subject populations and be sensitive to community attitudes in both the design and conduct of research involving humans.

Responsible Party: UNT Dallas Faculty, Staff and Students

4. Principal Investigators have the ultimate responsibility for the conduct of the research, the ethical performance of the research project, the protection of the rights and welfare of human subjects involved in research, and the strict adherence to any stipulations imposed by the IRB. A Principal Investigator must be a UNT Dallas faculty member or a UNT Dallas staff employee. The principal investigator must ensure that all key personnel for a research project are qualified, appropriately trained, and will adhere to the provisions of the approved protocol.

Responsible Party: UNT Dallas Faculty or Staff Member designated as the Principal Investigator by the UNT IRB

5. Any research activities carried out through a subcontractor or collaborator require the subcontractor or collaborator to certify that the use of human subjects in research has been approved by the IRB at the subcontractor's or collaborator's institution.

Responsible Party: UNT Dallas Faculty, Staff and Students and UNT Dallas Subcontractors and Collaborators

6. Student class assignments are generally not systematic data collection efforts intended to develop or contribute to generalizable knowledge. Accordingly, such assignments do not meet the federal regulatory definition of "research" and IRB application, approval and oversight is not needed. The course instructor is responsible for ensuring that the privacy and safety of human subjects involved in such class assignment projects are adequately protected.

However, when student class assignments are designed as systematic investigations designed to develop or contribute to generalizable knowledge, such a publication in an academic journal, then such assignments are "research" and do fall within the

jurisdiction of the IRB. Faculty members wishing to use class assignments as generalizable knowledge must apply to the UNT Institutional Review Board and obtain approval of these assignments before any data are collected from human subjects.

Responsible Party: UNT Dallas Faculty

7. Action in violation of this policy is subject to possible corrective action by the UNT Dallas Provost or UNT IRB that includes, but is 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.

The UNT IRB and the UNT Dallas Provost are responsible for determining if non-compliance is required to be reported to the federal Office for Human Research Protections and/or to the sponsoring agency or entity.

Responsible Party: IRB Chair and UNT Dallas Provost

8. UNT Dallas faculty, staff and students are responsible for notifying the UNT Dallas Provost regarding IRB-related concerns about human subjects research studies conducted at UNT Dallas or at any other location under the auspices of UNT Dallas. The UNT Dallas Provost shall notify the UNT IRB of all such IRB-related concerns.

Responsible Party: UNT Dallas Faculty, Staff and Students

References and Cross-references.

45 C.F.R. Part 46 -- Protection of Human Subjects, Subparts A, B, C, and D.

UNT Federal wide Assurance of Compliance (FWA) with DHHS, Office of Human Research Protections (OHRP)

UNT Dallas Policy No. 5.032, Reporting Child Abuse and Neglect

Office for Human Research Protections (OHRP) Policy Guidance

Forms and Tools.

Forms and instructions to be used by UNT Dallas faculty, staff and students when submitting proposals to the UNT IRB are available at: <http://research.unt.edu/ors/compliance/human.htm>

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