

Policies of the University of North Texas	Chapter 13
13.004 Use of Human Subjects in Research	Research

Policy Statement. The University of North Texas 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 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 faculty, staff and students shall comply with this policy. This policy applies to both funded and non-funded human subject research conducted at UNT, or at any other location if conducted by UNT faculty, staff or students under the auspices of UNT. This policy also applies if human subject research is conducted by UNT 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.

Human subject research at UNT shall comply with applicable federal statutes and regulations. The Vice President for Research and Economic Development is the UNT official with responsibility for oversight of use of human subjects research conducted at or under the auspices of UNT. The UNT Vice President for Research and Economic Development 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 Vice President for Research and Economic Development

The UNT IRB shall review all proposals for the use of human subjects in research; notify 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

When conducting human subject research, faculty, staff and student responsibilities include:

1. 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.
2. 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;
3. 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; and

4. considering racial, cultural, and gender diversity among the subject populations and being sensitive to community attitudes in both the design and conduct of research involving humans.

Responsible Parties: UNT Faculty, Staff and Students

An Investigator must be a full-time UNT faculty member or a full-time UNT staff employee whose job responsibilities include conducting human subjects research. Investigators, as defined here, 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. The Investigator must ensure that all key personnel (including Student Investigators) for a research project are qualified, appropriately trained, and will adhere to the provisions of the approved protocol. Student theses and dissertations involving human subjects research must be conducted under the direction of a Supervising Investigator (an Investigator, as defined here, who supervises the Student Investigator).

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

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 Faculty, Staff and Students and UNT Subcontractors and Collaborators

Student Class Assignments. 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 Faculty

Sanctions for Non-compliance. Action in violation of this policy is subject to possible corrective action by the 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 Vice President for Research and Economic Development 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 and UNT Vice President for Research and Economic Development

Reporting IRB Concerns. UNT faculty, staff and students are responsible for notifying the UNT IRB regarding IRB-related concerns about human subjects research studies conducted at UNT or at any other location under the auspices of UNT.

Responsible Party: UNT 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)

[Office for Human Research Protections \(OHRP\) Policy Guidance](#)

Forms and Tools.

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

Approved: 09/01/1983

Effective:

Revised: 08/94; 11/98*; 07/02; 01/05; 09/22/11

*Reviewed with no change

