



Policy Chapter: Chapter 13 Research and Innovation

Policy Number and Title: 13.004 Use of Human Subjects in Research

I. 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.

II. 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.

III. Policy Definitions

A. Human Subject

“Human subject,” in this policy, means a living individual about whom an investigator (whether professional or student) conducting research: (a) obtains information or biospecimens through intervention or interaction with the individual, and uses, studies, or analyzes the information or biospecimens; or (b) obtains, uses, studies, analyzes, or generates identifiable private information or identifiable biospecimens.

B. Institutional Review Board (IRB)

“Institutional Review Board,” in this policy, 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.

C. Interaction

“Interaction,” in this policy, means the communication or interpersonal contact between investigator and subject.

D. Intervention

“Intervention,” in this policy, means both physical procedures by which data or biospecimens are gathered (e.g., venipuncture) and manipulations of the subject or the subject's environment that are performed for research purposes.

E. *Private information*

“Private Information,” in this policy, means 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).

F. *Identifiable Private Information*

“Identifiable Private Information,” in this policy, means private information for which the identity of the subject is or may readily be ascertained by the investigator or associated with the information.

G. *Identifiable Biospecimen*

“Identifiable Biospecimen,” in this policy, means a biospecimen for which the identity of the subject is or may readily be ascertained by the investigator or associated with the biospecimen.

H. *Research*

“Research,” in this policy, 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.

The following activities are deemed not to be research per the federal definition of “Research”:

1. Scholarly and journalistic activities (e.g., oral history, journalism, biography, literary criticism, legal research, and historical scholarship), including the collection and use of information, that focus directly on the specific individuals about whom the information is collected.
2. Public health surveillance activities, including the collection and testing of information or biospecimens, conducted, supported, requested, ordered, required, or authorized by a public health authority. Such activities are limited to those necessary to allow a public health authority to identify, monitor, assess, or investigate potential public health signals, onsets of disease outbreaks, or conditions of public health importance (including trends, signals, risk factors, patterns in diseases, or increases in injuries from using consumer products). Such activities include those associated with providing timely situational awareness and priority setting during the course of an event or crisis that threatens public health (including natural or man-made disasters).
3. Collection and analysis of information, biospecimens, or records by or for a criminal justice agency for activities authorized by law or court order solely for criminal justice

or criminal investigative purposes.

4. Authorized operational activities (as determined by each agency) in support of intelligence, homeland security, defense, or other national security missions.

IV. Policy Responsibilities

A. Human Subject Research Oversight

Human subject research at UNT shall comply with applicable federal statutes and regulations. The Vice President for Research and Innovation 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 Innovation shall act as the signatory official for assurances with the U.S. Department of Health & Human Services/Office of Human Research Protections.

B. Use of Human Subjects

1. Approval

The UNT Institutional Review Board (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.

2. Responsibilities

When conducting human subject research, faculty, staff, collaborators conducting research under the oversight of UNT IRB, and students are responsible for:

- a. 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;
- b. obtaining IRB approval prior to implementing any changes to the approved protocol or informed consent form, except when necessary to eliminate apparent immediate hazards to the subjects;
- c. reporting to the IRB any serious or unexpected adverse events related or possibly related to human subjects participation within 10 working days of having become aware of the event;
- d. reporting to the IRB any unanticipated problem or incident that may involve risks to subjects and that occurs during the conduct of an approved protocol or human subjects participation within 10 working days of having become aware of the problem;
- e. ensuring risks are minimized by using procedures which are consistent with sound research design and which do not unnecessarily expose subjects to risk,

including implementing appropriate safeguards to protect the rights and welfare of human research subjects who may be vulnerable to coercion or undue influence;

- f. ensuring that individuals are adequately informed of the risks and benefits of research participation and the procedures that will be involved in the research, and that informed consent will be obtained from each prospective human research subject, or his/her/their legally authorized representative, in accordance with, and to the extent required, by federal regulations, state and local laws, and institutional guidelines; and
- g. considering racial, cultural, ability and gender diversity among the subject populations and being sensitive to community attitudes in both the design and conduct of research involving humans.

3. Principal Investigator

A Principal Investigator must be a full-time UNT faculty member or a full-time UNT staff employee whose job responsibilities include conducting human subjects research. Principal 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 Principal 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 and supervision of a Principal Investigator.

4. Non-UNT Collaborator

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, if present.

5. 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.

6. 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 Innovation 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.

7. Mandatory Reporting

UNT faculty, staff and students are responsible for notifying the UNT IRB regarding IRB-related concerns or potential non-compliance related to human subjects research studies conducted at UNT or at any other location under the auspices of UNT by contacting Research Integrity and Compliance at oric@unt.edu or by calling the UNT Trust Line at (877) 606-9187.

V. Resources/Forms/Tools

Forms and instructions to be used by UNT faculty, staff, and students when submitting proposals to the UNT IRB are available at: [UNT Human Subjects \(IRB\) web page](#)

VI. 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](#)

VII. Revision History

Policy Contact:	AVP of Research and Innovation
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