PURPOSE
The purpose of this Standard Operating Procedure (SOP) is to define Research Integrity and Compliance (RIC), Institutional Review Board (IRB) program, and Researcher procedures for performing human subjects research in compliance with federal and state regulations.

SCOPE
This SOP delineates systematic process activities and functions for compliance with the US Department of Health and Human Service, Office for Human Research Protections (OHRP) and Common Rule requirements, and University of North Texas (UNT) requirements for the management, coordination, and operation of the Institutional Review Board program. It applies to all staff members whom are engaged in the operations and support of the Institutional Review Board, and to all UNT researchers performing human subjects research.

DEFINITIONS/ABBREVIATIONS
1. Definitions
   1.1 Belmont Report: a statement of basic ethical principles and guidelines to guide research with human subjects prepared by the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research.
   1.2 IRB Analyst: Staff member of Research Integrity and Compliance that performs administrative activities, pre-reviews, reviews, and approvals for the Institutional Review Board program.
   1.3 Researcher: Any individual performing various tasks related to the conduct of human subjects research.
subjects research activities, including but not limited to obtaining informed consent from subjects, collecting and analyzing data, interacting with subjects, and communicating with the IRB.

2. Abbreviations
   2.1 SOP/SOPs: Standard Operating Procedure(s)
   2.2 OHRP: Office for Human Research Protections
   2.3 RIC: Research Integrity and Compliance
   2.4 IRB: Institutional Review Board
   2.5 PI: Principal Investigator

RESPONSIBILITIES
This SOP is applicable to all members of Research Integrity and Compliance and Institutional Review Board members who are involved in record keeping, reviewing, or approving research studies for the Institutional Review Board program. This SOP is also applicable to all UNT researchers performing human subjects research under the oversight of the UNT Institutional Review Board.

PROCEDURE
1. Compliance with Federal and State Regulations
   1.1 All human subjects research performed at UNT must be guided by the ethical principles set forth in the Belmont Report, from the National Commission for the Protection of Human Participants of Biomedical and Behavioral research, officially known as the “Ethical Principles and Guidelines for the Protection of Human Subjects Research.” This document is the guiding statement of ethical principles as part of UNT’s Federalwide Assurance (FWA) for the Protection of Human Subjects. All UNT human subjects research must comply with applicable federal/state laws and regulations governing research. This includes, but is not limited to, the following:
   1.1.1 UNT has an approved Federal wide Assurance (FWA) governed and regulated by the US Department of Health and Human Services (HHS) Office for Human Research Protections (OHRP). OHRP confirms UNT is in compliance with the United States Code of Federal Regulations (CFR), specifically 45 CFR part 46. Title 45 of the CFR is the principle set of rules and regulations issued by federal agencies of the United States regarding public welfare. 45 CFR part 46 details regulations related to the use of human subjects in research that is conducted, supported or otherwise subject to regulation by any federal department/agency as defined by the “Common Rule.”
   1.1.2 The Department of Education Family Education Rights and Privacy Act, collectively referred to as FERPA, for studies involving student educational records.
   1.1.3 The US Department of Health and Human Services (HHS) Health Insurance Portability and Accountability Act of 1996 (HIPAA) for studies involving health information.
   1.1.4 Food and Drug Administration (FDA) regulations. For studies involving investigational biologics, devices, diagnostic tests, or drugs, the UNT IRB complies with all requirements set forth in the Code of Federal Regulations, including:
   1.1.5 21 CFR 50
1.1.6 21 CFR 56
1.1.7 21 CFR 312
1.1.8 21 CFR 600
1.1.9 21 CFR 812

1.1.10 For studies funded/supported by the Department of Defense (DoD), or studies that include human subjects from a component of the DoD (including both military and civilian), all research activities comply with DoD regulations.

1.1.11 Texas State Law including:
1.1.11.1 Texas Family Code Section 261.101 for mandatory reporting of child or elder abuse or neglect; and
1.1.11.2 Senate Bill 212 for mandatory reporting of all events of sexual harassment, sexual assault, dating violence, or stalking that involve a current student or employee.

2. Compliance with University Policies

2.1 All human subjects research conducted by UNT researchers or reviewed by UNT IRB must comply with applicable institution policies and procedures, including but not limited to:

2.1.1 UNT Policy 13.004 on the Use of Human Subjects in Research.

REFERENCES

1. US Department of Health and Human Service, Office for Human Research Protections (OHRP)
2. 45CFR46
3. Department of Education Family Education Rights and Privacy Act
4. Food and Drug Administration (FDA) regulations
5. The US Department of Health and Human Services (HHS) Health Insurance Portability and Accountability Act of 1996 (HIPAA)
6. 21 CFR 50
7. 21 CFR 56
8. 21 CFR 312
9. 21 CFR 600
10. 21 CFR 812
11. DoD Regulations
12. Texas Family Code Section 261.101
13. Texas Senate Bill 212
14. UNT Policy 13.004