DIVISION OF RESEARCH & INNOVATION Research Integrity & Compliance	**Institutional Review Board Standard Operating Procedures**

Title: Non-Human Subjects Research Determinations

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PURPOSE

The purpose of this Standard Operating Procedure (SOP) is to define Research Integrity and Compliance (RIC) and Researcher procedures for the submission and review of all projects involving interactions, direct or indirect, with humans or the use of human specimens or data to determine if the project constitutes human subjects research requiring IRB review and approval.

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 (IRB) program. It applies to all UNT researchers performing projects involving direct or indirect interaction with humans or the use of human specimens or data.

DEFINITIONS/ ABBREVIATIONS

1. Definitions

1.1 Biomedical Research: Research performed: (1) to increase scientific understanding about normal or abnormal physiology, disease states, or development; (2) to evaluate the safety, effectiveness, or usefulness of a medical procedure, intervention, or product.

1.2 Clinical Research: Research performed to evaluate behavioral or biomedical interventions on disease processes or normal physiologic functioning. May include, but is not limited to, the study of drugs, biological products, or devices.

1.3 Social and Behavioral Research: Research performed to establish a body of knowledge

or to evaluate interventions in human subjects. This research may include surveys, interviews, observations, review of existing data, or experimental study interventions to better understand individual or group behaviors, mental processes, or social constructs.

1.4 Epidemiology Research: Research performed to understand health outcomes, interventions, or disease states to understand cost-effectiveness, intervention, efficacy or service delivery to specific populations.

1.5 *Human Subject:* As per DHHS regulations at 45 CFR 46.102(e) and the Common Rule, human subject is "a living individual about whom an investigator (whether professional or student) conducting research obtains information or biospecimens through intervention or interaction with the individual, and uses, studies, or analyzes the information or biospecimens; or obtains, uses, studies, analyzes, or generates identifiable private information or identifiable biospecimens."

1.1 *Human Subjects Research Activity:* Any activity that contributes to the scientific development or execution of a human subjects research study in a substantive, measurable way. This includes, but may not be limited to, activities involving recruitment, interaction, or intervention with human subjects, participation in the consent process by either leading it or contribution to it, and recording or processing identifiable private information.

1.2 *Principal Investigator:* The primary individual responsible for the preparation and conduct of a research grant, sponsored project, or human subjects research study, in compliance with applicable laws, regulations, and institutional policy governing the conduct of research.

1.3 *Quality Assurance/Quality Improvement Activity:* Projects with the primary goal of attempting to measure the effectiveness of programs or services.

1.4 *Repository Research*: Research utilizing stored data or materials from individually identified persons.

1.5 *Researcher:* Any individual performing various tasks related to the conduct of human 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.

1.6 *Research*: As per DHHS regulations at 45 CFR 46.102(d) and the Common Rule, research is "a systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to generalizable knowledge. For the purposes of this definition, the following is deemed not to be research:

- 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.
- 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).

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

2. Abbreviations

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

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 Principal Investigators and Researchers performing projects involving direct or indirect interaction with humans or the use of human specimens or data.

PROCEDURE

1. All planned projects involving interaction (direct or indirect) with humans or the use of human specimens or data should be reviewed by RIC for a determination that the activity does not constitute research involving human subjects.
2. Biomedical, Clinical, Social and Behavioral, Epidemiology, Repository, Quality Assurance/Quality Improvement, and any other research activities require IRB review when they meet the definitions of both 'Human Subject' and 'Research' as per DHHS regulations at 45 CFR 46 and the Common Rule.
3. Principal Investigator Responsibilities
   - 3.1 The Principal Investigator must complete the electronic Proposed Human Subjects Research Determination Form, providing a description of planned activities.
     - 3.1.1 The Principal Investigator must provide detailed information regarding study activities to aid the RIC staff to provide the appropriate determination.
   - 3.2 Upon receipt of the determination from the RIC office:
     - 3.2.1 If the project is determined to be Human Subjects Research as defined by DHHS regulations at 45 CFR 46 and requires IRB review and approval, the Principal Investigator must log in to the IRB Submission portal and submit a new study application. The Principal Investigator may not proceed with any Human Subjects Research Activity prior to receiving approval from the IRB.
     - 3.2.2 If the project is determined to be Non-Human Subjects Research and does not meet the definitions of DHHS regulations at 45 CFR 46, the Principal Investigator may store a copy of the determination and proceed with the project.
   - 3.3 During the conduct of the project:
     - 3.3.1 The Principal Investigator is required to notify the RIC office, by emailing untirb@unt.edu, in advance of any proposed substantive modifications to the project activity.
     - 3.3.2 The Principal Investigator must wait to receive approval to proceed with the proposed modifications from the RIC office prior to implementation of the

changes. If the modification request is determined to be substantial, a new Proposed Human Subjects Research Determination Form may be requested from the Principal Investigator.

3.3.3 The RIC office will determine if the proposed modification alters the project such that the project is then determined to be Human Subjects Research as defined by DHHS regulations at 45 CFR 46 and requires IRB review and approval.

4. RIC Staff Responsibilities

4.1 Upon receipt of the Proposed Human Subjects Research Determination Form:

4.1.1 The RIC staff member screens the Form for completeness. If information/material is missing, the RIC staff member will request this information/material from the Principal Investigator.

4.1.2 The RIC staff member will analyze and determine if the activity meets the definitions of 'research' and 'human subjects'.

4.1.3 If the RIC staff member requires additional information, they will contact the Principal Investigator via e-mail and review the response upon receipt. If the Principal Investigator does not respond within 60 days, the determination inquiry will be withdrawn.

4.1.4 If the RIC Staff member does not believe that the materials received are sufficient, they may request that the Principal Investigator make further clarifications and/or revisions. This process will continue until a determination can be made.

4.1.5 Once the IRB Analyst makes the determination, the determination will be noted on the electronic Form and the Form will be saved for record keeping. The determination will be sent back to the Principal Investigator on official documentation.

4.2 Modification requests submitted by the Principal Investigator to untirb@unt.edu will be reviewed on a case-by-case basis. If the modification request is determined to be substantial, a new Proposed Human Subjects Research Determination Form may be requested from the Principal Investigator.

REFERENCES

1. US Department of Health and Human Service, Office for Human Research Protections (OHRP)

APPENDICES

1. Proposed Human Subjects Research Determination Form