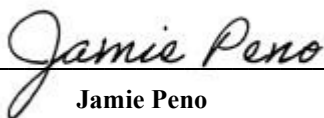
 DIVISION OF RESEARCH & INNOVATION Research Integrity & Compliance		Institutional Review Board Standard Operating Procedures	
Title: Researcher Roles and Responsibilities			
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PURPOSE

This Standard Operating Procedure (SOP) is to outline the general responsibilities of the Researchers who conduct research involving human subjects under the oversight of the Institutional Review Board (IRB) program.

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 requirements for the management, coordination, and operation under the oversight of the Institutional Review Board program. It applies to all Researchers and research staff involved in conducting human subjects research, as well as all IRB Members and IRB staff reviewing research involving human subjects.

DEFINITIONS/ ABBREVIATIONS

1. Definitions

- 1.1 *IRB Submission Portal*: A web-based system for preparing, submitting, and routing research studies for IRB approval. All information is stored in a cloud system and can be accessed securely from any location. Researchers receive electronic notifications whenever an action is required on their part to move the study through the review and approval process.
- 1.2 *Human Subject*: A living individual about whom a Researcher is conducting research by obtaining, generating, using, or analyzing information or biospecimens through intervention or interaction with the individual or their data.

- 1.3 *Researcher*: An individual performing various tasks related to the conduct of human subjects research activities, such as obtaining informed consent from participants, interacting with participants, collecting data and communicating with the IRB.
- 1.4 *IRB Analyst*: Staff member of Research Integrity and Compliance that perform administrative activities, pre-reviews, reviews, and approvals for the Institutional Review Board program.
- 1.5 *Principal Investigator*: The individual who is actively leading and/or supervising the initiation, execution, and completion of a research project in compliance with applicable laws, regulations, and institutional policy governing the conduct of research. It is ultimately the PI's responsibility to ensure that all personnel actively working on the project and interacting with human subjects are following the guidelines of the approved protocol and are treating subjects in a manner befitting ethical use of human subjects. The PI should be the party responsible for submitting the research protocol, providing the RIC or the IRB with requested changes in order to garner approval, and for following the guidelines stipulated for annual review of the protocol and submission of any modification requests.
- 1.6 *Research*: A systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to generalizable knowledge.
- 1.7 *Researcher*: An individual performing various tasks related to the conduct of human subjects research activities, such as obtaining informed consent from participants, interacting with participants, collecting data 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 Researchers who are involved in preparing, submitting, and conducting human subjects research at the University of North Texas.

PROCEDURE

1. The following classes of individual may serve as Principal Investigator on human subjects research studies conducted under the oversight of UNT IRB:
 - 1.1 A full-time UNT faculty member or a full-time UNT staff employee whose job responsibilities include conducting human subjects research.
2. The same individuals that are permitted to serve as Principal Investigator are also permitted to serve as Co-Principal Investigator on human subjects research studies conducted under the oversight of UNT IRB.
3. All other Researchers performing activities related to human subjects research in conjunction with the Principal Investigator or Co-Principal Investigator may serve as Key Personnel.
4. Student Investigators may be any UNT student that is working on a human subjects research study in conjunction with the Principal Investigator or Co-Principal Investigator.
5. Any personnel listed on the project may serve as the primary contact for the human subjects research study. The primary contact will be the point of contact, in addition to the Principal Investigator, for correspondence related to the study.
6. All personnel must complete mandatory training as set forth in the IRB procedures.

7. Ethical Obligations

7.1 All Researchers conducting human subjects research will ensure they fulfill their ethical obligations to protect the research participants including:

- 7.1.1 Obtain IRB approval or exemption prior to initiating human subjects research in accordance with RIC SOPs.
- 7.1.2 Obtain required training and renew training every three years.
- 7.1.3 Accept responsibility for protecting the rights and welfare of human subjects and comply with applicable UNT policies and procedures, and with federal regulations and guidelines.
- 7.1.4 Oversee the conduct of the research activities, including recruitment, obtaining consent, protocol procedures, managing data collection, storage, security and backup and accurate analysis of study data, in accordance with IRB approval or exemption.
- 7.1.5 Ensure that the research is conducted according to the IRB-approved protocol and any conditions set forth by the IRB when approval was given.
- 7.1.6 Report to the IRB all processes or actions that deviate from the protocol procedures as approved by the IRB.
- 7.1.7 Provide continuing renewal information to the IRB in accordance with the federal regulations and the IRB approval letter.
- 7.1.8 Submit closure information once the human subjects research study is completed.

7.2 PI will perform the additional tasks:

- 7.2.1 Delegate responsibilities to qualified study team members, commensurate with training, education and qualifications.
- 7.2.2 Ensure the entire study team has completed proper training to conduct the study in accordance with the IRB approval.
- 7.2.3 Ensure the study team has completed mandatory IRB training (i.e. CITI) and maintain that the study team completes mandatory training every 3 years.
- 7.2.4 Ensure the study team completes all required Conflict of Interest disclosures and complies with all Conflict of Interest procedures as set forth in the UNT policies and procedures.

8. Documentation and Communications

8.1 Researchers conducting human subjects research will ensure research activities are documented and reported to the IRB as necessary. This includes:

- 8.1.1 Maintaining files of all approved study documents such as:
 - 8.1.1.1 Protocol
 - 8.1.1.2 Informed consent documents
 - 8.1.1.3 Recruitment materials
 - 8.1.1.4 Study materials and tools (i.e. interview questions, surveys, etc.)
 - 8.1.1.5 Associated study correspondence (with the IRB, Sponsor agencies or companies, and Regulatory Authorities)
- 8.1.2 Researchers must report all of the following to the IRB:
 - 8.1.2.1 Any proposed changes to research activity, personnel, or study documents including, but not limited to, proposed modifications to the protocol, informed consent, recruitment materials, and study materials and tools.

- 8.1.2.2 Study progress reports in the form of annual renewals, if required per federal regulations.
- 8.1.2.3 Unanticipated problems or adverse events involving risks to subjects or others in accordance with federal regulations.
- 8.1.2.4 Noncompliance with regulations, IRB approval, IRB stipulations, or IRB SOPs.
- 8.1.2.5 Copies of any study monitoring or audit reports received by the Researcher, if available.

9. Addressing Concerns that Arise

- 9.1 Researchers conducting human subjects research are responsible for addressing concerns or issues that arise during the conduct of the study including:
 - 9.1.1 Identified hazards to research subjects. A report of the hazard and potential deviation to avoid increased risks to participants should be made promptly to the IRB.
 - 9.1.2 Concerns raised by members of the research team.
 - 9.1.3 Questions or concerns raised by research subjects before, during and after study completion.

10. Confidentiality

- 10.1 Researchers must maintain confidentiality of the subjects' records for the life of the study.
- 10.2 Records obtained during the conduct of a Federally Regulated Study must be kept in accordance with the corresponding federal regulations.

REFERENCES

- 1. US Department of Health and Human Service, Office for Human Research Protections (OHRP)
- 2. 45 CFR part 46

APPENDICES

- 1. IRB SOPs