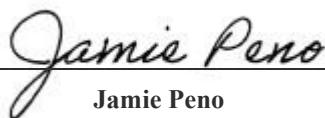
 DIVISION OF RESEARCH & INNOVATION Research Integrity & Compliance		Institutional Review Board Standard Operating Procedures	
Title: Research with a Data or Tissue Bank			
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 _____ Jamie Peno Assistant Vice President, Research Integrity and Compliance		_____ 4/1/2021 Date	
REVISION HISTORY			
Date	Section	Author	

PURPOSE

The purpose of this Standard Operating Procedure (SOP) is to describe the IRB oversight, and to outline the responsibilities of Principal Investigators when human subjects research includes the collection and storage of blood, tissue, or other biological materials (**excluding** embryos* or embryonic stem cells*) and/or health data that will be stored for future research not yet defined, including genetic (but **not** stem cell*) research.

*Contact Research Integrity and Compliance **immediately** if you have any plans or questions regarding research with embryonic stem cells or stem cells.

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 *Data or Tissue Bank*: An entity that receives, stores, processes and/or disseminates specimens and/or health information, as needed, for future research. It includes the physical location as well as the full range of activities associated with its operation.

- 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 *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.
- 1.4 *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.

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 Researchers performing human subjects research under the oversight of the UNT Institutional Review Board.

PROCEDURE

1. Research using data or biospecimens that are stored in Data or Tissue Banks is governed by the federal human subject protection regulations known as the Common Rule (45 CFR 46 and the HIPAA Privacy Rule (45 CFR 160 & 164).
2. IRB oversight is required to set up and maintain a research Data or Tissue Bank.
3. If a Researcher intends to set up a Data or Tissue Bank:
 - 3.1 Researchers must implement physical and procedural mechanisms for the secure receipt, storage, and transmission of data or tissue. These procedures must be reviewed by the IRB and must be sufficient to ensure the protection of subjects' privacy and the confidentiality of subjects' information.
 - 3.2 Participants must be notified of the intent within an informed consent document, which should include language for participants to opt-in or opt-out of storage of their data or tissue for future research purposes.
 - 3.3 The participant's decision as indicated on the consent/authorization must be respected and tracked.
 - 3.4 IRB oversight is required for each new research protocol that uses identifiable or re-identifiable information contained in the database. Researchers are responsible for submitting new Requests for Approval through the IRB submission portal for each

new use of the Data or Tissue Bank.

4. IRB approval, or IRB determination of exemption, is required before initiating any Data or Tissue Bank-related activity.
5. In addition to standard information with a Request for Approval, as required by UNT IRB SOPs, the IRB requires the inclusion of the following specific information:
 - 5.1 The specific conditions under which data/tissue may be accepted into the repository, including requirements for the FWA number for each site's IRB and a copy of the IRB approval letter from each site if including data or tissue from external sites;
 - 5.2 A detailed description of the physical and procedural mechanisms for the secure receipt, storage, and transmission of data and tissue to ensure the protection of subjects' privacy and the confidentiality of subjects' data/tissue;
 - 5.3 The specific conditions under which data and/or tissue may be shared with or released to research investigators, including procedures prohibiting or permitting the sharing of PHI associated with the data/tissues;
 - 5.4 Protocol for the collectors of data/tissue;
 - 5.5 Informed consent forms and written authorization for the collection sites.
6. The IRB is required to review any use of a UNT IRB approved or exempt Data or Tissue Bank. Additionally, the IRB must review any modification to previously approved research, including the addition of contributing sites, utilizing a UNT IRB approved or exempt Data or Tissue Bank.

REFERENCES

1. US Department of Health and Human Service, Office for Human Research Protections (OHRP)
2. 45 CFR 46
3. Food and Drug Administration (FDA) regulations
4. The US Department of Health and Human Services (HHS) Health Insurance Portability and Accountability Act of 1996 (HIPAA)
5. UNT Policy 13.004