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

Title: Use or Disclosure of Protected Health Information for Research

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Approval/Date:

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REVISION HISTORY		
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PURPOSE

The purpose of this Standard Operating Procedure (SOP) is to define the procedures for researchers to conduct research utilizing or disclosing Protected Health Information (PHI), and for the review and approval of research utilizing or disclosing PHI from the Institutional Review Board.

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 human subjects research.

DEFINITIONS/ ABBREVIATIONS

1. Definitions

1.1 *Deidentified Health Information:* Health information that neither identifies nor provides a reasonable basis to identify an individual. To achieve deidentification, the data may go through a formal determination by a qualified statistician, or have all 18 HIPAA identifiers removed from the data set in addition to any identifiers of the individuals relatives, household members, employers, and any other information that could potentially be used to identify the individual.

1.2 *HIPAA Identifiers:* Identifiers, as set forth by the HIPAA privacy rule, that are considered personally identifiable information. These include:

- Name

- Address (all geographic subdivisions smaller than state, including street address, city county, and zip code)
- All elements (except years) of dates related to an individual (including birthdate, admission date, discharge date, date of death, and exact age if over 89)
- Telephone numbers
- Fax number
- Email address
- Social Security Number
- Medical record number
- Health plan beneficiary number
- Account number
- Certificate or license number
- Vehicle identifiers and serial numbers, including license plate numbers
- Device identifiers and serial numbers
- Web URL
- Internet Protocol (IP) Address
- Finger or voice print
- Photographic image - Photographic images are not limited to images of the face.
- Any other characteristic that could uniquely identify the individual

1.3 *HIPAA Privacy Rule*: The "HIPAA Privacy Rule" establishes national standards to protect individuals' medical records and other personal health information and applies to health plans, health care clearinghouses, and those health care providers that conduct certain health care transactions electronically. The HIPAA Privacy Rule requires appropriate safeguards to protect the privacy of personal health information, and sets limits and conditions on the uses and disclosures that may be made of such information without patient authorization. The HIPAA Privacy Rule also gives patients rights over their health information, including rights to examine and obtain a copy of their health records, and to request corrections. The HIPAA Privacy Rule is located at 45 CFR Part 160 and Subparts A and E of Part 164.

1.4 *HIPAA Security Rule*: The "HIPAA Security Rule" establishes national standards to protect individuals' electronic personal health information that is created, received, used, or maintained by a covered entity. The HIPAA Security Rule requires appropriate administrative, physical and technical safeguards to ensure the confidentiality, integrity, and security of electronic protected health information. The HIPAA Security Rule is located at 45 CFR Part 160 and Subparts A and C of Part 164.

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 *Protected Health Information:* Individually identifiable information, including demographic information, which relates to a person's past, present, or future physical or mental health or condition, to the provision of health care to the person, to the past,

present, or future payment for the provision of healthcare to the person, and that identifies the person or for which there is a reasonable basis to believe can be used to identify the person.

1.7 *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 HIPAA- Health Insurance Portability and Accountability Act
2.2 IRB- Institutional Review Board
2.3 OHRP- Office for Human Research Protections
2.4 PI- Principal Investigator
2.5 RIC- Research Integrity and Compliance
2.6 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 human subjects research.

PROCEDURE

1. UNT is a covered entity whose business activities include both covered and non-covered functions. Accordingly, UNT has elected to consider itself a hybrid entity for HIPAA purposes and will designate its health care components. UNT's designated health care components must comply with the HIPAA Privacy Rule and the HIPAA Security Rule. All UNT components must comply with all UNT policies and procedures related to Protected Health Information Privacy and Security.
2. The use and disclosure of PHI in research must have appropriate authorizations and safeguards in place. The UNT IRB review process is responsible for determining which federal and Texas standards apply to the use and disclosure of PHI for research. All researchers and their staff must rigorously comply with the procedures of the IRB and of Research Integrity and Compliance in the use of PHI.
3. Whenever possible, de-identified PHI should be used for research. When PHI is to be used for research, including public health research, it must be deidentified and rendered anonymous.
    3.1 PHI is rendered anonymous whenever its identifying characteristics, or HIPAA Identifiers, are completely removed. PHI must be de-identified prior to disclosure to non-authorized users. De-identified PHI should be used for any permitted purpose whenever this is possible and feasible. In addition:
        3.1.1 PHI used for research should be de-identified at the point of data collection for research protocols approved by the IRB, unless the participant voluntarily and expressly consents to the use of his or her personally identifiable information or the researcher(s) obtain an IRB waiver of authorization.
        3.1.2 If PHI is de-identified by means of encryption, anyone involved in the research project must not disclose the encryption code and must not disclose the mechanism used to re-identify the information.

4. The Privacy Rule allows PHI to be used or disclosed for human subjects research under one of the following conditions:
    4.1 Permission is granted by the patient, through a written authorization form;
    4.2 The information is completely de-identified and no longer governed by the HIPAA Privacy Rule;
    4.3 The information is compiled into a "limited data set" and a data use agreement is executed;
    4.4 A waiver of privacy authorization is approved by the UNT IRB.
5. For Requests for Approval that involve receipt of PHI, the UNT IRB will require documentation of approval from the HIPAA Privacy Officer or HIPAA Privacy Board from the institution that is releasing PHI. The approval may involve a HIPAA authorization for release of PHI for the research study, an approved HIPAA waiver of authorization, or use of a limited data set (with appropriate safeguards in accordance with 45 CFR 164.514(e) and an executed Data Use Agreement).
    5.1 UNT researchers collecting, receiving, or utilizing PHI from external covered entities may be asked to sign a Business Associates Agreement (BAA) or Data Use Agreement (DUA) with the covered entity. The BAA and/or DUA will clarify that UNT researchers must comply with HIPAA and the covered entities' policies for the secure storage and use of the PHI as stated in the agreement.
    5.2 Once a Principal Investigator identifies that they may be collecting, receiving, or utilizing PHI from external covered entity, they must contact Research Commercial Agreements.
        5.2.1 Research Commercial Agreements can be contacted by emailing researchcontracts@unt.edu.
        5.2.2 Confirmation that Research Commercial Agreements has reviewed the plan for receipt of data will be requested by the UNT IRB.
    5.3 For Requests for Approval that involve the prospective collection of PHI, the IRB will also review the informed consent document to ensure that the use of PHI and efforts to minimize risks and protect confidentiality are appropriately described in the informed consent document, unless informed consent can be waived in accordance with 45 CFR 46.116(d).
        5.3.1 When appropriate, the IRB will also review the HIPAA authorization for release of PHI from the institution that is releasing PHI for consistency with the informed consent document.
        5.3.2 Researchers are required to use the UNT IRB Template consent forms.
6. The IRB reviews the investigator's plans to ensure privacy and confidentiality at the time of initial review in accordance with requirements of the Common Rule. Proposed changes to the research also are evaluated for impact on the subjects' privacy and confidentiality.
7. A privacy violation or a breach of confidentiality related to research data is considered an unanticipated problem and must be promptly reported by the Principal Investigator as an Incident to the IRB and other institutional authorities.
8. As required by federal regulation, the UNT IRB reviews the Principal Investigator's plans to protect the privacy of subjects and maintain the confidentiality of data.
    8.1 The UNT IRB considers privacy protections to be those relating to ensuring a subject's right to protect access to his/her person or access to personal information.
    8.2 The UNT IRB considers confidentiality provisions to be those relating to appropriate controls on the disclosure of study information.
    8.3 Unless otherwise authorized, study information must be disclosed only to approved members of the research team, Research Integrity and Compliance, the

UNT IRB, and federal regulatory agencies.

REFERENCES

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

APPENDICES

1. IRB SOPs