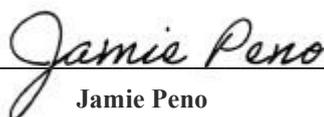


 DIVISION OF RESEARCH & INNOVATION Research Integrity & Compliance		Institutional Review Board Standard Operating Procedures	
Title: Certificates of Confidentiality			
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REVISION HISTORY			
Date	Section	Author	

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 studies require a Certificate of Confidentiality.

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 who 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 *IRB Analyst*: Staff member of Research Integrity and Compliance that performs administrative activities, pre-reviews, reviews, and approvals for the Institutional Review Board program.
- 1.2 *Confidentiality*: The principle that Researchers will not divulge information collected during the study conduct without the permission of the participant and that participants make this disclosure on a voluntary basis based upon trust that the information will be kept protected and secure. This generally refers to the obligations of the researchers and institutions to appropriately protect information disclosed to them by research

- participants.
- 1.3 *Certificate of Confidentiality*: Certificate issued by the National Institutes of Health and other Health and Human Services agencies, on a study by study basis, to protect identifiable research information from forced or compelled disclosure.
 - 1.4 *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.
 - 1.5 *Private Information*: Information which has been provided by a participant and which he/she/they reasonably expect will not be made public.
 - 1.6 *Privacy*: The principle that participants have control over the extent, timing, and circumstance of sharing their private information with others. Generally, privacy refers to the people involved in the research and the methods of gathering information from them.
 - 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.
 - 1.8 *Sensitive Information*: Data collected from participants that may require additional protections and if disclosed may place the research participant at risk of harm, adverse consequences, or be damaging to participants financial standing, employability, reputation, insurability, or mental health. Some examples may include psychological well-being, substance abuse, illegal behaviors, sexual attitudes, sexual preferences, sexual practices, litigation, and genetic information.

2. Abbreviations

- 2.1 CoC- Certificate of Confidentiality
- 2.2 HHS- Health and Human Services
- 2.3 IRB- Institutional Review Board
- 2.4 NIH- National Institutes of Health
- 2.5 OHRP- Office for Human Research Protections
- 2.6 PI- Principal Investigator
- 2.7 RIC- Research Integrity and Compliance
- 2.8 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. Certificates of Confidentiality (CoC) are issued by the NIH to protect the confidentiality of research data. These certificates prohibit disclosure of identifiable and/or Sensitive

Information to anyone not connected to the research study operations, except when the participant explicitly consents. A few specific exceptions do exist, however, attempts to force involuntary disclosure, for example by subpoena, of the information to any civil, administrative, legislative, criminal, or other proceeding at the federal, state, or local level will not be allowable.

1.1 Eligible studies include activities meeting the following criteria:

- 1.1.1 Defined as research involving human subjects
 - 1.1.2 Has been reviewed and approved by an IRB
 - 1.1.3 Involves collection of personally identifiable information
 - 1.1.4 Involves the collection of information that if disclosed could reasonably harm the participant.
2. While NIH and other HHS agencies issue CoCs to their funded researchers automatically, CoCs are not limited to federally funded research. A CoC may be requested for behavioral, biomedical, or other types of research that are being performed that include the collection or review of identifiable Sensitive Information.
 3. CoCs do not eliminate the need for Researchers to assure appropriate data privacy and confidentiality measures are in place. Please refer to the IRB SOP titled, “Research on Sensitive Information” for more details.
 4. Participants must always be informed, by the Researcher, of the protections provided by a Certificate of Confidentiality and any exceptions that apply. Informed consent documents must also describe the protections and any limitations of a CoC. Involuntary disclosures by a research participant, releases of information authorized in writing by the participant, and voluntary disclosures made by the Researchers are all considered limitations of the CoC.
 - 4.1 CoCs do not protect researchers from required disclosures under mandatory reporting requirements as outlined in UNT policy and state and federal regulations, including instances such as suspected child/elder abuse or neglect, mandatory reporting under Senate Bill 212, threats of violence or harm to self or others, and reasonable knowledge that a felony has or is being committed.
 5. Researchers are responsible for clearly stating in their IRB submission that a CoC is in place. A copy of the CoC must be provided with the IRB application.
 6. The IRB will evaluate whether the research protocol is consistent with the obligations set forth in the CoC to protect study information. The IRB will also determine if the consent language adequately discloses the CoC and any associated protections and limitations.
 7. If you believe your study qualifies for a CoC, you must reach out to untirb@unt.edu to discuss the instance. Furthermore, if your study is identified by the IRB to require a CoC, the Research Integrity and Compliance team will reach out to discuss the need and to help identify the next steps to obtain a CoC. It is the responsibility of the Principal Investigator to follow all requests provided by the IRB for study approval and research participant safety.

REFERENCES

1. US Department of Health and Human Service, Office for Human Research Protections (OHRP)
2. 45 CFR 46
3. UNT Policy Manual
4. UNT IRB SOPs
5. [NIH Policy for Issuing Certificates of Confidentiality](#)
6. [NIH Guide to Certificates of Confidentiality](#)