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

Title: Research on Sensitive Information

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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 describe the IRB oversight, and to outline the responsibilities of Principal Investigators when human subjects research includes the collection and storage of data on sensitive topics.

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 *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 *Private Information:* Information which has been provided by a participant and which he/she/they reasonably expect will not be made public.

1.5 *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.

1.6 *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.

1.7 *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 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 involving potentially Sensitive Information may require additional safeguards. The Researcher must include information within their IRB application about any particular risks to the participants based on the topic being studied, and how those risks will be mitigated.
   1.1 For confidentiality purposes, the Researcher should consider collecting anonymous data if possible. Coding the data and storing the data without identifiers, including signed consent forms, and separate from links to identifiers must also be considered.
   1.2 If the Researcher has a concern that the signed consent form is putting the participant

at increased risk, he/she/they can request a waiver of the requirement to obtain the signature on the consent form. However, these situations are reviewed on a case-by-case basis. For more information regarding "Waivers of Informed Consent," please review the IRB SOP titled "Waiver of Informed Consent or Documentation."

1.3 The Researcher should consider any necessary procedures to handle the possibility of a participant becoming upset during and/or after participation in the research. These potential risks must be included in the IRB application and consent form if applicable.

1.4 Depending on the nature of the research, the IRB may recommend that the Researcher provide the participant with contact information to counseling services that are both local and accessible 24 hours a day. These resources can be placed within the consent form and in a debriefing statement that is provided to the participant at the completion of study participation.

1.5 The Researcher must have a plan to deal with reports of self-harm or harm to others. All details must be provided within the IRB application and consent form for review and approval by the IRB.

2. UNT Researchers are considered mandatory reporters and must report any suspicions of child abuse or neglect, and elder abuse or neglect, to the proper authorities. Additionally, suspicions of known or potential sexual harassment, sexual assault, dating violence or stalking against a student or employee must be reported to the institution's Title IX Coordinator or a Deputy Title IX Coordinator.

   2.1 Please note that this is mandated in UNT policy as well as within regulations, including Senate Bill 212. Noncompliance with UNT policy and regulation reporting requirements may lead to corrective action, up to and including termination.

3. Researchers collecting sensitive data and utilizing a snowball recruitment sampling may be required, by the IRB, to provide their contact information for participants to give to other potential participants. This would replace the method of requesting names and contact information of potential participants to protect potential participant privacy.

4. Templates provided by the UNT IRB should be used for consent forms and recruitment materials. Updated templates can be found on the UNT IRB website.

5. The IRB will review each IRB submission in accordance with 45 CFR 46, institutional policies and procedures, and state and federal regulations. The IRB will determine if the researcher has adequately described and plans to implement appropriate provisions for mitigating risks to participants and for the protection of participant privacy and confidentiality.

   5.1 Some studies involving the collection of sensitive information may qualify for a Certificate of Confidentiality (CoC). In these cases, the IRB may require a CoC in order to receive study approval. Please see IRB SOP titled, "Certificate of Confidentiality" for more details.

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