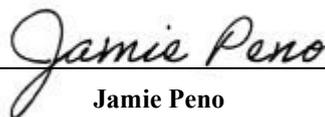


 <b>DIVISION OF RESEARCH &amp; INNOVATION</b> Research Integrity & Compliance		<b>Institutional Review Board</b> <b>Standard Operating Procedures</b>	
<b>Title:</b> Research with Native American or Alaskan Native Tribes			
<b>Effective Date:</b>	4/1/2021	<b>Document Number:</b>	IRB-SOP-19-0.1
<b>Approval/Date:</b>			
 _____ <b>Jamie Peno</b> Assistant Vice President, Research Integrity and Compliance		_____ 4/1/2021 <b>Date</b>	
<b>REVISION HISTORY</b>			
<b>Date</b>	<b>Section</b>	<b>Author</b>	

**PURPOSE**

This Standard Operating Procedure (SOP) describes the standards and parameters for the conduct, review, and approval of human subjects research with Native American or Alaskan Native Tribes. This SOP outlines the general responsibilities of the Researchers who conduct research with Native American or Alaskan Native Tribes 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 Analyst*: Staff member of Research Integrity and Compliance that perform administrative activities, pre-reviews, reviews, and approvals for the Institutional Review Board program
- 1.2 *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.

- 1.3 *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*: 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 IHS: Indian Health Service
- 2.6 PI: Principal Investigator

## **RESPONSIBILITIES**

This SOP is applicable to all University of North Texas Researchers who are involved in preparing, submitting, and conducting human subjects research. This SOP is also 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.

## **PROCEDURE**

### **1. General Oversight**

- 1.1 Research with Native American or Alaskan Native Tribes involving or conducted by UNT Researchers remains subject to the review and approval authority of the UNT IRB and the obligations undertaken by UNT in its Federal Wide Assurance on file with the federal Office of Human Research Protections (OHRP).
  - 1.1.1 The UNT IRB reviews and approves research involving Native American or Alaskan Native Tribes in compliance with the Common Rule and other applicable regulations and laws.
  - 1.1.2 The regulations that govern human subjects research under the Common Rule do not affect any state or local laws or regulations, including tribal law passed by governing bodies of Native American or Alaskan Native Tribes, that may otherwise be applicable and that provide additional protection for human subjects. (45 CFR 46.101(f))
  - 1.1.3 Proposed research involving Native American or Alaskan Native Tribes is partially regulated by a division of the Department of Health and Human Services called the Indian Health Service (IHS). Tribal nations fall within the IHS Federal Wide Assurance (FWA) and must be approved by the relevant

## IHS IRB.

### 1.1.3.1 The IHS website lists all relevant IRBs.

- 1.2 It is the responsibility of the Principal Investigator to identify the potential for enrollment of Native American or Alaskan Native Tribe members.
- 1.3 The Principal Investigator must make themselves familiar with the guidelines of the Native American or Alaskan Native Tribe where research will occur. If possible, the UNT Principal Investigator should work with a local collaborator in the Tribe where research will be conducted. Each Tribe has unique rules and procedures for conduct of research within their community.
- 1.4 Tribes have the authority to prohibit a project to move forward on their land or involving their populations.
- 1.5 Research projects that take place within Native American or Alaskan Native Tribes or on Native American or Alaskan Native Tribe land require compliance with UNT policies and procedures as well as the relevant laws and regulations of the Tribe. For this reason, additional review and documentation are required when conducting research outside with Native American or Alaskan Native Tribes.

## 2. IRB Submission and Review

- 2.1 When submitting a study that is to be conducted with Native American or Alaskan Native Tribes populations or on Native American or Alaskan Native Tribe land, the Principal Investigator must identify, in writing, this information.
- 2.2 The Principal Investigator is responsible for contacting the tribal nation to secure approval from the tribal nation's council or governing body.
  - 2.2.1 A copy of this approval must be uploaded within the IRB submission portal.
- 2.3 The Principal Investigator is responsible for identifying any additional requirements or tribal laws which would apply to the conduct of the research project or the protection of human subjects.
  - 2.3.1 A clear description of this information should be included within the IRB submission portal for review by the IRB.
- 2.4 The Principal Investigator is responsible for submitting the study for review by the UNT IRB through the IRB submission portal, in addition to the appropriate IHS IRB for approval.
  - 2.4.1 If the tribal nation does not have a functioning IRB per the IHS website, the IRB application and research protocol must be sent to [IRB@ihs.gov](mailto:IRB@ihs.gov).
- 2.5 The UNT IRB will request a copy of confirmation that IHS IRB has been contacted and has approved the project.
- 2.6 The UNT IRB may not review Requests for Approval involving Native American or Alaskan Native Tribes under Exempt review. Research studies involving these groups must go through either an expedited or full-board review.
- 2.7 Research Integrity and Compliance can provide guidance and assistance through this process if research involves Native American or Alaskan Native Tribes. If additional help is needed, the Principal Investigator may consult with Research Integrity and Compliance by emailing [untirb@unt.edu](mailto:untirb@unt.edu).
- 2.8 IRB approval times can vary for IRB application involving Native American or Alaskan Native Tribes. It is up to the Researchers to ensure they have submitted their application early, as some approvals can take months depending on the review level and the permissions and IRB and tribal nation review required from the Native American or Alaskan Native group.

## REFERENCES

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

## **APPENDICES**

1. IRB SOPs