

AIHEC Policy for Human Subjects in Research

Responsible office: AIHEC Student Success Team

Responsible person: AIHEC Director of Equity, Education Innovation & Research

Effective Date: [INSERT]

Last Review: [INSERT]

Policy summary: The purpose of the AIHEC Policy for Human Subjects in Research is to provide expectations for staff conducting research at Tribal Colleges and Universities, involving human subjects with the scope of their AIHEC duties. Research with American Indian and Alaska Native (AI/AN) individuals, Tribes, and communities requires special considerations and processes to protect data and tribal sovereignty.

Definitions

Common Rule

Federal Policy for the Protection of Human Subjects as adopted by (and codified in the regulations of) multiple federal agencies. For the purposes of this Policy and related policy guidance or procedure documents, the Common Rule refers to Subpart A of Department of Health and Human Services (HHS) regulations at Title 45, Part 46 of the Code of Federal Regulations ([45 CFR 46, Subpart A](#)).

The 2018 Common Rule and AI/AN Communities

The 2018 Common Rule contains two changes that benefit AI/AN Tribes:

1. It recognizes Tribal authority over research (**45 CFR 46.101(0), 45 CFR 46.102(k), 45 CFR 46.116(0), 45 CFR 46.116(j)**). Tribal sovereignty applied to the equivalent subsections in the pre-2018 Requirements but was not explicitly stated.
2. It has an exemption process for Tribes within the single IRB review system [**45 CFR 46.114(b)(2)(i)**] based on Tribal sovereignty. Tribes can ensure that mandated single IRB research has minimized harm and maximized benefit to them by themselves reviewing the research. The 2018 Common Rule thus helps raise awareness about Tribal sovereignty among IRBs, researchers, and HRPPs (Human Research Protection Programs).

The 2018 Common Rule, however, may also harm AI/AN Communities by its expansion of activities "deemed not to be research" [**45 CFR 46.1020**] to include "oral history" and "[p]ublic health surveillance activities." Many oral histories of AI/AN individuals make general statements about their community (see Left Handed, 2018). The report of the public health investigation detailing an outbreak of congenital syphilis, described previously, harmed that, Tribe. For those reasons and others already discussed, many AI/AN IRBs "go beyond the Common Rule." For

Federal wide Assurance (FWA) IRBs to "go beyond the Common Rule," the OHRP recommends that the IRB's institution include in its IRB policy that the IRB is to minimize harms to and maximize benefits for AI/AN Communities (DHHS, 2012, 2017).

Human Subject.

As defined in HHS regulation 45 CFR 46.102(e), Human Subject means "a living individual about whom an investigator (whether professional or student) conducting research: (i) Obtains information or biospecimens through intervention or interaction with the individual, and uses, studies, or analyzes the information or biospecimens; or (ii) Obtains, uses, studies, analyzes, or generates identifiable private information or identifiable biospecimens."

As defined in Food and Drug Administration (FDA) regulation 21 CFR 50.3(g) and 21 CFR 56.102(e), Human Subject means "an individual who is or becomes a participant in research, either as a recipient of the test article or as a control. A subject may be either a healthy human or a patient." See also 21 CFR 312.3(b) for additional definitions related to Human Subjects Research. Regulation 21 CFR 812.3(p) defines subject as "a human who participates in an investigation, either as an individual on whom or on whose specimen an investigational device is used or as a control. A subject may be in normal health or may have a medical condition or disease."

Institutional Review Board (IRB)

The generic name for any board, committee, or other group formally designated by an institution to review the conduct of Research involving Human Subjects.

Institutional Official (IO)

The individual who is legally authorized to act for the institution and, on behalf of the institution, including obligating the institution to the terms of the Federal wide Assurance filed with the Department of Health and Human Services Office of Human Research Protection (OHRP) for the protection of Human Subjects. For the purpose of this policy, the IO will be President Carrie Bill of AIHEC.

Research

The systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge, consistent with the HHS definition of research (45 CFR 46.102(l)).

Researchers and IRBs must include in their ethical assessments the potential harms and potential benefits as defined by the AI/AN Communities involved. Research With American Indian and Alaska Native Individuals, Tribes, and Communities **569** political entities, federally recognized Tribes have legal authority to permit or prohibit research and entry by researchers to/from their reservation or Tribal lands. Many Tribes have established policies and procedures to review and approve or disapprove proposed research, and some have their own IRBs

Introduction

The American Indian Higher Education Consortium (AIHEC) is committed to the ethical principles for the protection of Human Subjects in research set forth in the Belmont Report of the Nation Commission for the Protection of Human Subjects of Biomedical and Behavioral Research that underlie relevant federal regulations. The principles include:

- Respect for persons: the recognition of the personal autonomy and dignity of individuals, and the need for special protection of individuals with diminished autonomy. Under this principle, individuals must be given sufficient and comprehensible information to decide whether to participate in a study, and their consent must be voluntarily given, free from coercion and undue influence.
- Beneficence: an obligation to protect persons from harm by maximizing anticipated benefits and minimizing possible risks of harm. This principle requires assessing the nature and scope of the risks and benefits, and systematically assessing the risks and benefits.
- Justice: the selection of human subjects should be fair and equitable and that the risks and benefits of research should be distributed among subjects in a fair and equitable manner, with particular concern for subjects whose personal status or condition—such as children, prisoners, patients, impoverished persons, and others--places them in a vulnerable or dependent position.

Compliance/Responsibility

The U.S. Department of Health and Human Services codified its regulations for the protection of human subjects in research in the code of federal regulations at 45 C.F.R. 46, which includes five subparts. It is important for AIHEC staff to review [45 CFR 46](#) and be familiar with Subpart A (the Common Rule) and the robust set of protections for research subjects. Subparts B, C, and D provide additional protections for certain populations in research.

The AIHEC Director of Equity, Education Innovation & Research ensures that this policy is provided to each AIHEC staff member. The Director ensures the Human Subject in Research procedures (below) are properly executed and routinely updated. The Director also provides ongoing staff development related to 45 CFR 46 to help educate the organization on federal requirements.

The Director also aligns the AIHEC policy and procedures with federal requirements. The Director collaborates with Northwest Indian College (NWIC) to ensure IRB policy and processes remain free from undue influence in its decision-making process.

Research approved by NWIC IRB, as well as Tribal reservation IRBs, may be subject to further appropriate review and approval or disapproval by IRB committees.

Institutional Review Board Responsibilities

The IRB has the authority to:

- Approve, disapprove, or require modifications to research protocols;
- Suspend or terminate approval of Human Subject Research not being conducted in accordance with an IRB's requirements or that has been associated with unexpected serious harm to subjects; and
- Observe, or have a third party observe, the consent process and/or the conduct of Research.

Per AIHEC board motion, AIHEC's Institutional Review Board (IRB) is Northwest Indian College (NWIC)

The review performed by the NWIC IRB will meet the human subject protection requirements of its Office for Human Research Protections (OHRP)-approved Federal wide Assurance (FWA). The IRB at Northwest Indian College will follow written procedures for reporting its findings and actions to appropriate officials at AIHEC. Relevant minutes of IRB meetings will be made available to AIHEC upon request. AIHEC remains responsible for ensuring its compliance with the NWIC IRB's determinations and with the Terms of NWIC IRB's OHRP-approved FWA.

Investigator Responsibilities

All AIHEC staff, as well as hired AIHEC consultants, conducting Research involving Human Subjects within the course and scope of their AIHEC duties or contracts, regardless of whether the Research is funded and regardless of the source of funding, must submit Human Subject Research protocols to the IRB for approval or follow other AIHEC policies and/or procedures for obtaining an exempt determination PRIOR TO COMMENCING Research.

Investigators must maintain IRB approval for the lifespan of the project, submit continuing review documents to the IRB as necessary to maintain the approval, and follow all IRB and AIHEC policies for the protection of human subjects in the conduct of the project.

Investigators are responsible for completing the relevant procedures below.

Program Mangers/Project Directors are also responsible for ensuring other co-Principal Investigators or researchers involved in the Research project complete the relevant training as listed below.

Requirements and Procedures

Every AIHEC staff member is responsible for completing all required Human Subjects in Research training(s) prior to conducting Human Subjects Research. Upon completion of the training, the printable certificate of completion must be provided to AIHEC's Grants Administrator and AIHEC's Director of Equity, Education Innovation & Research, who will track and file completion certificates for each grant and grant application.

The Program Manager/Project Director must ensure all project members, inclusive of subrecipient staff and AIHEC consultants, have completed **one** of the following trainings relevant to their respective research protocol as well as any required training per grantor, to remain in federal compliance:

- Relevant [Collaborative Institutional Training Initiative \(CITI\)](#) training
 - Community-Engaged and Community-based Participatory Research
 - Social-Behavioral-Educational (SBE) Comprehensive
 - Social-Behavioral-Educational (SBE) Refresher 1 and 2
 - Public Health Research
 - Biomedical (when relevant)
- Indigenous Research training: rETHICS - Research Ethics Training for Health in Indigenous Communities
- Specific NSF or NIH requirements: Human Research Protection Foundational Training lessons 1-5

The Principal Investigator/Program Manager/Project Director must complete an Institutional Review Board application prior to beginning any Human Subjects in Research work.

- AIHEC utilizes NWIC IRB protocols and IRB committee. Some tribal communities require their own tribal IRB approval, and it is the responsibility of the Principal Investigator to apply to the appropriate IRB, in this case NWIC IRB would be secondary not primary.

Research Grants

- Prior to any grant submission, staff must first complete the AIHEC Proposal Summary Approval Form (PSAF).
- Once the PSAF form is approved by the President & CEO of AIHEC, the grant proposal must go through the AIHEC Research Team to seek approval by the AIHEC Research Committee.
- Once approval is confirmed, the researchers must provide a copy of their Human Subject Training and appropriate IRB approval to AIHEC's Grants Administrator, prior to data collection.