

	Title: <b>NWIC Institutional Review Board (IRB) Policy</b>	POL-806
Prepared By:	Preparer's Name/Title William L. Freeman Program Director, Center for Health	Date Prepared: 01/09/2018
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#### 806.1 POLICY STATEMENT

It is the policy of the Board of Trustees that the NWIC Institutional Review Board (IRB) meet all Federal and NWIC requirements to review and disapprove, modify, or approve research with human participants. The IRB must comply both with **Title 45 Code of Federal Regulations Part 46 Protection of Human Subjects (45 CFR 46)** and also with NWIC's Tribal-self-determined Components and Criteria (below).

#### 806.2 PURPOSE

The purpose of this policy is that the NWIC IRB fully comply: (A) with **45 CFR 46** and thus maintain its Federal wide Assurance (FWA) for the Protection of Human Subjects; and (B) also with NWIC's Tribal-self-determined Components and Criteria added to **45 CFR 46**. The additional Criteria include that, unless it defers, the Tribe, TCU, and Tribal-Based Organization (TBO) owns and controls all research data, biological and non-biological materials, and analyses from and about itself and participating individuals, using legally-effective terms approved by Tribal-based Attorneys. The intended result of this policy is that the NWIC IRB is recognized by Federal and all other research funders, and by Tribes/TCUs/TBOs, as the Tribal-self-determined IRB of record to review research they fund or take part in, respectively.

#### 806.3 SCOPE

This policy applies to the NWIC IRB.

#### 806.4 BACKGROUND

An IRB with an FWA must review and approve all Federally funded or conducted research before it may start. The NWIC IRB began in 2003 with Chair David Oreiro, and received its FWA #00003979. The Board of Trustees approved its Policies on October 9, 2013. The NWIC IRB is the IRB for NWIC, Lummi Nation, Swinomish Indian Tribal Community, Upper Skagit Indian Tribe, Northwest Washington Indian Health Board, American Indian Higher Education Consortium, and American Indian College Fund, thus enabling NWIC and those Tribes/TCUs/TBOs to receive Federally funded research grants and contracts.

IRBs with an FWA must follow **45 CFR 46** for their reviews of research, but **45 CFR 46** considers harms only to individuals, not to Tribes, TCUs, and TBOs. Yet too often, research has harmed Tribes, TCUs, and TBOs, and most research and IRBs have ignored self-determination and inherent Tribal sovereignty.

The Office of Human Research Protection (OHRP) has stated that institutions may add responsibilities to their IRB beyond those required by **45 CFR 46**.<sup>1</sup> This NWIC Policy makes the NWIC IRB responsible also to minimize harms to Tribes/TCUs/TBOs and to promote self-determination and Tribal sovereignty.

#### 806.5 RESPONSIBILITY

The IRB has primary responsibility. The Vice President for Administration and Campus Facilities has oversight responsibility.

#### 806.6 DEFINITIONS

**45 CFR 46:** Title 45 Code of Federal Regulations Part 46 - Protection of Human Subjects. This Policy is based on the *Revised 45 CFR 46* with effective date January 21, 2019.

**DMSOA (Data and Material Sharing and Ownership Agreement):** A legal agreement signed by the researcher's institution, grant recipient institution, Tribes/TBOs, and researcher that the Tribes/TBOs

control all data, materials, and analyses, to prevent misappropriation and misunderstanding of their data and materials, and to prevent research harms/risks and maximize research benefits to the Tribes/TBOs.

**FWA:** Federalwide Assurance of Compliance for the Protection of Human Subjects, issued by OHRP.

**Harms/risks:** “Harm” is the type and severity of the damage or injury, while “risk” is the likelihood or chance that the harm will occur. Tribal-self-determined harms include: econo-ecolo-psycho-social harms; and interference with the Tribe’s ways of life, values, spirituality, self-identity, and self-determination.

**OHRP:** Office for Human Research Protections in the Department of Health and Human Services. OHRP oversees IRBs for compliance with **45 CFR 46** and authoritatively interprets that regulation.

**Research reviewable by IRBs (Federal definition):** “systematic investigation [of currently living and identifiable individuals], including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge.” Oral histories are not generalizable and thus not reviewable. Public health investigations contribute to generalizable knowledge but are “deemed not to be research.”

**Research (Tribal-self-determined definition):** Systematic investigation of people (including not living or identifiable) and Tribes/TCUs/TBOs, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge. Because some public health investigations and oral histories have made harmful generalized statements about Tribes/TCUs/TBOs, they will be reviewed.

**TBO:** Tribal-Based Organization (e.g., TCUs, Indian Health Boards, Urban Indian Health Programs).

**Tribal-self-determined:** Self-determination by Tribes exercising their inherent sovereignty, and self-determination by TCUs and other TBOs as well.

806.7 THE IRB MUST COMPLY WITH TRIBAL-SELF-DETERMINED COMPONENTS AND CRITERIA  
The NWIC IRB will review all research by or about NWIC faculty, staff, and students and also research that Tribes/TCUs/TBOs ask it to review. It must fully comply with both **45 CFR 46** and the following Tribal-self-determined components and criteria. It will be a Tribal-self-determined IRB with an FWA.

#### **Structure of the IRB**

##### **A. IRB Membership (45 CFR §46.107)**

The NWIC President will appoint all IRB members. The IRB will have at least nine members with at least two who both are descendants of a Federally-recognized Tribe and also have primary expertise in non-scientific areas. Highest priority will be Elders interested in reviewing research.

##### **B. IRB Functions and Operations (45 CFR §46.108)**

At least one member who both is a descendant of a Federally-recognized Tribe and also has primary expertise in non-scientific areas must participate in all Full and Expedited reviews.

##### **C. NWIC IRB’s Registration and FWA with OHRP (45 CFR §46.502)**

The IRB’s Registration and FWA will include the NWIC IRB’s *Tribal-Self-Determined Principles in Human Research Protection*; see 806.9.

#### **IRB Review of Research Plans, Protocols, and Publications**

##### **D. “Human Subject Research” reviewable by the NWIC IRB (45 CFR §46.102)**

The IRB will review all Tribal-self-determined-defined research. See 806.6 DEFINITIONS.

##### **E. Exempt Research (45 CFR §46.104)**

Because the list of research “Exempt from IRB review” did not consider potential harms to communities, the IRB will review all “Exempt” research by its Expedited procedure.

##### **F. IRB Review of Research: Overview (45 CFR §46.109)**

The IRB will require informed consent by participating Tribes/TCUs/TBOs, not only by individuals. The IRB will review and approve, require modification, or disapprove all proposed presentations, research reports, and publications, in order to minimize harms/risks and maximize benefits to Tribes/TCUs/TBOs and to recognize and comply with self-determination and Tribal sovereignty.

##### **G. IRB Review of Research: “Expedited Review Procedures” (45 CFR §46.110)**

OHRP’s list of categories of research that IRBs may review by “Expedited review procedures” did not consider potential harms to communities. The IRB will review such research by full review.

##### **H. IRB Review of Research: Criteria for IRB Approval (45 CFR §46.111)**

The IRB will apply the criteria for IRB approval of research to Tribes/TCUs/TBOs/communities. The IRB will add criteria that each Tribe/TCU/TBO owns, controls, and determines who and what has access to the data, biological and non-biological materials, and analyses of itself and its members using legally-effective terms approved by Tribal-based Attorneys, unless it defers. The IRB may require the researcher’s institution to sign legal DMSOAs with each participating Tribe/TCU/TBO that contain those provisions, unless the Tribe/TCU/TBO defers.

- I. Non-Compliance, Adverse Events, Violations, Appeals, and Grievances (45 CFR §46.113)**  
The IRB will report all serious problems and responses to the Tribes/TCUs/TBOs in the research. It will consult with Tribal/TCU/TBO experts before responding to an appeal of any IRB decision.
- J. Cooperative Research (i.e., Single IRB) (45 CFR §46.114)**  
“Cooperative research” is reviewed by only a Single IRB. Such research has potential benefits and harms/risks to participating Tribes/TCUs/TBOs not known or understood by non-Tribal-based IRBs. The NWIC IRB thus will review such research. The IRB will not approve such research if the NWIC IRB’s conditions are not met, unless the participating Tribes/TCUs/TBOs defer.
- K. General Requirements of Voluntary Informed Consent (45 CFR §46.116)**  
The IRB will ensure that Informed Consent documents contain all Tribal-self-determined benefits, protections, and conditions for Tribes/TCUs/TBOs stated in the DMSOA, if any.
- L. IRB Reports to NWIC, Tribes, TCUs, and TBOs**  
The IRB will periodically report about its activities to the NWIC President and to all Tribes, TCUs, and TBOs for which the IRB reviews research.

806.8 RELATED NWIC INFORMATION

- A. Policy 403: Indigenous Research Policy
- B. Policy 404: Intellectual Property Policy

806.9 TRIBAL-SELF-DETERMINED PRINCIPLES IN HUMAN RESEARCH PROTECTION

A. Mi'kmaw Ethics Watch. (2000). *Mi'kmaw Research Principles and Protocols: Conducting Research With and/or Among Mi'kmaw People*.

[ <https://www.cbu.ca/indigenous-affairs/unamaki-college/mikmaq-ethics-watch/> ]

B. Canada’s Tri-Council Policy Statement, 2nd Ed. (2009). Chapter 9 “Research Involving the First Nations, Inuit, Métis, Peoples of Canada”

[ <http://www.pre.ethics.gc.ca/eng/policy-politique/initiatives/tcps2-eptc2/chapter9-chapitre9/> ]

C. Schnarch, Brian. (2004). “Ownership, Control, Access, and Possession (OCAP) or Self-Determination Applied to Research: A Critical Analysis of Contemporary First Nations Research and Some Options for First Nations Communities.” *Journal of Aboriginal Health*. 1 (1), 80-95.

D. Porsanger, Jelena, & Guttorm, Gunvor (Eds.). (2011). *Working with Traditional Knowledge: Communities, Institutions, Information Systems, Law and Ethics – Writings from the Arbediehtu Pilot Project on Documentation and Protection of Sami Traditional Knowledge*.

E. LaFrance, Joan & Nichols, Richard. (2009). *Indigenous Evaluation Framework: Telling Our Story in Our Place and Time*.

[ <https://portalcentral.aihec.org/Indigeval/Lists/IndigenousEvaluationFrmWork/AllItems.aspx> ]

806.10 ADDITIONAL STANDARD PRINCIPLES IN HUMAN RESEARCH PROTECTION

The Belmont Report.

Title 45 Code of Federal Regulations Chapter 46 Protections of Human Subjects.

806.11 REVIEW DATE

This Policy will be reviewed every three (3) years.

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<sup>1</sup> - OHRP Webinar 2012-11-08, “When PIs Come a'Knockin': Everything Investigators Want to Know but are Afraid to Ask,” pp. 6, 9, & 11 (at <https://www.hhs.gov/ohrp/sites/default/files/ohrp/education/training/piswebinartranscript.pdf> )

- In “3(c) U.S. and non U.S. Institutions” within “Federalwide Assurance for the Protection of Human Subjects” (at <https://www.hhs.gov/ohrp/register-irbs-and-obtain-fwafs/fwafs/fwa-protection-of-human-subject/index.html> [sic]): “For any research to which the FWA applies, the Institution also will comply with any additional applicable human subjects regulations and policies of the U.S. federal department or agency which conducts or supports the research and any other applicable federal, state, local, or institutional laws, regulations, and policies.” [Italics added.]