



MCW Office of Research Standard Operating Procedure

RESEARCH INVOLVING NATIVE AMERICAN OR ALASKA NATIVE TRIBES

Unit: Human Research Protections Program (HRPP), Office of Research

Applies to: Faculty and Staff involved in human research

PURPOSE:

When conducting human subjects research with Native American or Alaska Native Tribes, additional safeguards must be in place due to the unique concerns and procedures of each Tribe or Nation. Tribal nations themselves are best positioned to identify potential adverse outcomes in human subjects research involving Tribes or Nations.

The MCW IRB reviews and approves research involving Native American or Alaska Native Tribes in compliance with the Common Rule and other applicable regulations and laws.

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 the official governing body of an American Indian or Alaska Native tribe) that may otherwise be applicable and that provide additional protections for human subjects. (45 CFR 46.101(f))

DEFINITIONS:

Public health authority: an agency or authority of the United States, a state, a territory, a political subdivision of a state or territory, an Indian tribe, or a foreign government, or a person or entity acting under a grant of authority from or contract with such public agency, including the employees or agents of such public agency or its contractors or persons or entities to whom it has granted authority, that is responsible for public health matters as part of its official mandate. (45 CFR 46.102(k))

POLICY:

It is the responsibility of the Investigator to identify the potential for enrolling this population into the project.

Investigators seeking to conduct research with Native American or Alaska Native Tribes must consult with the local tribe about their research project and secure approval from the tribe.

Each tribe is unique and has its own rules and procedures for conducting research within their community. Tribes have authority to not allow a project to move forward on their land or involving their populations.

PROCEDURE:

1. Investigators when submitting a new eBridge PRO SmartForm should identify subjects from a tribal nation may be included.
2. Investigators should work with the tribal nation(s) to secure approval from the nation's council. This approval must be uploaded with the eBridge PRO SmartForm.
3. In addition, Investigators should work with the tribal council and/or nation to identify any additional requirements or tribal laws which would apply to the research, and protection of human subjects. This may include:
 - a. Recruitment methods,
 - b. Consent process and documentation
 - c. Storage and protection of data
 - d. Dissemination of final results including future access to dataInvestigators should describe how they will address these requirements in their project and/or eBridge PRO SmartForm.
4. If the project is supported by federal funds (e.g., NIH grant) Investigators should work to ensure the tribal council has a current FWA as this is a federal requirement for those who work a project which receives federal funding.

REFERENCES:

45 CFR 46.101(f)
45 CFR 46.102(k)

SUPPORTING DOCUMENTS:

N/A

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Approved By	
HRPP Authorized Official:	Ryan Spellecy, PhD, Director, HRPP Human Research Protections Program (HRPP) Office of Research Medical College of Wisconsin