

Native American or International Indigenous Populations in Human Research

Overview

Human Research that includes Native Americans or International Indigenous populations as part of the study population must adhere to the guiding principles identified in the University of Arizona policy on Tribal Consultation and the Arizona Board of Regents policy (1-118 Tribal Consultation). A project is considered to include Native Americans when:

- The research takes place in Indian Country, and/or on land under the control or jurisdiction of a sovereign tribe or among International Indigenous populations; or
- Human research is conducted in Indian Health Service (IHS) facilities or involving IHS staff or resources, or
- The research involves participation by members of a sovereign tribe or Indigenous community and that may foreseeably result in research results with implications specific to a tribe or to individuals as members of a tribe or Indigenous community, and the proposed publication or dissemination of that research; or
- The research actively recruits Native Americans or International Indigenous populations for enrollment or participation; or
- The research involves human subjects, including genetic testing or testing of blood, tissue, or other biological materials if the individual's membership in or affiliation with a tribe or Indigenous community is identified, and that is intended to or that may foreseeably result in conclusions or generalizations about a tribe or individuals as members of a tribe or Indigenous community.

Procedures

1. Submit documentation to the UA Human Subjects Protection Program of Native Nation or Indigenous community approval of the research protocol along with the IRB submission.
2. Copies of authorizations shall be submitted as a required component of the research proposal like any Site Authorization permission to receive IRB review. If it is not possible to obtain such authorization prior to IRB submission, please notify the Human Subjects Protection Program staff to discuss what alternatives exist.
3. The HSPP will identify a reviewer for research projects involving Native Americans or International Indigenous populations from the list of members on the IRB roster to serve as a secondary reviewer or consultant regarding the risks and benefits specific to the proposed population. This will be conducted as part of the IRB review process.



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Informed Consent and Genetics

Use of specimens for genetic research from Native Americans or International Indigenous populations could have implications for the group as a whole. To ensure that potential subjects are informed about the potential risks, the following paragraph should be used when a human research study involves Native Americans or Indigenous populations (as described above) and is conducting genetic research:

If you are Native American and agree to participate in this study there may be risks associated with the research that impact your community. Health information, especially genetic information, can be applied to more than just you. Genetic analysis may be able to provide information about a person's parents, siblings, children, or others. Some genetic research can produce new information about entire subpopulations and individual racial or ethnic groups. It is unknown exactly what the researchers will discover, because this study involves unspecified future research. Risks may include legal, financial, social, or physical harm. Information may be published that conflicts with your communities' culture, traditions, mythologies, or spiritual beliefs.