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;
- Human research is conducted in Indian Health Service (IHS) facilities or involving IHS staff or resources;
- The research targets Native Americans or International Indigenous populations for enrollment or participation;
- The research involves genetic testing or collection and testing of blood, tissue, or other biological materials in which the individual’s membership in or affiliation with an Indian Tribe or Indigenous community may be identified;
- The research may foreseeably result in conclusions or generalizations about an Indian Tribe or Indigenous community and/or its members; or
- The research collects, evaluates, publishes, or otherwise disseminates data that has implications for an Indian Tribe or Indigenous community.

Additional guidance and information on working with tribes and indigenous populations is available from the University of Arizona’s Native Peoples Technical Assistance Office (NPTAO). The University of Arizona NPTAO also provides specific information on AZ tribal research polices.

Submission Requirements

1. Submit documentation* in eIRB of Native Nation or Indigenous community consultation and approval of the research protocol along with the IRB submission.
   *Documentation of tribal approval can include letters or electronic communications of support or approval, tribal resolutions, contracts, permits, or other forms of agreement or evidence of consultation and approval.

2. Copies of authorizations shall be submitted in eIRB 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 as part of the IRB review process, as appropriate.

4. For each Native American or International Indigenous Population that will be the subject of the research, submit an Appendix for Native Americans and Indigenous Populations in eIRB.
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 included in the consent form 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 unspecific 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.

Definitions

- **Indian** means a person who is a member of a sovereign Indian Tribe as defined below. Indian is synonymous with American Indian, Alaska Native, and Native American.
- **Indian Tribe** means any state recognized tribe and any Indian or Alaska Native tribe, band, nation, pueblo, village, or community that the Secretary of the Interior acknowledges to exist as an Indian tribe pursuant to the Federally Recognized Indian Tribe List Act of 1994 (25 USC 479a).

Resources

- UA Tribal Consultation Policy: https://policy.arizona.edu/administration-university-relations/tribal-consultation-policy
- ABOR Tribal Consultation Policy 1-118: https://public.powerdms.com/ABOR/documents/1491525
- UA Native American Advancement, Initiatives & Research (NAAIR) Training & Resources: https://naair.arizona.edu/resources
- NAAIR Research & Engagement Getting Started: https://naair.arizona.edu/research-engagement/getting-started
- Indian Health Service Human Subjects Research Protections: https://www.ihs.gov/dper/research/hsrp/