

Dear Researcher,

Thank you for your interest in applying for a research permit with the Tohono O'odham Nation's (TON) Institutional Review Board (IRB). We, The Tohono O'odham Nation's IRB are responsible for ALL research within the geographical boundaries of any of the Nation's reservations. Members of the board are Tohono O'odham citizens who have been nominated by the TON Executive Branch and elected by the Nation's Legislative Council tasked to ensure the health and safety of tribal members, living and non-living materials, animate and inanimate entities located on the Tohono O'odham Nation as outlined in the Tohono O'odham Nation's Research Code. As a board, we are committed to ensuring that all researchers working with the Tohono O'odham Nation conduct themselves in accordance with the IRB's guidelines and operate with the highest integrity.

To submit a research project to the TON IRB for review, please draft a proposal that is 10 to 25 pages (double to 1.5 spacing, one-inch margins), not including informed consent sheets or other documents, that contains the following information listed below. Please be aware that depending on a project's topic and/or methodology the IRB may require consultation. The IRB may also request revisions before any review of the documents can take place. The information and documents needed for review are subject to change based on the nature of any given research project submitted. The TON IRB will view documents within 30 days after their submission and will make decisions regarding permits within 60 days after a project's initial review. Please submit a copy of the receipt for administration fees associated with the review of the proposal and permitting. The TON IRB is meant to be a resource for researchers, please feel free to email the board at IRB@tonation-nsn.gov if you have any questions or concerns.

Sincerely, Tohono O'odham Nation Institutional Review Board

Tohono O'odham Nation Institutional Review Board (IRB) Research Application

Instructions

Please complete all sections of this application. Incomplete applications will not be reviewed. Submit the completed application along with all required supporting documents, see Section 3 (e.g., remittance fee, funding/budget, research proposal, CV/resume for all research colleagues). Please be advised that each prompt requires a response. The Principal Investigator will need to read the research code.

Definitions

"Research" is the use of systematic methods to gather and analyze information for the purpose of proving or disproving a hypothesis, evaluating concepts or practices or otherwise adding to knowledge and insight in a particular discipline or field of knowledge or to demonstrate or investigate theories, techniques or practices. For the purpose of this Chapter, research includes but is not limited to the following:

- 1. Basic and clinical research.
- 2. Behavioral studies.
- 3. Anthropological studies.
- 4. Community based participatory research.
- 5. Practice based research.
- 6. Cultural or historical research.
- 7. Feasibility and other studies designed to develop, test and evaluate basic data in all phases of environmental and public health. Changes in development, testing, or evaluation must be pre-approved by the Tohono O'odham Nation Institutional Review Board ("IRB").
- 8. Research on plants, animals, water, land, air, or weather.

Section 1: Principal Investigator Information

- 1. Principal Investigator:
 - o Full Name:
 - o Title:
 - o Institution/Organization:

- o Department:
- Address:
- o Phone:
- o Email:

2. Researchers (if applicable):

- o Names, Titles, and Institutional Affiliations:
- 3. Curriculum Vitae (CV):
 - o Attach a current CV for the principal investigator and all other researchers.
- 4. Research Abstract:
 - Provide a brief summary (no more than 150 words) describing the purpose, goals, and significance of the study.

Section 2: Research Proposal

- Project Title:
- **Description of Research,** Provide a detailed description of the research, including:
 - o **Project Overview/Introduction:** Goals and objectives. All scientific, conceptual, methodological, or other field-specific terms must be defined.
 - **History of Topic:** There should be enough background information for a beginner reader on your research topic.
 - Research Questions
 - o **Type of Information Sought:** (State the intervention your research is attempting to make. The Board recognizes that research is a process and understands that a project's intervention may not be the same at the end of a research project.)
 - o Methodology and Data Collection Techniques
 - Outline how research participants will be recruited. If flyers or other materials will be used, the IRB requires researchers to send drafts with your research proposal. The Board understands that recruitment materials are subject to change; however, research materials are to be updated with the Nation's IRB for approval. List how participants will be compensated. (Note: The Board expects a high standard of compensation for research participants.)
 - Research with Non-Human Subjects: Such as plants and wildlife. Describe protective measures that will be applied during the phase of data collection. For example, you will limit the total number of survey days and crew size to minimize human traffic in the said wildlife habitat. (Note: The TON IRB prohibits the making of new walking/hiking trails and roads for data collection on the Nation so that wildlife is not disturbed. Historic trails and roads, and those made by Border Patrol agents may be used going in and out of the survey area. Describe survey drop-off and pick up locations if there are multiple crews walking transects.)
 - Emergency Management Plan: Describe your emergency management plan.
 The Tohono O'odham Nation is located in the Sonoran Desert where temperatures can reach triple digits. For this reason, it is imperative you develop

- an emergency plan with the contact information of appropriate emergency services (T.O.N. police department, hospital, etc.). If possible, take a satellite phone and always pack extra water and an emergency kit. We also ask that you consider whether your vehicle is appropriate for the terrain you will be working in.
- Location: If your project will be taking place at an archaeological site, village currently occupied, district, or any geographical location, state the location and why the location is important to your project. Provide location coordinates (UTMs preferred), maps, and shapefiles if any have been developed for your project. State how many times you will be visiting your proposed project site, when, and for the duration (e.g., every first and fourth Saturday of the month from 6 AM to 12 PM for a twelve-month period). If you will be visiting archives or other off-reservation sites for data collection, a list of these location/archives is required. (Note: Geographical and Location Data: The TON IRB prohibits point location maps and coordinates and other location data such as physical maps and shapefiles from being shared with anyone not listed on a project's IRB application. In your writeup, geographical and locational data should be referred to in broad terms like "centrally located on the Tohono O'odham Reservation" or "North of highway 86." The use of historic maps and location descriptions from already published material may be used.)
- **o** Any Alternative Testing Sites or Facilities
- o Disposal of Specimens and Data Upon Completion
- Secondary Use of any Retained Specimens or Data (if applicable)
- Informed Consent
 - If your project involves research with Tohono O'odham Elders (55 years or older), please indicate what role Elders will play in the research being proposed and why their knowledge is necessary to the research project.
 - The following will need to be taken into consideration when submitting a proposal that includes working with Elders:
 - During informed consent, the researcher must proactively offer to the Elder an opportunity to request a relative, or designated representative, to be present during all aspects of the research, including the informed consent session and any informational sessions. The researcher must strictly adhere to this requirement in all aspects of the research involving the Elder when a designated representative is requested.
 - During data collection, the researcher must offer an Elder an opportunity to request a relative, or designated representative, to be present and this request is to be adhered to and respected.
 - If applicable, the types of Elder compensation must include mileage for travel, per diem for attendance and meals, etc.
 - For research conducted within an Elderly Center, written permission must be granted by an authorized representative of the Center as well as the Elder.
 - In the event an Elder is subject to an Adult Protective Services case or Guardianship matter in Tribal Court, the researcher must obtain written

- approval by the Nation's Court for the Elder's participation in the research.
- The following will need to be taken into consideration when submitting a proposal that includes working with children/youth of the Nation:
 - During informed consent, a child must have a parent or legal guardian provide written consent to participate. There are no exceptions to this requirement.
 - During data collection, a parent or legal guardian must be present.
 There are no exceptions to this requirement.
 - Children who are subject to an open and ongoing Child in Need of Care case in Tribal Court or a child welfare case in State court are not allowed to participate in any research unless written permission is granted by the Court in which their case is pending. There are no exceptions to this requirement.

• Ethnographic Research & Ethnoarchaeology:

- State whether you will be using already documented interviews or if you will be creating new data by conducting interviews. Describe how your interviews will be taking place (virtual, in person, through email). If interviews are taking place in-person, the researchers must adhere to the Nation's health and environmental policies (e.g. epidemics, severe weather, etc.). Describe whether you will be creating new data through excavation. If so, provide state site number(s), clearly state current ownership of land, and how the creation of new data will benefit your ethnoarchaeology study. If you are working with a collection of artifacts, indicate where the collection is currently housed and where they originate from (e.g., housed at the Arizona Museum originally collected from AZ AA:12:34).
- Timelines: Provide a timeline that outlines how long it will take to complete data collection, when data collection will take place (e.g., twice a month for 3 months), and when other research tasks will approximately take place.
- Budget for Project
- o **Funding Sources** List all funding sources and their confidentiality restrictions. Identify pending funding applications. Budget for cultural sensitivity training, community education, and harm remediation.
 - List all data sharing and reporting requirements by the funding sources.
- Professional, Institutional, Personal Liability Insurance: Including vehicle liability insurance (if applicable). Note: Documentation of who is liable for the research project. For example, a certificate of insurance naming Tohono O'odham Nation as an additional insured.

Justification for Research Location:

- Thoroughly explain why the research can only be conducted on Tohono O'odham Nation lands.
- Thoroughly explain why the research can only be conducted with Tohono O'odham Nation citizens and/or community members.
- Describe any related research and how this study complements or differs from it.

Anticipated Benefits:

- Explain the anticipated benefits, including:
 - Contribution to the scientific and/or academic discipline
 - Impact on human subjects or participants
 - Benefits to the Tohono O'odham Nation
 - Benefits to Indian Country generally
 - Benefits to society at large
- o **Risk Assessment & Mitigation:** (Be advised 'not applicable' is not an appropriate response for this section.)
 - Identify risks to participants' physical or psychological well-being
 - Assess risks to the cultural, social, economic, or political well-being of the Nation and its communities
 - Describe steps taken to minimize risks and response plans for potential harm

Confidentiality & Data Protection:

- Detail how confidentiality will be maintained for individuals, families, villages, districts, and the Nation
- Describe how data will be stored, protected, and eventually destroyed
- List any legal or contractual obligations that could require a breach of confidentiality
- Attach signed data use agreements, informed consent forms, or other privacy documents
- List all data sharing and reporting requirements by the funding sources.

Community Engagement & District Consultation:

- Researchers are strongly encouraged to visit the village and district to share information about the research project to ensure the highest quality of implementation and transparency
- List the districts directly affected by this research
- Summarize discussions with district representatives, including support, opposition, or concerns
- Provide a supporting resolution from the village and district for your research. Note: A letter of support is also acceptable.

Biological Samples:

- Section 8101 of the Nation's research code defines biological samples as, but not limited to, "bacteria and other microorganisms, bacteria, plant, animal, or any human biological materials, genetic samples, any copies of the original genetic samples, any cell lines containing copies of the original genetic samples, and data derived from these samples."
- Section 8106 (9) of the Nation's research code also states, "Ownership of specimens, control by the individual research participants over the use of their own specimens, and the nation's control over the current and future use of the specimens must be disclosed and agreed to by the researcher and the IRB prior to a permit being issued."
- Researchers are required to always maintain a complete list outlining descriptions of the samples or information, the source of biological samples, the purpose of each sample, the person who is responsible at each

- location that will house physical samples collected from the Nation's citizens
- Upon the termination, cancellation, or the completion of a project, all biological samples must be returned to the Tohono O'odham Nation's Institutional Review Board
- Detail how biological samples will be returned to the Tohono O'odham Nation's IRB, and how the cost of equipment and the maintenance of biological samples will be paid
- Explain how the biological samples will be returned to the Tohono O'odham Nation's IRB once the proposed research is complete, is cancelled, or in the case that the proposed research is approved and later terminated
- Detail how the equipment necessary to maintain biological samples will be either donated or purchased for the Tohono O'odham Nation once the proposed project is complete, cancelled, or terminated
- Section 8109 (1) of the Nation's research code states "If the IRB decides to revoke a research permit or any portion thereof for good cause and requests the return of all biological samples, the researcher, and any other parties must immediately comply."
- Section 8109 (6) of the Nation's research code states "No entity may seek to patent or use for commercial purposes any biological materials obtained from the Nation or its members, from the Nation's Lands, or under the authority of the Nation. This includes genetic samples, any copies of the original genetic samples, and cell lines containing copies of the original genetic samples, and data derived from these samples."

Publication Rights & Ownership:

- Acknowledge in writing that the IRB retains publication control over research findings
- Confirm that the Nation has ownership of all work products resulting from this research
- Agree to obtain IRB approval prior to any publication

Authorship & Dissemination Plan:

- Explain how researchers will participate in authorship of articles, publications, and dissemination
- Explain how Tohono O'odham community members will participate in authorship of articles, publications, and dissemination

Specimen Ownership & Secondary Use:

- Define ownership of specimens, data, and other research materials produced during the research project
- Outline how individuals and the Nation will control use of specimens, data, and other research materials produced during the research project
- If secondary research is being planned that involves specimens, data, and other research materials produced during the initial research project, a new proposal must be submitted
- Disclose any known secondary research plans

Community Accessibility & Transparency:

- Describe how research findings will be communicated to participants and the Nation
- Describe plans to provide result findings and explanations in both O'odham and English
- An in-person presentation of findings is strongly encouraged

Study Changes Due to Unforeseen Circumstances & Unexpected Findings:

 All research changes that may occur after a permit is issued, and unexpected findings must be reported immediately to the IRB

Cultural Sensitivity Training:

• Agree to complete cultural sensitivity training through the Cultural Affairs Office at the researcher's expense

Use of Recording Devices:

- List all recording devices to be used (e.g., video, audio, photographs, maps, GPS, drawings)
- Explain how subjects will be informed about and consent to recordings
- Outline how recorded information will be used in research projects

Anticipated Completion Date:

Provide the expected completion date of the study

o Himdag and T-Apedag:

• O'odham Himdag, our way of life, and T-Apedag, our well-being, are central to how we organize our communities, our government, and conduct research. How will you take into consideration Tohono O'odham Himdag and T-Apedag in your research design and practices?

Positionality:

Describe how the positionality of all researchers involved in the proposed project might influence data collection and analysis. For example, will the researcher's academic or social position, cultural heritage, or gender benefit the research design and outcomes?

• American Indian Citizenship or Descendancy:

If you are a citizen or descendant of a federally recognized tribe, please attach proof of citizenship or descendancy. As an independent tribal IRB, it is not the IRB's position to determine anyone's citizenship status or identity. Being Tohono O'odham, Native American, or Indigenous is also not required when applying for a research permit. The Tohono O'odham Nation's Institutional Review Board is interested in working with researchers from all walks of life. However, we recognize the real violence of ethnic fraud and feel it is necessary to protect Tohono O'odham tribal members, histories, stories, and other materials. Thus, we find it necessary to ensure that when tribal membership is claimed that these claims are recognized and validated by the communities themselves.

Governance:

 Briefly offer 5-7 sentences about your understanding of the Tohono O'odham political system (e.g., the Tribal Nation's relationship to other Tribes).

Section 3: Required Attachments

- Principal and co-researchers' CVs
- 150-word research abstract
- Research proposal
- Informed consent forms (including secondary specimen use, if applicable)
- Confidentiality agreements
- Recruitment Material
- Data use agreements
- Cultural Sensitivity Training confirmation (upon completion)
- Remittance fee receipt
- Budget and funding sources
- Proof of insurance

Section 4: Certification & Signature

By signing below, I certify that all information provided in this application is accurate and complete. I agree to comply with the research code and requirements set forth by the Tohono O'odham Nation Institutional Review Board.

•	Principal Researcher Signature:
	Date:
•	Co-Researcher(s) Signature(s) (if applicable):
	Date:

IRB Review Decision:

- Grant full permission without modifications
- Grant permission with modifications to the proposal
- Deny the proposal
- Withhold a determination until a stated date

Additional Considerations

- The IRB reviews research proposals monthly
- Decisions by the IRB are issued within 60 days of receiving the complete research proposal

- The IRB does not consider proposals or issue permits to researchers, institutions, and organizations that are currently not in good standing or under investigation with the IRB. The following may result in a determination that the applicant is not in good standing with the IRB: non-compliance with approved protocols, violation of cultural protocols as outlined in a research permit, failure to obtain or maintain consent, unapproved changes to a research plan, inadequate reporting, data misuse or breach of confidentiality, failure to report finings (compliance), disregarding tribal sovereignty, disrespecting tribal leadership, or ethical misconduct. This list is not an exhaustive list that may trigger an investigation by the IRB.
- Avoid use of share file documents like Google Doc and other online portals that require permission to access.