

**TITLE 17 – HEALTH AND SAFETY**

**CHAPTER 8 – RESEARCH CODE**

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## **TITLE 17 – HEALTH AND SAFETY**

### **CHAPTER 8 – RESEARCH**

#### **Section 8101 Definitions**

“Adequate Knowledge” means that the potential research participant is informed of all possible risks and benefits of the proposed research.

“Biological Sample” means, but is 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.

“Commercial Purposes” means to sell, purchase, barter, trade, delay compensation for profit, exchange, transport, or offer to sell, purchase, barter, trade, delay compensation for profit, exchange, or transport.

“Human Subject” means a living or nonliving individual (including human remains) about whom a researcher conducting research obtains information or data through interaction with the individual, involving physical procedures by which data are gathered (for example, blood draws), and/or manipulations of the subject or the subject’s environment.

“Informed Consent” means a prospective participant’s voluntary agreement, based upon adequate knowledge and understanding of relevant information, to participate in research or to undergo a diagnostic, therapeutic, or preventive procedure. In giving informed consent, the subject may not waive or appear to waive any legal rights, or release or appear to release the applicant researcher, the funding source, or agents thereof from liability for negligence.

“Nation” means the Tohono O’odham Nation.

“Nation’s Lands” means all land within the exterior boundaries of:

- (a) the Sells Tohono O’odham Reservation established by the Executive order of February 1, 1917, and the Act of February 21, 1931 (46 Stat. 1202, chapter 267);
- (b) the San Xavier Reservation established by the Executive Order of July 1, 1874;
- (c) the Gila Bend Indian Reservation established by the Executive Order of December 12, 1882, and modified by the Executive Order of June 17, 1909;
- (d) the Florence Village established by Public Law 95-361 (92 Stat. 595); and
- (e) such other lands as may have been or may hereafter be added thereto by purchase, gift, act of Congress or otherwise.

“Publication” is the dissemination of any information, data, or compilation, whether confidential, by any method or media, including verbal, written or electronic communications, including periodic or final reports required by a grantor.

"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.

"Researcher " means any person, organization, business, or other entity which conducts or participates in the collection of data for research.

“Specimens” means any tangible and intangible data collected for research.

### **Section 8102 Scope and Applicability**

- (A) This Chapter is civil in nature and shall apply within the jurisdiction of the Nation. It shall also be enforceable outside the jurisdiction of the Nation to the maximum extent permitted by law with respect to research conducted on the Nation’s Lands, research using materials as to which the Nation has a claim of ownership, or research that the Nation formally approved by resolution or by permit.
- (B) This Chapter shall apply to all persons subject to the civil jurisdiction of the Nation, including members and non-members, Indians and non-Indians, and corporate and institutional persons who or which might conduct research on the Nation’s Lands.
- (C) This Chapter shall apply to all research conducted within the Nation, whether involving human subjects or not, and all research regarding materials wherever located as to which the Nation has a claim of intellectual, cultural, or other ownership.

- (D) This Chapter does not apply to research conducted by a department of the Nation's government if the research is within the scope of that department's delegated responsibilities.
- (E) This Chapter does not apply to research or surveys of archeological resources as defined in the Archeological Resources Protection Ordinance, Ordinance No. 06-84, or as it may be amended.

**Section 8103 Prohibited Acts**

It shall be prohibited for any person to conduct research within the jurisdiction of the Nation (whether involving human subjects or not) or the collection of materials (wherever located) unless the researcher has obtained a permit as specified in this Chapter. Failure to obtain a permit or to abide by its terms shall result in the civil penalties and sanctions specified in this Chapter.

**Section 8104 Institutional Review Board**

- (A) Board. The Tohono O'odham Nation Institutional Review Board ("IRB") is established to administer this Chapter and is vested with the power to approve or disapprove research proposals submitted pursuant to this Chapter.
- (B) Composition. The IRB shall consist of five enrolled members of the Nation with sufficient experience within their respective fields to effectively evaluate research proposals and perform the additional functions vested in the IRB by this Chapter.
- (C) Appointment. IRB members from the following fields shall be nominated by the Nation's chairperson and appointed by the Legislative Council:
  - (1) An individual with sufficient education and experience in the Nation's culture and traditions, including but not limited to an employee of the Cultural Affairs Office;
  - (2) An individual with sufficient education and experience in health care, including but not limited to an employee of the Tohono O'odham Health and Human Services Department;
  - (3) An individual with sufficient education and experience in academics, including but not limited to an employee or board member of the Tohono O'odham Community College or an employee of the Nation's Department of Education;
  - (4) An individual with sufficient education and experience in the field of elder care, including but not limited to an Tohono O'odham Nursing Care Authority employee or board member; and
  - (5) A Nation's member over the age of eighteen.
- (D) Terms. IRB members shall serve staggered three-year terms expiring on September 30 of the third year. In order to establish and maintain staggered terms, the Legislative Council may appoint three initial IRB member to a three-year term and two initial members to

two-year terms. Thereafter, all terms shall be for three years. IRB members shall serve until replaced, and shall be eligible for reappointment upon expiration of their terms.

(E) Officers.

(1) The IRB shall elect from its membership a chairperson, vice-chairperson, and secretary to two year terms in October every odd-number year. The IRB may appoint other officers as it deems necessary and may determine their duties, terms, and compensation by IRB resolution and bylaws.

(2) The IRB chairperson shall preside at IRB meetings, prepare meeting agendas which are subject to approval by the IRB, and shall perform other duties as may be prescribed by IRB bylaws.

(3) The IRB vice-chairperson shall perform the duties of the chairperson, in the chairperson's absence.

(4) The IRB secretary shall keep IRB meeting minutes, provide timely notice of IRB meetings to all IRB members, and keep on file at all times a complete and current copy of the IRB's resolutions and bylaws. On a quarterly basis, the IRB secretary, with approval from the IRB, shall provide the Legislative Council and the Nation's Chairperson with an updated list of permitted research proposals and any pending proposals.

(F) Removal. An IRB member may be removed with or without cause by the Nation's chairperson with the concurrence by majority vote of the Legislative Council.

(G) Resignation. An IRB member may resign at any time by giving written notice to the IRB chairperson and the Nation's chairperson. A resignation shall become effective at the time specified in the written notice or, if no time is specified, on the date of receipt by the Nation's chairperson. Any IRB member who fails to attend three consecutive, properly noticed IRB meetings or who fails to attend six properly noticed IRB meetings in any fiscal year shall, unless excused from attendance by the IRB chairperson, be considered to have resigned. An IRB member who was appointed as an employee or board member of an entity identified in Section 8104(C) shall be considered to have resigned from the IRB if he or she is no longer serving as an employee or board member of that entity.

(H) Vacancy. The IRB chairperson shall promptly notify the Nation's chairperson concerning any vacancy to be filled. A vacancy shall be filled for the unexpired portion of that term and shall reflect the same category of IRB member as the previously vacated position.

### **Section 8105 IRB Meetings**

(A) Meetings and Notice. The IRB shall meet to consider a research proposal within 30 days after it is provided to the IRB chairperson with any required applications or other

materials. The IRB may conduct additional meetings at the request of the IRB chairperson or by vote of a majority of the IRB. All IRB members will be given five days advance written notice of the meeting date, time, and location.

- (B) Quorum. The presence at a meeting of at least three IRB members shall constitute a quorum of the IRB for the transaction of any official action.
- (C) Actions. The act of a majority of the IRB members present and voting at a meeting with a quorum shall be recorded in writing as a resolution of the IRB and shall be considered an official approval or disapproval of any research proposal submitted under this Chapter. An official written record accurately describing all formal actions of the IRB shall be maintained in the form of written minutes.
- (D) Bylaws. The IRB may adopt and amend bylaws consistent with this Chapter and necessary for the orderly conduct of its business.
- (E) Records. The IRB's minutes and resolutions shall be available for review at all reasonable times by the IRB members, the Nation's chairperson, and members of the Legislative Council.
- (F) Expenses. The IRB members shall be reimbursed for reasonable expenses such as mileage incurred to attend meetings and performing duties incidental to their positions on the IRB. Subject to the appropriation of funds, the IRB members will be paid a stipend from the Nation's Executive Office's annual budget for attending IRB meetings.
- (G) Policies. The IRB shall adopt policies and procedures necessary to implement this Chapter, including a destruction of biological samples policy. Specifically, the destruction of biological samples policy shall outline procedures which safeguard and provide for the appropriate disposal of biological samples in a manner respectful of the Nation's culture and traditions.

### **Section 8106 Information to be Provided**

The IRB shall develop a review process which adequately implements the intent of this Chapter and which provides fundamental fairness to each applicant for a research permit. At a minimum, the following information shall be provided by an applicant in support of an application for a permit:

- (1) Description of the overall nature of the research being proposed, including but not limited to the goals and objectives and the type of information that will be sought from individuals or other participation involving individuals including: the donation of specimens; the type of information concerning the culture, religion and customs and practices of the Nation; alternative testing sites or facilities; disposal of specimens and data upon completion of the project; whether secondary use of any retained specimens is contemplated; informed consent regarding saved specimens and future uses; timelines; funding sources; and malpractice coverage of applicant.

- (2) Description of other related research and justification why the research should be done within the Nation's Lands at this time.
- (3) Expected benefits of the proposed research, primary or secondary findings, including immediate and long range benefits to: the science or discipline represented in the research; the sum total of human and scientific knowledge; human subjects or participants; the Nation; Native Americans generally; and society generally.
- (4) Risks associated with or inherent in the research, including risks to the physical or psychological well-being of individual human subjects or participants and risks of deleterious impact on the cultural, social, economic, or political well-being of the community. The assessment of risk will also address the steps that are being taken to minimize the risks and the steps that will be taken in the event the research harms participants or others.
- (5) Assurances of confidentiality of data as appropriately applied to individuals and, where necessary, to families, communities, and the Nation itself. The applicant shall provide assurances of confidentiality in writing for the life of the project; indicate how confidentiality will be protected after the project and for how long; indicate where and how data and other materials will be deposited and stored at the completion of the project, and destroyed; and indicate the circumstances in which confidentiality may be breached by legal or contractual obligations of the researcher. The applicant shall provide signed data use, informed consent forms, or other privacy agreements as applicable.
- (6) Information regarding discussions with affected districts and if those districts support, oppose, or raised concerns about the research proposal.
- (7) Acknowledgment by applicant that rights to license and publish material and information produced after permission is granted by the IRB shall be subject to IRB policies regarding publication. The Nation has a right to ownership of the work product created by the research or researcher. Works created for hire and copyrighted works transferred to the Tohono O'odham Nation shall be deemed to be the property of the Tohono O'odham Nation. Any permission to publish must be granted by the IRB prior to publication. The Tohono O'odham Nation reserves all rights not granted, including the right of review prior to publication. The IRB has sole authority to control publication of all research, disclosures, and findings.
- (8) An explanation as to how the principal researcher and co-researcher will participate in authorship of articles, publications, or other dissemination of information.
- (9) 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.
- (10) Opportunities for the Nation, individual subject communities, and individuals to have the research proposal fully explained to them in O'odham and English. Opportunities for the Nation, communities, and individuals, as appropriate, to receive

periodic reports on the progress of the research.

(11) Program study changes, changes in testing data, changes in methodology, and alternative or unexpected findings must be communicated throughout the project and preapproved, if possible, by the IRB.

(12) If the study is funded by any public or private sources, the applicant shall provide a full reference of this funding source and explanation of any limits on the confidentiality of research results. If the researcher is currently seeking funding, the researcher shall list all funding agencies for which proposals are being sought. Researchers shall budget funding to cover cultural sensitivity training, to provide adequate resources to cover community education and outreach efforts as a part of the research, and finally, to rectify any harm to, or exploitation of, Nation's property resulting from the research.

(13) All researchers, graduate students, and any other people involved in conducting the research will be required to undergo cultural sensitivity training to be provided at the researcher's expense. Costs will be determined based on the scope of the project. The training shall be provided by the Cultural Affairs Office.

(14) The proposal should outline what recording devices will be used in the project. Recording devices include, but are not limited to: motion picture cameras, audio/video recorders, tape recorders, mechanical, computerized or multimedia technology (CD-ROM), maps and hand drawings. The proposal should address a mechanism whereby the informants or subjects will understand clearly what the researcher plans to do with the recorded information and potential future uses before recording takes place. The proposal should address plans for publication of recorded information in the project or activity and in any other non-research project or activity.

(15) The anticipated completion date of the research proposal.

### **Section 8107 Permit Process**

(A) The IRB shall adopt policies and procedures necessary to implement this Section.

(B) Research proposals may be submitted to the Office of the Nation's Chairperson or directly to the IRB chairperson.

(C) The IRB shall review the applicant's research proposal using the criteria enumerated at 45 C.F.R. § 46.111 and Section 8106 of this Chapter.

(D) The IRB may:

(1) Grant full permission without modifications;

(2) Grant permission with modifications to the proposal;

(3) Deny the proposal; or

- (4) Withhold a determination until a stated date.
- (E) The IRB may revoke a research permit for good cause with written notice to the researcher.
- (F) No IRB member may participate in the initial or continuing review of any research proposal in which the member has a conflict of interest. An IRB member has a conflict of interest when the IRB member or the member's immediate family has a personal or financial interest in the research proposal. An IRB member with an actual or potential conflict of interest will promptly disclose the conflict to the other IRB members.
- (G) Decisions by the IRB shall be issued within 60 days of receiving the research proposal, unless a majority of IRB members vote for additional time to consider the request. IRB decisions may not be overruled or reversed, and may not be reviewed by any court.
- (H) The applicant shall remit to the Nation's Treasurer an application fee in the amount of \$50.00 to cover administrative costs associated with review of the proposal and permitting. The applicant shall include a copy of the administrative fee receipt with the research proposal materials.
- (I) If approved, the permit shall include the timeframe allowed for the researcher to conduct his or her research on the Nation's Lands.

### **Section 8108 Research Agreements**

- (A) An agreement specific to the research shall be negotiated so that studies proceed in a manner that is both culturally sensitive and protects the research participants, materials, and interests of the Nation.
- (B) The IRB, working in collaboration with the Office of Attorney General, shall establish uniform provisions protecting the Nation's interests in accordance with this Chapter that must be included in all research agreements.

### **Section 8109 Regulation of Biological Samples**

Any researcher who seeks to collect, acquire, or analyze any biological samples must agree and abide by the following conditions:

- (1) 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.
- (2) Upon completion of the research project, or termination or cancellation of the project at any time prior to completion, the biological samples must be completely and fully returned to the possession of the Nation.
- (3) No biological samples from this study may be released to, or used by, any other

researcher, research institution, or any other entity, whether public or private, without the prior and fully-informed written approval of the IRB.

- (4) If the IRB permits any biological samples to be stored in any other location, the researcher shall maintain at all times a complete list thereof. The list shall include a description of the sample or data, source, specific use or purpose of each item, responsible person at the location, and where the item is housed (e.g. in a “gene bank” or on a specific computer), and any relevant time lines with regard to use of, disposition, return, or destruction of the samples or data. The researcher shall provide an updated copy of the list to the IRB whenever changes are made. The updated list shall include identification of changes made since the last copy of the list was provided to the IRB.
- (5) Any situation where biological samples will leave the possession or control of the researcher will require review by and a separate agreement with the IRB and the external party in accordance with this Chapter.
- (6) 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, any cell lines containing copies of the original genetic samples, and data derived from these samples.

#### **Section 81010            Enforcement**

- (A) No research shall be performed within the jurisdiction of the Nation or otherwise subject to this Chapter unless the researcher has first received review, approval, and a permit from the Nation’s IRB. Any violation of this Chapter by any researcher shall be subject to the sanctions provided in this section.
- (B) Any outside agency or researcher conducting research within the jurisdiction of the Nation without a permit or otherwise in violation of this Chapter shall be subject to exclusion from the Nation in accordance with the Nation’s laws governing removal and exclusion.
- (C) Whenever it appears that a person has violated, or is violating, or is threatening to violate any provision of this Chapter, the Nation’s Attorney General or his or her designee may file an action in the Nation's Judicial Court (“Court”) to enforce this Chapter.
- (D) In any action brought for violation of this Chapter, the Court may grant injunctive relief to restrain the person from continuing the violation or threat of violation. The Court may order restitution, civil penalties, recovery of research properties and other work products, and such other relief that may be necessary to redress any injury suffered by the Nation, any person, family, organization, or community resulting from the violation.
- (E) The researcher’s funding source may be enjoined from any further research activities and the Nation may report the researcher and his or her funding source’s actions to other

tribes and appropriate organizations and federal, state, and local agencies.

- (F) Any member of the public may provide comments, concerns, or questions to an IRB member regarding any researcher, proposal, or research on the Nation. Any alleged violation of this Chapter may be reported to an IRB member.

**Section 81011            Notice to Other Persons or Institutions**

If a petition is filed pursuant to this Chapter, written notice shall be given to the researcher's sponsoring organization and/or funding source. If a judgment is entered against the researcher subject to this Chapter, written notice of the judgment shall be given to the researcher's sponsoring organization and/or funding source as well as to the professional organization or licensing agency of the researcher, the National Institutes of Health, the Nation's Chairperson, and the Legislative Council.