



**HO-CHUNK NATION CODE (HCC)
TITLE 3 - HEALTH AND SAFETY CODE
SECTION 3 - TRIBAL RESEARCH CODE**

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TABLE OF CONTENTS

1. Authority	1
2. General	2
3. Purpose	2
4. Scope and Applicability	2
5. Definitions	3
6. Unlawful Acts	4
7. Administration	4
8. Information to be Provided	4
9. Permit Process	6
10. Enforcement	6
11. Notice to Other Persons or Institutions	7

1. Authority.

a. Article V, Section 2(a) of the Ho-Chunk Nation Constitution ("Constitution") grants the Legislature the power to make laws, including codes, ordinances, resolutions, and statutes.

b. Article V, Section 2(h) of the Constitution grants the Legislature the power to enact all laws prohibiting and regulating conduct, and imposing penalties upon all persons within the jurisdiction of the Nation.

c. Article V, Section 2(r) of the Constitution grants the Legislature the power to protect and foster Ho-Chunk religious freedom, culture, language, and traditions.

d. Article V, Section 2(s) of the Constitution grants the Legislature the power to promote public health, education, charity, and such other services as may contribute to the social advancement of the members of the Ho-Chunk Nation.

e. Article V, Section 2(t) of the Constitution grants the Legislature the power to enact laws governing law enforcement on lands within the jurisdiction of the Nation.

f. 42 U.S.C. § 3515b requires the Secretary of Health and Human Services to adopt appropriate regulations for the use of federal funds to pay for any research program or

project or any program, project,, or course which is of an experimental nature, or any other activity involving human participants that present a danger to the physical, mental, or emotional well-being of a participant or subject.

g. 45 C.F.R. § 46.101 requires that research supported by a federal department or agency (defined by 45 C.F.R. § 46.102(e)) must be reviewed and approved by an institutional review board (IRB).

2. General.

a. The Legislature recognizes the value of medical, social and physical science research to the Nation, to the Indian people, and to society generally. The Legislature, accepting the Nation's responsibility to bear a fair share of the burdens and risks of research along with other communities, must also act to protect the safety and well-being of Tribal members subject to the Nation's jurisdiction.

b. The Legislature also has a fundamental responsibility to protect and preserve the culture of the Nation and to ensure that the IRB permitted activities are conducted in a way that does no harm to the culture of the Nation.

c. The Legislature has found that research has been conducted in ways that do not respect the safety and human dignity of human subjects and that do not recognize the legitimate interests of the Nation in the integrity and preservation of its culture and religion.

3. Purpose. The purpose of this Code is to define the Nation's research policies, and to establish a means by which tribal research policies will be administered by the Ho-Chunk Nation Institutional Review Board (IRB) and to provide for general procedures by which the IRB will grant permission to researchers to conduct research on Nation Territory. This Code provides for the following:

a. An application and permitting procedure that applicant researchers must comply with in order to obtain permission to conduct research of any kind within the jurisdiction of the Nation.

b. Standards of conduct designed to protect individuals, communities and the Nation itself from improper research procedures. The Ho-Chunk Nation IRB evaluates all proposals for appropriate ethical standards and expects compliance from applicant researchers.

c. Provisions to protect the rights of individuals and the Nation in data.

d. Provisions to ensure appropriate Nation and community participation in the design and evaluation of research, and appropriate local opportunities in employment in all research projects permitted on the trust lands and within the Ho-Chunk community.

4. Scope and Applicability.

a. This Code is civil in nature and hereby amends all existing legislation inconsistent with it.

b. This Code shall apply within the jurisdiction of the Nation. It shall also be enforceable outside the jurisdiction of the Nation as applicable law permits with respect to research conducted on the Nation lands or research using materials as to which the Nation has a claim of ownership.

c. This Code shall apply to all persons subject to the civil jurisdiction of the Nation, including members and non-members, Indians and non-Indians and other corporate and institutional persons who or which might undertake to conduct research on Nation lands, in partnership with the departments of the Nation. This Code does not apply to individuals who participate in research off the Nation's lands outside the parameters of this Code.

d. This Code is adopted pursuant to the Ho-Chunk Nation Constitution and Nation's laws.

e. This Code shall apply to all research (as defined elsewhere in this Code) conducted within the Nation's Territory, 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, legal or equitable.

5. Definitions.

a. "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.

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

c. "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 Code, research includes the following:

(1) Basic and clinical research.

(2) Behavioral studies.

(3) Anthropological and archaeological studies.

(4) Community based research.

(5) 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 Ho-Chunk Nation IRB.

d. "Researcher/Investigator" means any person(s), organization(s), business(es) or other entity(ies) which conducts or participates in the collection of data for research within the territorial jurisdiction of the Ho-Chunk Nation.

e. "Human Subject" means a living or nonliving individual (including human remains) about whom a researcher (whether professional or student) conducting research obtains information or data through intervention or 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.

f. "Specimens" means any tangible and intangible data collected for research.

6. Unlawful Acts. It shall be unlawful for any person to conduct research within the jurisdiction of the Nation (whether involving human subjects or not) or with respect to materials wherever located as to which the Nation has a legal or equitable claim of intellectual or cultural ownership unless the researcher has obtained a permit as specified in this Code. Failure to obtain a permit or to abide by its terms shall result in the penalties and sanctions specified in this Code.

7. Administration. The Ho-Chunk Nation IRB, established as an Authority by the Legislature, shall approve/disapprove research submitted pursuant to this Code.

a. There is established a Ho-Chunk Nation Institutional Review Board (IRB) to administer this Code.

a. The IRB Board of Directors shall submit the By Laws of the IRB to the Legislature for approval within thirty (30) days of this enactment.

8. Information to be Provided. The IRB shall provide the appropriate application forms and develop a review process which adequately implements the intent of this Code and which provides fundamental fairness to each applicant for a permit. At a minimum, the following information shall be provided by an applicant researcher in support of an application for a permit.

a. Description of the nature of the research being proposed, including 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, 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.

b. Description of other related research and justification why the research should be done within the Nation at this time.

c. 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; the Indian people generally; and society generally.

d. 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 ameliorative and curative steps that will be taken in the event the research causes actual harm to participants or others.

e. 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 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 or other privacy agreements as applicable.

f. 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. Works created for hire and copyrighted works transferred to the Ho-Chunk Nation shall be deemed to be the property of the Ho-Chunk Nation. Such works approved for publication may be subject to a royalty, and applicant may enjoy a non-exclusive irrevocable license at the discretion of the IRB. Any permission to publish must be granted by the IRB prior to publication. The Ho-Chunk Nation reserves all rights not granted, including the right of review prior to publication. Applicant acknowledges that a Disclosure Agreement must be signed by the principal investigator at the beginning of the process. The IRB has sole authority to control publication of all research, disclosures, and findings.

g. An explanation as to how the principal investigator and co-investigators will participate in authorship of articles, publications or other dissemination of information. The applicant must fulfill the requirements of authorship of the respective journal or publication in order to be listed as an author.

h. 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 IRB prior to a permit being issued. The permit gives research project, ownership, publication, license and other parameters to be followed.

i. Opportunities for the Nation, individual subject communities, and individuals to have the research project fully explained to them. Opportunities for the Nation, communities, and individuals, as appropriate, to receive periodic reports on the progress of the research.

j. Willingness of the researcher to involve the Ho-Chunk Nation IRB in the research and specific steps that will be taken. Program study changes, changes in testing data, changes in methodology, and alternative or unexpected findings must be communicated throughout the project and preapproved by the IRB.

9. Permit Process.

a. The IRB shall adopt policies and procedures.

b. The IRB reviews the applicant researcher's proposal using the criteria enumerated at 45 C.F.R. § 46.111.

c. 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.

10. Enforcement. This Code shall be enforced in the following manner:

a. No research shall be done within the jurisdiction of the Nation or otherwise subject to this Code unless the researcher has first received review, approval and a permit from the Ho-Chunk Nation IRB. Any violation of this Code by any researcher shall be subject to the sanctions provided in this section. Where circumstances indicate, particularly where enforcement of tribal rights and interests may be of special importance, the researcher, his/her sponsoring institution, and her/his funding source may be required to sign a contract with the Nation specifying contractual Nation rights in data or materials or with respect to ultimate publication.

b. Any outside agency or researcher conducting research within the jurisdiction of the Nation without a permit or otherwise in violation of this code shall be subject to permanent expulsion from Nation lands or expulsion for a term as determined by the Nation's Trial Court (Court).

c. Whenever it appears that a person has violated, or is violating, or is threatening to violate any provision of this Code, the Attorney General or his or her designee may file an action in the Ho-Chunk Nation Trial Court to enforce this Code.

d. In any action brought for violation of this Code, the prevailing party in such a legal action shall be awarded court costs, including attorney fees and any other relief the Court determines to be equitable. 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/or their funding source's actions to other tribes.

11. Notice to Other Persons or Institutions. If a petition is filed pursuant to this Code, notice shall be given to the research project's sponsoring organization and/or funding source. If a judgment is entered against the person(s) conducting the research project subject to this Code, notice of the judgment shall be given to the project's sponsoring organization and/or funding source as well as to the professional organization or licensing agency of the person conducting the research, and the National Institutes of Health.

Legislative History:

9/22/04	Legislature places the Ho-Chunk Nation Research Code out for 45-Day Public Review.
12/14/04	45-Day Public Review period ends.
2/9/05	Enacted as the Tribal Research Code (3 HCC § 3) by Legislative Resolution 2/9/05B.
5/5/05	Amended and Restated by Legislative Resolution 5/5/05B, which established the IRB and approved the By-Laws for the IRB Board of Directors

