

**United Houma Nation Institutional Review Board
(Research Committee) Ordinance**

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Section 1. Title.

This Ordinance shall be entitled the Institutional Review Board Ordinance of the United Houma Nation (UHN).

Section 2. Authority.

This Ordinance is enacted pursuant to the inherent sovereign authority of the United Houma Nation and in accordance with the Constitution of the United Houma Nation as specified in Art. VII, Sec.7.

Section 3. Purpose.

The Tribal Council, as the governing body of the United Houma Nation, in order to enhance our ability to be a self-governed and self-determined people declare the purpose of this Ordinance as follows:

- (a) To amend Standards Ordinance X in accordance with the Constitution as specified in Art. VII, Sec. 7; to establish a tribal Institutional Review Board (a.k.a. Research Committee) as a standing committee of the United Houma Nation;
- (b) To describe the authority delegated by the Tribal Council to the Nation’s Institutional Review Board;
- (c) To describe the relationship between the Tribal Council to the Nation’s Institutional Review Board;

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- (d) To describe the procedures and requirements which the Nation's Institutional Review Board must adhere to in order to achieve the goals of this Ordinance and the policies of the Tribal Council;
- (e) To protect the people, culture and natural resources of the Tribe and the Tribe's future generations from unauthorized scientific research;
- (f) To reduce the adverse effects of research and related activities on the Tribal community;
- (g) To ensure that researchers recognize Tribal control of research activities and that the Tribe has the right to all data and information generated or produced by such research;
- (h) To establish and provide a statutory basis for a process to review and govern any research, collection, database, or publication undertaken with any tribal citizen specifically because they are members of UHN or when UHN is asked to participate and recruit indigenous peoples into a research project;
- (i) To establish that all research activities conducted with tribal members and on tribally owned or rented lands must comply with this ordinance; and
- (j) That the Tribe reserves its right to deny permission and access for any research activities whatsoever.

Section 4. **General.**

- (a) The Tribal Council recognizes the value of medical, social and physical science research to UHN citizens, indigenous peoples, and to society generally. The Tribal Council disclaims liability for any injury resulting from an approved research project. Individual tribal citizens have no duty to participate in research and any individual participation in a research project is at their own risk.
- (b) The Tribal Council 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 Tribal Council 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.

Section 5. **Scope and Applicability.**

The provisions of this Ordinance will apply to the United Houma Nation Institutional Review Board established herein.

Section 6. **Definitions.**

Terms used in this Ordinance shall have the following specific meanings. Where a term is not defined by this section it will be given its ordinary meaning.

- (a) "United Houma Nation Tribal Community" includes Tribal members, their descendants and ancestors, and other individuals, families, clans, governments and people residing within the exterior boundaries of the UHN service area.

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- (b) "Service Area" shall refer to the United Houma Nation service area as defined by the UHN Constitution to include the following parishes: Terrebonne, Lafourche, St. Mary, Plaquemines, Jefferson, and St. Bernard.
- (c) "Tribal Member" shall refer to an enrolled "member" or "citizen" of the United Houma Nation Tribe.
- (d) "Tribe" means the United Houma Nation Tribe.
- (e) "Nation" shall mean the United Houma Nation.
- (f) "Tribal Council" shall mean the United Houma Nation Tribal Council.
- (g) "Policy" means a directive of the Tribal Council consistent with the United Houma Nation Constitution, Houma culture or other general principles by which the Tribal Council performs its obligation to the Houma People.
- (h) "Committee" means a Committee established by Ordinance of the Tribal Council.
- (i) "Board" means Institutional Review Board, a committee established through this Ordinance of the Tribal Council.
- (j) "IRB" means the United Houma Nation Institutional Review Board established by this Ordinance of the Tribal Council.
- (k) "Ad Hoc Committee/Working Group" a working group with a specific task assigned to it by the Tribal Council formed by resolution and not by ordinance.
- (l) "Constitution" refers to the United Houma Nation Constitution.
- (m) "Academic Research" means research carried out to obtain educational qualifications or as part of their academic career at a university or affiliated institutions.
- (n) "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. Research includes identification, description, classification, collection, database, recordation, analysis, and publication in their academic field and other investigative disciplines or approaches as identified by the Tribe. For the purpose of this Code, research includes, but not limited to the following types of research:
 - (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 health or mental health interventions or environmental mitigation or adaptation studies. Changes in development, testing, or evaluation must be pre-approved by the United Houma Nation IRB.
- (o) "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 with tribal members within the service area of United Houma Nation.
- (p) "Products of Research" means publications (including but not limited to reports, studies, articles, theses, books, manuscripts, sound recordings, film and video, media interviews, computer databases), public presentations (included invited talks, conferences, symposiums, workshops, trainings), field notes, illustrations,

- photographs, collected material artifacts, replicas, and specimens, including any derivative forms they may take such as translations, and communications through the electronic media (including the internet world wide web).
- (q) "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.
 - (r) "Specimens" means any tangible and intangible data collected for research.
 - (s) "Biodiversity" means the total variety of life in all its forms. It includes many levels that range from the level of alleles to the biosphere. The major elements of biodiversity include alleles, genes, populations, species, ecosystems, landscapes, and the ecological processes of which they are a part.
 - (t) "Biogenetic Resources" means biological and genetic resources, including plant material, animals, microorganisms, cells, and genes.
 - (u) "Biological Samples" 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.
 - (v) "Commercial Purposes" means to sell, purchase, barter, trade, delayed compensation for profit, exchange, transport, or offer to sell, purchase, barter, trade, delay compensation for profit, exchange, or transport.
 - (w) "Cultural Research" means any endeavor, by means of critical investigation and study of a subject, to discover new or collate old facts or hypotheses on a cultural subject, the latter being defined as any ethnographic or anthropological study, including basic data collection, studies of or incorporating traditional knowledge or classifications systems (e.g. studies of medicinal properties of plants), documentary films, archaeology, linguistics and ethno historical accounts.
 - (x) "Indigenous" means native, originating or growing naturally in a specific landscape. Also refers to people descending from the original inhabitants of the Western Hemisphere who have maintained distinct languages, culture, or religion from time immemorial.
 - (y) "Taboo/Sacred" means subject to which access is restricted to any degree. Such subjects can include places, names, knowledge, oral traditions, objects, and practices.
 - (z) "Traditional Indigenous Intellectual Property" means the indigenous cultural information, knowledge, uses, and practices unique to the Tribe's ways of life maintained and established over tribal homelands and aboriginal areas since time immemorial. This knowledge is based upon millennia of observation, habitation, and experience, and is a communal right held by the Tribe, and in some instances by individuals. This property includes, but is not limited to, the following:
 - i. Knowledge of remembered histories and traditions;
 - ii. Details of cultural landscapes and particularly sites of cultural significance;
 - iii. Records of contemporary events of historical and cultural significance;
 - iv. Sacred property (images, sounds, knowledge, material, culture, healing and health or anything that is deemed sacred by the community) ;

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- v. Knowledge of current use, previous use, and/or potential use of plant and animal species, soils, minerals, objects;
 - vi. Knowledge of preparation, processing, or storage of useful species;
 - vii. Knowledge of formulations involving more than one ingredient;
 - viii. Knowledge of individual species (planting methods, care for, selection criteria, etc.) ;
 - ix. Knowledge of ecosystem conservation (methods of protecting or preserving a resource) ;
 - x. Biogenetic resources that originate (or originated) on indigenous lands and territories;
 - xi. Tissues, cells, biogenetic molecules including DNA, RNA, and proteins, and all other substances originating in the bodies of Tribal members, in addition to genetic and other information derived therefrom;
 - xii. Cultural property (images, sounds, crafts, art, symbols, motifs, names, performances) ; and
 - xiii. Knowledge of systems of taxonomy of plants, animals, and insects.
- (aa) "Traditional Knowledge Right" means the traditional right of individuals to control the ways the information they provide is used and accessed. The issue of traditional knowledge rights arises when individuals either own or are the custodians of specialized (or usually taboo/sacred) knowledge and its communication. This knowledge can include names, ceremonies, designs or forms, oral traditions, practices and skills.

Section 7. **Unlawful Acts.**

It shall be unlawful for any person to conduct research within the Service Area 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.

Section 8. **Administration.**

The United Houma Nation establishes, as an Authority by the Council, an Institutional Review Board that shall be responsible for preparing recommendation to the full Tribal Council to approve or disapprove research submitted to the Nation pursuant to this Ordinance.

- (a) This Ordinance establishes a United Houma Nation Institutional Review Board (IRB) to administer and manage research conducted with and on United Houma Nation and its members.
- (b) The IRB shall submit the By Laws of the IRB to the Tribal Council for approval within sixty (60) days from the date the members are appointed.

Section 9. **Severability.**

Should any portion or provision of the Ordinance be deemed invalid, the portion or provision of the agreement deemed invalid shall be considered amended and shall be interpreted as closely to the original version's intent as possible. It is the intent of the Tribal Council that the remaining provisions of this Ordinance shall continue in full force and effect.

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Section 10. **Amendment**

This Ordinance can be amended only in accordance to the Administrative Procedures Ordinance Sec. 6 (h).

Section 11. **Institutional Review Board (Research Committee) Structure**

The IRB, as further described in its Bylaws, shall be structured and administered as are other Tribal Council Committees.

11.1 Membership and qualifications:

- (a) The IRB shall consist of five (5) members who shall each be citizens of the United Houma Nation or who identify as or are members of other indigenous tribal nations.
- (b) Each IRB member should have, at a minimum, a bachelor's degree and experience with research activities.
- (c) The IRB shall have a Committee (Board) Chair and at least one member who is a tribal council member elected annually by the members of the IRB.
- (d) The IRB members shall be required to attend annual training on the protection of human subjects during research.

11.2 Duties and Responsibilities. The Ordinance allocates the following specific duties and responsibilities to the Institutional Review Board:

- (a) The IRB shall adopt policies and procedures for applications for research with United Houma Nation and its members to include a timeline for review, bylaws, protocols, and procedures for seeking guidance from experts on subjects beyond the committee's expertise.
- (b) The IRB shall review the applicant researcher's proposal using the criteria enumerated at U.S. 45 C.F.R. § 46.111.
- (c) The IRB may:
 - i. Grant full permission without modifications;
 - ii. Grant permission with modifications to the proposal.
 - iii. Deny the proposal; or
 - iv. Withhold a determination until a stated date.
- (d) The IRB is responsible for overseeing the management and review of all research conducted with United Houma Nation and its members. To examine and comment on all proposals for research to be conducted with UHN members specifically because they are members of the UHN or when UHN is asked to participate and recruit indigenous peoples into a research project.
- (e) The IRB is responsible for reporting the status of all research approved conducted with United Houma Nation and its members through Tribal Council meetings and social media.
- (f) To coordinate and insure that affected Tribal properties', programs', and members' interests are protected and represented.
- (g) Submit recommendations regarding proposals to the Tribal Council for final approval.

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- (h) Coordinate and interact with the researcher(s) in order to ensure Tribal control of the research process and Tribal ownership of data and information generated by such research.
- (i) Negotiate the terms and conditions of a research agreement, and submit such agreement for execution by the Tribal Council.

11.3 Terms of Members. IRB members serve 3 year terms and may only serve a total of three terms.

11.4 Vacancy, Removal and Resignation. IRB members can resign of their own volition. Board members can be removed by a majority recommendation of the Board with the approval of the Tribal Council. Vacancies will be filled by the Tribal Council in accordance with Sec. 12 of this Ordinance.

11.5 Meetings and Voting. The IRB shall schedule regular meetings at least quarterly. Additional meetings are required if there is an active research application before the Board. Voting shall be by consensus. If consensus cannot be reached, then a majority vote shall prevail.

Section 12. **Appointment Procedures**

The Tribal Council may make appointments to the Institutional Review Board based upon the recommendation of the Board or on its own initiative. IRB members shall be citizens of the United Houma Nation or members of other indigenous tribal nations and subject to the same ethics code as the Tribal Council. As pursuant to the Committee Standards Ordinance, Section 10 Appointment Procedures, Tribal Council members will serve on Committees but shall not constitute over fifty (50) percent of the Committee membership, except for the Tribal Government Committee. Therefore, Tribal Council members shall not constitute over fifty (50) percent of the Institutional Review Board. The Tribal Council shall appoint all IRB members by resolution.

Section 13. **Reporting**

The IRB will report to the Tribal Council at the first scheduled Council meeting following the Board meeting. At least one (1) IRB committee member shall be present at the Tribal Council meeting to present the report and two (2) members shall be present by phone.

Section 14. **Records**

The IRB shall keep records of meetings such as sign-in sheets and minutes and shall make them available to the Tribal Council for review.

Section 15. **Exceptions**

Nothing in this Ordinance would prevent the formation of informal Ad Hoc Working Groups to deal with situations and events not included in the scope of this Ordinance.

Section 16. **Implementation**

The IRB has sixty (60) days from the date the IRB members are appointed to comply with the stipulations and regulations herein.