

***Project Name* RESEARCH PROTOCOL CODE**

WHEREAS, pursuant to the _____ Treaty, [or Executive Order or Agreement] the [Tribe] reserved the [Tribe] Reservation (hereinafter "Reservation") for present and future generations of the [Tribe] peoples, and the Name Tribal Council has a duty and responsibility to protect the Reservation and traditional aboriginal homelands of the Name peoples; and

WHEREAS the Reservation forms a sizeable geographic area for the exercise of Tribal jurisdiction, supports a residing population, is the basis for the Tribal economy, and provides an irreplaceable forum for cultural vitality based on religious and cultural traditions premised on the sacredness of land; and

WHEREAS the original territory of the [Tribe], including land off-Reservation, contain significant cultural and religious sites which continue to be utilized by Tribal members; and

WHEREAS the [Tribe], by and through the Tribal Council, has the inherent sovereign authority to regulate the conduct and activities on all lands within the jurisdiction of the [Tribe], and as expressly established in the Constitution of the [Tribe], to promulgate, adopt, and enact laws for the control and regulation on all lands within the jurisdiction of the [Tribe], and to protect the health, economic security, and general welfare of the Tribe and its members

NOW THEREFORE BE IT ENACTED BY THE COUNCIL OF THE [Tribe] an Ordinance to be known as the "***Project Name***–Research Protocol Code "

SECTION 1. GENERAL POLICY BACKGROUND STATEMENT.

1.1 The natural and cultural landscapes, including wildlife, flora, fauna, waters, and biogenetics, among others, located on aboriginal and present day Tribal lands are owned by the [Tribe] and the disposition, development, and utilization thereof are under the [Tribe's] full control and supervision.

1.2 The integrity and orientation of past, present, and future generations of the [Tribe] peoples are founded upon a unique and invaluable cultural, historical and environmental ethic. This Tribal ethic defines and perpetuates a communal identity, language, history, and value system which involves an irrevocable cultural attachment to the native landscape ecology, and the human inseparability and interdependence with species and biological diversity.

1.3 The [Tribe] has the right of self-determination and in exercising that right must be recognized as the exclusive owner of indigenous traditional and cultural knowledge.

1.4 Indigenous knowledge, cultural and biogenetic resources, and intellectual property rights have been, and continue to be, damaged, destroyed, stolen, misappropriated, both on and off the Reservation and Tribal members have been the subjects of research for decades, with little benefit returning back to the community from the research.

1.5 The [Tribe] finds that it is in the best interest of the Tribal community to establish a Research Protocol Code and research review mechanism for [Name of study on Grant] research study (tribally known as ***project name***) to prevent the continued abuses, to protect the people's traditional knowledge and properties, and thereby to ensure our rights to continue to practice traditional lifeways and long term survival thereof.

1.6 The established Research Protocol Code and research review process is developed as a mechanism to improve relations between the [Tribe] and scientists/researchers, and to promote collaboration within the framework of mutual respect, equity, and empowerment, and to identify benefits and risks to the Tribal community.

SECTION 2. PURPOSE

1. **Title**. This Code shall be known as the ***Project name***–Research Protocol Code.

2.1 **Purpose.** The purpose of this Code shall be to set forth the conditions under which investigators, researchers and others may perform *Project name* research activities on living human subjects within the territorial jurisdiction of the [Tribe].

Specifically, the purpose of this Code is to:

1. Protect tribal people, culture, and natural resources of the [Tribe] and the [Tribe's] future generations from unauthorized scientific research, materials or data generated from research;
2. Reduce the adverse effects of *Project name* research and *Project name* research-related activities on the Tribal community;
3. Ensure that *Project name* researchers recognize Tribal sovereignty and jurisdiction including Tribal control of research activities and that the Tribe owns all data and information generated or produced by such research;
4. Establish and provide *Project name* research protocols and principles to ensure mutual respect and knowledge sharing;
5. Establish a *Project name* Research Review Committee (RRC) to review research protocols, IRB procedures, and data dissemination activities, including but not limited to publications and conference presentations; and
6. Establish that all research activities conducted on the Reservation must comply with this code.

SECTION 3. POLICY

2. **Policy.** It is the policy of the *Project name* research project to ensure that:

1. All persons within the territorial jurisdiction of the [Tribe] are free from harmful, intrusive, ill-conceived or otherwise offensive research, investigative procedures, or misuse or misappropriation of research findings and biological and genetic materials;
2. *Project name* research is beneficial, community-based, culturally relevant, and consistent with [Tribes'] health priorities and concerns;
3. The Tribe, being sovereign, has the right of self-determination and in exercising that right must be recognized as the exclusive owner of indigenous traditional knowledge, data products, and all genetic and biological materials associated with the study
4. *Project name* research information and all biological material and data generated by and about [Tribe] individuals, communities, and culture represent the inalienable intellectual properties of the [Tribe] Peoples and over which the [Tribe] provide oversight;
5. A *Project name* research protocol code with a corresponding data sharing agreement is developed as a mechanism to improve relations between [Tribe] researchers and staff with [University] researchers and staff, and to promote collaboration within a framework of mutual respect, equity, empowerment, and to identify the potential benefits and risks to the [Tribe] and [Tribal] community

SECTION 4. GUIDING PRINCIPLES FOR *Project Name*

3. **Principle of Full Informed Consent After Full Disclosure and Consultation.** *Project name* research should not be conducted until there has been full consultation with and approval from all potentially affected Tribal community institutions or their corresponding leaders and individual members. Full disclosure consists of the full range of potential benefits and harms of the research, all relevant affiliations of the [University] partners seeking to undertake the research, and all sponsors of the research.
 1. **Principle of Immediate Risks and Benefits to the [Tribal] Community.** *Project name* research should be of immediate benefit to the [Tribal] community, and the risks associated with the research should be less significant than the benefits to be gained.
 2. **Principle of Confidentiality.** This principle recognizes that the [Tribe] has the right to exclude from publication and/or to have kept confidential any information concerning their culture, traditions, mythologies, or spiritual beliefs. Furthermore, researchers and other potential users shall guarantee such confidentiality.
 3. **Principle of Cultural Respect.** This principle recognizes the necessity for researchers to respect the integrity, spirituality of the culture, traditions, and relationships of [Tribal] members with the world, and to avoid the imposition of external conceptions and standards.

4. **Principle of Mutual Respect.** This principle recognizes that research partners must value and prioritize indigenous epistemologies, knowledge, cultural protocols, and healing practices. Indigenous “scientists” and expert knowledge already exist within indigenous communities and should be involved throughout the research partnership wherever and whenever appropriate.
5. **Principle of Communication.** This principle recognizes the necessity for researchers and **[Tribal]** partners to engage in respectful communication and that the research partners must respect the expected standards of communication when on or in tribal jurisdiction boundaries commensurate with community expectations and standards. Moreover, this principle acknowledges that there are often differing communication styles-both verbal and nonverbal and that all parties agree to address misunderstandings in style in respectful ways.
6. **Principle of Empowerment.** This principle recognizes that the **[Tribe]** has full rights of empowerment and that all *project name* affiliates and advisory/consultative boards are fully empowered to oversee research activities reflecting their rights to self-determination and sovereignty. Empowerment also means that each affected party feels that their needs are being met through a fair and equitable manner. Empowerment also means that research authorship must be shared between the **[Tribal]** community and the researchers.
7. **Principle of Equity.** This principle recognizes that the research partners and the **[Tribal]** partners strive for evenhandedness and fairness in their deliberations. This principle also recognizes that equity is the sharing of resources. Both the researchers and the **[Tribe]** must bring equity to any research contract, agreement, or understanding. Each of the participants in a good research agreement must evaluate such equity in relation to the research. Finance or money is only one form of equity. Community knowledge, networks, personnel and political or social power are other forms of equity useful to the project. Each of these commodities has value and both parties must continuously review equity over the duration of the research project.
8. **Principle of Prior Rights and Self-Determination.** This principle recognizes the Name Tribes’ sovereign status and all prior rights and self-determination associated with tribal sovereignty in their jurisdictional boundaries and with their tribal members. All *Project name* staff and research partners must comply with Tribal regulations and Prior Rights established by the Name Tribes. This principle recognizes that Name Peoples, traditional societies, and local communities have prior, proprietary rights and interests over all air, land and waterways, and the natural resources within them that the Name Peoples have traditionally inhabited or used, together with all knowledge and intellectual property and traditional resource rights associated with such resources and their use.
9. **Principle of Relevance.** For research partners to achieve relevance, they must actively engage the community from the earliest phases of the research endeavor in conceiving the aims of the project. This might involve meetings with key community members and **[Tribal]** leaders, community forums and feasts, and extensive outreach to determine what the community itself defines as important to its health and well-being. Relevance also extends to the methodology of the research. Interventions should be developed with the needs of the indigenous community at the forefront.
10. **Principle of Resilience.** Research should acknowledge the community’s strengths and its stalwart resilience in the face of multiple assaults on tribal autonomy and integrity. Much of the early work in Indian country focused exclusively on pathologic conditions, such as alcohol addiction and childhood abuse. Although these topics were serious concerns for tribes, the research was conducted without regard to contextual, structural, and historical factors that contributed to these problems or to the large majority of tribal members who avoided these problems. All *Project name* research partners will strive to focus first on the strengths and resilience of **[Tribe]** Peoples in all research endeavors including publications and materials produced thereafter.
11. **Principle of Reflection and Reflexivity.** Prior to engaging with Native communities, research partners could benefit from careful reflection upon their positionality vis-à-vis community members. Most university-based research partners have a privileged status in society, owing to educational and socio-economic advantages. If they are members of the dominant racial group in the U.S., they have additional advantages based on their White privilege as well. Acknowledging these privileges -- not disingenuously denying them -- can improve the partnership. Reflection involves an ongoing process of self-awareness of emotional reactions as well.
12. **Principle of Reciprocity.** Reciprocity should characterize the research partnership, which should be collaborative and mutually respectful, with knowledge exchanged in both directions. Western and

indigenous knowledges, when appropriate as determined by **[Tribe]**, should be reciprocally shared, mutually understood and respectfully exchanged.

13. **Principle of Responsibility.** This principle recognizes the obligation for the research to enhance community capacity to conduct research. Research endeavors should seek to incorporate Native youth and students in particular into research activities to stimulate their interest in research and provide experiences to bolster their opportunities for future training. Second, research partners have the responsibility of disseminating research findings and research products in culturally meaningful ways after first receiving tribal approval. This can mean publishing in tribal newsletters as well as peer-reviewed journals, with community partners acknowledged as authors according to their contributions. The dissemination process also may involve other forms such as digital storytelling; documentaries; photography or, and other visual presentation; theater; or community events in which the findings are reported in an accessible fashion. Finally, research partners must be responsible for anticipating the implications of their findings and communicating these issues directly to *Project name* tribal partners.
14. **Principle of Retraditionalization.** Retraditionalization involves incorporating traditional and ancestral knowledge and methods into the formulation of research questions and the process of scientific inquiry as determined by Tribal cultural authorities. Building on the principles of respect and relevance, it involves the practice of co-embracing hybridized methodologies while maintaining an indigenous core. Whenever possible, tribal and research partners should co-develop mechanisms for developing innovative indigenous methodologies or hybrid methodologies that combine, where appropriate, Western and indigenous approaches. All **[Tribe]** tribal cultural and spiritual knowledge, including written, oral, visual, etc. are the sole traditional intellectual property rights of the **[Tribe]** and will not be used without explicit permission from appropriate cultural authorities. All non-tribal partners are expected to respect this knowledge when it is shared and not to misuse or appropriate it for personal gain or otherwise inappropriate purposes. Furthermore, all partners are expected to respect sacred knowledge and traditional intellectual property rights at all times as the exclusive traditional intellectual property rights of **[Tribe]**.
15. **Principle of Self-Determination.** This principle recognizes that **[Tribe]** peoples and their communities have a right to self determination and those researchers and associated organizations will acknowledge and respect such rights in their dealings with **[Tribe]** peoples and communities.
16. **Principle of Inalienability.** This principle recognizes the inalienable rights of the **[Tribe]** peoples in relation to their traditional territories and the natural resources within them and associated traditional knowledge. These rights are collective by nature but can include individual rights. It shall be for **[Tribe]** peoples to determine for themselves the nature and scope of their resource rights in relation to this project.
17. **Principle of Traditional Guardianship.** This principle recognizes the holistic interconnectedness of humanity with ecosystems of the land and the obligation and responsibility of **[Tribe]** peoples to preserve and maintain their role as traditional guardians of these ecosystems within their territorial boundaries through the maintenance of **[Tribe]** cultures, mythologies, spiritual beliefs, and customary practices.

SECTION 5. RESEARCH REVIEW COMMITTEE ESTABLISHED FOR *[Project Name]*

5.1 There is hereby established a Research Review Committee (RRC) for *[project name]*, which shall be comprised of three tribal members (3) and two (2) academic research partners (the principal investigator and co-investigator). Two of the three tribal members shall be appointed to serve on this committee by **[Tribal agency]**. The **[Tribal agency]** Executive Director will serve Chair of the RRC and also as one of the three tribal members serving on the RRC. As Chair of the RRC, The Executive Director for Health and Human Services will have final authority for RRC decision-making on behalf of Name Tribe. All recommendations by the RRC will be processed through the RRC Chair who, upon approval, will forward the recommendations to the identified appropriate Tribal authorities (e.g., Name attorneys or Tribal Council) or when appropriate will act as Tribal proxy for approving the recommendations on behalf of the Name Tribes. The RRC will review all scientific proposals, products and provide oversight of all research protocols and data sharing agreements related to the study.

The RRC will meet monthly (or on an as needed basis) and will have the following duties:

- a. To examine and comment on all proposals for research (including theses, dissertation projects, secondary data analyses, and grant supplements) not already established by the *Project name* and make recommendations

- for their approval or disapproval to the study team as well as the Tribe;
- b. To review and finalize data sharing agreements;
- c. To review all IRB materials, human subjects forms, including consents;
- d. To review all reports, publications, conference presentations, press releases, and other public data results in preparation for tribal approval and prior to any public dissemination activities;
- e. To submit recommendations regarding all proposals, IRB-related materials, and data dissemination products to the Tribe for final approval;
- f. To coordinate with researchers to ensure Tribal control of the research process and Tribal ownership of data and information generated by such research;
- g. To negotiate the terms and conditions for new *Project name* research projects (e.g., secondary data analyses), IRB materials and protocols, new data sharing agreements, and dissemination venues and products and submit recommendations to the Tribe for approval;
- h. To establish publications guidelines, data sharing agreements, conference presentation request guidelines, and other related codes to coordinate and ensure that affected Tribal programs', departments', and members' interests are protected and represented.

SECTION 6. COMMUNITY ADVISORY BOARD ESTABLISHED FOR *həli?dx*"

6.1 A Community Advisory Board (CAB) has already been established with approval by the [Tribal agency]. The CAB consists of ## members from project related Tribal programs, departments, and elders who provide cultural oversight, project input related to all outreach materials, survey instruments, and intervention procedures. The CAB provides primary cultural and community oversight to ensure that the needs of the community are addressed in the research project. Related to the CAB the research team (both **University** and **Tribe**) in association with the CAB may pull together special community consultants (e.g., elders' advisory group) on an as needed basis for specific expertise or cultural consultation.

The CAB will meet monthly and has the following duties:

- a. To examine all outreach materials and protocols;
- b. To examine all interview materials for cultural and clinical health relevance;
- c. To examine all findings in aggregate to provide direct feedback for incorporation into findings and reports as well as publications;
- d. To provide guidance and network opportunities to ensure appropriate consultation is achieved by key community members as the study progresses;
- e. To examine all research protocols for cultural and clinical relevance for the tribal community; and
- f. To be available for consultation to the RRC.

SECTION 7. DEFINITIONS

1. **Definitions.** For purposes of this Research Protocol Code:

7.1 "**Name Tribal community**" includes Tribal members, their descendants and ancestors, and other individuals, families, institutions and people residing within the exterior boundaries of the Name Reservation as well as enrolled Tribal members living off-reservation.

- 1. "**Tribal member**" means an Individual who is enrolled in the Name Tribe.
- 2. "**Tribe**" mean the [Name of Tribe].
- 3. "**Research partner**" means any researchers or doctoral students on the [University] research team, including indigenous and non-Indigenous personnel, research staff, research scientists and all research investigators.
- 4. "**Principal Investigator and Investigators**" means any researcher from the [University] or Name that are listed as lead investigators for this project on the [project name on grant] grant. The Principal Investigator assumes primary responsibility for the research integrity of the study and adherence to tribal and national standards for research integrity and study implementation.
- 5. "**Research**" includes scholarship and data-collection activities that are designed to develop or broaden traditional and academic-based knowledges to address a particular problem or condition among the

people. It includes identification, description, classification, collection, database, recordings, analysis, and publication in fields including, but not limited to: medicine, nursing, social work, psychology, environmental sciences, anthropology, public health, sociology, film and media studies, and other investigative disciplines or approaches.

6. **“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.
7. **“Biogenetic resources”** means biological and genetic resources, including plant materials, animals, microorganisms, blood products, cells, and genes.
8. **“Biogenetic samples and materials”** means, but is not limited to: bacteria and other microorganisms, plant, animal or any human biological materials (e.g., blood), genetic samples, any copies of the samples, any cell lines containing copies of the original genetic samples, and data derived from these samples.
9. **“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.
10. **“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 qualitative study, including data collection, studies of or incorporating traditional knowledge or classifications systems (e.g., studies of medicinal properties of plants), documentary films, digital storytelling, photography, or other ethno-historical accounts.
11. **“Products of research”** means publications (including but not limited to reports, studies, articles, theses, dissertations, manuscripts, sound recordings, digital photos and video, media interviews, and data transcripts, recordings, and computer databases), field notes, illustrations, photographs, sound recordings, collected material artifacts, replicas, and any derivative forms of products, including translations, communications through electronic media (including the internet and world wide web).
12. **“Reservation”** means all lands inside or outside the exterior boundaries of the [Tribe] reservation which is under jurisdiction of the [Tribe], and such lands as may hereafter be obtained or added to the jurisdiction of the tribe.
13. **“RRC”** means the 5 member Research Review Committee established by this Code.
14. **“Taboo/Sacred”** means subject to which access is restricted to any degree by [Tribe]. Such subjects can include but are not limited to places, names, knowledge, oral traditions, objects, and practices.
15. **“Traditional 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 areas since time immemorial; this knowledge is a communal right held by the Tribe. This property includes, but is not limited to the following
 1. Knowledge by remembered histories and traditions;
 2. Details of cultural landscapes and particularly sites of cultural significance
 3. Records of contemporary events of historical and cultural significance;
 4. Sacred property, including images, sounds, knowledge, material, culture or anything that is deemed sacred by the community;
 5. Knowledge of current use, previous use, and/or potential use of land, water, plant and animal, fish, insect species;
 6. Knowledge of planting methods, ecosystem conservation, preparation, formulation, processing or storage of species, land, or environs;
 7. Biogenetic resources that originate (or originated) or indigenous lands and territories;
 8. Tissues, cells, biogenetic molecules including DNA, RNA, and proteins, and all other substances and blood products originating from the bodies of Tribal members, in addition to genetic and other information derived therefrom;
 9. Cultural property (images, sounds, crafts, art, symbols, motifs, names, practices and performances); and
 10. Knowledge of systems of taxonomy of plants, animals, insects, and other beings.

SECTION 8. REGULATIONS OF BIOLOGICAL SAMPLES

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

following conditions with regard to research with biological materials.

8.2 The Tribe may, at any time, decide to withdraw from the research project or any portion thereof, and request the return of all biological samples. The researcher, and any other parties, must comply.

8.3 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 Tribe.

8.4 No biological samples from this study may be released to, or used by, any other researcher(s), research institution, or any other entity, whether public or private, without the prior and fully-informed written approval of the Tribe.

8.5 If the Tribe permits any biological samples to be stored in any other locations, 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(s) 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 Tribe whenever changes are made. The updated list shall include identification of changes made since the last copy of the list was provided to the Tribe.

8.6 Any situation where biological samples will leave the possession or control of the researcher will require a separate agreement between the Tribe and the external party in accordance with this Code.

8.7 No entity may seek to patent or commercialize any biological materials obtained from the Tribe, from the Tribe's jurisdiction, or under the authority of the Tribe. 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 9. NEW DATA COLLECTION, ANALYSES, OR RESEARCH PROPOSAL REQUIREMENTS.

It is likely that investigators not already established in the original grant or current supplemental grants will want access to either *project name* data for secondary data analyses or will want to develop *project name*-related new studies. In the case of secondary data analyses or supplemental studies not originally provided for in the *project name* grant, all proposals must be prepared with the following criteria for the RRC review and tribal approval prior to conducting any new analyses or launching new *project name*-related studies. New studies include, but are not limited to: masters theses, doctoral dissertations, supplemental grant proposals, and other related activities to procure new information from secondary data analyses or new data with additional studies. This section outlines the content for a request to the RRC in order to access *project name* data or to request a grant proposal or to conduct another study related to *project name* study from investigators not on the original grant or the diabetes supplemental grant.

9.1 Time Frame. As a cooperative venture, research requires an appropriate time frame for Tribal review and approval. Researchers not originally listed as investigators on the *project name* must begin working with the RRC in the earliest stages of planning their proposals. Depending on the nature of the proposed project, researchers are advised to allow sufficient time for the RRC to thoroughly review and understand all aspects of the study, ask questions and resolve differences. Even the simplest of proposals must be submitted at least one month prior to the anticipated project start date. The RRC reserves the right to reject last minute proposals.

9.2 Format. A short (a maximum five (5) pages, single sided) synopsis of the project shall be submitted to the RRC. A full length proposal should be submitted as a supplement, but the requested summary must contain sufficient information to allow the RRC to make an informed decision. The RRC may require that the CAB review the proposal prior to or after the RRC review. The following information must be included in any request for approval of a new research project by outside investigators:

a) Statement of the Issue/Problem/Research Question: The research applicant shall briefly describe the issue/problem the applicant is addressing by the proposed research. Specific questions related to this issue/problem and the theoretical rationale behind the questions shall be set forth. If the applicant has a specific hypothesis, the applicant shall briefly set forth such hypotheses.

b) Intent/Benefit to the Tribe: The research applicant must clearly outline and discuss the intent of the research project and the benefit(s) that the project, research or activity will have to the Tribal community. Some questions to

be answered are: 1) what are the anticipated consequences or results/outcomes of the project; 2) what groups will be affected and what groups will benefit; and 3) in what ways will these groups and the Tribe's benefit?

c) Method: As a part of the application process, the applicant shall briefly describe the procedure for the collection of all data to be used in the study. Included shall be a description of subjects, settings, proposed procedure and the nature of the data to be collected.

d) Confidentiality: A very important part of the application process is a description on how confidentiality will be protected. The applicant shall identify the circumstances under which the obligations of the researcher may constitute a breach of confidentiality. A description shall be given on how individual participants will be informed of the degree of confidentiality that will be maintained throughout the study. The Tribe maintains that unless otherwise specified, only aggregate data, not individual data, shall be published or released to the general public. All individual identifiers such as names, addresses and phone numbers must be kept confidential and no sale or transfer of databases outside the specific research project shall be allowed. The applicant must state in their application summary whether the Tribal community will be identified in any data released to the general public.

e) Disposition of Data and Samples: A portion of the application process shall describe how individual participants will be informed of how data and samples will be used. Both the Tribal community and the participants must clearly understand what the researcher plans to do with the information and samples that are collected. A description of the plans to provide individual participants with their own personal results must be provided. In addition, the research applicant shall describe how the community at large will be educated or empowered by this study. A description of the frequency and manner by which the aggregate data and progress reports will be shared with the RRC must be set forth. Furthermore, communication strategies to present aggregate data to the community at large shall be described.

f) Risks: The applicant must describe any potential legal, financial, social, physical or psychological risks that are anticipated in the research. Any risks of deleterious impact on the cultural, social, economic or political well-being of the Tribe or Tribal members shall be assessed. The assessment of risk will also address the steps that will be taken to minimize, ameliorate or repair any actual harm caused to the Tribal community by the research. Explanation shall also be given on how potential risks will be explained to participants and how the risks are justified by the potential benefits of the research. This category does not exempt the researcher from providing, upon approval to move forward by the RRC and tribe, a full human subjects proposal.

g) Funding/Budget: 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, Tribal property resulting from the research.

h) Cultural Sensitivity Training: All investigators, researchers, graduate students and any other people involved in the research will be required to undergo cultural sensitivity training to be provided by the Tribe.

i) Equity: The proposal must demonstrate how the participants and the Tribe will be given a fair and appropriate return for cooperation in the research. Just compensation or fair return includes but is not limited to: obtaining copies of the research findings, authorship, co-authorship or acknowledgment, royalties, fair monetary compensation, copyright, patent, trademark, compensation for expenses incurred in reviewing/advising researchers, coverage of training/education or outreach expenses or other forms of compensation.

j) Consent: The proposal must address mechanisms for informed consent, which may be required from individual participants, families, clans or the Tribal Government. The applicant shall list all the agencies, professionals, government representatives or individuals within the Tribal community with which the applicant has previously discussed the proposed research and whether or not these people have given their informed consent, or other support, to the research.

k) Empowerment: The applicant shall describe how individuals and Tribal members will be empowered by the research process through employment, training or outreach efforts. Native American preference must be given in employment and training in all phases of the project or activity, especially where the research is occurring on the Reservation. The Tribal preference laws shall govern the order of priorities in hiring.

l) Intellectual Property Rights: The application shall address the plans (pre, during and post-project) for publication or commercialization of the research findings. If such publication or commercialization is contemplated, the applicant shall address how the Tribal community shall share in the authorship of publications or commercialization of the research findings. The Tribe also needs to know how the Tribal community will have access to the project, research data or findings for the Tribe's own use. Researchers must inform the RRC of journals,

publishing houses or conferences that they plan to print or present the results of their studies before papers are submitted or presented. The proposal must demonstrate a process whereby the RRC and the Tribe will have an opportunity to review, critique and approve the results of all studies before any publication, presentation, news conferences or release of data to the general public occurs. Researchers shall be responsible for addressing, correcting and satisfying the concerns of the Tribe in both drafts and final reports, papers or data summaries before they are released to the general public.

m) Data Ownership/Archive: The Tribe reserves the right to require the deposit of raw materials or data, working papers or product in a tribally designated repository, with specific safeguards to preserve confidentiality. Duplicates of data or split samples may be required to be stored in such a local archive.

SECTION 10. REVIEW OF NEW RESEARCH PROPOSALS RELATED TO *Project name* AND REVIEW PROCESS.

10.1 All research proposals for theses, dissertations, secondary data analyses, or supplemental studies from doctoral students and researchers not identified in the *project name* grant must be complete before the RRC considers the proposal. A proposal is complete when it contains all of the information required in Section 9 that is necessary for the RRC to decide whether or not the proposal should be considered.

10.2 Any research summaries and support documents requested by the RRC pursuant to the proposal process should be sent to the Executive Director of Health and Human Services for Name Tribes.

10.3 The RRC shall review the application materials that are submitted and either:

a) Return the proposal to the researcher with requests for additional information or with suggestions for clarification or change; or b) Forward the proposal and request to the Tribal governing body or *Project name* Community Advisory Board with a recommendation for approval or disapproval; or c) Consult with other Tribal members, Tribal elders, professionals, technical experts or specialists for a second evaluation before sending recommendations to the Tribal governing body.

10.4 The review process and approval of the research is complete when the researcher receives a letter of notification from the RRC and enters into a binding research agreement that contains the obligations and responsibilities of the parties. Upon approval, principal investigators, researchers, graduate students and any others involved in the research shall undergo cultural sensitivity training at the researcher's expense before any project begins within the Reservation. The RRC expects periodic progress reports and will use these reports to update the Tribal governing body on the status of the project.

SECTION 11. MODIFICATIONS OF AN APPROVED PROJECT

11.1 If the researcher wishes to make substantial changes in his or her research project after receiving approval from the Tribe, he or she must submit a summary of the proposed modifications to the RRC.

11.2 Modifications in the data collection procedures must be reviewed by the RRC and approved by the Tribal governing body. Modifications to the research project shall not be implemented until the researcher and the RRC have amended the research agreement and permits, and the researcher receives written approval from the RRC.

SECTION 12. RESERVATIONS AND TERMINATION.

12.1 The Tribe reserves the right to:

a) Withdraw consent to use or release information and/or prevent the publication of data which is unauthorized, insensitive, misrepresents or stereotypes Tribal people or will harm the health, safety or welfare of the Tribe or the Tribal environment.

b) Deny researchers the opportunity to conduct research in any Tribal community within Tribal jurisdiction. In addition, other researchers or scientists from the same research institution may be denied any future access to the Reservation.

c) Withdraw approval for projects. Should this occur, the Tribe will explain the rationale for withdrawing approval

and explain why this project or the release of data is deemed to be harmful to individuals or the Tribal community at large. In the case of withdrawal of approval by the Tribe, all information and copies of data must be returned to the Tribe.

d) Exclude individuals from the Reservation.

e) Seek injunctive relief, including an order restraining a person from continuing to enter onto the Reservation.

SECTION 13. PROHIBITED CONDUCT.

13.1 No person shall conduct any academic research or cultural research without first obtaining approval by the RRC pursuant to Section 5 of this Code;

13.2 No person shall conduct any academic research or cultural research without obtaining a fully executed research agreement pursuant to Section 5 of this Code;

13.3 No person shall collect, acquire, or analyze any biological samples without abiding by the provisions of Section 5 and Section 8 of this Code;

13.4 No person shall alter, damage, disturb, excavate, removed, or desecrate and biodiversity related resources, biogenetic resources, or traditional indigenous intellectual property on or of the Reservation or Tribe;

13.5 No person shall, while on the Reservation, conduct any visitation, inventory, collection, research, or filming related to any biodiversity related resources, biogenetic resources, or traditional indigenous intellectual property, or disturb any animals, vegetation, or landscapes of the Reservation or Tribe without prior permission per the RRC in Section 5 of this Code;

13.6 No person shall sell, purchase, exchange, transport, receive, or offer to sell, purchase, exchange, transport, or possess any biodiversity related resources, biogenetic resources, biological samples, or traditional indigenous intellectual property if such resource or property was obtained in violation of this Ordinance or any permits.

SECTION 14. EFFECTIVE DATE

14.1 This Code is effective upon the co-signatures of the [University] Principal Investigator and the [Tribe] [Tribal agency] recognizing mutual agreement of the Code **and** upon date of passage by the [Tribe] Council.