

**GILA RIVER INDIAN COMMUNITY
SACATON, AZ 85247**

ORDINANCE GR – 05 – 09

**THE GILA RIVER INDIAN COMMUNITY HEREBY ENACTS THE MEDICAL AND
HEALTH CARE RESEARCH ORDINANCE TO BE CODIFIED AS TITLE 17, CHAPTER
9 OF THE GILA RIVER INDIAN COMMUNITY CODE**

WHEREAS, the Gila River Indian Community Council (the "Community Council") is the governing body of the Gila River Indian Community (the "Community"); and

WHEREAS, the Community Council is empowered by Article XV Sections 1(a)(9) and 1(a)(19) of the Constitution and Bylaws of the Gila River Indian Community (approved March 17, 1960) to pass ordinances to promote and protect the health, peace, morals, education, and general welfare of the Community and its members; and

WHEREAS, the Community recognizes the value of Medical and Health Care Research to the Community and its members; and

WHEREAS, the Community has a fundamental policy to protect and preserve the culture of the Community and to ensure medical and health care research conducted on the Gila River Indian Reservation (the "Reservation") is done in a way that does not harm the culture of the Community; and

WHEREAS, the Community also desires to ensure that Medical and Health Care Research is conducted in a manner which respects the dignity and rights of human subjects; and

WHEREAS, the Community wishes to adopt a Medical and Health Care Research Ordinance and establish a means by which Community research policies related to medical and health care will be administered by the Community and to provide for procedures by which the Community will grant permission for persons to conduct Medical and Health Care Research on the Reservation; and

WHEREAS, the Medical and Health Care Research Ordinance has complied with pre-adoption notification procedures pursuant to Title 5, Chapter 7, Section 5.703 of the Gila River Indian Community Code; and

WHEREAS, the Legislative Standing Committee recommends enactment of the Medical and Health Care Research Ordinance with the concurrence of the Health and Social Standing Committee.

NOW, THEREFORE, BE IT ENACTED, the Community Council hereby enacts the Medical and Health Care Research Ordinance which shall be codified as Title 17, Chapter 9 of the Gila River Indian Community Code.

BE IT FURTHER ENACTED, that the Medical and Health Care Research Ordinance shall be effective immediately.

BE IT FINALLY ENACTED, that the Governor, or in the Governor's absence, the Lieutenant Governor is hereby authorized to take all steps necessary to carry out the intent of this enactment.

CERTIFICATION

Pursuant to authority contained in Article XV, Section 1, (a) (7), (9), (18), (19), (b) (8), (10), and Section 4 of the amended Constitution and Bylaws of the Gila River Indian Community, ratified by the Tribe

January 22, 1960, and approved by the Sec. of the Interior on March 17, 1960, the foregoing Ordinance was adopted on 15 April, 2009, at a regular Community Council Meeting held in District 3, Sacaton, Arizona at which a quorum of 16 Members were present by a vote of: 16 FOR; 0 OPPOSE; 0 ABSTAIN; 1 ABSENT; 0 VACANCIES.

GILA RIVER INDIAN COMMUNITY

GOVERNOR

ATTEST:

COMMUNITY COUNCIL SECRETARY

Chapter 9. MEDICAL AND HEALTH CARE RESEARCH CODE

This Code shall be known as the "Gila River Indian Community Medical and Health Care Research Code" (the "Code").

9.101 FINDINGS AND POLICY

The Gila River Indian Community Council (the "Community Council"), the governing body of the Gila River Indian Community (the "Community"), recognizes the value of Medical and Health Care Research to the Community and its members. The Community Council must act to protect the safety and well-being of its members and other individuals who are subject to the jurisdiction of the Community. The Community has a fundamental policy to protect and preserve the culture of the Community and to ensure that activities permitted on the Gila Indian Reservation (the "Reservation") are conducted in a way that does no harm to the culture of the Community. The Community Council has found that Medical and Health Care Research has been conducted in ways that do not respect the human dignity of human subjects and that do not recognize the legitimate interest of the Community in the integrity and preservation of its culture.

9.102 PURPOSE

The purpose of this Code is to define Community research policies related to Medical and Health Care, and to establish means by which tribal research policies related to Medical and Health Care will be administered by the Community and to provide for procedures by which the Community will grant permission for persons to conduct Medical and Health Care research on the Reservation. The Code establishes:

- A. An application and permitting procedure with which applicant Medical and Health Care researchers must comply in order to obtain permission to conduct Research on the Reservation;
- B. Standards of conduct designed to protect Community members and the Community itself from improper Medical and Health Care Research procedures;
- C. Provisions to protect the rights of Community members, other individuals subject to the jurisdiction of the Community, and the Community in data related to Medical and Health Care Research; and
- D. Provisions to ensure appropriate Community participation in the design and evaluation of Medical and Health Care Research, and appropriate local opportunities in employment and all Medical and Health Care research projects permitted on the Reservation

9.013 SCOPE

- A. This Code is civil in nature and hereby supersedes all existing Community ordinances inconsistent with it.
- B. This Code is adopted pursuant to the Constitution and Bylaws of the Gila River Indian Community (March 17, 1960) in the exercise of Article XV (Powers of the Gila River Indian Community Council). Specifically, this Code asserts that Community's power to provide for the welfare and safety of the Community (Article XV, Section 1(a)(9)), the Community's power to tax and regulate business on the Reservation (Article XV, Section 1(b)(3)&(6)), and the Community's power to exclude non- members from the Reservation (Article XV, Section 1(b)(4)).
- C. This Code shall apply within the exterior boundaries of the Reservation. It shall also be enforceable outside the boundaries of the Reservation to the extent applicable law permits with respect to Medical and Health Care Research on the Reservation or Medical and Health Care Research using materials as to which the Community has a claim of ownership or control.
- D. This Code shall apply to all persons subject to the jurisdiction of the Community, including Community members and nonmembers, Indians and non-Indians, and other corporate and institutional entities who or which might undertake to conduct Medical and Health Care Research on the Reservation.
- E. This Code shall apply to all Medical and Health Care Research (as defined elsewhere in this Code) conducted on the Reservation, whether involving human subjects or not, and Medical and

Health Care Research regarding materials wherever located as to which the Community has a claim of intellectual, cultural or other ownership, legal or equitable, or over which it has a claim of control arising by virtue of this Code, the terms and conditions of any permit issued under this Code, any agreement, or otherwise.

9.104 DEFINITIONS

- A. As used in this Code, "Medical and Health Care Research" means 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 the Medical and Health Care fields of knowledge or to demonstrate or investigate theories, techniques or practices in the Medical and Health Care fields. For the purpose of this Code, Medical Health Care Research includes:
1. Basic and clinical research; and
 2. Longitudinal studies regarding diabetes and other diseases and human conditions.
 3. Clinical trials to include but not limited to pharmaceuticals, test, procedures and apparatus of any kind.

This Code does not prohibit day to day Research conducted on the Reservation by Community departments and entities, provided that this day to day Research may not be published without the Community Council's review and approval.

9.105 UNLAWFUL ACTS

It shall be unlawful for any person or entity to conduct Medical and Health Care Research on the Reservation or with respect to materials wherever located as to which the Community has a legal or equitable claim of intellectual, cultural or other ownership or a claim of control unless the primary investigator conducting the Medical and Health Care Research has obtained a permit as specified in this Code. Failure to obtain a permit or to abide by its terms and conditions shall result in penalties and sanctions specified in this Code.

9.106 ADMINISTRATION

There is hereby established a Community Research Reviewed Committee (the "Committee") to approve Medical and Health Care Research proposals permitted pursuant to this Code. The Committee shall be composed of the Chief Executive Officer and Chief Medical Officer of the Gila River Health Care or their designee, three members of the Health and Social Standing Committee (or its designees), and the Director of the Health Resources Department or his or her designee. The General Counsel or his or her designee shall act as an advisor to the Committee. The Committee shall receive staff support from the Gila River Health Care and the Health Resources Department. A reasonable fee may be assessed by the Committee for processing applications under this Code; any monies generated are for the exclusive use of the administration of this Code.

9.107 INFORMATION TO BE PROVIDED

The Committee shall prepare the appropriate application and other forms and shall develop a review process which adequately implements the intent of this Code and which provides fundamental fairness to each applicant conducting Medical and Health Care Research for a permit. At a minimum, the following information shall be provided by a Medical and Health Care applicant researcher in support of an application for permit:

- A. Description of the nature of the Medical and Health Care 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 any donation of biological specimens), the

- time to complete the projects, and a description of any information to be compiled concerning culture, customs and practices of the Community, either historical or contemporary.
- B. Descriptions of other related Medical and Health Care Research and a description of why the Research is timely and relevant.
 - C. Expected benefits of the proposed Medical and Health Care Research, including immediate and long-range benefits represented in the Medical and Health Care Research, the sum total of human and scientific knowledge, human subjects or participants, and the Community.
 - D. Risks associated with or inherent in the Medical and Health Care 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 would be taken to minimize the risks and the ameliorative and curative steps that would be taken in the event Medical and Health Care Research causes actual harm to participants or others.
 - E. Whether Medical and Health Care data is to be maintained as confidential and, if so, the means to preserve confidentiality. The applicant shall describe an assurances of confidentiality for the life the project, indicate how confidentiality will be protected after the Medical and Health Care Research is completed and for how long, indicate where raw data and other materials will be deposited in storage at the completion of the project, and indicate the circumstances in which confidentiality may be breached by legal or contractual obligations of the Researcher.
 - F. The application should answer questions the Committee considers relevant to the project including, but not limited to: Who will own the data from the Medical and Health Care Research? What control will the individual medical and Health Care Research participants have over the use of their own data? What control will the Community or Medical and Health Care Research participants have over the current and future use of the data, and how will the control be exercised? What control will the Community have over publication and other dissemination of results? Who will own specimens – human biological materials – from the Research? What control will the individual Medical and Health Care Research participants have over the use of their own specimens? What control will the Community have over the current and future use of the human biological material, and how will the control be exercised?
 - G. Opportunities for the Community, the Districts of the Community and individuals to have the Medical and Health Care Research fully explained to them and opportunity to comment on the Medical and Health Care Research; opportunity for the Community, Districts, and individuals, as appropriate to have periodic reports on the progress of the Medical Health Care Research and to comment on periodic and draft final reports. The burden of this Code is on the researcher to show, to the Committee's satisfaction, that Community, District, or individual input would be inappropriate.
 - H. Provisions of Indian preference in employment in all phases of the project. Preference shall be to Indians who are members of federally recognized Indian tribes.
 - I. The applicant shall describe how it will keep the Committee informed of all unexpected adverse events arising from the Medical and Health Care Research, and how the Committee shall be kept informed of Research progress on an annual basis, if the Research is a multi-year project.
 - J. If the Research involves human subjects research, the applicant shall provide a draft of any necessary Informed Consent form(s) it intends to use for review and possible revision by the Committee.
 - K. If the Research involves biological specimens, the applicant shall state whether biological specimens will be stored by the researcher after Research is completed, for possible use in future research or for other reasons, or whether biological specimens will be returned to the donor(s) or destroyed.
 - L. The applicant shall also identify those persons or entities that will have access to the biological specimens during Research and shall state whether such specimens will be collected with, or delinked from, personal identifiers of the donor(s).

- A. No Medical and Health Care Research shall be conducted on the Reservation or otherwise unless the researcher has first received a permit from the Committee according to the procedures specified herein. Where off-reservation enforcement of Community rights and interest may be of special importance, the researcher, his or her sponsoring institution or her or his funding source, may be required to sign an agreement with the Community concerning rights in data or materials or with respect to the ultimate publication.
- B. Any person or entity conducting Medical or Health Care Research on the Reservation without a permit issued pursuant to this Code, in violation of the terms and conditions of the permit, or otherwise in violation of this Code shall be subject to removal and permanent exclusion from the Reservation as determined by the Community Court in accordance with the Gila River Indian Community Law and Order Code, Title 5, Chapter 1, Sections 5.101 through 5.104.
- C. Whenever it appears that a person or entity had violated, or is violating, or is threatening to violate any provision of this Code, the Community Research Review Committee, the Community or any aggrieved person may file a civil suit in Community Court to enforce his Code.
- D. In any action brought for a violation of this Code, the Community Court may grant injunctive relief, including a temporary or permanent restraining order, to restrain a person or entity from continuing violation or threat of violation of this Code. The Community Court may order restitution, civil penalties not to exceed \$10,000, and such other relief as may be necessary to redress any injury suffered by any person, family, and organization, the Community or District of the Community resulting from a violation of this Code. The prevailing party in such a legal action shall be awarded court costs.
- E. If a civil suit is filed to enforce his Code, notice shall be given to the research project's sponsoring organization and/or funding source as well as to the professional organization or licensing agency of the person conducting the Research.

9.109 PROCEDURES FOR THE CONTINUING REVIEW OF RESEARCH

The Committee shall adopt procedures and forms. All forms and written procedures to be utilized by the Committee in administering this Code shall be subject to Community Council Approval.

9.110 CONTINUING REVIEW OF RESEARCH ACTIVITIES

The Committee shall regularly review all research activities subject to the authority of this Code. If the Research conditions change, the Committee may require that Research regulated under this Code be amended consistent with the changed conditions. If the Committee determines that Research regulated by the Code changes in the scope or effect of the Research, the Committee may rescind any research permit or otherwise limit the scope of research activities permitted under the permit.