Policies and Procedures for Submission of Study Proposals to Research Committee
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PURPOSE:

American Indian communities have long been the subject of focus study [both scientific and social] regarding health and social issues facing those communities as well as the larger society of the United States. Many of the advances in medical care, pharmacology, and other approaches and applications to disease have been achieved on the basis of long-term (longitudinal) studies based in part if not primarily on the American Indian community. Without doubt, the contribution of American Indian people to scientific knowledge and the resultant advances for all the people of the United States have been major.

However, recent events in the conduct of research among American Indian Tribes have created awareness that true collaborations and partnerships must be established that maintain and protect the interest and rights of the parties involved. In part the assurance of full accountability(s) has not existed between investigator(s) and community. Likewise, true benefit for participation sometimes remains unixed. Further, recent practice(s) of research questions the ethics of research in a multicultural economic setting. There are many issues surrounding the conduct of research among tribes of the United States.

This proposal summarizes the Community’s voice regarding the conduct of research and benefit in which the participation – benefit ratio is undefined and therefore unrealized.

COMMUNITY RESEARCH REVIEW COMMITTEE:

The establishment of the Community Research Review Committee pursuant to the Community’s Medical and Health Care Research Code represents the Community effort to establish guidelines and oversight of research based on the foundations of self-determination and self-direction in order to participate as a true collaborator.

Therefore the intent is to define the structures, expectations, and protocol(s) or procedures that will insure all research, it’s intent, and outcome is managed such that the Community not only benefits directly, but that Community Members, others residing in the Community, and the Community as a whole are protected.

COMPOSITION OF THE RESEARCH REVIEW COMMITTEE:

The Committee shall be composed of the chief executive officer and chief medical officer of the Gila River Health Care or their designee, three (3) 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.

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1 Gila River Indian Community Code: Title 17, Chapter 9.
2 See Title 17, Chapter 9, Section 9.106.
AUTHORITY:

The Authority to establish the Community’s Research Review Committee, which will function as a Research Review Board (RRB), is the Community’s Medical and Health Care Research Code codified at Title 17, Chapter 9, of the Gila River Indian Community Law and Order Code.

The Research Review Committee is vested with authority to make determinations for the granting of research privileges to individuals, organizations, or entities involved in medical and health care research.

INFORMATION REQUIRED:

At a minimum, the following information shall be provided by a Medical and Health Care applicant researcher in support of an application for a permit:

A. Description of the nature of the Medical and Health Care Research being proposed, including the goals and objectives and 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. Description 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. The applicant must also provide an approval from the applicant's Internal Review Board approving applicant’s proposal and determining applicant's proposal is valid.

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 are 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 of 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 and stored at the completion of the project, and indicate the circumstances in which confidentiality may be breached by legal or contractual obligations of the researcher and other legal requirements that are required for example, a business associate agreement.

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 be 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 the exercise, as well is how confidentiality of patient information will be protected? 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 the exercise?

G. Opportunities for the Community, the Districts of the Community and individuals to have the Medical and Health Care Research fully explained to them an opportunity to comment on the Medical and Health Care Research; opportunities for the Community, Districts, and individuals, as appropriate to have periodic reports on the progress of the Medical and Health Care Research and to comment on periodic and draft final report. 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 subject research, the applicant shall provide a draft of any necessary Informed Consent form 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. The applicant will also be required to state the type of specimen that will be collected and the disposition of each type of specimen.

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 de-linked from, personal identifiers of the donor(s).

PROCESS:

All research proposals shall be submitted to the Research Review Committee. A tracking mechanism shall be assigned each proposal for monitoring by Research Review Committee staff.

The staff will provide within two weeks of receipt (10 working days) a summation of the assigned proposal for review and discussion by the Research and Review Committee.

The summation shall consist of:

1. A statement of what is to be investigated including theory and hypothesis, protocol summation, and outcome or results;
2. What data is to be gathered/method for gathering;
3. The proposed rationale for why the Community members and others are candidates for research;
4. The target population for focus;
5. Length of study;
6. Funding source;
7. Proposed collaboration; and
8. Benefits as proposed by the research group.
Staff will include with the summation written recommendations regarding the proposal merits (strengths and weaknesses) and a Pro and con summation sheet, which shall be provided to the Research Review Committee.

APPROVAL:

An Approval for the proposal for presentation shall be in the form of a motion by the Research Review Committee and by a majority of the Research Review Committee. A quorum other Research Review Committee shall be three (3) members of the Research Review Committee.

Once approved for presentation, the Research Review Committee may schedule a Request for Presentation with the Investigators. This Request for Presentation will be scheduled within a reasonable time following Approval. A date, time, and place shall be designated by the Research Review Committee staff within a reasonable time period.

The investigators will be required to provide a concise overview [Power Point, or similar] to the Research Review Committee and staff of the proposal addressing those questions and the "INFORMATION REQUIRED" in this document and the Medical and Health Care Research Code.

ENGAGING THE STUDY:

Within 15 days of the Investigator Presentation the Research Review Committee will determine if the Community wishes to engage the study, as follows:

1. If the decision is to engage, a letter of invitation to Submit a Full Proposal shall be mailed via Registered Mail within 10 working days following the decision. The Investigators must submit the following:
   1.1 A Full Proposal.
   1.2 Sign an agreement with the Gila River Indian Community to abide by all the requirements of the Research Review Committee and any conditions imposed by the Research Review Committee.
   1.3 Documentation of Investigator Clearances [as required].

2. If the decision is to decline:
   2.1 A Decision To decline shall be sent by the Research Review Committee to the requestor. Declination Decisions are final and not subject to appeal. Final approvals for research proposal shall not be granted until clearance(s) are forwarded.

GRANTING CONTINUING PRIVILEGES:

The Research Review Committee retains the authority to discontinue research if there has been non—compliance with the Community’s Medical and Health Care Research Code as determined by the Research Review Committee.