GILA RIVER INDIAN COMMUNITY

Guidelines and Instructions, Introduction, Letter of Intent, Sample Letter and Agreement

Gila River Indian Community
Sacaton, Arizona 85247

Research Review Committee

Research Proposal Guidelines
For Medical and Health Care Related Research

You are invited to participate with us in research that will improve our People's lives. The proper protocol is identified here in order to have you follow our rules of etiquette.

Letter of Intent

1. Before any approaches made to our People, our Programs or our Institutions or any other Community body you must provide the Gila River Research Review Committee (RRC) a Letter of Intent (your letterhead) in which you will officially notify the Gila River Indian Community of your wish to engage in a research endeavor. See Letter of Intent to Conduct Research – SAMPLE.

Completing the Application Process

2. You will be asked to complete a Study Summary which condenses your proposal into a concise packet that will allow a predetermination of the value and feasibility of your study intent. This Summary must be submitted with your Letter of Intent. A LIMIT OF 2 PAGES IS ENFORCED. Do not submit your full proposal at this time. See Study Summary Guideline.

Resource Assessment

Attached you will find a copy of the Study Summary Checklist and "Basic Guidelines – Proposing Your Study and Agreements." It is provided to give you an overview of the requirements that will be asked of you if you want to consider conducting research. Please direct any questions you may have to Ms. Wanda Manuel, Alternative Research Liaison at 520– 550–8000.

GILA RIVER INDIAN COMMUNITY
RESEARCH REVIEW COMMITTEE

Study Summary Checklist

Please include the following:

1. Your Organization's Name.
2. Your Organization's Address.
3. Principal Investigator Name.
4. Principal Investigator Address, Phone Number, and E-Mail Address.
5. Additional Investigator(s) Name and Title (vitae is required of each person as an attachment).
6. Name of Study.
7. Length of Study.
8. Summary of Intent: A synopsis of your proposed study background, theory, and hypothesis should be included. This should be in layman language and easily understood. If you are submitting a protocol in order to collect data, samples, records of any sort, or any other type of collection for the study or a later applied research methodology clearly identified as "Protocol." (Be succinct and to the point.)
9. Who the study subjects will be.
10. Proof of Liability (Amount and Type).
11. IRB status [in process, approved, not submitted] and if Human Subjects are involved.
12. A statement is required identifying the study type, whether it (or something similar) has been conducted and if so, why it is being replicated.
13. A clear outline of anticipated results that will directly benefit the Community or its members.

GILA RIVER INDIAN COMMUNITY
RESEARCH REVIEW COMMITTEE

Research Proposal Guidelines Introduction

Thank you for considering the Gila River Indian Community (the "Community") as a potential partner in your research endeavor. You will find our application process a simple process of submitting a basic outline of your idea. We will want to know some specific things about your status as an organization and support systems. These will be outlined in the Guidelines.

These documents are designed to help you propose your investigation. We will want to know certain things about you, your organization, your study, and what assurances you have in place or will propose to have in place. All medical and health care research conducted in our Community is done in collaboration with our people and institutions. We have a series of protocols in place that will help us understand what you want, what you hope to accomplish, and how it will benefit our community and our future. We will also explain the steps you will follow to process your proposal to a decision stage.

The Gila River Indian Community reserves the final decision to allow research endeavors to be conducted. This is exclusive. Community decisions are final and the process and deliberations regarding your proposal are private and confidential and will not be disclosed to you.

You may or may not be invited to meetings regarding your proposal of the discretion of the Research Review Committee. Unless requested, meetings regarding your proposal are considered exclusive only to the Gila River Indian Community Research Review Committee and its membership and therefore considered closed. It is customary for us to ask for a presentation during which time you will be asked a series of questions regarding you, your organization, your purpose, the proposal, and most importantly, the benefit to the Community.

Research and the advancement of knowledge are essential to finding cures to diseases that affect all of mankind. Our Community has been a central focus of many kinds of research and we have contributed much to the advancement of medicine and medical care in many areas. We expect that mutual benefit will result as an outcome of our collaboration and hope to benefit from your proposal. We wish you well and hopefully lasting collaborative relationship will result from your interest in our Community.

Thank you.

GILA RIVER INDIAN COMMUNITY
RESEARCH REVIEW COMMITTEE

Information and Requirements regarding Medical and Health Care Related Research

These guidelines and instructions describe how we will want you to propose your study. Our Community follows long traditions in decision-making and you may find it very different from what you are used to. The Gila River Indian Community is a sovereign body and is recognized by the United States government. Therefore, it is, for all intents and purposes, a nation unto itself. It has its own languages, government, rules, culture, traditions, laws, regulations, and boundaries. This is presented in an appreciation for the circumstances and environment in which you are proposing to work.

Personal and Professional Conduct

At all times you are considered a guest of our land and people. We allow outside agencies to conduct work on our land as a privilege to them. Mutual respect is the common denominator. We expect the highest of ethics and respect from all investigators.

Information – Data Systems

We have an extensive database regarding our people. It is exclusive property and we have total proprietary and use rights to and over it. Its use, access, and/or dissemination will only be done in an agreement. Access to our data through second and third parties must be identified. The Gila River Indian Community (the "Community") maintains ownership and therefore grants privileges regarding all information contained in all health records, datasets, data transfers, archives, and any other source of information regarding the demographics, health status, health indices, service utilizations, financial data, or any other data or information considered either directly or indirectly related to the health of the Community.

All information or data gained during your study is considered the property of the Community and therefore a formal agreement on its disclosure, use, publication (in any form), inclusion and other reports, or comparisons must be in place.

Overview of Requirements

You will be asked to:

1. Identify any and all coworkers, secondary researchers, secondary institutions, affiliated groups organizations, or any entity that will have access to your data either during or after the study is done, prior to publication, or during its analysis.
2. Provide assurance that all data will not be disclosed, shared, or transferred to any other organization, individual or entity outside of the expressed agreement with the Gila River Indian Community.

Property and Propriety

3. Identify the Gila River Indian Community as a Co-Investigator as part of your proposal. Your study is of great interest to us and we reserve the right to be identified as co-researcher/investigator based on the level of involvement in the proposal development – implementation process, tribal entity expertise and resources that will be involved for review, facility access, access to the people, access to data, staff assignment, data extrapolation, etc.

Intellectual Property

4. As the researcher you have the right to maintain the research methodology as intellectual property. However, if the Community at any point during proposal, review, or discussion proposes changes to methods, technique, instruments, approach, or any other action that affects the body of the proposal, the research, or its implementation, the research will be considered a mutual proposal and therefore the Gila River Indian Community will have rights to that intellectual property and will be accorded privileges, recognition, or any other benefit customary to co–investigators.

Disclosures [Conflict of Interest]

5. Identify your organization and organizational affiliations it has maintained or proposes to engage related to your proposed study.
6. Identify any patents, individual or shared, royalty agreements, individual or shared, any subsidies from profit oriented entities, remuneration of any kind from commercial companies, or any personal benefit you have received or are in agreement to receive related to the area of research you are proposing to conduct from any non-governmental agency, body, company, or business.
7. Disclose any other individual researchers, research organizations, analytical bodies, reviewing bodies, associations or affiliations who will either have a part in your study or who stand to gain access to data or information as a result of your study (outside of academic publication).

Proprietary Agreements

8. Agree in the event you, associates, or your organization stands to gain in any way, whether through patent, associated or shared royalty, or one-time remuneration, that the Gila River Indian Community will benefit a fair and equitable percentage of any and all compensation for the length of the said grounds for compensation.
9. Agree that in the event the data, findings or any other results or outcomes based on the People of the Gila River Indian Community are used in whole or in part in the a.) development of or, b.) trial studies of, salable products and said products become commercially available, or rights to manufacture and sell such products are established, or there is a transfer of commercial rights to manufacture such products, the Gila River Indian Community will be entitled to fair compensation and will maintain a shared royalty rights according to laws and regulations regarding patents, royalties, and any other compensations involved.

Samples

10. Provide assurance that (all) sample(s) of any kind, especially those biologic in nature will not be used beyond the scope of your proposed research in any manner outside of the agreed-upon use of those samples.
11. Agree that all samples are the property of the individual, the group, and in aggregate, the Community, and therefore the individual must provide expressed exclusive approval for its use outside of the Gila River Indian Community and the proposed study. In aggregate, whether identified or not, the samples are exclusive property of and any use of them outside of the proposed study must have approval of the Gila River Indian Community.
12. Identify the method by which you will safeguard all samples, the lengths you proposed to maintain said samples, where they will be housed, and method of disposal.
13. Provide an identifying method that accounts for all samples in one location and a method to assure an accounting percent for use during your study. We will want to know the aggregate of each sample group in some form of a measuring format and periodic reports of remaining sample sizes. At the end of your study you will be asked to report on remaining sample sizes and destruction. The destruction must be done by a non-affiliated commercial laboratory which provides the final accounting for the sample size. Discrepancies will be considered a breach of faith and the sponsoring organization or agency will be held liable to compensate the Gila River Indian Community from loss and mishandling of Community Information.
14. Agree that no other organization, body, agency, individual, or group will be given access to samples in any form during or after the research period unless a prior agreement exists.
15. Agree that in the event you are aware of, are asked, or approached in any manner by a non-authorized organization, group, or entity to access samples (biologic in nature or medical data access) you will formally notify the Gila River Indian Community.

Accounting

16. Provide a quarterly report of associated in-kind costs incurred by the Gila River Indian Community as Co–Investigators in support of your research. Our time, our facilities, our services, our staff, our programs, and our People and their access are considered support assets to your study which we finance. CPT and DRG charges will be used to determine the Community's contribution. Each individual encounter will equal the Medicaid pay scale for accessing the patient study group that currently the Gila River Health Care Corporation receives as a base rate per encounter. Blood draws, measurements, etc. will be based on the current allowable charges. Individuals who are part of the study shall be determined employees of the study and will be accounted for at $50 per interaction. You will be asked to make an estimation of intake costs for each encounter.
17. Make a determination of the value of each sample of any kind you take and maintain. This will be added to the overall cost incurred by our Community in support of your research.

Publications

If your study will ultimately end in some form of Academic Publication, what you present, how you present it, and conclusions you draw are of great interest to us. As co-investigators we will expect to participate in your final drafts and publication.

18. Present an outline of the publication for consideration. During that presentation we will be interested in your conclusions and summaries. Please present these. Ramifications and

Implications of this study should be presented. Highlight and explain what will have a direct impact on us, our issues, and indicate how we could help implement the findings.

19. We will need to know what publishers or institutions will be solicited for publishing.
20. Agree that the Gila River Indian Community will be identified in the publication of co-investigators and note will be given to the contribution(s) as they apply.

Liability Coverage

21. Identify liabilities and risks to participants [individual or institutional] that may exist in your study.
22. Provide proof and level of Liability Coverage for individuals and General Liability coverage for causal or property damage or loss.

THANK YOU

GILA RIVER INDIAN COMMUNITY

A MEMORANDUM OF AGREEMENT (MOA) REGARDING MEDICAL AND HEALTH CARE RELATED TO RESEARCH CONDUCTED AT GILA RIVER INDIAN COMMUNITY

THIS AGREEMENT is made this _____day of _____, _____, by and among the Gila River Indian Community (hereinafter, "the Community"), a federally recognized Indian tribe with administrative offices located at 525 W. Gu u Ki, Post Office Box 97, Sacaton, Arizona 85247 and the _____ (hereinafter, "**Research Group**"), with offices located at
(Your Organization's Name)
_____.
(Your Organization's Address)

1. **Purpose of Agreement.**

The purpose of this Agreement is to set forth understandings and agreements among the Community and **Your Organization's Name** necessary for approval of all current and future Medical and Health Care related research conducted with the Community and involving Community members and other research participants.

2. **Scope of Agreement.**

This Agreement covers all medical and health care research currently being proposed to be undertaken by **Your Organization** within the Community, especially that research involving Community members and/or institutions.

3. **Effect of Agreement.**

This agreement applies to all medical and health related research conducted by **Your Organization** within the Community, especially medical and health care related research involving Community members, as of the date of this Agreement.

4. **Approval of Medical and Health Care Research.**

(a) Procedure. No medical or healthcare related research may be undertaken within the Community, including, but not limited to, medical and health care research involving Community members. All research proposals, protocols for procedures must be submitted to the Community's Research and Review Committee (RRC) for initial review. The sponsoring organization conducting any medical or health care related research proposals, protocols for procedures must submitted to the RRC the identity of its sub–organizations, subcontractor(s) or grantee(s) if such entities are involved in the research either on-site or external. Any medical or health care related research proposal, protocol or procedure reviewed by the RRC to comply with the content requirement and conditions of this Agreement and the Community's Medical and Health Care Research Code codified at Title 17, Chapter 9 of the Community's Law and Order Code. If requested, **Your Organization** personnel shall be required to appear before the RRC to further explain your medical or health care related research under consideration.

(b) Amendment to Approval Procedures. The RRC reserves all rights to unilaterally alter procedures for approval of medical or medically related research at any time.

(c) Content of Research Proposals, Protocols and Procedures. Proposals, protocols and procedures for the conduct of any medical or healthcare related research within the Community shall be

separate from one another when the focus or parameter of the scientific investigation is considered a separate "study." At no time shall a "blanket" or "open-ended" agreement exist between **Your Organization** and the Community in which varying study parameters exist under one approved medical or healthcare related research "project." When reviewing a specific medical or healthcare related research proposal, protocol or procedure for approval or disapproval, the RRC may, at its discretion, request that a separate proposal, protocol or procedure be prepared for different aspects of a medical or health care related research investigation if it deems such action to the appropriate and necessary.

(d) Short term medical or medically related research study shall be identified as such and shall be required to be preapproved by Council under the procedures of this Agreement every two (2) years. Longitudinal or long-term medical or medically related research study shall be identified as such and shall be required to be re-approved by the RRC under the procedures of this Agreement every two (2) years.

(e) All medical or health care related research proposals, protocols or procedures submitted to the RRC for approval shall identify by name all research investigators or research organizations (commercial or academic) outside of the submitting organization, including subcontractors or grantees, who will sponsor, participate, receive benefit, or in any way be recognized or act as a beneficiary as a result of the research studies conducted within the Community. If all such research investigators organizations are not known at the time the research is submitted for approval, the submitting organization shall have a continuing obligation to inform the RRC in writing within 30 calendar days after information on such research investigators organizations becomes available. Final approval shall be contingent upon identification by the submitting organization of all known individuals and entities involved in the research within the Community, including those individuals or entities participating in the Community study but their actions or participation occurs outside the Community.

(f) No medical or health care related research proposal, protocol or procedure will be approved by the RRC unless it is written in plain English that is easily understood by a layman. All scientific or medical or healthcare related terms must be defined so as to be understood by a layman.

(g) No medical or medically related research proposal, protocol or procedure will be approved by the RRC if it contains unnecessarily vague terminology with uncertain meaning, including, but not limited to, such terms as: "etc.," "others," "entities," "associates," "affiliates," "sister organizations," "collaborators," "standard procedure," and "routine." At its discretion, the RRC may require more detailed explanations of any provision of a medical or health care related research proposal protocol or procedure prior to approval.

(h) No medical or healthcare related research proposal, protocol or procedure will be approved by the RRC unless it contains a clear and reasoned explanation as to why the research is occurring in the Community, especially research involving Community members.

5. **Conflicts of Interest**.

All research investigators research organizations identified in any approved medical or health care related research will be required to provide information to the RRC disclosing any proprietary interest in any other research investigator, person, organization or entity that would benefit financially, including ownership of any intellectual property rights (trademark, copyright or patent), monetary benefits, or any other type of benefit or entitlement accruing as a result of such research, now or in the future.

Your Organization agrees that any remuneration of any kind made to research participants, and especially Community members, as a recruitment incentive or participation in any approved medical

or health care related research shall not be for payment or license in any form for the taking, storage, distribution, or use of biologic material, genetics, biologic waste, medical information, demographic information of that individual, family, group or the Community as a whole.

6. **Liability**.

Your Organization agrees to provide liability coverage, personal and property, during the duration of your study.

Your Organization agrees to inform each participant in an approved medical or healthcare related research of **Your Organization**'s Liability Coverage and have available a known process and support mechanism in support of individual or group filing of complaint, charges of any kind, or receivership of benefits future loss, pain, or suffering of any kind as a result of research activity.

7. **Assistance with Community Member Treatment.**

Your Organization agrees to affirmatively assist individuals participating in approved medical or medically related research with obtaining necessary medical treatment for identified disease or health conditions requiring medical treatment.

8. **Historical Accounting of Prior Research – – Not Applicable**.

9. **Education of Community Volunteers Regarding Scope and Intent of Research.**

Your Organization agrees that in all written and verbal presentations to research participants volunteering for any approved research, the intent, goal and expectation of outcome of research shall be clearly and fully communicated each participant.

Your Organization agrees through its research investigators, or other personnel who have interaction with Community members or through any other form of media interaction with the Community to refrain from creating an impression that it is engaged in direct research work yours to health issues of the Community, unless, the research is specific to and identified as "curative."

In conducting any medical or medically related research in which cures or curtailment or slowing of complications are understood not to be the immediate and primary focus of the research, **Your Organization** agrees to work with the Community to develop a written consent form that ensures that participant volunteers understand that the purpose of the research being agreed to is limited to gaining generalized scientific understanding and knowledge rather than a search for an immediate cure or relief of a symptom(s) or complication(s).

Your Organization agrees to publish on a Community–wide basis a mailing to each household and provide presentations for the general Community populace providing the intent and purpose of your research studies involving Community members in order to clarify the intent of the research once said research has been formally approved by the RRC.

Your Organization shall make its Mission Statement or purpose clear to all Community members.

10. **Confidentiality.**

Your Organization agrees that it will treat all information provided to it by the Community, community members or the research participants with the strictest confidentiality standards that meet at least the minimum federal and state medical privacy requirements.

Your Organization agrees to develop a specific Plan of Privacy and Protection of Confidentiality for all medical or healthcare related research matters undertaken at the Community to assure each Community member and the Community of the whole that adequate measures are in place to protect the identity, samples, information, family tree(s), blood quantum, genetic tracings, or any other such identifiers contained in records or samples.

11. **Biologic Samples – Storage and Use.**

Your Organization shall identify the sample type, amount, and proposed use of biologic samples and all medical and healthcare related research proposals with approval.

All biologic samples shall be taken pursuant to approved medical or health care related research are understood to be the private property the Community as a whole and its individual Community members, and other research participants, and are therefore owned individually by such members and other research participants and collectively by the Community.

Your Organization does not have in any form, past or present, an inherent property right, or rights to license such biologic samples in whole or in part absent written agreement with Community, individual Community members, or other research participants.

At any time, the RRC may request return of any biologic material held by **Your Organization**.

Identifiers, markers, coding, or other means of identifying samples as Pima, Maricopa, or other terms applied to the Community or its members shall be provided by **Your Organization** to the RRC for the purpose of tracking or identifying the disposition of sample(s) taken during this period.

The RRC may request at any time that **Your Organization** prepare a report regarding the use or intent for use of any and all biologic samples taken under an approved medical or healthcare related research study to ensure that such samples are not being used outside the scope of the approved study for which the sample was taken.

Your Organization agrees to inform the RRC of any proposed uses of biologic or record samples exceeding the scope of any approved medical or medically related research study and obtain consent for such uses by the RRC.

Your Organization agrees to provide a Plan of Containment specifying the Plan that will be used to protect and ensure the Community and RRC of the proper storage and destruction of biologic samples.

Your Organization agrees to prohibit the use of biologic samples taken from Community members or other research participants by any commercial for-profit entities of any kind, or for research supported in part or in full by commercial enterprises where proprietary rights (including patent, trademark or copyright or ownership and scientific advancements) will result in a commercial enterprise unless the use is expressly agreed to by the RRC.

Your Organization agrees to provide a Plan of Secondary Distribution should the need for secondary distribution of biologic samples to research investigators or organizations other than those identified in approved medical or healthcare related research be identified. The Plan shall include names, locations, intent for use, containment and disposal plants, proprietary agreements, rights, protections and any other necessities to ensure protection of the samples used by the secondary receivers.

12. **Medical Data, Access, and Use.**

All data specific to the membership of the Community as identified by the Resources Patient Management System (RPMS) coding, or any other data management system coding including information about tribal affiliation, immunity of residents, facility, or service unit or other Community or personal information, is considered the property of the Community and the Community retains rights over its use.

Your Organization agrees to provide the RRC information regarding how such data is to be used to transfer throughout its sub–Institute, sub–organization, affiliates and subcontractors and grantees if the case applies.

Your Organization further agrees to ensure that all data specific to the Community and its members contained within the RPMS, or any other data system is consistent with guidelines set forth by the RRC.

Your Organization agrees to notify the RRC in a proposal format in the event such data is to be used or accessed by any sub–organization, affiliates, subcontractors and grantees, or any entity outside of **Your Organization** if the use is not proposed in the original proposal.

13. **Publication.**

Any and all publications of research findings from approved medical or health care related research conducted at the Community shall be provided to the RRC in full manuscript with a one-page summary of at least sixty (60) calendar days prior to publication. The full manuscript shall be presented to the Gila River Indian Community Council (the "Community Council") for its approval, and the Community Council retains the right to disapprove proposed revision of publication proposals in full or in part if it determines the publication is not in the best interests of the Community. For the record, the RRC on behalf of the Community Council shall forward a disclaimer to the publisher in the event of disapproval.

Any published work shall identify the Community as a co–research investigator and shall include the name and title of the Governor of the Community, and the Chair of the Council's Health and Social Standing Committee.

14. **Conduct and Relations with Community Members.**

At all times, **Your Organization** representatives shall conduct themselves with the highest standards of professionalism and ethics. At no time shall **Your Organization**, its associates, or representative approach Community members or other prospective research participants to solicit support for proposed medical or healthcare related research studies before RRC approval of such research.

Failure to abide by this section shall, at the discretion of the RRC, result in revocation or dismissal of submitted proposals, proposal for procedures prior approved research.

At no time shall **Your Organization**, its associates, or representatives use the political or Community processes of the Community, including its Departments, Leadership, or Community Council Members, non-governmental bodies of the Community members, or Community groups to attempt to gain support for medical or health care related research proposals before final approval by the Council.

The RRC reserves the right to ask for the formal removal of any member of the research investigator group, associate research group, or individuals there of any capacity associated with the conduct of the approved medical or healthcare related research.

15. **Effective Date**.

This Agreement shall become effective immediately upon execution of all parties to the MOA.

16. **Initial Term and Renewal**.

The term of this Agreement shall be two (2) years. This Agreement may be renewed for subsequent two-year (2) periods upon written consent by the Parties.

17. **Amendment; Voluntary Termination.**

This Agreement may be amended in writing at any time with the Parties' mutual written consent. It may be terminated by any Party upon sixty (60) calendar days' written notice or by the RRC for material violation of the Medical Health Care Research Code for material breach of this MOA.

18. **Correspondence.**

Required correspondence shall be transmitted via US mail, certified, return receipt requested, to the Parties at all of the addresses listed on page one of this Agreement, and shall be deemed received on date of the first signature thereof.

19. **Non-Assignment**.

No Party may assign or transfer any right, obligation, or interest under this Agreement without the prior written consent of each Party, notwithstanding the foregoing, the rights, obligations, and interests under this Agreement sub–organizations, sub–Institute, sub–contractors, and grantees of **Your Organization**.

20. **Choice of Law**.

It is a further intention of the parties that performance of the terms of this MOA shall be in accordance with an pursuant to the laws of the Gila River Indian Community and that any action, special proceeding or other proceeding that may arise from in connection with or by reason of this MOA shall be resolved pursuant to the laws of the Gila River Indian Community and in its courts. The Parties hereby specifically acknowledge that nothing in this Agreement shall constitute a waiver, express or implied, of the Community's sovereign immunity.

21. **Entire Agreement**.

This MOA sets forth the entire agreement among the Parties with respect to the subject matter addressed herein. All prior and contemporaneous agreements, representations, and understandings of the Parties, verbal or written, pertaining to the subject matter hereof are hereby superseded.

IN WITNESS WHEREOF this Agreement has been executed at Sacaton, Arizona.

GILA RIVER INDIAN COMMUNITY:

By: _____ _____
Governor Date

By: _____ _____
Chair of the RRC Date

Approved as to form:

By: _____ _____
General Counsel Date

<u>Your Organization</u>

By: _____ _____
Date

GILA RIVER INDIAN COMMUNITY
RESEARCH REVIEW COMMITTEE

Your Study Proposal Summary for Medical and Health Care Related Research

Your Submission of this document will help us evaluate your RESEARCH INTENT. This is not your full proposal. It should be written such that any untrained non-scientist would understand your proposal. Proposals that are hard to understand will be returned. In your submission please use the headings (in bold) and answer or address the query as stated in the outline.

What are you proposing to study?

1. Begin with a concise and short Problem Statement.
2. What part of the Problem will the study focus on?
3. The nature of the study – Please indicate the type of study you are proposing – pure research, replication study, clinical trial, compared of study, retrospective study, longitudinal, combinations, etc.
4. Where do you propose to conduct your study?
5. Who will be the focus of your study?
6. Length of study.

Your Rationale

1. What is the theory (if applicable) you base your study on?
2. What do you hope to find, approve or disapprove (hypothesis)?

Method(s) you will use in your study

1. Blind, double-blind, chart review, interview, etc.
2. Has this study been done elsewhere? Please provide a statement of yes or no. If Yes, you will be asked to provide a summary of prior study findings and defend why you want to replicate or very the study with the people of the Gila River Indian Community in your proposal.

Associates, Fellows, Other Researchers

1. Names of persons or organizations that will be DIRECTLY involved in your study.
2. Are any secondary researchers are sponsors of all to have not been identified? Please answer Yes or No.
3. If Yes, please identify.

Risks and Liabilities

1. What are the risks involved to the people, the Community, yourself, co–workers, your organization?

2. Will any invasive methods be employed? If Yes – you must explain and indicate how this will be managed. If Yes, – ***you must provide proof of medical liability in coverage limits*** as the Gila River Indian Community and its entities will not responsible for any liabilities as a result of your study in any fashion.

3. Will individual information be identified accessed or stored in any part of your study? If Yes – You must explain how and indicate how this storage will be managed. If Yes – ***you must provide proof of liability and coverage limits*** as the Gila River Indian Community and its entities will not be responsible for any liabilities.

4. Indicate your agreement below by checking "Yes" to post on your solicitation material, intake material, or any other material used to educate, make aware, or create understanding that all liabilities are expressly your; that the Gila River Indian Community will be held harmless; and, that each participant will be aware of and have access to a process to file a tort, suit, any claim, a complaint, or investigate issues of liability for your organization, insurance carrier or other bodies involved in liability coverage for you and your study.

   YES: _____ NO: _____

   Indicate your agreement below by checking "Yes" to notify the Gila River Indian Community Research and Review Committee in the event a participant does file, investigate, or indicates dissatisfaction or issue their involvement.

   YES: _____ NO: _____

Protection of Information

1. Will you be transporting, in any method, information that can be considered sensitive or that will come under HIPPA regulations?

   YES: _____ NO: _____

   If Yes, you must indicate what will be transported and your containment and management plan.

2. Will you be asked or are you planning to share any information you access, receive, solicited or unsolicited, view, or know of, with any other person, agencies, institutions, or academic groups other than those two have identified?

   YES: _____ NO: _____

   If Yes, list and explain why you are proposing they will have access, or what they will do with the information.

Protection and Management of Samples

Will your research involve the taking of any biologic material in any form?

YES: _____ NO: _____

If Yes, you will be asked to provide a separate document with your formal proposal indicating your plan of what will be sampled, how much, what will be used for, length of storage, type of storage, your proposed or perceived rights, if any, over said samples, your plan of education to let participants know their rights over contributed samples, rights of agreement for future use, and destruction or discontinuance plans of samples.

Consequences of Not Conducting This Research

Please answer the following: if this study was not conducted would there be any consequences to the ***existing health*** of the people, or improvement in the ***existing health*** of the people? Please be concise.

Benefits and Benefactors

1. In your estimation who would benefit most from your findings? Circle the following that apply:

   Institutions, medical practice, the advancement of scientific knowledge, other research. Please explain.

2. Who will benefit from your research outside of the Gila River Indian Community?

3. Will the Gila River Indian Community benefit directly from your study? Do not propose possibilities, but rather provide real-time benefits that we can expect apply to the problem as it relates to our People and the problem of the study.

4. Will we be able to use your findings in a practical manner? Be specific in your statement or summary.

5. How long will it take for the Gila River Indian Community to benefit directly in a practical manner from your study?

6. Propose to us the Impact of your study on the Problem.

Official Review/IRB

1. Has an IRB approved your proposed study?

   YES: _____ NO: _____

If No, you will be asked to withdraw your submission.

2. Does your organization require other reviews and approvals of your study?

   YES: _____ NO: _____

If Yes, list what they are and by what organizations.

3. Will the study be published?

   YES: _____ NO: _____

Costs

What do you estimate the cost to you or your organization to conduct the study? Please provide an estimated cost summary of what you expect the Community will contribute to your research.

Proprietary Considerations

1. Do you have any interests whether to or from any commercial groups, companies, investors, for-profit organization, nonprofit organizations, or individuals in your study?

   YES: _____ NO: _____

If Yes, you must explain those interests:

2. Is your Investigation supported in any matter by Commercial Enterprises of any kind, investors, or any other body that potentially stand to gain in any fashion from your research?

   YES: _____ NO: _____

3. Do you or your organization stand to gain in any manner, now or in the future, monetary reward, gifts, or any privileges from any person, company, investor, or entity you are in association with?

   YES: _____ NO: _____

4. Do you have any existing interest or future interest in patents, copyrights, intellectual rights or any other form of ownership to any products, processes, property, production or manufacturing including composition or design of said items that are related to or will result as an outcome of the study?

   YES: _____ NO: _____

   If Yes, list and explain.

5. Have you in any manner approached individuals, groups, organizations, programs of the Community, governing bodies of the Community, concerned groups the Community prior to the submission of this Application?

   YES: _____ NO: _____

   If Yes, please identify.

Agreements

You must submit a signed Statement of Agreements and Conditions in which you agree to the terms and requirements of the Gila River Indian Community regarding your research. This can be submitted during the preliminary review or with your initial contact the Community. If you do not, your proposal will be withdrawn from consideration. Please call the Alternative Research Liaison, at 520 – 550 – 8000 extension 224 or submit an e-mail to Wanda.Manuel@gric.nsn.us for a copy of the Agreement.