### Tribal Seal_10GILA RIVER INDIAN COMMUNITY RESEARCH APPLICATION

**Date:**

**Protocol Title:**

**Name of Principal Investigator:**

**Title/Affiliation of the PI:**

**Address:**

**Phone:**       **Fax:**

**Email:**

**Name of Co-Investigator(s):**

**Address:**

**Phone:**      **Fax:**

**Email:**

1. **What does the Project Propose to Study:**
2. Begin with a concise and short problem statement.
3. What part of the problem will the study focus on?
4. The nature of the study – Please indicate type of study proposed, e.g. pure research, replication study, clinical trial, comparative study, retrospective study, longitudinal, combinations, etc.
5. Where will the study be conducted?
6. Who is the focus of the study?
7. What is the estimated length of the study?
8. Describe why the research is timely and relevant
9. Describe the type of information that will be sought from participants.
10. Describe any information to be compiled concerning culture, customs or practices of the Community, either historical or contemporary.
11. **Rationale:**
12. What is the theory, if applicable, the study is based upon?
13. What is the study intended to find, prove, or disprove [hypothesis]?
14. **Method(s):**
15. Blind, double blind, chart review, interview etc.
16. Has this study been done before elsewhere? Yes [ ] No [ ]

If yes, provide a summary of prior study findings and defense of replicating or varying the study with the members of the Gila River Indian Community.

1. **Associates, Fellows, Other Researchers:**
2. Provide names and contact information for any persons and organizations that will be directly or indirectly involved in the study, and include a statement of how they will be involved.
3. Names and contact information for superior or supervisor over the principal investigator.
4. Are any secondary researchers or sponsors involved who have not been identified?

Yes [ ] No [ ]

If yes, provide names and contact information.

1. **Risks and Liabilities:**
2. What are the risks involved to the Community, its members, researchers, co-workers, and the project’s organization? Include risks to physical or psychological well being.

Will any invasive methods be employed? Yes [ ] No [ ]

 If yes – provide proof of medical liability and coverage limits as the Gila River Indian Community and its entities will not be responsible for any liabilities as a result of the study.

 2. What are the risks of deleterious impact on the cultural, social, economic or political well being of the Community?

3. Describe what steps have been taken to minimize risks and the ameliorative and curative steps taken in the event the research causes actual harm.

4. Describe how you keep the GRIC RRC informed of any unexpected adverse events from the research.

1. **Protection of Data and Information:**
	* + 1. Describe assurances of confidentiality for the life of the research project.
			2. Describe how confidentiality will be protected after the research is completed and for how long.
			3. Describe where raw data and other materials will be deposited and stored at the completion of the protocol.
			4. Describe circumstances in which confidentiality may be breached by legal or contractual obligations of the researcher.
2. Will you be transporting, in any method, information that can be considered sensitive or that will come under HIPAA regulations? Yes [ ] No [ ]

 If yes, indicate what will be transported and a containment and management plan.

6. Are you planning to share any information or do you anticipate sharing any information (solicited or unsolicited) with any other person, agencies, institutions, or academic groups other that those already identified? Yes [ ] No [ ]

 If yes, list and explain why you are proposing they have access, what they will do with the information, and how you will respond to requests to share information.

7. Will participant information be identified, accessed, or stored in any part of the study? Yes [ ] No [ ]

 If yes –explain how and indicate how this [storage] will be managed.

 If yes –provide proof of liability and coverage limitsas the Gila River Indian Community and its entities will not be responsible for any liabilities.

1. **Protection and Management of Biologic Samples:**
2. Will the research involve the taking of any biologic material in any form?

Yes [ ] No [ ]

If yes, explain the formal protocol indicating what will be sampled, how much, what it will be used for, length of storage, type of storage, any proposed or perceived rights over said samples, an education plan informing participants of their rights over contributed samples, rights of agreement(s) for future use, and destruction or discontinuance plans of samples.

1. Provide names and contact information for any person or entities that will have access to biological specimens during research.
2. **Consequences of Not Conducting this Research:**

If this study is not conducted, would there be consequences to the existing health of Community members, or an improvement in the existing health of Community members? Please be concise.

1. **Benefits and Benefactors:**
2. Who would most benefit from any findings arising from the study?

[ ] institutions; [ ] medical practice; [ ] the advancement of scientific knowledge; [ ] other research. Explain.

1. Who will benefit from the research outside of the Gila River Indian Community?
2. Will the Gila River Indian Community benefit directly from the study?

Do not propose possibilities – provide real time benefit that the Community can expect to apply to the problem as it relates to its members and study participants.

1. Will the Community be able to use study findings in a practical manner? Be specific.
2. How long will it take for the Gila River Indian Community to benefit directly in a practical manner from the study?
3. What is the projected impact of the study on the issue presented?
4. Describe the immediate and long range benefits represented in the research. Fully explained to them and provide opportunity to comment on the research.
5. Describe the opportunities for the Community, Districts and Community members to have the research explained to them and opportunities for comment on the research.
6. Describe how you will comply with Indian preference in employment in all phases of the study.

1. **Official Reviews / IRB:**
2. Has an IRB approved the proposed study? Yes [ ] No [ ]

If yes, documentation must be provided demonstrating IRB Clearance of the full proposal. If no, the research proposal submission will be withdrawn.

1. Does the proposing organization require other reviews and approvals of a study?

Yes [ ] No [ ]

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

1. Will the study be published? Yes [ ] No [ ]

Describe where and when.

1. Provide the name and contact for the IRB.
2. **Costs:**
3. What is the estimated cost to the researchers or organization to conduct this study?

Provide an estimated summary of what the Community is expected to contribute to any approved research.

1. **Proprietary Considerations:**
2. Are there any interests, whether to or from, any commercial groups, companies, investors, for profit organizations, non-profit organizations, or individuals in the proposed protocol? Yes [ ]  No[ ]

If yes, explain the interests.

1. Is the proposed protocol supported in any manner by commercial enterprises of any kind, investors, or any other body that potentially stands to gain in any fashion from the research? Yes [ ]  No [ ]

If yes, explain.

Do the researchers or organization stand to gain in any manner, now or in the future, monetary reward, gifts or any privilege(s) from any person, company, investor, or entity they are in association with? Yes [ ]  No [ ]

If yes, explain.

1. Are there any interests or future interests 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 this protocol? Yes [ ]  No [ ]

If yes, list and explain.

1. Have you been approached by any individual(s), groups, organizations, programs of the Community, governing bodies of the Community, and/or concern groups of the Community prior to the submission of this application? Yes [ ]  No [ ]

If yes, identify.