



PROTOCOLS INVOLVING BIOLOGICAL SAMPLING AND PROPRIETARY AGREEMENTS

A. If a protocol involves biological sampling, which includes samples of research participant's blood, tissue, urine or other sample from the body, the following terms will be included in a Memorandum of Agreement that must be executed prior to beginning of any research:

1. Biological samples provided and taken under an approved protocol are neither donations nor gifts to the PI or sponsoring organization. All biological samples are provided under bailment (transfer of possession and not ownership), with the expectation that the samples be returned to the participant, his/her heir, or if none are living then to the Community as soon as the purpose for the bailment ceases or upon death of the participant.

- a. At the time the participant gives informed consent, the participant must indicate whether he/she wants the biological samples returned or destroyed.
- b. If biological samples are returned they will be returned to the participant or his/or her heir, or if none are living then to the Community.
- c. The participant may also elect to have his/her biological samples destroyed or returned upon death of the participant.

2. The biological samples will be used for only the approved research project and will not be used beyond the scope of the approved research in any manner outside of the agreed upon use of the samples. Any new or different use is considered outside the scope of authorized approval and requires a new request, new proposal, new approval and new authorization.

3. The sample type, amount, and specific proposed use of biologic samples shall be identified in all medical and health related research proposals submitted for approval.

4. The PI agrees to provide a detailed description of the method in which samples will be safeguarded to the GRIC RRC, the length of time proposed to maintain the samples, the exact location (name, address of facility) where they will be housed,

name, title, and address of facility, if biological samples will be housed in a separate location other than the home office of the PI.

5. The PI and/or sponsoring organization agrees to develop a written plan, and provide a copy to the GRIC RRC, for the privacy and protection of confidentiality for biological samples taken from GRIC members, to ensure 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. All samples will be stored anonymously with no personal identifiers, including geographic areas or tribal affiliation.

6. 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.

7. Biological samples may not be transferred from one location to another, and may not be transferred from the authority of one colleague to another within the hierarchy of the research project or organization. Additionally, the samples shall not be shared or accessible to any other researcher other than the PI listed on the proposal for purpose(s) of the approved protocol.

8. If the protocol includes storage or use of a database to maintain collected GRIC member biological samples, the GRIC RRC may request a separate report be prepared and presented to the GRIC RRC at any time regarding the status of the storage facilities and/or the progress on the use or intent of the biologic sampling data.

9. If the protocol includes storage or use of a database to maintain collected GRIC member biological samples, the GRIC RRC Chairman may designate a representative or representatives to visit the location of the biological sample storage facility and/or database location at any time, and be afforded all access to storage and database files, which shall include but not limited to: security and accessibility procedures taken to secure the storage facility and/or database, and any other procedure, process, filing or tracking system which pertains to GRIC member's biological samples. The PI agrees to accommodate such a request and all travel costs shall be incurred by the PI or the PI's sponsoring organization. All travel details, records or notes of the GRIC RRC designees, and all documentation/records of the GRIC member biological database will be maintained as part of and in accordance with the GRIC RRC research records.

10. There will be no unauthorized secondary uses which include but are not limited to: stored biological materials that include identifiers, testing, growing or storing of any genetic material not explicitly mentioned in the original proposal; contacting tribal members in the future following their permit deadlines; trying to obtain tribal member medical information; using genetic material from the placenta or umbilical cord; obtaining genetic material through surgery or biopsy for the benefit of an

unauthorized researcher's agenda; sharing or selling genetic material to a laboratory not explicitly stated in the original proposal, even if the researcher is doing the same research at a different laboratory.

11. Cell lines may not be created to immortalize the samples for additional studies.

B. Upon completion of the research project, termination or cancellation of the protocol, the PI shall immediately destroy or return the samples as indicated on the Informed Consent executed by the participant. If the research protocol is terminated or cancelled by the RRC, the PI will be notified in writing of the decision and the PI and/or sponsoring organization will have sixty (60) days to comply with the GRIC RRC directive.

1. For biological samples that have been designated to be destroyed, a representative or representatives designated by the Chairman of the GRIC RRC from the Gila River Indian Community must be present and sign/witness any chain of custody, destruction of biological samples or any other document; all personnel and travel costs will be incurred by the PI.

2. For biological samples that have been designated to be returned to the participant, the PI will coordinate the return with the GRIC RRC. The PI will be fully accountable for the return of each sample. The costs incurred for return of the biological samples shall be incurred by the PI or the sponsoring organization, which may include but not be limited to: packing, shipping, transportation, preservation methods, and compliance with any state or federal regulations on transportation of biological samples.

3. Discrepancies or non-compliance with the GRIC RRC's decision may be a breach of good faith or breach of contract and the PI, sponsoring organization or agency may be held liable to compensate the Gila River Indian Community for loss and mishandling of Community property.

4. A final report will be made to the GRIC RRC regarding the end of the study; which shall include the amount of samples and the resulting outcome of the samples, whether, and when, destroyed or returned to the participant or the Community.

C. Proprietary Agreements

1. Intellectual property includes any intangible properties protectable as to ownership under the laws of patent, copyright, trademark, or trade secret, and rights in tangible research materials.

1. The Community asserts its right to take title to any patentable inventions or discoveries and tangible research materials arising from the undertaking of Community approved research; of which the Community may grant reservation of partial rights to the PI or the University where the research was originally granted.

a. The PI will take all necessary steps, within any required timeframes, under the Bayh-Dole Act and 37 CFR § 401.14(g) to exercise and protect the Community's title.

2. Any royalties or income from any materials that lead to patent, copyright or trademark, or saleable products as a result of the research approved by the Community may be shared in a fair and equitable percentage between the Community and the PI, as agreed to in Memorandum of Agreement between the Community and PI.