**Policy**
Research involving material that can be linked, directly or indirectly by a code, to personal information concerning the source of the material constitutes research that is subject to federal regulations and IRB approval. Research using unlinked samples also requires IRB review, as the IRB needs to ensure that the process by which the material is rendered unidentifiable is appropriate and secure. Research using human genetic material or genetic testing poses special concerns and always requires IRB review. For VA investigators there may be additional tissue banking review and documentation requirements; the HRPP will coordinate reviews of proposals involving tissue banking by VA investigators with the VA R&D office.

**IRB Review Procedures**
The IRB will consider the application by means of an expedited or full-IRB review process providing that the project meets the criteria for such review. In order to facilitate review of the project, the investigator will set forth the following in the Application for IRB Review:

1. A thorough justification of the research design, including a description of procedures used to minimize risk to subjects,
2. A full description of the process by which samples will be obtained,
3. Any plans to obtain access to medical records of the subjects, and
4. A full description of the mechanisms that will be used to maximize the protection against inadvertent release of confidential information.

The investigator should address the relevant aspects of these issues in an appropriate manner in the consent document.

The principal risk of such research is primarily psychosocial in nature, resulting from the inappropriate release of information to the subject and third parties. The IRB will consider the research to be of minimal risk if:

1. The study adequately protects the confidentiality of personally identifiable information, and isolates research results from the subject's general medical records
2. The study does not involve the inappropriate release of information to third parties, including other researchers and institutions, and
3. If appropriate, the study design incorporates a plan for whether, when and how to reveal findings to the sources or their physicians, with disclosure to the subject permitted only when all the following apply:
   a. The findings are scientifically valid and confirmed
   b. The findings have significant implications for the subject's health concerns, and
   c. A course of action to ameliorate or treat these concerns is actually available.
Expedited review may be permitted if it is determined that the investigator has adequately addressed these issues.

Informed Consent Requirements
Informed consent from the subject is generally required for research involving human biological material. In the case of research involving existent identified or coded samples, it may not be feasible to obtain such consent. If in the original consent document subjects anticipated and agreed to further participation in this way, then additional consent is unnecessary. However, documents may not exist or, when they exist, they are do not address the possibility of such research. In such cases, unlinking, or new consent may be necessary to conduct the research, unless a waiver of informed consent is possible.

The IRB may waive the requirement for informed consent if the requirements appropriate. The determination of minimal risk must be made, as described above. In determining whether a waiver of consent would adversely affect the rights and welfare of subjects, the IRB will consider whether:

1. The waiver would violate any state or federal statute or customary practice regarding an entitlement to privacy or confidentiality;
2. The study will examine traits commonly considered to have political, cultural, or economic significance to the study subjects; and
3. The study's results might adversely affect the welfare of the subject's community (if applicable).

If the study poses more than minimal risk and consent cannot practicably be obtained, the removal of identifiers may be required.

In general, a separate informed consent form should be used. In addition to the required and optional elements of informed consent, the informed consent form should contain the following additional elements, if applicable.

1. If research results of the reuse of the specimen will this be conveyed to the subject.
2. If the subject will be re-contacted after the original study is completed.
3. If the subject requests, the specimen and all links to the clinical data will be destroyed.
4. That refusal to participate does not affect the subject’s ability to participate in any associated therapeutic research.
5. If the proposed research study involves the potential for psychosocial harm to the subject's family members, relatives or members of the subject's ethnic group;
6. If the research has a reasonable likelihood of leading to the development of a commercial product, subjects should be informed that they might not benefit from the product.
7. If the investigator has any commercial interest from which he/she may benefit financially, directly or indirectly.
8. If the specimen will be used for future research and allow the subject the choice of how the specimen will be used. The consent should provide subjects with a sufficient number of options to help them and fully clarify the present and future uses of their samples. Options might include:
a. Refusal to use their samples in any research,
b. Permitting use of their samples only in unidentified or unlinked form,
c. Permitting coded or identified use of their samples for the present study only, with further contact required to do further studies,
d. Permitting coded or identified use of their samples for any study relating to the condition for which the sample was originally collected, with further contact allowed to seek permission for other types of studies,
e. Permitting coded use of their samples for any future study.

Storage and Reuse of Specimens

Human biological material is not considered to be "banked" (stored) if the specimens are used for only the specific purposes defined in the protocol and are destroyed either when the specific use is completed or at the end of the protocol. Specimens collected and stored for future research purposes are considered "banked" specimens. Reuse of specimens must be consistent with the consent under which they were collected, and the reuse must only occur through an IRB-approved protocol.

If the specimens are sent to an institution outside of UCSD for testing or use as defined in an IRB-approved protocol, a written understanding between the UCSD or VASDHS investigator and the outside institution must specify the use of the specimens as defined in the protocol and that the specimens will be destroyed or returned to the Principal Investigator once the analysis is completed. A copy of this written understanding must be on file before work may commence. This may occur through a Material Transfer Agreement (MTA) of UCSD or VASDHS.

Once the specific analyses are performed the remainder of the specimens must be destroyed or returned to the Principal Investigator for destruction. The remaining quantity may not be retained or stored by the outside institution. If the specimens are destroyed at another institution, that institution must certify in writing to the Principal Investigator the destruction of the specimen.

The investigator storing the banked specimens must retain a copy of the original consent, a record of the use of the specimens, and the protocols under which they were used.

The minimal amount of person-identifiable data necessary should be shared with outside institutions, and use of “de-identified” (in HIPAA parlance) data is preferred in all cases if it meets the scientific objectives of the study. In some cases the IRB may require that a Certificate of Confidentiality be obtained.

If specimens are to be received by UCSD or VASDHS for testing or use, the UCSD or VA investigator must obtain IRB approval before the work may begin. In addition, the Principal Investigator must provide a written letter of assurance indicating that samples were collected with appropriate institutional approvals and certifying that confidentiality will be maintained. The outside investigator will provide documentation of IRB approval or documentation of a determination of exemption. Consent forms, or protocols from the outside investigator may also be required. A copy of these documents will be placed in the study file.
Procedures

1. Investigator provides necessary information and documentation
2. IRB member will review the information provided and informed consent form according to criteria outlined in Section 703, ensure that informed consent documents and methods are in compliance with regulations, make assessments as to risks, benefits, and adequacy of subject protections and make recommendations as to the appropriate IRB action.

Applicable Regulations

45 CFR 46.110
OHRP Guidance on Research Involving Coded Private Information or Biological Specimens
VA Directive 2000-043; Banking of Human Research Subjects' Specimens
Clarification Memo Regarding VA Directive 2000-43