University of California, San Diego
Human Research Protections Program
Institutional Review Board
Standard Operating Policies and Procedures

Section 3.16
Registry/Repository/Banking Use of Data/Specimens

Policy

Registries/Repositories involve the collection of data/specimens. A registry is typically considered a collection of data. A repository is typically considered a collection of specimens. Data/Specimens collected and stored for future research purposes are considered "banked." Data/Specimens are not considered to be "banked" (stored) if the data/specimens are used for only the purposes defined in the protocol and are destroyed either when that use is completed or at the end of the protocol.

Research involving the collection of these materials 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 typically requires convened IRB review.

IRB Review Procedures

The IRB will consider the application by means of a convened IRB or an expedited 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. The purpose of the registry/repository/banking use of the data/specimens.
2. The data/specimens that will be collected.
3. Procedures for the collection of the data/specimens including from whom the data/specimens will be collected, whether the data/specimens will be collected during research or clinical procedure(s) or both, etc.
4. The risks associated with registry/repository/banking including risk of re-identification.
5. The specific methods for protection privacy and confidentiality of data/specimens collected as well procedures to minimize any other risks associated with registry/repository/banking including re-identification.
6. The procedures associated with obtaining informed consent/permission/assent. If appropriate, these procedures should include the re-consenting a child when the child becomes an adult and/or for each use of data/specimens. If a waiver of consent/assent is requested, justification for the granting of such a waiver must be provided.
7. The procedures for contacting participants in the future, if appropriate.
8. The procedures for withdrawing data/specimens by participants. If data/specimens cannot be withdrawn, justification must be provided.

9. Whether results from research done in association with the data/specimens will be disclosed. If so, the procedures for providing the information must be described including to whom and when the findings will be disclosed, scientific validity and need for confirmation, risks and risk management procedure to minimize those risks such as referral to geneticist and/or other specialist. If not, justification for not providing results must be provided.
10. The conditions/procedures for release of data/specimens to "other" investigators provided, if appropriate. Note: if this is a NIH-funded research for which the NIH Genomic Sharing (GDS) Policy applies, see below.
11. Whether an advisory committee for the distribution of data/specimens is associated with the study. Is so, a description of the committee and their procedures must be provided.

National Institutes of Health (NIH) Genomic Data Sharing (GDS) Policy

As noted by NIH guidelines, "The GDS Policy applies to all NIH-funded research that generates large-scale human or non-human genomic data as well as the use of these data for subsequent research. Large-scale data include genome-wide association studies (GWAS), single nucleotide polymorphisms (SNP) arrays, and genome sequence, transcriptomic, metagenomic, epigenomic, and gene expression data, irrespective of funding level and funding mechanism (e.g., grant, contract, cooperative agreement, or intramural support)."

If a study is subject to the GDS Policy, the Research Plan must include a specific genomic data sharing plan. This plan must clearly indicate how the GDS Policy expectations will be satisfied as well as "denote the type(s) of data to be submitted, which data repository(s) data will be submitted to, the appropriate uses of the data (i.e. data use limitations), and the data sharing timeline."

Further, in regards to risks of participant identification, the guidelines include, "The GDS Policy stipulates that human data submitted to NIH-designated data repositories, such as dbGaP, are to be coded and de-identified by the submitting investigator, and the key to the code that links the data to specific individuals held by the institution. In order to minimize the risk that research participant identities could be readily ascertained, data should be de-identified by standards consistent with both HIPAA and the Common Rule." The Investigator must ensure the Research Plan addresses these issues, as appropriate.

Guidelines also note "An Institutional Certification stipulating the appropriate uses of data submitted should be provided by the Authorized Institutional Official(s) of the submitting institution prior to award of funding (or the start of research for NIH intramural investigators) when genomic data generation is proposed. The purpose is to assure that submission of data to an NIH-designated data repository is consistent with the GDS Policy and with the informed consent of the original study participants." It is the Investigator's responsibility to ensure the submission provides sufficient information to allow for the verification of information included on the Certification. Fillable Institutional Certification Forms are available on the GDS website at https://gds.nih.gov/Institutional_Certifications.html.

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 data/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 wishes to withdraw consent for the use of the data/specimen, this may be done at any time without penalty or loss of benefits to which the participant is otherwise entitled, and in this event, the data/specimen will be withdrawn, if possible, but the data/specimen already distributed for research use will not be retrieved.
4. That refusal to participate does not affect the subject’s ability to participate in any associated 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 by including a “Moore clause.”
7. If the investigator has any commercial interest from which he/she may benefit financially, directly or indirectly.
8. If the data/specimen will be used for future research and to allow the subject the choice of how the data/specimen will be used. Federal guidelines include the

following: “When considering the use of a tiered or specific consent approaches, investigators should balance responsibility of protecting participants’ interests with the potential loss of opportunities for public benefit due to limitations on future research uses.” The consent should clarify the present and future uses of the participant’s data/specimens. The consent may provide subjects with broad wording of the future use of the data/specimens or wording with sufficient number of options. Options might include the following:

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.

9. Information regarding the California Genetic Information Nondiscrimination Act (CalGINA).
10. The possibility of “re-identification” of “de-identified” data that could potentially be used to discriminate against or stigmatize participants, their families, or groups. In addition, there may be unknown risks.
11. There will be no direct benefit to the participant from secondary research that may be conducted.

The National Human Genome Research Institute provides an excellent resource for wording that may be used in the consent to address these various elements including wording for “broad versus a specific consent…considerations for families…considerations for identifiable populations…studies involving children…studies involving participants who cannot give consent…data and sample sharing through data repositories and biobanks…return of results and incidental findings to participants.” This resource can be found at https://www.genome.gov/27559024/informed-consent-special-considerations-for-genome-research/.

Reuse and Storage of Data/Specimens

Reuse of data/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 data/specimens are sent to an entity outside of UCSD for testing or use as defined in an IRB-approved protocol, an appropriate agreement must be in place between the outside entity and UCSD. The agreement may include specific use of the specimen as defined in the protocol and/or destruction of specimens or return of specimens to UCSD, as appropriate. This may occur through a Material Transfer Agreement (MTA) of UCSD.

The minimal amount of person-identifiable data necessary should be shared with outside entities, 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 for testing or use, the UCSD 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.

Applicable Regulations

45 CFR 46.110
OHRP Guidance on Research Involving Coded Private Information or Biological Specimens
National Institutes of Health Genomic Data Sharing
The National Human Genome Research Institute