

CREATING A REGISTRY-REPOSITORY

This document outlines issues that should be addressed in the protocol and eIRB application for a Registry-Repository.

Definitions

Registry: A registry or data bank is a collection of information elements maintained in a database.

Repository: A repository or tissue bank is a collection of biological specimens (biospecimens). When the repository contains phenotype data that can be linked to the biospecimens, the repository is both a registry and a biospecimen repository (Registry-Repository).

Background and Purpose of Research.

The protocol should include sufficient background information to explain the purpose of the Registry-Repository. Usually, the purpose involves the intent to provide a resource for future research.

Research Procedures

Each of the items below should be considered and addressed in the protocol and IRB application. The application should include information about the other sites. If the study is multicenter and the CHOP PI is responsible for the Registry-Repository, then the eIRB application and protocol should include this information and Form DCC completed to describe the process for provision of study oversight by the CHOP PI.

If tissue will be transferred to another institution then a Materials Transfer Agreement, executed by the Office of Technology Transfer will be needed.

If repositories will include protected health information, the obtaining and maintaining of the information must comply with relevant HIPAA provisions. Relevant issues should be addressed in the application. The IRB website has several pages on the impact of the HIPAA Privacy rule on research Registry-Repositories.

Biospecimen Repository

- Describe all subjects who will provided data-biospecimens. If there is more than one group (normals, parents, index cases, etc.) separate inclusion/exclusion criteria should be included for each group.
- If the Repository will maintain a link between subjects individually identifiable data and the biospecimens, provide a justification. If the link will be maintained by the provider, include the criteria, if any whereby the subjects' identifiers could be shared with the Repository. This information should be included in the consent form.
- Include a discussion regarding whether or not subjects will have their medical data updated over time or if they will be approached to provide additional specimens.

Describe the process by which the Repository will link new data/biospecimens to the coded data/biospecimens maintained in the Repository. This information should be included in the consent form.

- Explain whether or not information will be obtained from medical records. If there is an intent to update subjects data in the future, subjects should be permitted to Opt-Out. This information should be included in the consent form.
- State whether or not your lab is clinically certified under CLIA (Clinical Laboratory Improvement Act) or other licensing authority. If the labs are not CLIA certified, then under CHOP IRB policies, the results may not be returned to providers of the specimens or to subjects.
- If subjects may be contacted for participation in future research, this should be included and subjects must be permitted to Opt-Out.
- When explaining the genetics component of your research, please address the following concerns:
 - Ability to detect clinically significant information. For example, markers of disease susceptibility, evidence of previously undiagnosed or unrecognized illnesses, or susceptibility to illness. If clinically significant results will be returned to subjects, the consent form should inform subjects that they have a right to be informed (or not) about the results. An Opt-In – Opt-Out section of the consent form should be included. A plan for genetic counseling for interpretation of the genetic results should be included in the protocol and the consent. Results must be performed in a CLIA certified lab in order to return results to subjects.
 - Protections in place to prevent employers or insurers to gain access to research data. The protections should be consistent with GINA (Genetics Information Nondiscrimination Act).
 - Commercial developments. If there is the possible intent to commercialize any information or that could involve donated biospecimens, the proposed rights of investigators and donors should be addressed. The consent should clearly state whether or not donors will have any ownership rights.
- Use of stored samples for future research. The protocol should outline the process by which data/biospecimens will be shared with investigators. Describe the process that will be used to determine which investigators may use banked tissue or have access to database information.
- Process to ensure appropriate IRB oversight or HIPAA Authorization. The policies governing provision of data to investigators should be clearly outlined.
 - If individually identifiable data will be provided to investigators a new IRB-approved protocol will be required prior to providing the data/biospecimens.
 - If coded data/biospecimens constituting a limited dataset will be provided, then the Repository must enter into a data use agreement with the recipient (even if they are at CHOP). In addition, the agreement should clarify that

the Repository will not provide individually identifiable materials to the recipient.

- If deidentified data/biospecimens will be provided, then this secondary use will not require any IRB approval or oversight.
- Plans for protecting the confidentiality of data/biospecimens. Explain the procedures and protections in place for keeping study data confidential.

Registry

- Data to be maintained in the Registry. The protocol should list the data variables that will be in the database, including individually identifiable data. When available, a copy of the screen print out of the database, listing all variables can be attached to the protocol or as to eIRB instead of listing all variables in the protocol.
- Maintenance of Identifiable Data. The protocol should cover how individually identifiable data will be maintained separately from the main database. If any identifiable data must be maintained (e.g., date of birth, dates of service, etc.) with the dataset, provide a justification. This information should be included in the consent form.
- Describe the process for coding data and where the coding will be executed (e.g., at the site, by an honest broker, by the Registry personnel). This information should be included in the consent form.
- Codes linking subjects to data. The protocol should cover who, if anyone, will retain the key to code linking subjects to identifiers. For example, this could be the provider of the data or the Registry.
- If the Registry will maintain for any information that can directly or indirectly (via the key to the code) identify the subjects, a justification must be included. This information should be included in the consent form.
- The protocol should describe the intended duration for maintaining a link between individually identifiable data and the research dataset and the process for destroying the link.
- When participants turn 18 years of age, the process for reconsenting or destroying the link between individually identifiable data and the research database should be described.
- Database operations. Explain who will have access to the database and who will determine who may receive a copy of the dataset for research (e.g., oversight committee).
- Plans for protecting the confidentiality of Registry data. Explain the procedures and protections in place for keeping study data confidential.