



**GUIDELINE FOR RESERACH INVOLVING REPOSITORIES
(Databases, Repositories, and Registries)**

This guideline establishes the requirements for RSRB review and approval of research involving data and/or specimen repositories for research purposes, such as the collection, submission, storage, and management of data/specimens, the use of stored data/specimens (e.g., to conduct primary or secondary analyses), and storage and use of information used to contact potential subjects for recruitment purposes (“future contact”). Typically, databases that are mixed use (both clinical and research) do not require RSRB review. The RSRB should be consulted as necessary for further guidance on RSRB review requirements.

Note: For regulatory purposes, registries, data banks and tissue banks are all considered “repositories”; therefore, any reference within this guidance to ‘repositories’ applies equally to data banks, tissue banks, and registries.

1. Definitions

Database – A collection of information elements (i.e., data) arranged for ease and speed of search and retrieval. Databases may be maintained electronically or may be paper record systems. Examples of databases include:

- a. A set of observations (i.e., data) from a research study
- b. An electronic file of a medical provider’s patients
- c. A collection of diagnosis, treatment, and follow-up information from a subsection of a hospital’s patients
- d. A file of outcomes information compiled for quality assurance activities
- e. A list of potential research subjects (e.g., future contact database)

Registry (Data Bank) – A collection of information elements or a database whose organizers:

- a. Receive information from multiple sources
- b. Maintain the information over time
- c. Control access to and use of the information by multiple individuals and/or for multiple purposes, which may evolve over time

Registries are often coded, which allows identifiers to be removed from the main registry database. The identifier with the link to the data is maintained separately from the registry to protect the donor’s identity. Examples of well-known registries and data banks include:

- a. Centers for Disease Control & Prevention (CDC) State Cancer Registries
- b. National Registry of Myocardial Infarction (NRFMI)
- c. The National Practitioner Data Bank
- d. The US 2010 Census Data Bank

Repository (Tissue Bank) – A collection of biological specimens (human tissue material) stored for subsequent use for research purposes. Repositories usually include demographic and/or medical information about the individuals from whom the specimens were obtained. The information is coded, which allows identifiers to be removed from the main repository database. The identifiers, with the link to the dataset, are maintained separately from the registry to protect the donor’s identity.

Examples of well-known repositories include:

- a. The National Human Radiobiology Tissue Repository
- b. The National Institute on Aging (NIA) Cell Repository
- c. The National Marrow Donor Program (NMDP) Research and Outcomes Repositories

Collection Investigator – A researcher with primary responsibility for the collection (or submission) of data/specimens to a repository. The collection Investigator is responsible for maintaining an original, signed consent form and authorization from a subject, which corresponds to the data/specimens contained in the repository, unless a waiver of consent and HIPAA authorization is granted by the RSRB.

Repository Investigator – A researcher with primary responsibility for the storage, management, and distribution of data/specimens stored in a repository. [Note – An individual may be both the Collection Investigator and the Repository Investigator.]

Recipient Investigator – A researcher who wishes to use data/specimens stored in a repository for research purposes. Routinely, a recipient Investigator does not have access to identifiable information of donors or to information that readily links the data to identifiable information about the donor.

- To determine whether the activity involves human subject research and what level of review may be required by the RSRB, refer to the [Guideline for Determining Human Subject Research](#) and [Policy 501 Levels of RSRB Review](#).

2. Types of Repository Protocols

There two types of protocols related to repositories: a) collection/storage protocols, and b) protocols to use the stored data/specimens (“Use protocol”).

a. Collection/Storage Protocol

Protocol

The protocol must describe the collection of data/specimens for the repository, how the data/specimens will be identified, and how the data/specimens may be accessed, used, and shared. Protocols to establish and operate a repository should describe how the repository is in compliance with federal regulations (when applicable), UR policies, and at minimum, should include the information contained in the [Repository Protocol Template](#). Based on the nature of the information stored in the repository, a Certificate of Confidentiality may be required to protect the identifiable information collected through the repository from forced disclosure (consult with RSRB as needed).

For repositories maintained outside of the University of Rochester, the use and disclosure of the data/specimens to be submitted to the repository must comply with any conditions stipulated by the collecting institution’s IRB. The Collection Investigator should include information about the repository where the data/specimens will be stored. This may be described directly within the protocol, or it may be a supplemental document provided by the repository describing how data/specimens will be identified, and how the data/specimens may be accessed, used, and shared.

Consent

Unless the RSRB has granted a waiver to obtain consent and HIPAA authorization, a key responsibility of the Collection Investigator is to ensure that informed consent is obtained and documented from each donor-subject in accordance with federal regulations at 45 CFR 46.116, 21 CFR 50 Sub-Part B, 45 CFR 164, and the RSRB approved protocol. All of the usual elements of consent and HIPAA authorization apply and the consent/authorization process should clearly

inform subjects about all aspects of the repository as described in the protocol. **Please note that the subject is giving consent to store the collected data/specimens, not to use the data/specimens for future research. It is important to describe any possible future uses, if known, but these future uses require additional IRB review and approval.**

b. “Use” Protocol

Research projects involving the use of data/specimens from a repository (i.e., database, repository or registry) are consistent with any other research review required by the RSRB. They must be submitted to the RSRB to make a determination of requirements for RSRB oversight (i.e., [determining human subject research](#)) and, as applicable, to approve the initiation and continuance of such research activities. Use the [Specimen and Record Review](#) protocol template as guidance for writing a protocol for the use of specimens or data from an already established repository.

3. Privacy Policies for the Research Use of Databases/Repositories/Registries

Investigators conducting research using databases, registries or repositories must ensure that University and RSRB policies and procedures for the HIPAA privacy rule of protected health information (PHI) are adhered to, as applicable, when submitting applications for RSRB review. In addition, recipient Investigators seeking access from the repository to specimens/data that is de-identified coded, or a limited data set may be required to sign a usage or data use agreement with the University. See URM and Affiliates HIPAA Privacy [Policy 0P25 Procedure](#) for more information regarding these policies and procedures.

For additional information regarding sending/receiving data or specimens outside of the UR, refer also to the RSRB procedures for [Sending & Receiving Data/Specimens to/from Outside Institutions](#).

4. Repositories Used for Future Contact

Subject contact information may be collected into a single database (repository) and used to contact subjects to participate in a research study (“Future Contact Database”). The repository may include subjects who previously participated or are currently participating in research studies, as well as individuals who have not yet participated in research but would like to in the future. Refer to the [Future Contact Consent Template](#) or the [Future Contact Oral Script Template](#) on the RSRB Consent Form Templates website.

The circumstances for how the repository will be used will determine whether the “future contact” database requires a separate RSRB application. In most cases, a separate RSRB application is required. However, a separate RSRB application is not required if the subject’s contact information will only be used to contact the subject within the context of that study. For example, a follow-up study or sub-study within the same RSRB application.

Procedures for Future Contact Repositories Requiring Separate RSRB Application

- i. The protocol will include a description of the process by which subjects will be notified of the future contact repository and how consent for inclusion in the database will be obtained. Consent may be obtained with a separate consent form approved under the RSRB application for the future contact database, or may be included with a description and optional check box for the subject to opt in to future contact on an actively enrolling study.
Note: The repository application does not need to maintain a list of active studies through which subjects will be recruited; rather, only the main active study needs to indicate recruitment into the repository (i.e., an amendment may be necessary).

- ii. The RSRB will review the application, protocol and consent documents ensuring that all of the elements itemized above have been addressed.
- iii. The Investigator (or as delegated) will maintain the repository in the manner approved by the RSRB and ensure protocol amendments and personnel changes are submitted as appropriate, as well as progress reports per RSRB continuing review requirements.
- iv. Actively enrolling research studies that will provide subject's the opportunity to be included in a separate future contact database will need to reference that future contact RSRB case number in the RSRB protocol (i.e., amendment may be necessary if not a new submission).

Procedures for Repositories Not Requiring Separate RSRB Application

- i. The Investigator ensures that the study consent document includes a description that the future contact is related to the activities of the research study in which the subject may agree to participate, as well as any applicable checkbox options in the document's signature blocks.
- ii. The RSRB will review the study application, protocol and consent documents provided by the Investigator ensuring that all of the elements itemized above have been addressed.

5. Utilizing an Established Future Contact Repository for Recruitment

Already established RSRB approved repositories may provide a resource for researchers to recruit for additional research studies. As such, if an Investigator proposes to use a currently established future contact repository (e.g., database) for purposes of recruitment into a new study, the following procedures should be followed:

- i. The Investigator will ensure that the nature of the study that will utilize the repository falls within the scope/purpose of the currently established repository (e.g., if subjects provided consent to be contacted about studies on autism, subjects in the database should not be contacted about studies unrelated to autism – this also pertains to the protection of subject privacy within the context of the research protocol).
- ii. The Investigator will ensure the individual accessing the repository is listed on the RSRB application by confirming that either:
 - a) The Investigator requesting to use the repository has routine access to it (i.e., is listed as study personnel on the RSRB application); OR
 - b) Someone with routine access to the repository will make the initial contact with potential subjects regarding the study (e.g., a sub-investigator listed on the RSRB approved database application mails an information letter to potential subjects providing a written description of the study and the study team's contact information, and those interested in participating in the new study may then contact the study team directly.)
- iii. The Investigator (or as delegated) should reference the RSRB approved repository's case number and provide a description of how the database will be utilized in the protocol and when completing the RSRB application.
- iv. The RSRB will review the referenced active study's application, protocol and consent documents to verify the following:
 - a) The repository referenced in the protocol has been RSRB approved and the repository is open (i.e., not closed).
 - b) The individual(s) making the initial contact with potential subjects has routine access to the repository and is listed on the RSRB application.

Referenced Templates:

[Repository Protocol Template](#)

[Specimen and Record Review Protocol Template](#)

[Future Contact Consent Template](#)

[Future Contact Oral Script Template](#)