



EARLY SPRING 2010

Establishing Research Repositories and Databases

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The creation of repositories and databases allow for access to and the use of biological specimens and data by multiple researchers and/or for multiple research projects (including projects not yet identified). When subjects provide biospecimens or private identifiable data, concerns arise regarding privacy and confidentiality. A database or repository protocol must include specific details about controlling the collection, storage, use and sharing of the information and biospecimens.

Biospecimen repositories and databases established for research purposes via the following activities constitute HUMAN SUBJECTS RESEARCH and requires prior IRB review and approval.

- ◆ **Creating a repository/database through intervention/interaction with individuals**
- ◆ **Creating a repository/database by obtaining identifiable private biospecimens or information about individuals**

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[What should researchers consider when establishing a repository or database?](#)

WHAT DOES THE BANK* LOOK LIKE?

- ◆ **What is being banked– data or biospecimens?**
- ◆ **What is the purpose of the research bank? What populations are represented?**
- ◆ **How is the bank organized? Are single or multiple sites involved?**
- ◆ **Could the bank be used for future research projects not currently known?**



IRB Staff Contact Information

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HOW WILL DATA/BIOSPECIMENS BE MANAGED?

- ◆ **What is the source of the data or biospecimens? Prospective collection, discarded biospecimens, and/or from other research projects?**
 - ◆ *Also see “CONSENT ISSUES” on Page 2*
- ◆ **How will the data/biospecimens be labeled? Direct identifiers or indirect identifiers—linked by a code to subjects?**
- ◆ **If the data/biospecimens will be de-identified, how will this process be done?**
- ◆ **When will the de-identification process take place?**
- ◆ **Who will de-identify the data/biospecimens?**

**In this article, the word “bank” refers to a variety of methods of collection of human biospecimens (including data). A bank is a place that receives, stores and distributes material.*



HOW WILL THE BANK BE ACCESSED?

- ◆ Who will have access to the subjects identities?
- ◆ If the bank will be used for future research purposes, what processes are in place for reviewing the appropriateness of the requests to use the bank?
- ◆ How will the bank prioritize requests for use?
- ◆ Will additional data be provided to researchers with the biospecimens? If yes, what type of data? Does it include protected health information?



CONSENT ISSUES:

- ◆ Will informed consent be obtained or can a waiver of consent be justified [[45 CFR 46.116d](#)]?
- ◆ If access and disclosing PHI, will HIPAA authorization be obtained or can a waiver of HIPAA be justified?
- ◆ Who will obtain consent from subjects? Will recruitment materials be used?
- ◆ An explanation of the informed consent process must include: what will be collected, maintained (with what identifiers) and for how long.
- ◆ Will the bank be shared with other researchers for future research projects? If yes, to ensure that future research is allowable— when describing the purpose of the bank provide broad aims so as not to limit the use of the data/biospecimens. For example, “Data will be shared with other researchers studying cancer. No private identifiable information about you will be provided to other researchers.”
- ◆ Will subjects be given the opportunity to withdraw their data/biospecimens from the bank?
- ◆ What about risks? Is the possibility of a breach of confidentiality appropriately explained? Are the other risks/discomforts adequately addressed in the consent form?

HOW WILL THE BANK BE SECURED?

- ◆ Data must be secure to ensure the subjects’ privacy.
- ◆ Consider obtaining a NIH Certificate of Confidentiality for maintenance & sharing of sensitive data.
- ◆ Is there an agreement in place with recipient researcher before data / biospecimens from the bank are transferred? Does the agreement explain how the data/biospecimens can be used?
 - ◆ Note: Recipient researcher may need IRB approval from their own institution if private identifiable information is provided by the bank.

APPENDICES?

- ◆ Don’t forgot to complete the applicable appendices as part of the IRB submission!

MORE INFORMATION ABOUT RESEARCH REPOSITORIES AND DATABASES:

- ◆ [Office for Human Research Protections Guidance on Repositories](#)
- ◆ [National Cancer Institute Best Practices for Biospecimen Resources](#)
- ◆ [Report of the Public Responsibility in Medicine and Research \(PRIM&R\) Human Tissue / Specimen Banking Working Group– Part I Assessment and Recommendations \(March 2007\)](#)

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**TIPS FOR CONTINUING REVIEW
 SUBMISSIONS**

To ensure that the IRB is conducting a substantive and meaningful continuing review of the research, be sure to address the following issues in the continuing protocol application:

- ◆ Provide a thorough summary of the research activities since last IRB review (i.e., initial review or last continuing review). Include a detailed description of the progress of the study. Also provide a brief summary of any interim findings or trends, and plans for the next approval period.
- ◆ The current risk/benefit assessment must be sufficiently detailed to assist the IRB in determining whether continuation of IRB approval is appropriate. Be sure to provide a summary of any direct benefits experienced by subjects. Also consider whether there has been a change in the risk/benefit profile taking into account the information gathered during the past approval period such as DSMB reports, interim results, reportable events/problems and/or changes in scientific knowledge.
- ◆ Make sure that the enrollment numbers are consistent with what was reported in prior years.
- ◆ For biomedical research where informed consent process often takes place prior to the screening procedures, remember to include "screen failures" in your enrollment numbers. **From the IRB's perspective, any person who signs a consent form is "enrolled" in the study.**
- ◆ Review any unanticipated problems and adverse events that have been reported to the IRB and insure that reports are up-to-date.
- ◆ For Multi-center studies: Ensure that any additional information from the Sponsor or Coordinating Center is provided to give a complete picture of study's progress.

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