

August 9, 2018

## Guidance for Research Repositories

The following guidance was developed to provide considerations for establishing a repository, information to address in the IRB submission, and informed consent cautions. In addition, it provides guidance and includes the NIH Decision Chart to help determine when secondary research conducted by recipient researchers, may or may not require IRB review.

- [RESEARCH BIOSPECIMEN BANK GUIDANCE](#)
- [RESEARCH REGISTRY GUIDANCE](#)

## Realigning Consent Templates

The [Sample Repository/Registry/Bank Consent template](#) has been updated and posted under [Informed Consent Templates](#) on the ORI website and on page 2 of default view in E-IRB Templates .

It may be used when:

- 1) creating a repository that will procure and share material or
- 2) by investigators who wish to store and share material from existing studies for future secondary research. **NOTE:** We are finalizing a revised version of the medical informed consent templates in which the ICF appendix for future use is included only when the PI will store specimens or data for his/her own future secondary use (no sharing). Therefore, if the protocol or detailed consent indicates sharing will occur, the investigator would provide a separate consent using applicable portions of the Sample Repository Consent. Reply with questions or comments regarding this realignment.



## IRB Review of Research Repositories: Observations/Inquiries

While the general term “repository”, refers to any data or human tissue saved and set aside for research, the studies involving the practice may be referred to as a bank, registry, data-repository, secondary database, or other term.

Regardless of the term used, the following presents few observations or inquiries, which have led to the development of guidance and potential future edits to the IRB application.

1. If you’ve seen one, then you’ve seen... one. There is extensive variation and diversity in how banks, registries, and data-repositories function. The goals may be similar or even duplicative, but there is great variation in the material collected, procedures involved, infrastructure, and operations.
2. They seem to be everywhere. Many are submitted through the expedited review mechanism. The IRB application has an attribute for the collection of specimens for banking, but it would be challenging to

quantify the number of data registries or repositories currently in operation. This raises the question regarding duplication of effort. Multiple repositories can also be confusing for patients invited to participate and subjects enrolled in one or more repositories.

- 3.** Could they obtain the desired information or specimens from existing established and IRB approved banks, repositories, data trusts, registries, or commercial vendors? Is there a valid scientific justification for developing a new bank/registry?
- 4.** Many include self-imposed restrictions and limitations. The purpose of a bank may be broad and the use and sharing may be unrestricted. Limitations and restrictions, self-imposed or not, that are communicated in the consent process, must be honored. Operating outside of the terms of the consent is a protocol violation and potential non-compliance.
- 5.** Including multiple options within an informed consent may enhance the participant's sense of self-determination. However, if the consent includes tiered options, subsequent research use or sharing must comply with the participant's wishes. The investigator proposing use of a "tiered option consent" should describe the system that will be used to label, track and use data or specimens according to the participant's choices.
- 6.** Who is minding the shop? Some proposed protocols fail to designate study personnel to procure and manage material, maintain master code lists, act as an honest broker, ensure use or sharing is consistent with the consent, secure or destroy material as indicated in the IRB approved protocol, etc. The repository description should demonstrate adequate staff and infrastructure that is commensurate with the complexity of the bank or registry.