

**IRB REVIEW OF BIOREPOSITORIES LOCATED AT  
THE PORTLAND VA MEDICAL CENTER**

**FREQUENTLY ASKED QUESTIONS (FAQs)**

**A. How do I determine if biorepository activities (contributing or receiving specimens) require IRB review?**

Submit the Proposed Project Questionnaire. IRB staff will determine, in consultation with an IRB chair if necessary, whether the research meets the definition of human research, and therefore requires IRB review. If the research is determined to be human research, the IRB is responsible for review and approval or disapproval and, if appropriate, whether the human research activities are exempt.

**B. When does the collection and storage of human specimens for research become a biorepository?**

The collection and storage of human specimens becomes a research biorepository when specimens collected prospectively or retrospectively will be used for future research.

**C. When is informed consent required for the collection and storage of specimens in biorepositories?**

Informed consent is required for the collection and storage of directly or indirectly identifiable excess clinical samples AND for collection and storage of any specimens obtained solely for research (research specimens) in a biorepository. In such cases, the contributing investigator must obtain informed consent from each tissue specimen donor using an IRB-approved consent form.

**D. How may researchers access specimens from the biorepository?**

Researchers may submit the following requests to a biorepository:

1. **Recipient researcher requests specimens with identifiable information (directly identifiable specimens):** The biorepository can only release specimens with identifiable information to researchers who have obtained IRB approval for a specific protocol. As part of that review, the IRB must determine whether or not the original consent signed by the specimen donor covers the proposed use.

If the original informed consent does not cover the proposed use (nature and purpose), the IRB may require the researchers to obtain separate informed consent for this new study or may waive the requirement for informed consent if regulatory requirements for such a waiver are met. In general, the IRB recommends seeking consent from the specimen donor that broadly covers all anticipated research. Although re-contact of subjects for new consent is not impossible, nor prohibited, it may be impractical and

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annoying if frequent. Advance planning and description of research plans at the time of initial consent may obviate these difficulties. If the IRB requires new informed consent, and the original informed consent does not include the subject's permission for future contact, the specimens **cannot** be used for these new studies until new informed consent is obtained.

2. **Recipient researcher requests coded specimens:** The biorepository may release specimens that retain a link (code) to identifiable information about the specimen donor if the following conditions are met:
  - a. The informed consent signed by the donor covers the research.
  - b. The specimen is "coded" when it is passed to the recipient investigator and the recipient investigator will never have access to the code that would enable identification of the specimen.

If these conditions for coded specimens are not met, then the requirements for release of specimens with identifiable information must be followed.