Banking Specimens for Future Use Guidance

Version Date: May 27, December 11, 2014

Guidance on banking biological specimens

An increasing number of researchers are choosing to store and maintain tissue, blood, and other biological specimens for unspecified future use. Specific IRB approval is required for banking of specimens. An investigator can obtain IRB review of a tissue bank either through a stand-alone application (e.g., for the creation and maintenance of a tissue bank) or, if the specimen collection occurs in conjunction with a specific research project, by explicitly building into the IRB application the intent to store tissue for future use. In order for the IRB to approve the banking of specimens for future research, the following information needs to be provided:

- A description of how the specimens will be stored, including whether they will be stored in an identifiable manner (e.g., direct or indirect identifiers are associated with them)
- A description of where the specimens will be stored and the security protections in place to minimize the risk of breach of confidentiality
- Whether the banking of specimens is optional and if not, whether the consent form adequately describes that participation in the project means the subjects' specimen(s) will be stored indefinitely for future use
- The procedures in place by which subjects can withdrawal their specimens from long-term banking or whether de-identification makes withdrawal impossible
- Limits on intended future use (e.g., the specimens will only be used in cancer-related research).
- If the future research involves the study of biomarkers or genes that may reveal a predisposition to a particular disease or to a condition requiring special consideration and confidentiality protections, then individual subjects must be informed of the results. The plans for releasing the results of specimen testing to individual subjects must be described.
- The proposed consent process used to inform potential subjects of the purpose of the bank, procedures, whether any clinical information is stored with the specimen(s), whether the samples will be identifiable, the risks and how these are minimized, potential benefit, privacy and confidentiality protections, etc.

The IRB reviews subsequent research involving banked specimens to determine whether:

1. The source of the samples raises any ethical concerns such that the University of Wisconsin-Madison would not wish to be associated with such research; and
2. Explicit consent was obtained from the individuals for the use of their specimens in research.

Additional considerations:
• Researchers are typically expected to obtain informed consent from subjects for the inclusion of their specimen(s) in a bank for future use
• Future studies utilizing the banked specimen(s) must obtain separate IRB approval or exemption
• Under the HIPAA Privacy Rule separate permission is required for the storage of biological materials as well as each research use of identifiable materials. Written authorization from subjects for each research use of their protected health information must be obtained or a waiver of such authorization sought from the IRB for a use for which written authorization was not previously obtained.

See Also:

• Informed Consent and HIPAA Authorization