Policy
Department: HUMAN RESEARCH PROTECTIONS PROGRAM
Policy Number: III.F.1
Section: IRB Review Procedures
Review Responsibility: HRPP Policy and Procedure Committee
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Subject: Procedure for Research with Human Tissue, Blood, Genetic Material, and Data

Procedure:
This procedure outlines the process for establishing and extracting specimens/data for use in research.

I. Investigator Responsibilities.
   A. Investigators who plan to collect specimens/data prospectively or retrospectively (previously stored) for
      1. pre-defined research purposes only in connection with a single IRB approved proposal should submit the “Standard or Expedited” to the IRB.
   B. Investigators who plan to collect specimens/data prospectively or retrospectively (previously stored), for undefined future research purposes that will be
      shared (within or outside of VU or VUMC), used again, or stored for research purposes beyond the scope of the Investigator’s originally approved IRB application should
      submit the “Standard or Expedited Application” and corresponding informed consent documents (ICDs) located on the HRPP website at http://www.mc.vanderbilt.edu/irb/.
   C. Investigators who plan to prospectively add to existing specimen/data collections, that have not been established as IRB approved “research repositories”, should submit the “Standard or Expedited Application” and corresponding ICDs located on the HRPP website at http://www.mc.vanderbilt.edu/irb/.
   D. ICDs must be submitted with the application or a request for a waiver of consent should be completed according to HRPP policies and procedures. For studies which involve DNA/genetic sampling, the current IRB-approved genetic template language should be included in the ICD. The document is available on the HRPP website at http://www.mc.vanderbilt.edu/irb/.
   E. The Investigator should apply for a Certificate of Confidentiality, if applicable.
   F. The repository should only release specimens/data in accordance with its IRB approval. In addition, specimens/data should not be released to an Investigator without
      receiving written documentation of IRB approval for research using the specimens/data.
   G. The Investigator will comply will all HRPP policies and procedures applicable to the collection, use, storage, and re-use of all human tissue, blood or genetic material and all data that are generated within, transferred to, or transferred from VU or VUMC for research purposes.

II. IRB Committee Responsibilities.
   A. The IRB will determine whether or not the specimens/data can be identified with the participant and whether specimens/data were collected retrospectively or will be
      collected prospectively.
   B. The IRB will assess the repository to assure that adequate measures have been taken to protect the confidentiality of participants. This review will include:
      1. The type of specimens or data to be banked;
      2. Whether the specimens/data are identified or coded;
      3. What procedures are in place to “de-identify” the specimens/data;
      4. Will the collection of specimens/data require interaction with human subjects;
      5. Are the specimens/data “on the shelf” at the time the proposal is initiated;
      6. Will informed consent be required;
      7. Who will manage the repository;
      8. How and where will the specimens/data be stored and released; and
9. What will happen to the specimens/data should the subject withdraw informed consent or the Investigator should leave the Institution.

C. If an Investigator plans to send any specimens/data to an outside repository for storage that can be traced back to a participant, the IRB may:
   1. Request the identification of the Repository as well as a copy of its IRB approval;
   2. Request an external “Data Use Agreement” between the outside Repository and the Investigator; and/or
   3. Request a Certificate of Confidentiality be obtained by the Investigator to assure participant confidentiality if there is not an IRB overseeing an outside repository, or when genetic information or tissue samples are involved.

D. The IRB will review the informed consent documents to verify the inclusion of the essential elements of consent. In addition, the IRB will review the informed consent document(s) for a description of the storage, use, and release of the specimens/data that will be submitted to the repository.
   1. When the repository contains genetic specimens/data, the IRB will verify that the IRB genetic template language has been included within the informed consent documents or as a rider to the informed consent documents for the specific study in which the repository will be used.
   2. If a Certificate of Confidentiality is applicable, the IRB will recommend that the Investigator apply for a Certificate of Confidentiality. In addition, the IRB will verify receipt of a Certificate of Confidentiality and that a description of this protection is included in the informed consent documents, as well as any Investigator plans for voluntary disclosure.

E. The IRB may review requests for repositories through expedited review procedures when identifiers are used in the storage and/or release of the specimens/data for research purposes and the research meets a specific review category as outlined in 45 CFR 46.110 (F). If the request for a repository does not meet a specific category as outlined in 45 CFR 46.110 (F), the IRB must review the request by the full Committee.

F. The IRB may review and approve studies of specimens/data received from a repository. The IRB, or designee of the IRB, may determine that the use of de-identified specimens in storage that will be released for use in research does not qualify as human subjects research.

G. All reviews will be conducted under the appropriate HRPP policies and procedures applicable to the level of review.

III. HRPP Regulatory Compliance Analyst (RCA) Responsibilities.
A. The RCA will pre-review the repository application to assure that it meets the requirements for setting up a repository under HRPP policies and procedures.
B. The RCA will verify that a description of the conditions under which the specimens/data will be stored, utilized and released are adequate, or request clarification from the Investigator.
C. Correspondence requesting pre-review changes are to be sent to the Investigator by the RCA.
D. Letters requesting revisions from the Reviewer, and final approval letters are to be drafted using the appropriate template and forwarded to the IRB Chairperson or his/her Designee for signature.
E. The Investigator will be promptly notified in writing of the IRB determination.
F. The RCA will complete database entries as appropriate.