

Children's
Hospital & Regional Medical Center
Office of the Vice President for Research

OPERATING PROCEDURES/POLICIES

Committee: Institutional Review Board
Policy Number: IRB-34
Effective Date: June 20, 2005

POLICY TITLE:

RESEARCH REPOSITORIES OF HUMAN MATERIALS AND/OR DATA

POLICY:

The establishment and management of repositories for research purposes that collect and store human materials (biological specimens, tissue) and/or data requires review and oversight by the IRB. The IRB shall ensure that adequate provisions are in place to protect the privacy and confidentiality of the donors and their materials and data.

DEFINITIONS:

Research repository means the collection, establishment and operation of a bank containing materials (e.g., human tissue, biological specimens) and or data for use in future research.

PROCEDURE:

- 34.1 Researchers shall obtain IRB approval for the establishment and operation of **research** repositories of human materials and/or data that are managed and operated by Children's.
- 34.2 This policy applies to the establishment of **research** repositories and does not cover the use of biological specimens or data obtained from clinical repositories managed and operated by Children's.
- 34.2 The principal investigator responsible for oversight of a research repository shall submit an IRB application that provides detailed plans for the collection,

storage and distribution of data and materials. At minimum, the IRB shall require plans that specify:

- A. What data and materials will be collected and stored.
- B. How the data and materials will be used in future research. As a general rule, the IRB shall request that future research uses be limited to research regarding the condition or disorder of the donor. For example, research on cancer or tumors, research on diabetes.
- C. The provisions for protecting the privacy and confidentiality of the donors throughout all stages, i.e., during the collection, transmission to the repository, storage, and distribution for research of the stored materials and data.
- D. The provisions for collecting data and materials, including the consent materials used to obtain consent. When data and materials are collected from many sites and sent to the repository, the researchers must provide detailed plans on how collection of data and materials, including consent, will be accomplished at these sites.
- E. The provisions for distributing stored data and materials to future researchers. Those responsible for the oversight of the repository must have in place provisions to ensure that the recipient of the data or materials has IRB approval for the research to be done with the materials and data.
- F. The steps to be taken if a donor or their legal representative decides to withdraw from the repository.
- G. The provisions in place for disclosure of the results of the research to the donors or their legal representatives.

Collection of Materials and Specimens

- 34.3 The IRB shall require researchers to obtain the consent and authorization of the donor or their legal representative to permanently store their materials and data, including protected health information (PHI), in a repository for future research. The Principal Investigator may request the IRB to approve a waiver of consent and waiver of authorization to use PHI and shall provide the IRB documentation in sufficient detail for the IRB to determine if the research meets the federal regulations for waiver of consent and waiver of authorization under HIPAA.
- 34.4 The IRB shall ensure that the consent form contains all the required elements for obtaining informed consent (see IRB policy 13). The consent form shall provide donors or their legal representatives specific information regarding:
- A. How the privacy and confidentiality of donors will be protected and maintained in the collection, storage and distribution of their materials and data;
 - B. How the materials and data will be used in future research;
 - C. What will happen to the materials and data previously donated if the donor wishes to withdraw from the repository

- D. Whether the results of research done with the stored materials and data will be made available to the donors and their legal representatives and if so, under what circumstances and by what means.
 - E. That there are no provisions for compensating donors who provide materials and/or data if future research leads to commercial products or services.
- 34.5 The IRB shall advise the principal investigator on the need to obtain informed consent from donors who were minors at the time the materials or data were collected for the repository, once the minor reaches the legal age of consent. Among the factors the IRB will consider when making this determination are: a) the ability of the researchers to locate and contact the donors; b) whether the collection of materials and data is ongoing or a one-time donation; c) whether the materials and data can be de-identified; d) the nature and sensitivity of the research being done with the materials and data in the repository; and e) was assent obtained from the minor at the time materials and data were collected for the repository.
- 34.6 If the materials and data collected for the research repository are obtained from multiple sites the IRB shall request the principal investigator develop for the participating sites:
- B. A collection protocol
 - C. Sample consent form
 - D. Recruitment materials
 - E. Plan to require that investigators at other sites check with their local IRB regarding the requirements for local IRB review of the research repository. The PI shall require documentation that local IRB review has been done before receiving materials and data from that site.
 - F. Reminder that investigators at other sites should check their institutional policies regarding the transfer of materials and data for research.
- 34.7 The IRB shall require that the collection of materials and data for the research repository be done in a manner that allows potential donors or their legal representative sufficient time to consider the request and that minimizes any undue influence or pressure to donate materials or data. The IRB shall require the collection and transmission of materials and data be done in a manner that protects the confidentiality of the donor.

Storage

- 34.7 The IRB shall require that the researchers responsible for oversight of the research repository have procedures in place to ensure that informed consent and HIPAA authorization have been obtained from the donors or their legal representatives before specimens are stored in the repository.

