

10.0 Research with Human Biologic Material

10.1 General information

The HSC oversees the collection or use of human biologic material for research purposes. Prior HSC approval is required when the use of these materials qualifies as human subjects research. Use of human biologic material that is currently associated with personal identifiers, or was associated with personal identifiers at any time, is subject to the authority of the HSC.

Human biologic material refers to any material of human origin. This includes, but is not limited to, molecular material such as DNA, cells, tissues (blood, bone, muscle, tumor, etc.), organs (liver, heart, lung, etc.), fluids (such as amniotic fluid, cerebrospinal fluid, saliva, etc.) or waste (hair, nail clippings, urine, feces, etc).

Human biologic material may be classified into four levels of identification: The levels include:

1. **Unidentified specimens (anonymous):** Specimens that were obtained and stored without any identification that may link the specimen to a specific individual.
2. **Unlinked specimens (anonymized or de-identified):** Specimens that may have been acquired from identified individuals, but all identifiers or codes have been removed and destroyed. For unlinked specimens, it would be extremely difficult for the investigator, the repository or a third party to identify the person who provided the specimen. See also the definition for de-identified information below.
3. **Coded samples:** Specimens labeled with a code rather than a name or other personal identifier. When such specimens are obtained from a repository, the repository usually retains information that links the code to a particular individual. Using this information, the investigator, the repository or a third party could determine which particular person or small group of identifiable individuals provided the specimen.
4. **Identified specimens:** Specimens collected and supplied to investigators with personal identifiers sufficient to allow identification of the person who provided the material.

De-identified specimens are those that do not specifically identify an individual. Also, there is no reasonable basis to believe that the information associated with the specimen could be used to identify an individual. In order for a specimen to be considered de-identified, the following elements must be removed: name; address; names of relatives; names of employers; birth date; telephone number; fax number; e-mail addresses; social security number; medical record number; health plan beneficiary number; account number; certificate/license number; any vehicle or device serial number; web URL; Internet Protocol Address; finger or voice prints; photographic images (e.g. full facial photographs); and any other unique identifying number, characteristic, or code.

Human cell lines obtained from a commercial provider, human cells about which all information has been published or unidentified specimens obtained from a commercial provider are not considered human subjects research and do not require HSC approval for use.

10.2 Review by HSC

I. Use of existing specimens

- A. To be considered “existing,” specimens must be “on the shelf” at the time of the HSC application.
- B. Research using existing unidentified or unlinked specimens that were not collected for a research purpose is not human subjects research and does not require HSC review or an exemption determination, provided that the data will not be submitted to the FDA.
- C. Research using existing specimens that were not collected for a research purpose is not human subjects research and does not require HSC review or an exemption decision if (a) the holder of the specimens provides them to the investigator in such a manner that human subjects cannot be identified, directly or through linked identifiers, and (b) the data will not be submitted to the FDA.
- D. If identifiable information about the specimens is available to the investigator but the investigator records only data that do not allow the subjects to be directly or indirectly identified, the research might be exempt, provided the data will not be submitted to the FDA.
- E. If the investigator will maintain a code or other identifiers in order to perform the research, the proposal will be reviewed using expedited procedures

II. Use of existing specimens obtained from another institution

- A. Investigators must consult with HSC prior to the use of existing materials obtained from another institution, to ensure federal regulations and institutional requirements are met.
- B. During the review process, the HSC will require information about whether the specimens were originally obtained for clinical purposes or collected specifically for research, whether informed consent was obtained and whether another IRB approved the collection of the specimens.

III. Prospective collection of specimens

- A. Prospective collection of specimens for the primary purpose of creating a repository
 - 1. Expedited review procedures may be used, if the collection of specimens is non-invasive or otherwise meets the criteria for expedited review outlined in federal regulations.
 - 2. Expedited review procedures may be used, if the research involves materials collected solely for non-research purposes, i.e., all material obtained was necessary for clinical purposes and no additional amount of material was obtained in order to perform the research
 - 3. Prospective collection of materials in the two circumstances listed above may be considered minimal risk research, provided the HSC determines

that investigator has an adequate plan to protect the confidentiality of the information.

4. HSC may determine that the prospective collection of specimens is not human subjects research, if the specimens are collected solely for clinical purposes and provided to the investigator in a de-identified fashion by an individual who is not associated with the research being proposed.
 5. Prospective collection of specimens may require informed consent. Section 10-4 outlines specific consent requirements.
- B. Collection of specimens secondary to a clinical trial
1. Plans to collect specimens will be reviewed by HSC during the review of the clinical trial.
 2. Proposals to add specimen collection to an approved clinical trial will be reviewed at a convened HSC meeting.
 3. Consent to bank specimens collected during a clinical trial for future research purposes must be obtained separately from the consent for participation in the clinical trial. The separate consent can be obtained with either (1) a stand-alone consent document or (2) an addendum to the main consent. The storage of specimens for other future research which is not related to the endpoints of the main clinical trial must be optional.

V. Additional institutional requirements

- A. When biologic specimens are sent as research tools to collaborators at other institutions or agencies, the shipment may require the recipient to sign a Material Transfer Agreement.
- B. When considering such transfers, investigators must consult with the Technology Transfer Office of the KUMC Research Institute.

10.3 Investigator responsibilities specific to repositories of human biologic materials

- I. Investigators who conduct human subjects research to collect human biologic materials and investigators who maintain human biologic materials for human subjects research have additional responsibilities, as follows:
- A. Submit to HSC a protocol that describes the justification and specific aims of the research; source of the specimens; removal procedures; recruitment strategies (if applicable); criteria for releasing specimens to collaborators
 - B. Ensure that specimens are handled in compliance with requirements from the KUMC Institutional Research Safety Committee
 - C. Develop a plan for secure storage of the specimens
 - D. Develop a plan to protect the confidentiality of coded or identified specimens
 - E. Obtain prior informed consent when required by HSC
 - F. Submit to HSC any proposed changes to the operation or purposes of the repository

- G. Obtain a user agreement from any recipients of specimens who are not included in the HSC-approved list of research personnel. The HSC provides a sample user agreement.

10.4 Consent and Authorization Requirements

- I. Unless exempt, waived or determined to be not human subjects research, prospective collection of coded or identified specimens must be done using written informed consent and privacy authorization. General consent statements for clinical or surgical procedures do not meet federal requirements for informed consent and authorization.
- II. In addition to the basic elements of consent, the informed consent for collection and use of specimens will address the following issues:
 - A. Method of obtaining specimens and whether the research activity involves use of leftover specimens or obtaining additional specimens for the research
 - B. Ability to participate in the clinical trial without participating in the specimen banking
 - C. Topics of research for which the specimens will be used
 - D. Description of the personal identifiers and medical information that will be maintained with the specimen
 - E. If the specimens are coded, a description of the coding system and whether a subject's identity can be ascertained from the code
 - F. The identity of the person(s) who will maintain the key to the code
 - G. Description of the future users of the specimens or their associated information
 - H. Description of the identifiers and medical information that will be shared with future users of the specimens
 - I. Dissemination of individual study results to the investigator, the subject or neither
 - J. Assurance that individual study results will not be placed in the subject's medical record
 - K. Physical risks, if the specimen will be obtained by the removal of extra materials specifically for research purposes
 - L. Risks of breach of confidentiality
 - M. The planned length of storage of specimens
 - N. Subject's right to cancel use of his/her specimen and associated information
 - O. Procedures for requesting withdrawal of specimen from further research
 - P. Potential commercial developments from the specimens
 - Q. Location and secure storage of the specimens; location and secure storage of the data
 - R. The potential for future research uses, with an assurance that if investigators propose to use the specimens for purposes not described in the consent form, a request must first be approved by an institutional review board that protects the rights of research participants. The board will determine whether researcher have to re-contact participants to obtain their permission.

III. Investigators must retain signed consent form, but these should not be stored in a way that allows identification of an otherwise unidentified specimen.