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IRB SOP 10.0 Research With Human Biologic Material, pre-2018 requirements

1. Purpose:

This SOP outlines the use of human biological materials for any project approved before the new common rule was implemented.

Responsible Personnel:

Background:

Regulation and Guideline Reference(s):

OHRP Guidance on Coded Private Information or Biological Specimens NIH Genome-Wide Association Studies (GWAS) Policy

NIH Genome-Wide Association Studies (GWAS) Policy

2. Procedure:

10.1 Research with Human Biologic Material

I. General Information

- A. The IRB oversees the collection or use of human biologic material for research purposes. Prior IRB approval is required when the use of these materials qualifies as human subjects research.
- B. **Human biologic material** refers to any material of human origin. This includes, but is not limited to, 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 identifiers such as name, date of birth, social security number or other direct identifiers. 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. Codes must be constructed using the minimum necessary identifiers to accomplish the research purpose. When such specimens are obtained from a repository, the repository usually retains information that links the code to a particular individual.
 4. **Identified specimens:** Specimens collected and supplied to investigators in a manner that would allow the investigators to readily ascertain the identity of the individual, either directly or through identifiers linked to the individual.
- C. **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.
- D. **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 IRB approval for use.

10.2 Review by IRB

I. Secondary Use of Biospecimens for Research

- A. To be considered "secondary use," specimens must have been obtained for non-research purposes or for purpose separate from a currently-proposed research activity.
- B. Secondary use of de-identified specimens does not require IRB review or an exemption determination, provided that the data will not be submitted to the FDA.
- C. Research using other types of specimens that were not collected specifically for the proposed research is not human subjects research and does not require IRB 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. Secondary Use of Specimens Obtained from Another Institution

- A. Investigators must consult with IRB prior to the use of materials obtained from another institution, to ensure federal regulations and institutional requirements are met.
- B. During the review process, the IRB will require information about whether the specimens were

originally obtained for clinical purposes or collected specifically for research. If the original research was under the oversight of an external IRB, the KUMC IRB will require a copy of the IRB approval and the informed consent document.

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 by the IRB, 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 by the IRB, 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 IRB determines that investigator has an adequate plan to protect the confidentiality of the information.
4. IRB 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 IRB during the review of the clinical trial.
2. Proposals to add specimen collection to an approved clinical trial will be reviewed at a convened IRB meeting if the method of collection is greater than minimal risk. Specimen collection that meets minimal risk criteria can be reviewed by the IRB using an expedited process.
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 (1) a stand-alone consent document, (2) an addendum at the end of the main consent or (3) a clearly labeled and distinct section of the consent form that outlines the planned collection. The storage of identifiable specimens for other future research which is not related to the endpoints of the main clinical trial must be optional.

10.3 Investigator Responsibilities Specific to Creating 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 the IRB a protocol that describes the justification and specific aims of the research; source of the specimens;; recruitment strategies (if applicable); criteria for releasing specimens to collaborators; and process to withdraw samples from the repository at the request of the subject.
 - B. Ensure that specimens are handled in compliance with requirements from the KUMC Institutional Biosafety Committee
 - C. Develop a plan for secure storage of the specimens

- D. Develop a plan to protect the confidentiality of coded or identified specimens (if applicable)
- E. Obtain prior informed consent when required by IRB
- F. Submit to IRB proposed changes to the operation or purposes of the repository that impact the uses of the specimens or confidentiality and data security provisions.

10.4 Consent and Authorization Requirements

- I. Unless, waived or determined to be not human subjects research by the IRB, 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 discussed in SOP 7.3, the informed consent for collection and use of specimens will address the following issues, as applicable to the research purposes:
 - 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) or entity 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. Descriptions of genetic research, if planned, and the types of information that could be obtained through genetic analysis
 - N. Explanation of plans to share genetic data from the specimens with national groups or government databases
 - O. The planned length of storage of specimens
 - P. Subject's right to cancel use of his/her specimen and associated information
 - Q. Procedures for requesting withdrawal of specimen from further research
 - R. Potential commercial developments from the specimens
 - S. Location and secure storage of the specimens; location and secure storage of the data
 - T. An assurance that if investigators propose to use identifiable 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 researchers have to re-contact participants to obtain their permission.

- III. If investigators plan to conduct genome-wide association studies (GWAS), then their collection, use and distribution of the GWAS data must meet requirements outlined in the HRPP Policy on Genome-Wide Association Studies, posted on the IRB's website and the KUMC Policy Library.
- IV. Investigators must retain signed consent form, but these should not be stored in a way that allows identification of an otherwise unidentified or unlinked specimen.

Attachments:

Approval Signatures

Approver	Date
Steffani Webb: Vice Chancellor for Administration	12/10/2019
Lisa Hoebelheinrich: Chief Compliance Officer	12/10/2019
Annie Fors: QA Director	12/4/2019
Karen Blackwell: Director HRPP	12/2/2019
Kyle Stephens: Assistant Director	11/29/2019

Applicability

KU Medical Center, KU SoM Wichita

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