Purpose:

Responsible Personnel:

Background:

Regulation and Guideline Reference(s):

OHRP Guidance on Coded Private Information or Biological Specimens

NIH Genome-Wide Association Studies (GWAS) Policy

KUMC References:

Attachment(s):

Definitions:

Procedure:

General Information

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.

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. 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.

**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 IRB approval for use.

### 10.2 Secondary Research that is Federally Funded or Supported

**I. IRB Submission Requirements**

A. To be considered “secondary research,” specimens must have been obtained for non-research purposes or for purpose separate from a currently-proposed research activity.

B. Secondary research with coded or de-identified specimens does not require IRB review or an exemption determination, provided that the data will not be submitted to the FDA. Investigators can request a written determination by submitting a request for Not Human Subjects Research.

C. When requesting approval for secondary research involving identifiable biospecimens, the investigator may submit a document that serves as both the IRB application and the study protocol. A template is provided on the IRB website.

D. The submission must be accompanied with a copy of the data collection sheet and administrative certification for the IRB submission from the investigator's department.

E. Institutional requirements for study personnel to have current training in human subjects protection and a current conflict of interest disclosure apply to this category of research.

**II. IRB Review**

A. 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 can be approved under 45 CFR 46.104(d)(4)(ii), provided the data will not be submitted to the FD

B. If the investigator records or obtains identifiable health information about the specimens, the IRB will review the research under expedited review procedures. Approval under 45 CFR 46.110(F)(5) will be considered. A waiver of consent is granted if the study meets the criteria in 45 CFR 46.116(f).

C. The research will be subject to other institutional requirements for HIPAA privacy and data security.

III. 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, whether informed consent was obtained and whether another IRB approved the collection of the specimens.

10.3 Secondary Research that is Not Federally Funded or Supported

I. IRB Submission Requirements

A. To be considered “secondary research,” specimens must have been obtained for non-research purposes or for purpose separate from a currently-proposed research activity.

B. Secondary research with coded or de-identified specimens does not require IRB review or an exemption determination, provided that the data will not be submitted to the FDA. Investigators can request a written determination by submitting a request for Not Human Subjects Research.

C. When requesting approval for secondary research involving identifiable biospecimens, the investigator may submit a document that serves as both the IRB application and the study protocol. A template is provided on the IRB website.

D. In the IRB submission, the investigator must confirm that the research does not meet any of the institutional criteria for being federally funded or supported.

E. The submission must be accompanied with a copy of the data collection sheet and administrative certification for the IRB submission from the investigator’s department.

F. Institutional requirements for study personnel to have current training in human subjects protection and a current conflict of interest disclosure apply to this category of research.

II. IRB review

A. Secondary research involving identifiable specimens, that is not federally funded or supported, is reviewed under Flexible IRB Review Policy, provided the data will not be submitted to the FD. Flexible IRB Review is further described in SOP 20.

B. The research may be subject to other institutional requirements for HIPAA privacy and data security.

10.4 Secondary Research Involving Specimens from External Source

I. Identifiable Specimens that are Publicly Available

A. Investigators should consult with the IRB prior to conducting research with identifiable specimens that are publicly available. If federally funded, the research may qualify for approval under 45 CFR 46.104(d)(4)(i).

B. Additional institutional requirements may apply for HIPAA privacy, data security and legal counsel
II. Secondary Use of Specimens Obtained from Another Institution
   A. Investigators must consult with the 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.

10.5 Collection of Specimens Secondary to a Clinical Trial
   I. Plans to collect specimens will be reviewed by the IRB during the review of the clinical trial.
   II. 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.
   III. 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.

10.6 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 the IRB
      F. Submit to the IRB proposed changes to the operation or purposes of the repository that impact the uses of the specimens or confidentiality and data security provisions.
   II. 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. Alternatively, if the project does not have federal funding or support, the proposal will be reviewed under Flexible IRB Review.
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. Prospective collection of materials using invasive procedures must be reviewed and approved by the convened IRB.

5. The 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.

B. Prospective collection of specimens may require informed consent. Section 10.7 outlines specific consent requirements.

10.7 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 subjects 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.

References:
45 CFR 46.104(d)(4)
OHRP Guidance on Expedited Review Procedures
OHRP Guidance on Coded Private Information or Biological Specimens
NIH Genome-Wide Association Studies (GWAS) Policy

Attachments:

Approval Signatures

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<thead>
<tr>
<th>Approver</th>
<th>Date</th>
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<tbody>
<tr>
<td>Steffani Webb: Vice Chancellor for Administration</td>
<td>12/10/2019</td>
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<tr>
<td>Lisa Hoebelheinrich: Chief Compliance Officer</td>
<td>12/10/2019</td>
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<tr>
<td>Annie Fors: QA Director</td>
<td>12/4/2019</td>
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<tr>
<td>Karen Blackwell: Director HRPP</td>
<td>11/26/2019</td>
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<tr>
<td>Kyle Stephens: Assistant Director</td>
<td>11/21/2019</td>
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Applicability

KU Medical Center, KU Public Policies and Procedures, KU SoM Wichita