UNIVERSITY OF SOUTH ALABAMA

IRB SOP 801
Research Involving Data and Biological Specimens

Purpose

The purpose of this policy is to describe the requirements for IRB approval (or exemption) and informed consent for any of the following:

- Data and/or biological specimens collected for research purposes
- Data and/or specimens collected, stored, and/or distributed for *future research uses*
- Previously collected data/specimens used for *secondary research*.

Scope

This policy applies to all individuals under the auspices of the University of South Alabama conducting human subject's research that either creates/uses repositories or other collections of data and/or biological specimens.

Definitions

Anonymous: Unidentified (i.e., personally identifiable information was not collected, or if collected, identifiers were not retained and cannot be retrieved); information or materials (e.g., data or specimens) that cannot be linked directly or indirectly *by anyone* to their source(s).

Coded: Direct personal identifiers have been removed (e.g., from data or specimens) and replaced with a number, letter, symbol or a combination thereof (i.e., the code) for purposes of protecting the identity of the source(s); but the original identifiers are retained in such a way that they can be traced back to the source(s) by someone with the code.

De-identified: All direct personal identifiers are *permanently* removed (e.g., from data or specimens), no code or key exists to link the information or materials to their original source(s), and the remaining information cannot reasonably be used *by anyone* to identify the source(s).

Existing: Data or specimens that have already been collected and stored at the time the research is proposed to the IRB for determination of whether the research is exempt. Material collected after the date of initial submission to the IRB is not existing for purposes of this policy.

Identifier: Information that identifies a person or could be used to identify a specific person. For purposes of human research, names, codes linked to names, social security numbers, patient ID numbers and other such commonly-used data elements are considered identifiers. However the Health Insurance Portability and Accountability Act (HIPAA) definition is broader, including a specific list of data elements.

Repository: Collection of data and/or specimens obtained and stored for future research uses and/or distribution, including a collection not originally or primarily obtained for research purposes. Repository may also be referred to as "tissue banking".

Specimen: Many biological material obtained from or derived from patients or human research subjects. This includes, but not limited to, fixed, frozen or fresh pathology or autopsy specimens, or body fluid (e.g., blood, urine, saliva, semen, cerebrospinal fluid), and cells.

Leftover/Remnant Specimen: Remaining portion of a specimen obtained for clinical purposes that is no longer needed for its original purpose and that would otherwise be discarded.

Secondary Research: Study of existing information or materials (e.g., data or specimens) that have been previously collected for a purpose (including non-research purposes) other than the currently proposed activity.

Policy

The use of human specimens for research is regulated. All prospective collection of human specimens for research requires prior written IRB approval and informed consent from the subject.

The secondary use of existing human specimens for research purposes can be permitted under certain situations. Some types of secondary use require prior review and authorization by the IRB

The information below describes the oversight requirements that correspond to the various ways in which human specimens may be used in research.

1.0 Use of Existing Human Specimens that Does Not Require USA IRB Review: Activities That Are Not Human Subjects Research

1.1 Laboratory research with *commercially available* tissue specimens, cell lines, or other human cells does not meet the definition of "research involving human subjects" and may be performed without IRB approval or exemption as long as the work is not FDA- regulated.

1.2 Research with *autopsy* specimens does not meet the definition of "research involving human subjects" and may be performed without IRB approval or exemption. Research involving decedents' PHI is subject to HIPAA regulations. HIPAA authorization (or waiver) is generally not required for use or disclosure of PHI for research involving decedents only, with appropriate representations from the researcher.

1.3 Research with previously collected *anonymous* (see "Definitions" above) data and/or specimens does not meet the definition of "research involving human subjects" and may be performed without IRB approval or exemption *only* when the data/specimens to be studied were not collected specifically for the current research.

1.4 Research with previously collected *coded* data and/or specimens does not meet the definition of "research involving human subjects" and may be performed without IRB approval or exemption *only* when **all** of the following conditions are met:

- The data and/or specimens to be studied were not collected specifically for the current research
- Investigator(s) cannot "readily ascertain" the identity of the source(s) of the coded data or specimens because one or more of the conditions below is met:
  - The investigators and the holder of the "key" enter into an agreement prohibiting the release of the key to the investigators under any circumstances (until the source individuals are deceased)
  - IRB-approved written policies and procedures for the repository or data coordinating center prohibit the release of the key to the investigators under any circumstances (until the source individuals are deceased).

1.5 Research with *remnant* specimens does not meet the definition of "research involving human subjects" and may be performed without IRB approval or exemption *only* when their use meets the conditions for *anonymous* or *coded* specimens above.

2.0 Exempt Research

2.1 Research involving *existing* data and/or specimens is exempt when **all** of the following conditions are met:

- All data and/or specimens are available, or "on the shelf," at the time the research is submitted for an exempt determination
- The sources of the data and/or specimens are publicly available or the information is recorded by the investigator in a way that participants cannot be identified, directly or through identifiers linked to the participants
- The research is not subject to FDA regulations.

Note: An investigator may not de-identify data and/or specimens under his or her control (e.g., data collected by the investigator for another purpose or study) for future research uses without IRB review.

2.2 Prospective collection of biological specimens is not exempt from IRB review. Prospective data collection may be exempt in certain cases (e.g., some research qualifying under exempt category #1), depending on the nature of the data and population from whom the information is collected. For more information see *SOP: Exempt Research.*

3.0 Secondary Uses of Previously Collected Data/Specimens

3.1 IRB approval or exemption is required for secondary research uses of previously collected data and/or biological specimens, unless only *anonymous* or *coded* data/specimens are used as described above (see "Activities That Are Not Human Subjects Research").

3.2 Secondary research uses of *non-research* collections of data/specimens (e.g., data or specimens that are retained for purposes other than research, such as clinical or educational records, archived pathology specimens, etc.) require IRB approval or exemption, as such collections have not been established as repositories with IRB- approved procedures for releasing materials that consider human subjects protection requirements.

3.3 Secondary (i.e., "new") uses of data/specimens obtained for *primary research purposes* by an investigator with IRB approval (or exemption) require IRB review of an amendment or a new protocol describing the proposed secondary use, depending on the previous approval (or exemption) and the new research objective(s). Informed consent may also be required for this new use (as described below), depending on the scope of the original consent and the newly proposed research.

3.4 Research using previously collected data and/or specimens must be consistent with the scope and terms described in the original informed consent process/document, as applicable. If consent was not obtained (e.g., data/specimens obtained for non-research purposes) or the original consent does not adequately include the proposed secondary use, specific informed consent for the new research may be required. De-identification or coding of data/specimens should not be used as a means for circumventing the original terms of consent. Except in unusual circumstances, informed consent is required when identifiable data and/or specimens are used.

3.5 Informed consent (and HIPAA authorization, when applicable) can be waived by the IRB for minimal risk non-exempt research with previously collected data and/or specimens when the research meets the regulatory criteria for waiver (see "Informed Consent Requirements" below).

3.6 Protocols for using previously collected data and/or biological specimens for research purposes should include the following information, as applicable:

- Purpose of using data/specimens
- Type(s) of data/specimens to be studied
- Source(s) and circumstances under which the data/specimens were collected
- State of the data/specimens to be obtained (i.e., identifiable or coded)
- If the data include individually identifiable protected health information
- Whether informed consent (and HIPAA authorization, when applicable) was obtained for collection and future use of data/specimens
- Physical location/equipment and security provisions for data/specimen storage
- Process for destruction or de-identification of identifiable or coded data/specimens at the end of the retention period.

3.7 Investigators may not share data and/or specimens with collaborators (internal or external to USA) for secondary research purposes without IRB approval. Distribution of data and/or specimens for secondary research uses beyond a single transfer described in a specific IRB-approved protocol generally requires approval for a repository (see "Repositories – Collection, Storage, and/or Distribution of Data/Specimens" below).

3.8 Confidential disclosure agreements (CDAs), data use agreements (DUAs), or material transfer agreements (MTAs) may be required for sharing research data or specimens with non-USA collaborators. For more information, please contact Office of Commercialization and Industry.

3.9 Access to and/or use of identifiable patient information from medical records or clinical databases for research purposes must comply with the requirements of the HIPAA Privacy and Security Rules and university policy.

3.10 The proposed use of student education records in research must comply with the requirements of the Family Educational Rights and Privacy Act (FERPA). For information about the release of student records at USA, contact the Office of the University Registrar or USA's FERPA questions and answers.

4.0 Repositories – Collection, Storage, and/or Distribution of Data/Specimens

Research repositories are routinely used for the purposes and in the manner specifically described in the IRB-approved protocol and informed consent document under which the information was collected. However, investigators wishing to use a repository for research that differs in any way from that described in a protocol approved by the IRB must submit a new or amended protocol for IRB review before initiating the new project.

4.1 Data and specimen repositories/banks may range from materials held by a single investigator in his/her office or laboratory to large networks with central coordinating centers. Although the size, purpose, types of information and materials stored, and populations from whom the data/specimens are collected may also vary widely, creating a data and/or specimen bank for *future research purposes* (i.e., rather than using data/specimens only for pre-defined analyses as described in a specific IRB-approved protocol) is defined as "research involving human subjects;" and IRB review and approval is required.

4.2 Informed consent is required for collection of data and/or biological specimens to be stored for future research (see "Informed Consent Requirements" below). HIPAA authorization is also required when the data include protected health information.

4.3 Protocols for creating data and/or biological specimen repositories for research purposes should include the following information, as applicable:

- Purpose of collecting and storing data/specimens
- Type(s) of data/specimens to be collected and stored
- Source(s) and circumstances of data/specimen collection (i.e., obtained directly from participants or from a secondary source)
- How the data/specimens will be stored/coded (i.e., identifiable, coded, or de-identified)
- If the data include individually identifiable protected health information
- Physical location/equipment and security provisions for data/specimen storage
- Length of time data/specimens will be stored
- Any limits on data/specimens' intended future use (e.g., for cancer research only)
- With whom data/specimens may be shared (including non-USA State researchers)
- Policies/process for requesting and releasing data/specimens
- How data/specimens will be released (i.e., identifiable, coded, or de-identified)
- Procedures to withdraw participants' data/specimens from future research
- Plan for continuing repository operations in the absence (or departure) of the principal investigator
- Process for destruction or de-identification of identifiable or coded data/specimens at the end of the retention period.

Additional considerations:

- Inventory and/or database management procedures for the materials in the repository
- Quality assurance procedures (i.e., cross check samples, data, consents, and withdrawals, etc.)

4.4 Consideration should be given to obtaining a National Institutes of Health (NIH) Certificate of Confidentiality to protect the confidentiality of banked identifiable or coded data/specimens. Certificates of Confidentiality are intended to protect information that, if disclosed, could have adverse consequences for research participants or damage their financial standing, employability, insurability, or reputation. Examples include information about the following:

- HIV, AIDS, and other sexually transmitted diseases
- Sexual attitudes, preferences, or practices
- Use of alcohol, drugs, or other addictive products
- Illegal conduct
- Participants' psychological well-being or mental health
- Genetic studies, including future use of stored biological samples.

For more information about Certificates of Confidentiality, see *SOP 1205: Certificate of Confidentiality*

4.5 Methods for handling and storing data (including the use of personal computers and portable storage devices) must comply with university policies. Restricted data, including protected health information, must be encrypted if stored or used on portable devices, if removed from a secure university location, or if electronically transmitted.

5.0 Informed Consent Requirements

5.1 Informed consent must be obtained for collection and storage of data and/or biological specimens for future research.

5.2 Investigators and IRBs should balance the ethical obligation to provide sufficient information regarding possible *future research uses* of stored data and/or specimens during the consent process for banking with the practical issues of trying to anticipate and describe all possible research uses of these materials. However, the consent process for collecting and banking data and/or specimens should be as specific as possible regarding the circumstances and any risks associated with data/specimen collection, as well as the procedures for maintaining the

security and confidentiality of the stored materials. In addition to the required elements of informed consent, the consent process should include the following information, as applicable:

- Description of the data/specimens to be collected and how they will be obtained
- Any risks associated with obtaining the data/specimens
- How the data/specimens will be used (to the extent known)
- Any limits on data/specimens' intended future use (e.g., for cancer research only)
- Whether any identifying information will be retained, and if so, how it will be stored
- Certificate of Confidentiality information (when a Certificate is obtained)
- Description of the repository, including physical location, security procedures, etc.
- Who will have access to the data/specimens
- How long the data/specimens will be stored
- With whom data/specimens may be shared (including non-Ohio State researchers)
- How to withdraw data/specimens from future research
- Whether or not participants may be re-contacted in the future (e.g., for consent to future research, to return research results, etc.).
- Voluntariness of participation

5.3 If data and/or specimens may be commercialized, the consent process/document must include language that complies with state law.

5.4 When identifiable specimens and/or genetic information are stored and may be released for future research, the consent process/document should also include language describing the protections provided by the Genetic Information Nondiscrimination Act.

5.5 The informed consent process/document must not include any exculpatory language through which subjects are made to waive or appear to waive any legal rights regarding the collection or use of their data and/or specimens.

5.6 Research using previously banked data and/or specimens should be consistent with the scope and terms described in the original informed consent process/document, as applicable. If consent was not obtained (e.g., data/specimens obtained for non-research purposes) or the

original consent does not adequately include the proposed secondary use, specific informed consent for the new research may be required. Except in unusual circumstances, informed consent is required when identifiable data and/or specimens are used.

5.7 Informed consent (and HIPAA authorization, when applicable) can be waived by the IRB for minimal risk non-exempt research with previously collected data and/or specimens when the research meets the regulatory criteria for waiver. Waiver of HIPAA authorization can also be granted (when applicable) by the IRB for secondary uses of existing data and/or specimens in exempt research.

6.0 Reporting Individual Results to Subjects

For general repository activities, it is probably best to plan not to provide results of future studies to the subjects. Much of the future research will be conducted without identifiers, and it is unlikely that most research will yield results that, if known, would affect the patients' health care or family planning. In fact, there are many cases in which it would be unethical to provide results to patients, such as when the research is in the early stages and the clinical significance has not been established. On the other hand, if there is a good chance that research will yield results that could affect the subjects' medical care, it may be appropriate to tell subjects that if such identifiable results are obtained, the subjects will be contacted and asked if they wish to be informed of the results. The decision about whether to provide any results to subjects will depend on the ethical implications of each protocol.

Note: Results obtained from a laboratory that does not meet the standards of CLIA (Clinical Laboratory Improvement Act) may not be used to direct patient care. In these cases, the subject could be notified that an issue has been identified, and that the subject or in some cases the investigator can notify the subject's physician so that their physician may follow-up with standardized testing when appropriate.

7.0 IRB Oversight

Operation of a research repository and its data management center under the auspices of the USA is subject to oversight by the USA IRB. Proposals to establish a repository must be submitted to the IRB specifying the conditions under which data and specimens may be accepted and shared, and ensuring adequate provisions to protect the privacy of subjects and maintain the confidentiality of data. The IRB also reviews and approves a sample collection protocol and informed consent document for distribution to sample collectors and their local IRBs.

University Related Documents:

SOP 1205: Certificate of Confidentiality
SOP 502: Exempt Research

References:

OHRP's Issues to Consider in the Research Use of Stored Data or Tissues
OHRP's Guidance on Research Involving Coded Private Information or Biological Specimens
OHRP Video: Research Use of Human Biological Specimens and Other Private Information

History:

Effective Date:
Revisions: November, 2018

Responsible Office:

Office of Research Compliance and Assurance