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*

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

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*

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 specimens repositories for research purposes should include the following information, as applicable:

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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

University Related Documents:

SOP 1205: Certificate of Confidentiality
SOP 502: Exempt Research

References: