SOP 1.2.4 Biobanks and specimen/data repositories

General Description:

The collection of specimens or data for research purposes is human subjects research. Biological specimen banking/repositories should be subject to oversight by an Institutional Review Board (IRB). For the purposes of this document, biobanks and research repositories store human biological specimens/data for current or future research purposes.

The following are definitions or examples of creation or usage of repositories that are considered human subjects research under 45 CFR 46.102 and fall under the Mason IRB purview.

- Mason researchers creating a research repository/database ***through intervention or interaction with individuals***
- Mason researchers creating a research repository/database ***by obtaining identifiable private information***
- Mason researchers obtaining identifiable private information, samples or data ***from a GMU-affiliated or non-affiliated research repository/database.***

Generally, the Mason IRB must review the conditions under which identifiable data and specimens obtained for research purposes may be acquired, used and shared by Mason researchers. The following descriptions include types of data sharing research intent.

- GMU PI-initiated biorepository: the Mason PI is collecting and banking specimens only for his/her studies and specimens will not be shared with researchers, inside or outside of the university
- Shared Biorepository: specimens are collected and banked at Mason for one or more researchers and shared with other researchers inside or outside of Mason (shared biorepository).
- Known Research Purpose: specimens/ data are collected for a known research/investigative direction or study
- Future/Unspecified Research Purpose: specimens/data are collected for use in future research activities, the purpose of which may not yet be known or will be determined at the time of IRB review.

The Mason IRB must review and approve a protocol that describes the operation of the repository/biobank, including specimen and data storage, specimen and data sharing, withdrawal of specimens, informed consent process, and a privacy and confidentiality protection plan.

Informed Consent

Written informed consent should be obtained from each subject in accordance with Department of Health and Human Services (HHS) regulations at 45 CFR 46.116, unless waived by the IRB (See SOP Waiver of Consent). Included among the basic elements of informed consent should be a clear description of (i) the operation of the repository; (ii) the specific types of research to be conducted; (iii) conditions under which data and specimens will be released to recipient-investigators; and (iv) procedures for protecting the privacy of subjects and maintaining the confidentiality of data.

Informed consent information describing the nature and purposes of the research should be as specific as possible. Where human genetic research is anticipated, informed consent information should include the required GINA (Genetic Information Nondiscrimination Act) language. Informed consent documents may not include any exculpatory language through which subjects are made to waive or appear to waive any

legal rights. The Investigator may request and the IRB may approve a consent procedure that omits or alters some or all of the elements of informed consent as per federal regulations and IRB Policy, but investigators should note that in requesting a waiver, they must justify that the research could not practicably be carried out without the waiver or alteration.

Re-contacting of donor-subjects for new consent may be required by the IRB when the intended research use of the material is not consistent with the original purpose noted in the consent form used at the time the material was collected. Additionally, the IRB may also require a new consent procedure once a donor-subject reaches the age of majority and the materials were stored by the donor-subject during his/her childhood.

Usage Agreements
A written usage agreement for recipient-investigators should be implemented for all appropriate parties and must recognize that the research material may only be utilized in accordance with the conditions stipulated by the approved IRB protocol. Any additional use of the material requires prior review and approval by the IRB and, where appropriate, by an IRB at the recipient site.

Development of Repository
IRB review must ensure adequate provisions are in place to protect the privacy of subjects and maintain the confidentiality of data. The following criteria apply to a Mason PI-dedicated on-site repository:

- PI must serve as the biorepository director and be responsible for all collection, access and sharing of information or specimens,
- PI must establish the necessary banking protocol(s), which undergo continuing review at least annually by the IRB (unless deemed exempt),
- The proper informed consent procedures must be completed, indicating the use of samples for current and/or future (known or unknown) usage,
- PI must collect only the minimum necessary from the subjects and their records,
- Identifiable data linked to specimens must be stored in a locked file cabinet or in an electronic file that meets university security rules,
- Data use agreement (DUA) or data transfer agreements (DTA) must be utilized for accessing and/or sharing of data or samples from the repository.

HIPAA
HIPAA regulations apply when the research study involves the 1) use or disclosure of PHI from a covered entity to create the research or repository database, and/or 2) subsequent use or disclosure of PHI from a covered entity in the repository/database. HIPAA authorization can be obtained to create a repository, but that authorization does not cover subsequent research uses of identifiable data.

Procedures:

1. **Creation of Repository SOP.** Standard operating procedures for the repository should be drafted by researchers in consultation with appropriate authorities at Mason, including, but not limited to, facility managers, Information Technology Unit, and the PI's department. A successful repository or bank should have an effective operational plan for specimen/data/record acquisition, handling, tracking, distribution and final disposition. A well-developed operational plan will include written policies and procedures, as well as a secure system for managing records.

2. **IRB Review**
    a. Before a repository or biobank is established to store data or tissues intended for research purposes, the IRB shall review and approve a protocol that describes the operation of the

repository/biobank, including specimen and data storage, specimen and data distribution, withdrawal of specimens, informed consent process, and privacy and confidentiality protection plan.

b. The IRB will ensure the following questions are addressed:
    i. Who has responsibility for the integrity of the repository and who can have access to the repository for research purposes and how is access granted?
    ii. What is the process for informed consent related to the registry specimen bank?
    iii. How is privacy and confidentiality ensured?
c. Continuing Review will occur at the designated intervals as deemed appropriate.

Related Forms, Guidance, and SOPs:

- Waiver of Consent; 45 CFR 46.116(f)
- Based on UCLA "Guidance and Procedure: Data and Specimen Repositories".
- OHRP-Guidance on Research Involving Coded Private Information or Biological Specimens (2004).
- 45 CFR 46.116
- OHRP- Issues to Consider in the Research Use of Stored Data or Tissues. (1997)

Responsibility:

Execution of SOP:
Principal Investigator
Study Team Members
IRB Staff

Approval and Version History:

Please contact irb@gmu.edu if you have any questions about this policy or the version and approval history.

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Approved By	Title and Division	Date Approved
Aurali Dade	Associate Vice President, Research Development, Integrity and Assurance	November 19, 2014
Greg Guagnano	IRB Chairperson	November 19, 2014