INSTITUTIONAL POLICY & PROCEDURE

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TITLE: Institutional Review Board Special Considerations
SC 509 Biorepository and Biospecimen Research

ORIGINATOR: Institutional Official

APPROVAL: Institutional Official

POLICY STATEMENT: Research repositories are designed to store human biological specimens/data for future research. Research on human biological materials has led to critical discoveries that have improved public health care. Mercy Health IRB requires repositories receive IRB review, but they are not, in and of themselves considered research as they are designed for the storage of specimens and/or data. They are not intended to answer any research questions themselves. They are a bank of data or specimens held to be used for future research. Future research in which the data and/or specimens will be used will require separate approval for each individual study. This policy describes Mercy Health IRB requirements pertaining to the establishment and usage of biorepository data and biospecimen banks to be used for future research purposes. The IRB acts as a steward, on behalf of biospecimen and biorepository research participants, to ensure the protection of their private health information within a research setting.

This policy also describes the Mercy Health IRB criteria pertaining to the collection of specimens to be sent for storage at collaborating/cooperative regional or national biorepositories. Plans for contributing specimens and/or data to a biorepository or biospecimen bank will be considered on a case by case basis, however, general participant protections apply. As research biorepositories and future biospecimen research become more and more common within study protocols or as a free-standing research endeavor it is important for the Mercy Health IRB to provide clear expectations and guidance with regard to the collection, storage and use of human data and specimens.

GENERAL PROVISIONS:

Access to and Use of Existing Collections of Biospecimens
Existing collections of biospecimens may have been developed over a period of time without use of written consent from subjects, or a limited consent from subjects may have been obtained during clinical procedures. Recontact of donors may be difficult or impossible. In such situations, investigators should submit an initial application package (See IRB SOP RR 402) to the Mercy Health IRB for access to and use of the existing biospecimen collection and should define the procedure to deidentify the biospecimens they propose to use for research purposes. Such procedures to deidentify the biospecimens per HIPAA standards should be approved by the IRB. The investigator must also define if data is to be released with the specimens. If data is to be included in the release of specimens, the protocol should clearly define the elements of data to be released, plan for coding, deidentification and tracking.

The Mercy Health IRB may determine that a usage protocol is not covered by this policy if the data/specimens in the registry cannot be linked, directly or indirectly (via code), to any living human entity or if the dataset to be obtained will have no codes or identifiers AND if the registry data was not obtained for the specific protocol in question. The OHRP Guidance Document: “Research Involving Coded Private Information or Biological Specimens” will be used to determine applicability for IRB review.
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New Collections of Biospecimens and Data
During the collection of biospecimens or data for a biorepository the Mercy Health IRB provides evaluation and oversight of all elements of repository activity; the conditions for collection, secure storage, maintenance, and appropriate sharing of the data and/or tissues with internal and external investigators. Specifically, the IRB determines the parameters for sharing data and/or tissues (which are identifiable within the repository) including whether additional informed consent of subjects is required.

Typically, the parameters for allowance of release of biospecimens and information involve formal, written agreements stipulating conditions as follows:
(1) The repository shall not release any identifiers to the investigator.
(2) The investigator shall not attempt to recreate identifiers, identify participants, or contact participants.
(3) The investigator shall use the data and/or specimens as outlined in the written protocol and approved by the Mercy Health IRB.

The investigator shall comply with any conditions determined by the Mercy Health IRB to be appropriate for the protection of participants.

When collecting biospecimens for current research purposes. The protocol document must include a plan for the following:
1. Maintaining the security and confidentiality of the samples or data.
2. Assurance that all biospecimens or records contributed to the biorepository or biospecimen bank are accompanied by a signed current IRB-approved banking consent document, unless the IRB has made other provisions.
3. A plan for collection, preparation, storage and release of the samples.
4. A plan for destruction of the biospecimens and/or data populating the biorepositories in anticipation of the conclusion of the study.

In general protocols for biorepository and biospecimen use should define the general nature of the testing that will occur using the samples or data. A detailed description of the steps and processes used to link biospecimens and identifiable information, and procedures used to maximize the protection against inadvertent release of confidential information.

In the case of collaborative research (where specimens are collected at Mercy Health) are sent elsewhere, the research protocol should describe a plan for the collection, transfer, and maintenance of such biospecimens outside of Mercy Health. When research biospecimens are no longer being collected at Mercy Health for transfer to the outside entity, and study stipulations are met, the study can be closed with the IRB.

Informed Consent Requirements
The common rule permits the IRB to consider waiving the informed consent in situations in which there is:
1) Minimal risk
2) Respect for the rights and personal autonomy of the individual
3) It is impracticable to obtain consent (e.g. the samples were archived many years in the past and there is no current means of contacting the individuals)
4) Notification will be made to the individuals when possible

In recognition of the potential importance of archived samples for research, the HIPAA regulations that went into effect in 2003 permit the use of unidentified samples collected prior to April 14, 2003, without informed consent under certain circumstances. Private information is considered identifiable if it can be linked to a specific individual by the investigators either directly or indirectly through coding systems. In assessing risk the IRB will consider whether the proposed activity involves the prospective collection of samples or is a retrospective and will use archived samples.

When informed consent to the research use of human biospecimens is required, it should be obtained separately from informed consent to clinical procedures (i.e., not combined with a general surgery or pathology consent). The person who obtains informed consent in the clinical setting should make clear to potential subjects that their refusal to consent to the research use of biological materials will in no way affect the quality of their clinical care.

The informed consent statement must include the required elements of an informed consent (see IRB SOP IC 701). In addition, the storage and use of biospecimens collected and utilized for research purposes requires special consideration and explanation of issues specific to the research that is being proposed.
The informed consent document should address the following in addition to the standard informed consent criteria outlined in 21 CFR 50 and must also include HIPAA Authorization elements as outlined in 45 CFR 164:

1) The purpose and background of the biorepository or biospecimen collection
2) The type of specimen or data to be collected (i.e. blood, tissue, urine, swab)
3) How and when the specimen or data will be collected
4) Where the specimen or data will be stored
5) How long the specimen or data will be stored
6) How the specimen will be used (for lung cancer research, any cancer research, any disease research)
7) When/if the specimen or data will be destroyed
8) Who has access to the specimen or data (will commercial organizations be allowed to access the specimen or data?)
9) If genetic information will be evaluated, used or discovered how it will be protected and who may have access to that information.
10) A statement outlining that it is possible new products or information may be developed through the course of use of the participants specimens or data and that the participant has no proprietary rights to the intellectual property or income from the new product or new information.

The informed consent document should include pertinent information, allowing the research participant to determine whether:

- The data/tissues collected may be used for research related to a specific problem or disease,
- The data/tissues collected may be used for research directed to any reasonable research question pertaining to health care

Collection of Biospecimens for Future Research Purposes

In the event an investigator proposes the collection of biospecimens for future research purposes he or she must be specific in the description of what the future research focus will be. The investigator should describe the specimen will be used for future research purposes and then identify the specific type of research it could be used for (i.e. detecting, preventing, studying the cause of, diagnosing, or treating). A biospecimen being collected for future research could be stored for use for all of those things and if so, the informed consent should state the future research purpose as clearly as possible. The investigator should follow the steps described above for developing an informed consent and protocol.

The IRB will consider the following issues when reviewing biorepositories being established for future research

1) Tissue ownership
2) Privacy
3) Confidentiality
4) Mechanisms for withdrawing specimens from the repository
5) Oversight of future research involving the banked specimens
6) Repository operations
7) Informed consent process

Establishing or Participating in a Biorepository

Before a biorepository may be established to store data or tissues intended for future research purposes, the IRB shall review and approve plans submitted by a qualified investigator, including who will exercise control over the biorepository.

If contributing to a biorepository outside of Mercy Health, the protocol should describe the control and management of the registry. The registry plan should also describe the role(s) of other individuals who may have access to the registry, (e.g. for data entry or retrieval purposes, including non-Mercy Health investigators, if applicable). The IRB recommends that the PI implement standard operating procedures that describe individuals who may have such access, for what reasons, and an explanation of the expectations of their training. The IRB may require standard operating procedures be developed or provided for a particularly complex or sensitive registry.

The registry PI should describe procedures for releasing identifiable or coded registry data to registry usage protocol investigators. Such procedures should correspond to information described within the registry informed consent form, if applicable. Such procedures should be clearly described in cases where Mercy Health PIs will be contributing data/specimens to a collaborating institution.

Definitions:

Biorepository: An organized collection of retrievable, identifiable information (pertaining to living humans) that is intentionally maintained for use as a prospective instrument for the conduct of research. A research registry may also be called a Biorepository.

Biospecimen: A quantity of tissue, blood, urine, or other human-derived material. Examples of biospecimens include: subcellular structures (e.g., DNA), cells, tissue (e.g., bone, muscle, connective tissue, and skin), organs (e.g., liver, bladder, heart, and kidney), blood, buccal swabs, saliva or other body fluids, and waste (e.g., urine and stool)
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Biospecimen bank: Biospecimens collected for future research purposes as part of a specific protocol are stored together as a source for future research activity.

REFERENCES:


NCI Office of Biorepositories and Biospecimen Research


ATTACHMENTS:
SC 509-A Worksheet for Review of Biorepository and Biospecimen Research

PROCEDURE: All Mercy Health Campuses

<table>
<thead>
<tr>
<th>Responsibility</th>
<th>Action</th>
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<tbody>
<tr>
<td>IRB Specialist/IRB Coordinator</td>
<td>1. Review incoming submissions and determine if they are a focused biospecimen or biorepository research project.</td>
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<td>2. Inform IRB Chairperson of receipt of a biospecimen or biorepository submission package.</td>
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<td>3. Prepare biospecimen or biorepository submission package for IRB Review.</td>
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<td>4. Provide review package to IRB Chair for review. IRB Chair may assign a designated reviewer.</td>
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<td>5. Issue correspondence as advised by the IRB Chairperson.</td>
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<tr>
<td>IRB Chairperson</td>
<td>1. Review incoming submissions that are focused on biospecimen and biorepository research. May assign a designated reviewer.</td>
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<td>2. Complete worksheet as appropriate.</td>
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<td>3. Inform IRB Clinical Research Assistant/IRB Coordinator of completed review.</td>
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<tr>
<td></td>
<td>4. Advise IRB Clinical Research Assistant/IRB Coordinator of correspondence to be issued.</td>
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<td>IRB Committee</td>
<td>1. Review protocols containing plans for a biorepository or biospecimen research via an appropriate category (expedited or full committee review as assigned). If a registry proposes to collect and store sensitive data or biospecimens, such that the potential risk is greater than minimal risk, utilize full board review.</td>
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<tr>
<td>Investigator</td>
<td>1. Submit biorepository and biospecimen research to the Office of the IRB for review prior to implementation of any study activity.</td>
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2. Ensure the integrity of the biorepository.
3. Ensure that the biorepository is protected.
4. Monitor and record all releases of specimens and data related to biorepositories and biospecimen research.
5. Prepare and submit biospecimens as required by the protocol.

CONCURRENT CONSENTS:
Institutional Official [Signature]