University of Michigan Medical School Central Biorepository Policy  
Establishment of New Biospecimen Collections within the Central Biorepository

I. Purpose

The UMMS Central Biorepository (“CBR”) is an institutionally supported core biorepository facility and database for research that is composed of multiple human biospecimen collections. This policy operates subject to the University of Michigan Medical School (UMMS) Policy Governing Tissue Sample Collection, Ownership, Usage, and Disposition Within All UMMS Research Biorepositories (“UMMS Tissue Ownership Policy”) and applies to all biospecimens submitted to the CBR for storage. This policy establishes requirements intended to ensure that all biospecimens held by the CBR have been acquired and managed responsibly and in accord with all applicable regulations, policies, and sound ethical principles.

II. Principles

A. The CBR is institutional infrastructure intended to advance the UMMS research mission by increasing the quality and efficiency of human biospecimen studies and by facilitating collaboration among U-M investigators.

B. Long-term storage of biospecimens allows development of collections sizable enough to enable high-quality scientific investigations of them. At the same time, for the CBR to be a valuable institutional resource and financially sustainable, use of CBR biospecimens for active research must keep adequate pace with deposit of new CBR biospecimens. Therefore the CBR will accept deposits of biospecimens that can reasonably be expected to be used in a timely manner for quality research purposes.

C. In accordance with the UMMS Tissue Ownership Policy, CBR resources are donated by research participants to the University, with the University retaining the ownership of these biospecimens and any derivatives, unless stipulated otherwise by research agreements for which biospecimens are collected.

III. Policy

A. The CBR may accept any human biospecimens that are prospectively collected according to processes developed jointly by the contributing investigator’s team and CBR personnel. In very rare circumstances, the CBR Governance Committee may consider exceptions to the
prospective-collection requirement by taking into account a retrospective collection’s quality, purpose, associated data, safety, and expected duration of storage.

B. The CBR operates at Biosafety Level ("BSL") 2 and will not accept biospecimens categorized as BSL 3 or 4.

C. Biospecimens may be deposited into the CBR for storage for specific periods of time, until a specific target number of specimens is met, or indefinitely.

D. Investigators seeking to establish a biospecimen collection within the CBR must gain approval from the CBR Director and/or the CBR Governance Committee. Approval for entry will not be unreasonably withheld from project teams that provide a completed CBR Application for Storage and meet the requirements of Subsection E, below.

E. Requirements for participation. Establishment of a CBR biospecimen collection requires that contributing investigators:

1. State a clear and defensible initial or potential research purpose for creation of the proposed biospecimen collection. Establishment of a biospecimen collection for future research meets this requirement when it can reasonably be expected that the collection will be adequately in demand among the research community.

2. Describe the funding intended to support the proposed biospecimen collection.

3. Allow the CBR to make available limited information about deposited biospecimens to other investigators and be willing to review proposals for secondary use of deposited biospecimens, according to the CBR policy “Use and Distribution of CBR Biospecimens and Data.”

4. Seek consent from biospecimen donors according to the CBR policy “Consent and HIPAA Privacy Rule Authorization.”

5. Submit with each biospecimen the following associated data, as appropriate:
   a. Donor information: sex; race/ethnicity; age at time of collection;
   b. Diagnosis under investigation, if any;
   c. Type and appropriate details of collection procedure;
   d. Date of collection;
   f. Records or verification of donor consent and/or authorization;
g. Any additional data (e.g. clinical, survey, laboratory results, etc.) fundamental to the biospecimen’s research value that can be accommodated by the CBR laboratory information management system.

Exceptions to (3) and/or (4) of this subsection may be sought by special application to the CBR Governance Committee. Terms of any nonstandard arrangements approved by the Governance Committee will be documented.

F. Subsequent to approval for entry and prior to acceptance of biospecimens into the CBR, the following materials must be prepared or compiled by CBR personnel and/or contributing study teams:

1. A signed and completed *CBR Study Requirements Specification* document;
2. Logistics, workflow, kit preparation, and other operations documents;
3. An Oversight Committee charter as described in the UMMS Tissue Ownership Policy, if necessary;
4. Either:
   a. Project ID (HUM# or REP#) from a University of Michigan Institutional Review Board (IRB);
   b. Current documented approval from another IRB registered with the U.S. Department of Health and Human Services Office for Human Research Protections (OHRP);
   c. Current documented approval from another appropriate ethics committee, only if the project is not subject to U.S. federal regulations;
   d. A letter of determination, issued by an IRB or other appropriate ethics committee, that the project need not undergo committee review; or
   e. Sufficient evidence to support a determination that the project need not undergo IRB or ethics committee review.
5. A signed *CBR Biospecimen Submittal Agreement* or copy of another controlling Submittal Agreement; and
6. Unsigned copies of all consent and/or authorization documents, and other documented agreements, under which any of the biospecimens being deposited will be collected, except those documents uploaded to the U-M eResearch system.
IV. References

University of Michigan Medical School (UMMS) Policy Governing Tissue Sample Collection, Ownership, Usage, and Disposition Within All UMMS Research Biorepositories:

CBR Application for Storage

CBR Policy GOV003 – Use and Distribution of CBR Biospecimens and Data

CBR Policy GOV005 – Consent and HIPAA Privacy Rule Authorization

CBR Study Requirements Specification Document

CBR Biospecimen Submittal Agreement

V. History of Policy

A. Original Approval Date

July 16, 2015

VI. Approval on behalf of the UMMS CBR Governance Committee

Signed by: Victoria Blanc, Director UMMS CBR on 7/24/2015
(Signed/original document on file at CBR)