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

I. Purpose

The UMMS Central Biorepository (CBR) is a repository of human biospecimens that serves as central storage facility, point of research access, and administrative hub for research using these biospecimens and data associated with or derived from them. 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 CBR resources. This policy establishes requirements intended to ensure that all CBR resources are acquired and managed responsibly and in accord with all applicable regulations, policies, and sound ethical principles.

II. Definitions

CBR program: A U-M research effort that participates in the CBR by collecting biospecimens and storing all or some of those in the CBR.

CBR resources: Biospecimens collected under a CBR program and data associated with or derived from those biospecimens for research.

Collection: The CBR resources comprised by a single CBR program.

III. 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.

IV. 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.

B. The CBR Governance Committee may approve transfer of a preexisting collection to the CBR by taking into account the retrospective collection’s quality, purpose, scientific value, associated data, safety, and expected duration of storage.

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

D. 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.

E. Investigators seeking to establish or transfer a biospecimen collection to the CBR must gain approval from the CBR Director or the CBR Governance Committee. Approval for entry will not be unreasonably withheld from project teams that provide to the CBR a completed formal request for services, undergo an audit of any retrospective biospecimens for which storage is requested, and meet the requirements of Subsection F below.

F. 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 establishment of the biospecimen collection within the CBR. Establishment of a biospecimen collection solely for future unspecified 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 **GOV003 Use and Distribution of CBR Biospecimens and Data**.

4. For prospective collections, seek consent from biospecimen donors according to the CBR policy **GOV005 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;
   e. Records or verification of donor consent and/or authorization;
   f. 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 (LIMS).

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.

G. 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. Documentation of the details required to enable accounting of the biospecimen collection by the CBR LIMS and to establish joint work processes;

2. As applicable, logistics, workflow, kit preparation, and other operations documents;

3. An Oversight Committee charter for the Collection, 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.

V. References

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

GOV003 Use and Distribution of CBR Biospecimens and Data

GOV005 Consent and HIPAA Privacy Rule Authorization

GOV004-T01 Biospecimen Submittal Agreement

45 CFR 46 (2009)

VI. History of Policy

A. Initial Approval Date:

July 16, 2015

B. Revisions
1. 06/15/2017: Scope of this policy harmonized with that of the CBR Certificate of Confidentiality; titles removed from referenced work documents.

VII. Approval on behalf of the UMMS CBR Governance Committee

Signed by: Victoria Blanc, Director of University of Michigan Medical School Central Biorepository on 15 June 2017
(original signed document on file at CBR)