University of Michigan Medical School Central Biorepository Policy
Use and Distribution of Central Biorepository Biospecimens and Data

I. Purpose

The University of Michigan Medical School ("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 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 a framework for appropriate utilization of CBR resources. It:
- Fosters collaboration among U-M investigators;
- Provides a means for equitable access to CBR resources;
- Ensures that use and distribution of CBR resources meet all regulatory, legal, and ethical standards;
- Promotes use of CBR resources for scientifically sound and valuable research; and
- Facilitates efficient and proper distribution of CBR resources.

II. Definitions

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

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

Collection: All the CBR resources comprised by a single CBR program.

Primary Use: A specific research use (i.e., testing of a specific hypothesis or set of hypotheses) for which a resource was initially acquired in compliance with all applicable legal requirements.

Secondary Use: Any other research use, whether proposed by the investigator who acquired and/or deposited the resource into the CBR or by any other investigator.

Use Proposal: An application to the CBR seeking approval for a
Secondary Use of CBR resources.

Oversight Committee: A committee for review of Use Proposals concerning a particular Collection. Oversight Committees are subject to standards established in the UMMS Tissue Ownership Policy.

III. Principles

A. In accordance with the UMMS Tissue Ownership Policy, CBR resources are donated by patients and 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.

B. Meritorious Secondary Uses of CBR resources are valuable opportunities for collaboration among investigators, strengthen the research portfolio of the University of Michigan Medical School, and speed the pace of research.

C. The investigators who deposit any particular biospecimens into the CBR are typically in the best position to assess the merit of Use Proposals pertaining to those biospecimens.

D. The CBR Governance Committee is chartered to act as an Oversight Committee under the UMMS Tissue Policy.

IV. Policy

A. Distribution Requests will be fulfilled only for:
   1. Primary Uses; and
   2. Secondary Uses that have been approved by either:
      a. the CBR Governance Committee, acting as an Oversight Committee;
      or
      b. the otherwise designated Oversight Committee(s) for the Collection(s) from which the requested resources originate.

B. Any Use Proposal seeking CBR resources from multiple Collections may be reviewed only by the CBR Governance Committee rather than by the multiple designated Oversight Committees, except to whatever extent other agreements require that those committees also review such a Use Proposal.

C. When the CBR Governance Committee acts as an Oversight Committee, each principal investigator who deposited any of the
CBR resources subject to the Use Proposal under review will be included as a voting member of the Committee.

D. Any change in the scope of a use approved under Section IV(a)(2), above, must be approved by the Oversight Committee(s) that granted the initial approval.

E. Decisions made on Use Proposals under Section IV(a)(2)(ii), above, may be appealed to the CBR Governance Committee by any involved party. Decisions made by the CBR Governance Committee on Use Proposals may be resubmitted with changes or, thereafter, appealed to the Dean of the Medical School or the Dean’s designee. Appeals must be submitted in writing and must present the appellant’s specific disagreements with the judgment of the committee.

F. The CBR Governance Committee may suspend or terminate approval of research using CBR resources if an investigator fails to comply with applicable policies or procedures or to exercise his/her access within a reasonable period of time.

V. Procedures

A. Designation of Oversight Committees. Any investigator depositing materials into the CBR may request, during the onboarding process or at any later time via the CBR Director, that the CBR Governance Committee designate a committee other than itself as the Oversight Committee for any Collection(s) contributed by that investigator. The CBR Governance Committee may so designate that committee if it meets the standards established for Oversight Committees in the UMMS Tissue Ownership Policy.

B. Use Proposals. In most cases, Use Proposals will be developed in collaboration with the investigators who contributed the CBR resources of interest. Investigators interested in preparing a Use Proposal for submission to an Oversight Committee may contact the CBR at any time for assistance, such as a request for study contact information, or what information each Oversight Committee requires for its review. Secondary Uses will be considered fully approved and actionable when the following have been provided to CBR staff:

1. Documented approval of the Use Proposal by the designated Oversight Committee(s) for the CBR resources sought, including a clear statement of the approved aims and hypotheses to be tested;

2. A description of the CBR resources approved for distribution under the use, including but not limited to their type, number,
and quantity;

3. Documented approval by a federally registered Institutional Review Board or other appropriate ethics committee;
   or
   Sufficient detail (including all data elements that will be combined and associated with the biospecimens sought) for the CBR to determine that the proposed project is not regulated by human subjects protections regulations;

4. Signed copies of required Materials Transfer Agreements and/or Data Use Agreements.

The CBR may provide letters of conditional approval, such as for grant applications, when one or more of the above elements has not yet been completed. However, such conditional approval will not permit distribution of CBR resources.

Investigators are encouraged to keep CBR staff as informed as possible as Use Proposals develop so that issues can be anticipated and managed, necessary documentation can be timely prepared, and CBR staff can assemble any additional materials to assist in Oversight Committee review.

C. Recording approved uses. The CBR will maintain records of the uses for which CBR resources may be distributed. CBR staff will provide investigators with copies of any such records relevant to their approved uses.

D. Distribution of biospecimens. CBR staff will distribute requested biospecimens, and will track these distributions, after receiving the following information from the requestor:
   • The approved use to which the resources will be put;
   • The specific resources being requested, with reference to Sample IDs, including alternates;
   • Any sample processing requirements; and
   • Shipping address.

E. Distribution of biospecimen-associated and biospecimen-derived data. Requested data accommodated by the CBR laboratory information management system (LIMS) will be transferred to approved users in accord with the CBR’s current technical capabilities. CBR staff will provide approved users with available information about how CBR-resource data accommodated by systems other than the CBR LIMS can be sought.

F. Amendments. Investigators may contact CBR staff to seek approval for changes to the scope of a previously approved project (e.g., any change to hypothesis being tested, or to type, number, or quantity of biospecimens sought). CBR staff will route the amendment to the
appropriate Oversight Committee(s) for review and approval, as necessary. No distributions will be made beyond the terms of the documented approval. IRBMED will be notified of any amendment to CBR approval, as necessary.

G. Suspension or termination of committee approval. The CBR Director may, after exhausting reasonable efforts to resolve perceived investigator compliance issues, suspend distribution of CBR resources to the investigator. Any such case will be brought to the CBR Governance Committee for resolution no sooner than seven days and no later than forty-two days from the date of suspension. In resolving any such issues, the Governance Committee will follow institutional policies and procedures and report cases to other institutional entities, including IRBMED as appropriate.

VI. References

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

45 CFR 46 (2009)

VII. History of Policy

A. Original Approval Date: 03/10/2015

B. Revisions

1. 05/19/2015: Reformatted with no substantive changes.

2. 06/15/2017: Scope of this policy harmonized with that of the CBR Certificate of Confidentiality; removed references in procedures section to specific actions in the LIMS that are no longer being used.

VIII. 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

(origininal signed document on file at CBR)