University of Michigan Medical School Central Biorepository Policy
Institutional Review Board Oversight of the Central Biorepository

I. Purpose

This policy is to ensure that Central Biorepository (“CBR”) operations, and research projects facilitated by the CBR, undergo appropriate ethics committee review to protect human research subjects.

II. Policy

A. The CBR will operate subject to initial and continuing review by the U-M Medical School Institutional Review Boards (“IRBMED”).

B. The CBR will accept biospecimens and/or data only from research projects with one of the following:
   1. Current documented approval from IRBMED;
   2. Current documented approval from another IRB registered with the U.S. Department of Health and Human Services Office for Human Research Protections;
   3. Current documented approval from another appropriate ethics committee, only if the project is not subject to U.S. federal regulations;
   4. A letter of determination that the project does not meet an applicable definition of human subjects research; or
   5. Sufficient evidence to support a determination that the project does not meet an applicable definition of human subjects research.

C. The CBR can make determinations as to whether secondary research projects requesting use of CBR specimens and/or data are subject to U.S. federal regulations of human subjects research and IRB oversight.

D. CBR biospecimens and/or data will be made available only to research projects determined not to be human subjects research or which have current approval.

III. Procedures

A. Initial registration/approval of the CBR with IRBMED will be sought through the IRBMED eResearch Regulatory Management system.

B. Amendments to the CBR IRBMED approval, and continuing review of
the CBR, will operate according to IRB MED procedures.

C. CBR personnel, in consultation with IRBMED as necessary, will review documentation submitted by each prospective contributing project to verify that the project meets the requirement of Section II of this policy.

D. Secondary research projects seeking access to CBR resources may request a CBR determination that the project does not meet the definition of research involving human subjects according to U.S. federal regulations. The CBR will make the determination in accordance with IRMBED requirements and in consultation with IRBMED as necessary. The determination and its rationale will be documented and retained, and a copy will be provided to the project team that sought the determination.

E. CBR personnel will review documentation submitted by each proposed secondary project to verify that it meets the requirements of Section II of this policy.

IV. References and Definitions

45 C.F.R. 46 (2009)

V. History of Policy

A. Original Approval Date: 10/16/2014 (approval by vote of CBR Governance Committee)

B. Revisions
   1. 05/18/2015: Reformatted with no substantive changes.

   2. 06/15/2017: Reapproved on routine review with no substantive changes.

VI. 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)