University of Michigan Medical School Central Biorepository Policy
Consent and HIPAA Privacy Rule Authorization

I. Purpose

This policy aims to ensure that donor preferences are given due respect in the conduct of research projects that are facilitated by the Central Biorepository (“CBR”). 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 biospecimens and associated data stored in and managed by the CBR (“CBR resources”). It applies only to CBR resources and not to biospecimens stored or data managed elsewhere. It promotes the ethical use of UMMS resources and sustained public trust in U-M research activities. This policy addresses the following specific issues:

1. Advance consent and authorization;
2. Permissible secondary uses of biospecimens;
3. Information to be disclosed to prospective donors;
4. Tracking of consent and authorization;
5. Management of consent and authorization for minors;
6. Donor withdrawal of consent and authorization.

Principles. Human research participants are entitled to choose whether to begin and continue participation as research subjects based on any available information they would want to know about that research. The CBR will facilitate not only research projects that are planned before the time at which donor permission is sought, but also projects that will be planned after that time. In order to respect donors as persons, all practicable efforts should be made to provide donors with material information about the research in which they participate, including the possibility of future unspecified use of donated biospecimens and/or data.

II. Policy

A. Advance consent and HIPAA Privacy Rule authorization. The CBR will store biospecimens only if they have been collected via a consent and authorization process that meets all legal and institutional requirements. To be valid under this policy, consent and authorization must have been granted voluntarily by individuals capable of consenting, or by an appropriate surrogate, after the individual or surrogate has been informed of all available material information regarding the proposed research activity. If an Institutional Review Board (IRB) and/or HIPAA Privacy Board determines that
consent/authorization are not required for the project, the project must show documentation of the waiver(s) issued by the committee(s).

B. **Permissible secondary uses of biospecimens.** Any biospecimen held by the CBR will be distributed for secondary research use only if the use is compatible with any prior consent/authorization(s) given by the donor from whom the biospecimen is derived. IRB interpretation of prior permissions will be sought when necessary, and CBR interpretations of prior permissions will be made according to the decision chart “Determining whether proposed secondary uses are compatible with prior consent.” The CBR will also recognize determinations that proposed secondary uses are compatible with prior donor permissions when those determinations are made by a designated Oversight Committee approved by an IRB to perform this function.

C. **Information to be disclosed to prospective donors.** Investigators who acquire biospecimens from individual donors at the University of Michigan for deposit into the CBR are required, except with CBR Governance Committee approval, to seek permission for unspecified future research by employing the CBR consent/authorization templates, which are based on U-M templates for repository projects. The CBR templates will be updated as necessary by CBR personnel to ensure they meet all relevant laws, regulations, professional and ethical standards, and CBR policies. Investigators seeking consent/authorization from individual donors at the University of Michigan for deposit into the CBR are required, as permitted by funding and other agreements, to disclose the following to prospective donors:

1. That donation to the CBR is voluntary and one’s healthcare will not be affected by the decision not to participate.

2. That donors agree to any and all future research uses to which donated samples might be put via the CBR.

3. A description of any additional procedures necessary for donation to the CBR.

4. An explanation of how materials and data will be coded or de-identified, as applicable.

5. An explanation of confidentiality protections to be implemented and their limits.

6. That donated specimens will be linked to medical information about the donor.

7. That donated biospecimens and linked data may be shared with other researchers at U-M and elsewhere.

8. That research data may be posted in public databases.
9. That, and how, the donor may withdraw from participation.

10. That even upon donor request, biospecimens and data no longer in the CBR's possession cannot be destroyed.

11. That the donor is granting permission to be re-contacted regarding their willingness to participate in research that requires additional information or tissue samples from them.

12. That the donor is granting permission to be re-contacted in the event that an investigator wishes to return individual research results.

13. That donated biospecimens and data may be used by for-profit companies in the development of commercial products.

14. That donors will not receive compensation for commercialized value of research that results from donated tissues or data.

15. A description of protections and limitations of the U.S. Department of Health and Human Services Certificate of Confidentiality, as long as such a Certificate is in effect for the CBR.

D. Further communication about CBR research. To allow donors to continue receiving information about the research to which they have contributed, the CBR will publicize general information on its website about the research projects conducted using CBR biospecimens.

E. Documentation of consent and authorization. The CBR will at all times retain access to any documented terms of each original donation. The CBR will not acquire or possess signed copies of consent or authorization forms.

F. Management of consent and authorization for minors. Projects that contribute biospecimens obtained from minors will be asked to describe their plans to either:

1. obtain consent from those subjects when they become adults; or

2. seek from an appropriate ethics committee or IRB waiver of consent that will be in effect at the time of donor majority and that contemplates any secondary research uses facilitated by the CBR.

G. Withdrawal of consent/authorization. The CBR will honor, to the fullest extent possible and in accord with documented terms of donor consent, donor requests that biospecimens derived from the donor and data associated with the donor not be used in further research.

III. Procedures

A. Development of consent/authorization documents.

1. During the initial application process, projects that are interested
in contributing to the CBR will be provided with copies of the two-piece CBR permission templates and asked to confirm their willingness to employ them for prospective collection of specimens.

2. For projects that have previous IRB approval at the University of Michigan, CBR staff will access prior approved consent documents through the eResearch system. For projects that do not, CBR staff will request copies of any prior consent and other relevant documents.

3. CBR staff will work with the contributing project team to develop versions of the templates for their project.

4. The project team will include the resulting documents in an application or amendment for IRB review and approval.

B. Tracking of consent and authorization. Contributing projects will be asked to provide any and all documents that bear on allowable future uses of any CBR materials, except those documents contained in the U-M eResearch system. Each unique version of such documents will be reviewed and cataloged by the CBR so that applicable restrictions and allowances that pertain to any given CBR materials can be identified.

C. Verification that proposed Secondary Uses are compatible with consent, authorization, and other agreements. CBR staff will receive and administer proposals for Secondary Uses of CBR materials. As candidate biospecimens for distribution are identified, the restrictions and allowances associated with those specimens will be reviewed, and a report of these will be provided to the investigator(s) who contributed the specimens to the CBR and/or the Oversight Committee(s) responsible for deciding on the Use Proposal.

D. Withdrawal of permission by the donor. Donors who wish to withdraw their materials from further research may contact either the PI of the particular project to which they contributed biospecimens or the CBR directly. Contributing projects and the CBR will forward such requests to each other. Donor withdrawal of permission for future research will result in destruction of all specimens held in the CBR derived from the donor. Disposal of the biospecimens will be recorded in the CBR laboratory information management system.

IV. References and Definitions

45 CFR Part 46 (2009)

45 CFR Parts 160, 162, and 164
UMMS Tissue Ownership Policy: “Tissue Sample Collection, Ownership, Usage, and Disposition Within All UMMS Research Biorepositories” found on the Medical School Intranet under Research Policies

Decision Chart: “Determining whether proposed secondary uses are compatible with prior consent”

U-M Biorepository Consent templates

V. History of Policy

A. Original Approval Date
   July 16, 2015

B. Revision History
   1. 01/26/2016: §II.A edited to allow for post-collection consent processes that have been approved by an IRB.
   2. 03/19/2018: §III(D) edited to clarify that all biospecimens are destroyed following withdrawal of consent.

VI. Approval on behalf of the UMMS CBR Governance Committee

Signature: Victoria Blanc           Date: 03/19/2018

Title: Director, UMMS Central Biorepository

(original signed document on file at CBR)