

 UNIVERSITY OF MICHIGAN MEDICAL SCHOOL MICHIGAN MEDICINE		CENTRAL BIOREPOSITORY
Title	Memorandum of Understanding Regarding Use of CBR Resources	

The CBR will provide certain materials (biospecimens and/or data associated with or derived from them) (“CBR resources”) from individuals who have participated as research subjects in CBR Programs (“CBR participants”), for use in the research project described below. This document outlines data management practices to protect these CBR participants and promote responsible conduct of research.

RESEARCH PROJECT INFORMATION

Oversight Committee approving this use of CBR resources	
Principal investigator for secondary use (PI):	
Project title:	
U-M eResearch ID (HUM#):	
Proposal or Request ID (assigned by CBR):	
Type of biospecimens requested	
Associates and staff of PI who will access and use these CBR resources	

1. The CBR resources provided are to be used only for the purposes specified in the approved CBR Use Proposal Form and the corresponding U-M eResearch application listed above.
2. The CBR, in collaboration with the Data Office for Clinical and Translational Research (“Data Office”), may provide coded datasets for analysis. Any datasets in the PI’s possession that include identifying information that is unnecessary for data analysis are to be destroyed upon receipt of the coded datasets. The Data Office will retain keys to the code and will be able to obtain more information about individual subjects later, if necessary and appropriate.
3. No information identifying these CBR participants, or their relatives or associates, is to be obtained without prior Institutional Review Board (“IRB”) and if appropriate, the approval of the primary study Oversight Committee.
4. These CBR participants, and their relatives and associates, are not to be contacted without prior IRB and primary study Oversight Committee approval.
5. The PI is responsible for protecting the confidentiality and privacy of CBR participants’ information contained in or represented by the distributed CBR resources.
6. The PI is responsible for creating and maintaining a secure data environment, and IRB approval may require a written data management plan that describes the technical, physical, and administrative controls in place to secure distributed CBR resources from unapproved uses and disclosures.
7. The CBR resources provided under this Memorandum are protected by a Certificate of Confidentiality (CoC) issued by the National Institutes of Health. Investigators receiving



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CBR resources are responsible for ensuring that CoC protections are upheld. Specifically, the PI and study team agree to:

- a. Maintain strict data security protocols to prevent unauthorized access, use, or disclosure of protected information;
 - b. Not release any protected information in response to a subpoena, discovery request, or other legal demand unless specifically compelled by law (e.g., mandated reporting of child abuse or harm to self/others) or with the explicit consent of the participant;
 - c. Inform all staff, associates, and agents with access to CBR resources of the CoC protections and ensure their compliance with these requirements.
8. In the event that the study team is contacted for compelled disclosure of information regarding CBR participants, the PI is to contact the University of Michigan Office of General Counsel immediately.
 9. The PI is responsible for any misuse and inappropriate disclosures made by project staff, associates. The PI will ensure that all such individuals understand and agree to the same restrictions and conditions set forth in this Memorandum.
 10. The PI is to report any unapproved uses, disclosures, or inadvertent re-identifications to the Michigan Medicine Compliance Office immediately.
 11. The PI will take any actions as directed by the responsible U-M units to mitigate any harmful effects of any unapproved uses or disclosures of these CBR resources.
 12. No portion of these CBR resources or their derivatives is to be transferred to third parties without prior primary study Oversight Committee and any other required institutional approvals.
 13. All biospecimens are to be handled as if potentially infectious, and the PI is responsible for ensuring the safe handling of biospecimens.
 14. CBR policy (GOV001) requires that the CBR and associated investigators be acknowledged or included as authors in publications, grant applications, and presentations that result from the use of these CBR resources. Specifically, use the following language for CBR acknowledgment: **"The authors acknowledge the University of Michigan Medical School Central Biorepository (RRID:SCR_026845) for providing biospecimen storage, management, and distribution services in support of the research reported in this publication/grant application/presentation."**
 15. The PI agrees to provide the CBR Director or designee with copies or links to all publications and presentations generated from the use of CBR resources or services.
 16. The CBR Director will work with the PI to resolve any perceived compliance issues regarding this project, and either the CBR Director or the PI may bring disputes to other responsible institutional individuals and entities for assistance with resolution.

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Principal Investigator

Date