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 PI is responsible for any misuse and inappropriate disclosures made by project staff and associates.

8. The PI is to report any unapproved uses, disclosures, or inadvertent re-identifications to the University of Michigan Health System Compliance Office immediately.

9. 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.

10. 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.

11. 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.

12. All biospecimens are to be handled as if potentially infectious, and the PI is responsible for ensuring the safe handling of biospecimens.

13. 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.

14. 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.

Principal Investigator Date