University of Michigan Medical School Central Biorepository ("CBR")
Memorandum of Understanding Regarding Use of CBR Resources

The CBR plans to provide certain materials (biospecimens and/or data associated with or derived from them) ("CBR resources") from individuals who have participated as research subjects in the CBR ("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 (PI): _____

Project title: _____

CBR Use Proposal ID: _____

U-M eResearch ID (HUM#): _____

Type of biospecimens included (type none if this request is for data only: _____

Genotyping Data ☐yes ☐ no

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 CBR Use Proposal Form and the corresponding U-M eResearch application listed above.

2. No information that would identify these CBR participants, or their relatives or associates, is to be obtained without prior Institutional Review Board ("IRB") and CBR approval.

3. After completion of any IRB-approved use of identifiable information for cohort development purposes, and prior to distribution of CBR resources, the CBR, in collaboration with the Data Office for Clinical and Translational Research ("Data Office"), will provide coded datasets for final 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.

4. These CBR participants, and their relatives and associates, are not to be contacted without prior IRB and CBR approval.

5. The PI is responsible for protecting the confidentiality and privacy of CBR participants' information contained in or represented by these 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 these CBR resources from unapproved uses and disclosures.

7. The PI is responsible for any misuses 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 CBR and 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 CBR and any other required institutional approvals.

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

13. CBR policy requires that the CBR and associated investigators be acknowledged or included as authors in publications, grant applications, and presentations that result from 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