UNIVERSITY OF MICHIGAN

Data Office for Clinical & Translational Research | **Central Biorepository** | **Precision Health**

Responsible Use of Patient Data and/or Biospecimens Disclosure Attestation

The use of Michigan Medicine's Patient Data and biorepository resources for research or quality improvement purposes is a privilege, not a right. With this privilege comes the responsibility to protect the privacy of individuals who are the subjects of the data and/or biospecimens, to not use, disclose, or transfer data or biospecimens other than as permitted and to appropriately secure the data and/or biospecimens just like Michigan Medicine must do by federal and state law.

Data will not be released to you until you demonstrate that the data will be secured through appropriate administrative, physical, and technical control throughout the life of the project. **Even if all sensitive identifiers are removed from a dataset, the researcher must maintain highly ethical and secure handling practices with the patient data.** Michigan Medicine and Precision Health reserve the right to terminate your access and use of its data should it find that you are in violation of any of the terms and conditions defined herein or as required by law.

Information for users of Precision Health Resources:

This form must be filled out and signed by each user, regardless of role. Please return the signed document to PHDataHelp@umich.edu. **Access will not be granted until the signed document has been received.**

***A faculty sponsor is required for staff and student users of Precision Health Resources.**

Faculty sponsors must discuss ethical and secure data handling and use with the sponsored user. To document this discussion, the attached form must be completed by the sponsored user and signed by both the user and the faculty sponsor.

PROJECT SPECIFIC INFORMATION

User Name: _____

Uniqname: _____ **Role:** _____**Faculty** _____ **Staff*** _____**Student***

User Department: _____ **HUM #:** _____

Project title: _____

Faculty Sponsor*: _____ **Department:** _____

Resource(s) requested (check all that apply):

☐ **PROMPT survey data, unlinked from EHR** ☐ **PROMPT wearable data, unlinked from EHR**

Storage location:_____

Precision Health (PH), the Data Office for Clinical and Translational Research (DOCTR), and the Central Biorepository (CBR) will grant access to patient data and/or biospecimens with the explicit expectation that all responsible data and/or biospecimen use and disclosure provisions outlined below are adhered to (user must initial each item):

_____ I am responsible for protecting the privacy of the individuals' information contained in the Patient Data Set entrusted to me throughout the life of my project.

_____ I am responsible for creating and maintaining a secure data environment throughout the life of my project and must provide, upon request, my written data management plan describing the technical, physical, and administrative controls that I have in place to secure the Patient Data Set from unapproved uses and disclosures.

_____ I may not make any attempt to identify or contact individuals whose health information is contained in the Patient Data Set entrusted to me; unless the information was provided for recruitment purposes as approved by the IRB.

_____ I may use and disclose the Patient Data Set only as permitted by my approved IRB application.

_____ I must report all unapproved uses, disclosures or inadvertent re-identifications of Protected Health Information to Michigan Medicine Privacy office immediately upon discovery. Send notice to compliance-group@med.umich.edu.

_____ I cannot disclose, transmit, or share the Patient Data Set with University of Michigan users who have not been approved for use or outside the University of Michigan without appropriate approvals and without having the appropriate agreements in place with the other U-M users or non-UM entity. Contact DOCTR https://research.medicine.umich.edu/our-units/data-office-clinical-translational-research

_____ I will not remove the Patient Data Set from the designated storage location described above; removal of summary aggregate data for purposes such as manuscript, poster, seminar and grant proposal development, is permitted.

_____ 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 DOCTR will provide coded datasets for final analysis. Any datasets in the PI's possession that include identifying information that is unnecessary are to be destroyed upon receipt. DOCTR will retain keys to the code and will be able to obtain more information about individual subjects later, if necessary and appropriate.

User Signature: _____ **Date:** _____

Sponsor* Signature:_____ **Date:** _____