

Responsible Data Use & Disclosure

Attestation

The use of the University of Michigan's Health System's (UMHS) protected health information 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, to not use or disclose the data other than as permitted and to appropriately secure the data, just like UMHS must do by federal and state law.

Data containing protected health information will not be released to you until you demonstrate that the data will be secured through appropriate administrative, physical, and technical controls throughout the life of the project. UMHS reserves the right to terminate your access and use of its protected health information should it find that you are in violation of any of the terms and conditions defined herein or as required by law.

DEFINITION

HIPAA means the Health Information Portability Accountability Act of 1996, Public Law 104-191 (as amended.)

Covered Entity (CE) means any entity required to comply with HIPAA privacy and security rules. The University of Michigan Hospital System (UMHS) is considered a covered entity because it provides health care services. 45 CFR 160.103.

Protected Health Information (PHI) means information, including demographic data, that is created or received by a covered entity relating to the past, present or future provision of health care or payment for the provision of health care to an individual that either directly identifies an individual or may be used to identify an individual. 45 CFR 160.103.

Limited Data Set (LDS) are data sets stripped of certain direct identifiers specified in the privacy rule. LDS is not de-identified information under the HIPAA privacy rule. 45 CFR 160.103.

Minimum Necessary Standard limits how much protected health information may be used, disclosed, and requested for research or other health care operational functions. The use and disclosure of protected health is limited to only what is necessary to satisfy a particular purpose or carry out a specific function. Minimum necessary standard is a key HIPAA privacy rule protection. 45 CFR 164.502(b).

PROJECT SPECIFIC INFORMATION

Project Title (include HUM #, if applicable): Studies of complex genetic metabolic disease traits in multiple deidentified datasets, Part II - HUM00059029

Purpose of data use and disclosure: [Custom Data Pull (Need DOCTR Analyst to pull the data / fee required)]

Data Type: De-Identified Data Set

Who will have access to the data: All team members have access to data

The University of Michigan Health System agrees to release certain data to the Principal Investigator with the expectation that all responsible data use and disclosure provisions outlined below are adhered to:

- a) You confirm that your request for Protected health information meets the minimum necessary standard, i.e., you requested only the minimum necessary information to satisfy your particular purpose or function.
- b) You may use and disclose the Protected Health Information only as permitted by your approved eResearch Regulatory Management application or as permitted by your contract, if no IRB review is required.
- c) You are responsible for protecting the privacy of the individuals' Protected Health Information contained in the data entrusted to you throughout the life of your project.
- d) You are responsible for creating and maintaining a secure data environment throughout the life of your project and must provide, upon request, your written data management plan describing the technical, physical, and administrative controls that you have in place to secure the Protected Health Information from unapproved uses and disclosures.
- e) You may not make any attempt to identify or contact individuals whose Protected Health Information is contained in the data set entrusted to you unless the personally identifying information was provided for recruitment purposes as approved by the IRB.
- f) You are responsible for all misuses and inappropriate disclosures made by you or by your study team.
- g) You must report all unapproved uses, disclosures or inadvertent re-identifications of Protected Health Information to the UM Health Systems Privacy Office immediately upon discovery. Send notice to compliance-group@med.umich.edu.
- h) You must take action to mitigate any harmful effects caused by all unapproved uses or disclosures of Protected Health Information.
- i) You must promptly notify the Health System's Privacy Office if you receive a subpoena, court or administrative order or other discovery request or mandate asking you to release any part of the Protected Health Information upon receipt of such a request. Send notice to compliance-group@med.umich.edu.
- j) You cannot disclose, transmit or share Protected Health Information outside the University of Michigan without appropriate approvals and without having the appropriate agreements in place with the non-UM entity. Contact the Honest Broker Office <http://research.med.umich.edu/honest-broker-office>.

By signing this document, the Principal Investigator attests that he or she has read each term and condition and understands their role and responsibility in relation to data privacy and data security.

Elizabeth Speliotēs

11/07/18

Name of Principal Investigator (Print)

Date:

Signature of Principal Investigator