



# U-MIC TRANSCRIPT

## Michigan Genomics Initiative (MGI)

As part of the U-M Precision Health Initiative, increased integration is becoming possible across several large-scale institutional research resources.

- MGI (Michigan Genomics Initiative) enrolls patients undergoing surgery at UMHS, obtaining a blood sample for genetic sequencing, as well as consent to link this to structured patient health data and specimens kept for future research analysis, and consent to be contacted by researchers for future studies.
- Central Biorepository houses and processes biospecimens collected through MGI and other research sample collection studies.
- DataDirect is a self-serve tool enabling access to UMHS clinical data such as diagnoses, encounters, procedures, medications, labs and more.

IRB requirements for researchers obtaining data and/or biospecimens depends in large part on the identifiability of data/specimens requested, and on whether the individuals have already provided consent to be contacted for research purposes.

Researchers may use DataDirect, a self-service tool, to assemble a cohort of interest from the more than 4 million unique patients across UMHS's electronic health record system

- Cohort mode provides aggregate counts; no individual-level information is accessible. No IRB application is required.
- Deidentified mode, which includes **only** the MGI cohort of about 60,000 participants, allows users to access individual-level structured patient health data without any HIPAA identifiers. An IRBMED "not regulated" determination is required by the system.
- PHI mode allows users to access and download structured patient health data including PHI. Only PHI types relevant to the specific research are accessible, consistent with an IRBMED approval or "exempt" determination; this only sometimes includes personal identifiers.

PHI mode can be used to identify potential subjects for a prospective study, including contact information. PHI mode also can be used to assemble a dataset for secondary analysis, which may only require a HIPAA "limited data set."

DataDirect identifies which patients have consented to MGI and/or other studies affiliated with CBR. For a given cohort, researchers can request associated genetic data or associated biospecimens. Genomic data may include analyzed genetic data that is de-identified (such as SNP data), which can be transferred to a secure, virtual machine environment pre-loaded with a wide range of tools for researchers' custom analyses. When genomic data is combined with clinical data, UM's Data Office for Clinical and Translational Research, or DOCTR, acts as the honest broker to strip direct identifiers.

Participants may be re-contacted in the future for follow-up studies if they have a genotype or clinical condition of interest to investigators across the U-M research enterprise. Keep in mind, however, that returning research-level genetic results back to MGI participants is not permitted. MGI Committees

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must approve biospecimen requests and requests to re-contact MGI patients, in addition to IRB approval or exempt determination.

Whenever requesting access to MGI resources, be sure to reference MGI study HUM00071298 in your IRBMED application.

Contact the IRB or the Data Office for Clinical and Translational Research for more information about the Michigan Genomics Initiative.

*Posted: November 6, 2019*