

Precision Health at the University of Michigan Policy on Access to Genomic, Health, and Summary Data, Biospecimens, and Re-contact of Research Participants Enrolled in the Michigan Genomics Initiative

I. Purpose and scope

Precision Health is an interdisciplinary program at the University of Michigan, spanning across all colleges, schools, centers and institutes to 1) develop fundamental social, medical, computational, and engineering science; 2) translate basic science discoveries into promising treatments that are evaluated in partnership with Michigan Medicine patients and regional health systems; and 3) evaluate and increase the public health impact of effective therapies, working with community health systems, policy makers, and payers to implement these therapies nationally. A key component of Precision Health is understanding the interplay among genetics, environmental and social variables, and medical phenotypes to develop and promote effective disease treatments and therapies.

This policy establishes a framework for appropriate access to resources derived from research participants in Michigan Genomics Initiative (MGI), as well as procedures enabling re-contact of MGI participants by investigators secondary to the program. This policy outlines ways to

- Respect the contributions and protect the rights of the research participants;
- Ensure that use and distribution of MGI resources meet all regulatory, legal, and ethical standards;
- Foster collaboration among University of Michigan (U-M) investigators and between U-M and outside investigators;
- Provide a means for equitable and efficient access to MGI resources;
- Promote the use of MGI resources for scientifically sound and valuable research.

II. Definitions

Michigan Genomics Initiative (MGI) A subsidiary initiative of Precision Health at U-M; a collaborative research effort among physicians and researchers with the goal of combining patient electronic health records with genomic data and biospecimens to gain novel biomedical insights. For the purposes of this document, MGI comprises both MGI Strategic Cohort and MGI Franchise (see below).

MGI Strategic Cohort A population of participants enrolled in alignment with Precision Health strategic research initiatives. Precision Health personnel and resources are employed in the cohort design, patient enrollment, and sample collection. The regular members of the Precision Health MGI Resource Committee have sole decision-making authority regarding the use and distribution of biospecimens and data collected from these patients.

MGI Biospecimen Franchise A program of study initiated by an individual investigator, or investigative team, who has a reason for enrolling a cohort of patients for their own

research, and would like to contribute to, and benefit from the MGI program, but not participate in MGI otherwise. These contributions are comprised of samples for DNA isolation and genomic analysis.

MGI resources Biomaterials and/or data regarding individuals participating in MGI, as defined below.

1. MGI strategic cohort resources
 - a. Biospecimens
 - b. Genomic data
 - c. Health-related data, separate from the EHR, collected or generated as part of MGI
 - d. MGI participant rosters enabling re-contact of patients for future studies

2. MGI resources derived from an MGI Biospecimen Franchise
 - a. Biospecimens collected or processed using funds from Precision Health
 - b. Genomic data derived using funds from Precision Health
 - c. Health-related data, separate from the EHR, derived using funds from Precision Health
 - d. MGI Franchise participant rosters enabling re-contact of patient for future studies.

Access Permission provided to a scientific investigator to obtain MGI resources for their own research projects.

Access request An application to the Precision Health program through the Data Office for Clinical & Translational Research (DOCTR) to obtain access to MGI resources.

Health-Related Data Clinical, prescription, health claims, survey, epidemiological, environmental, and other data types representing factors that reflect or affect the health of MGI participants.

Genomic Data Data collected across the set of chromosomes and genes from an individual, often to identify genes' functions and their combined influence on the growth, development and health of that person¹, and/or among populations.

Precision Health MGI Access Committee A Precision Health oversight committee for review of Access Requests concerning MGI biospecimens and/or if re-contact of MGI participants is required. This committee is subject to standards established in the *Governing University of Michigan Medical School (UMMS) Research Biorepositories Policy*.

III. Principles

- A. In accordance with the *Governing University of Michigan Medical School (UMMS) Research Biorepositories Policy*, MGI resources are provided for research by patients and research participants to the University, with the

¹ Adapted from the World Health Organization definition of "Genomics".

University retaining the ownership of these biospecimens, derivatives, and data, unless stipulated otherwise by research agreements for which biospecimens or data are collected.

- B.** Precision Health resources are to be used widely by the research community.
- C.** Meritorious uses of MGI resources are valuable opportunities for collaboration among investigators, strengthen the research portfolio across the University of Michigan, and speed the pace of research.
- D.** The investigative team which contributes MGI resources are typically in the best position to assess the merit of access requests pertaining to those biospecimens, data and research participants.
- E.** Biospecimens are limited resources. Potential uses of these resources are reviewed for scientific value; amounts of biospecimens distributed are limited to the minimum necessary for fulfillment of each project.
- F.** Research participants enrolled in MGI have agreed to be re-contacted by investigators as part of their consent to the project. Nevertheless, it is important to respect that re-contact places a burden on research participants. Access requests to patient rosters are reviewed for scientific value and potential burden placed on patients; re-contact permissions will be evaluated in consideration of the number of times certain patients have been approached by virtue of participation in MGI, and the anticipated effect on the well-being of these research participants. Case by case review may be required.

IV. Policy

- A.** The Precision Health MGI Access Committee is chartered to act as an Oversight Committee under the UMMS Tissue Policy. This Committee makes decisions regarding whether and how a proposed use of MGI resources may be fulfilled.
 - a. This Committee has the authority to
 - i. delegate such decisions to subcommittees, at its discretion
 - ii. define the terms and conditions under which uses of MGI resources may be automatically fulfilled
 - b. The Precision Health MGI Access Committee includes (but is not necessarily limited to)
 - i. Regular members
 - a. A Co-Director of Precision Health
 - b. Precision Health Cohort Development Faculty Representative
 - c. Biosciences Initiative Representative
 - d. Precision Health Cohort Development Director
 - e. Medical School Data Office Representative
 - f. Medical School Central Biorepository Representative

- ii. *Ad hoc* members
 - a. MGI Franchise Principal Investigators as required when requests include patients enrolled via their research program.

B. Access requests can be made for the following MGI resources, by any researcher investigator, internal or external to U-M. However, external investigators must have a U-M collaborator to gain access.

1. Genomic data
2. Biospecimens
3. Participant rosters for re-contact
4. Any combination of the above, with or without health data from research participants

C. Approvals

1. IRB approval, determination of exempt human subjects, or non-human subjects research is required before any request for access to individual-level MGI resources is fulfilled.
2. Requests for genomic data with or without additional health-related data, that do not include re-contact of research participants or access to their biospecimens, usually are deemed pre-approved by the Precision Health MGI Resource Committee. Therefore, these requests do not typically require specific committee review.
 - a. Access requests to individual-level MGI genomic data with or without health data are facilitated by the Data Office for Clinical & Translational Research (DOCTR).
3. **When the Access Request includes re-contact of MGI research participants or access to biospecimens, the Precision Health MGI Resource Committee reviews the proposal.** MGI Franchise investigators participate *ad hoc*, as appropriate (if their study participants are involved). The Committee evaluates the proposal based on the following:
 - a. Scientific merit
 - b. Size of requested research cohort
 - c. As applicable:
 - i. Number and amount (e.g. μg , μl , etc.) of biospecimens to be used in the proposed research
 - ii. Number of MGI participants to be re-contacted
 - iii. Methods of re-contact, including what information will be provided to potential research participants for enrollment purposes
 - iv. Number of research programs in which participants from proposed cohorts are already participating
 - v. Potential impact to existing research within the MGI or Precision Health program



- vi. Scarcity of the resources (e.g. a unique or rare patient population; limited amounts of DNA remaining)
4. When the access request includes distribution of individual level data of any kind to industry, non-academic, and non-governmental institutions, approval must be provided by the Data and Biospecimen Use Committee.
5. Decisions made on access requests under Section C3 above, may be appealed to the Chair of the Precision Health Executive Committee, if the requestor is dissatisfied with the outcome of the first review. Appeals must be submitted in writing and must present the appellant's specific disagreements with the judgment of the committee.

V. Procedures

A. Access requests

1. For access to any MGI resources investigators must first submit an access request through the DOCTR office.
2. Research Scientific Facilitators consult with the investigators for project scope, cohort identification, and timeline to completion. Timelines are dependent on the complexity of request and investigator preparedness.
3. A DOCTR-internal regulatory review of the application material is performed and including verification of investigator attestation of approved uses of MGI resources.
4. For access to biospecimens or for re-contact of research participants, the Research Scientific Facilitators forward the request to the Precision Health MGI Access Committee for discussion and approval.
5. Access requests for biospecimens and/or patient re-contact are considered fully approved and actionable when the following have been provided to or by DOCTR staff
 - a. Documented approval by the Precision Health MGI Access Committee for the MGI resources sought by the investigator;
 - b. A description of the MGI biospecimen resources approved for distribution under the use, including but not limited to their type, number, amount, and processing as appropriate;
 - c. A proposed list of patients identified for re-contact or a plan for identifying those to be re-contacted, as appropriate;
 - d. Documented approval by a federally registered Institutional Review Board or other appropriate ethics committee, as necessary;
 - e. Approval from the Data and Biospecimen Use Committee for access requests including sharing of individual level data to industry, non-academic, and non-governmental institutions;
 - f. Signed copies of required Materials Transfer Agreements and/or Data Use Agreements, which may include conditions set by the Precision Health MGI Access Committee, as appropriate.
6. The Precision Health MGI Access Committee may provide letters of conditional approval, such as for grant applications, when one or more of the above elements has not yet been completed. However, such

conditional approval will not permit distribution of or access to MGI resources, until such time as all components are received.

B. Tracking

1. Multiple University of Michigan departments play a role in fulfillment of data, biospecimen, and cohort access requests. A variety of data systems operating independently of, or in conjunction with each other may be used to keep track of the following events and data. The responsibility of each office or unit is described below.
2. The DOCTR will maintain records of the uses under which MGI resources may be distributed. DOCTR staff will provide investigators with copies of any such records relevant to their approved uses.
3. The Central Biorepository (CBR) will maintain records of the number and type of biospecimens distributed, when and to whom, and the source of the MGI collection (e.g. Strategic or Franchise collection).
4. The Precision Health Cohort Development office is responsible for tracking and monitoring which research participants have been contacted for studies in addition to MGI strategic and/or the MGI franchise, the number of such studies that each individual has been contacted for, and their response.

C. Amendments

1. Investigators may contact the DOCTR staff to seek approval for changes to the scope of a previously approved project (e.g., any change to hypothesis being tested, or to type, number, or quantity of biospecimens sought).
2. Any change in the scope of an approved use, must be submitted to the Precision Health MGI Resource Committee for separate approval.

D. Suspension or termination of committee approval.

The DOCTR may, after exhausting reasonable efforts to resolve perceived investigator compliance issues, suspend distribution of MGI resources to the investigator. Any such case will be brought to the Precision Health MGI Access Committee for resolution no sooner than seven days and no later than forty-two days from the date of suspension. In resolving any such issues, the Precision Health MGI Access Committee will follow institutional policies and procedures and report cases to other institutional entities, including IRBMED as appropriate.

VI. References

- A. Governing University of Michigan Medical School (UMMS) Research Biorepositories Policy
- B. U-M Medical School Procedures Governing Human Data & Biospecimen Transfers to Industry or Non-Academic & Non-Governmental Entities

VII. History of Policy

- A. Original Approval Date
- B. Revision History and Summary of Changes

VIII. Approval on behalf of the Precision Health Executive Committee

Signature: _____

Date: _____