PRECISION HEALTH
UNIVERSITY OF MICHIGAN

University of Michigan Precision Health Policy

Contact Information from 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 collaborative research effort with the goal of combining patient electronic health records with genomic data and biospecimens to gain novel biomedical insights. In addition to enabling genome-wide association studies (GWAS) for MGI, biospecimens are banked for future, as yet unknown research purposes. The MY PART study (Michigan and You – Partnering to Advance Research Together, previously known as Precision Health Participant Community or PHPC) is an expansion of the original MGI cohort and is included in the definition of MGI.

Michigan Genomics Partner ("Partner"): A program of study initiated by one or more investigators, who wish to enroll a cohort of patients for their own research and would like to collaborate with Precision Health. Specifically, Partners agree to enroll patients into MGI and contribute biospecimens for DNA isolation and analysis. GWAS data generated as part of MGI are delivered back to the Partner via standard PH procedures. The partnership requires prior approval by the Precision Health Cohort Development Working Group.

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

- Biospecimens
- Genomic data
- Health-related data, separate or derived from the electronic health record (EHR) generated using funds from Precision Health

*Participant rosters enabling re-contact of patients for future studies are “co-owned” by Precision Health and the Partner (see below).

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: Genotype data collected across the set of human chromosomes and genes from one or more individuals. Within PH, this is currently genotype array data in MGI.

Precision Health MGI Access Committee: A Precision Health oversight committee that reviews Access Requests concerning MGI biospecimens and/or re-contact of MGI participants . This committee is subject to standards established in the University of Michigan Medical School Policy Governing Research Biorepositories.

III. Principles

A. MGI resources are provided for research by patients and research participants to the University, with the 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. MGI Partners are typically in the best position to assess the merit of access requests pertaining to those biospecimens 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.
    a. Access requests to patient rosters will be reviewed for scientific value and potential burden placed on patients.
    b. 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

1. The Precision Health MGI Access Committee is chartered to act as an Oversight Committee under the University of Michigan Medical School Policy Governing Research Biorepositories. 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 will represent the following units, departments, divisions, and/or have certain subject matter expertise as defined below. One person may fulfill more than one role.
            1. Precision Health Leadership (e.g. a co-Director)
            2. Precision Health Cohort Development
            3. Medical School Data Office
            4. Medical School Central Biorepository
            5. Research Genetics
        ii. Ad hoc members
            1. MGI Partner Principal Investigators will be invited or consulted when requests include patients enrolled via their research program.
            2. Persons with relevant expertise beyond that of the regular committee, e.g. the Institutional Review Board, may also be invited.
    c. Access requests can be made for the following MGI resources, by any researcher, internal or external to U-M. However, external investigators must have a U-M collaborator to gain access.

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

V. Approvals

1. All requests
    a. 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 MGI resources that do not include re-contact of research participants or access to their biospecimens

a. These requests are deemed pre-approved by the Precision Health MGI Resource Committee, and do not typically require specific committee review.
b. 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. Requests for MGI resources including re-contact of research participants and/or access to their biospecimens
    a. The Precision Health MGI Resource Committee reviews the proposal
    b. The Committee evaluates the proposal based on the following:

        i. Scientific merit
        ii. Size of requested research cohort
        iii. Potential impact to existing research within the MGI or Precision Health program
        iv. Scarcity of the resources (e.g., a unique or rare patient population; limited amounts of DNA remaining)
        v. As applicable:

            1. Number and amount (e. g., µg, µl, etc.) of biospecimens to be used in the proposed research
            2. Number of MGI participants to be re-contacted
            3. Methods of re-contact, including what information will be provided to potential research participants for enrollment purposes
            4. Number of research programs in which participants from proposed cohorts are already participating

    c. MGI Partner investigators are notified if their study participants are involved in a recontact request. Partner PIs are invited to the Committee ad hoc to discuss such requests as necessary.
    d. 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.
    e. Decisions made on access requests under Section V.C.3, 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.

VI. Procedures

A. Access requests
    a. For access to any MGI resources investigators must first submit an access request through the DOCTR office.
    b. 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.
    c. A DOCTR-internal regulatory review of the application material is performed including verification of investigator attestation of approved uses of MGI resources.
    d. 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.

e. 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.

f. 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
    a. Multiple University of Michigan units 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.
    b. 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.
    c. 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 Partner collection).
    d. 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
    a. 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).
    b. 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.
    a. 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.

VII. References

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

Approval on behalf of the Precision Health Executive Committee

Signature: _____

Date: _____