PRECISION HEALTH
UNIVERSITY OF MICHIGAN

University of Michigan Precision Health Policy
Establishing a Michigan Genomics Partnership

I. Purpose and Scope

Precision Health is an interdisciplinary program at the University of Michigan, spanning across colleges, schools, centers, and institutes that seeks 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 partner 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 health phenotypes to develop and promote effective disease prevention, treatments, and therapies.

This policy outlines the ways in which individual investigators may collaborate with Precision Health (PH) by contributing to the participant cohort and leveraging Precision Health infrastructure for genomic data acquisition and analysis.

II. Definitions

Michigan Genomics Initiative (MGI): 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. 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. Genomic 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.

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

a. Biospecimens collected or processed using funds from Precision Health
b. Genomic data derived using funds from Precision Health
c. Health-related data, separate or derived from the EHR, generated using funds from Precision Health
d. Participant rosters enabling re-contact of patients for future studies*

*Participant rosters enabling re-contact of patients for future studies are "co-owned" by Precision Health and the Partner.

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**.**

III. Principles

A. Precision Health is a University of Michigan infrastructure which includes, but is not limited to, resources for recruiting participants into Precision Health research initiatives, such as MGI. This includes deposition of biospecimens, and health-related and genomic data from research participants into repositories broadly available for research uses.
B. Precision Health resources are intended to be used widely by the U-M research community and beyond. Use of these resources beyond U-M requires active involvement of a U-M researcher.
C. Representation across a wide range of disease or therapeutic areas and a diverse research cohort in terms of age, sex, ancestry, race, socioeconomics, and geography is fundamental to the success of the project. Precision Health may engage with Partners to enrich the participant pool across these health, social, and environmental criteria.
D. Principal investigators (PIs) of Partners may receive benefits to their research projects conferred by use of Precision Health infrastructure and resources.
E. In accordance with the Michigan Medicine Tissue Ownership Policy, Precision Health resources are donated by research participants to the University, with the University retaining ownership of these data, biospecimens, and any derivatives, unless stipulated otherwise by the research agreements under which the biospecimens are collected.
F. Partner PIs agree to *The Michigan Genomics Initiative Acknowledgement and Authorship Policy*, when authoring manuscripts, presentations, and posters.

IV. Policy

A. Application and Agreement
    1. The Precision Health Cohort Development Working Group has decision-making authority for approving requests to become a Partner.
    2. Partner provides biospecimens to PH for DNA isolation and genotyping, according to PH standards. Partner also provides controlled access to research participants for recontact, according to procedures below.
    3. PH makes participant genomic data available to Partner, as per PH standard process.
    4. Access to non-genomic study data generated by the Partner may be provided to PH, as mutually agreed between PH and Partner.
    5. The Partner PI or other key stakeholder attests that the study team will conform to Precision Health policies, procedures, and technologies.
B. Funding
    1. The Partner provides funds for research coordinators, sample collection kits, development of study-specific survey tools, and resources for their administration.
    2. Precision Health funds the isolation of DNA from whole blood, saliva, or other biospecimen approved by PH Leadership, genotyping of germline DNA, and long-term storage of DNA at the Central Biorepository for research purposes.
    3. Precision Health funds honest brokering services to maintain a secure linkage between participants' genomic data and their phenotype data from sources like the electronic health record.
    4. The Partner funds the collection, processing, and storage of any biospecimens beyond those agreed upon by PH.

C. Enrollment
   1. Partner enrolls participants expressly stating that the study is aligned with U-M Precision Health and MGI.
   2. Partner recruiters are trained on MGI consent procedures, including the description of MGI, processes for collection of survey data, and participant engagement.
   3. Partner is required to use Central Biorepository informed consent and HIPAA authorization templates provided by IRBMED for participants contributing biospecimens and data to MGI.
   4. Partner may provide participants the option to opt-out of MGI by using two consent forms: 1) for the Partner project only, and 2) for biorepository consent and pamphlet templates. Participants who opt-out of MGI sign only the first consent form.

D. Regulatory and Governance
   1. Partner obtains human subjects research approval from IRBMED.
   2. Secondary access to Partner biospecimens, health related data, and genomic data obtained using Precision Health funds is governed by Precision Health policies and procedures.
   3. Access requests for Partner participant rosters for re-contact are reviewed initially at the Precision Health MGI Access Committee, followed by Partner review.
   4. Partner approval of proposed secondary contact is required before delivery of participant information to a requesting PI.
   5. Partner may require re-contact embargo periods or re-contact limits. Such embargos and limits are approved by the Precision Health Cohort Development Working Group and Partner PI prior to initiation of the Partner project enrollment.

V. Procedures

A. Applications
   1. Partner requests are submitted to the PH Cohort Development Working Group where they are reviewed at least semi-annually.
   2. Requests for Partner status contain, at a minimum:
      a. Description of project including significance and objectives
      b. Brief introduction to the principal and co-investigators
      c. Description of the cohort, proposed number of enrollees, patient demographics, locations of enrollment, and scientific rationale and justification for inclusion of the cohort into Precision Health
      d. Whether survey, wearable, or other technology support is required
      e. Requests for financial or in-kind support, if any
      f. Protocol activities beyond basic PH requirements, as relevant

B. The Precision Health Cohort Development Working Group evaluates the application for:
   1. Contribution of the proposed cohort to strategic aims of PH
   2. Overlap with existing MGI cohorts
   3. Impact on PH budget
   4. Duration of proposed collaboration
   5. Feasibility of implementation among PH partners, especially the Data Office for Clinical and Translational Research, Central Biorepository, and Advanced Genomics Core. The PH Cohort Development Working Group consults representatives from these units as needed.

6. The Working Group reserves the right to limit the number of participants enrolled into MGI via the Partner.
7. Research Facilitators within PH inform the Partner of approval, approval with contingencies, or a choice not to collaborate. Final approval is provided via letter.
8. Partner must agree to the terms and conditions of participation via initialing and signing this document.

C. Regulatory and Governance
1. Each Partner submits a unique IRB application for study approval, referencing the PH repository REP and any other necessary HUM or REP numbers. The final approved protocol is submitted to the PH Cohort Development Working Group.
2. If the Partner includes biospecimen collection at sites external to U-M, the Partner provides copies of all consent and/or authorization templates in use at those locations, and other relevant documents to PH.
3. Precision Health Clinical Research Coordinators train the Partner study team on MGI recruitment procedures, including assessment of understanding.
    a. During recruitment, Partner Research Coordinators inform patients that they are being enrolled in the Partner study, which participates in MGI at the University of Michigan, subject to secondary access procedures of MGI.
    b. If one overarching consent and authorization form is used for the Partner, then the participant is notified that they are being enrolled in that study and MGI simultaneously. If there are two consent and authorization forms used, then the participant is given the option of enrolling in the Partner study, MGI, or both.
    c. When a participant is being recruited to MGI, it is particularly important to highlight the potential for broad use of genomic data, partnerships with industry, resultant issues of privacy, and to evaluate the participants' understanding of these issues.
    d. The Partner agrees to include a minimum set of PH survey elements in the recruiting process and to return these data to the PH dataset.
    e. Prior to initiating enrollment, Partner and PH cohort development will discuss participants' engagement in existing PH surveys.
4. Requests for secondary access to Michigan Genomics Resources follow procedures outlined in *The University of Michigan Precision Health Policy on Access to Genomic, Health, and Summary Data, Biospecimens, and Re-contact of Research Participants Enrolled in the Michigan Genomics Initiative*.
5. Secondary access to biospecimens and data obtained as part of the Partner, but not considered Precision Health resources, is governed by policies and procedures developed by the Partner, and in accordance with other relevant U-M policies.

D. Termination or withdrawal
1. Each year, the Partner is evaluated for continued participation in PH based on evolving strategic goals of Precision Health and Partner metrics. Continued Precision Health support is based upon holistic evaluation of the following information, and reviewed in collaboration with the Partner:
    a. Enrollment rate
    b. Cohort demographics

c. Attainment of diversity goals
d. Available Precision Health resources

2. PH may choose to end the partnership based on the above discussions, budgetary issues, or any other reason, at its sole discretion.
3. Partner may choose to withdraw from continued participation in PH, for any reason, at its sole discretion, by informing the PH Cohort Development of this decision.
4. Biospecimens and the data generated from the Partner while participating in PH will remain under the terms established within this policy.

VI. References

A. Medical School Governing UMMS Research Biorepositories Policy. This policy promotes the effective use of University of Michigan Medical School (UMMS) resources to gather, store, and disseminate human biological specimens intended for research use in accordance with federal and state laws and regulations and sound scientific and ethical principles. It specifies the governance of biospecimen collection, usage, and disposition within all UMMS research biorepositories.

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

C. Michigan Genomics Initiative Acknowledgment and Authorship Policy. This document outlines how and to what extent MGI and related entities are recognized in publications, grant applications, and presentations that use MGI resources.

VII. History of Policy

A. Initial Approval Date: 20 April 2021

B. Revisions
1. N/A

Partner Principal Investigator Attestation: I have read and understand this University of Michigan Precision Health Policy, "**Establishing a Michigan Genomics Partnership"** and agree to abide by the terms and conditions established herein.

Partner PI Signature: _____

Partner PI Name: _____

Date Signed: _____