

NIH POLICY FOR SHARING GWAS DATA

Charge to the

Participant Protection and Data Management Steering Committee (PPDM)

Purpose

The NIH Genome-Wide Association Studies (GWAS) Participant Protection and Data Management Steering Committee (PPDM) advises the Senior Oversight committee (SOC) of the programmatic and policy needs and opportunities related to ensuring robust policies and mechanisms for providing privacy and other research protections to the interests of individuals whose data reside within the NIH GWAS data repository. The PPDM serves as the principal trans-NIH committee to promote communication across the Institutes and Centers (ICs) and to initiate the development and on-going review of specific policies and procedures related to issues of participant protection in GWAS data submission, data management, and data distribution.

Function

The PPDM charge is to stimulate dialog and promote common principles and procedures for requesting and receiving access to GWAS data through the NIH Data Access Committees (DACs). This committee also is specifically tasked with considering the ethics and other participant protection concerns related to the submission of GWAS data by funded institutions in order to promote consistency in the application of the GWAS Policy to incoming datasets. Topics will include procedural standards for data submission, data access, and principles for data security in the secondary use of GWAS data. In particular, the TSC will include a significant focus on ensuring that the DAC procedures and operating practices are consistent across ICs. The PPDM shall provide analyses and make recommendations to the SOC on policy or procedures related to activities within its purview, as well as working directly with its membership to promote common practices across the agency. As needed, PPDM special working groups may be appointed by the chair(s) for specific tasks and time periods. A PPDM member will generally serve as the chair of each special workgroup. Broad representation by IC staff on these working groups will be encouraged as appropriate in order to facilitate discussion from various perspectives and promote consensus in decision making.

Recommendations to the SOC may be based on analyses or recommendations received from established working groups or internal committee work. The PPDM will be asked to work with the Advisory Committee to the Director Working Group for GWAS Participant and Data Protection to consider specific topics within the committee's charge.

Membership

Members of the PPDM will include the Chairs of NIH DACs as well as representatives from appropriate NIH Offices with human subjects and ethics expertise, as determined by the PPDM Chair(s).

The NIH Director will approve the PPDM chair(s) and chair responsibilities will rotate as appropriate. The PPDM chair(s) will provide staff to serve as the Executive Secretary for the committee.

Meetings

Regular meetings of the PPDM will be held at least bimonthly or as otherwise determined to be necessary by the PPDM Chair(s). The Executive Secretary will be responsible for facilitating the preparation of meeting minutes for approval by the chair(s) and distribution to the PPDM members and the SOC Chair(s).

Sunset Provisions

The Charter for the PPDM exists in perpetuity. A periodic review of the charter will occur with current members every three years. Any amendments or termination of the PPDM shall require the approval of the NIH Director.

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Roster for

Participant Protection and Data Management Steering Committee (PPDM)

Chairman:

Michael Gottesman, DIR

Richard Wyatt, Executive Secretary

Craig Woodside, Staff

DAC Chairs (NIH DACs known to date):

Richard Anderson, NIGMS (NIGMS)

Stephen Chanock, NCI (CGEMS)

Hemin Chin, NEI (NEI)

Valentina Di Francesco, NIAID (NIAID)

Katrina Gwinn, NINDS (NINDS)

Emily Harris, NHGRI (GAIN)

Old, Susan, NHLBI

Brad Ozenberger / Gary Temple, NHGRI (TCGA)

Rebekah Rasooly, NIDDK (NIDDK)

Winnie Rossie, NIA (NIA)

Joni Rutter, NIDA Representative (NIDA)

Susan Shurin, NHLBI (NHLBI)

Lu Wang, NHGRI, (NHGRI)

Other HSR Expertise:

Sally Amero, OER representative

Ellen Gadbois CRpac representative (alt. Marianna Bledsoe)

Christine Grady, Bioethics

Charlotte Holden, OHSR representative

Elaine Ayres, CC/BTRIS

Ex-Officio Members:

Valerie Bonham, OGC

Laura Lyman Rodriguez, NHGRI (Staff Liaison to SOC)