The NIH GWAS Data Sharing Policy

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Policy for Sharing of Data Obtained in NIH Supported or Conducted Genome-Wide Association Studies (GWAS)

AGENCY: National Institutes of Health, HHS.

ACTION: Notice.

Background

The NIH is interested in advancing genome-wide association studies (GWAS) to identify common genetic factors that influence health and disease. For the purposes of this policy, a genome-wide association study is defined as any study of genetic variation across the entire human genome that is designed to identify genetic associations with observable traits (such as blood

Policy Announced: August 28, 2007
Effective Date: January 25, 2008

GWAS Homepage: http://gwas.nih.gov/
The greatest public benefit will be realized if data from genomic studies are made available, under terms and conditions consistent with the informed consent provided by individual participants, in a timely manner to the largest possible number of investigators.

- Respect for Participants
- Data Sharing
- Freedom to Operate
NIH Data Management Overview

Data Collection

Submitting Investigators

NIH Genomic Data Repository

Certificate of Confidentiality

Identifying information removed, replaced with random unique code

CoC Advised

Informed Consent

Research Participants

Data Use Limitations
Data Use Limitations

NIH Data Management Overview

Research Participants

Submitting Investigators

NIH Genomic Data Repository

Recipient Investigators

Data Collection

Submission & Management of Data

Distribution & Secondary Use of Data

Informed Consent

Identifying information removed, replaced with random unique code

Data Access Request by Consent Groups

Data Use Limitations
Data Access

Genotype & Phenotype Data → dbGaP Database

Public Access

Controlled Access

Study Protocol Descriptive Information

Coded Genotypes Phenotypes Pre-computes

All potential users

Data Access Committee

- Review data use limitations

Requested Research Use

- Co-signed by institution
- Agree to terms of use
- Agree to Code of Conduct
Data Use Certification Agreement

Terms and conditions include that requesters will:

- be responsible for compliance with federal, state, and local policies
- only use the data for the specified research use
- not identify study participants
- not transfer data beyond approved users
- immediately notify the DAC if a security breach occurs
- submit brief annual updates on research and publications
- be identified as an Approved User within the dbGaP
- acknowledge other GWAS policies
- abide by Genomic Data User Code of Conduct
Public Disclosure under FOIA

- dbGaP GWAS data will be coded and deidentified.
- Policy concern remains that the extensive genomic data in dbGaP is intrinsically unique.
- NIH intends to deny FOIA requests for individual-level genomic data.
- ACD Working Group recommended seeking a legislative exception for genomic data.
Compelled Disclosure

- Law enforcement and other judicial requests for data are handled under different procedures than FOIA requests.

- Standard protection is provided through the Secretary’s “301(d)” authority (aka Certificates of Confidentiality).
  - Certificates are issued for a single project.
  - Submitting Investigators are encouraged to consider requesting a Certificate of Confidentiality.
  - dbGaP has received a Certificate.
Exceptions to Data Deposition

- Policy notes that there will be cases where data deposition may not be appropriate
- Requests for exceptions are to come in within the grant Data Sharing Plan
- To date: 7 requests granted
  - Limited consent
  - Legal restrictions
  - Localized geographic representation
Data Use Experience

- Over 300 available studies (more in pipeline)
- Over 500 organizations across the research community and from 36 countries with Approved Users
- Number of active projects continues to increase substantially each year
- Estimates indicate >450 publications per year
- 3539 approved projects since dbGaP launch and there have been 16 Data Management Incidents
Stewardship & Oversight

NIH Director

Senior Oversight Committee

Technical Standards And Data Submission Steering Committee

Participant Protection & Data Management Steering Committee
Fast Forward to 2012

- The Power of Statistics
- Accessibility of Technology
- Participant-focused Research

- Participant Directions
- Media Coverage
- Policy Developments
Systems of Trustsight

- Researcher
- Policy & Regs
- Local Oversight
- Participant Willingness
- Project/Resource Procedures
- Oversight & Policy
For more Information & Updates

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