National Human Genome Research Institute

GAIN Data Access Policies and Procedures

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NHGRI
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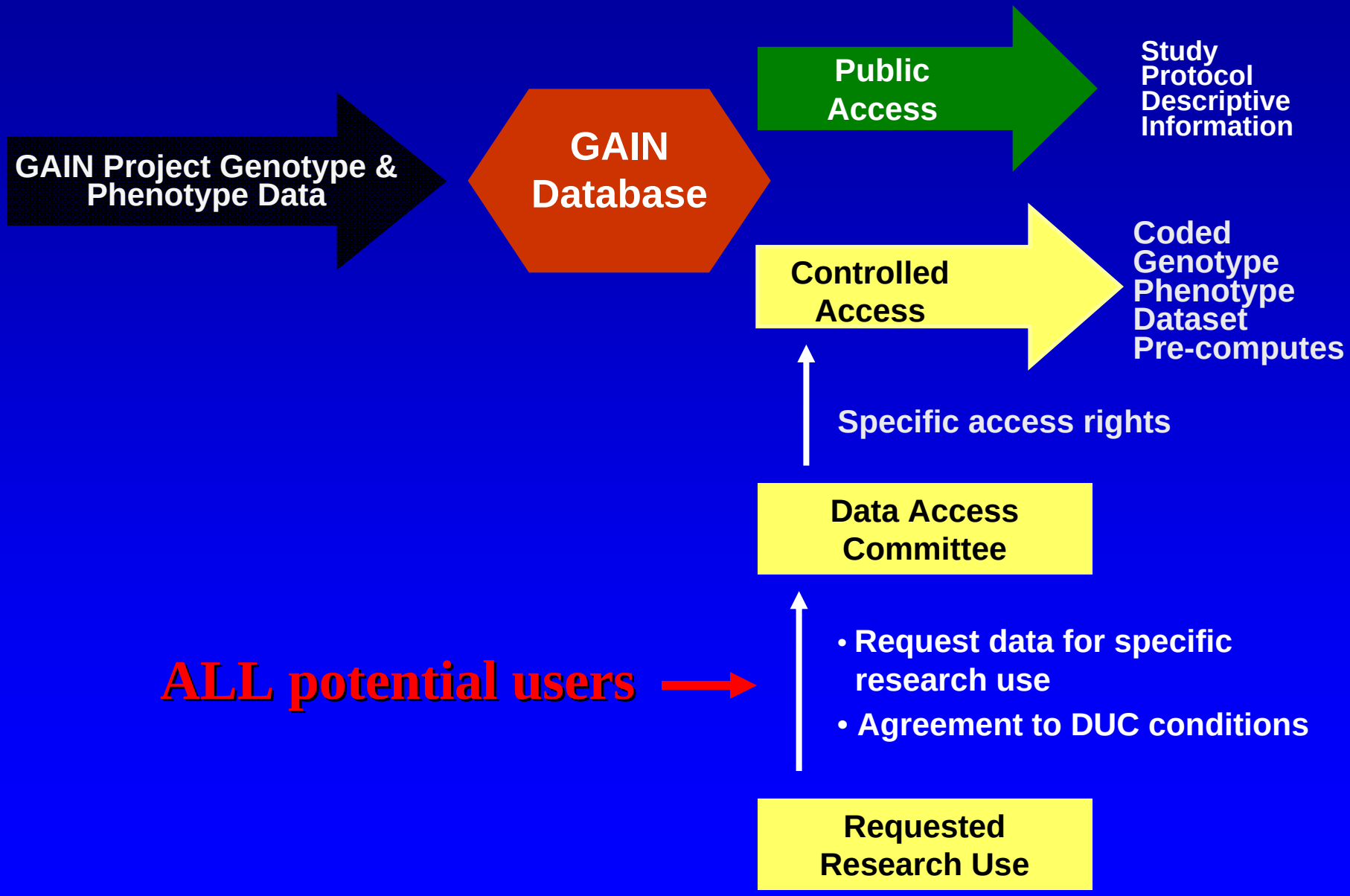
National Institutes of Health

Department of Health & Human Services - USA

Guiding Principle of GAIN:

The greatest public benefit will be achieved if results of whole genome association studies are made immediately and broadly available

GAIN Data Access Overview



Data Flow through GAIN

Data Collection → Submission & Management of Data → Distribution & Secondary Use of Data

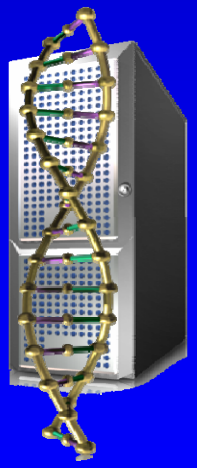
Research Participants

Informed consent

Submitting Investigators

Identifying information removed, replaced with random unique code

GAIN Database



Data Access Request for Coded data

Recipient Investigators

Potential Identifiers

- Geographic subdivisions smaller than the state may be needed for genetic-environmental interaction studies
- Dates smaller than a year may be needed for some studies
- The keycode will be retained by the Contributing Investigator so that data can be updated or withdrawn from future distribution

Data Access

Data Collection

Submission & Management of Data

Distribution & Secondary Use of Data

Research Participants

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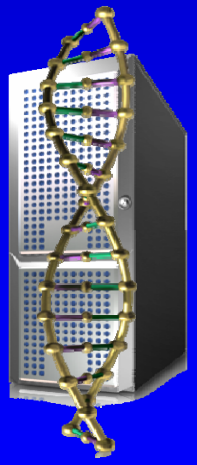
GAIN Database



Data Access Request for Coded data

Recipient Investigators

Human Subjects Issues – Data Access

- OHRP has confirmed that secondary data users will not be conducting human subjects research under 45 CFR 46
- Access to datasets will be provided for a defined research use
  - Proposed use should respect original informed consent
- Requestors and home institutions will be responsible for compliance with applicable federal, state, and local laws and policies

  For example: 45 CFR 46
  HIPAA
  Local institutional review
- Requestors and home institutions will submit a Data Use Certification agreement acknowledging GAIN policies and stipulating appropriate use of the data

Data Use Certification Agreement

- **Investigators and home institutions will certify through Data Use Certification that investigators agree:**
  - **to review informational material on responsible GAIN data use**
  - **to follow specified research use**
  - **to disseminate research results broadly and acknowledge GAIN & Contributing Investigators in published or presented work**
  - **to acknowledge GAIN policies on Publication and Intellectual Property**
  - **to submit brief annual updates on research progress and publications**
  - **not to identify study participants**
  - **not to transfer data**

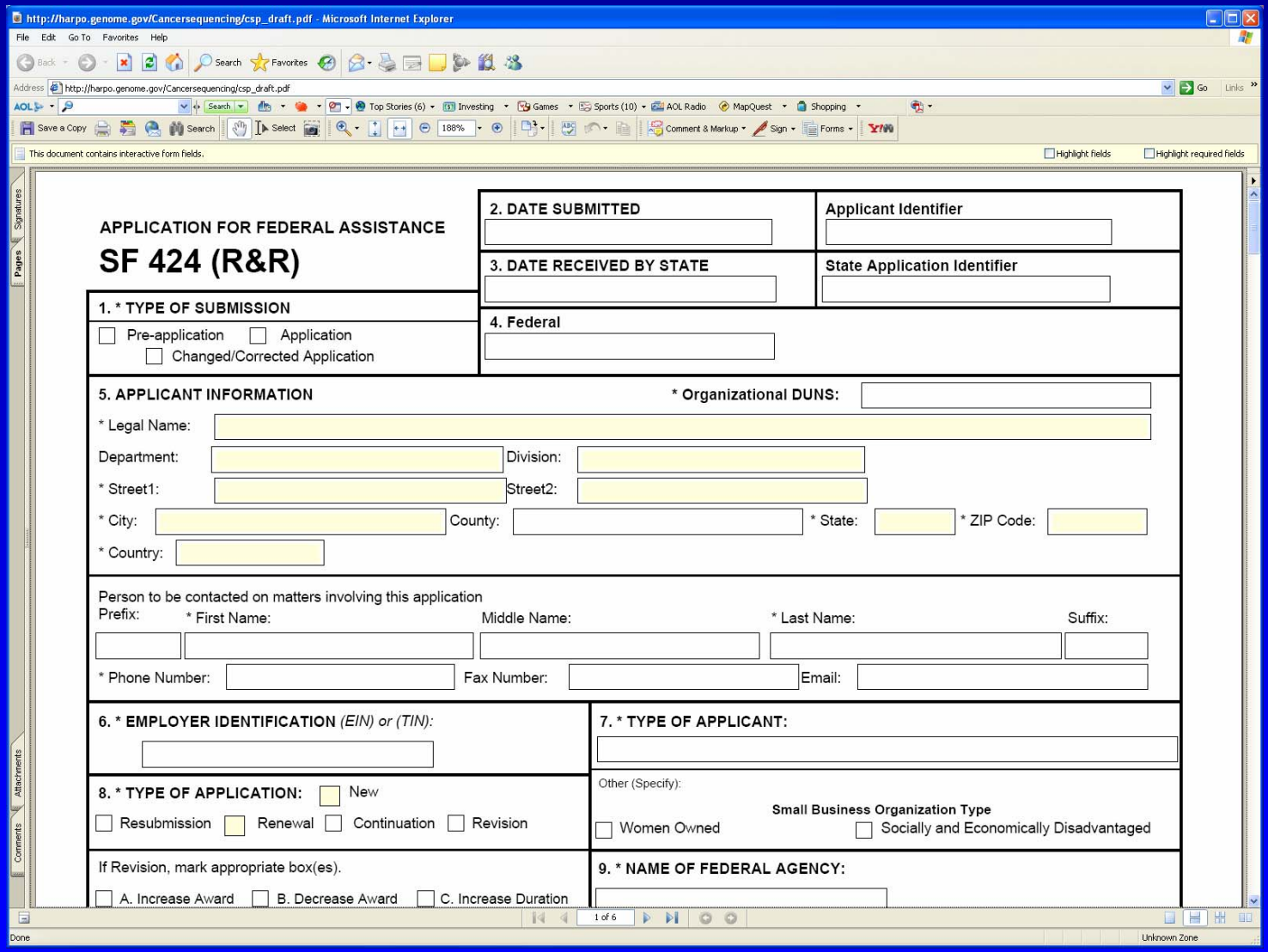
Data Access Committee

- Federal staff with expertise in genome wide association studies, relevant disease areas, bioethics, and privacy/confidentiality issues
- DAC Review will include:
  - Proposed research statement
  - Investigator and institutional background
  - Data Use Certification statements
- If additional expertise is desired, individual input may be sought from external parties, such as:
  - Patient advocates
  - Individuals familiar with specific identifiable communities

Data Access Committee (continued)

- Login credentials will be assigned
- Annual reports will be reviewed for research activity and any new issues relevant to ongoing access
- Annual reports will request information on:
  - Publications, presentations of GAIN data analysis
  - Data security issues
  - Intellectual property generated
  - Potential health implications

Anticipated Data Access Request Form



Expect access request process to go live in early spring 2007

Monitoring and Oversight

- **Independent Data Use Review Board (DURB) will review the data distribution and use practices going forward**
  - **Constituted with external scientific, bioethics, and statistics expertise, as well as at least one "public" member**
  - **Review summary reports of access granted (Approved Users & Institutions)**
- **Will consider data use practices retrospectively through review of:**
  - **GAIN-related publication information**
  - **Ongoing research uses as described in annual reports**
  - **Reports of any data security problems**
  - **Other information as needed to evaluate on-going practices or emerging concerns**

Monitoring and Oversight (continued)

- May make recommendations for policy or procedural changes in light of any potential impact on:
  - the preservation of participant protections
  - the scientific process (e.g., publication issues)
  - emerging issues
- Any recommendations for policy changes will be forwarded to the GAIN Steering Committee and the FNIH Board of Directors
  - Meeting summaries and any recommendations will be made publicly available through the GAIN website

NIH Public Consultation on Sharing Genetic Data

NATIONAL INSTITUTES OF HEALTH
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Genome-Wide Association Studies (GWAS)

- OER Home
- Funding Opportunities
- Applications & Forms
- Awarded Grants
- Grants Policy
- eRA
- About OER

The NIH is interested in advancing Genome-Wide Association Studies (GWAS) to identify common genetic factors that influence health and disease because the information derived from such studies will be essential for developing new approaches to reduce disease burden and promote health. GWAS are currently 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 pressure or weight), or the presence or absence of a disease or condition. The goal of the proposed policy is to advance science for the benefit of the public through the creation of a centralized NIH GWAS data repository. The purpose of this Website is to support the public consultation process to inform policy development activities.

The "Overview" section of this site presents the essential background and responses to frequently asked questions on GWAS. The remaining sections on this page focus on the notices released to date which will result in a request for information through which the National Institutes of Health (NIH) will solicit advice and comments.

Overview

- Background

Notices and Announcements

- Submit a Comment - Comments may be submitted through November 30, 2006.
- NIH Press Release (08/30/2006) - NIH Seeks Input on Proposed Repository for Genetic Information
- Federal Register Notice (08/30/2006) - Request for Information (RFI): Proposed Policy for Sharing of Data Obtained in NIH Supported or Conducted Genome-Wide Association Studies (GWAS)
- NIH Guide Notice NOT-OD-06-094 (08/30/2006) - Request for Information (RFI): Proposed Policy for Sharing of Data obtained in NIH supported or conducted Genome-Wide Association Studies (GWAS)
- NIH Guide Notice NOT-OD-06-071 (05/15/2006) - Notice to Applicants for NIH Genome-Wide Association Studies

Comments or Questions?

- Please send email to GWAS@nih.gov.

Google: "GWAS policy"

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GAIN Program

GAIN HOME PAGE

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  - Data Use Certification
  - Oversight Procedures
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- Using GAIN Data
- GAIN FAQs

Updated 11/25/2006

POLICIES AND PROCEDURES

Important: Updated GAIN Data Access Policy:Click Here>>

| Updated Data Access Policy |
| Updated Publication Policy |
| Updated Intellectual Property Policy |

Introduction

GAIN policies and procedures are designed to facilitate the discovery of genetic variants related to health and disease in a manner that respects the research participants whose data and materials have been contributed to GAIN to generate the genotype-phenotype datasets. GAIN policies also are intended to encourage the development of new prognostic, diagnostic, preventive, and therapeutic products while safeguarding the important and unique contributions made by the scientists who collected the biological samples and associated phenotype data over many years (the Contributing Study Investigators).

The Foundation for the National Institutes of Health (FNIH) and its private and public sector partners in GAIN are committed to creating a resource founded on the principle of no cost, rapid, and complete release of GAIN Project Datasets for use by investigators throughout the global scientific community who, along with their institutions, certify their agreement with GAIN policies (Approved Users). All participants in GAIN (Contributing Study Investigators, their Institutions, GAIN Partners, and Approved Users) are expected to promote the policies on data access, publication, and intellectual property. Specific terms and requirements for study participation in GAIN can be found in the GAIN Submitting Applicant Policy Agreement. Specific terms and conditions for access to and use of GAIN Project Datasets by Approved Users, can be found in the GAIN Data Use Certification document.

The FNIH Board of Directors, in consultation with the GAIN Steering Committee, will make all final decisions concerning GAIN policies. All GAIN policies are subject to change by the FNIH Board of Directors or the GAIN Steering Committee as deemed necessary to sustain program principles and priorities, or to ensure the highest standards for responsible research conduct within GAIN operating procedures. Access to the GAIN Database, managed by the National Center for Biotechnology Information (NCBI), National Library of Medicine, will be overseen by the National Institutes of Health in accordance with United States Government rules and policies. All changes to GAIN policies or procedures will be posted on the GAIN website.

Definitions of terminology used in these documents are found in the GAIN Glossary.

http://www.fnih.org/GAIN/policies.shtml