

GAIN Publication and Intellectual Property Policies

David Wholley

Director, Genetic Association Information Network
Foundation for the National Institutes of Health

GAIN Kickoff and Analysis Workshop Meeting, Herndon, VA
November 29-30, 2006



FOUNDATION
FOR THE
National Institutes of Health

GAIN Policies – Publication

- Contributing Study PIs will have the exclusive right to submit publications analyzing GAIN Project Datasets for nine months after their respective genotype-phenotype dataset is made available
- All other appropriate uses of the data are permitted during this period (i.e., data analysis for specified research areas)
 - However all resulting presentations and publications must acknowledge the GAIN Database and the original Contributing Study investigators
- GAIN Analysis Workshops bring together PIs and their analytical experts with other qualified statistical experts to provide knowledge exchange and support

GAIN Policies – Intellectual Property

- Consensus is that GAIN data should be pre-competitive
 - Avoid premature claims on pre-competitive information; promote opportunity to develop IP and file claims on downstream developments (e.g., therapeutics)
- Data should be placed in the public trust for the broadest array of users to develop
 - Data in the GAIN Database is made immediately and simultaneously available to all (“no early look”)
 - Users agree not to pursue claims that would prevent or block access to, or use of, any element of GAIN Data or a GAIN Project Dataset, or conclusions drawn directly from those data
- GAIN will include pre-computed associations with GAIN datasets, so these become prior art (e.g., significant association results, linkage disequilibrium data, etc.)

Monitoring and Oversight

- Applicants and Users must acknowledge these policies through the Applicant Policy Agreement and the Data Use Certification, respectively.
- Independent Data Use Review Board (DURB) will review the data distribution and use practices going forward
- Will consider observed practices retrospectively through review of:
 - Approved access summaries (Approved Users & Institutions)
 - GAIN-related publication information
 - On-going research uses as described in Approved User annual reports
- DURB may recommend policy changes to the GAIN Steering Committee and FNIH Board of Directors based on emerging issues

GAIN Program



GAIN HOME PAGE

- ▶ [Partnerships](#)
- ▶ [Overview](#)
- ▶ [Policies and Procedures](#)
- ▶ [Genotyping & Analysis](#)
- ▶ [Instructions for Applicants](#)
- ▶ [Using GAIN Data](#)

Updated: 02/08/2006

GENETIC ASSOCIATION INFORMATION NETWORK (GAIN)

The Genetic Association Information Network (GAIN) is a public-private partnership of the Foundation for the National Institutes of Health, Inc. (FNIH), which will include corporations, private foundations, advocacy groups, concerned individuals, and the National Institutes of Health (NIH) ([Overview](#)). This initiative will take the next step in the search to understand the genetic factors influencing risk for complex diseases. Through a series of whole genome association studies, using samples from existing case-control studies of common diseases, the project will contribute to the identification of genetic pathways that make us more susceptible to these diseases and thereby facilitate discovery of new molecular targets for prevention, diagnosis, and treatment.

GAIN aims to release data as broadly and rapidly as possible, with equal opportunity for access by all potential research users. Unlinked genotypic data will be openly and freely accessible without need for prior approval. Linked genotypic and phenotypic data will be made available to all qualified users at the same point in time and through the same access approval mechanisms with no special access provided to GAIN partners. Appropriate policies and procedures will protect the confidentiality of study participants and recognize the intellectual contributions of the researchers who contribute the samples and the phenotype data to GAIN ([Policies and Procedures](#)).

FNIH is actively seeking additional funding Partners to participate in GAIN ([Partnerships](#)).

Application for Genotyping Services

Applications from investigators wishing to submit material from existing studies for genotyping will be reviewed by technical experts from academia, government, and industry ([Overview](#)). Note that GAIN will not support the collection of new samples, data, or consent. Applications will be submitted through the FNIH's online application site ([Instructions for Applicants](#)). Applicants and their institutions will be required to abide by GAIN policies for data access, publication, and intellectual property ([Policies and Procedures](#)). Phenotype and exposure data will be submitted directly to the National Library of Medicine's National Center for Biotechnology Information (NCBI). Applicants will be required to provide a copy of the entire data set proposed for whole-genome association study, with a copy of the data documentation, for evaluation purposes only, at the time the application is submitted ([Instructions for Applicants](#)).

Projects selected for genotyping will submit DNA samples directly to the genotyping provider at a later date ([Genotyping and Analysis](#)).

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