

Genetic Association Information Network (GAIN) Data Use Certification

Introduction and Statement of Policy

The Genetic Association Information Network (GAIN) is a public–private partnership formed with the goal of identifying genetic variants that contribute to diseases of major public health importance by catalyzing genome-wide association analyses on samples from existing studies that include large numbers of affected and unaffected individuals. GAIN is founded on the principle that scientific progress will be most efficient and innovative if data are readily available to all investigators in the research community. Contributing Study Investigators who provide phenotype data and DNA samples from participants to a GAIN Project have committed to this principle and their professional investments and intellectual contributions will be fundamental to the ultimate success of GAIN.

GAIN Project Datasets (genotype-phenotype datasets along with pre-computed calculations of the datasets themselves) to be distributed under this certification process will be coded; the GAIN Database will not receive personal identifying information. However, due to the extensive phenotype and genotype data included, GAIN Project Datasets will be provided to investigators who, along with their institutions, have certified their agreement with the requirements and terms of access detailed below. It is the intent of the GAIN Steering Committee that Approved Users of GAIN Project Datasets should recognize the limitations imposed by the original informed consent agreements of Contributing Studies as listed on the GAIN Database.

To promote the responsible use of the GAIN Project Datasets all investigators seeking access to GAIN Project Datasets, and their institutions, should acknowledge their agreement with the [Policies and Procedures](#) described on the GAIN website, which are articulated within this Data Use Certification. For collaborative projects, any independent collaborating investigator from another institution should complete a separate Data Use Certification.

Definitions of terminology used in these documents are found in the [GAIN Glossary](#).

Terms of Access

1. Requesting Investigator (“Requestor”)

The Requestor has reviewed and understands the guiding principles for responsible research use and data handling of the genotype and phenotype data included within Gain Project Datasets as described in the on-line material provided through the GAIN website.

2. Research Use

The Requestor agrees that he/she shall use the GAIN Project Dataset solely in connection with the research project described in the Data Access Request, which includes the project title, the Requestor’s name and institution, the names of any independent collaborators and their institutions, a 1-2 paragraph description of the research objectives and design, and a brief analysis plan (Research Plan Attachment). New uses of these data outside those described

above will require submission of a new application; substantive modifications to the research project will require submission of an amendment to this application. The Requestor further agrees that he/she shall use the GAIN Project Dataset(s) only in accordance with the parameters described on the GAIN website for appropriate research uses, and any limitations on such use, of this dataset. The Requestor and his/her institution further acknowledge that they are responsible for ensuring that all uses of the data are consistent with federal, state, and local laws and any relevant institutional policies.

It is anticipated that, at least in some cases, the GAIN Project Datasets will be updated with additional information and will be so identified by an appropriate version number. Unless otherwise indicated, all statements herein are presumed to be true and applicable to the access and use of all versions of the GAIN Project Datasets.

3. Public Posting of Approved User's Research Use

The Requestor agrees that, if he or she becomes an Approved User, information about the proposed research use can be posted on a public web site that describes the GAIN projects. The information may include the Approved User's name and institution, project name, Research Use Statement, and non-technical summary of the Research Use Statement.

4. Non-Identification

The Requestor agrees not to use GAIN Project Datasets, or any other information, to identify or contact individual participants from whom phenotype data and DNA samples were collected.

5. Non-transferability

The Requestor agrees to retain control over the data, and further agrees not to distribute the individual data in any form to any entity or individual other than his/her research staff or trainees or independent collaborating investigators listed in the GAIN Data Access Request under "Research & Related Senior/Key Person Profile" who also agree to the terms within this Data Use Certification, subject to applicable law. The Requestor agrees to store GAIN Project data on a computer with adequate security controls, and to maintain appropriate control over the data. Best practices for computer security and data control are available online at <http://www.ncbi.nlm.nih.gov/projects/gap/pdf/dbGaPLLevel2SecurityProcedures.pdf>. The Requestor and Requesting Institution acknowledge responsibility for ensuring appropriate use of these data and agreement to the terms of this document by research staff.

The Requestor agrees that if he/she changes institutions then a new Data Use Certification in which the new institution acknowledges and agrees to GAIN Policies and Procedures and the terms of access will be required.

6. Intellectual Property

By requesting access to GAIN Project Dataset(s), the Requestor and his/her home organization (Requesting Institution) acknowledge the intent of the GAIN Steering Committee to see that Approved Users follow the GAIN [Intellectual Property \(IP\) Policy](#), as summarized below:

Achieving maximum public benefit is the ultimate goal of GAIN. The Steering Committee believes that GAIN data should be considered as pre-competitive, and urges users to avoid making IP claims on the data. However, the Steering Committee also recognizes

the importance of the later development of IP on downstream discoveries, especially in therapeutics, which will be necessary to support full investment in products that the public needs.

In this spirit, it is expected that GAIN-supported data and conclusions derived therefrom will remain freely available, without requirement for licensing, for applications such as, but not necessarily limited to, the following: the use of markers in developing assays or diagnostic tools; the use of combinations of markers in multiplex assays; and the use of markers as guides toward identification of new drug targets.

The GAIN Steering Committee encourages licensing practices consistent with the recommendations cited in NIH's [Best Practices for the Licensing of Genomic Inventions](#) and in the [NIH Research Tools Policy](#).

7. Publication

While GAIN seeks to accelerate the rapid advancement of scientific knowledge through publication, it recognizes the effort that the Contributing Study Investigators and their institutions have made in obtaining the Submitted Samples and the associated Submitted Data that were the basis for the GAIN Project Datasets.

In accordance with the GAIN [Publication Policy](#), the Requestor agrees that for nine months beginning from the date on which a GAIN Project Dataset is made available through the GAIN Database, he/she will not submit any article for publication or any abstract for presentation, or make any presentations based on the requested GAIN Project Dataset(s). This condition is not applicable if it is so indicated in the GAIN Database, or if the primary investigator who contributed the Submitted Data to GAIN provides written consent.

8. Research Use Reporting

In order to ensure that GAIN policies and procedures for participant protection and data use are adhered to throughout the course of GAIN-related research projects, Approved Users of GAIN data agree to provide annual feedback on how the GAIN data have been used and any results such as publications and patents that have been generated as a result of access to the GAIN data. This information will be used to inform the GAIN Steering Committee in its oversight of GAIN, and by NIH staff to support program oversight and management activities. It will also inform assessment of GAIN policies by the GAIN Data Use Review Board (DURB).

Approved Users thus agree to provide a brief annual report summarizing the progress of the research specified within this Data Use Certification for the period of time that the Data Use Certification is in effect. The report form will be available through the GAIN data access web site. The report should include a brief update on the research, describing the potential significance of any findings and plans for further research; any scientific presentations that included GAIN findings with the name, bibliographic citation (if any), and submission date of these meetings; any publications that included GAIN findings with the title, authors, bibliographic citation, and submission date of the publications; any breaches in data security (for example, accidental data distribution beyond Approved Users); and a brief description of any non-proprietary downstream intellectual property generated or intended to be generated as a result of using GAIN data. Approved Users are also asked to provide any general comments regarding the effectiveness of GAIN, such as ease of access and use, appropriateness of data format, challenges in complying with GAIN policies, and suggestions for improving GAIN data access or the program in general.

Annual reports for Years 1 and 2 of this Certification should be submitted on the first day of the month following the anniversary date of this Certification (as indicated by the date the data were made accessible to the Approved User). The Year 3 annual report should be submitted as an attachment to any renewal Data Use Certification submitted, or by the last day of the month following the anniversary date of this Certification.

In addition to annual reporting, Approved Users agree to notify the GAIN Data Access Committee (DAC) of any breaches in data security or adverse events within 3 business days of when the Approved User or Institution was notified of the event. The notification should include the date and nature of the event, what was done to address it, and what is being done to prevent further problems.

All reports and notifications should be sent to:

Emily L. Harris, PhD, MPH
GAIN Data Access Committee Chair
e-mail: gaindac@mail.nih.gov
FAX: 301-435-1580

9. Dissemination of Research Results and Acknowledgment of GAIN

It is the intent of GAIN to promote the dissemination of analyses of GAIN Project Dataset(s) as widely as possible. Requestors are strongly encouraged to publish their results in peer-reviewed journals.

The Requestor agrees to acknowledge GAIN, the Contributing Study Investigator(s) who contributed the phenotype data and DNA samples from his/her original study, and the primary funding organization that supported the contributing study in all oral and written presentations, disclosures, and publications resulting from any analyses of the GAIN Project Dataset(s). The Requestor further agrees that the acknowledgment shall include a reference to the specific version of the GAIN Project Dataset(s) analyzed and to the GAIN Database.

A sample statement to be used in acknowledgments is:

“Funding support for *[insert name of contributing project]* was provided by *[insert funding organization]* and the genotyping of samples was provided through the Genetic Association Information Network (GAIN). The dataset(s) used for the analyses described in this manuscript were obtained from the GAIN Database found at *[insert URL]* through dbGaP accession number *[XXX]*. Samples and associated phenotype data for the *[insert name of contributing project]* were provided by *[insert name of Contributing Study Investigator]*.”

10. Non-Endorsement, Indemnification

The Requestor and his/her institution acknowledge that although all reasonable efforts have been taken to ensure the accuracy and reliability of the data in the GAIN Database, GAIN and its Partners do not and cannot warrant the results that may be obtained by using any data included therein. GAIN and the GAIN Partners disclaim all warranties as to performance or fitness of the data for any particular purpose.

No indemnification for any loss, claim, damage or liability is intended or provided by any party under this agreement. Each party shall be liable for any loss, claim, damage, or liability that said party incurs as a result of its activities under this agreement, except that the NIH, as an

agency of the United States, assumes liability only to the extent provided under the Federal Tort Claims Act, 28 U.S.C. 2671 et seq.

11. Termination and Violations

This Data Use Certification will be in effect for a period of three years from the date the data were made accessible to the Approved User. At the end of this time period, the Approved User agrees to destroy all copies of the GAIN Project Dataset(s).

Consideration will be given to a renewal of this agreement upon submission of a new Data Use Certification.

GAIN may terminate this Data Use Certification and immediately revoke access to all GAIN Project Datasets at any time if the Requestor is found to be no longer in agreement with the policies, principles and procedures of GAIN.

12. Exceptions

Contributing Study Investigators who provided the Submitted Data and Submitted Samples used to generate a particular GAIN Project Dataset are exempt from certain provisions of this Data Use Certification, as follows:

1. Contributing Study Investigators and Collaborating Investigators with access to participants' personal identifiers are exempt from Terms of Access, provision 4 (Non-Identification), if they have appropriate Institutional Review Board (IRB) approval to retain the participant identities and to re-contact participants.
2. Contributing Study Investigators are exempt from Terms of Access, provision 7 (Publication).

By signing and dating the GAIN Data Access Request form, the Requestor and Requesting Institutional Official represent and warrant the Requestor's qualifications for access to and use of GAIN Project Dataset(s) and certify their agreement to the GAIN principles, policies and procedures for the use of GAIN Project Datasets as articulated in this document. Requesting investigators further acknowledge that they have shared this document and the GAIN policies and procedures with any research staff who will participate in the use of the GAIN Project Dataset. Institutional Business Officials also acknowledge that they have shared this document and the relevant GAIN policies and procedures with appropriate institutional organizations, such as the Office of Technology Transfer and the Office for Human Subjects Research.