

DATA USE CERTIFICATION AGREEMENT
PGRN-RIKEN MAYO-NSABP Prevention Study

Introduction and Statement of Policy

The National Institutes of Health (NIH) GWAS Data Repository was developed to archive and distribute results of studies examining the relationships between genotype and phenotype. Such studies include genome-wide association studies, medical sequencing, and molecular diagnostic assays. Implicit in the Database of Genotypes and Phenotypes (dbGaP) is the view that scientific progress in this area will be greatly enhanced if the data are readily available to all investigators in the research community. This Data Use Certification (DUC) Agreement contains the core elements recommended by NIH at <http://grants.nih.gov/grants/gwas/> dated 5/21/08 and posted 7/10/08. The effective date of this agreement shall be the Approved Access Date as specified on the NIGMS Data Access Committee (DAC) approval notification.

Dataset access will only be provided to research investigators who, along with their institutions, have certified their agreement with the expectations and terms of access detailed below. It is the intent of the NIH and the National Institute of General Medical Sciences (NIGMS) that users of GWAS datasets recognize any restrictions on data use delineated within the original informed consent agreements of contributing studies, as identified by the submitting institutions and stated on dbGaP.

This agreement is made between the NIGMS, NIH, and the parties as defined below including:

- Requester - the home institution/organization requesting access to the GWAS dataset on behalf of the Principal Investigator (PI) who will use the requested data
- Approved Users - upon approval this will include the PI, collaborators at the home institution, their trainees and support staff involved in this project, and the institution's Information Technology Director, who has the authority to vouch for IT capacities at the institution; the names of all personnel proposed must be listed in the Senior/Key Persons portion of the request
- Institutional Signing Official - the designated organizational official with the authority to sign on behalf of the Requester and credentialed through the eRA system

By submission of the attached Data Access Request (DAR), the Requester agrees that if approved, the PI named and all individuals listed in the "Senior/Key Person Profile" portion of the DAR (which should include the Information Technology Director), will become Approved Users of the requested dataset. If there are multiple institutions involved (multiple Requesters), each must submit its own DAR through its own Institutional Signing Official with its own Approved Users defined.

Responsibilities regarding NIH GWAS policies and procedures (<http://grants.nih.gov/grants/gwas/>)
The Requester and the PI acknowledge that they have shared this document and NIH GWAS policies for use of GWAS datasets with all Approved Users. The Institutional Signing Official attests to the Approved Users' qualifications for access to and use of the dataset and certifies agreement to the NIH policies articulated in this document. The Institutional Signing Official also acknowledges that NIH GWAS policies were shared with the appropriate institutional organizations (e.g., Office of Human Subjects Research, Office of Information Technology, Office of Technology Transfer, etc.) and assures compliance with local policies related to technology transfer, information technology, privacy, and human subjects research.

1. Research Use

Research Use is use solely by Approved Users for the specific research project described in the DAR and approved by the DAC. New uses of the data by persons not listed, or use outside of that described in the current DAR, will require submission of a new DAR. The research use must be consistent with the use(s) permitted by the submitting organization.

For this project, the PI and the submitting organization have stipulated the following restriction on data usage, which is reflected in the Consent Group statement at dbGaP:

Data Use Restriction

- Health Research (HR)
 - Mayo Clinic data may be used only for genetic studies to learn about, prevent, or treat health problems
- Investigators must state in the DAR their intention to publish or otherwise broadly share any findings from their study with the scientific community

2. Data Confidentiality

Approved Users agree to keep the data confidential.

3. Sale of Data

Approved Users agree that no elements of an NIH GWAS dataset may be sold, in whole or in part, to any individual or organization at any time for any purpose.

4. Data Security

Approved Users agree to ensure physical and IT data security per *dbGaP Security Best Practices* (http://www.ncbi.nlm.nih.gov/projects/gap/pdf/dbgap_2b_security_procedures.pdf). They specifically acknowledge that they will handle the requested dataset according to current standards for data encryption during storage and transport; this includes the maintenance of appropriate controls over any copies or derivatives of the data. This agreement includes a commitment that all Approved Users have completed required institutional computer security training, e.g., <http://irtsectraining.nih.gov/>, or the equivalent.

5. Legal Obligations

Approved Users agree to follow all applicable laws, regulations, and local institutional policies.

6. Non-Identification

Approved Users agree to not use the requested dataset, either alone or in concert with any other information, to identify or contact individual participants from whom data and samples were collected.

7. Non-Distribution

Approved Users agree to not distribute or share any data elements from the NIH GWAS dataset with any individuals except those who are identified on the DAR.

8. Public Listing of Research Uses

Approved Users agree to a public listing on the dbGaP website of a summary of the approved research use statement along with the PI's name and organizational affiliation. Publications resulting from the use of NIH GWAS datasets will also be posted.

9. Violations Reporting

Requesters agree to notify the NIGMS DAC of any unauthorized data sharing, breaches of data security, or inadvertent data releases that may compromise data confidentiality within 24 hours of when an incident is identified. Notification should include information regarding the incident and a brief description of the actions taken to immediately remediate the situation.

Within 3 business days of notification, the Requester (through the Institutional Signing Official), agrees to submit to the NIGMS DAC a more detailed written report including the date and nature of the event, actions taken or to be taken to correct the issue(s), and processes developed to prevent further problems, including specific information on timelines anticipated for action.

NIGMS, NIH, or another entity designated by NIH may investigate any data security incident. Approved Users and their associates agree to support investigations and provide information within the limits of applicable local, state and federal laws and regulations. In addition, Requesters and Approved Users agree to work with NIGMS and NIH to assure that plans established to address identified problems are mutually acceptable.

10. Publication and dbGaP Acknowledgements

Approved Users agree to an embargo period of 12-months after the data is made available on dbGaP. During the embargo period, approved users with authorized access may view and use the data but not share any conclusions derived from it publicly in any form including public presentations, disclosures, websites or blogs, or submission of abstracts or publications. The embargo period for this dataset will end on October 14, 2010.

Approved Users should acknowledge the NIH GWAS Data Repository and the submitter (see Project-Specific sections below) who contributed the GWAS dataset in all publications resulting from analyses of the dataset, including the dbGaP accession number to the specific version of the dataset analyzed.

For this dataset, the PI and the depositing organization have requested that the following acknowledgement statement be used: Samples and associated genotype and phenotype data used in this study were provided by the Mayo Clinic. Funding support for the Mayo Clinic was provided through a cooperative agreement with the National Institute of General Medical Sciences (NIGMS), Grant U01 GM61388. The datasets used for analyses described in this manuscript were obtained from dbGaP at <http://www.ncbi.nlm.nih.gov/gap> through dbGaP accession number [phs000210.v1.p1]. Dr. James Ingle and his collaborators request that publications resulting from this data cite their original publication (reference to appear on dbGaP before the end of embargo period).

11. Intellectual Property

The Requester acknowledges the intent of NIH to assure that Authorized Users follow the intellectual property principles in the NIH GWAS Policy for Data Sharing (<http://grants.nih.gov/grants/guide/notice-files/NOT-OD-07-088.html>). NIH believes that these data should be considered pre-competitive and urges Approved Users to avoid making IP claims derived directly from the GWAS dataset. It is expected that these NIH-provided data, and conclusions derived from these data, will remain freely available, without requirement for licensing.

NIH encourages broad use of GWAS datasets coupled with a responsible approach to management of intellectual property derived from downstream discoveries in a manner consistent with the NIH's Best Practices for the Licensing of Genomic Inventions (www.ott.nih.gov/policy/genomic_invention.html) and the NIH Research Tools Policy (grants.nih.gov/grants/intell-property_64FR72090.pdf).

12. Access Period, Reporting, and Renewals

Approved Users will have access to the requested dataset for a period of one year from the Approved Access Date. A final report describing the research use of the requested dataset is due to the NIGMS DAC not later than one year following the Approved Access Date. The report should briefly note significant findings, list all publications or presentations that resulted from the use of the requested dataset, and relate any difficulties with the access process. Approved Users seeking more time to use the dataset than a period of one year from the Approved Access Date should submit a new DAR; a data use report should also be submitted in order for the new DAR to be evaluated.

The report will be used to evaluate the effectiveness of the DAC procedures for participant and submitter protection and for facilitating GWAS data access by the research community. The information should be submitted in the form of a letter from the PI, co-signed by the Institutional Signing Official, and submitted to the DAC Chair at the e-mail address below under Contact Information.

13. Changes to Research Projects

Approved Users agree that if they change institutions during the dataset access period, they will submit a new DAR in which the new institution agrees to the NIH GWAS data use policies and this DUC before any data use may resume. All versions of data stored at the prior institution must be destroyed, and this should be documented through a final report to the NIGMS DAC as described above.

14. Destruction of Data

Approved Users agree to destroy all copies of the requested dataset, and all derivatives that contain individual-level information, at the end of the dataset access period.

15. Terminations

NIH or NIGMS may terminate this agreement and immediately revoke access to all NIH GWAS datasets at any time, if the Requester is found not to be in compliance with the GWAS policies, principles and procedures of NIH.

16. Contact Information

All notifications, including data security incident notifications and all written reports, should be sent to: NIGMSDBGAPDataAccessCommitee@mail.nih.gov

17. Non-Endorsement, Indemnification Statement

The Requester and Approved Users acknowledge that although all reasonable efforts have been taken to ensure the accuracy and reliability of the GWAS data, NIH, NIGMS and contributing investigators do not and cannot warrant results that may be obtained by using any of the data elements. NIH, NIGMS, and all contributors 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.

Addendum to the Data Use Certification Agreement Modification of Data Security Terms and Best Practices

Effective for all dbGaP Data Access Requests submitted on or after March 23, 2015, Section 6 of the Data Use Certification Agreement is replaced in its entirety by the following:

6. Data Security and Data Release Reporting

The Requester and Approved Users, including the institutional IT Director, acknowledge NIH's expectation that they have reviewed and agree to manage the requested dataset(s) according to the current NIH Security Best Practices for Controlled-Access Data Subject to the GDS Policy and the institutional IT security requirements and policies, and that the institution's IT security requirements and policies are sufficient to protect the confidentiality and integrity of the NIH controlled-access data entrusted to the Requester.

If approved by NIH to use cloud computing for the proposed research project, as outlined in the Research and Cloud Computing Use Statements of the Data Access Request, the Requester acknowledges that the IT Director has reviewed and understands the cloud computing guidelines in the NIH Security Best Practices for Controlled-Access Data Subject to the GDS Policy.

Requesters and PIs agree to notify the NIGMS DAC of any unauthorized data sharing, breaches of data security, or inadvertent data releases that may compromise data confidentiality within 24 hours of when the incident is identified. As permitted by law, notifications should include any known information regarding the incident and a general description of the activities or process in place to define and remediate the situation fully. Within 3 business days of the NIGMS DAC notification, the Requester, through the PI and the Institutional Signing Official, agree to submit to the NIGMS Data Access Committee a detailed written report including the date and nature of the event, actions taken or to be taken to remediate the issue(s), and plans or processes developed to prevent further problems, including specific information on timelines anticipated for action.

All notifications and written reports of data security incidents should be sent to:

NIGMS Data Access Committee URGENT: NIGMSDBGAPDataAccessCommittee@mail.nih.gov

GDS mailbox: gds@mail.nih.gov

NIH, or another entity designated by NIH may, as permitted by law, also investigate any data security incident. Approved Users and their associates agree to support such investigations and provide information, within the limits of applicable local, state, and federal laws and regulations. In addition, Requesters and Approved Users agree to work with the NIGMS and NIH to assure that plans and procedures that are developed to address identified problems are mutually acceptable and consistent with applicable law.

Addendum to the Data Use Certification

Effective for all dbGaP study datasets registered prior to July 31, 2013

- Annual Data Use Reports will no longer be submitted by email to the relevant Data Access Committee(s) (DACs), as stated in the Data Use Certification(s) associated with the datasets you are requesting.
- Principal Investigators are now expected to submit online research progress updates through the dbGaP system, as part of the annual renewal process or close-out process.