National Institute of Neurological Disorders and Stroke
Data Use Certification

Version date October 10, 2007

Contact: ninds-dac@mail.nih.gov

Introduction and Statement of Policy

The National Institute of Neurological Disorders and Stroke (NINDS) is distributing genotype and phenotype data 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. NINDS is committed to 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 NINDS Project have committed to this principle and their professional investments and intellectual contributions will be fundamental to the ultimate success of NINDS-supported research.

NINDS 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 NINDS Database will not receive personal identifying information. However, due to the extensive phenotype and genotype data included, NINDS 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 National Institute of Neurological Disorders and Stroke that Approved Users of NINDS Project Datasets should recognize the limitations imposed by the original informed consent agreements of Contributing Studies as listed on NINDS study descriptions in the NCBI dbGaP database.

For collaborative projects, any independent collaborating investigator from another institution should complete a separate Data Use Certification.

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 NINDS Project Datasets as described in the on-line material provided through the NINDS website.

2. Research Use

The Requestor agrees that he/she shall use the NINDS 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 NINDS Project Dataset(s) only in accordance with the parameters described on the NINDS 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 NINDS 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 NINDS 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 NINDS 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 NINDS 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 NINDS 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 NINDS 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/dbGaPLevel2SecurityProcedures.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 NINDS Policies and Procedures and the terms of access will be required.

6. Intellectual Property

> By requesting access to NINDS Project Dataset(s), the Requestor and his/her home organization (Requesting Institution) agree to adhere to NIH's Best Practices for the Licensing of Genomic Inventions and in the NIH Research Tools Policy.

7. Publication

NINDS places no restrictions on the Requestor regarding the timing of publications derived from use of the requested NINDS Project Dataset(s).

8. Research Use Reporting

In order to ensure that NINDS policies and procedures for participant protection and data use are adhered to throughout the course of NINDS-related research projects, Approved Users of NINDS data agree to provide annual feedback on how the NINDS data have been used and any results such as publications and patents that have been generated as a result of access to the NINDS data. This information will be used by NIH staff to support program oversight and management activities. It will also inform assessment of NINDS policies by the NINDS 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 NINDS 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 NINDS findings with the name, bibliographic citation (if any), and submission date of these meetings; any publications that included NINDS 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 NINDS data. Approved Users are also asked to provide any general comments regarding the effectiveness of NINDS, such as ease of access and use, appropriateness of data format, challenges in complying with NINDS policies, and suggestions for improving NINDS 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 NINDS 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:

Dr Katrina A Gwinn, MD
NINDS Data Access Committee Chair
e-mail: ninds-dac@mail.nih.gov
FAX: +1 (301) 402-1501

9. Dissemination of Research Results and Acknowledgment of NINDS

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

The Requestor agrees to acknowledge NINDS, 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 NINDS Project Dataset(s). The Requestor further agrees that the acknowledgment shall include a reference to the specific version of the NINDS Project Dataset(s) analyzed and to the NINDS 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 by the National Institute of Neurological Disorders and Stroke (NINDS). The dataset(s) used for the analyses described in this manuscript were obtained from the NINDS Database found at *[insert URL]* through dbGaP accession number *[XXX]*."

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 NINDS Database, NINDS does not and cannot warrant the results that may be obtained by using any data included therein. NINDS disclaims 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 NINDS Project Dataset(s).

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

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

12. Exceptions

Contributing Study Investigators who provided the Submitted Data and Submitted Samples used to generate a particular NINDS 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.

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

GLOSSARY OF TERMS

1. NINDS Project: Projects funded by the National Institute of Neurological Disorders and Stroke with data in dbGaP include both studies with research results and information related to NINDS supported repositories.

3. Contributing Study Investigators: Investigators funded by the National Institute of Neurological Disorders and Stroke who collected the phenotypic data and genetic samples for inclusion in the dbGaP study submission.

5. NINDS Project Dataset: contains participant genotype data and the relevant phenotype and exposure data. This resource is managed for NINDS by the National Center for Biotechnology. Included are descriptive information about each NINDS study and the user interface for accessing these data.

6. Approved Users: Research investigators who have submitted a request to access NINDS Project Dataset through the completion of the proceeding Data Use Certification document. The Data Use Certification requires electronic signatures from the requesting investigator and his/her Institutional Business Official. Submission of the Data Use Certification indicates that the signers represent and warrant their qualifications for access to and use of the NINDS Project Dataset and certify their agreement to the NINDS principles, policies, and procedures for the use of the NINDS Project Dataset as articulated in that document.

7. Institutional Business Official: A member of the Requesting Investigator's home organization with the authority to commit the organization to the terms of the application and certify their organization's agreement to the terms delineated in the Data Use Certification.

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 NINDS 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 NINDS DAC notification, the Requester, through the PI and the Institutional Signing Official, agree to submit to the NINDS 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:
NINDS Data Access Committee URGENT: natalia.volfovsky@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 NINDS 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.