NEI Study of Age-Related Macular Degeneration (NEI-AMD)
Data Use Certification
Version Date 19 May 2009
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Introduction and Statement of Policy

NEI Study of Age-Related Macular Degeneration (NEI-AMD) is a collaborative study of NEI-funded investigators. The GWAS of these cohorts were funded by the National Eye Institute (NEI) with the goals of:

1. Identifying the genes and genetic variations associated with age-related macular degeneration.

2. Identify copy number variants (CNVs) associated with age-related macular degeneration.

The NEI feels that scientific progress in eye disease research will be greatly enhanced if the genetic and phenotypic data produced by the NEI-AMD are readily available to all investigators in the research community.

NEI-AMD Project datasets (genotype-phenotype datasets along with pre-computed analyses of them) to be distributed under this certification process will be coded, with many variables that might enable individual participants to be identified, e.g. birth dates, removed or otherwise modified. However, due to the extensive phenotype and genotype data included in the NEI-AMD Project Datasets, investigators along with their institutions will have to certify their agreement with the requirements and terms of access detailed below. It is the intent of the NEI Data Access Committee (NEI DAC) that Approved Users of NEI-AMD Project Datasets should recognize and accept the limitations imposed by the original informed consent agreements of NEI-AMD.

To promote the responsible use of the NEI-AMD Project Datasets, all investigators and their institutions seeking access to NEI-AMD Project Datasets shall acknowledge their agreement with the Policies and Procedures that 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 this document are found in the NEI-AMD 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 NEI-AMD Project Dataset(s) as described in this Data Use Certification document.

2. Research Use

The Requestor agrees that he/she shall use the NEI-AMD Project Dataset(s) for appropriate research uses and will adhere to any limitations on such use in accordance with the parameters described in this Data Use Certification document. 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.

In this spirit, it is expected that NEI-AMD data and conclusions derived 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.

It is anticipated that, at least in some cases, the NEI-AMD Project Dataset(s) 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 NEI-AMD Project Dataset(s).

3. Non-Identification

The Requestor agrees not to use NEI-AMD Project Datasets, or any other information, to identify or contact individual participants from whom phenotype data and DNA samples were collected. (This condition is not applicable to Contributing Study Investigators who provided the phenotypic data and genetic samples used to generate the NEI-AMD Project Dataset(s), if they have appropriate institutional approval to retain the participant identities or re-contact participants.)

4. 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 independent collaborating investigators who also agree to the terms within this Data Use Certification, subject to applicable law. The Requestor and his/her 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 NEI/NIH Policies and Procedures and the terms of access will be required.

5. Intellectual Property

By requesting access to NEI-AMD Project Dataset(s), the Requestor and his/her home organization (Requesting Institution) acknowledge the intent of the NEI to see that Approved Users follow the NIH Intellectual Property (IP) policy as outlined below:

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

The NEI DAC 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.

6. Research Reporting

While NEI 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 phenotypic data and genetic samples that were the basis for the NEI-AMD Project Dataset(s).

The Requestor agrees to submit an annual report that includes manuscripts submitted for publication and a description of any violations of the terms of controlled access involving the NEI-AMD Project Datasets.

7. Data Access Renewal Period

Initial access is granted for one-year from the date of the Data Access Committee approval. Automatic renewal is coincident with the submission of the annual report described in Section 6.

8. Dissemination of Research Results and Acknowledgment of NEI-AMD

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

The Requestor agrees to acknowledge NEI and the NEI-AMD Research Group in all oral and written presentations, disclosures, and publications resulting from any analyses of the NEI-AMD Project Dataset(s). The Requestor further agrees that the acknowledgment shall include 1) a reference to the specific version of the NEI-AMD Project Dataset(s) analyzed and 2) an acknowledgement.

A sample statement to be used in acknowledgments is:
"The dataset(s) used for the analyses described in this manuscript were obtained fromfrom the NEI Study of Age-Related Macular Degeneration (NEI-AMD) Database found at [insert URL] through dbGaP accession number [XXX]. Funding support for NEI-AMD was provided by the National Eye Institute. We would like to thank NEI-AMD participants and the NEI-AMD Research Group for their valuable contribution to this research."

9. 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 NEI-AMD Project Dataset(s), the TES Research Group does not and cannot warrant the results that may be obtained by using any data included therein. The NEI-AMD Research Group disclaims all warranties as to the accuracy of the data in the NEI-AMD project dataset(s) or the acceptable 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.

By signing and dating this Data Use Certification, the Requestor and his/her Institutional Official represent and warrant the Requestor's qualifications for access to and use of NEI-AMD Project Dataset(s) and certify their agreement to the NEI-AMD principles, policies and procedures for the use of NEI-AMD Project Datasets as articulated in this document. Requesting investigators further acknowledge that they have shared this document and the NEI-AMD policies and procedures with any research staff that will participate in the use of the NEI-AMD Project Dataset(s). Institutional Business Officials also acknowledge that they have shared this document and the relevant NEI-AMD 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. The NEI Study of Age-related Macular Degeneration (NEI-AMD) is major NEI-funded collaborative research projects designed to improve our understanding of the genetic bases of age-related macular degeneration. The dbGap database consists of over 2500subjects with these measurements and genotyping data.

2. Contributing Study Investigators: The NEI-AMD Study Investigators who collected the phenotypic data and genetic samples genotyped for the dbGaP. These investigators are listed on the research group websites.

3. NEI-AMD Project Dataset: contains the AMD genotype data and the relevant phenotype and exposure data of over 2500 participants. This resource is managed for NEI-AMD by the National Center for Biotechnology. Included are descriptive information about NEI_AMD and the user interface for accessing these data.

4. Approved Users: Research investigators who have submitted a request to access NEI-AMD Project Dataset through the completion of a Data Use Certification (Put link here.) document. The Data Use Certification requires 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 NEI-AMD Project Dataset and certify their agreement to the policies, and procedures for the use of the NEI-AMD Project Dataset as articulated in that document.

5. 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 NEI 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 NEI DAC notification, the Requester, through the PI and the Institutional Signing Official, agree to submit to the NEI 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:
NEI Data Access Committee URGENT: neidac@nei.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 NEI 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.