

Instructions for Principal Investigators Requesting Authorized Access to NIAGADS Datasets

Last revised 4/11/2023

Principal investigators (PIs) seeking access to NIAGADS datasets are urged to review the following information before initiating a data access request. By signing and appending the [Data Use Certification Document](#) it is understood that the Principal Investigator and the Institution will abide by the policies and standards set forth in that document.

All documents including the Data Use Certification Document and those listed below should be uploaded in PDF format to www.niagads.org/data/request. Any questions may be directed to the NIAGADS Data Access Administrator at niagads@penntestmed.upenn.edu. <https://grants.nih.gov/grants/guide/notice-files/notod-14-124.html>

1. **Minimum Qualifications to Submit a NIAGADS Project Request as a Investigator.** Investigators must be permanent employees of their institution at a level equivalent to a tenure-track professor or senior scientist with responsibilities that most likely include laboratory administration and oversight. Laboratory staff and trainees such as graduate students, and postdoctoral fellows are not permitted to submit project requests.
2. **Supplemental Documentation.** *The following four (4) REQUIRED documents must be uploaded with the pdf file during the NIAGADS application process in order for the Data Access Request to be considered complete.*
 - **IRB approval in compliance with the [NIH Genomics Data Sharing Policy \(GDS\)](#).** The Investigator must submit a current IRB approval for the proposed project that will use NIAGADS data.
 - **Derived/Secondary Data Return Plan.** The Investigator must describe the derived/secondary data that will be returned to the NIA Genetics of Alzheimer's Disease Data Storage Site (NIAGADS): see [Sample-Data-Return-NIAGADS \(WORD\)](#).
 - **National Institute of Aging (NIA) Genomic Data Sharing Plan.** This document must be signed by the Investigator and his/her Institutional Signing Official: see [NIA Genomics Sharing Policy](#).
 - **The NIAGADS Data Distribution Agreement.** This document must be signed by the Investigator and his/her Institutional Signing Official: see [NIAGADS-DDA \(PDF\)](#).

NOTE: All documents related to the application should be provided in English. For institutions where English is not the primary language, please provide translations of documents along with the original document. Translated documents should be signed by the institutional

signing official.

3. **Accessing Additional Datasets After Initial Approval.** Investigators who would like to access additional dataset(s) for use in an existing approved project should (1) revise the existing approved project request to include the new datasets and (2) update the Research Use Statement as appropriate. Investigators do not need to submit a new project request unless the dataset will be used for research outside of the scope of the approved Research Use Statement.

4. **Collection of Principal Investigator, Institutional and Contact Information.** Contact information for PIs and their institutions will be provided in the Biographical sketch. See: <https://grants.nih.gov/grants/forms/biosketch.htm> for the template and additional information.

5. **Small or Recently Established Institutions.** Investigators from a small or newly established organization may be asked for additional information and documentation, such as a curriculum vitae, basic institutional information, and an information technology (IT) security plan. These documents are used by NIH to gauge the requestor's ability to comply with the expectations outlined in the NIH Security Best Practices for Controlled-Access Data Subject to the Genomic Data Sharing (GDS) Policy and [GDS Policy](#).

6. **Research Use Statement.** The approval of project requests depends primarily on a carefully written Research Use Statement (2,200 characters max): see [Research-Use-Template.doc](#). The statement should include the following components:
 - Objectives of the proposed research;
 - Study design;
 - Analysis plan, including the phenotypic characteristics that will be evaluated in association with genetic variants;
 Further project information will be gathered in the [Supplemental-Information.pdf](#) form.
 - Explanation of how the proposed research is consistent with the data use limitations for the requested dataset(s); and
 - Brief description of any planned collaboration with researchers at other institutions, including the name of the collaborator(s) and their institution(s).

Important!

- Research should not deviate from the description in the approved Research Use Statement.
- To expand the scope of a project after approval, investigators must submit a revised Research Use Statement for approval.
- Conducting research not described in the Research Use Statement is a violation of the terms in the Data Use Certification agreement, which may lead to termination of data access and other penalties.

The NIAGADS Data Use Committee will review the Research Use Statement to confirm that the proposed research is consistent with all applicable data use limitations for the

requested dataset(s).

An inconsistency between the proposed research and the applicable data use limitations, or insufficient detail to make this determination, is the most common reason for data requests to be rejected.

Tips for drafting a successful Research Use Statement:

*Tip: Prepare and save the Research Use Statement, Cloud Use Statement, if applicable, and the non-technical summary in a word processing application. **Note:** There is a 2,200 character limit (including spaces) for the Research Use Statement.*

- For projects that aim to evaluate phenotypic characteristics that were not the primary focus of the original study (e.g., the project proposes creating a new outcome variable from existing variables in the original study), explain how the use of the phenotypic characteristics are consistent with the data use limitations for the requested dataset(s).
- For projects that intend to use the dataset(s) to develop or evaluate performance of new analytical methods, include a sentence indicating how this work is relevant to the specific disease dataset(s) being studied, such as “This methodological work will advance the understanding of the genetic bases of strabismus, cranial nerve abnormalities, and associated disorders.”
- Special care should be taken when requesting datasets from more than one study in NIAGADS.
 - Clarify whether datasets will be combined (with NIAGADS or other sources) or analyzed separately for your analyses.
 - Describe the outcome variables proposed for the project and explain how their use is consistent with any data use limitations for each of the requested datasets.

7. Cloud Use Statement and Cloud Servicer Provider Information (if applicable).

Investigators who wish to use cloud computing for storage and analysis of NIAGADS data will need to indicate in their Data Access Request (DAR) that they are requesting permission to use cloud computing and identify the cloud service provider or providers that will be employed. They also will need to describe how the cloud computing service will be used to carry out their proposed research: see [Supplemental-Information.pdf](#).

8. **Non-Technical Summary.** As part of the project request, investigators will provide a non-technical summary of their proposed research. If the project is approved, this statement will be publicly available for lay audiences to read the purpose and objectives of the research: see

Non-technical summaries must be no more than 1,100 characters (including spaces).

[Research-Use-Statement-Template.doc](#).

For External Collaborations:

To share NIAGADS data with collaborators outside of the PI's institution, the collaborators must submit a project request with (1) the same project title and (2) a Research Use Statement and Cloud Use Statement, if applicable, that references the collaboration (for smaller collaborations, the name and institution of the collaborating PI(s) or for larger efforts, the consortium name).

9. **Staff and Collaborator Contact Information.**

Provide the full legal names and contact information for internal collaborators (i.e., those employed at the PI's institution, but not directly supervised by the PI). Trainees and staff directly supervised by the PI, such as graduate students, postdoctoral fellows, and technicians, do not need to be listed on the project request. External collaborators should be listed in the external collaborator(s) section of the project request applications. Data exchange between all collaborators must be consistent with the NIH Security Best Practices for Controlled-Access Data Subject to the Genomic Data Sharing (GDS) Policy and [GDS Policy](#): see [Supplemental-Information.pdf](#).

10. **Information Technology (IT) Director Contact Information.** Provide the full legal name and contact information for the IT Director, who is expected to be a senior IT official with the necessary expertise and authority to affirm the IT capacities at an academic institution, company, or other research entity. The IT Director is expected to have the authority and capacity to ensure that the NIH Security Best Practices for Controlled- Access Data Subject to the NIH GDS Policy and the institution's IT security requirements and policies are followed by the Approved Users: see [Supplemental-Information.pdf](#).