APPLICATION INSTRUCTIONS

Questions? Email: niagads@pennmedicine.upenn.edu.

This page contains information about the process and documentation necessary to submit a Data Access Request (DAR). For step-by-step user instructions on navigating the Data Access Request Management (DARM) system, please visit https://dss.niagads.org/documentation/using-the-darm/pi-user-guide/.

Prerequisites for submitting an application:

- **Investigators qualifications for initiating an application.** Investigators must be permanent employees of their institution at a level equivalent to a full-time assistant, associate, or full professor 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.
- **Authentication.** Submitting Investigators and their Institutional Signing Official must have an eRA Commons ID in order to log into the DSS. The Signing Official's eRA Commons ID is needed in order to submit the application on the investigator's behalf.

Additional Third Party Authentication:
Some datasets require additional approval from the original submitting study in order to access the data through NIAGADS DSS. For additional information, navigate to the Third-Party Access page.

Required Supplemental Documents:

The following are to be uploaded with your Data Access Request submission:

1. **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 DSS data. In order to be considered current, the IRB letter must have at least six months remaining before it expires.
2. **IRB Protocol** that was submitted to the Investigator's institutional IRB.
3. **The NIAGADS Data Distribution Agreement**. This document must be signed by the Investigator and his/her Institutional Signing Official: see **NIAGADS DDA**.
4. **National Institute of Aging (NIA) Genomic Data Sharing Plan.** This document must be signed by the Investigator and his/her Institutional Signing Official: see **Alzheimer's Disease Genomics Sharing Plan**.

The following is to be sent to NIAGADS via email:

1. **Data Transfer Agreement (DTA)**. The DTA should be sent to NIAGADS via email in parallel to the submission of your DAR. Please note that a DTA will need to be filled out and submitted to NIAGADS each time a new project is submitted. The Principal Investigator is responsible for ensuring that all lab personnel with access to the data distributed by NIAGADS DSS sign the DTA. This includes all individuals (investigators, trainees, staff, graduate students, postdoctoral fellows, technicians, and internal collaborators). Each time a new lab member is hired or will access the data, a DTA Amendment will need to be filled out and submitted to University of Pennsylvania for countersignature. If multiple lab members are added at different time points, the amendment will need to be re-submitted each time.

   Please email the signed DTA and amendment, if necessary, to niagads@pennmedicine.upenn.edu for University of Pennsylvania to countersign. NOTE: it must include your proposed research use statement as well as the project title and DAR ID generated after submission: see NIAGADS DTA. Principal Investigators from the University of Pennsylvania will need to submit a Personnel Data Protection Agreement in place of the DTA. The same conditions of the DTA apply to this document.

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.*

External Collaborations:

Investigators can share data with collaborators outside of the PI's institution. The collaborators must submit parallel project requests with (1) the same project title and (2) the same 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). 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.

Data Access Request Management (DARM) System Instructions

1. **Log into the Data Access Request Management (DARM) system by going to** http://dss.niagads.org/login.

2. **Basic Project Information and Principal Investigator Information**. Provide the project name, institutional affiliation, and Signing Official's eRA commons ID. In the next section, provide your contact information (full legal name, position, organization, department, email address, phone number, etc.)

3. **Signing Official Contact Information.** A Signing Official (SO) has institutional authority

to legally bind the institution in grants administration matters. The individual fulfilling this

role may have any number of titles in the grantee organization. The label, "Signing Official," is used in conjunction with the NIH eRA Commons. For most institutions, the SO is located in its Office of Sponsored Research or equivalent.

4. **Information Technology (IT) Director Contact Information.** 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.

5. **Research Use Statement (RUS).** The statement should include the following components (2,200 characters max):
   - Objectives of the proposed research;
   - Study design;
   - Analysis plan, including the phenotypic characteristics that will be evaluated in association with genetic variants;
   - If applicable, a brief description of any planned collaboration with researchers at other institutions, including the name of the collaborator(s) and their institutions(s).

   The NIAGADS ADRD Data Access Committee (NADAC) will review the RUS to confirm that the proposed research is consistent with all applicable data use limitations for the requested dataset(s).

6. **Non-Technical Summary.** This non-technical summary of your proposed research plan will be made publicly available for lay audiences to read (1,100 characters max).

7. **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. Investigators must return data to NIAGADS either immediately upon acceptance of journal publication or patent application submission, or at the end of the data access agreement, whichever is earlier.

8. **Cloud Use Statement and Cloud Server Provider Information (if applicable).** NIH notice of Cloud Computing- Investigators who wish to use cloud computing for storage and analysis 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, if applicable.

9. **External Collaborator Contact Information.** An external collaborator is a collaborator of the PI on this DAR who is not employed at the PI's institution and has submitted a parallel application as described above. The external collaborator's names and institution must be provided here.

10. **Data Use Certification.** By checking the box under this section, you are agreeing to the terms outlined in the Data Use Certification.