Institutional Certification for Alzheimer's Disease and Related Dementias (ADRD) Studies*

This document has been adapted from the NIH Genomic Data Sharing Policy's Institutional Certification document for the purposes of sharing data from ADRD studies.

Date: _____ [MM/DD/YYYY]
Name of GPA: Karyn N. Onyeneho, Ph.D., M.S.
NIAGADS Data Access Committee Chair, NIA, NIH, DHHS
7201 Wisconsin Avenue
Gateway Room 2S600
Bethesda, MD 20814

Re: Institutional Certification of _____ [NAME OF INSTITUTION] to Accompany Submission of the Dataset from _____ [ORIGINAL STUDY NAME[1]] for _____ [PROJECT TITLE FOR DATA TO BE SUBMITTED] to an NIH-designated data repository.

Dear Karyn N. Onyeneho,

The submission of data to the NIH-designated data repository is being made with institutional approval from _____, along with appropriate institutional approvals from collaborating sites, as listed on the next page.

The _____ hereby assures that submission of data from the study entitled _____ to an NIH-designated data repository meets the following expectations, as defined in the NIH Genomic Data Sharing Policy:

- The data submission is consistent, as appropriate, with applicable national, tribal, and state laws and regulations as well as relevant institutional policies.
- Any limitations on the research use of the data, as expressed in the informed consent documents, are delineated in the table on page 3.
- The identities of research participants will not be disclosed to NIH-designated data repositories.
- An Institutional Review Board and/or Privacy Board, and/or equivalent body, as applicable, has reviewed the investigator's proposal for data submission and assures that:
  - The protocol for the collection of genomic and phenotypic data is consistent with 45 CFR Part 46.[2]
  - Data submission and subsequent data sharing for research purposes are not inconsistent with the informed consent of study participants from whom the data were obtained;
  - Consideration was given to risks to individual participants and their families associated with data submitted to NIH-designated data repositories and subsequent sharing, including unrestricted access to genomic summary results;
  - To the extent relevant and possible, consideration was given to risks to groups or populations associated with submitting data to NIH-designated data repositories and subsequent sharing, including unrestricted access to genomic summary results; and
  - The investigator's plan for de-identifying datasets is consistent with the standards outlined in the NIH Genomic Data Sharing Policy (see section IV.C.1.).

The individual –level data are to be made available through (check one)

☐ **controlled-access**[3]

☐ **unrestricted access** [4]

If **unrestricted access** is marked, the data use limitations table on the following page(s) does not need to be completed.

NIH provides genomic summary results[5] (GSR) from most studies submitted to NIH-designated data repositories through unrestricted access. However, data from data sets considered to have particular 'sensitivities' related to individual privacy or potential for group harm (e.g., those with populations from isolated geographic regions, or with rare potentially stigmatizing traits) may be designated as "sensitive" by _____.

In such cases, "controlled-access" should be checked below and a brief explanation for the sensitive designation should be provided. GSR from any such data sets will only be available through controlled-access.

The genomic summary results (GSR) from this study are only to be made available though
☐ **controlled-access.**

Explanation if controlled-access was selected for GSR:

Institutional Certification

NIH expects the submitting institution(s) to select one of the three standard Data Use Limitations (DULs) for appropriate secondary use, or, if necessary, create a customized DUL. DULs are developed based on the original informed consent of the participant(s).

Data Use Limitations

General Research Use	GRU	Use of the data is limited only by the terms of the Data Use Certification.
Health/Medical/Biomedical	HMB	Use of the data is limited to health/medical/biomedical purposes, does not include the study of population origins or ancestry.
Disease-specific [list disease]	DS	Use of the data must be related to the specified disease.
Other		[ENTER CUSTOMIZED TEXT, IF APPLICABLE]

Additional modifiers to the standard DULs (e.g., Not-for-profit Use Only) can be indicated, if appropriate. Use of the modifiers should have a basis in the informed consent from the participants or in special knowledge of the preferences of the original study population.

Data Use Limitation Modifiers

IRB approval required	IRB	Requestor must provide documentation of local IRB approval.
Publication required	PUB	Requestor agrees to make results of studies using the data available to the larger scientific community.
Collaboration required	COL	Requestor must provide a letter of collaboration with the primary study investigator(s).
Not-for-profit use only	NPU	Use of the data is limited to not-for-profit organizations.
Methods	MDS	Use of the data includes methods development research (e.g., development of software or algorithms)
Genetic studies only	GSO	Use of the data is limited to genetic studies only.

Using the tables above, please indicate in the form below the consent group(s) for each collaborating study site. Use one row per consent group.

Collaborating Site Name	**Data Use Limitation**	**Data Use Limitation Modifiers (optional)**
Eg: Cohort for Alzheimer's disease	HMB	IRB
Eg: Cohort for Alzheimer's disease	Disease-specific [Neurological disorders]	IRB, NPU

Sincerely,

Investigator:

Name: _____ Title: _____

Signature: _____ Date: _____

Institutional Signing Official:[6]

By signing below, I certify on behalf of _____ that, in addition to myself, an IRB or Privacy Board or equivalent body, as applicable, and other relevant senior-level institutional staff (e.g., Dean, Vice President/Provost for Research, Chief Science Officer) have reviewed the requirements in this certification and agree that the submission meets them.

Name: _____ Title: _____

Signature: _____ Date: _____

References

1. Original Study Name should reflect the name of the original IRB-approved study (e.g. cohort or case-control study, clinical trial) under which participants provided informed consent and biospecimens were collected (e.g., Nurses' Health Study, Framingham Heart Study).
2. 45 CFR Part 46. Protection of Human Subjects. See http://www.gpo.gov/fdsys/pkg/CFR-2013-title45-vol1/xml/CFR-2013title45-vol1-part46.xml
3. Data made available for secondary research only after investigators have obtained approval from NIH to use the requested data for a particular project.
4. Data made publicly available to anyone.
5. Genomic summary results are results from primary analyses of genomic research that convey information relevant to genomic associations with traits or diseases across datasets rather than data specific to any one individual research participant (e.g., genotype counts and frequencies; allele counts and frequencies; effect size estimates and standard errors; likelihoods; and p-values).
6. Under the NIH Genomic Data Sharing Policy, an Institutional Signing Official is generally a senior official at an institution who is credentialed through the NIH eRA Common system and is authorized to enter the institution into a legally binding contract and sign on behalf of an investigator who has submitted data or a data access request to NIH.