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

Date: _____ [MM/DD/YYYY]
Name of GPA: Jean Tiong-Koehler, Ph.D.
NIAGADS Program Administrator, NIA, NIH, DHHS
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.

To the National Institute on Aging Genetics of Alzheimer's Disease Data Storage Site (NIAGADS)):

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 the 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 (GDS) Policy:

- The data submission is consistent, as appropriate, with all 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 for Institutional Certification Data Use Limitations (DUL) in this document.
- The identities of research participants will not be disclosed to NIH-designated data repositories.
- An Institutional Review Board (IRB), 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 sharing through, NIH-designated data repositories for research purposes are consistent 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 data 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 data submitted to NIH-designated data repositories and subsequent sharing, including unrestricted access to genomic summary results; and
  - The investigator's plan for de-identifying the dataset(s) is consistent with the standards outlined in the NIH Genomic Data Sharing (GDS) Policy (See section IV.C.1).

---

* Certification must be provided for all sites contributing samples. If more than one site is contributing samples, the primary site may submit one Institutional Certification indicating that they are providing certification on behalf of all collaborating sites. Alternatively, each site providing samples may provide its own Institutional Certification.

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

Availability of Individual-Level Human Data

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.

Is the individual-level, human data to be submitted funded in whole or in part by NIH?

☐ **Yes** ☐ **No**

Is the individual-level, human data to be submitted covered by a CoC?

☐ **Yes** ☐ **No**

IMPORTANT: If your research involves the generation of individual-level, human genomic data and is funded in whole or in part by NIH, your research is automatically deemed to be issued by a Certificate of Confidentiality (CoC). For more information, see the NIH Certificates of Confidentiality webpage.

Does the information to be submitted include **identifiable, sensitive information?**

☐ **Yes** ☐ **No**

IMPORTANT: Research in which identifiable, sensitive information is collected or used includes research that:

- Meets the definition of human subjects' research as defined in the Federal Policy for the Protection of Human Subjects (45 CFR 46), including exempt research except for human subjects research in which participant information cannot be identified or their identity cannot readily be ascertained, directly or through identifiers;
- Is collecting or using human biospecimens that are identifiable or that have at least a very small risk of being used to deduce the identity of an individual;
- Involves the generation or use of individual level human genomic data from biospecimens, regardless of identifiability; or
- Involves any other information where there is at least a very small risk that a person could be identified.

Is the identifiable, sensitive information to be submitted covered by a CoC?

☐ **Yes** ☐ **No**

IMPORTANT: Note that research subject to the NIH Certificates of Confidentiality Policy that involves the generation, collection, or use of identifiable, sensitive information that is funded in whole or in part by NIH is automatically deemed to be issued a Certificate of Confidentiality (CoC). For more information, see the NIH Certificates of Confidentiality webpage.

Availability of Genomic Summary Results

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 _____ and public posting would be prohibited.

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

☐ **Controlled Access**

If "controlled access" is checked, include a brief explanation for the sensitive designation:

Institutional Certification Data Use Limitations (DUL)

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

SIGNATURE PAGE FOR THIS INSTITUTIONAL CERTIFICATION

SUBMITTED AND AGREED TO BY:

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-2013http://www.gpo.gov/fdsys/pkg/CFR-2013-title45-vol1/xml/CFR-2013-title45-vol1-part46.xmltitle45-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. For the purposes of the NIH GDS Policy, GSR are defined to include those provided by a study's investigator, if any, as well as summary statistics that may be computed by relevant NIH-designated data repository across all non-"sensitive" studies with data included in that repository. GSR include systematically computed statistics such as, but not limited to: 1) frequency information (e.g., genotype counts and frequencies, or allele counts and frequencies); and 2) association information (e.g., effect size estimates and standard errors, and p-values). (NOT-OD-19-023)
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 the institution and an investigator who has submitted data or a data access request to NIH.