<https://www.nia.nih.gov/research/dn/alzheimers-disease-genomics-sharing-plan>

## Alzheimer's Disease Genomics Sharing Plan

[**NIA Policies and Guidance for Sharing of Resources and Data From Studies on the Genomics of Alzheimer's Disease**](https://www.nia.nih.gov/sites/default/files/nia_ad_gsp_fnl_2_posted_2_27_15.doc) (MS Word, 92K)

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### Background

The National Institutes of Health (NIH) advocates making available to the public the results and accomplishments of the activities that it funds. NIH assures that research resources developed with public funds become readily available to the broader research community in a timely manner for further research, development, application, and secondary data analysis in the expectation that this will lead to products and knowledge of benefit to the public health. Resources arising from NIH-funded research that are expected to be shared include data, biological materials, and pertinent methods of analysis. As an Institute of the NIH, the National Institute on Aging (NIA) follows the NIH policy that whenever possible research resources be made available to qualified investigators in a timely manner.

On August 27, 2014 NIH released the [NIH Genomic Data Sharing Policy](http://gds.nih.gov/03policy2.html) that promotes sharing, for research purposes, of large-scale human and non-human Genomic Data generated from NIH-funded research. Please see the NIH policy statement at the website for specific information on policy implementation. In addition, NIA supports infrastructure and related policies to facilitate data and sample sharing arising from its Alzheimer’s Disease (AD) Genetics Initiative, a research initiative to assist in the identification of the risk and protective factor genes/loci for Alzheimer’s disease.

#### NIA Funded Infrastructure Supporting Alzheimer’s Disease Sample Sharing

The NIA [National Cell Repository for Alzheimer’s Disease (NCRAD](http://www.ncrad.org)), currently at Indiana University, invites investigators to use this resource for AD sample sharing. More information can be obtained from the website or through an NIA Division of Neuroscience program official. A "NCRAD Executive Committee" (NEC) provides guidance to NCRAD, the coordinator of the NIA Genetics Initiative, NCRAD staff, and NIA staff who have jointly established: 1]. eligibility criteria, 2]. guidance on protection of human subjects, confidentiality, and compliance with relevant laws and regulations, and 3]. operating procedures for the sharing of biological samples and Associated Phenotypic Data.

NCRAD is a national repository established to facilitate access by qualified investigators to samples from well phenotyped cases and controls, and longitudinally followed, multiply affected families along with Associated Phenotypic Data for the study of the genomics of late onset Alzheimer’s disease.

#### NIA Funded Infrastructure Supporting Alzheimer’s Disease Genomic Data Sharing

The [National Institute on Aging Genetics of Alzheimer’s Disease Data Storage Site (NIAGADS)](https://www.niagads.org/), currently at the University of Pennsylvania, is a national genomics data repository established in order to facilitate access by qualified investigators to genotypic data for the study of the genomics of Alzheimer’s disease. NIAGADS along with other NIA approved sites will make these Genomic Data and Associated Phenotypic Data available to qualified investigators in the scientific community for secondary analysis in accordance with standards established by the NIA.

#### The Alzheimer’s Disease Sequencing Project

An initiative called the [“Alzheimer's Disease Sequencing Project” (ADSP)](https://www.niagads.org/adsp/content/home) that moves the field closer to achieving National Alzheimer’s Project Act (NAPA)” and  [Public Law 111-375](https://www.congress.gov/111/plaws/publ375/PLAW-111publ375.pdf) goals was launched in 2012. The overarching goals of the ADSP are to: identify new genomic variants contributing to increased risk of developing Late-Onset Alzheimer's Disease (LOAD); identify new genomic variants contributing to protection against developing Alzheimer's Disease; provide insight as to why individuals with known risk factor variants escape from developing Alzheimer’s disease; and examine these factors in multi-ethnic populations as applicable in order to identify new pathways for disease prevention. NIA recently updated the definition of Alzheimer’s Disease to include Alzheimer’s Disease Related Dementias ([NOT-AG-17-007l](https://grants.nih.gov/grants/guide/notice-files/NOT-AG-17-007.html)).

ADSP phenotype and genetic data are made available to the research community at large immediately after quality control checks and variant calls are completed ([NOT-AG-16-033](https://grants.nih.gov/grants/guide/notice-files/NOT-AG-16-033.html)). NIAGADS is the Data Coordinating Center for the ADSP. ADSP phenotype and genetic data are made available to the research community through NIAGADS.

### Definition of the Policies and Guidance for Sharing of Resources and Data from Studies on the Genomics of Alzheimer’s Disease

The “NIA Policy for Sharing of Resources and Data from Studies on the Genomics of Alzheimer’s Disease” is a revision of the “NIA Policies and Guidance for Sharing of Resources and Data from Studies on the Genetics of Alzheimer's Disease,” last revised 1/24/2008. “The NIA Policy for Sharing of Resources and Data from Studies on the Genomics of Alzheimer’s Disease” is now referred to as the “**NIA AD Genomics Sharing Policy**.” The NIA AD Genomics Policy continues the [NIA AD Genetics Sharing Policy](https://www.nia.nih.gov/research/dea/alzheimers-disease-genomics-sharing-plan) for existing awards. As for the previous policy, the NIA AD Genomics Sharing Policy applies to NIH funded studies in the area of the genomics and genetics of Alzheimer’s disease.

The NIA AD Genomics Sharing Policy applies to all NIA-funded large scale Alzheimer’s disease genetic and genomic research as defined in the NIH Genomic Data Sharing Policy. As for the NIH Genomic Data Sharing Policy, in certain instances NIA may expect submission of data from smaller scale research projects in the area of the genetics and genomics of Alzheimer’s disease based on the state of the science, the NIA’s programmatic priorities, and the utility of the data for the research community.

### How to Comply With the NIA AD Genomics Data Sharing Policy

It is expected that Genomic Data obtained by genomic methods and “Associated Phenotypic Data” will be made available as soon as possible, in accordance with the NIH Genomics Data Sharing Policy (see the [supplemental table](http://gds.nih.gov/PDF/Supplemental_Info_GDS_Policy.pdf), PDF, 59K). “Associated Phenotypic Data” is defined as de-identified data on family structure, age, sex, vital status, psychopathology, diagnosis, and other clinically relevant associated phenotypic information, stripped of all personal identifiers and thus with no reasonable chance of being linked to the individuals from whom they were obtained.

Confirmation of Institutional Review Board (IRB) approval and Institutional Certification for sharing AD Genomic Data as defined in the NIH Genomics Data Sharing Policy should be provided to NIA prior to award. NIA will typically review compliance with Genomic Data sharing plans at the time of the annual progress report or other appropriate scientific review.

#### Sample Sharing

It is the expectation of the NIA that biological samples and Associated Phenotypic Data for the genomics of late onset Alzheimer’s disease be deposited at NCRAD**.**Qualified investigators will be able to use biological samples and Associated Phenotypic Data supplied by NCRAD. Application for use will be made directly to NCRAD.

Sharing of biological samples, Associated Phenotypic Data, and resources through NCRAD may be accomplished by contacting NCRAD staff at <https://www.ncrad.org/apply_to_bank.html> and following the application process defined at the website for transferring biological samples to NCRAD. NIA requests a copy of any pre-existing Material Transfer Agreements (MTAs) that apply to the samples associated with each award. Existing MTAs may be electronically mailed to the NIA program official responsible for the award along with the signed sharing plan agreement. For AD biological sample sharing, the NIA AD Genomics Data Sharing Policy follows the NIH Genomics Data Sharing Policy with respect to informed consent and local advisory board/institutional review board (IRB) approval.

Sharing of biological samples and Associated Phenotypic Data between qualified investigators (other than through NCRAD) may be accomplished, if consistent with applicable law and institutional policy, via a Material Transfer Agreement like that described at <https://www.ott.nih.gov/resources>.

Whether stored at NCRAD or at the grantee Institution, biological samples along with relevant subsets of Associated Phenotypic Data should be available for release to qualified investigators no later than within one year of the completion of the funded project period for the parent award or upon acceptance of a subset of data for publication, or public disclosure of a submitted patent application, whichever is earlier, even if a competing renewal application is submitted**.** For biological samples and for Associated Phenotypic Data, a record of requests for data and biological specimens including relevant names and Institutions, and the action taken on them should be documented and retained by the investigator and reported with the annual progress report for the non-competitive renewal of the funded award as well as in the final progress report.

#### Data Sharing

It is the policy of the NIA that all Genomic Data derived from NIA funded studies for the genomics of late onset Alzheimer’s disease, including secondary analysis data, be deposited at the NIA’s central genomic data repository, [NIAGADS](https://www.niagads.org/) or another NIA approved site or both whenever possible**.** It is expected that investigators applying for data derived by the ADSP will follow the process to comply with the AD Genomics Data Sharing Policy.

### Additional Resources

Please consult the web pages cited below for information related to sharing policies and patent issues:

* [The NIA home page](https://www.nia.nih.gov/).
* [The NCARD website at Indiana University](https://ncrad.iu.edu/)
* [The National Institute on Aging Genetics of Alzheimer’s Disease Data Storage Site (NIAGADS) at the University of Pennsylvania](http://www.niageneticsdata.org/)
* [The NIH Genomic Data Sharing Policy](http://gds.nih.gov/03policy2.html)
* [The NIH Data sharing website](http://grants.nih.gov/grants/policy/data_sharing/index.htm)
* [The NIH GWAS page](http://grants.nih.gov/grants/gwas/index.htm).
* [The dbGaP website](http://www.ncbi.nlm.nih.gov/sites/entrez?db=gap).
* [The NIH Grants Policy Statement](http://grants.nih.gov/grants/policy/nihgps_2013/)
* [The sharing of data for awards that exceed $500,000 direct costs in any one year of funding](http://grants2.nih.gov/grants/policy/data_sharing/).
* [Final NIH Statement on Sharing Research Data](http://grants.nih.gov/grants/guide/notice-files/NOT-OD-03-032.html).
* [The sharing of research resources and intellectual property for research purposes to qualified individuals within the scientific community in accordance with the NIH Grants Policy Statement](http://grants2.nih.gov/grants/intell-property.htm).

These sites provide documents that define terms, parties, and responsibilities for sharing; prescribe the order of disposition of rights; prescribe a chronology of reporting requirements; and delineate the basis for and extent of government actions to retain rights.

[Principles and Guidelines for Recipients of NIH Research Grants and Contracts on Obtaining and Disseminating Biomedical Research Resources: Final Notice](http://grants.nih.gov/grants/intell-property_64FR72090.pdf) (PDF, 150K) Federal Register / Vol. 64, No. 246

"[Public Health Service Policy Relating to Distribution of Unique Research Resources Produced with PHS Funding](http://grants2.nih.gov/grants/guide/notice-files/not96-184.html)" was published in the NIH GUIDE, Volume 25, Number 23 (1996).

### Expectations for the Content of AD Genomics Sharing Plan

The document below sets forth the expectations for a sharing plan which upon submission to the NIA, and acceptance by NIA, would be incorporated into the terms and conditions placed on the Notice of Grant Award (NGA). The NIA program official responsible for this project will work with the Principal Investigator during the process of instituting the sharing plan. Please return a signed copy of a document that addresses all of the terms shown below within 15 calendar days of receipt of this communication.

#### Guidance for Sharing of Resources and Data from Studies on the Genomics of Alzheimer’s Disease

Grant/Contract number:

Grant/Contract Title:

Principal Investigator:

Date of Notice of Grant Award:

Program Official:

### Alzheimer’s Disease Genomic Sample Sharing

1. The Principal Investigator agrees to maintain biological samples, including but not exclusive to: DNA and/or cell lines; and/or cerebrospinal fluid (CSF); and/or RNA; and Associated Phenotypic Data at his/her parent Institution. The Principal Investigator agrees that the names and Institutions of persons either given or denied access to the biological materials and Associated Phenotypic Data, and the basis for decisions will be summarized in the annual progress report of the non-competitive renewal for each year of award. If the NIA determines in the future that there is scientific benefit to maintain biological samples at an NIA approved repository, the Principal Investigator agrees that s/he will deposit biological samples and Associated Phenotypic Data at an NIA approved repository. Should it be determined that samples will be deposited at NCRAD, then the Principal Investigator agrees that following review of protocols and acceptance by NCRAD, s/he will deposit biological samples and Associated Phenotypic Data at NCRAD.
2. The Principal Investigator agrees that biological samples along with relevant subsets of Associated Phenotypic Data, as well as Genomic Data resulting from the research will be available for release to qualified investigators as soon as possible, but no later than within one year of the completion of the funded project period for the parent award or upon acceptance of a subset of data for publication, or public disclosure of a submitted patent application, whichever is earlier, even if a competing renewal application is submitted.
   * + 1. The Principal Investigator agrees that in the case of biological samples that are in limited supply, a local committee will help to determine which investigators will have access to these samples and Associated Phenotypic Data. The Principal Investigator further agrees that the local committee will be established through his/her Institution.
       2. The Principal Investigator agrees that in the case of biological samples, the local committee will weigh several factors including the amount of the sample remaining, the amount that the Principal Investigator will need to complete ongoing work, and the significance of the research question.
3. In the event that only DNA is being used, but cell lines are not being prepared, the Principal Investigator agrees that the DNA will be stored at his/her Institution or research site and made available to other qualified investigators as summarized in items 1 and 2. The Principal Investigator understands that if s/he, his/her colleagues, or the NIA determine that there is scientific need for cell lines to be made from his/her samples at a later time, then the Institution, the investigator, and the NIA may develop a plan to prepare the cell lines.
4. The Principal Investigator agrees that in the event that his/her study involves the preparation of cell lines that are not to be deposited at NCRAD, the cell lines and Associated Phenotypic Data derived in the present study will be stored at his/her Institution or institutionally approved study site and made available to other qualified investigators as summarized in item 1.
5. In the event that his/her study involves the preparation of cell lines that are not initially deposited at NCRAD, the Principal Investigator understands that at a later time s/he may be requested to arrange with NCRAD for the cell lines to be considered by the NCRAD Executive Committee for deposition. The Principal Investigator understands that, if so requested, the expense for this undertaking will be incurred by NCRAD and the NIA.
6. The Principal Investigator agrees that sample sharing and sharing of the subset of phenotypic data with other investigators can be accomplished via a Material Transfer Agreement (MTA). The Principal Investigator agrees to send pre-existing MTAs to the program official responsible for this award. The MTA should state that recipients of samples that have been obtained through NIA funding agree to place genomic outcome data in NIAGADS or another NIA approved site or both to which qualified investigators will have access.
7. Where applicable, the MTA should state that recipients of samples that have been obtained through NIA funding agree to place Genomic Data in NIAGADS or another NIA approved site or both, to which qualified investigators will have access. Genomic Data, including secondary analysis data, resulting from the research should be released to NIAGADS or another NIA approved site or both as soon as possible in keeping with the NIH Genomic Data Sharing policy. **NIA reserves the right to distribute, through NIAGADS, or another NIA** **approved Genomic Data repository, any and all Genomic Analysis Data and Associated Phenotypic Data to others and to use it for its own purposes.**
8. The Principal Investigator agrees to use the NIH approved MTA if s/he is transferring samples to NCRAD. The Principal Investigator agrees to send pre-existing MTAs to the program official responsible for this award.

### Alzheimer’s Disease Genomic Data Sharing

1. The Principal Investigator agrees to place Genomic Data in NIAGADS or another NIA approved site or both. The Principal Investigator agrees to place secondary analysis Genomic Data in NIAGADS or another NIA approved site or both. The Principal Investigator understands that qualified investigators will have access to these data.
2. The Principal Investigator agrees that Genomic Data resulting from the research will be released to NIAGADS or another NIA approved site or both in keeping with the NIH Genomic Data Sharing Policy. **NIA reserves the right to distribute, through NIAGADS, any and all Genomic Analysis Data and Associated Phenotypic Data to others and to use it for its own purposes.** NIAGADS may also make available upon request from NIA, Genomic Data to be deposited at an NIH database which will follow NIH policy and applicable law to protect the privacy and confidentiality of the individuals who participated in the original genetic association studies.
3. The Principal Investigator agrees to obtain appropriate consent from subjects participating in the study as described in the NIH Genomic Date Sharing policy statement.
4. The Principal Investigator agrees to obtain IRB approval or concurrence that is in accord with the NIH Genomic Data Sharing Policy.
5. The Principal Investigator agrees to obtain Institutional Certification that submission of data to the NIA approved data repository is being made with institutional approval.

By signing below, the signee acknowledges that the information in this document has been read and agrees to the terms and conditions prescribed herein.

Signature of the Principal Investigator/Date

Printed name of the Principal Investigator

Signature of Institutional Official/Date

Printed name of the Institutional Official