

Alzheimer's Disease Neuroimaging Initiative (ADNI) Data Sharing and Publication Policy

Introduction

Sharing ADNI data with the general scientific community is an objective established from the onset in the Request for Applications and is supported by the ADNI Executive Committee and representatives of the National Institute on Aging. In preparation for this level of data sharing, each of the ADNI sites included the following wording within subject consent documents.

“Study investigators will maintain and be responsible for deciding how your data will be used for future research. All links with your identity will be removed from the data before they are shared. Only de-identified data, which does not include anything that might directly identify you, will be shared with ADNI members and the general scientific community for research purposes.”

The ADNI Executive Committee has created and charged the Data and Publications Committee (DPC) with the task of establishing policies to implement this requirement, as well as recommending procedures for dealing with acknowledgement issues. The DPC began meeting in July 2005 by teleconference to address these issues. This document outlines the DPC recommendations for sharing data from the ADNI as well as policies for publication and publication credits for those who use ADNI data. The intent of these policies is to facilitate the sharing of data with all interested investigators, to encourage academic productivity, and to provide a mechanism for tracking and archiving data requests, intended analyses and publications related to and resulting from ADNI data.

Data Requests

The expectation of both the ADNI Executive Committee and the NIA has been that the ADNI de-identified data would be made available to the general scientific community within a very short timeframe. The DPC does not believe it is feasible to adjudicate who is “qualified” and who is not, however to maintain compliance with language in the informed consent documents indicating that data will be shared with members of the “scientific community,” the DPC will review the applications of each investigator requesting data and make a judgment based on their affiliation with a scientific or educational institution, and on the basis of the reason for the request. It is anticipated that most requests will be legitimate and can be approved rapidly, and that only a few will require clarification. The DPC does not feel it is appropriate to monitor IRB compliance by the applicant, however requestors will be asked to provide IRB numbers and expiration dates.

Therefore, we recommend full, open access of all de-identified ADNI imaging and clinical data to individuals who register with the ADNI and agree to the conditions in the “ADNI Data Use Agreement” and who undergo limited screening by the DPC. These data fall under the definition of a “Limited Data Set” as defined in 45 CFR Part 164.514.

Data Request Application and Tracking

A web-based, semi-automated Data Sharing Application and Tracking system has been instituted to manage the data requests. Users will complete a web-based application form and a Data Use Agreement. When the application is received and approved by the DPC, the applicant

will be given permission to access the data using the on-line interactive query interface. Applicants will be required to provide the following information:

- Name
- Address and Contact information
- Academic Affiliation (if any) or Institution/Company Name
- Proposed analyses with a named lead investigator on each analysis
- Certification to each point of the Data Use Agreement.

Applicant information will be available to other registered data users so that other data users can see what analyses are underway. This should help applicants decide whether to join in research already underway, compete with these projects or select another research topic. Applicants will receive annual requests to update the application information. These requests will also solicit responses to the following queries about manuscripts:

- Title of each manuscript in development
- Lead (or senior) author of each manuscript in development and contact information for that author
- Status of each manuscript in development (In development, In submission, In press/published)
- Citation of each published manuscript
- Upload a file of each published manuscript

Non-compliance with the required updates will jeopardize further access to ADNI data. The purpose of listing each proposed analysis with a lead investigator is to allow and encourage investigators considering similar projects to collaborate and to identify an individual who is taking responsibility for the use and reporting of requested data.

Publication Policy

The ADNI DPC will not attempt to evaluate the scientific merit of proposed analyses, nor evaluate proposed abstracts. The DPC will be charged with the administrative review of manuscripts only.

Regardless of what subset of data is used in analyses or publications, as part of the Data Use Agreement, investigators will be asked to agree to a Publication Policy as follows:

- All manuscripts will acknowledge the methods of ADNI data gathering using language recommended by the ADNI (see Data Use Agreement).
- All manuscripts will acknowledge the support of NIA using the NIH grant number for the ADNI, as well as naming the financial sponsors of the ADNI (see Data Use Agreement).
- In addition to the named authors, all manuscripts will be submitted with an acknowledgement of the ADNI on the author line using a corporate acknowledgement phrase followed by an asterisk (see Data Use Agreement). The asterisk will point to a web site listing that will list the names of the ADNI leadership, key senior contributors to the ADNI project design and/or organization, as well as up to 3 collaborators from each ADNI recruitment site (the site PI and two other individuals designated by the site PI).

- Manuscripts will be submitted to the ADNI DPC for administrative review prior to submission. The purpose of this review will be to make sure that all of the above requirements are met.
- Full citation of all published manuscripts will be provided to the ADNI upon acceptance of manuscripts.
- A copy of the manuscript will be provided to the ADNI upon publication of the manuscript. If permitted by the journal, a version of the article or link to the article will be available online at the ADNI website.

Tracking of Data Use and Publications

If ADNI data are used in publications, authors will be required to:

1. Add ADNI acknowledgement (see Data Use Agreement)
2. Include recommended language describing ADNI methods and data gathering
3. Cite ADNI sponsors (see Data Use Agreement)
4. Provide manuscript to ADNI DPC for review 2 weeks prior to planned submission (see Data Use Agreement)
5. Apprise ADNI of acceptance or rejection
6. Provide manuscript citation to ADNI upon acceptance
7. Provide URL to published work, if possible.

Unusual Situations

It is expected that most users of ADNI data will follow these guidelines in good faith and that most analyses will be of reasonable quality. The DPC does not intend to review manuscripts for scientific quality, preferring to let the peer-review process sort out quality. It is recognized that ADNI data may even be used to support publications with conflicting results. However, we do anticipate the possibility of some unusual circumstances.

1. **Egregiously Poor Manuscripts.** If a review of a proposed manuscript reveals that it is egregiously poor in terms of language, writing or sensible substance, the DPC can recommend to the authors that it not be submitted without significant revision. If the authors choose to submit the manuscript anyway, the DPC will have three options: 1) request that the acknowledgement credit be withheld; 2) request that the authors publish a statement to the effect that while ADNI data were used, the ADNI did not find this manuscript of sufficient merit to warrant submission for publication, or; 3) revocation of privileges to use ADNI data in the future.
2. **Failure to Follow Data Use Agreement.** If users inadvertently violate the Data Use Agreement, it is likely that they will self-correct as infractions are discovered. If users willfully violate the Data Use Agreement, the sole sanction available to the ADNI will be to revoke access to the ADNI data.
3. **Fraudulent Use of Data.** Open access using only email registration raises the possibility that individuals could obtain access to data under false pretenses. Should the DPC discover an attempt to publish data obtained fraudulently, the data user will be sanctioned through NIH communication with them or their academic supervisors. As soon as the DPC becomes aware of any breach of the Data Use Agreement, immediate steps will be taken to cure the breach or end the violation. This may include discontinuing the user's data access and/or reporting the violation.

4. **Journal Objections.** It is possible that journal editors may object to the acknowledgement format with the caveat that those ADNI names credited have gathered data but not participated in the analysis and writing of the paper. The DPC can authorize exceptions to the acknowledgement policy or can negotiate with journal editors as needed on a case-by-case basis.

Committee Structure and Funding

The ADNI Data and Publications Committee was formed by the ADNI Executive Committee and will make recommendations to the Executive Committee regarding these and other related policies. Data and publications issues will be adjudicated by the DPC, however, if investigators disagree with the decisions of the DPC, they can appeal to the EC for final arbitration.

Alzheimer's Disease Neuroimaging Initiative (ADNI)
DATA USE AGREEMENT

I request access to data collected by the Alzheimer's Disease Neuroimaging Initiative (ADNI) for the purpose of scientific investigation, teaching or the planning of clinical research studies and agree to the following terms.

1. I will receive access to de-identified data and will not attempt to establish the identity of, or attempt to contact any of the ADNI subjects.
2. I will not attempt to make direct contact with ADNI PIs or staff at sites concerning the specific results of individual subjects.
3. I will not further disclose these data beyond the uses outlined in this agreement and my data use application and understand that redistribution of data in any manner is prohibited.
4. I will require anyone on my team who utilizes these data, or anyone with whom I share these data to comply with this data use agreement.
5. I will accurately provide the requested information for persons who will use these data and the analyses that are planned using these data.
6. I will respond promptly and accurately to annual requests to update this information.
7. I will comply with any rules and regulations imposed by my institution and its institutional review board in requesting these data.

If I publish abstracts using data from ADNI, I agree to the following:

8. I will cite ADNI as the source of data and the ADNI funding sources in the abstract as space allows.
9. Acknowledgement of ADNI will not be cited in the authorship line of the abstract.

If I publish manuscripts using data from ADNI, I agree to the following:

10. On the by-line of the manuscript, after the named authors, I will include the phrase "for the Alzheimer's Disease Neuroimaging Initiative*" with the asterisk referring to the following statement and list of names:

*Data used in preparation of this article were obtained from the Alzheimer's Disease Neuroimaging Initiative (ADNI) database (adni.loni.usc.edu). As such, the investigators within the ADNI contributed to the design and implementation of ADNI and/or provided data but did not participate in analysis or writing of this report. A complete listing of ADNI investigators can be found at:

http://adni.loni.usc.edu/wp-content/uploads/how_to_apply/ADNI_Acknowledgement_List.pdf



[For manuscripts that use metabolomics data generated by the Alzheimer's Disease Metabolomics Consortium (ADMC) in the by-line of the manuscript, after the named authors, I will include the phrase "for the Alzheimer's Disease Metabolomics Consortium**" with the double asterisk referring to the following statement and list of names;

**Data used in preparation of this article were generated by the Alzheimer's Disease Metabolomics Consortium (ADMC). As such, the investigators within the ADMC provided data but did not participate in analysis or writing of this report. A complete listing of ADMC investigators can be found at: <https://sites.duke.edu/adnimetab/team/>.

11. I will include language similar to the following in the methods section of my manuscripts in order to accurately acknowledge data gathering by the ADNI personnel. Depending upon the length and focus of the article, it may be appropriate to include more or less than the example below, however inclusion of some variation of the language shown below is mandatory.

Data used in the preparation of this article were obtained from the Alzheimer's Disease Neuroimaging Initiative (ADNI) database (adni.loni.usc.edu). The ADNI was launched in 2003 as a public-private partnership, led by Principal Investigator Michael W. Weiner, MD. The primary goal of ADNI has been to test whether serial magnetic resonance imaging (MRI), positron emission tomography (PET), other biological markers, and clinical and neuropsychological assessment can be combined to measure the progression of mild cognitive impairment (MCI) and early Alzheimer's disease (AD). For up-to-date information, see www.adni-info.org.

12. I will acknowledge funding by the ADNI in the support acknowledgement section of the manuscript using language similar to the following:

Data collection and sharing for the Alzheimer's Disease Neuroimaging Initiative (ADNI) is funded by the National Institute on Aging (National Institutes of Health Grant U19 AG024904). The grantee organization is the Northern California Institute for Research and Education.

In the past, ADNI has also received funding from the National Institute of Biomedical Imaging and Bioengineering, the Canadian Institutes of Health Research, and private sector contributions through the Foundation for the National Institutes of Health (FNIH) including generous contributions from the following: AbbVie, Alzheimer's Association; Alzheimer's Drug Discovery Foundation; Araclon Biotech; BioClinica, Inc.; Biogen; Bristol-Myers Squibb Company; CereSpir, Inc.; Cogstate; Eisai Inc.; Elan Pharmaceuticals, Inc.; Eli Lilly and Company; EuroImmun; F. Hoffmann-La Roche Ltd and its affiliated company Genentech, Inc.; Fujirebio; GE Healthcare; IXICO Ltd.; Janssen Alzheimer Immunotherapy Research & Development, LLC.; Johnson & Johnson Pharmaceutical Research & Development LLC.; Lumosity; Lundbeck; Merck & Co., Inc.; Meso Scale Diagnostics, LLC.; NeuroRx Research; Neurotrack Technologies; Novartis Pharmaceuticals Corporation; Pfizer Inc.; Piramal Imaging; Servier; Takeda Pharmaceutical Company; and Transition Therapeutics.

Metabolomics Consortium (ADMC) will include the following language:

Data collection and sharing for this project was funded by the Alzheimer's Disease Metabolomics Consortium (National Institute on Aging R01AG046171, RF1AG051550 and 3U01AG024904-09S4).

13. I will submit all manuscripts to the ADNI Data and Publications Committee (DPC) prior to submitting to a journal. This review will not be a scientific review, but is intended to ensure that items 7-12 above are correctly implemented. The DPC will maintain confidentiality of the manuscript and will complete its review within 2 weeks.
14. I will ensure that Investigators who utilize ADNI data use appropriate administrative, physical and technical safeguards to prevent use or disclosure of the data other than as provided for by this Agreement.
15. I will report any use or disclosure of the data not provided for by this Agreement of which I become aware within 15 days of becoming aware of such use or disclosure.

IMPORTANT NOTE: It is the policy of the Alzheimer's Disease Neuroimaging Initiative to make analyzed data available to investigators as quickly as possible. However, data analysis for this project is expected to take years as methods for analysis of these datasets evolve. Therefore, I understand that any processed data that I download might be preliminary and that results may change as new methods of analysis are implemented. I will familiarize myself with the analysis methods so that I am aware of the limitations of these data prior to using them for scientific purposes.

Finally, because "preliminary data" will be posted on the database, in the event that I download data from the ADNI database for the purposes of analysis and future publication in the form of abstracts and/or publications, I will note the version of the data I download, and I will check the database to determine if updated data has been provided prior to submission of any material for publication.

I understand that failure to abide by these guidelines will result in termination of my privileges to access ADNI data.

Electronic Signature of User