

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 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 recommend procedures for dealing with authorship 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 user agreement (see User 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
- Citation of each published abstract
- Upload a file of each accepted/published abstract

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 User 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 User 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 User 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 authorship phrase followed by an asterisk (see User Agreement). The asterisk will point to a printed listing (if allowed by the journal) or 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 on-line at the ADNI web site.

Tracking of Data Use and Publications

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

1. Add ADNI group authorship as permitted by the journal in question (see User Agreement)
2. Include recommended language describing ADNI methods and data gathering
3. Cite ADNI sponsors (see User Agreement)
4. Provide manuscript to ADNI DPC for review 2 weeks prior to planned submission (see User Agreement)
5. Apprise ADNI of acceptance or rejection
6. Provide manuscript or abstract 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 group authorship 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 User Agreement.** If users inadvertently violate the User Agreement, it is likely that they will self-correct as infractions are discovered. If users willfully violate the User 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 group authorship 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 authorship 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.