



DOMINANTLY INHERITED ALZHEIMER NETWORK (DIAN)

Data and Tissue Sharing, Notifications, Publications, and Authorship Policies

These policies are intended to promote collaborative, high quality dissemination of DIAN study findings in a timely, accurate, and just manner. They address: access to data; notification of presentations and publications; internal manuscript review; and writing group membership and authorship. We adopt a broad definition of ‘investigator’; in general the term applies to any faculty person at a DIAN site (or who is on the DIAN Steering Committee) who is directly involved in the DIAN study. An investigator may nominate someone at their site who is not usually involved with DIAN to work on a specific study.

ACCESS TO DIAN DATA/TISSUE

We follow the principles of Productivity (with Recognition of the investigator who develops a research idea and does the work to publish it), Transparency, Fairness, and Inclusiveness. The following policies regarding access to DIAN data are intended to provide structure to the request process, respect for intellectual contributions, and standards regarding security/confidentiality. For specific policies on the sharing of tissue and biospecimens, please see the DIAN Resource Allocation Review Committee Guidelines.

Priority of Access and Review/Approval Process: To respect intellectual contributions of DIAN investigators and collaborators, the following system has been adopted.

“Tier 1” - Analyses that lead to publications that address DIAN’s Specific Aims as proposed in its 2007 application to the National Institute on Aging are “Tier 1” manuscripts. These analyses are led by the investigators who are responsible for developing and achieving those Aims. The Principal Investigator of DIAN (PI) will work with the leaders of each DIAN Core to facilitate the data analyses to achieve the stated aims and publish the results. Each Core differs in its data entry and quality control (QC) completion rates, so the pace of analyses will vary. Once an analysis is requested to address one or more of DIAN’s Specific Aims by a Core Leader, DIAN will notify all Steering Committee members to encourage those who wish to play a role meriting co-authorship to indicate their interest to the project leader. Co-authors will be included based on accepted standards of academic authorship, as guided by the Inclusiveness principle. It is possible that Tier 1 publications may have one or few named authors if they represent group authorship. In the event of a single author, a list of co-authors who are members of the study writing group should be included in supplemental material to the publication. In some cases, group authorship with no named authors may be warranted.

“Tier 2” – Data analyses to support manuscripts can be developed and proposed by anyone in DIAN: Core Leaders, Site Leaders, other SC members, or any student, fellow, or investigators designated by a DIAN Site Leader. Once a request for a “Tier 2” analysis is approved (see process below), Steering Committee members will have the opportunity to contribute to the project. The duration of Tier 2 proposed manuscript exclusivity is 1 year from time of data release, meaning that no other investigator can pursue the same project during that year. If at the end of the year, no manuscript has been produced others may request permission to develop manuscripts on the same proposal. DIAN investigators may submit Tier 2 data analyses and manuscript proposals unless their site is nonqualified, (i.e. fails to meet enrollment and compliance goals set by the DIAN PI), in which case they may request data access for Tier 3 manuscripts. Publications by DIAN investigators not considered ‘Tier 1’ but that use data gathered by all DIAN study members are written by designated DIAN writing groups whose members are named as authors. When the concept for a DIAN Tier 2 paper is proposed to the DIAN Steering Committee, a lead author (or co-lead authors) is also proposed, as well as possible co-authors. However, approved Tier 2 proposals are distributed to all DIAN sites and interested DIAN investigators may ask the lead authors (or co-lead authors) to participate meaningfully such that co-authorship is

merited. The lead author (or co-lead author) determines the order of listing of co-authors. For all Tier 2 papers, a list of members of the DIAN study group will be submitted in a supplement to the manuscript.

“Tier 3” - One year after a data freeze, those data become available to all investigators within and outside of DIAN. Such projects/manuscripts will follow the “Tier 2” review and approval process (see next section). Publications by investigators outside DIAN that are not Tier 1 or 2 would list the DIAN Study Group in the acknowledgments with the required paragraph at the end of this document.

Review and Approval Process for Data Access

Tier 1 data requests/proposals are reviewed and approved by the DIAN Principal Investigator.

Tier 2 data requests/proposals are submitted to DIAN’s Administration Core. All DIAN Core Leaders and all DIAN Site Leaders will serve as a “data request review” panel; the DIAN PI will assign 2-3 members of the panel to review each request and provide reviews (and recommendations to approve or not) to all other panel members within 7 days. All proposed Tier 2 and 3 (see below) data requests will be distributed by email to the DIAN Steering Committee for approval within 2 weeks. Thus, this policy places additional responsibility on the Steering Committee members to review and approve requests in an expeditious manner.

Tier 3 data requests/proposals use the same review and approval process as Tier 2 requests.

Summary of Data Access Procedures				
	Who	What	Time frame for Data Access	Review process
Tier 1	DIAN Core Leaders and Investigators	Core publications that address the aims included in the grant application.	Any data freeze at discretion of Core Leader, unless data for same purpose already claimed	Review and approval by DIAN PI
Tier 2	Any DIAN Site Leader and/or their designated DIAN investigator from a qualified DIAN site (i.e. one that meets DIAN enrollment and compliance guidelines)	Other aims using DIAN data nominated by any qualified DIAN investigator	Any data freeze but not directly overlapping Tier 1 projects	Review by 2-3 members of Steering Committee (SC) selected by PI, approval by full SC
Tier 3	Any DIAN Site Leader and/or their designated DIAN investigator from a non-qualified site; non-designated investigators within or external to DIAN sites.	Aims using DIAN data nominated by any investigators	Access to dataset 1 year after release (freeze date) but not overlapping Tier 1 or 2 projects	Review by 2-3 members of Steering Committee (SC) selected by PI, approval by full SC
<ul style="list-style-type: none"> • Declaring an intention to pursue a topic does not guarantee approval of the project. A formal request must be submitted to the DIAN Administration Core for processing. • Access to tissue from DIAN participants will follow the same availability policy – tissue will be available for sharing with Tier 3 investigators 1 year after it has been processed and banked, to coincide with the data freezes. 				

Requesting Data

De-identified DIAN data will be made available to investigators to conduct analyses after approval by the DIAN Steering Committee.

All requests for data must be submitted in writing via the electronic data request form available at the data sharing website (www.DIAN-info.com). The request form will include investigator affiliation, contact information, funding support, institutional review board (IRB) approval (if applicable) and a brief description of the project, including specific aims, study design, characteristics of the data requested and analysis plans. Investigators requesting data also will be required to sign a data user agreement and an acknowledgement agreement, as specified below. Applications for data use will be reviewed by the DIAN Steering Committee. The number, type and disposition of the requests will be tracked by the DIAN Administration Core and a data sharing report will be generated for progress and final reports to the National Institute on Aging (NIA). Each data request will specify the data elements required to do the planned analyses, and the database personnel will prepare a file containing only these data elements, together with the participant identification number so that questions about particular individuals can be resolved without the investigator's knowledge of the participant's identity. Image data will be available to approved investigators in raw and post-processed formats via the DIAN Data Archive.

Data Documentation: The research community at large will be informed of the procedures to utilize data from the study through a project website. The website will provide information about the data that are available, a detailed description of the cohort, and an overview of the methods by which data have been collected and stored. The website will also provide an electronic data request form.

Criteria for Review: Data requests will be reviewed based on the following criteria:

- scientific merit and feasibility (e.g. availability of DIAN resources to fulfill the request)
- appropriateness of the investigator's qualifications and resources to protect the data.
- appropriateness to DIAN goals/themes

Preparation of data: There will be 3 data freezes of the DIAN data each year that include all data that have passed relevant quality control processes at the time of the 'freeze.' Biostatistics Core personnel will prepare the frozen dataset for sharing and provide statistical consultation if appropriate.

All precautions to ensure confidentiality must be taken by recipients of DIAN data. The final dataset will be stripped of identifiers prior to release for sharing and be transferred only with encryption and password protection by the Biostatistics Core. However, there is always the possibility of deductive disclosure of participant identity because participants are limited to specific institutions, and the dataset contains detailed demographic information, as well as detailed prospective information about their disease and mutation status, living situation, neighborhood variables, etc. Thus, we will make the data and associated documentation available to users only under the following prerequisites:

1. Recipient of data will provide documentation of IRB approval valid for the analysis of DIAN data (or acknowledgment from your IRB that receiving coded data without access to identifiers is not considered "research" requiring review).
2. Recipient of data will provide assurance of ability to secure dataset in accordance with the most stringent protections possible compliant with local IRB and Health Insurance Portability and Accountability Act (HIPAA for US sites) standards for such sensitive data
3. Recipient of data will provide a signed code access agreement for data usage – code access agreements are a simple statement that the recipient of the data will use the data only for research purposes and will not attempt to identify any individual participant
4. Recipient of data will guarantee that mutation data will be destroyed when analyses are complete.
5. If a DIAN dataset is to be shared with a DIAN Site, the site leader must identify a party at the site who will conduct the analyses to receive the mutation data set. This individual must not have

contact with participants nor play any role in data processing that involves interpretation or judgment to avoid un-blinding of study personnel or biasing of the data.

Genetic data sharing: Participants also will be asked to participate in the NIA/NIH genetic data sharing program. The genetic data sharing program is a national resource supported by the NIA that prepares and stores cell lines and DNA samples and makes them available to scientists who would otherwise have no access to this information. Transformed cell lines from all DIAN participants are created and stored at the National Cell Repository for Alzheimer's Disease (NCRAD) where the DNA is extracted, stored, and provided to investigators after review and approval by the DIAN Resource Allocation Review Committee and the DIAN Steering Committee. Relevant clinical and biomarker data would be obtained from the DIAN Biostatistics Core.

DIAN Informed Consent: The DIAN consent forms include a statement informing participants that de-identified data may be shared with authorized investigators, following guidelines for preserving confidentiality through coded identities and consistent with HIPAA requirements. DIAN participants and/or their relative/guardians have the right to have the material and/or data destroyed or made anonymous at any time. If consent to participate in the study is withdrawn, and the participant and/or his/her relative/guardian no longer wish their DNA to be used, NCRAD will destroy any unused samples. However it may not be possible to retrieve or destroy samples that have already been distributed to other investigators.

Samples and data may be shared with commercial entities with the possibility that the research done may be used to develop new products. The participant will receive no financial compensation for the development of new products that result from the use of his/her biological sample (blood, cell line), clinical and demographic data, biomarker data, and/or genetic data.

Obligations incurred when accepting DIAN data:

- Acceptance of DIAN data obligates the recipient to cite/reference the NIA grant (Dominantly Inherited Alzheimer Network, U01AG032438) in any presentation or publication that may result from this research. Language will be included in each DIAN publication following listed authors stating. Please see paragraph at end of this document.
- Should publications result from the use of DIAN data now or in the future, the recipient agrees to notify the DIAN Executive Director with details (reference or PubMedCentral ID#) and provide a copy of the publication to the DIAN Administration Core so that DIAN may report productivity derived from our resources to the funding agency, the NIA. Such publications require compliance with National Institutes for Health (NIH) public access policies.
- Should funding result from this research now or in the future, please notify the DIAN Executive Director (contact information below) with details (grant title, sponsor, number, dollar total, dates) so that DIAN may report productivity derived from our resources to NIA.
- No sharing of data with a third party is allowed without permission of the DIAN Steering Committee.

Suggested timeline for data requests:

1. Allow 30 days for the review process
2. Allow 30 days for interaction with the Biostatistics Core to provide dataset.

NOTIFICATIONS, MANUSCRIPT REVIEW AND AUTHORSHIP

The DIAN publication policy applies to all public and scientific communication of unpublished data that result from any DIAN-related activity. All investigators on the DIAN study must abide by established DIAN policies and procedures. The Principal Investigator of DIAN adjudicates all disputes over leadership of analyses, authorship, etc. and decisions will be final.

Notifications:

Communications from the DIAN Study may be classified as press releases, interviews, public web site postings, presentations (includes poster and accompanying abstract) or publications that contain unpublished DIAN data. The DIAN Administration Core should be notified of all such communications, preferably before they appear or are presented.

Manuscript Review:

Manuscripts should be submitted to the DIAN Administration Core at least 4 weeks prior to submission to a journal in order to allow time for review and response to recommendations.

Authorship:

Publication Authorship: DIAN is a collaborative study; all DIAN sites enroll participants and submit their data and tissue to the Coordinating Center at Washington University. At a minimum, therefore, each site merits (at least) one author on all DIAN publications. The site leader will determine who that person should be (default is the site leader). In some instances, it may be justifiable that more than one representative from a particular site be extended authorship. This can be proposed by the project leader (i.e., first author) with the DIAN Principal Investigator.

As each of DIAN's Cores also is responsible for DIAN's data and biospecimens, each Core leader also merits authorship. Finally, non-Core leaders, non-site leader members of the Steering Committee also should be considered for authorship (but are not mandatory). The decision to extend authorship to all Steering Committee members will be made by the project leader (i.e., the first author) in consultation with the PI for DIAN. If included, it is permissible to have the masthead read "First Author" and the DIAN Steering Committee" with the individual Steering Committee members listed in an appropriate section of the presentation or manuscript. **All publications based on DIAN data will include "The Dominantly Inherited Alzheimer Network (DIAN)" as an author.**

Abstract Authorship: The categories and authorship rules for abstracts accompanying presentations are as stated above but may have limitations on the number of authors permitted. If authorship is limited or impractical to include all authors then "The DIAN Study Group" would be listed as an author. A full list of members is not included.

Other Personnel as Authors: The writing group for a manuscript may include trainees, study coordinators, and other personnel as authors, providing that each author was involved in the analysis and writing of the paper.

Arbitration: When conflicts exist regarding DIAN publications, written summaries of the conflict submitted by those involved will be reviewed by the DIAN Administration Core. The DIAN PI will adjudicate the resolution. Any DIAN investigator who wishes to opt out of any automatic authorship listing may do so in writing to the DIAN Administration Core.

Press releases, interviews, and presentations (without published abstracts) usually do not have authors. When presentations are accompanied by published abstracts, the authorship rules for the abstracts are the same as for other types of publications, as described in this document

Designation of DIAN Study Members in Supplements to Publications: Supplemental material can accompany manuscripts when space is limited. Supplemental material for DIAN publications should recognize non-author DIAN members and their contribution to the study. All professional members who have the approval of the Principal Investigators and have served in a substantial capacity with the study are listed. Every clinical site and all collaborating entities are listed as participating centers. The Administration Core will be responsible for maintaining the list of all current DIAN investigators for inclusion in publications and will update this list as needed on the DIAN investigator website. Those scientific, federal, or commercial organizations providing funding are also recognized.

Required language to appear in acknowledgments of all publications using DIAN resources:

"Data collection and sharing for this project was supported by The Dominantly Inherited Alzheimer's Network (DIAN, U01AG032438) funded by the National Institute on Aging (NIA). This manuscript has been reviewed by DIAN Study investigators for scientific content and consistency of data interpretation with previous DIAN Study publications. We acknowledge the altruism of the participants and their families and contributions of the DIAN research and support staff at each of the participating sites for their contributions to this study."

For a listing of current DIAN sites, please see the DIAN website (www.DIAN-info.org)

IN SUPPORT OF THESE POLICIES THE DIAN PI AND ADMINISTRATION CORE WILL:

- Organize the submission, review and approval processes for data requests and manuscripts (to include a statistical review if necessary).
- Receive and track notifications of interviews and press releases, abstracts, presentations and publications of unpublished DIAN data.
- Ensure that all publications and presentations acknowledge the funding agency: National Institute on Aging, NIH, U01AG032438, meet current public access requirements, and report to DIAN productivity to NIA.
- Maintain a website that will:
 - Inform the research community at large of the procedures to utilize data from the study through a project website.
 - Provide information about the data that are available, a detailed description of the cohort, and an overview of the methods by which data have been collected, and a data dictionary
 - Provide an electronic data request form
 - Provide a list of all Steering Committee members, current DIAN investigators, language for acknowledgment of DIAN and its source of funding
 - Maintain a list of DIAN study presentations and publications and routinely review the progress of DIAN proposals for data analyses to support future publications and presentations
 - Post all approved DIAN data requests/proposals for transparency and documentation of intention to pursue specific projects. Investigators wishing to initiate a project with DIAN data or tissue can search previous or existing DIAN projects to avoid duplication or competition and to invite collaboration.