

The National Institute on Aging (NIA) Division of Neuroscience (DN) provides the following sample Data Management and Sharing Plan for a hypothetical project proposing to collect clinical data from human subjects. Click [here](#) for more sample plans from NIA.

## DATA MANAGEMENT AND SHARING PLAN

### Element 1: Data Type

#### A. Types and amount of scientific data expected to be generated in the project:

*Summarize the types and estimated amount of scientific data expected to be generated in the project.* Demographic and clinical data will be acquired from 200 amyloid-positive, cognitively normal older adults with symptomatic insomnia. The types of clinical data include amyloid-beta (A $\beta$ ), tau, phosphorylated tau, NPTX2, sTREM2, and NFL from CSF; A $\beta$ , tau, and phosphorylated tau from plasma; and cognitive status assessments.

#### B. Scientific data that will be preserved and shared, and the rationale for doing so:

*Describe which scientific data from the project will be preserved and shared and provide the rationale for this decision.*

All individual-level clinical and laboratory data will be preserved and made broadly available to the scientific community. Recruitment progress and final results will be documented at ClinicalTrials.gov. It is our mission to ensure dissemination of clinical results of sufficient quality to validate and replicate research findings.

#### C. Metadata, other relevant data, and associated documentation:

*Briefly list the metadata, other relevant data, and any associated documentation (e.g., study protocols and data collection instruments) that will be made accessible to facilitate interpretation of the scientific data.*

In addition to the subject level data described above, digital research material including but not limited to images, spreadsheets, protocols, and analysis scripts will be archived and made available.

### Element 2: Related Tools, Software and/or Code:

*State whether specialized tools, software, and/or code are needed to access or manipulate shared scientific data, and if so, provide the name(s) of the needed tool(s) and software and specify how they can be accessed.*

The clinical data will be analyzed with custom Python code written using the statsmodels, numpy, and pandas packages, all of which are freely available. All code will be shared on our lab's GitHub website and the main readme.md file for the project will include instructions and parameter choices for the GUI-based analyses.

### Element 3: Standards:

*State what common data standards will be applied to the scientific data and associated metadata to enable interoperability of datasets and resources, and provide the name(s) of the data standards that will be applied and describe how these data standards will be applied to the scientific data generated by the research proposed in this project. If applicable, indicate that no consensus standards exist.*

In compliance with the National Institutes of Health (NIH) Common Data Elements Repository, clinical data will be collected using the appropriate instruments for the initial and follow-up visits.

In compliance with NIA's Clinical Research Operations & Management System (CROMS), monthly study records will be reported to CROMS and will be consistent with standardized formats using the follow instruments:

Enrollment Template	Screening Template	Enrollment Data Elements	Screening Data Elements
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### Element 4: Data Preservation, Access, and Associated Timelines

#### A. Repository where scientific data and metadata will be archived:

*Provide the name of the repository(ies) where scientific data and metadata arising from the project will be archived; see [Selecting a Data Repository](#).*

All clinical trial data with accompanying metadata will be stored at the National Centralized Repository for Alzheimer's Disease and Related Dementias (NCRAD) and the Laboratory of Neuroimaging Image and Data Archive (LONI IDA). NCRAD is an NIH-funded repository that collects and maintains biological specimens and associated data on study volunteers from Alzheimer's disease and related dementias studies. LONI IDA is an NIH-funded repository that collects neuroimaging and related clinical data.

**B. How scientific data will be findable and identifiable:**

*Describe how the scientific data will be findable and identifiable, i.e., via a persistent unique identifier or other standard indexing tools.*

Data will be findable for the research community through NCRAD and LONI IDA. A publicly accessible study page will be established when this application is funded. For all publications, the corresponding data will be assigned a digital object identifier (DOI). This data DOI will be referenced in publications to allow the research community easy access to the exact data used in publications.

**C. When and how long the scientific data will be made available:**

*Describe when the scientific data will be made available to other users (i.e., no later than time of an associated publication or end of the performance period, whichever comes first) and for how long data will be available.*

As defined within PAR-23-081 for early-stage clinical trials, all study data, including post-randomization trial data, raw and processed primary data, will be made available to the scientific community at the time of publication or within 9 months of database lock, whichever comes first.

NCRAD and LONI IDA will make decisions about how long to preserve the data. As of present, NCRAD and LONI IDA have not deleted any deposited data. New repositories will be chosen in the event that NCRAD and/or LONI IDA elect to delete any deposited data within the lifetime of the award and this Plan will be updated.

**Element 5: Access, Distribution, or Reuse Considerations**

**A. Factors affecting subsequent access, distribution, or reuse of scientific data:**

*NIH expects that in drafting Plans, researchers maximize the appropriate sharing of scientific data. Describe and justify any applicable factors or data use limitations affecting subsequent access, distribution, or reuse of scientific data related to informed consent, privacy and confidentiality protections, and any other considerations that may limit the extent of data sharing. See [Frequently Asked Questions](#) for examples of justifiable reasons for limiting sharing of data.*

All research participants will be consented for broad data sharing.

**B. Whether access to scientific data will be controlled:**

*State whether access to the scientific data will be controlled (i.e., made available by a data repository only after approval).*

A committee to oversee data sharing of all datasets will review requests from qualified investigators that initiate requests for clinical trial data. All requests will be reviewed for scientific merit and feasibility. A Data Use Agreement (DUA) will be put in place with any academic group or scientists before any transfer of data. Investigators receiving the data will be required to abide by the conditions of these agreements. All data queries/requests will be logged in a data repository tracking log.

**C. Protections for privacy, rights, and confidentiality of human research participants:**

*If generating scientific data derived from humans, describe how the privacy, rights, and confidentiality of human research participants will be protected (e.g., through de-identification, Certificates of Confidentiality, and other protective measures).*

All data will be de-identified prior to receipt by the repository. Internal study ID numbers and Global Unique Identifiers (GUIDs) will be generated separate from personal identifiers. A master key document will be securely maintained by the study team connecting participant identifiers to study IDs and will be separate from de-identified data. The NIA GUID instance allows researchers to aggregate data from the same research participant without different laboratories having to share personally identifiable information about that research participant. Personally identifiable information will not be shared.

Informed Consent: Participants will be informed that de-identified data will be stored and shared with other institutions or companies as approved by a Scientific Review Committee and in accordance with all applicable regulations. Written informed consent will be obtained at the beginning of the first study visit. Potential participants will have discussed the data sharing process for the study over the phone at least once in addition to having read recruitment materials and completed screening instruments.

**Element 6: Oversight of Data Management and Sharing:**

*Describe how compliance with this Plan will be monitored and managed, frequency of oversight, and by whom at your institution (e.g., titles, roles).*

The Office of Sponsored Programs at State University that will be administering this award has created a data management and sharing plan compliance system as part of their process for submitting the annual NIH progress report. That Office will be collecting information related to the number of research participants whose data are deposited each reporting year. The Office of Sponsored Programs will also look at the data DOIs from publications and will include that information in the annual progress report.