

Plan Overview

A Data Management Plan created using DMPTool

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Title: Innovative Deep Phenotyping of African Americans at Risk for Alzheimer's disease

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Project abstract:

A critical gap in Alzheimer's disease (AD) and Alzheimer's disease related disorders (ADRD) clinical research is the vast under-representation of Black/African American (AA) older adults. It is well-documented that AD+ADRD is more prevalent in AA individuals relative to white individuals of European ancestry. Early detection of AD+ADRD is critical for clinical trials aiming to develop optimal therapeutics. Without adequate representation of AA in cognitive and biomarker studies

examining the earliest changes in AD+ADRD, the diagnostic, prognostic, and clinical utility of promising biomarkers and their effects on cognition cannot be established. Therefore, there is a pressing need to include and deeply phenotype AAs using novel cognitive and biomarker assessments that consider the multiple co-morbidities identified in this population. The deep phenotyping of 270 non-Hispanic AA older adults in the proposed research study and our resource sharing plan will accelerate efforts to gain critically needed knowledge of AD+ADRD in a seriously underrepresented AA group.

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Innovative Deep Phenotyping of African Americans at Risk for Alzheimer's disease

Data Type

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.*

Describe data in general terms that address the type and amount/size of scientific data expected to be collected and used in the project (e.g., 256-channel EEG data and fMRI images from ~50 research participants). Descriptions may indicate the data modality (e.g., imaging, genomic, mobile, survey), level of aggregation (e.g., individual, aggregated, summarized), and/or the degree of data processing that has occurred (i.e., how raw or processed the data will be)

The proposed research will include data collected from 270 Black/African American (AA) older adult participants, approximately 180 will be diagnosed with amnesic Mild Cognitive Impairment (aMCI) and 90 will be cognitively unimpaired. The dataset will include self-reported demographic information, comprehensive clinical information including medical and psychiatry history, and extensive neuropsychological test data. Biological markers collected will be blood based and clinical assessments of medical comorbidities including cerebrovascular disease, *diabetes* and metabolic risk, as well as measures of *chronic kidney disease*, genetic, inflammatory markers, plasma-based markers of AD and neurodegeneration, as well as neuroimaging data including structural MRI, *extra-cellular free water data*, and amyloid PET. The data will be raw, individual data and include a mix of modalities, imaging, survey, genomic, and practitioner assessment. To protect research participants identities, de-identified individual and aggregate data will be made available for sharing.

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 de-identified data collected will be preserved and be made available for data sharing with investigators in the wider research community upon request. We believe that the deep phenotyping proposed will result in extremely valuable information that will be essential to share efficiently given the national priority to advance knowledge about Alzheimer's disease (AD) and Alzheimer's disease related disorders (ADRD) in this underrepresented group.

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.

To facilitate interpretation of the data, a codebook with relevant variable names and their explanation will be created, shared, and associated with the relevant dataset.

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 data will be available in csv format which can be accessed with most standard software and tools. Special tools are not necessary.

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

The data we collect are common of that of Alzheimer's disease research and other medical settings research. It should be interoperable with other datasets with minimal manipulation.

Data Preservation, Access, and Associated Timelines

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](#)

Data will be stored in a REDCap database and a de-identified, privacy protected version will be made available upon request, after entering a data sharing agreement that stipulates protection of participant's identity and information, as well as appropriate use.

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.

Each record will have a unique identifier called 'record_id' that can be used to connect different components of the data.

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.

Data will be made available after the data sharing agreement is approved. Users must agree to destroying the data after proposed analyses are completed, that data will not be redistributed to third parties.

Access, Distribution, or Reuse Considerations

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.

We will make the data available to users under a Data Sharing/Data Use Agreement. The user must agree to the following conditions: (1) data will be used solely for research purposes and not to identify any individual participant; (2) data will be kept secure using appropriate computer technology; (3) the data will be destroyed after proposed analyses are completed; (4) data will not be redistributed to third parties; (5) any publications or presentations resulting from the data will properly acknowledge the data resource and National Institute on Aging in accordance with standard guidelines. Researchers who are interested in using data collected from this study may contact the study MPI Dr. Loewenstein and submit a brief research proposal indicating the research question and variables that are relevant to their research. Upon executing the Data Sharing/Data Use Agreement a data set will be created and electronically delivered using a secure data transfer system.

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).

To access data a request must be made to the MPI with rationale and explanation of the nature of the data use, in addition a user agreement must be entered (detailed in the previous) which will protect participants and their data.

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 and will not be shared until users enter a data sharing agreement under the conditions described above.

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).

MPI's will have shared responsibility of overseeing the data management and sharing.

Planned Research Outputs

Dataset - "Deep Phenotyping of African-Americans at Risk for Alzheimer's disease"

Data will be stored in a secure REDCap database and a de-identified, privacy protected version will be made available upon request, after entering a data sharing agreement that stipulates protection of participant's identity and information, as well as appropriate use. We plan on making data available to NICRAD and other databases that study Alzheimer's disease and related disorders.

Planned research output details

Title	Type	Anticipated release date	Initial access level	Intended repository(ies)	Anticipated file size	License	Metadata standard(s)	May contain sensitive data?	May contain PII?
Deep Phenotyping of African-Americans at Risk for ...	Dataset	Unspecified	Open	NCBI		None specified	None specified	Yes	No