

## Plan Overview

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*A Data Management Plan created using DMPTool*

**DMP ID:** <https://doi.org/10.48321/D16W62>

**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

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.

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.

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.

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

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 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.

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

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.

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.

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.

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

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

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## 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.

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### 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               |