Guidance for Management and Sharing of NACC Data

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Background:
This document is a guide for developing the Data Management and Sharing (DMS) Plan language specific to NACC and Uniform Data Set (UDS) data for the six recommended elements of a DMS Plan. All ADRCs are required to submit a DMS Plan under the Final NIH Policy for Data Management and Sharing (NOT-OD-21-013). Each ADRC is **also expected** to include details for management and sharing of non-NACC and non-UDS data in their DMS Plan. Sample DMS Plans are available (https://sharing.nih.gov/data-management-and-sharing-policy/planning-and-budgeting-for-data-management-and-sharing/writing-a-data-management-and-sharing-plan#sample-plans).

Element 1: Data types

NACC data encompasses five primary types as of January 2023:

- **NACC Uniform Data Set (UDS)** of longitudinal standardized clinical and neurocognitive phenotypic data collected annually from participants at each ADRC.
- **Neuropathology** autopsy data collected at death; non-standardized.
- **Neuroimaging data** (MRI, amyloid and tau PET)
- **Biological Sample** data for fluid biomarkers.
- **Genotypic and Genomic data.**

Subject counts by data type are available via NACC websites and are dynamic.

Data collection for the NACC UDS is ongoing from the associated ADRCs. Guidelines and administration tools for the collection of NACC UDS clinical data are determined by NACC through its associated task forces and working groups and are readily available for reference online: DOI:10.6069/0wbkxvqg

Element 2: Related Tools, Software and/or Code

Validation and quality control of UDS data occur during upload to the main NACC database maintained by the University of Washington.

NIA-funded ADRCs upload data through password protected membership portals. Consistency and quality of UDS data is evaluated using proprietary SAS scripts developed and maintained by NACC staff. Data that does not pass validation must be corrected by ADRCs to be included in the dataset.

Bulk submission data files can be reviewed by Centers for quality control outside the NACC framework using the open source NACCulator tool made available by the CTS-IT of the University of Florida on their GitHub site.

Element 3: Standards

Data dictionaries and metadata level standardization of the described NACC data types are freely available and outlined in the “Forms & documentation” section of the NACC website (DOI:10.6069/0wbkxvqg). Conventions around variable naming, data quality, and continuity are provided by NACC and described in these data dictionaries for all data types described in Element 1.

MRI and PET data for ADRC participants will be collected in accordance with the acquisition protocols outlined by Standardized Centralized Alzheimer’s and Related Dementias Neuroimaging (SCAN). Non-SCAN compliant MRI and PET images and biomarker data are available and data dictionaries can be found on the NACC website as referenced above.

Training materials related to NACC UDS administration are also made available online. “Coding Guidebooks” and the “Instructions for the Neuropsych Battery” contain NACC guidelines for instrument administration that may differ from guidelines in instrument specific documentation. Examples include the MoCA, classic CDR interview administrations, NPI-Q administration and the FTLD module additions to the CDR.

Element 4: Data Preservation, Access, and Associated Timelines

ADRCs will utilize NACC as the data repository for UDS data collected from ADRC participants. Data housed in the NACC system includes ADRC site identifiers and participant identifiers unique for each participant. UDS data and metadata for all previously described data types are preserved through routine uploads of validated data to the NACC database systems. Preservation of other data types are conducted by NCRAD (biological samples), LONI (raw neuroimaging data), and NIAGADS (genotypic data) with access for all data facilitated by NACC. Data types are aligned by mapping of site-specific participant IDs to NACC IDs using the “PTID to NACCID Map” in the ADRC Portal.

Other data requesters accept the terms of the NACC Data Use Agreement and can submit requests for data for formal review at the NACC website. Date request policies and expectations are outlined in the NACC Handbook ***DOI: NACC Handbook UDSv3.*** Publications utilizing NACC data are required to acknowledge NACC grants and submit abstracts and manuscripts to NACC for review during the publication process.

ADRCs upload NACC data at regular intervals and its associated collaborators according to data types and metadata listed above. NACC performs quality control and derivation of variables requiring calculations on new data added to the repository on a quarterly basis referred to as a data freeze. Each data freeze is given a unique identifier to allow easier comparisons of data analysis.

Element 5: Access, Distribution, or Reuse Considerations

ADRC site level consent development is supported through NACC resources regarding consent best practices, which include language around data storage, access, and capacity assessment: (DOI:10.6069/p6jw2zxf). Other data requesters accept the terms of the NACC Data Use Agreement (DUA) and can submit requests for data for formal review at the NACC website.

Date request policies and expectations are outlined in the NACC Handbook (DOI:10.6069/g8v9cdx7). Publications utilizing data uploaded to NACC are required to acknowledge NACC grants and submit abstracts and manuscripts to NACC for review during the publication process as outlined in the Authors Checklist found on the NACC website.

Access to scientific data is made available through the NACC data request process and available after the signing of a DUA. Storing and sharing procedures through NACC systems are designed according to NIH GCDMP practices and standards which are outlined on the NACC website and the terms of the Data Use Agreement.

All data users are required to complete and sign a NACC DUA prior to dataset access. The NACC Data Use Agreements are designed to ensure appropriate use of the data solely by the individuals identified in the data request, ensure NACC is informed of intended manuscript submission, and ensure that NACC (and all ADRCs submitting data to NACC) are appropriately acknowledged in any publications. All data users are required to complete and sign a Data Use Agreement prior to dataset access. All collaborators on a project requesting NACC data are bound by the terms of the DUA and can freely share provided datasets amongst each other. NACC data utilization is limited to the data streams outlined above.

NACC distributes deidentified datasets to protect the privacy of study participants. All Data Requests are reviewed by the NACC Data Use Committee prior to distribution. The NACC Data Use Committee determines if researchers are provided with the Investigator or Commercial data file. This review ensures that participant's consent to participate in commercial-based research activities is respected.

Element 6: Oversight of Data Management and Sharing

ADRCs can monitor their NACC and UDS performance, data quality, and data summarizations through monthly reports from NACC, which are also sent to NIA. ADRC member sites have specific membership credentials allowing access to their working datasets for uploading of site NACC data and confirming accuracy.

Hyperlinks are not allowed in the Data Management and Sharing Plan that is submitted to NIA. However, we are including these links that you may find helpful in drafting your guidance.

Additional Resources:

UDS Data Summary Tables	https://naccdata.org/requesting-data/data-summary/uds
UDSv3 NACCulator	https://github.com/ctsit/nacculator
Author Checklist	https://naccdata.org/publish-project/authors-checklist