NAPS Data Access Policy

Data Sharing & Publication Policies for NAPS

The North American Prodromal Synucleinopathy (NAPS) Consortium was established as a multicenter collaborative project to further research in REM sleep behavior disorder (RBD) and synucleinopathies. The goals of the project can be best achieved through collaborative and open access to data and biospecimens, while respecting the intellectual contributions of principal- and co-investigators. This document presents the policy for access to data, access to biospecimens, access to neuroimaging data/scans, other participant-derived data, and publications. The development of these policies was greatly aided by the availability of policies developed for the Dominantly Inherited Alzheimer Network (DIAN), the Alzheimer Disease Cooperative Study (ADCS), Advancing Research & Treatment for Frontotemporal Lobar Degeneration (ARTFL), Longitudinal Evaluation of Familial FrontoTemporal Dementia Subjects (LEFFTDS), and ARTFL LEFFTDS Longitudinal Frontotemporal Lobar Degeneration (ALLFTD) programs.

As defined by the DIAN policy, 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 NAPS data are intended to provide structure to the request process, respect for intellectual contributions, and standards regarding security/confidentiality. This policy only applies to NAPS data and not data collected from an investigator's own research.

Definitions

Data – all information pertaining to, but not limited to, the following: demographics, clinical, family history, neurophysiological, neuropsychological, neuroimaging, and biofluid measures. This includes the raw data and data derived from analyses of clinical, neurophysiological, neuropsychological, neuroimaging, and biofluid samples and measures.

Biospecimens – samples of DNA, RNA, plasma, serum, CSF, and other biological specimens obtained from research participants, and any products derived from these samples (including but not limited to proteins, neurofilament light chain, etc.).

Authorship – making substantial contributions to study data or analysis, AND meaningful contributions to the revision of a manuscript for intellectual content.

Data and Biospecimens Committee

The Principal Investigators will designate a group of co-investigators to serve on a Data and Biospecimens Committee for the NAPS Consortium. This Committee will be responsible for the review of data and specimen requests and manuscripts.

Levels of analyses for data or biospecimens

The NAPS Consortium will follow a policy covering access to data with the intent of publication that acknowledges different levels of involvement. Regardless of the level described below, a formal data request must be submitted for review and tracking purposes.

Level 1 analyses are those that are specified in the aims in the original application(s) to the NIH. The respective principal and co-investigators will be responsible for specifying the analyses and writing the manuscripts that relate to these aims. The timing of Level 1 manuscripts will be left to the discretion of the NAPS Investigators; these manuscripts must be approved by the NAPS executive committee.

Level 2 analyses are those proposed by NAPS Consortium co-investigators that are not among the aims of the project in the original application(s). NAPS co-investigators may nominate a colleague or trainee within their team as a leader of such analyses or perform the analyses themselves. Level 2 manuscripts require approval by the Data and Biospecimens subcommittee.

Level 3 analyses are those proposed by qualified researchers who are not investigators in NAPS. Such analyses may be proposed at any time, and the data that will be provided will be drawn from a prior data freeze 12 or more months prior. Proposals for level 3 analyses will first be reviewed by the Data and Biospecimens Committee and any applicable Core leaders. Final approval requires agreement from the majority of the NAPS Consortium site investigators and majority of Executive Committee members, who will discuss requests at least quarterly. Criteria for review are described below. Publications arising from these analyses would list the NAPS Consortium funding in acknowledgements.

Requesting Data

Data requests for all levels should be submitted in writing to the Data and Biospecimens Committee. The standardized application process requests that the prospective authors specify the principal hypotheses, the materials needed (variables or biospecimens) and the analytic plan. The data request form and current review schedule can be accessed here.

Data requests will be reviewed using the following criteria:

- Scientific merit
- Feasibility (e.g. availability of NAPS resources to fulfill the request)
- Appropriateness of the investigator's qualifications and resources to protect the data
- Appropriateness to NAPS goals/themes

After a request is approved, de-identified data will be made available to investigators to conduct analyses. All analyses will be based on data sets that have been prepared, cleaned and frozen from time to time as determined by the Executive committee and influenced by the rate of recruitment. A Data Use Agreement (DUA) will be required for all data distributions; the DUA will specify requirements for returning results, proper acknowledgment, and any biospecimen-specific procedures.

Requesting Biospecimens

Biospecimens are a scarce commodity and will be released to co-investigators in a manner that parallels the levels of hierarchy described above. Requests for biospecimens will be reviewed by the Data and Biospecimens Committee, and will require final approval by majority of the NAPS investigators and Executive Committee. Biospecimen samples will be distributed through the National Cell Repository for Alzheimer's Disease and Related Dementias (NCRAD). A Materials Transfer Agreement (MTA) will be required for all biospecimen distributions; the MTA will specify requirements for returning results, proper acknowledgment, and any biospecimen-specific procedures. Biospecimen requests may be

rejected despite scientific merit if the distribution would substantively deplete the available samples. Biospecimen assay results must be returned prior to distribution of any linked data from the NAPS database.

Returning Results
New data generated through analyses of NAPS datasets must be returned to the NAPS Consortium for possible inclusion in the project database or into another NIH-approved government database such as dbGap or NIAGADS. A 12-month embargo will be placed on returned data to allow publication of results.

Manuscript review
If a data request is approved for a Level 2 or Level 3 analysis, the requestors understand that overlapping data and biospecimens requests may be approved for other researchers, which may result in competing simultaneous analyses and publications. All manuscripts, regardless of level, must be submitted to the Data and Biospecimens Committee *at least 30 days* prior to submission. The NAPS Data and Biospecimens Committee and Executive Committee reserve the right to require changes in the manuscript to avoid conflict or overlap with other existing or planned analyses or publications; and to ensure proper description of informed consent, approach to confidentiality, acknowledgements of NAPS Consortium investigators and funding sources, disclosure of potential and actual conflicts of interest, and other required information. It is possible, in the case of overlapping analyses by more than one group, that the NAPS Data and Biospecimens Committee and Executive Committee will deny approval for a manuscript submission.

Abstracts: In many meetings, Abstracts are often featured in press releases and thus might get wide media and professional attention. Hence, Abstracts must be cleared by the Data and Biospecimens Committee, just like full-length manuscripts. Because Abstracts are sometimes prepared under relatively stringent time constraints, authors must submit abstracts at least 10 business days in advance of the abstract due date. The NAPS Publications Committee reserves the right to require modifications to the abstract in the same manner as described for manuscripts above.

Protection of Confidentiality
All precautions to ensure confidentiality must be taken by recipients of NAPS Consortium data. The final dataset will be stripped of identifiers prior to release for sharing and be transferred only with encryption and password protection. The code linking a subject's identity to data will be maintained in a secure place and will only be accessible to research staff on a need-to-know basis. In accordance with the NIH policy for non-exempt human subjects research with multi-sites submitted for due dates on or after January 25, 2018, NAPS2 enrolling sites are expected to use a single Institutional Review Board (sIRB) to conduct the ethical review required for the protection of research participants. The sIRB policy does not apply to foreign sites. All United States sites are required to have a fully executed reliance agreement with the sIRB before they are approved to enroll subjects. Foreign sites are required to have local IRB approval prior to starting enrollment. When known, exact genetic mutations will not be recorded in the National Institutes on Aging (NIA), National Institute of Neurological Diseases and Stroke (NINDS), National Alzheimer's Coordinating Center (NACC), National Sleep Research Resource (NSRR), National Cell Repository for Alzheimer's Disease and Related Dementias (NCRAD), Laboratory of NeuroImaging (LONI), database of Genotypes and Phenotypes (dbGaP), Central Neuroimaging Data Archive (CNDA) databases nor will it be entered into NAPS on-line electronic data capture system.

A parallel database to the NAPS electronic data capture system will be used to track and record genotyping data. Separation of this sensitive data is necessary to prevent accidental disclosure of

participant mutation status to a member of the research team. Any research data that goes outside of the study group will be coded with a second unique identifier (which is different from the NAPS study ID, another unique identifier) to limit the risk of loss of confidentiality. A separate dataset with genetic and/or biospecimen data associated with this second unique identifier for each subject will be generated. A Global Unique Identifier (GUID), which is a randomly generated de-identified code unique to each participant, derived from the National Institute on Aging (https://bricsguid.nia.nih.gov), will be generated for each participant and may be used to link de-identified datasets. There is always the possibility of deductive disclosure of participant identity because participants are limited to specific institutions, and the dataset contains some demographic information, as well as detailed prospective information about their disease and mutation status, living situation, etc. Thus, we will make the data and associated documentation available to users only under the following prerequisites:

- Recipient of data will provide documentation of IRB approval valid for the analysis of NAPS data (or acknowledgment from your IRB that receiving coded data without access to identifiers is not considered "research" requiring review).
- 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.
- 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.
- Recipient of data will guarantee that mutation data will be destroyed when analyses are complete.

Authorship

Collaborative and collegial engagement is a key to deciding upon authorship. Any author of a manuscript or publication based on NAPS Consortium data or biospecimens must meet appropriate standards for authorship, as defined in “Definitions” section. Other personnel as Authors: NAPS investigators may include trainees or other site personnel as co-authors provided that they meet standards for authorship as defined above.

First Authors: First authors of any NAPS Consortium publication should be those who generate the first draft and take principal responsibility for crafting the final version.

Senior Authors: For Level 1 manuscripts, the senior author(s) should be the principal investigator(s), including “on behalf of the NAPS Consortium”. For Level 2 manuscripts, the senior author(s) should be the NAPS Investigator who sponsored the data and biospecimen request; and/or a NAPS principal investigator(s), including “on behalf of the NAPS Consortium.”

Co-Authors: Any NAPS investigators or personnel meeting criteria for authorship should be included as named author(s), regardless of level of request. A list of NAPS Consortium investigators can be found here.

Level 1 analyses: All site co-investigators and relevant core leaders will be invited to participate as co-authors, with the expectation that all included authors will meet the standards for authorship. The senior author determines the order of listing of co-authors.

Level 2 analyses: All site co-investigators and relevant core leaders meeting standards for authorship should be invited to participate as co-authors for manuscripts. The senior author determines the order of listing of co-authors.

Level 3 analyses must: All NAPS personnel meeting criteria for authorship should be invited to participate as co-authors for manuscripts. All publications, abstracts, and presentations must acknowledge NAPS Consortium funding in acknowledgements.

Obligations incurred when accepting NAPS data:

- Acceptance of NAPS data obligates the recipient to cite/reference the funding sources for the NAPS Consortium in any presentation or publication that may result from this research. Language will be included in each NAPS publication following listed authors that acknowledges the NAPS Consortium and its funding sources. Please see paragraph at the end of this document.
- Should publications result from the use of NAPS Consortium data now or in the future, the recipient agrees to notify the NAPS Executive Committee with details (reference or PubMedCentral ID#) and provide a copy of the publication so that the projects may report productivity derived from our resources to the funding agencies.
- Publications require compliance with National Institutes for Health (NIH) public access policies, including a PubMedCentral ID (PMCID) linked with the relevant NIH funding details.
- Should funding result from data or biospecimens from the NAPS Consortium, now or in the future, the investigators must notify the Data and Biospecimens Committee with details (grant title, sponsor, number, dollar total, and dates) so that NAPS may report productivity derived from our resources to NIH.
- As described in the "Returning results" section above, new data created through analysis of NAPS must be provided to the Data and Biospecimens Committee for possible inclusion in the NAPS database and other NIH-approved governmental databases. Such data will be subject to distribution in future NAPS datasets.
- No sharing of data with a third party is allowed without explicit permission of the Data and Biospecimens Committee.

Intellectual Property

Any intellectual property, patents, copyrights, or similar that arise from work of a NAPS investigator or an external investigator using NAPS (NAPS1, NAPS2, or any future stages of the NAPS Consortium) resources will belong to the NAPS Consortium. Any and all revenues from intellectual property, patent, copyrights, or similar must be transferred to the NAPS Consortium for the purposes of further research or clinical work in RBD and related topics.

Required acknowledgement language

"Data collection and dissemination of the data presented in this manuscript were supported by the NAPS Consortium (R34 AG056639 and U19 AG071754 funded by the National Institutes of Health), the National Centralized Repository for Alzheimer's Disease and Related Dementias (U24 AG021886), and the National Alzheimer's Coordinating Center (U24 AG072122). The authors acknowledge the invaluable contributions of the participants in NAPS Consortium as well as the assistance of the support staffs at each of the participating sites. "

Summary table

	Data/specimens request review	Data dispensed	IRB[1] required?	DUA/MTA required	Last author	NAPS Consortium as author	NAPS Consortium in acknowledgement	Abstract/Manuscript Review deadline
Level 1	Rolling	last data freeze	No, included in NAPS	Possible	NAPS PI or investigator	Must include	Yes	Rolling
Level 2 abstract	Quarterly	last data freeze[2]	Yes	Yes	NAPS Investigator sponsor or PI	Must include unless list all individually	Yes	10 business days
Level 2 manuscript	Quarterly	last data freeze[2]	Yes	Yes	NAPS Investigator sponsor or PI	List individually	Yes	1 month
Level 3 abstract	Quarterly	Data freeze 12+ mo prior[2]	Yes	Yes		No[3]	Yes	10 business days
Level 3 manuscript	Quarterly	Data freeze 12+ mo prior[2]	Yes	Yes		No[3]	Yes	1 month

[1] IRB approval or letter stating IRB approval is not required

[2] Biospecimen assay results or derived data (such as from neuroimaging or polysomnography) must be returned prior to receiving linked data.

[3] In certain instances, if substantial NAPS Consortium resources support any publication, the executive committee will require addition of "NAPS Consortium" as an author and inclusion of a list of NAPS investigators in an appendix.

NAPS Consortium

Executive Committee

Brad Boeve – NAPS Consortium Principal Investigator
Yo-El Ju – NAPS Consortium Principal Investigator
Ron Postuma – NAPS Consortium Principal Investigator
NAPS Deputy Director (Jennifer McLeland) or NAPS Program Manager
Representative from NIA/NINDS