NAPS CONSORTIUM
For REM Sleep Behavior Disorder

Data Sharing & Publication Policies for NAPS

The North American Prodromal Synucleinoapthy (NAPS) Consortium was established as multicenter collaborative projects to further research in REM sleep behavior disorder 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, 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), and Advancing Research & Treatment for Frontotemporal Lobar Degeneration (ARTFL), & Longitudinal Evaluation of Familial FrontoTemporal Dementia Subjects (LEFFTDS).

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 specimens obtained from research participants, and any products derived from these samples (including but not limited to proteins, neurofilament light chain, etc.).

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 requests and manuscripts.

Types of analyses and related requests 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.

Level 1 analyses are those that are specified in the specific aims of the project found 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 specific aims. The timing of Level 1 manuscripts will be left to the discretion of the NAPS Principal Investigators; these manuscripts must be

approved by the NAPS executive committee. The NAPS Principal Investigators may designate a colleague to take the lead, but the ultimate decision is that of the principal investigators. In the spirit of collaboration and inclusiveness, all site co-investigators will be invited to participate as co-authors, with the expectation that all site co-investigators will meet the standards for authorship described below. The lead author (or co-lead author) determines the order of listing of co-authors.

Level 2 analyses are those proposed by NAPS Consortium co-investigators that are not among the specific 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. Once again, all site co-investigators will be invited to participate as co-authors. The lead author (or co-lead author) determines the order of listing of co-authors.

Level 3 analyses are those proposed by qualified researchers who are not investigators in NAPS. Such analyses may be proposed one year after a data freeze. Proposals for level 3 analyses will be reviewed by the Data and Biospecimens Committee, and final approval by majority of the NAPS Consortium sites and executive board members. Criteria for review are described below. Publications arising from these analyses would acknowledge the NAPS Consortium investigators as co-authors, would list the NAPS Consortium funding in acknowledgements, and would list NAPS investigators in an appendix.

Requesting Data

Level 2 and Level 3 data requests should be submitted in writing to the Data and Biospecimens Committee. A standardized application process will be developed that will ask the prospective authors to specify the principal hypotheses, the materials needed (variables or biospecimens), the analytic plan, and assurance of non-overlap with another request.

Data requests will be reviewed using the following criteria:

- Scientific merit and 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.

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 board. Biospecimen samples will be distributed through the National Cell Repository for Alzheimer's Disease (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.

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 six-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 must agree to prepare a manuscript in a timely manner, typically one year from date of data release, but the final duration will be determined by the Data and Biospecimens Committee. The requesters must also submit the manuscript to the Data and Biospecimens Committee at lease 30 days prior to submission for publication. 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.

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 1 week 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. All United States sites are required to have submitted the NAPS Certificate of Confidentiality with their IRB application before they are approved to enroll subjects. 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 Cell Repository for Alzheimer's Disease (NCRAD), 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. In general, first authors of any NAPS Consortium publication should be those who generate the first draft and take principal responsibility for crafting the final version. For Level 1 and Level 2 manuscripts, the senior author(s) should be the principal investigator(s). Co-authors must also meet appropriate standards for authorship such as making substantial contributions to study data, and meaningful contributions to the revision of the manuscript for intellectual content. All publications based on NAPS data must also include “for the NAPS Consortium Investigators”, as an author.

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.

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.

Required acknowledgement language

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