Data Sharing & Publication Policies for ARTFL and LEFFTDS

LEFFTDS & ARTFL were established as multicenter collaborative projects to further research in the frontotemporal degenerations. The goals of both projects 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 policies of the two projects 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) and the Alzheimer Disease Cooperative Study (ADCS).

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 ARTFL & LEFFTDS data are intended to provide structure to the request process, respect for intellectual contributions, and standards regarding security/confidentiality.

Definitions

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

Biospecimens – samples of DNA, RNA, plasma, serum, CSF, PBMC, fibroblasts, etc., and any products derived from these samples (including but not limited to proteins, induced pluripotent stem cells, etc.).

Publications Committee

The Principal Investigators have designated a group of co-investigators to serve on a Publications Committee of LEFFTDS & ARTFL. This Committee will be responsible for the review of data requests and manuscripts.

Types of analyses and related requests for data or biospecimens

LEFFTDS & ARTFL 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 two projects found in the original applications to the NIH. Because the aims of ARTFL and LEFFTDS are separate, the approach to manuscripts may be project-specific, i.e. just LEFFTDS or just ARTFL, or could involve both groups of investigators. The respective principal and co-principal 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 LEFFTDS & ARTFL Principal Investigators; these manuscripts must be approved by the ARTFL and LEFFTDS joint executive committee. These 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 may be proposed by co-investigators in LEFFTDS & ARTFL so long as they are not among the specific aims of L or A. A & L 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 ARTFL/LEFFTDS Executive Committee or a designated Publications 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 ones that are proposed by qualified researchers who are not investigators or co-investigators in ARTFL and LEFFTDS. Such analyses may be proposed one year after a data freeze. Proposals that fall under level 3 will be reviewed by a Publications subcommittee established by the ARFTL/LEFFTDS Executive Committee. Criteria for review are described below. Publications arising from these analyses would acknowledge either the LEFFTDS or ARTFL Study Group (or both) as co-authors, would list the ARTFL and LEFFTDS funding in acknowledgements, and would list LEFFTDS & ARTFL investigators in an appendix.

Requesting Data

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.

Level 2 and Level 3 data requests should be submitted in writing to the ARTFL/LEFFTDS Executive 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, an assurance of non-overlap with another request.

Level 3 data requests will be reviewed using the following criteria:

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

Requesting Biospecimens

Biospecimens (blood, blood products, and cerebrospinal fluid) from LEFFTDS & ARTFL participants 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 ARTFL/LEFFTDS Executive Committee and Biospecimens and Genetics Committee. Biospecimen samples will be distributed through the National Cell Repository for Alzheimer's Disease (NCRAD). An 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 LEFFTDS & ARTFL datasets must be returned to the Executive Committee 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, determined jointly by the requestors and the ARTFL/LEFFTDS Executive or Publications Committee. The requesters must also submit the manuscript to the ARTFL/LEFFTDS Executive Committee/Publications Committee prior to submission. The ARTFL/LEFFTDS Executive Committee reserves the right to require changes in the manuscript to avoid substantial conflict or overlap with other LEFFTDS and ARTFL publications and to ensure proper description of informed consent, approach to confidentiality, acknowledgements of LEFFTDS & ARTFL investigators and funding sources, and disclosure of potential and actual conflicts of interest.

Protection of Confidentiality

All precautions to ensure confidentiality must be taken by recipients of LEFFTDS & ARTFL data. The final dataset will be stripped of identifiers prior to release for sharing and be transferred only with encryption and password protection by the ARTFL and LEFFTDS data management team. 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 ARTFL or LEFFTDS 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 LEFFTDS & ARTFL on-line electronic data capture system.

A parallel database to the LEFFTDS & ARTFL 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 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 NINDS Parkinson's Disease Biomarker Program

(http://pdbp.ninds.nih.gov/data-management), 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 LEFFTDS & ARTFL 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 LEFFTDS & ARTFL publication should be the ones who generate the first draft and who 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 ARTFL and LEFFTDS data must also include “for the LEFFTDS Study Group”, “for the ARTFL Study Group,” or if both, “for the LEFFTDS & ARTFL Study Group” as an author.

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 LEFFTDS & ARTFL Publications 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 to the LEFFTDS & ARTFL Publications Committee. The LEFFTDS & ARTFL Publications Committee reserves the right to require modifications of the abstract regarding proper description of informed consent, proper approach to confidentiality, proper acknowledgements of LEFFTDS & ARTFL investigators and funding sources, substantial overlap or conflict with other LEFFTDS & ARTFL manuscripts, and proper disclosure of potential and actual conflicts of interest.

Other personnel as Authors: ARTFL & LEFFTDS investigators may include trainees or other site personnel as co-authors provided they meet standards for authorship as defined above.

Obligations incurred when accepting LEFFTDS & ARTFL data:

- Acceptance of LEFFTDS & ARTFL data obligates the recipient to cite/reference the GRANTS in any presentation or publication that may result from this research. Language will be included in each ARTFL & LEFFTDS publication following listed authors that acknowledges LEFFTDS & ARTFL. Please see paragraph at end of this document.

- Should publications result from the use of LEFFTDS & ARTFL data now or in the future, the recipient agrees to notify the ARTFL/LEFFTDS 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, the NIA and NINDS. Such publications require compliance with National Institutes for Health (NIH) public access policies.

- Should funding result from this research now or in the future, please notify the ARTFL/LEFFTDS Executive Committee (contact information below) with details (grant title, sponsor, number, dollar total, and dates) so that ARTFL and LEFFTDS may report productivity derived from our resources to NIA, NINDS and NCATS.

- As described in the "Returning results" section above, new data created through analysis of ARTFL & LEFFTDS must be provided to the Executive Committee for possible inclusion in the LEFFTDS & ARTFL database and other NIH-approved governmental databases. Such data will be subject to distribution in future LEFFTDS/ARTFL datasets.

- No sharing of data with a third party is allowed without permission of the ARTFL/LEFFTDS Executive Committee.

Required acknowledgement language

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