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12. **Purpose**

We are pleased to share data with you. This document defines the standard operating procedure/policy for distribution of clinical, behavioral, neuroimaging, and genetic data from the Duke Neurogenetics Study (DNS) Database/Repository utilized and/or maintained by the Laboratory of NeuroGenetics (LoNG) at Duke University. The term “DNS data and samples” used throughout this document is defined to include without limitation clinical, behavioral, neuroimaging, and genetic data acquired and maintained by the LoNG.

This document is intended to help standardize the conduct of research among our research group, students and collaborators in the interest of smooth communication. Its contents are drawn from the guidelines of the American Psychological Association, American Medical Association, Duke University Medical Center, and National Institutes of Health. Please consider this checklist as you conduct data-sharing research with us. We ask that you follow each of the policies and procedures listed below.

We share data with a large number of collaborators, who live in many countries, and who work at many different levels of training and expertise. This memo is intended both to instruct students who are embarking on their first research project, and to remind senior professors who are embarking on their thousandth research project. We have listed here the practices that help to keep our working relationships comfortable and productive. We hope they work for you too.

Thank you,

Ahmad R. Hariri, PhD

Director, LoNG

[ah154@duke.edu](mailto:ah154@duke.edu)

919-684-8408

1. **Scope**

Data sharing promotes many research goals of the LoNG and its collaborators. Data sharing allows scientists to expedite the translation of research results into knowledge, products, and procedures to improve human health. Sharing data reinforces open scientific inquiry, encourages diversity of analysis and opinion, promotes new research, makes possible the testing of new or alternative hypotheses and methods of analysis, supports studies on data collection methods and measurement, facilitates the education of new researchers, enables the exploration of topics not envisioned by the initial investigators, and permits the creation of new datasets when data from multiple sources are combined.

1. **Getting Started: Agreeing to the Data Sharing Policies**

The LoNG facilitates data sharing while protecting DNS data and samples from unauthorized access. The DNS Database/Repository contains DNS data and samples owned by the LoNG. The LoNG requires that collaborators adhere to the policies and procedures outlined below when sharing data:

1. Discuss the research idea with Professor Hariri to ascertain its general feasibility.
2. Review and, if agreeable, return a signed copy of the *Data Use Certification Form* (accompanying this document) as a PDF to LoNG staff.
3. If necessary, request in writing from Dr. Hariri a copy of the DNS data dictionary and protocols to familiarize yourself with the DNS data.
4. Prepare a brief concept paper for the proposed study. A template for the *Concept Paper Proposal* can be found at haririlab.com/projects. A concept paper should minimally contain:
   1. Your name and affiliation, the date, a working title for the project or paper.
   2. Brief statement of the hypothesis or topic and its significance.
   3. Which type of data and which variables you will need.
   4. What analyses you will perform.
   5. A *Response Form* has detailed options of what sort of role the Laboratory of Neurogenetics will contribute to the project (e.g., authorship roles: contribute to design & data, help with analyses, help with writing, critique drafts).
5. Send Professor Hariri your *Concept Paper Proposal* and *Response Form* for review.
6. The *Response Form* will be returned to you with a decision in most cases within 2 weeks. If the proposal is deferred for further discussion, please be in touch with Professor Hariri. If the proposal is approved, then we are in business and have an active collaborative project.
7. **Data Storage and Subject Privacy**

After obtaining approval to use DNS data, contact LoNG staff to obtain the necessary data. The research collaborator agrees to take the following precautions in protecting DNS data:

1. Before sharing, subject identifiers are removed/replaced according to the HIPAA Limited Data Set (http://hipaa.wisc.edu/ResearchGuide/limiteddatasets.html).
2. All portable computers in a collaborator’s lab including laptops and storage media (USB, CD or DVD) containing DNS data must be encrypted using NIST FIPS 140-2 approved encryption.
3. Electronic data are stored in storage systems restricted to authorized users only.
4. Password authentication is required for all documents shared with collaborators and all events of data sharing are logged. Events of data sharing between LoNG and collaborator are logged by the LoNG. Events of data sharing between collaborator and potential 3rd party approved by LoNG are logged by collaborator.
5. All DNS data and samples are required to be coded with a research identifier that is not derived from or related to information about the subject.
6. **Contacting DNS Participants for Ancillary Studies**

Sometimes the proposed research can only be accomplished by recruiting DNS participants into ancillary studies directed by research collaborators. As per the approved DUMC IRB protocol, the LoNG has the sole authority to contact DNS participants, and can do so, with approval, on behalf of research collaborators. In order for the LoNG to contact participants for ancillary studies, the following is required:

1. Contact Professor Hariri to discuss the selection criteria.
2. Once a selection process is identified, LoNG staff can query the DNS Database/Repository for an estimate of the number of subjects meeting the selection criteria.
3. The research collaborator (including research collaborators at Duke) is required to obtain IRB approval at his or her institution to recruit DNS participants for an ancillary study research project.
4. Once approval has been obtained, the research collaborator is required to send a PDF copy of the approval to LoNG staff to keep on record at the LoNG.
5. The research collaborator completes a template email (see the **Appendix**) that will be sent out to participants by the LoNG meeting the study criteria.

**7.0 Data Sharing Process**

DNS data and samples contained within the DNS Database/Repository may be shared with investigators outside of the LONG through the following procedure:

1. The collaborator completes and signs the DNS Data Use Certification, and provides this and a copy of the approved IRB or Certification of Exemption from IRB Review (if applicable) to Professor Hariri and LoNG staff.
2. Professor Hariri reviews the request for data, evaluating the credentials of the requestor and the scientific merit of the proposed project. Decision to collaborate is conveyed to the applicant collaborator.
3. Any research conducted using DNS data and samples contained within the DNS Database/Repository must have a protocol approved by the DUHS IRB, non-medical IRB of Duke University, or other (i.e., non-Duke) university or institutional IRBs.
4. When DNS data and samples are shared with investigators who have obtained IRB approval consistent with the above, all shared information will only be identified by unique study IDs limiting access of PHI to authorized personnel of the LONG.
5. After completion of the investigation, the dataset and any or all derived data must be securely destroyed.
6. Collaborator will send a copy of the study results to Professor Hariri after study completion.

**8.0 Ethics Training**

The LoNG has the responsibility to oversee all research activities related to the DNS. It is a requirement that all investigators have completed the NIMH research ethics training course in human subjects protection, or equivalent training from their own country. Even if NIH does not actively fund research, knowledge of human subjects protection is still a requirement of DUMC IRB who approves and monitors the DNS. Increasingly, journals are also asking for this documentation. Therefore, by accepting data from us to analyze, the researcher should understand they are attesting to us that they have completed research ethics training. If you have not yet taken a course, it is easy to take by going to: <http://www.citiprogram.org/default.asp?language=english>

**9.0 Working with DNS Data**

1. Consult the DNS data dictionary and read previously published papers from the DNS or LoNG to get information about the data you plan to use.
2. When you place your request for data, take the time to think carefully about what variables you will need and discuss this with Professor Hariri.
3. Look at the frequency distribution of a variable before you use it.
4. Report any bug in a file in writing to LoNG staff.
5. Use “comments” in your command files for data analysis, so that others can retrace your steps later.
6. Save all your printouts in a labeled notebook (electronic or paper). These must be saved for 5 years.

**IF YOU CREATE NEW VARIABLES FROM THE BASIC DATA**

1. We ask that you provide to us any new variables that are published in your paper.
2. When you create a new variable give it the following features: value labels for the coded numeric values (e.g., 0 = no, 1 = yes)
3. Prepare a file and documentation for all new variables you created for the study. Include the variable labels and value labels. Documentation includes how you made the variable and its frequency distributions, including the derivation code used to create each variable from the base-data variables themselves (i.e., before any re-codes etc) -- this makes it easier to see what exactly was done.
4. Send the file and documentation to LoNG staff.

**10.0 Reporting DNS Data**

1. Do not feel compelled to re-create the wheel; use our existing languages for the "methods" section for consistency across publications. Look at recent submissions for bits to copy and/or see haririlab.com/methods.
2. Request access to our reference system if you like, to help construct your reference list.
3. Include the date and the electronic file name, as well as page numbers, on every printed version of the manuscript.
4. Acknowledge all appropriate individuals, agencies and grants on your manuscript. This is not optional, it is required by funding agencies.

**SAMPLE TEMPLATE FOR ACKNOWLEDGEMENTS SECTION (DUKE NEUROGENETICS STUDY)**

**ACKNOWLEDGEMENTS:**

Research assistance was provided by [name, name].

Helpful comments on earlier drafts were provided by [name, name].

This research received support from grant [name, funding sources],

**BEFORE YOU SUBMIT FOR PUBLICATION:**

All primary authors need to log the annotated script of their data analysis with LoNG staff.Professor Hariri and a data manager (DM) will then review the script and rerun all analyses to check against the manuscript. Specifically, here is what we ask that all authors provide:

1. Script for new variables you have created.
2. Script for final analyses (in SPSS, STATA, Mplus, SPM, FSL, MATLAB, etc.) with documentation included in the script. It would be especially helpful if you could orient us in the script to the manuscript (e.g., analyses for Table 1, etc.).
3. Professor Hariri must approve the penultimate draft before it is circulated among collaborators.
4. Send a copy to all collaborating co-authors for review and approval.
5. Specify the target journal.
6. Ask collaborators to send written permission to submit the paper if journal requires it.
7. Allow PI’s and collaborators 3 weeks from the date of receipt to review the paper.

**SUBMITTING FOR PUBLICATION REVIEW:**

Log a copy of the submitted paper and letter to the editor with LoNG staff, both dated with the electronic file name on the document.

**DOING REVISIONS:**

1. Send a copy of the editor's letter and reviews to all co-authors.
2. Invite them to comment or contribute to the revision process.
3. Professor Hariri must approve the resubmission revised draft before it is sent back to the editor.

**WHEN THE PAPER IS ACCEPTED FOR PUBLICATION:**

1. Send LoNG staff the Word file of the final version for filing in the electronic reprint system.
2. Send a copy of the paper to all collaborators with the citation for their vitae.
3. The DNS data remains the property of the LoNG and Duke and cannot be used for further analyses without express written permission.

**DURING THE PROCESS TOWARD PUBLICATION:**

Notify LoNG staff when you get the copy-edited version and the page-proof version.

**ONCE PUBLISHED:**

1. Send PDF to all co-authors.
2. Send LoNG staff a PDF and the PMCID.

**IF THERE IS MEDIA COVERAGE OF THE PROJECT:**

1. Consult with Professor Hariri about drafting a fact sheet for journalists.
2. Deliver copies of all media articles, or websites, to LoNG staff.

**IF YOU GIVE A LECTURE OR POSTER PRESENTATION ON YOUR WORK:**

1. Notify LoNG staff of the title, date, and context of the presentation. We may need to report these for our progress reports to funding agencies.
2. Oral presentations do not require a concept paper.

**Appendix**

Hello,

Thank you again for your participation in the Duke Neurogenetics Study (DNS).

We are writing to ask if you are interested in participating in a new study affiliated with the DNS. The purpose of the study is to [insert brief, general purpose].

For this study, you would be asked to:

[insert 3-5 bullet points describing the study procedures].

If you complete this study, you will be compensated $XX for your time.

If you are interested, please go to the following link to complete the online screening form [or contact XXXX at (xxx) XXX-XXXX].

[Internet link to be inserted]

Thank you for considering participating in this new study

All the best,

Ahmad R. Hariri, PhD (Director)

Duke Neurogenetics Study

Laboratory of NeuroGenetics

Duke University