

## **The Health and Aging Brain Study: Health Disparities The Data Access and Publication Committee Proposal and Publication Policy**

### **Overview**

Data from the Health and Aging Brain Study: Health Disparities (HABS-HD) will be made broadly available to the research community. The Data Access and Publications Committee (DAPC) reviews all proposals, and any qualified scientist can submit a request for publicly available data. Biospecimen requests and ancillary study proposals are reviewed by a separate process and do not fall under this Policy. Collaborators must fill out an initial application using the ITR Data Access and Publication (DAP) Proposal Form which will be reviewed by the HABS-HD DAPC.

### **1) Data Access, Policies, and Procedures**

This document outlines the Health and Aging Brain Study data sharing policies, procedures, and publication credits for those who use HABS-HD data. The intent of these policies is to facilitate the sharing of data with all interested investigators, to encourage academic productivity, and to provide a mechanism for tracking and archiving data requests, intended analyses and publications related to and resulting from the data. All requests for HABS-HD data will be reviewed by the DAPC and/or the HABS-HD Executive Committee. Investigators will be asked to fill out a proposal and sign a data use agreement. Researchers must also obtain IRB approval from their own institutional review boards as appropriate.

Note: The HABS-HD consent contains the following language related to data sharing: “Your data will be labeled with a coded identifier to protect your identity. Study investigators will maintain and be responsible for deciding how your data will be used for future research. All links with your identity will be removed from the data before they are shared. Only de-identified data, which does not include anything that might directly identify you, will be shared for research purposes.”

### **Data Request Application and Tracking**

A web-based, semi-automated Data Portal and Tracking system has been instituted to manage the data requests. Users will complete a web-based application form, and a Data Use Agreement. Once submitted the proposal will undergo review by the DAPC. Non-compliance with the HABS-HD data access policies or violation of the Data Use Agreement will jeopardize further access to HABS-HD data.

### **Dataset Limitations**

The limitations will only provide investigators with deidentified data files that do not contain individual identifiers.

#### **a) Goals**

- i) To encourage high quality studies, publications, and presentations utilizing the data from the HABS-HD Study to advance the science of brain aging and health disparities in cognitive aging among Mexican Americans, Hispanic/Latino populations and other ethnicities.

#### **b) Scope of the Guidelines**

The guidelines cover papers (including methods, meta-analyses, validation, or any other analyses that include ITR data), abstracts, poster presentations, oral presentations, letters, meeting proceedings, and

extended abstracts that use any HABS-HD data. These policies remain active after funding of the studies end.

**c) Types of Publications**

These cover any publication, presentation, or report that utilizes HABS-HD data. These include:

- i) Study wide papers addressing primary aims/hypothesis of the study
- ii) Secondary analyses that are related to but are not the primary aims/hypothesis of the study
- iii) Papers reporting data from funded ancillary studies
- iv) Method/validation papers
- v) Letters to editors and other forms of publication

**d) Publication Policy**

The HABS-HD DAPC will not evaluate the scientific merit of the proposals. The DAPC will be charged with the administrative review of manuscripts only. As part of the Data Use Agreement, investigators will be asked to agree to a Publication Policy as follows:

- i) All manuscripts will acknowledge the methods of HABS-HD data gathering outlined in the DUA.
- ii) All manuscripts will acknowledge the support of NIA using the NIH grant numbers found in the Data Use Agreement.
- iii) In addition to the named authors, all manuscripts will be submitted with an acknowledgement of “The HABS-HD Study Team” on the author line followed by an asterisk (see Data Use Agreement). The asterisk will list the names of the HABS-HD study members as outlined in the DUA.
- iv) Lead authors are responsible for submitting pre-submission versions of the manuscripts to the Data Access and Publication Committee for review prior to submission to a journal.
- v) Full citation of all published manuscripts or abstracts will be submitted through the HABS-HD data portal.
- vi) A copy of the manuscript will be provided upon publication of the manuscript. If permitted by the journal, a version of or link to the article will be displayed on the HABS-HD website.
- vii) Authors will respond to annual productivity requests in a timely manner.

**e) Tracking of Data Use and Publications**

If HABS-HD data are used in publications, authors will be required to:

1. Add HABS-HD acknowledgement (see Data Use Agreement)
2. Include recommended language describing HABS-HD methods and data gathering
3. Provide manuscript to HABS-HD DAPC for review 2 weeks prior to planned submission (see Data Use Agreement)
4. Respond to annual requests for productivity updates
5. Provide manuscript citation to HABS-HD upon acceptance
6. Provide URL to published work, if possible.

**f) ITR Data Use Agreement**

- i) The study lead will be responsible for submitting a signed Data Use Agreement.
- ii) The study lead will be responsible for ensuring that the paper and authorship team adhere to the Data Use Agreement.

**g) Standard Acknowledgements**

**i) HABS-HD**

- (1) The official name of the HABS-HD study for scientific purposes is “Health and Aging Brain Study: Health Disparities (HABS-HD).” The full name should be listed in the Method/Participants section of the manuscript. “HABS-HD Study” can be utilized after first completely spelling out the study name.
- (2) All papers, abstracts and presentations (oral and poster) should list the grant(s) that support the study whose data is being used. All studies using HABS-HD data should acknowledge the parent cohort grant as follows: “Research reported in this publication was supported by the National Institute on Aging of the National Institutes of Health under Award Numbers R01AG054073 and R01AG058533, R01AG070862, P41EB015922 and U19AG078109. The content is solely the responsibility of the authors and does not necessarily represent the official views of the National Institutes of Health.”

**h) Timeline for Proposal Review**

Proposals will be sent to the committee via e-mail for review every two weeks. Incomplete proposals will be sent back to the requestor for more information prior to sending to the committee. Submitters should be made aware of the 2-week timeline for approval. Committee members will be given 36 hours to review and provide feedback. If no feedback is received, the proposal will default to others to approve.

**i) HABS-HD Paper Review**

- i) The study lead will submit the pre-submission version of the manuscript to the Data Access and Publications Committee for review. The Committee is not meant to “police” the data or the study PI’s. The Committee will review all pre-submission manuscripts for the following:
  - (1) Appropriate citation of the study and funding.
  - (2) Appropriate presentation of the study population.
  - (3) Fit of the manuscript with the approved study proposal.
- ii) While such instances are not expected, the Committee will address issues that arise such as the following:
  - (1) Egregiously poorly written work. If the Committee identifies problems with language, sensibility of the work or other issues with the writing style of the manuscript, the Committee can recommend that the work not be submitted for publication without substantial revision. If the manuscript is published against the Committee’s written statement, the Committee can (1) request a statement be added that the Institute did not approve the submission of the publication and/or (2) revocation of access to Institute data in the future.
  - (2) Failure to follow the Data Use Agreement. If identified, the Committee will notify the study lead of the issue and request the problem be fixed. If users willfully violate the Data Use Agreement, the Committee will revoke access to the Institute’s data.
  - (3) Fraudulent use of the data. Identification of fraudulent attempts to obtain Institute data will result in immediate revocation of access to the HABS-HD database and reporting the violation to the user’s academic institution.
- iii) If investigators disagree with the Committee’s decisions, s/he can appeal to the Executive Committee for final arbitration.
- iv) The Committee will initiate semiannual inquiries regarding the status of approved projects for updates. Failure to respond to these inquiries will result in lack of access to the HABS-HD database.

- v) Studies that have been approved may expire and authorship potentially re-assigned if the manuscript has not been submitted for publication within 18 months from the date of approval of the Study Proposal.
- vi) The study lead of proposals arising from ancillary studies funded from other institutions will be asked to submit a summary of their manuscript for informational use.