Form # 1 I. Requirements for Receiving Restricted Data from MHAS

Sealy Center on Aging, University of Texas Medical Branch 301 University Blvd. Galveston, TX 77555-0177

In order to receive MHAS Restricted Data, **all** of the following requirements must be met:

A. Researcher with a permanent position

Researchers currently holding a permanent position at an institution with a Human Subjects Review Process may receive MHAS Restricted Data. Researchers not in a permanent position at an institution will need to have (2) researchers that are currently in a permanent position to be listed in the research plan to be submitted to MHAS

B. Affiliation with an institution with a Human Subjects Review Process

The institution with which the researcher is affiliated with must have a review process to uphold confidentiality rights of participants that provide data in studies.

C. Research Proposal

Applicants for MHAS Restricted Data must provide a 1-3 page research proposal to include research goals, the types of variables from MHAS Restricted Data expected to be used, and an explanation why the restricted data is needed for your research purposes apart from unrestricted data.

Each research project proposed, applicants must provide:

- Project Title
- Project Summary (a one paragraph abstract)
- Study Team Information for each team member, defined as anyone who will have access to the restricted data, provide Name, Role on Project, Contact Information (Complete business street address, email, telephone)

D. Restricted Data Protection Plan

Review the Developing a Data Protection Plan form and investigate the mechanisms that are available to you to meet its requirements at the site(s) at which the restricted data will be managed, analyzed, and stored. This may require some discussion with

computing personnel at your institution, and perhaps even obtaining permission to acquire special hardware or software. If you intend to maintain Internet connectivity, you should read The Restricted Data Environment: Issues Relating to Network-Connected Clients. Once you have assured yourself that you can meet the requirements set forth in both documents, draft your Restricted Data Protection Plan and mail a copy to MHAS as specified in Section III.D. below. MHAS staff will review the draft plan, and may require some amendments. Do not be surprised if your Take careful note that the Restricted Data Protection Plan must define and treat variables/fields **derived** from the original restricted dataset as restricted data.

(It is possible for a variable derived from original restricted data to be later reclassified as unrestricted, and even included in future releases of unrestricted datasets with appropriate credit to the creator. The MHAS Data Confidentiality Committee will consider requests from researchers to reclassify derived restricted variables. Such requests for reclassification should explain why you believe that the derived variables do not significantly increase the risk of identification of individual persons, families, households, employers, and benefit providers, compared to other unrestricted data; are accompanied by the computer code used to create the derived variables, and documentation of the rationale and the analytic utility of the derived variables; and include a data file containing MHAS ids, the original restricted and unrestricted variable(s) used to create the derived variables, and the derived variables.)

(Aggregate statistical summaries of data and analyses, such as tables and regression formulae, are not "derived variables" in the sense used in the Agreement, and are not subject to the requirements of the Restricted Data Protection Plan and the Agreement.)

E. Human Subjects Review

The chairperson of your institution's Institutional Review Board/Human Subjects Review Committee must certify that the Board/Committee has reviewed and approved your Restricted Data Protection Plan (and the portions of your Research Plan that deal with respondent anonymity and data security, if any), as approved by (UTMB? SCOA), in accordance with the standards and procedures used for ***live human subjects***. Expedited review is acceptable. No exemptions, such as for "secondary data analysis", may be used in this aspect of the human subjects review. MHAS respondents are indeed live human subjects, and MHAS will be going back to them for more data in the future. The enclosed Certification of Human Subjects Review form should be used for the certification. Because the IRB/HSRC review at

your institution must include the Research Plan and Restricted Data Protection Plan that ***have been*** approved by MHAS, you should not submit your proposal for IRB/HSRC review until you have received the MHAS approvals.

F. Agreement for Use of Restricted Data from the Mexican Health and Aging Study

The Restricted Data Investigator applying for MHAS Restricted Data, ***all*** other persons who will have access to the restricted data, and a representative of the Receiving Institution, must sign the Agreement for Use of Restricted Data from the Health and Retirement Study. You may wish to submit the blank form of the Agreement in advance to your institutional signatory, to determine whether they are willing to sign it. You should address the following requirements in the Agreement:

1. Restricted Data can be used ***only*** for research and statistical purposes, and the Research Plan must specify ***all*** of the research projects that will make use of the restricted data. It is ***not*** permitted, for example, for a faculty member to obtain the data for her own research project and then "lend" it to a graduate student to do related dissertation research, even if the graduate student is a Research Staff signatory, unless this use is specifically stated in the Research Plan.

2. You must either destroy, or return to MHAS, ***all*** versions of the Restricted Data and data derived from it, regardless of the form in which it exists (tapes, hard disk, diskettes, and other physical media) within 24 months, or such other period as is specified in the approved Research Plan, or upon a demand from MHAS. Researchers who need additional time should make a formal written request for an extension at least 30 days prior to the expiration date, and HRS will give prompt consideration to such requests. However, neither the initial time period, nor any extension of it, may exceed the time period of the grant or contract under which the data are being analyzed. One implication of the time limits is that you should assure yourself that you have adequate time available to do the data management and analysis you have planned. In brief, you may ***not*** retain ***any*** copies of or data derived from the restricted data, after the conclusion of the contract period. MHAS staff will store the physical media containing such data for you, at your request for up to two years, so that it can be available to you if you obtain a second Agreement for further analysis.

3. All Co-Investigators and Research Staff must have a formal affiliation with the receiving institution, and must specify that affiliation and job title in the signature blocks of the Agreement and Supplemental Agreement of Research Staff. If new persons become affiliated with the research project, and are to

have access to the restricted data, an additional Supplemental Agreement of Research Staff must be signed by the new persons and the Restricted Data Investigator, and approved by MHAS staff, before the new person is given access to the restricted data.

4. MHAS will permit persons who were not original Principal Investigators or Co-Principal Investigators on current federal research grants or contracts, to be added to such a project as a Co-Principal Investigator and to become Co-Investigators on Agreements for the Use of Restricted Data from MHAS, provided the Principal Investigator of the federal grant or contract signs the Agreement as the Restricted Data Investigator, and MHAS is provided a copy of the federal agency's written approval of the addition of the new Co-Principal Investigator.

5. Your institution must agree to treat violations of this agreement, and allegations of such violations, as violations and allegations of violations of its policies on scientific integrity and misconduct, as to substance, procedures, and penalties.

6. The representative of your institution who signs the Agreement must have the authority to bind the institution contractually.