Form #7 (1) Confidentiality Agreement Restricting Disclosure and Use of Data From The Mexican Health and Aging Study

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

This agreement is entered into the _____ day of _____, 20___ between the Mexican Health and Aging Study (MHAS) and the _____ (Receiving Agency) wherein _____ (Investigator) is the researcher responsible for the projects using the MHAS restricted use files.

Whereas, MHAS has a data bank containing confidential information, and

Whereas, the Investigator has an IRB-approved study requiring access to one or more files of the said data bank, and has submitted that plan to the MHAS study (the Research Plan), and

Whereas, the Investigator and all other persons having access to MHAS restricted data under this agreement are bound by this agreement and

Whereas, the Investigator has submitted a plan to keep data confidential (the Data Protection Plan).

In consideration of the MHAS providing access to an MHAS Restricted Dataset to the Investigator, the co-Investigator(s), the Supplemental Users, and the Receiving Agency agree that:

1. "Restricted data" under this agreement includes both the original restricted data files provided by MHAS, and any variables or fields derived from them.
2. Restricted data will be used solely for scientific and public policy statistical research, and not for any administrative or law enforcement purpose.
3. Restricted data will be used to generate only statistical summary information that does not permit the identification of any individual person, family, household, either directly or inferentially.
4. Aggregate statistical summaries of the data and analyses (frequency tabulations, magnitude tabulations, means, variances, regression coefficients, and correlation coefficients) are not considered to be Restricted Data. Such information may be freely published by the Investigator and may be used for ongoing research programs approved under this agreement.

When producing tabulations for distribution, the following guidelines are to be employed:

- Magnitude Data: Ensure that no cells/strata with n < 3 are produced.

- Frequency Data: Apply a marginal threshold of n >= 5 and cell threshold of n >= 3 to all tabulations.

- Protecting against complementary disclosure: Additional cells may be suppressed, i.e., complementary disclosure, to make sure the primary suppressions cannot be derived by subtraction from published marginal totals.

5. Researchers are prohibited from publishing results that identify geographic areas below the level of categories of community size. Under certain circumstances restricted data users with access to state-level geographic information may wish to report state-level summary information. In such cases, analysis results must be submitted to the Mexican Health and Aging Study for review and approval prior to presentation or publication.

6. No attempt will be made to identify any individual person, family, household, or employer.

7. If an individual person, family, household, employer, or benefit provider is inadvertently identified, or a technique for doing so is discovered, the users of the restricted data who made the identification or discovery will promptly report the identification or discovery to MHAS.

8. No attempt will be made to link restricted data with any other dataset, except as specified in the approved Research Plan; specifically, there may be no linkages of:

    a. Any MHAS restricted dataset with any other MHAS restricted datasets; or

    b. Any MHAS restricted dataset containing geographic information at a level of aggregation more detailed than categories of community size, except with explicit written permission from the MHAS.

    c. Any MHAS restricted dataset with any other dataset without written approval from MHAS.

9. The MHAS restricted datasets are and remain the sole property of the MHAS and Investigators will not disclose them to any third party. The Receiving Agency agrees that in response to any request for Restricted Data, it will refuse to disclose the Restricted Data. Receiving Agency will immediately notify MHAS of any such requests.

10. Use of restricted data provided by MHAS to the Investigator will be confined to the research described in the Research Plan submitted to and approved by MHAS; the approved Research Plan is incorporated by reference into this Agreement.

11. Use of restricted data provided by MHAS to the Investigator will be in accordance with the Restricted Data Protection Plan submitted to and approved by MHAS; the approved Restricted Data Protection Plan is incorporated by reference into this Agreement.

12. Access to restricted data will be limited solely to the Investigator(s) who are signatories to this agreement and to research staff who are signatories of Supplemental Agreements with Research Staff approved by MHAS.

13. The Investigator(s) will ensure that all originals and copies of Restricted Data, on whatever media, will be either returned to MHAS, or destroyed, within 24 months of the date of the original restricted data is shipped to the Investigator (or such other date as is specified in the approved Research Plan), or within 5 days of a written request from MHAS; and the Investigator will certify to MHAS that this return/destruction has occurred. Extensions to this agreement may be granted by MHAS upon review of a written request from the Investigator(s), and providing all other approval conditions remain in effect.

14. The Investigator(s) will provide annually within 30 calendar days of the anniversary of this agreement the following:

    a. Project title, Investigator(s), and current contact information.

    b. Progress report, including a summary of current work, project titles, and brief justification for continued access to the data.

    c. Detail of changes or modifications in the research and/or data protection plans.

    d. Copy of and citations for any papers, publications or presentations using the restricted data.

    e. Proof of current IRB approval for projects using restricted data, which must be renewed annually. Note that only Full or Expedited IRB reviews are acceptable. Projects using restricted data do not qualify for IRB Exemption as secondary data analysis.

    f. Updated list of authorized users under this agreement. A new Supplemental User Agreement must be completed and signed for each new user. List should include access termination dates for those no longer requiring access to the restricted data.

    g. A detailed description of the location(s) of the restricted data users and the data itself – including street address, building number and office number(s).

15. All Research Staff signing Supplemental Agreements with Research Staff have a formal affiliation with the Receiving Agency and with the research project described in the Research Plan, and will have access to restricted data only under the supervision of the Investigator(s). The Supplemental Agreements with Research Staff are incorporated by reference into this Agreement.

16. The Receiving Agency has an Institutional Review Board/Human Subjects Review Committee; and proof of the certification has been provided to MHAS.

17. The Research Plan and Restricted Data Protection Plan approved by MHAS (and the portions of the Research Plan approved by MHAS that deal with respondent anonymity and data security, if any) have been reviewed and approved by the Receiving Agency's Institutional Review Board/Human Subjects Review Committee, using the standards and procedures for live human subjects, and a certification of that approval has been provided to MHAS. IRB approval must be at either the Full or Expedited level; access to these data does not qualify as exempt secondary analysis.

18. The Receiving Agency represents that it has in place policies and procedures on scientific integrity and misconduct. The Receiving Agency recognizes that certain violations of this agreement might constitute actions covered by such policies and procedures. If the MHAS notifies the Receiving Organization's office responsible for scientific misconduct that a violation of this agreement has occurred and alleges that the violation constitutes scientific misconduct, the Receiving Organization will handle the allegation according to its policies and procedures applicable to scientific integrity and misconduct.

19. The Representative of the Receiving Agency is a person authorized to enter into contractual agreements on behalf of the Receiving Agency.

20. If MHAS determines that this Agreement has been violated, MHAS may:

    a. Prohibit any of the signatories of this Agreement, and of any Supplemental Agreements with Research Staff, from obtaining access to any MHAS Restricted Data.

    b. Report the violation(s) to the Receiving Agency's office responsible for Code of Conduct on the safeguard of confidential information, and request that sanctions be imposed on the person(s) responsible for the violations.

    c. Report (directly or through the National Institute on Aging) the violation(s) to funding agencies with a recommendation that current funding be terminated, and future funding denied, to the Investigator(s), the Research Staff, and any other person implicated in the violation(s).

INVESTIGATOR

Signature/Date

Typed Name

Title

Institution

Building Address

Street Address

City, State, Zip

Phone

Fax

Email

CO-INVESTIGATOR

Signature/Date

Typed Name

Title

Institution

Building Address

Street Address

City, State, Zip

Phone

Fax

Email

RECEIVING AGENCY REPRESENTATIVE

_____
Signature/Date

_____
Typed Name

_____
Title

_____
Institution

_____
Building Address

_____
Street Address

_____
City, State, Zip

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Phone

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Fax

_____
Email

MEXICAN HEALTH AND AGING STUDY REPRESENTATIVE

_____
Signature Date

Rebeca Wong
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Mexican Health and Aging Study
Sealy Center on Aging
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