

NHATS-CMS Linked Files Restricted Data Use Agreement

This agreement, effective as of the last date of signature ("Effective Date") is entered into by and between the Johns Hopkins University on behalf of the National Health and Aging Trends Study (NHATS) and the _____ (Receiving Agency) wherein _____ (Investigator) is the researcher responsible for the projects using the NHATS restricted use files. For the sake of clarity, the Investigator is not a party to this Agreement.

This agreement is in effect until the investigator notifies NHATS that the project has ended or until 3 years from the effective date, whichever occurs first. A 3-year extension may be requested.

Whereas, the Receiving Agency and all other persons having access to NHATS Restricted data under this agreement are bound by the precepts of Receiving Agency's Code of Conduct for Employees and the Privacy Act of 1974 (5 USC 552a), which delineates the standards of conduct for individuals relating to the use of nonpublic information and the sanctions and criminal penalties for the misuse or disclosure of such data, and

Whereas,

1. The Investigator has a permanent, faculty-level appointment at the Receiving Agency, and the Co-Investigator(s), if any, have faculty-level appointments at the Receiving Agency.
2. All Research Staff signing Supplemental Agreement 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.
3. The Receiving Agency has an Institutional Review Board/Human Subjects Review Committee registered with the Department of Health and Human Services (DHHS); and proof of the certification has been provided to NHATS.
4. A Restricted Data Security Plan has been submitted by the Investigator and approved by NHATS; the approved Restricted Data Security Plan is incorporated by reference into this Agreement.
5. The Investigator's Research Plan and the Restricted Data Protection Plan approved by NHATS (and the portions of the Research Plan approved by NHATS that deal with respondent confidentiality and data security, if any) have been reviewed and approved by the Receiving Agency's DHHS-registered 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 NHATS. IRB approval must be at either the Full or Expedited level; access to these data does not qualify as exempt secondary analysis.

In consideration of NHATS providing access to an NHATS Restricted Dataset, the Receiving Agency agrees and the Investigator, Co-Investigator(s), and Research Staff acknowledge that:

1. "Restricted Data" under this agreement includes both the original Restricted Data files provided by NHATS, 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 or family (or facility if applicable) 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 $n < 11$ are produced.
 - Frequency Data: Apply a marginal threshold of $n \geq 11$ and cell threshold of $n \geq 11$ 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 will use approved data transfer procedures for uploading or downloading information from the secure data enclave. Information may only be removed from the enclave after being approved by NHATS staff. Transcription, screenshots, screensharing, and other forms of information transfer that circumvents the disclosure review process are not allowed.
 5. To cite NHATS as the data source in any publications or research based upon these data. See www.nhats.org for the latest funding acknowledgement statements.
 6. Researchers are prohibited from publishing, or distributing in unpublished form, results that identify geographic areas below the level of Census Division. Researchers agree to remove from presentation or publication any results identified by NHATS reviewers that identify geographic areas below the level of Census Division.
 7. No attempt will be made to identify any individual person, family, or facility. If an individual person, family, or facility is inadvertently identified, or a technique for doing so is discovered, the Investigator, Co-Investigator, or Research Staff person who made the identification or discovery will promptly report the identification or discovery to NHATS (email: nhatsdata@westat.com; subject line: Director of NHATS).
 8. No attempt will be made to link Restricted Data **with any other dataset**, except as specified in the Research Plan reviewed and approved by NHATS.
 9. Use of Restricted Data provided by NHATS will be confined to the research described in the IRB-approved Research Plan submitted to and approved by NHATS; the approved Research Plan is incorporated by reference into this agreement.
 10. Use of Restricted Data provided by NHATS will be in accordance with the Restricted Data Security Plan submitted to and approved by NHATS. Restricted Data provided by NHATS may not be accessed by person located in "countries of concern" as identified pursuant to 28 CFR Part 202.
 11. Access to Restricted Data provided by NHATS will be limited **solely** to the Investigator(s) who are signatories to this agreement, and to Research Staff who are signatories of the Supplemental Agreement with Research Staff.
 12. The NHATS Restricted Datasets are and remain the sole property of NHATS and Johns Hopkins University. The Investigator will not disclose them to any third party. The Receiving Agency agrees that in response to any request for Restricted Data under the federal Freedom of Information Act, 5 U.S.C. 552, it will refuse to disclose the Restricted Data on grounds that it is not a Receiving Agency of record subject to disclosure under that Act or is alternatively exempt from disclosure under that Act. Receiving Agency will immediately notify NHATS and Johns Hopkins University of any such requests.
 13. The Investigator(s) will provide:

- a. Project title, Investigator(s), and current contact information
 - b. Detail of changes or modifications in the research and/or Data Security Plans
 - c. Citations for any publications (and PMCID(s)) from these data to NHATS (nhatsdata@westat.com; subject line: NHATS citations) upon request
 - d. Proof of current IRB approval for projects using restricted data. Note that only Full or Expedited IRB reviews are acceptable. Projects using restricted data do not qualify for IRB Exemption as secondary data analysis.
 - e. An updated list of authorized users under this agreement. A new Supplemental Agreement with Research Staff 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.
 - f. A description of the location(s) of the restricted data users– including street address, building number and office number(s).
14. The Receiving Agency represents that it has policies and procedures on scientific integrity and misconduct in place. The Receiving Agency recognizes that certain violations of this agreement might constitute actions covered by such policies and procedures. If NHATS notifies the Receiving Agency's office responsible for scientific misconduct that a violation of this agreement has occurred and alleges that the violation constitutes scientific misconduct, the Receiving Agency will handle the allegation according to its policies and procedures applicable to scientific integrity and misconduct.
15. The Representative of the Receiving Agency is a person authorized to enter into contractual agreements on behalf of the Receiving Agency.
16. If Johns Hopkins University on behalf of NHATS determines that this Agreement has been violated, Johns Hopkins University on behalf of NHATS may:
- a. Prohibit any of the signatories of this Agreement, and of any Supplemental Agreements with Research Staff, from obtaining access to any NHATS 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).
 - d. Utilize such other remedies as may be available to it under law.
17. The Receiving Agency assumes all liability for damages which may arise from its use, storage, disclosure, or disposal of the Data. NHATS will not be liable to the Receiving Agency for any loss, claim, or demand made by the Receiving Agency, or made against the Receiving Agency by any other party, due to or arising from the use of the Data by the Receiving Agency, except to the extent permitted by law when caused by the gross negligence or willful misconduct of the Provider.
18. Incorporation by reference
- a. NHAT-CMS Linked Files Data Security Plan
 - b. NHATS Acceptable Use Policy

Investigator

Signature/Date

Typed Name

Title

Institution

Building Address

Street Address

City, State, Zip

Phone

Fax

Email

NHATS User Name**Co-Investigator**

Signature/Date

Typed Name

Title

Institution

Building Address

Street Address

City, State, Zip

Phone

Fax

Email

NHATS User Name

NOTES: NHATS User names may be obtained by registering at <https://www.nhats.org/user/register>. For additional Co-Investigators, reproduce this page. The requesting Investigator should sign with each Co-Investigator.

Receiving Agency Representative

NHATS Representative

Signature/Date

Signature/Date

Typed Name

Jennifer Schrack, PhD, Principal
Investigator
National Health and Aging Trends Study
Johns Hopkins University School of
Public Health
2024 E. Monument Street, Suite 2-700
Baltimore, MD 21205
Phone: 410-502-9328
Email: nhats-cms-data@umich.edu

Title

Institution

Building Address

Street Address

City, State, Zip

Phone

JHU Representative

Fax

Email

Signature/Date

FOR INTERNAL USE ONLY

EFFECTIVE DATE:

AGREEMENT END DATE: