

**Obtaining Restricted Genetics Data from the National
Health and Aging Trends Study Restricted Data
Repository**

October 2023 (Version 2.0)

TABLE OF CONTENTS

Contents

I. Introduction	2
II. The MiCDA Virtual Data Enclave.....	2
III. Requirements for NHATS Restricted Data Repository Applications.....	2
IV. Acceptable Uses of the Restricted Data.....	5
V. Modifications to the DUA	5
VI. Sanctions for Violation of the Agreement	6
VII. Forms	7
VIII. Memorandum to IRB/Human Subjects Review Committees	19

I. Introduction

This document describes procedures for researchers to access Restricted Genetics Data files from the National Health and Aging Trends Study (NHATS) via the NHATS Restricted Data Repository. NHATS Restricted Data Files require additional protections to minimize risks of identifying participants. Access to these files is available to qualified researchers through a partnership with the Michigan Center on the Demography of Aging (MiCDA) at the University of Michigan's Institute for Social Research.

NHATS Restricted Genetics Data files cannot be linked to other restricted data files, including Centers for Medicare and Medicaid Services (CMS) files and restricted geographic data. However, NHATS Restricted Genetics Data may be linked to public and sensitive NHATS and NSOC data files accessed through the NHATS Restricted Data Repository.

Each application for access to the NHATS Restricted Genetics Data from the Restricted Data Repository will be reviewed by NHATS for conformance with the requirements outlined in these materials. Each application must state specific research aims and work scope to be performed. The NHATS Restricted Data Repository does not accept umbrella applications for networks, centers, or other coordinating efforts. Questions regarding the application process may be sent to: NHATS-restricted-data@umich.edu. Please use the subject heading: Restricted Genetics Data Application query (Investigator Name).

II. The MiCDA Virtual Data Enclave

The MiCDA Virtual Data Enclave (VDE) provides remote access to the NHATS Restricted Data Repository through a virtual desktop infrastructure. Data remain on MiCDA enclave servers and are accessed and analyzed by approved users virtually via an encrypted connection.

High Performance Computing (HPC) Server. The MiCDA enclave also provides access to a High Performance Computing (HPC) Unix server. Users who request access to the NHATS Restricted Genetics Data will be given access to the HPC server. The HPC server runs Linux. PLINK is available within the HPC for genomics analysis.

Security measures. Login to the enclave requires two-factor authentication. Data files cannot enter or be removed from the NHATS repository by the researcher. Output and programs will be reviewed for disclosure risk by the repository director or their designee prior to removal. Users agree to access data only from locations specified in the MiCDA Data Security plan form. Users agree not to transcribe results as specified in MiCDA's Secure Data Enclave Acceptable Use Policy and not to attempt to identify subjects as specified in the ISR Pledge of Confidentiality.

Software. Each workstation is equipped with a suite of statistical software (including SAS, Stata, SPSS, MatLab, ArcGIS, R, and Stat/Transfer) and Microsoft Office. PLINK also is available through the enclave's HPC server.

III. Requirements for NHATS Restricted Data Repository Applications

Investigator (Applicant) Requirements

To be eligible to apply for NHATS Restricted Genetics Data, an Investigator must:

- have a PhD or other terminal degree (e.g. MD-MPH) and hold a full-time faculty-level (or equivalent research) appointment at a U.S.-based university or research institution,
- be affiliated with an Institution that holds a Federal Wide Assurance (FWA) from the Office for Human Research Protection of the Department of Health and Human Services (see <https://www.hhs.gov/ohrp/register-irbs-and-obtain-fwas/fwas/fwa-protection-of-human-subject/index.html>), and
- be a current recipient, as Principal Investigator or Co-Principal Investigator, of research funds from a federal agency. Other sources of support (e.g. foundation, academic institution) will be considered on a case-by-case basis. These funds may be (but are not required to be) a source of support for the proposed work scope.

Investigators collaborating at different institutions must have one Investigator at each institution who meets the qualifications to apply if both institutions are requesting access to the data through the MiCDA enclave.

Pre- or Post-doctoral students interested in applying for access to NHATS Restricted Genetics Data must have their mentor/advisor apply as the applicant and may be listed as Research Staff on the application.

Roles

Investigator - This individual is considered the principal investigator of the project and must meet all applicant requirements

Co-Investigator – This individual collaborates with the requesting investigator and must hold a faculty-level (or equivalent research) appointment at the Investigator’s institution

Research Staff – This individual must have a formal affiliation with the Investigator’s institution and be under the supervision of the Investigator

Receiving Agency Representative – This individual has authority to sign the NHATS Data Use Agreement on behalf of the Investigator’s Institution. The representative must have the authority to bind the institution contractually.

User – This individual is requesting an account in the MiCDA Virtual Data Enclave to access the NHATS Restricted Data Repository and may be the Investigator, Co-investigator or Research Staff listed on the application.

All Investigators, Co-investigators and Research Staff who will work with the NHATS Restricted Data must be on the NHATS DUA, must be registered NHATS users (see <https://www.nhats.org/user/register>), and must have a formal affiliation with the Requesting Investigator’s institution.

Collaborating Investigators at another Institution - A collaborating investigator at another institution who wishes to access the NHATS Restricted Data Repository must submit a separate application (see Application Process). The individual will be designated the Investigator for their institution and must meet all investigator requirements. They may include additional Co-Investigators and Research Staff from their institution on their application. All Investigators, Co-Investigators and Research Staff at collaborating institutions who will work with the NHATS

Restricted Genetic Data must be on the collaborating Investigator's DUA, must be registered NHATS users (see <https://www.nhats.org/user/register>), and must have a formal affiliation with the collaborating Investigator's institution.

Key elements of the data protection plan

- Currently supported Operating System
- Anti-virus software (even for Macs)
- Affirmation that the computer monitor position prevents eavesdropping (private office preferred)
- A privacy screen if accessing the Enclave from a shared office, a cubicle, or other shared workspace
- The address from which connections to the Enclave will be made
- Telephone number at which DUO (dual factor authentication system) can call the researcher
- If the computer is owned by the researcher's institution, the institution's IT Group must review and sign the data protection plan

Application Process

The application process requires the following steps:

Step 1: Applicants must first submit a Data Access Request (DAR) to the National Institute on Aging Genetics of Alzheimer's Disease Data Storage Site (NIAGADS). More information on how to apply for access can be found on the NIAGADS website:

<https://dss.niagads.org/documentation/data-application-and-submission/application-instructions/>.

Note: If you plan to use the NHATS Restricted Genetics files with phenotypic information from the NHATS files, you must obtain approval from NIAGADS, but there is no need to download the NHATS Genetics files from NIAGADS. Access to the NHATS Genetics files will be provided to you in the MiCDA Virtual Data Enclave once you have NIAGADS and NHATS approvals in place.

Step 2: Once NIAGADS has approved the DAR, complete and sign the required NHATS forms and documents (see Section VII), including your NIAGADS approval. Be sure all individuals listed on the NHATS DUA are registered NHATS users (see <https://www.nhats.org/user/register>).

Step 3: Submit the application materials electronically to NHATS-restricted-data@umich.edu using the subject heading: Restricted Genetic Data Application (Requesting Investigator Name).

Step 4: NHATS will review the documents submitted. Any questions, or needed revisions, will be communicated to the Requesting Investigator.

Step 5: Once NHATS approves the application, the data use agreement will be countersigned by NHATS and Johns Hopkins University. MiCDA accounts will then be set up and users will be given access to files in the DUA. A fully executed DUA will be sent to the applicant along with instructions on how to log into the MiCDA Virtual Data Enclave.

Investigators collaborating at different institutions must each complete a separate application with a common title, file request form, and research plan. A separate DUA and IRB approval (or proof that another institution serves as the IRB of record) is required for each institution. Only individuals at the applicant's own institution should be listed as Co-Investigators, Research Staff or users on a given application. To facilitate sharing within the enclave, both investigators should complete the form for "Investigators collaborating at different institutions".

IV. Acceptable Uses of the Restricted Data

Restricted data. As specified in the NHATS Restricted NHATS DUA, restricted data – both original files and variables or fields derived from them - can be used *only* for scientific and public policy statistical research purposes that are specified in the Research Plan and only for statistical (summary) reporting that does not permit identification of an individual, family or facility either directly or indirectly. Each application must state specific research aims and work scope to be performed. The NHATS Restricted Data Repository does not accept umbrella applications for networks, centers, or other coordinating efforts.

Repository use. Only approved individuals may be given an account in the Michigan Center for the Demography of Aging (MiCDA) Virtual Data Enclave (VDE), which houses the NHATS Restricted Data Repository. As specified in **MiCDA's Acceptable Use Policy**, (1) Users may only access the enclave from approved locations and equipment specified in the MiCDA Data Security plan form; (2) Users must position the screen to prevent unauthorized user from viewing the NHATS restricted data and lock the computer when they step away; (3) Users may not print, take screenshots, pictures, screen-share, transcribe or otherwise duplicate data or results of data analysis; and (4) Users may not share login information (account name, password or token values) or permit viewing of their VDE account including output. Finally, as specified in the **ISR Pledge of Confidentiality**, users may not attempt to identify NHATS subjects.

Disclosure review. Prior to removal, all output and programs will be reviewed for disclosure risk by the NHATS restricted data repository director or their designee. Tabulations with cells/strata < 11, including minimum and maximum values for individual cases, may not be removed from the NHATS restricted data repository. Additional cells may be suppressed if they may lead to uncovering cells/strata size <11 through subtraction. Tabulations and/or visual representations or coefficients based on geographic areas below the Census Division may not be removed from the enclave.

V. Modifications to the DUA

All changes to project team members or institutional affiliations require an updated DUA and MiCDA Enclave application. New study staff members should complete the Restricted Data Supplemental Agreement with New Research Staff form. Substantial changes to the research aims and any new requested linkages also require an updated research plan and/or file request form.

Before access to the data is to be granted to an additional collaborator, or to an existing collaborator at a new institution, a modified DUA with the new collaborator/institution must be submitted and approved, a modified research plan must be submitted (if applicable), and all MiCDA Virtual Data Enclave paperwork must be submitted and approved. It is *not* permitted for a faculty member to obtain access to the data for his/her own research project and then "share" their account information with a graduate student or a colleague. It is also *not* permitted for a faculty member who changes institutions to continue accessing the NHATS Restricted Data Repository. Once all paperwork is approved the individual will be given access to the restricted data.

DUAs expire once the investigator notifies NHATS that the project has ended or 3 years from the date entered on page 1 of the DUA, whichever occurs first. Once the DUA expires, all MiCDA accounts will be

closed, unless a 3-year extension has been requested and approved.

Complete the Restricted Data Repository Modification Cover Sheet: Genetics Files when requesting a modification. Details on required documentation when requesting a modification are provided on the cover sheet.

VI. Sanctions for Violation of the Agreement

The NHATS *Restricted Genetics Data Use Agreement* specifies four possible sanctions against researchers who violate the terms of the agreement:

- 1) Denial of future access to NHATS Restricted Data;
- 2) Report of the violation to the Receiving Institution's office responsible for scientific integrity and misconduct, with a request that sanctions be imposed under the institution's scientific integrity and misconduct policy;
- 3) Report of the violation to research funding agencies, with a recommendation that all current research funds be terminated, and all future funds be denied, to the Investigator(s) and to all other persons implicated in the violation; and
- 4) Such other remedies as may be available to NHATS under law.

If NHATS staff determine that there may have been a violation of the Agreement, NHATS will communicate the allegations in writing to the Investigator and offer the investigator an opportunity to respond in writing. NHATS may also, at the time the allegations are communicated, remove access to NHATS Restricted Data by Investigator(s), Co-Investigators and Research Staff.

If NHATS determines that the allegations of violations were incorrect, NHATS will restore access under the conditions of the original Agreement. If NHATS determines that the allegations of violations of the Agreement were in any part correct, it will determine the appropriate sanction. If the sanction includes notification of funding agencies with a recommendation to terminate current and deny future research funding, NHATS will communicate its notification of violations and recommendations to the NHATS Program Officer at the National Institute on Aging, who will in turn convey it to appropriate officials at the NIH Office of Scientific Integrity, and other federal agencies.

National Health and Aging Trends Study (NHATS): Restricted Data Repository Forms: Genetics Files

VII. Forms

- Investigator Form
- Project Forms
 - Project title and abstract
 - Restricted Data Repository Research plan
 - CV or Biosketch for Investigator and Co-Investigator(s)
 - Copy of NIAGADS Approval
 - Copy of award letter documenting research funds and the source(s) of these funds
 - Copy of IRB approval
- Restricted Data Repository File Request Form
- Signed copy of the NHATS Restricted Data Repository Restricted Data Use Agreement
- Signed NHATS Supplemental Restricted Data Use Agreement with Research Staff (if applicable)
- Investigators Collaborating Across Institutions (if applicable)
- List of users requesting MiCDA VDE Access
- For each user
 - Signed MiCDA Sensitive Data Enclave Acceptable Use Policy (for each user)
 - Signed Institute for Social Research Pledge to Safeguard Respondent Privacy (for each user)
 - Signed MiCDA Virtual Desktop Infrastructure Data Security Plan

National Health and Aging Trends Study (NHATS): Restricted Data Investigator Form: Genetics Files

Investigator:

NAME

SIGNATURE

NHATS REGISTRATION EMAIL ADDRESS

DATE OF SIGNATURE

PHONE CONTACT

Institution where Investigator holds appointment:

NAME

STREET ADDRESS

CITY, STATE , ZIP

LINK to WEBSITE or URL of INSTITUTION

National Health and Aging Trends Study (NHATS): Restricted Data Repository Research Plan: Genetics Files

Project Title: _____

Abstract: 250 word limit

Applicants must provide a short (2-3 page) research plan that includes

1. A statement of the aims of the research;
2. A description of the files and variables from the NHATS restricted genetics data that will be used in analyses;
3. A description and justification for NHATS sensitive data files, if any, that you plan to merge with the NHATS restricted genetics data;
4. A statement as to why the unrestricted versions of those variables, if any, are not adequate for your research purposes. For example, polygenic scores are available as NHATS Sensitive Files.

Each applicant must also submit:

1. For each investigator and co-investigator at your institution, include a curriculum vita or biosketch.
2. A copy of your award letter documenting evidence of funding.
3. A copy of your project's IRB approval. At the end of this packet is a letter from Jennifer Schrack, PI of NHATS, should your IRB require explanation as to why we are requesting review

National Health and Aging Trends Study (NHATS): Restricted Data Repository File Request Form: Genetics Files

Check all folders that are being requested:

Currently available:

- ✓ NHATS Genetic Files
- ✓ NHATS Genetic Crosswalk File

Other available files (Check if you would like access):

- NSOC Sensitive Files
- NHATS Sensitive Files
- NHATS Sensitive COVID-19 Files
- NHATS Sensitive Polygenic Scores
- ✓ NHATS Public Use Files

National Health and Aging Trends Study (NHATS): Restricted Data Repository Data Use Agreement: Genetics Files

This agreement is entered into the _____ day of _____, 20__ 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 date entered on page 1, 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 Protection Plan has been submitted by the Investigator and approved by NHATS; the approved Restricted Data Protection 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.
6. The Investigator is a current recipient, as a Principal Investigator, of research funds from an agency of the United States government, or another NHATS-approved funding source, and a copy of the award letter has been provided to NHATS.

In consideration of NHATS providing access to an NHATS Restricted Dataset, the Receiving Agency agrees and the Investigator, Co-Investigator(s), and the Supplemental Users 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.

National Health and Aging Trends Study (NHATS): Restricted Data Repository Data Use Agreement: Genetics Files

- 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.
- To cite NHATS as the data source in any publications or research based upon these data. The following citation should be included in any research reports, papers, or publications based on these data:
In text: "National Health and Aging Trends Study (NHATS) is sponsored by the National Institute on Aging (grant number NIA U01AG032947) and was conducted by the Johns Hopkins University."
In references: "National Health and Aging Trends Study. Produced and distributed by www.nhats.org with funding from the National Institute on Aging (grant number NIA U01AG032947)."
 - Researchers are prohibited from publishing, or distributing in unpublished form, results that identify geographic areas below the level of Census Division. 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 NHATS for review and approval. Researchers agree to remove from presentation or publication any results identified by NHATS reviewers that identify geographic areas below the level of Census division.
 - 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).
 - 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.
 - 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.
 - Use of Restricted Data provided by NHATS will be in accordance with the Restricted Data Protection Plan submitted to and approved by NHATS.
 - 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.
 - 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

National Health and Aging Trends Study (NHATS): Restricted Data Repository Data Use Agreement: Genetics Files

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 protection plans
 - c. To provide 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. 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. NHATS Restricted Data Repository MiCDA-Virtual Data Enclave Acceptable Use Policy
 - b. Institute for Social Research University of Michigan Pledge to Safeguard Respondent Confidentiality
 - c. MiCDA Enclave Virtual Desktop Infrastructure Data Security Plan

National Health and Aging Trends Study (NHATS): Restricted Data Repository Data Use Agreement: Genetics Files

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

NOTE: 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.

National Health and Aging Trends Study (NHATS): Restricted Data Repository Data Use Agreement: Genetics Files

RECEIVING AGENCY REPRESENTATIVE

Signature/Date

Typed Name

Title

Institution

Building Address

Street Address

Street Address

City, State, Zip

Phone

Fax

Email

NHATS REPRESENTATIVE

Signature

Date

Jennifer Schrack, Principal Investigator
National Health and Aging Trends Study
Johns Hopkins University School of Public Health
615 N. Wolfe Street E7144
Baltimore, MD 21205
Phone: 410-502-9328
Email: jschrac1@jhu.edu

JOHNS HOPKINS UNIVERSITY REPRESENTATIVE

Signature

Date

National Health and Aging Trends Study (NHATS): Restricted Data Repository Supplemental Agreement with Research Staff: Genetics Files

The undersigned Research Staff, in consideration of their use of Restricted Data from the National Health and Aging Trends Study, acknowledge:

- A. That they have read the associated National Health and Aging Trends Study (NHATS) Restricted Data Use Agreement.
- B. That they are “Research Staff” within the meaning of the NHATS Restricted Data Use Agreement.
- C. To comply fully with the terms of the Agreement.

The Investigator named in the NHATS Restricted Data Agreement agrees that the persons designated herein are Research Staff within the meaning of the associated NHATS Restricted Data Use Agreement.

The Investigator agrees to ensure that each Research Staff person signs this Supplemental Agreement.

Research Staff

NAME TYPED OR PRINTED	SIGNATURE	DATE
-----------------------	-----------	------

JOB TITLE & INSTITUTION	NHATS User Name
-------------------------	-----------------

NAME TYPED OR PRINTED	SIGNATURE	DATE
-----------------------	-----------	------

JOB TITLE & INSTITUTION	NHATS User Name
-------------------------	-----------------

NAME TYPED OR PRINTED	SIGNATURE	DATE
-----------------------	-----------	------

JOB TITLE & INSTITUTION	NHATS User Name
-------------------------	-----------------

Restricted Data Investigator

NAME TYPED OR PRINTED	SIGNATURE	DATE
-----------------------	-----------	------

National Health and Aging Trends Study (NHATS): Restricted Data Repository Data Use Agreement Extension: Genetics Files

We request a 3-year extension of the agreement entered into the _____ day of _____, 20__ 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.

Investigator

Co-Investigator

Signature/Date

Signature/Date

Typed Name

Typed Name

Title

Title

Institution

Institution

Building Address

Building Address

Street Address

Street Address

City, State, Zip

City, State, Zip

Phone

Phone

Fax

Fax

Email

Email

NHATS User Name

NHATS User Name

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

National Health and Aging Trends Study (NHATS): Restricted Data Repository Data Use Agreement Extension: Genetics Files

RECEIVING AGENCY REPRESENTATIVE

Signature/Date

Typed Name

Title

Institution

Building Address

Street Address

Street Address

City, State, Zip

Phone

Fax

Email

NHATS REPRESENTATIVE

Signature

Date

Jennifer Schrack, PhD, Principal Investigator
National Health and Aging Trends Study
Johns Hopkins University School of Public Health
615 N. Wolfe Street E7144
Baltimore, MD 21205

Phone: 410-502-9328

Email: jschrac1@jhu.edu

JOHNS HOPKINS UNIVERSITY REPRESENTATIVE

Signature

Date

National Health and Aging Trends Study (NHATS): Restricted Data Supplemental Agreement with New Research Staff: Genetics Files

The undersigned Research Staff, in consideration of their use of Restricted Data from the National Health and Aging Trends Study, acknowledge:

- A. That they have read the associated National Health and Aging Trends Study (NHATS) Restricted Data Use Agreement.
- B. That they are “Research Staff” within the meaning of the NHATS Restricted Data Use Agreement.
- C. To comply fully with the terms of the Agreement.

The Investigator named in the NHATS Restricted Data Agreement agrees that the persons designated herein are Research Staff within the meaning of the associated NHATS Restricted Data Use Agreement.

The Investigator agrees to ensure that each Research Staff person signs this Supplemental Agreement.

Research Staff

NAME TYPED OR PRINTED	SIGNATURE	DATE
-----------------------	-----------	------

JOB TITLE & INSTITUTION	NHATS User Name
-------------------------	-----------------

NAME TYPED OR PRINTED	SIGNATURE	DATE
-----------------------	-----------	------

JOB TITLE & INSTITUTION	NHATS User Name
-------------------------	-----------------

Restricted Data Investigator

NAME TYPED OR PRINTED	SIGNATURE	DATE
-----------------------	-----------	------

NHATS Representative

Jennifer Schrack NAME TYPED OR PRINTED	SIGNATURE	DATE
---	-----------	------

National Health and Aging Trends Study (NHATS): Restricted Data Repository Collaborating Investigators at Other Institutions: Genetics Files

If applicable, list Collaborating Investigators at other institutions. A separate application must be submitted on behalf of the Investigator at each institution.

Collaborating Investigator #1

Name

Title

Institution

Email

Collaborating Investigator #3

Name

Title

Institution

Email

Collaborating Investigator #2

Name

Title

Institution

Email

Collaborating Investigator #4

Name

Title

Institution

Email

Note: Do not list Co-Investigators or Research Staff at the collaborating institution here. A separate application must be submitted by the Collaborating Investigator at each institution and Co-Investigators/Research Staff at those institutions should be listed on the collaborating Investigator's application.

National Health and Aging Trends Study (NHATS): List of Users Requesting MiCDA Enclave Access: Genetics Files

List all users who will require access to the MiCDA Virtual Data Enclave to work on the project. Copy this sheet to add more users. All users must be listed on the NHATS Data Use Agreement either as Investigator, Co-Investigator or Research Staff.

User #1 (Begin with Investigator)

_____	_____
First Name	Last Name

Title	

Department	

Institution	

User #2

_____	_____
First Name	Last Name

Title	

Department	

Institution	

User #3

_____	_____
First Name	Last Name

Title	

Department	

Institution	

National Health and Aging Trends Study (NHATS): Restricted Data Repository Modification Cover Sheet: Genetics Files

Investigator Name: _____

Project Title: _____

Please indicate the type of amendment(s) you are requesting and complete the required forms listed below. Documents should be emailed to nhats-restricted-data@umich.edu.

- Adding a new Research Staff person
 - Supplemental Agreement with New Research Staff
 - MiCDA Secure Data Enclave Acceptable Use Policy (AUP)
 - Institute for Social Research Pledge to Safeguard Respondent Confidentiality
 - MiCDA Enclave Virtual Desktop Infrastructure (VDI) Data Security Plan
 - List of Users Requesting MiCDA Enclave Access

- Adding a new Co-Investigator
 - Investigator form in the Data Use Agreement
 - MiCDA Secure Data Enclave Acceptable Use Policy (AUP)
 - Institute for Social Research Pledge to Safeguard Respondent Confidentiality
 - MiCDA Enclave Virtual Desktop Infrastructure (VDI) Data Security Plan
 - List of Users Requesting MiCDA Enclave Access

- Removing Research Staff or Co-Investigators
 - Email nhats-restricted-data@umich.edu to remove Research Staff or Co-Investigators from a project.

- Changing the Investigator
 - Letter to NHATS letter explaining the change in Investigator
 - Investigator form in the Data Use Agreement
 - Data Use Agreement (DUA) listing the new Investigator

- Updating a Data Security Plan
 - Complete a new MiCDA Enclave Virtual Desktop Infrastructure (VDI) Data Security Plan

- Modifying research aims or work scope (Note: Modifying aims or work scope may require a new application. Contact nhats-restricted-data@umich.edu for guidance.)
 - Update the Research Plan (tracked and clean versions)
 - Submit IRB approval for new work scope

- Extending a project
 - Complete the Restricted Data Repository Data Use Agreement Extension form

- Closing a project
 - Complete the Restricted Data Repository Close Out form

**Forms to be completed by each user requesting
access to the NHATS Restricted Data Repository**

NHATS Restricted Data Repository
MiCDA-Secure Data Enclave
Acceptable Use Policy (AUP)

- 1.** I understand that I have the primary responsibility to safeguard the information contained in the MiCDA Virtual Data Enclave (VDE) from unauthorized use, disclosure, inadvertent modification, destruction, or denial of service.
- 2.** Access to the VDE is for authorized purposes only. Access to these resources is a revocable privilege and is subject to content monitoring and security testing.
- 3.** I will only use equipment approved by the sponsoring project to access the SDE.
- 4.** I will only access the VDE from the location approved by the sponsoring project.
- 5.** I will position my computer screen to prevent unauthorized user from viewing VDE data. I will lock my computer if I step away from it.
- 6.** I will use approved data transfer procedures for uploading or downloading information from any system or storage media. I will not introduce unauthorized software.
- 7.** I will not print or reproduce VDE data.
- 8.** If I observe anything on the SDE (or system that I use to access it) which indicates inadequate security, then I will immediately notify my Enclave representative.
- 9.** The following activities are specifically prohibited by any user on the MiCDA VDE:
 - 9.1.** Use of information systems for unlawful or unauthorized activities such as file sharing of media, data, or other content that is protected by Federal or state law, including copyright or other intellectual property statutes.
 - 9.2.** Attempts to strain, test, circumvent, or bypass network or SDE security mechanisms, or to perform network or keystroke monitoring.
 - 9.3.** Disabling or removing security or protective software and other mechanisms and their associated logs from the SDE.
 - 9.4.** Modification of the SDE, software installed therein, use of it in any manner other than its intended purpose, or adding user-configurable or unauthorized software such as, but not limited to, commercial instant messaging, commercial Internet chat, collaborative environments, or peer-to-peer client applications.
 - 9.5.** Installation of software, changing configuration of the SDE, or connecting the SDE to an unauthorized computer.
 - 9.6.** Sharing personal accounts and authenticators (passwords and/or token values) or

permitting the use of remote access capabilities to any unauthorized individual.

9.7. Taking screenshots, pictures, screen-sharing, transcribing or otherwise duplicating images of any Enclave systems or their interfaces. This includes data, whether original or derived, and the results of data analysis.

10. I acknowledge and consent to the following conditions when I access the MICDA SDE:

10.1. The Survey Research Center (SRC) routinely intercepts and monitors communications on the Enclave for purposes including, but not limited to, penetration testing, communications security monitoring, network operations and defense, and personnel misconduct investigations.

10.2. SRC may inspect, and if necessary remove, data stored on the SDE.

10.3. Data stored on the Enclave are not private, are subject to routine monitoring and inspection, and may be disclosed to the sponsoring project, my employer, and any regulating bodies.

10.4. The SDE includes security measures (e.g., authentication and access controls) to protect the sensitive data stored within--not for my personal benefit or privacy.

11. I will immediately report suspicious system activity or concerns to my SDE representative.

By signing this user agreement, I am acknowledging that I accept and will abide by all the terms and conditions described above.

Signature

Date

Printed Name

Institute for Social Research University of Michigan

PLEDGE TO SAFEGUARD RESPONDENT CONFIDENTIALITY

I have read the Institute for Social Research Policy on Safeguarding Respondent Confidentiality, and pledge that I will strictly comply with that Policy. Specifically:

I will not reveal the name, address, telephone number, or other identifying information of any respondent (or family member of a respondent or other informant) to any person other than an employee directly connected to the study in which the respondent is participating.

I will not reveal the contents or substance of the responses of any identifiable respondent or informant to any person other than an employee directly connected to the study in which the respondent is participating, except as authorized by the project director or authorized designate.

I will not contact any respondent (or family member, employer, other person connected to a respondent or informant) except as authorized by the project director or authorized designate.

I will not release a dataset (including for unrestricted public use or for other unrestricted uses) except in accordance with authorization, policies and/or procedures established by ISR and the Center with which I am affiliated.

I will take all necessary precautions to avoid unintended disclosure of confidential information, including securing of paper and electronic records, computers, user IDs and passwords.

I agree that compliance with this Pledge and the underlying Policy is: 1) a condition of my employment (if I am an employee of ISR), and/or 2) a condition of continuing collaboration and association with ISR (if I am an affiliate of ISR). I understand that violation of this Policy and Pledge may result in disciplinary action, up to and including termination of employment or severance of any relationship with ISR and the applicable research project.

If I supervise affiliates who have access to ISR respondent data (other than unrestricted public release datasets), I will ensure that those affiliates adhere to the same standards of protection of ISR respondent privacy, anonymity, and confidentiality, as required by this Pledge and the associated Policy.

Signature:

Typed or printed name: _____ Date: _____

Affiliation (if non-ISR employee): _____

**MiCDA Enclave Virtual Desktop Infrastructure (VDI) Data Security Plan
Complete ONE Form for EACH User and EACH User Location**

Work Location: From where will you log in? CHOOSE ONE: Home Office*

Address (*Office address should include office #, building name, street address, city, state, and zip)

Workstation Specifications:

Make/model: _____

Desktop Laptop

Operating System (Please note version #):

Windows Version: _____

Mac Version: _____

Workstation Login Access: Who can log into your workstation?

Yourself: Other(specify): _____

What information is required at login on your computer? Do you have a private or shared office?

User name: Yes No Password: Yes No Private Shared

Workstation Monitor Position: Describe how your workstation is positioned to prevent unauthorized viewing (check windows and doors):

Workstation Antivirus: Describe **brand and version** of antivirus software installed on workstation:

Windows Defender Symantec McAfee

Sophos Norton Version: _____

Other(specify brand/version): _____

Data Resource(s) Requested (select all that apply):

NHATS Genetics

Other(specify): _____

Smartphone Number: Download of DUO Mobile application is required for Two-Factor Authentication

() - -

Use of a smartphone is the simplest, fastest, and most cost-effective method for two-factor authentication. If this is not possible, a standard cellular phone or landline may be used, but expect delays and potential future costs associated with these methods.

Investigator Name		
User Name	NHATS User Name	User Institution
User Signature	Date	User Email
Provide signature of an IT Representative familiar with the workstation described. *Required unless it is a personally owned machine used in a home office		
IT Department Contact Name	IT Contact Title	IT Contact Telephone
IT Contact Signature	Date	IT Contact Email

NHATS Data Protection Plan Requirements

Work Location

This may be a home office, or Institutional workspace. It must be a designated, consistent location. Private offices are preferred. If a user is working in a shared office, or a cubicle, or other shared workspace, a privacy screen is required. If the location is an Institutional workspace, an office number must be designated.

Workstation Specifications

The MiCDA SDE can be accessed from both Windows and Mac computers. User must designate the make/model (i.e. HP Z420), form factor (i.e. desktop, laptop), and operating system with version number. Any computer may be used, but the operating system must be one that is currently supported by the software maker.

Workstation Login Access

Users must designate who can login, and how that is controlled. Login access is typically controlled via username and password. Whether this a local only account or centrally provisioned and controlled account should be noted. If more individuals than the NHATS user can login, access to user files must be restricted by user account. This must be noted on the Data Protection Plan.

Workstation Monitor Position

Monitor(s) must be positioned to prevent viewing by unauthorized individuals. Users should describe how their monitor(s) is/are positioned in their workspace in relation to windows and doors. If a user is working in a shared office, or a cubicle, or other shared workspace, a privacy screen is required.

Workstation Antivirus

An actively updated antivirus application must be installed. NHATS reserves the right to deny use of an antivirus at the project's discretion.

VIII. Memorandum to IRB/Human Subjects Review Committees

Memorandum to IRB/Human Subjects Review Committees

MEMORANDUM

TO: Institutional Review Boards/Human Subjects Review Committees

FROM: Jennifer Schrack, PhD, Principal Investigator, National Health and Aging Trends Study (NHATS)

RE: Review of Proposals for Analysis of NHATS Restricted Data

The National Health and Aging Trends Study (NHATS) is an ongoing longitudinal study of Americans ages 65 and older, sponsored by the National Institute on Aging (U01AG032947). The National Study of Caregiving periodically interviews caregivers of NHATS participants.

NHATS makes available to researchers both public use datasets, available to all researchers, and restricted datasets, available only under agreement to researchers who meet rigorous conditions. Public use datasets contain no identifying information and pose minimal risk of respondent identification. These files are distributed via download from our website (www.nhats.org); conditions of use require agreement by the user not to attempt to identify study participants. Restricted datasets contain information that NHATS believes increases the potential risk of identification of study participants.

Because of the potential risk of identification of participants, we request that you review portions of proposals to use restricted data from NHATS, and to do so using the same standards you would use for studies of live human subjects. Although researchers using NHATS restricted datasets are conducting "secondary data analysis", the increased potential risk for identification of NHATS study participants (who are, for NHATS, live human subjects) makes inappropriate the usual "exemption" applied to "secondary analysis" of anonymized datasets. We have attempted to minimize these risks by offering data through a secure virtual data enclave at the University of Michigan's Institute for Social Research. Nevertheless, the researcher is still responsible for adhering to a data security plan in order to ensure respondent confidentiality and privacy.

We are not asking that you review the entire National Health and Aging Trends Study. That review has been done by the relevant committees at the Johns Hopkins University and the National Institute on Aging, the primary sponsor of NHATS.

If you have any questions about the nature and scope of what we are asking, please contact:

Jennifer Schrack, PhD, Principal Investigator
National Health and Aging Trends Study
Johns Hopkins University School of Public Health
615 N. Wolfe Street E7144
Baltimore, MD 21205
Phone: 410-502-9328
Email: jschrac1@jhu.edu