

**Obtaining Restricted CMS Data
for the National Health and Aging
Trends Study (NHATS)**

October 2023 (Version 6.0)

Contents

I. Introduction	2
II. The NIA Data LINKAGE (LINKAGE) Enclave.....	2
III. CMS Files Available	2
IV. Requirements for NHATS-CMS Linked Files Applications	4
V. Acceptable Uses of the Restricted Data.....	6
VI. Modifications to the DUA	7
VII. Sanctions for Violation of the DUA.....	8
VIII. Forms	9
IX. Memo to IRB/Human Subjects Review Committees	30

I. Introduction

This document describes procedures for researchers to access Centers for Medicare and Medicaid Services (CMS) data files linked to the National Health and Aging Trends Study (NHATS). These linked files are NHATS Restricted Data that require additional protections to minimize risks of identifying participants. Access to these files is available to qualified researchers via the NIA Data LINKAGE Program (LINKAGE).

Researchers interested in access to other NHATS Restricted Data, including Geographic Data for NHATS and NSOC, should apply following procedures provided in “Obtaining National Health and Aging Trends Study Restricted Data from the NHATS Restricted Data Repository” (see <https://www.nhats.org/researcher/data-access>). With the exception of HRR and restricted tracker files, other restricted data files are not permitted to be linked to NHATS-CMS Linked Files. Requests for other geographic-based contextual linkages will be reviewed on a case-by-case basis. Investigators should review “Instructions to Link Geographic-based Contextual Variables to NHATS-CMS Linked Files” (see https://nhats.org/researcher/data-access/sensitive-data-files?id=restricted_data_files).

Each NHATS-CMS Linked Files application 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. NHATS does not accept umbrella applications for networks, centers, or other coordinating efforts. Questions regarding the application process may be sent to: nhats-cms-data@jh.edu using the subject heading: *NHATS-CMS linked data question*.

II. The NIA Data LINKAGE (LINKAGE) Enclave

NHATS-CMS Linked Files are accessed through the NIA Data LINKAGE (LINKAGE) Enclave. The LINKAGE Enclave is a secure virtual desktop for accessing CMS data linked to NIA-funded studies. Data remain on the LINKAGE enclave servers and are accessed and analyzed by approved users virtually via a secure connection. For more information on the LINKAGE Enclave, please visit the NIA Data LINKAGE Program website: <https://www.nia.nih.gov/research/dbsr/nia-data-linkage-program-linkage>.

III. CMS Files Available

Files are organized by calendar year and are available as shown in the table below. All NHATS participants are included in all files although years of data vary due to factors such as length of enrollment in the Medicare program or death. Requests may be made for specific years or for all years as indicated on the NHATS-CMS Linked Data Request Form (see Section VIII). In addition to specifying files and years of data, requestors select a file format: (1) Standard format, which omits geographic and provider identifiers (meets the needs of most researchers), or (2) Provider format, which omits geographic identifiers but includes provider identifiers (justification required).

The LINKAGE Enclave also includes a complete set of NSOC and NHATS sensitive files that may be requested. In addition, the Enclave includes all NHATS public use files.

Table 1. CMS Files Available in the LINKAGE Enclave

Files	Years Available
Medicare Enrollment Data	
Master Beneficiary Summary File (MBSF): Base – Segment (A/B/C/D)	2006 - 2021
Medicare Summary Files	
Master Beneficiary Summary File (MBSF): Chronic Conditions	2006-2020
Master Beneficiary Summary File (MBSF): Cost & Utilization	2006-2020
Master Beneficiary Summary File (MBSF): Other Chronic or Potentially Disabling Conditions	2006-2020
Medicaid Enrollment Data	
Medicaid Analytic eXtract (MAX) Personal Summary (PS) Enrollment Data	2006-2015
TMSIS Analytic Files (TAF) Demographic and Eligibility (DE) Enrollment Data	2014-2019
Medicare Part A & B Claims Data	
Medicare Carrier (PB) Claims	2006-2021
Medicare Durable Medical Equipment (DM) Claims	2006-2021
Medicare Home Health (HH) Claims	2006-2021
Medicare Hospice (HS) Claims	2006-2021
Medicare Inpatient (IP) Claims	2006-2021
Medicare Outpatient (OP) Claims	2006-2021
Medicare Skilled Nursing Facility (SN) Claims	2006-2021
MedRIC-Built Medicare Provider Analysis & Review (MedPAR)	2006-2020
Part C Claims Data	
Medicare Carrier Encounter Claims	2015-2019
Medicare Durable Medical Equipment (DME) Encounter	2015-2019
Medicare Home Health Agency (HH) Encounter Claims	2015-2019
Medicare Inpatient (IP) Encounter Claims	2015-2019
Medicare Outpatient (OP) Encounter Claims	2015-2019
Medicare Skilled Nursing Facility (SNF) Encounter Claims	2015-2019
Medicare Part D Medication Therapy Management (MTM)	2013-2019
Medicaid Claims Data	
Medicaid Analytic eXtract (MAX) Inpatient (IP) Claims	2006-2015
Medicaid Analytic eXtract (MAX) Long Term Care (LT) Claims	2006-2015
Medicaid Analytic eXtract (MAX) Other Services (OT) Claims	2006-2015
Medicaid Analytic eXtract (MAX) Prescription Drug (RX) Data	2006-2015
TMSIS Analytic Files (TAF) Inpatient (IP) Claims	2014-2019
TMSIS Analytic Files (TAF) Long Term Care (LT) Claims	2014-2019
TMSIS Analytic Files (TAF) Other Services (OT) Claims	2014-2019
TMSIS Analytic Files (TAF) Pharmacy (RX) Data	2014-2019
Inpatient Rehab Facility-Patient Assessment Instrument (IRF-PAI) CMS Questionnaire/MedRIC Categories	2006-2020

Long Term Care Minimum Data Set (MDS) CMS Questionnaire/MedRIC Categories	2006-2021
Medicare Part D Prescription Drug Event (PDE) MedRIC Categories	2006-2021
Outcome and Assessment Information Set (OASIS) CMS Questionnaire/MedRIC Categories	2006-2021

IV. Requirements for NHATS-CMS Linked Files Applications

To be eligible to receive NHATS-CMS Linked Files, an Investigator must:

- 1) 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, and
- 2) 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 <http://www.hhs.gov/ohrp/assurances/assurances/filasurt.html>).

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 LINKAGE enclave.

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

Roles referenced in this document:

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 (DUA) on behalf of the Investigator’s Institution. The representative must have the authority to bind the institution contractually.

All Investigators, Co-Investigators and Research Staff who will have access to the NHATS-CMS Linked Files 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-CMS Linked Files 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-CMS linked 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.

For Investigators who are applying for funding to support use of the NHATS-CMS linked files, NHATS is willing to provide a written statement to accompany applications.

Key elements of the data protection plan include:

- 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 LINKAGE 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

External File Linkages

External files approved for linkage with NHATS-CMS linked data files include a file containing Hospital Referral Regions (HRR) linked to NHATS SPs and restricted tracker files that contain the date of the NHATS interview. These files will be made available to approved researchers in the LINKAGE enclave. For more information on how the HRRs were developed go to <https://www.dartmouthatlas.org/data/>.

Plans to link to the HRR or restricted tracker files should be specified in the applicant's research plan and indicated in the HRR & Restricted Tracker Files Request Form (Section VII).

Requests for other geographic-based contextual linkages will be reviewed on a case-by-case basis. Investigators should review "Instructions to Link Geographic-based Contextual Variables to NHATS-CMS Linked Files" (see https://nhats.org/researcher/data-access/sensitive-data-files?id=restricted_data_files).

Users may request to bring other non-identifiable contextual files into the LINKAGE Enclave via an approved research plan and NHATS DUA. Complete the External File Request Form to request to bring non-identifiable files into the enclave. Files will be vetted by NHATS staff.

Application Process

Obtaining the NHATS-CMS Linked Files requires approval and a DUA from NHATS, a National Institute on Aging (NIA) DUA, and review and approval by NIA. The steps in the process are described below.

Investigators with existing projects under a CMS data use agreement who would like to request new files need to file new applications and obtain new DUAs from NHATS and NIA.

Application for an NHATS DUA

Step 1: To initiate a new application, complete and sign the required forms and documents (see Section VIII for forms). Forms should be downloaded, completed, signed, and submitted as PDFs to nhats-cms-data@jh.edu. Please use the subject heading: *NHATS-CMS Linked Restricted Data Application*.

- Checklist for Application
- Investigator Form
- Project Title, Abstract, Research Plan
- Data Protection Plan
- Copy of IRB approval
- NHATS-CMS Linked Data Request Form

- HRR & Restricted Tracker Files Request Form (if applicable)
- External File Linkage Request Form (if applicable)
- Signed copy of the NHATS Data Use Agreement
- Signed NHATS Supplemental Data Use Agreement with Research Staff (if applicable)

IRB/Human Subjects approval at the Investigator's institution should use standards for live human subjects. IRB approval must be at either the Full or Expedited level; access to these data **does not** qualify as exempt secondary analysis. A memo explaining the type of human subjects review that is being requested by NHATS and the reasons for it is provided for use as needed (see Section IX).

Step 2: NHATS will review the documents submitted. Any questions, or needed revisions, will be communicated to the Investigator.

Step 3: Once NHATS approves the application, the DUA will be countersigned by NHATS and Johns Hopkins University. The applicant will receive:

- A fully executed DUA
- A letter for submission to LINKAGE (<https://www.nia.nih.gov/research/dbsr/nia-data-linkage-program-linkage>) that indicates NHATS approval of the application.

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 or Research Staff on a given application.

Application Process to Obtain NIA DUA following NHATS DUA Approval

An NIA DUA is required to access the NHATS-CMS Linked Files in the LINKAGE Enclave. To obtain an NIA DUA, please follow the instructions at <https://www.nia.nih.gov/research/dbsr/access-or-share-linkage-data>.

V. Acceptable Uses of the Restricted Data

Restricted data. As specified in the 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. NHATS does not accept umbrella applications for networks, centers, or other coordinating efforts.

Repository use. Only approved individuals may be given an account in the LINKAGE enclave, which houses the NHATS-CMS Linked Data Files. **Users may only access the enclave from approved locations and equipment specified in the Data Security plan form. Users must position the screen to prevent unauthorized user from viewing the NHATS restricted data and lock the computer when they step away. Users may not print, take screenshots, pictures, screen-share, transcribe or otherwise duplicate data or results of data analysis, even with members of their study team. Users may not share login information (account name, password, or token values) or permit viewing of their account including output.**

Disclosure review. Prior to removal, all output and programs will be reviewed for disclosure risk by the NHATS compliance officer. Tabulations with cells/strata ≤ 10 , 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 ≤ 10 through subtraction.

VI. Modifications to the DUA

All changes to project team members or institutional affiliations require an updated DUA and Application materials. 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 and a modified research plan must be submitted (if applicable). 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 enclave without approval. Once all paperwork is approved the individual will be given access 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. A 3-year extension may be requested by submitting a signed Restricted Data Use Agreement Extension Request to nhats-cms-data@jh.edu.

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

Adding New CMS Files to an Existing Project After Approval

The steps below should be followed for requests to add new CMS files to an existing LINKAGE enclave project consistent with the Research Plan in the DUA.

Step 1: To add new CMS files to an existing NHATS DUA, complete and sign the required forms and documents (see Section VIII) listed below and submit these as PDFs to nhats-cms-data@jh.edu. Please use the subject heading: *NHATS-CMS Linked Restricted Data Application Update*.

- Investigator Form
- NHATS-CMS Linked Data Request Form
- HRR & Restricted Tracker Files Request Form (if applicable)
- External File Linkage Request Form (if applicable)

Step 2: NHATS will review the documents submitted and any questions, or needed revisions, will be communicated to the Investigator. Once NHATS approves the application, the applicant will receive a letter for submission to LINKAGE indicating NHATS approval of the application to update the existing DUA to add new CMS files. Follow the instructions at <https://www.nia.nih.gov/research/dbsr/access-or-share-linkage-data>.

VII. Sanctions for Violation of the DUA

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

- 1) Denial of all 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 federal research funding agencies or other funding source, 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 the 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 all files within the LINKAGE enclave. If NHATS determines that the allegations of violations were incorrect, NHATS will return LINKAGE enclave access to the Investigator 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 federal funding agencies with a recommendation to terminate current and deny future federal 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): Application Checklist

VIII. Forms

Submit this Checklist with Initial Application:

- By checking this box, the applying Investigator confirms that all individuals on the DUA are registered NHATS users

Forms and Documents for Initial Application:

- Investigator form
- Project Form
 - Project title and abstract
 - Research Plan
 - CV or Biosketch for Investigator and Co-Investigator(s)
 - Copy of IRB approval
- NHATS-CMS Linked Data Request Form
- HRR & Restricted Tracker Files Request Form (if applicable)
- External File Linkage Request Form (if applicable)
- Signed copy of the NHATS Data Use Agreement
- Signed NHATS Data Supplemental Agreement with Research Staff (if applicable)
- Investigators Collaborating Across Institutions (if applicable)
- List of Users Requesting LINKAGE Enclave Access
- Data protection plan for each user

National Health and Aging Trends Study (NHATS): Investigator Form

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): NHATS-CMS Linked Files Project Form

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 NHATS-CMS Linked Files and variables that will be used in analyses
3. A justification for requesting HRR files (if applicable)
4. A justification for requesting restricted tracker files (if applicable)
5. A justification for other non-identifiable external linkages (if applicable)

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 project's IRB approval. At the end of this packet is a letter from Jennifer Schrack, PhD, PI of NHATS, should your IRB require explanation as to why we are requesting review.

National Health and Aging Trends Study (NHATS): NHATS-CMS Linked Files Request Form (May 2022)

Restricted Investigator: _____

Title of Research Proposal: _____

- New Application
 Update (adding files) to existing NIA DUA

1) Select NHATS files requested

- NSOC Sensitive Files
 NHATS Sensitive Files
 NHATS Sensitive COVID-19 Files
 NHATS Public Use Files

2) Select Years Requested and file format

Standard format: Omits geographic and provider identifiers (meets the needs of most researchers)

Provider format: Omits geographic identifiers but includes provider identifiers (justification required)

Files	Years Available	Years Requested	File format (Standard or Provider)
Medicare Enrollment Data			
Master Beneficiary Summary File (MBSF): Base – Segment (A/B/C/D)	2006 - 2021		
Medicare Summary Files			
Master Beneficiary Summary File (MBSF): Chronic Conditions	2006-2020		
Master Beneficiary Summary File (MBSF): Cost & Utilization	2006-2020		
Master Beneficiary Summary File (MBSF): Other Chronic or Potentially Disabling Conditions	2006-2020		
Medicaid Enrollment Data			
Medicaid Analytic eXtract (MAX) Personal Summary (PS) Enrollment Data	2006-2015		
TMSIS Analytic Files (TAF) Demographic and Eligibility (DE) Enrollment Data	2014-2019		
Medicare Part A & B Claims Data			
Medicare Carrier (PB) Claims	2006-2021		
Medicare Durable Medical Equipment (DM) Claims	2006-2021		
Medicare Home Health (HH) Claims	2006-2021		
Medicare Hospice (HS) Claims	2006-2021		
Medicare Inpatient (IP) Claims	2006-2021		
Medicare Outpatient (OP) Claims	2006-2021		
Medicare Skilled Nursing Facility (SN) Claims	2006-2021		
MedRIC-Built Medicare Provider Analysis & Review (MedPAR)	2006-2020		
Part C Claims Data			
Medicare Carrier Encounter Claims	2015-2019		

National Health and Aging Trends Study (NHATS): NHATS-CMS Linked Files Request Form (May 2022)

Medicare Durable Medical Equipment (DME) Encounter	2015-2019		
Medicare Home Health Agency (HH) Encounter Claims	2015-2019		
Medicare Inpatient (IP) Encounter Claims	2015-2019		
Medicare Outpatient (OP) Encounter Claims	2015-2019		
Medicare Skilled Nursing Facility (SNF) Encounter Claims	2015-2019		
Medicaid Claims Data			
Medicaid Analytic eXtract (MAX) Inpatient (IP) Claims	2006-2015		
Medicaid Analytic eXtract (MAX) Long Term Care (LT) Claims	2006-2015		
Medicaid Analytic eXtract (MAX) Other Services (OT) Claims	2006-2015		
Medicaid Analytic eXtract (MAX) Prescription Drug (RX) Data	2006-2015		
TMSIS Analytic Files (TAF) Inpatient (IP) Claims	2014-2019		
TMSIS Analytic Files (TAF) Long Term Care (LT) Claims	2014-2019		
TMSIS Analytic Files (TAF) Other Services (OT) Claims	2014-2019		
TMSIS Analytic Files (TAF) Pharmacy (RX) Data	2014-2019		
Inpatient Rehab Facility-Patient Assessment Instrument (IRF-PAI) CMS Questionnaire/MedRIC Categories	2006-2020		
Long Term Care Minimum Data Set (MDS) CMS Questionnaire/MedRIC Categories	2006-2021		
Medicare Part D Prescription Drug Event (PDE) MedRIC Categories	2006-2021		
Outcome and Assessment Information Set (OASIS) CMS Questionnaire/MedRIC Categories	2006-2021		

2) Provide a brief justification if provider format is requested. Note: This should be addressed in detail in your research plan for NHATS-CMS linked data.

National Health and Aging Trends Study (NHATS): HRR & Restricted Tracker Files Request Form

- Check here if requesting HRR files and provide a short justification below. This should be addressed in detail in your research plan for NHATS-CMS linked data.

- Check here if requesting restricted tracker files and provide a short justification below. This should be addressed in detail in your research plan for NHATS-CMS linked data.

National Health and Aging Trends Study (NHATS): NHATS-CMS Linked Files External File Request Form

List additional files that you plan to bring into the enclave (their purpose/contents should be described and justified in your research plan). **Files must be non-identifiable**. Below, for each file listed, provide the following:

- a) source and brief description of contents in the file
- b) how you will link (e.g. CCN, etc)
- c) whether the file will be imported from the MiCDA enclave

An example is provided.

Filename	Source and Brief Description of Contents	Linkage Variable	Is this file being imported from the MiCDA enclave?
Example: CMS Provider of Services (POS) File	The POS files provided by the Centers for Medicare and Medicaid Services (CMS) contain provider certification, termination, accreditation, ownership, and other characteristics. Location, name, and other identifiable information will be dropped before linking to NHATS-CMS files.	CMS Certification number (CCN)	No
1.			
2.			
3.			
4.			
5.			

National Health and Aging Trends Study (NHATS): NHATS-CMS Linked Files Restricted Data Use Agreement

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.

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): NHATS-CMS Linked Files Restricted Data Use Agreement

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 $n \leq 10$ are produced.
- Frequency Data: Apply a marginal threshold of $n > 10$ and cell threshold of $n > 10$ 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. 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 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)."

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 Protection Plan submitted to and approved by NHATS.
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.

National Health and Aging Trends Study (NHATS): NHATS-CMS Linked Files Restricted Data Use Agreement

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 the NHATS 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.

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.

National Health and Aging Trends Study (NHATS): NHATS-CMS Linked Files Restricted Data Use Agreement

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): NHATS-CMS Linked Files Restricted Data Use Agreement

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 Bloomberg 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): NHATS-CMS Linked Files Restricted Data Supplemental Agreement with Research Staff

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.

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): NHATS-CMS Linked Files Restricted Data Use Agreement Extension Request

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

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): NHATS-CMS Linked Files Restricted Data Use Agreement Extension Request

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): NHATS-CMS Linked Files Restricted Data Supplemental Agreement with New Research Staff

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.

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): NHATS-CMS Linked Files Restricted Data Collaborating Investigators at Other Institutions

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 #2

Name

Title

Institution

Email

Collaborating Investigator #3

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 LINKAGE Enclave Access

List all users who will require access to the LINKAGE 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)

Legal First Name

Legal Last Name

Institution

Business Email Address

Business Telephone Number

User #2

Legal First Name

Legal Last Name

Institution

Business Email Address

Business Telephone Number

User #3

Legal First Name

Legal Last Name

Institution

Business Email Address

Business Telephone Number

National Health and Aging Trends Study (NHATS): NHATS-CMS Linked Files Modification Cover Sheet

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-cms-data@jh.edu.

- Adding a new Research Staff person
 - Supplemental Agreement with New Research Staff
 - Data Protection Plan
 - List of Users Requesting LINKAGE Enclave Access

- Adding a new Co-Investigator
 - Investigator form in the Data Use Agreement
 - Data Protection Plan
 - List of Users Requesting LINKAGE Enclave Access

- Removing Research Staff or Co-Investigators
 - Email nhats-cms-data@jh.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 Data Security Plan

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

- Requesting a new external file linkage
 - Restricted NHATS-CMS Linked Files External File Request Form
 - Update the Research Plan (tracked and clean versions) to describe and justify the purpose and contents of the linkage(s)
 - 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

National Health and Aging Trends Study (NHATS): Data Protection Plan

Complete ONE Form for EACH User and EACH User Location

Work Location: From where will you log in? CHOOSE ONE: <input type="checkbox"/> Home <input type="checkbox"/> Office* Address (*Office address should include office #, building name, street address, city, state, and zip) _____		
Workstation Specifications: Make/model: _____ <input type="checkbox"/> Desktop <input type="checkbox"/> Laptop Operating System (Please note version #): <input type="checkbox"/> Windows Version: _____ <input type="checkbox"/> 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: <input type="checkbox"/> Windows Defender <input type="checkbox"/> Symantec <input type="checkbox"/> McAfee <input type="checkbox"/> Sophos <input type="checkbox"/> Norton Version: _____ Other(specify brand/version): _____		
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. The only products currently forbidden for use with systems accessing the MiCDA are Kaspersky and 360 Labs. Most other antivirus products will be approved. NHATS reserves the right to deny use of an antivirus at the project's discretion.

IX. Memo to IRB/Human Subjects Review Committees

National Health and Aging Trends Study (NHATS): Memo for IRBs or HSRCs Regarding NHATS Review

Memorandum for IRBs or HSRCs Regarding NHATS Review

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 (U01 AG032947). 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 the NHATS 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 the NIA LINKAGE Enclave—a secure virtual desktop for accessing NIA-funded study data that has been linked to Centers for Medicare & Medicaid Services (CMS) data. 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 conducted 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 Bloomberg School of Public Health
615 N. Wolfe Street E7144
Baltimore, MD 21205
Phone: 410-502-9328
Email: jschrac1@jhu.edu