# US Department of Health and Human Services

## Privacy Impact Assessment

### Date Signed:

07/18/2025

### OPDIV:

NIH

### Name:

NIA GSS: Healthy Aging in Neighborhoods of Diversity across the Life Span (HANDLS)

**PIA Unique Identifier:**

P-4959054-532376

**The subject of this PIA is which of the following?**

Minor Application (stand-alone)

**Identify the Enterprise Performance Lifecycle Phase of the system.**

Operations and Maintenance

**Is this a FISMA-Reportable system?**

No

**Does the system include a Website or online application available to and for the use of the general public?**

Yes

**Identify the operator.**

Agency

**Is this a new or existing system?**

Existing

**Does the system have Security Authorization (SA)?**

Yes

**Indicate the following reason(s) for updating this PIA.**

PIA Validation

**Describe in further detail any changes to the system that have occurred since the last PIA.**

This validation is intended to refresh content. There have been no substantial changes since the last assessment.

**Describe the purpose of the system.**

Healthy Aging in Neighborhoods of Diversity across the Life Span (HANDLS) collects research study information including clinical data, data from personal assessments, cognitive tests, physical exams, medical histories and other diagnostic test and images using mobile medical research vehicles. These vehicles serve as community-based platforms for clinical research. The mobile medical research vehicles are tools for creating effective methods for recruiting and retaining non-traditional research participants into age-related clinical research. HANDLS is planned as a 20-year longitudinal study.

**Describe the type of information the system will collect, maintain (store), or share.**

The information collected includes name, date of birth (DOB), social security number (SSN), mailing address, phone number, medical record number (MRN), medical notes, email address, medical/photographic images and medical/test results. Tests conducted include blood and urine tests, Electrocardiograms (EKGs) and bone scans. In addition, HANDLS uses specific account information for log in. This includes user credentials (identification (ID) and password) and user role (s).

**Provide an overview of the system and describe the information it will collect, maintain (store), or share, either permanently or temporarily.**

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**Does the system collect, maintain, use or share PII?**

Yes

**Indicate the type of PII that the system will collect or maintain.**

Social Security Number
Date of Birth
Name
E-Mail Address
Mailing Address
Phone Numbers
Medical Records Number
Medical Notes
Medical/Photographic images
Medical/test results
User credentials, user role(s)

**Indicate the categories of individuals about whom PII is collected, maintained or shared.**

Employees
Public Citizens
Patients

**How many individuals' PII is in the system?**

500-4,999

**For what primary purpose is the PII used?**

Personally identifiable information (PII) is used to categorize study participants in keeping with and as required by the study.

**Describe the secondary uses for which the PII will be used.**

N/A

**Identify legal authorities governing information use and disclosure specific to the system and program.**

42 U.S.C.§ 241
42 U.S. Code § 282
42 U.S. Code § 284
42 USC § 285e

**Are records on the system retrieved by one or more PII data elements?**

Yes

**Identify the number and title of the Privacy Act System of Records Notice (SORN) that is being use to cover the system or identify if a SORN is being developed.**

09-25-0200, Clinical, Basic and Population-based Research Studies of the National Institutes of

**Identify the sources of PII in the system.**

Directly from an individual about whom the information pertains
In-Person
Other
Government Sources
Other Federal Entities
Non-Government Sources
Public

**Identify the OMB information collection approval number and expiration date**

Section 2035, exempts research conducted by NIH from Paperwork Reduction Act (PRA) requirements.

**Is the PII shared with other organizations?**

Yes

**Identify with whom the PII is shared or disclosed and for what purpose.**

**Describe any agreements in place that authorizes the information sharing or disclosure.**

N/A

**Describe the procedures for accounting for disclosures.**

The system owner will work with the application administrator to identify persons requesting a individual's information. Tracking the recipient and purpose of PII disclosures to a outside party is a manual process and varies for each application.

**Describe the process in place to notify individuals that their personal information will be collected. If no prior notice is given, explain the reason.**

The research study consent form is used to notify individuals that their personal information will be collected. Each participant must acknowledge and sign the consent form.

**Is the submission of PII by individuals voluntary or mandatory?**

Voluntary

**Describe the method for individuals to opt-out of the collection or use of their PII. If there is no option to object to the information collection, provide a reason.**

All participants sign a consent form acknowledging their anonymity and rights Once signed, participants may opt-out of the collection, but their consents remain in force.

**Process to notify and obtain consent from individuals whose PII is in the system when major changes occur to the system.**

All participants sign a Institutional Review Board (IRB) approved informed consent form acknowledging their voluntary participation in the study. If/when major system changes occur, study participants are apprised when they are re-visited.

**Describe the process in place to resolve an individual's concerns when they believe their PII has been inappropriately obtained, used, or disclosed, or that the PII is inaccurate.**

To address personally identifiable information (PII) concerns, participants may call the NIA Privacy Office or write to the study official/manager. Participants should reasonably identify the record and specify the information being contested, the corrective action sought, and reasons for requesting the correction, along with supporting information to show how the record is inaccurate, incomplete, untimely, or irrelevant. The right to contest records is limited to information, which is incomplete, irrelevant, incorrect, or untimely (obsolete).

**Describe the process in place for periodic reviews of PII contained in the system to ensure the data's integrity, availability, accuracy and relevancy.**

HANDLS staff review the data security in the system at least annually as part of NIA's annual information security review. In addition, internal chart reviews are conducted after each study visit ensuring PII integrity and accuracy, cross checking the electronic record with paper medical research record and updating records when necessary. The NIA Clinical Research Protocol Office performs routine clinical monitoring visits to the HANDLS research site to ensure the safety and conduct. Monitoring visits are performed quarterly to assure that clinical research is in compliance with Food and Drug Administration (FDA), HHS domestic regulations and Clinical Practice Guidelines (GCP). Additionally, at the end of each study wave (about every three to four years), HANDLS staff adjudicate each participant's status to confirm accurate study status.

**Identify who will have access to the PII in the system and the reason why they require access.**

**Describe the procedures in place to determine which system users (administrators, developers, contractors, etc.) may access PII.**

Determinations are made based on Role-based access controls and least privilege.

**Describe the methods in place to allow those with access to PII to only access the minimum amount of information necessary to perform their job.**

User rights are provisioned based on controls within the system, allowing users only access to the minimum amount of PII necessary to perform their job.

**Identify training and awareness provided to personnel (system owners, managers, operators, contractors and/or program managers) using the system to make them aware of their responsibilities for protecting the information being collected and maintained.**

According to NIH policy, all personnel who manage or operate NIH applications must successfully complete annual security and privacy awareness training.

**Describe training system users receive (above and beyond general security and privacy awareness training).**

Role-based training, specific to roles and regulations, is provided.

**Do contracts include Federal Acquisition Regulation and other appropriate clauses ensuring adherence to privacy provisions and practices?**

Yes

**Describe the process and guidelines in place with regard to the retention and destruction of PII.**

03-001, Clinical Care Services Records. Cut off annually at end of fiscal year. Destroy 7 years after cutoff (DAA-0443-2019-0001-0001).

01-002, Research Records that Support Intellectual Property Rights. Cut off annually after the patent is filed. Destroy 30 years after cutoff (DAA-0443-2017-0002-0001).

01-003, Records of All Other Intramural Research Projects. Cut off annually at termination of project/program or when no longer needed for
scientific reference, whichever is longer. Destroy 7 years after cutoff (DAA-0443-2012-0007-0003).

**Describe, briefly but with specificity, how the PII will be secured in the system using administrative, technical, and physical controls.**

Physical controls include 24x7 guards of mobile units used to collect data, Personal Identify Verification (PIV), key cards and closed-circuit TV.

Technical controls include User identification (ID), passwords, network firewall, Virtual Private Network (VPN), Intrusion Detection System, Role Based Access Controls, System logs.

Administrative controls include system security and contingency plan. Files are backed up regularly and stored offsite. Contract clauses ensure adherence to privacy provisions and practices, least privilege through role-based access, and policies for retention and destruction of PII.

**Identify the publicly-available URL:**

https://handls.nih.gov/

Note: web address is a hyperlink.

**Does the website have a posted privacy notice?**

Yes

**Is the privacy policy available in a machine-readable format?**

Yes

**Does the website use web measurement and customization technology?**

No

**Does the website have any information or pages directed at children uner the age of thirteen?**

No

**Does the website contain links to non- federal government websites external to HHS?**

No

**Is a disclaimer notice provided to users that follow external links to websites not owned or operated by HHS?**

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