US Department of Health and Human Services

Privacy Impact Assessment

Date Signed:

07/17/2025

OPDIV:

NIH

Name:

NIA GSS: Clinical Research System

PIA Unique Identifier:

P-5102863-778631

The subject of this PIA is which of the following?

Major Application

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 and update the security authorization date. There have been no substantial changes since the last assessment.

Describe the purpose of the system.

The National Institute on Aging (NIA) Clinical Research System's (CRS) is a repository for clinical data and clinical data analysis.

The NIA Intramural Research Program (IRP) Clinical Research System is comprised of two components that support NIA Intramural Research Program clinical research at all sites (Biomedical Research Center, NIH main campus and Harbor Hospital Center). This includes support of direct participant care research activities as well as providing a central data warehouse for data manipulation and analysis.

The CRS components, OpenClinica and Participant Admissions System (PAS), support the entire continuum of research activities from direct patient care and subsequent data manipulation and analysis. OpenClinica provides a Food and Drug Administration (FDA) compliant, audited data collection environment which is used for collection and warehousing of data from all protocols for subsequent analysis as well as providing a repository of information that is accessed in the course of research subject patient care activities. Participant Admissions System (PAS) represents the system by which participant contact and basic demographic information is acquired and stored, while also allowing management and scheduling of clinical research and participant care activities. PAS, providing basic participant information such as demographics, medical record and study identification (ID) numbers.

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

Potential participants are interviewed over the phone to gather information on their eligibility. On rare instances, participants may be interviewed in person at the clinical unit.
Personally Identifiable Information collected and entered into the system includes Name, Date of Birth (DOB), Address, Phone number and Email address. Questions are asked about health and medical conditions that determine if the participant is eligible to be scheduled for the study screening visit at the clinical unit. These questions are study specific and include height and weight, history of disorders such as high blood pressure, diabetes, cancer, liver or kidney disease, current medications and supplements, smoking history, pregnant or breastfeeding, etc.

If selected for a study, participants meet with a clinical care coordinator done on-site at the NIA Clinical Research unit at Harbor Hospital. Additional information collected during the intake, and subsequent visits includes mother's maiden name, social security number, medical record number, next of kin (NOK), medical imaging, blood samples notes and primary care provider. Information is used in examining the clinical questions addressed by the study; to contact consenting participants with the results of testing; to collect follow-up information; and as part of the clinical research.

Non-personally identifiable information (PII) data collected include Protocol number, scheduling information and the types of tests conducted.

CRS uses specific login information using the NIH Identity,
Credential, and Access Management (IAM) Services which
maintains its own unique privacy impact assessment (PIA) on record, with all legal authorities documented. The purpose of the IAM is to authenticate and authorize all users and computers in a Windows domain type network, assigning and enforcing information security policies for all computers and installing or updating software. The IAM collects unique user credentials and stores them in a encrypted format. The IAM is a essential service which facilitates and governs network access to various resources.

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
Mother's Maiden Name
E-Mail Address
Mailing Address
Phone Numbers
Medical Records Number
Medical Notes
Primary care provider, demographics
Medical imaging and blood work
Health history

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?

PII is used for research (demographic medical anomalies) and participant communications.

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

PII may be used for patient compensation, when applicable.

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.

09-25-0217 NIH Business System (NBS)

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
Email
Other

Non-Government Sources
Public
Private Sector

Identify the OMB information collection approval number and expiration date

N/A. This system is exempt from an OMB Information Collection Number through Public Law 114-255, 21st Century Cures Act, Section 2035: Exemption for the National Institutes of Health from the Paperwork Reduction Act requirements.

Is the PII shared with other organizations?

No

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

During the interview process, participants are informed and asked to sign a consent form that the collection of their PII is necessary in order to participate in the study. Initial contact with participants is usually made over the phone, although walk-ins to the clinical unit occur on a rare basis. Study screening scripts include asking the participant if they consent to answering questions about

themselves, their health and other personal questions as per the study eligibility requirements. Participants at that entry point do not need to provide all the requested PII information, however, a minimum amount of responses may be needed to determine eligibility and then if they agree, the minimum amount of PII to schedule a visit (i.e. name, age, phone contact) if found eligible at that stage of recruitment. Once a participant arrives on the NIA Clinical Unit for their study screening visit, they are asked to complete an admissions form that includes their name, address, next of kin, etc. If they do not wish to complete the information, then they are not allowed to continue with the screening process. At the time of screening for a study, the study is discussed in detail with the participant and they are informed of their rights which include the right to drop out of the study at any time. If they choose not to sign the informed consent, they are not able to participate in the study.

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.

Participation is voluntary. If a participant doesn't want to provide the necessary PII to participate in a study, they do not participate.

Participants can opt out of providing their Social Security Number (SSN) in studies that do not have any participant monetary compensation.

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

Participation in the study is voluntary. There are no procedures in place at this time to notify participants when there are changes to the system. All participants sign a consent form acknowledging their anonymity and rights.

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.

Study participants can opt-out of the study at anytime, and depending on the study, participants can choose which PII they provide the study coordinator. If they have concerns regarding their PII, they may contact the Clinical Protocol Coordinator.

If a participants PII has been inappropriately obtained, used or disclosed, the incident would be reported to the Clinical Director, Office for Human Research Protections (OHRP) and the Intramural Review Board (IRB) if required. Depending on the results of the review/investigation, action may or may not be requested. In the case that PII is inaccurate, documentation by the participant may be required in order for a change to be made in the NIA data system(s). Participant is also given a copy of their signed consent and there is a section that lists the contact phone numbers for Principal investigator as well as the NIA Protocol Office, the NIA Clinical Director and the Office of Human Research Compliance (OHRC).

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

System administrators conduct bi-monthly reviews/audits of PII in the study.

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.

There is a required system access form to grant access to use the system and there are different security levels to access sensitive data. The form must be signed by multiple approvers. Approvers include Clinical Nurse Manager, NIA Clinical Director and Principal Investigator.

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.

System users can only access data at their security level. There is a required system access form to grant access to use the system and there are different security levels to access sensitive data. The form must be signed by multiple approvers. Users log into the system using NIH IAM. IAM maintains its own PIA.

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.

The NIH Security Awareness Training course is used to satisfy this requirement. According to NIH policy, all personnel who use NIH applications must complete security awareness training every year.

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

There is periodic group/one-on-one training on system use according to the user's security/access level.

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 guards, identification badges, key cards and closed circuit television (TV).

Technical controls include user identification (ID), passwords, firewall, Personal Identity Verification (PIV) card, and Virtual Private Network (VPN).

Administrative controls include system security and contingency plan, PIV card, 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://www.nia.nih.gov/research/labs/blsa/join-blsa

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?

Yes

Select the type of website measurement and customization technologies is in use and if it is used to collect PII.

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?

Yes

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

Yes