US Department of Health and Human Services

Privacy Impact Assessment

Date Signed:

08/05/2025

OPDIV:

NIH

Name:

NIAMS Clinical Research Support System (CRSS)

PIA Unique Identifier:

P-4966251-760658

The subject of this PIA is which of the following?

Minor Application (child)

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?

No

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.

Describe the purpose of the system.

The purpose of the National Institute of Arthritis and Musculoskeletal and Skin Diseases (NIAMS) Clinical Research Support System (CRSS) is to facilitate support of NIAMS funded grants.

There are two parts to the system:
1. A centralized clinical research management database (NIAMS Clinical Studies Database) is used internally by NIAMS and Navitas Clinical Research (NCR) staff to manage and track human subject clinical study elements, metrics, and milestones for NIAMS funded individual research grants.

2. The NIAMS Clinical Study Website is used to house and share clinical study documents, related committee information and materials with NIAMS staff, monitoring members and Investigators.

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

The purpose of the NIAMS CRSS is to facilitate support of NIAMS funded grants.

There are two parts to the system:
A centralized clinical research management database (NIAMS Clinical Studies Database) is used internally by NIAMS and NCR staff to manage and track human subject clinical study elements, metrics and milestones for NIAMS funded individual research grants. The Database contains a brief description of each grant and key metrics, such as the number of participants enrolled and meeting project milestones. This information is used to track progress and serious adverse events (SAEs). The grant review module collects a brief description of the grant, if it is a clinical trial, the number and age of participants, type of intervention (if applicable), number of sites and a description of the planned safety monitoring. The Dashboard module provides the NIAMS program staff with an overview of each of the grants within their portfolio.

The NIAMS Clinical Study Website is used to house and share clinical study documents, related committee information and materials with NIAMS staff, monitoring members and Investigators. The Website stores safety monitoring meeting materials for upcoming and past meetings including agenda, meeting minutes and deidentified safety reports. It also houses study materials such as protocols, Manuals of Operating Procedures, Informed Consent Form Templates, and Case Report Form templates. The website also contains a study roster with the names and business contact information (email address, phone number, mailing address) for the Monitoring Body and study team members. The Clinical Study Website is only available to NIAMS staff, study teams/investigators and Monitoring Body members.

This system is contracted through NCR. Access to both aspects of the system are controlled with unique user accounts and passwords.

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.

Name
E-Mail Address
Mailing Address
Phone Numbers
Username and password

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

Employees
Business Partner/Contacts (Federal/state/local agencies)

How many individuals' PII is in the system?

500-4,999

For what primary purpose is the PII used?

Username and login are used to access the Clinical Research Support System. Name and contact information is used to contact team and study members.

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.

Section 301 of the Public Health Service Act, describing the general powers and duties of the Public Health Service relating to research and investigation (42 U.S.C. 241).

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.

09-25-0225 NIH Electronic Research Administration (eRA)

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

Identify the sources of PII in the system.

Directly from an individual about whom the information pertains
Online
Government Sources
Within the OPDIV
Non-Governmental Sources
Private Sector

Identify the OMB information collection approval number and expiration date

N/A

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.

The organization determines and documents the legal authority that permits the collection, use, maintenance, and sharing of personally identifiable information (PII), either generally or in support of a specific program or information system need. Navitas Lifesciences (NLS) determines and documents the legal authority that permits the collection, use, maintenance, and sharing of PII complying with project requirements and supporting clients, including NCR. This authorization is included as part of a contract signed by NLS and its clients or it may be included in a data sharing/use agreement or similar agreement. NLS may also require additional authority supporting subject research which could require the oversight of an Institutional Review Board and the approval to gather information from subjects via a signed consent form by the subject.

Describe the procedures for accounting for disclosures.

NIAMS staff, NIAMS approved monitoring body members, and study team members are allowed to access the system through system user account setup. After the user successfully passed user account authentication the accessing privilege is then limited by the user role on what they can read and/or edit in the system. Audit logs are used to disclose what information is shared between NIAMS and NCR.

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

NIAMS grantees provide the information during the grant application process.

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.

Grantees may opt out of providing PII, but they are then no longer eligible for grants.

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

In the event of a major change to the system, users would be notified by email. However, no changes are expected.

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.

Users may contact the NCR support center through the email address provided on the site application, or through the NIAMS Project Officer.

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

Periodic audits are conducted to ensure the data’s integrity, availability, accuracy and relevancy.

The CRSS system manager performs periodic review on system user table and send queries to project manager on those users have not logged on for more than a year. If confirmed, the account will be disabled.

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 based on role based access controls and least privilege. 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.

User account request from the NIAMS Contract Manager, executed by NCR information technology (IT) support and system administrator, confirmed with notification to the Contract Manager.

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.

Access to PII is assigned to personnel based upon current job responsibilities and least privilege. Specific login to the system is required by each user.

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 NIH personnel who use NIH applications, including NCR staff on the NIAMS suitability roster, must complete security awareness training annually. There are five categories of mandatory IT training (Information Security, Counterintelligence, Privacy Awareness, Records Management and Emergency Preparedness).

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

NCR provides their own annual IT security training for NCR staff.

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.

Records are retained and disposed of under the authority of the NIH Records Retention Schedule.

Item 02-004 - Extramural Program and Grants Management Oversight Records.
These records are generated during the administration and execution of extramural program activities. This schedule item is intended to capture all extramural program and grants management records that are not part of an official case file (Item 0001 or 0002) or animal welfare assurance file (Item 0003). These records support the operations, compliance, reporting, and oversight functions of the NIH Extramural Program and the financing of research endeavors with the purpose of ensuring scientific integrity and public accountability of the NIH extramural research portfolio. Extramural program and grants management oversight records are consolidated under one common temporary

retention item.
Disposition: Cut off annually. Destroy 3 years after cutoff. DAA-0443-2013-0004-0004

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

Physical Controls: The IT hardware used to host protected information is located in a secured NCR server room. The room is only open to authorized personnel whose access is monitored by locking doors with badge readers for both ingress and egress. Each discrete ingress and egress event is logged. The facility is under 24-hour surveillance by facilities security for security and environmental hazards.

Technical Controls: Access to IT hardware and software are restricted to approved IT technical personnel. Access controls lists and event logs are maintained and monitored to detect unauthorized, suspicious or malicious activity. Access lists are restricted to approved IT technical personnel. Two factor authentication are used for access. File integrity and auditing software are employed on hardware.

Administrative Controls: All technical personnel who access IT systems are authorized by NCR management. All personnel have taken mandatory security and privacy training classes and annual refreshers. All personnel must comply with security and privacy policies and/or standard operating procedures.