# US Department of Health and Human Services

## Privacy Impact Assessment

### Date Signed:

12/16/2025

### OPDIV:

NIH

### Name:

NIAID Access Clinical Data Site (NACDS)

**PIA Unique Identifier:**

P-1818829-253925

**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?**

New

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

Yes

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

**Describe the purpose of the system.**

The National Institutes of Infectious Diseases (NIAID) Access Clinical Data Site (NACDS) is a minor child application, secure cloud-based platform designed to facilitate secondary research and the re-use of valuable datasets. Hosted on NIAID's robust cloud infrastructure known as "Monarch Spaces," NACDS provides researchers with access to datasets from NIAID-sponsored clinical trials, including those focused on COVID-19.

The platform is designed to foster collaboration among the basic and clinical research communities. Researchers can request access to these datasets through the NACDS website,
enabling them to conduct further analysis and contribute to ongoing scientific discoveries.

NACDS also serves as a comprehensive resource for researchers by offering a review of available datasets and providing relevant links to published literature and detailed clinical trial information. This integrated approach ensures that researchers have the necessary tools and information to maximize the impact of their secondary research efforts.

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

The NIAID Access Clinical Data Site (NACDS) is a secure, cloud-based platform that collects, maintains, and shares various types of information to facilitate secondary research and the re-use of valuable datasets. Specifically, the system collects clinical trial datasets from NIAID sponsored studies, including those focused on COVID-19. The clinical trial datasets may contain medical notes and subsequent research data, as well as clinical trial researchers' information such as their names, email addresses, phone numbers, medical notes and records numbers that are aligned with institutional affiliations, and research proposals.

The NACDS's databases serve as data repositories for the clinical trial data, as well as the system's audit log repository, which contains the access logs, usage data, and metadata related to the number of downloads for each published literature/clinical trial information accessed by each username/user ID numbers. Additionally, the platform may store communication data from collaboration features like forums or messaging. This integrated approach ensures that researchers have comprehensive resources and tools to maximize the impact of their secondary research efforts.

Users log in to the NACDS application using the NIH Identity, Credential, and Access Management (IAM) Services, which maintains its own unique privacy impact assessment (PIA) on record, including all legal authorities documented. The purpose of IAM Services 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 Services collect unique user credentials and stores them in an encrypted format. The IAM Services are an 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.**

Name
E-Mail Address
Phone Numbers
Medical Records Number
Medical Notes
Usernames
User ID numbers

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

Employees
Public Citizens
Vendor/Suppliers/Contractors
Patients

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

100-499

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

The content of the clinical trial's data files often bear the names of the staff who prepared those documents, reports, filings, etc., which are necessary to provide unaltered clinical trial data for further research purposes.

The user's personally identifiable information (PII) (i.e., the email address, name) is necessary to be entered into the system for audit record and investigation purposes, as the information is matched up to the data access request(s) (DARs).

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

System Administrators will utilize the user's contact information as necessary to complete system use investigations on an as-needed basis.

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

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**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.**

09-25-0156 Records of

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

Directly from an individual about whom the information pertains

Email

Online

Government Sources

Within OpDiv

Other HHS OpDiv

Other Federal Entities

Non-Governmental Sources

Public

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

Since Email is only collected for login, PRA/OMB clearance is not required.

**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.**

In order for users to receive the requested data, they must have an active Data Use Access Request (DAR) approved. These
DARs are active for 1 year, at which time, the access to the data set is closed until another DAR is entered. The information submitted as part of the DAR request process is submitted via another system outside of the NACDS boundary and is not in scope for this PIA.

The need for an Interconnection Security Agreement (ISA)/ Memorandum of Understanding (MOU) is not necessary
as the NACDS and the system where DARs are processed are between NIAID and NIH.

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

Disclosure may be made to HHS contractors and collaborating researchers, organizations, and State and local officials for the purpose of conducting evaluation studies or collecting, aggregating, processing or analyzing records used in evaluation studies. The recipients are required to protect the confidentiality of such records.

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

All individuals who have their data retained the clinical datasets stored within NACDS are aware that the data is privy to be shared in the name of furthering research. They are informed that the information is redacted, not parsed, nor written to the database to be searchable.

**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.**

For all users and clinical personnel who have their information in the clinical datasets housed within NACDS are informed at the start of the process that the clinical datasets are to be shared to further clinical research. Those who do not wish to participate are informed that there is no ability to pull their data out of the research post-publication. These communications occur through other channels not included in NACDS' processes.

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

Each NIH employee is informed of information collection practices upon orientation. Staff may not opt-out of the information collection as it is a condition of employment and used for various valid business purposes by the hospital including preparation of various documents, reports, filings, etc.

Those participating in the clinical trials have consent forms provided to them at the time of their participation. Those forms are handled outside of NACDS.

All users requesting clinical trial data must have an active Data Use Access Request (DAR) approved. These DARs are active for 1 year, at which time, the access to the data set is closed until another DAR is entered. The information submitted as part of the DAR request process is submitted via another system outside of the NACDS boundary and is not in scope for this PIA.

**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.**

A Privacy Rights Complaint Form is available to individuals when they believe that their PII has been inappropriately used or disclosed. The NIH Privacy Office will review the complaint and respond to the concern within 30 business days. Complaints could also be submitted to the System Manager, who would investigate and share findings with the NIAID Information Systems Security Officer (ISSO) and NIH Privacy Officer.

Business Owners and System Owners are the owners of the data within and they are responsible for all communications that would notify the users of any changes to the system and the data therein.

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

PII housed within the NACDS are validated for accuracy prior to be uploaded into the system. Those forms are then retained as part of a historical repository to track the documentation uploaded at a point-in-time and will not be changed post-upload in order to retain the historical entries within the system.

**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.**

Access to information on the system is role-based, with minimum required access assigned based on the user's job responsibilities.

**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.**

The NACDS instance is configured to provide users with defined roles that control the level of permission a user is configured to have.

General users are those who are accessing NACDS to retrieve clinical data associated with their approved DAR. Attempts to access other clinical trial data not associated with their approved DAR will trigger the user to fill out another DAR request for access to that site.

For System Administrators, these users are configured with roles that will allow the user to access only the PII necessary to perform their assigned job responsibility. If the user does not have the role(s) needed to access parts of the system where PII is located, the system will not show them that it exists.

**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 awareness training. Training is completed on the http://irtsectraining.nih.gov site with valid NIH credentials. Administrators and Privileged Users require additional training specific to their roles and responsibilities.

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

All users receive general security and privacy awareness training that is mandatory and recorded, however each Program Manager is responsible for training their users in the system's use beyond basic training requirements.

**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.**

[Disposition Authority Agency DAA-0443-2012-0007-0001] - Cut off annually at termination of project/program or when no longer needed for scientific reference. Transfer to the National Archives in five year blocks when the newest records in the block are 15 years old.

The only PII housed within NACDS audit logs are the user’s first/last names, their usernames, user ID numbers, and email addresses, which are deemed necessary for audit logging / investigatory purposes. These records are created as part of the user identification and authorization process to gain
access to systems. Records are used to monitor inappropriate systems access by users.

Includes records such as user profiles; log-in files; audit trail files and extracts; system usage files; cost-back files used to assess charges for system use Destroy 6 years after password is altered or user account is terminated, but longer retention is authorized if required for business use.

[Disposition Authority: DAA-GRS-2013-0006-0004]
Medical Staff Credentialing Records, participant records are temporary records that can be destroyed 30 years after cutoff, which is one year after the medical staff member leaves patient care. [Disposition Authority: DAA-0443-2012-0007-0011]

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

Administrative: Documented processes have been in place to determine and grant the appropriate

role-access to all data, including PII housed within the system. This access will be reviewed periodically as defined in process documentation to validate the continued access to the systems and the PII.

Technical: Users who have the appropriate role/group permissions have the ability to view PII data, while those that do not have such access cannot view PII. All data is contained to the NACDS system.

Physical Controls: The NACDS system is housed with a virtual machine container as part of the Monarch cloud infrastructure. This infrastructure is housed within Amazon AWS datacenters, which adhere to strict physical controls that no third-party entities, such as NIH personnel, may gain access to the data center without requesting access through AWS Physical Access processes.

**Identify the publicly-available URL:**

https://accessclinicaldata.niaid.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?**

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?**

No