US Department of Health and Human Services

Privacy Impact Assessment

Date Signed:

03/11/2025

OPDIV:

NIH

Name:

NLM Data Center ClinicalTrials.gov

PIA Unique Identifier:

P-2417478-252031

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?

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

Significant System Management Change

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

ClinicalTrials.gov was moved from the National Library of Medicine Data Center General Support System to under the Biomedical and Biological Information System General Support System. The point of contact was also updated.

Describe the purpose of the system.

ClinicalTrials.gov (government) is a web-based resource that provides patients, their family members, health care professionals, researchers, and the public with easy access to information on publicly and privately supported clinical studies on a wide range of diseases and conditions. The website is maintained by the National Library of Medicine (NLM).

The information found on ClinicalTrials.gov is provided and updated by the sponsor or principal investigator of the clinical study. To obtain information, users of the ClinicalTrials.gov public website

enter a query. The request is then processed by the search engine on ClinicalTrials.gov servers and results are returned to the user as a webpage.

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

ClinicalTrials.gov collects information about clinical studies (study purpose, design, eligibility criteria, outcomes), and makes it publicly available to patients, their families, health care professions, researchers, and the public. Summary-level information (not information about individual participants) about the study results by arm or study group (number of participants starting and completing, demographic information, outcomes, and adverse event information) is collected and posted publicly.

The clinical trial registration and results information is submitted through the online Protocol Registration and Results System (PRS) and stored on Agency servers. Organizations that sponsor clinical studies must request an account in the PRS to provide clinical trial information using an application form that collects the following information from the publicly accessible website:

Organization information including type, name, address, abbreviation and acronyms (optional); Parent Organization (if any);

Country;
Official Representative information including phone, email, organization and website (optional), Funding Organization (optional);
Regulatory Authority, and Regulatory Authority Address.

The name, phone number, email address of the individual who is authorized to update and maintain data in the PRS must also be provided, along with the username, password, and organization. Information about these individuals is not posted on the data bank or otherwise made publicly available. Information about the sponsor, title, phone number, email address, and mailing address. The name and title of the sponsor or responsible party is publicly posted, but contact information is not.

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

ClinicalTrials.gov collects information about clinical studies (study purpose, design, eligibility criteria, outcomes), and makes it publicly available to patients, their families, health care professions, researchers, and the public.

Summary-level information (not information about individual participants) about the study results by arm or study group (number of participants starting and completing, demographic information, outcomes, and adverse event information) is collected and posted publicly.

The clinical trial registration and results information is submitted through the PRS and stored on Agency servers. Organizations that sponsor clinical studies must request an account in the PRS to provide clinical trial information using an application form that collects the following information from the publicly accessible website:

Organization Information including Type, name address, Abbreviation and Acronyms (optional);
Parent Organization (if any);
Country;
Official Representative Information including phone, email, organization and website (optional), Funding Organization (optional);
Regulatory Authority and Regulatory Authority Address.

The name, phone number, email address, and mailing address of the individual who is authorized to update and maintain data in the PRS must also be provided, along with the username, password and organization. Information about these individuals is not posted on the data bank or otherwise made publicly available.

Information about the sponsor of the trial must be submitted at the time of trial registration, including the name of the sponsor, title, phone number, email address, and mailing address. The name and title of the sponsor or responsible party is publicly posted, but contact information is not.

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
Organization Information, Country; Official Representative Information.
Username, password and organization of the individual who is authorized to update and maintain data in the PRS.
Sponsor title.

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

Employees
Public Citizens
Business Partner/Contacts (Federal/state/local agencies)
Clinical Study Sponsors/ Responsible Parties

How many individuals' PII is in the system?

100,000-999,999

For what primary purpose is the PII used?

The primary purpose for the use of Personally Identifiable Information (PII) is to provide users with Contact information to respond to requests for information/assistance, provide quality review comments, and to initiate compliance/enforcement actions.

PII is also used to provide functional access via established NIH authentication and authorization protocols.

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

Not applicable.

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

Section 402(i) and 402(j) of the Public Health Service Act.

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

No

Identify the sources of PII in the system.

Directly from an individual about whom the information pertains

Online

Government Sources

Within the OPDIV

Other HHS Operating Divisions

Non-Government Sources

Public

Other

Identify the OMB information collection approval number and expiration date

OMB Control Number: 0925-0586, expires on March 31, 2026.

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.

There is an interconnection security agreement in place between the FDA and ClinicalTrials.gov, which has been in effect since October 17, 2022.

Describe the procedures for accounting for disclosures.

Audit logs are used to disclose what information is shared and tracked between the FDA and NLM.

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 data elements for collected information are posted publicly, unless labeled explicitly as "Will not be made public - for administrative purposes only" in the ClinicalTrials.gov Data Elements Definition documents (Responsible Party Contact Information).

Additionally, submitters are required to review and agree to a code of conduct statement before submitting PII.

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.

Individuals have the option to not enter their PII during the registration process. However, failure to enter PII will result in not being able to register and use ClinicalTrials.gov.

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

PRS account administrators and users are notified of major changes to the PRS through the "What's New in the ClinicalTrials.gov PRS" webpage. They may update or change the PII provided previously when a major change occurs (or at any time for any valid reason).

Note that to date, we have not made any major changes to the PRS that affect disclosure or data uses of PII. However, if modifications were to be made in the future that result in a major change in the disclosure or use of collected PII, in addition to adding information to the "What's New in the ClinicalTrials.gov PRS" webpage we would also be able to notify each PRS account administrator and user by email and provide a way for concerned individuals to contact ClinicalTrials.gov directly.

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.

Individuals who have concerns about the accuracy of the PII can contact ClinicalTrials.gov or revise the information directly through their account.

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

ClinicaTrials.gov data providers are required to review and update submitted information at least once every 12 months in general; more frequently for certain data elements (e.g., Responsible Party Contact Information).

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. 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.

Access to PII is assigned to personnel based upon current 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.

Periodic review of system users' roles are done to assure access is current with user's technical/functional role in administering, developing, and supporting the daily job functions of ClinicalTrials.gov.

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. Training is completed on the http: //irtsectraining.nih.gov site with valid NIH credentials.

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

Those individuals with privileged access accounts are required to complete a role-based training course every year specific to their position and role.

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 01-003 -Records of All Other Intramural Research Projects These records do not meet the retention criteria for Item I-0001

Records of Intramural Research Records or for Projects of Historical Significance, or Item I-0002 - Research Records that Support Intellectual Property Rights. Intramural research records related to planning, development, oversight and execution of biomedical research projects and programs performed by NIH research staff, contractors or under collaborative research and development agreements (CRADAS)
Disposition: 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-0113-2012-0007-0003)

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

Administrative Controls: System users are approved by ClinicalTrial.gov's management for access based on their technical/functional role in administering, developing, and supporting ClinicalTrials.gov' daily job functions, and administrators perform periodic reviews to assure users adhere to system policies.

Technical Controls: Access to the system is controlled by NIH log-in which authenticates the user prior to granting access. Access level and permissions are controlled by the system and based on user, role, organizational unit, and status of the report. All servers have been configured to remove all unused applications and system files and all local account access except when necessary to manage the system and maintain integrity of data.

Physical Controls: The servers reside in the NLM Data Center where policies and procedures are in place to restrict access to the machines. This includes guards at the front door and entrance to the machine room.

Identify the publicly-available URL:

https://clinicaltrials.gov/
https://register.clinicaltrials.gov/
https://prsinfo.clinicaltrials.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?

Yes