US Department of Health and Human Services

Privacy Impact Assessment

Date Signed:

11/21/2025

OPDIV:

NIH

Name:

Cancer Therapy Evaluation System

PIA Unique Identifier:

P-3234659-949854

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?

Yes

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.

PIA Validation

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

Updated Security Authorization date in Q8a.

Describe the purpose of the system.

The mission of the National Cancer Institute's (NCI) Cancer Therapy Evaluation Program (CTEP) is to improve the lives of cancer patients by finding better ways to treat, control and cure cancer. CTEP accomplishes this mission by funding an extensive national program of cancer research and by sponsoring clinical trials to evaluate new anti-cancer agents, with a particular emphasis on translational research to explain molecular targets and mechanisms of drug effects.

The NCI CTEP Enterprise System (CTEP-ESYS) is the repository for the information gathered and shared for these clinical trials.

The purpose of the CTEP-ESYS is to assure patient safety, meet the NCI CTEP scientific,

administrative and operational program mission, and all regulatory requirements for NCI CTEP clinical trials.

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

CTEP-ESYS collects, maintains, and shares administrative/ operational, scientific, safety and regulatory data related to clinical trials. Information is used to assure patient safety; for scientific decision making, study drug management, regulatory oversight; and to facilitate administrative operations.

The information that CTEP-ESYS collects, maintains or shares include investigators and clinical trial support staff information, patient data, protocol documents, clinical trial sites/networks information, disease information and classification, drug inventory, drug orders and drug shipments, safety reports, site audit reports, Investigational New Drug (IND) submission records.

This specifically covers the following:

For Investigators: Name, Email Address, Mailing Address, Phone Numbers and Month/Year of Birth for contact and verification purposes. Employment Status, Employment History, Certificates and Education Records, Publications, to collect, maintain (store), or share. (Subsequent Memberships, Honors, Medical Licenses, Clinical Trial Support questions will identify if this information is PII and ask History and Trainings to enable sponsor to determine that about the specific data elements.) investigators are qualified to participate on a clinical trial per United States Food and Drug Administration Code of Federal Regulations (US FDA CFR).

For Clinical Trial Support Staff: Name, Email Address, Mailing Address, Phone Numbers and Month/Year of Birth for contact and verification purposes.

For Patient Drug Orders: Patient identification (ID) and Patient Initial (two to three characters) are used for patient safety.

Study drug repository prints patient specific study drug labels containing this information. Once study drug is labeled, it is shipped to the clinical network pharmacies where drugs are dispensed/administered to the patients identified on the label. Patient ID and Patient Initials are used as a verification prior to dispensing/administering drug to the patients.

For Patient Safety Reporting: Patient ID and Patient Month/ Year of Birth for adverse event reporting. The sponsor reviews this information in real-time to assure continuing patient safety for each clinical trial and meet US FDA CFR.

Users log in to this system 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 a encrypted format. The IAM Services are 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.

Date of Birth
Name
E-Mail Address
Mailing Address
Phone Numbers
Certificates
Education Records
Employment Status
For Investigators: Employment Status, Employment History, Certificates and Education Records, Publications, Memberships, Honors, Medical Licenses, Clinical Trial Support History and Trainings to enable sponsor to determine that investigators are qualified to participate on a clinical trial per US FDA CFR.
For Investigators and Clinical Trial Support Staff: Name, Email Address, Mailing Address, Phone Numbers and Month/Year of Birth for contact and verification purposes.
For Patient Drug Orders: Patient identification (ID) and Patient Initial (two to three characters) are used for patient safety. Study drug repository prints patient specific study drug labels containing this information. Once study drug is labeled, it is shipped to the clinical network pharmacies where drug is dispensed/administered to the patients identified on the label. Patient ID and Patient Initials are used as a verification prior to dispensing/administering drug to the patients.
For Patient Safety Reporting: Patient ID and Patient Month/Year of Birth for adverse event reporting. The sponsor reviews this information in real-time to assure continuing patient safety for each clinical trial and meet US FDA CFR.
For Demographics Analysis: Patient Zip Code and Patient Date of Birth to be able to answer demographic queries related to NCI/CTEP sponsored trials. Date of birth is only used to calculate exact patient age for demographic analysis. It is not displayed in any reports.

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

Employees
Public Citizens
Business Partner/Contacts (Federal/state/local agencies)
Patients
Investigators and clinical trial support staff at participating institutions.

How many individuals' PII is in the system?

1,000,000 or more

For what primary purpose is the PII used?

The primary purpose of the PII is to support cancer research, clinical trials related activities and meet FDA regulatory requirements.

PII (Name, Email Address, Mailing Address, Phone Numbers and Month/Year of Birth) is collected for investigators and clinical trials support staff participating in the clinical trials for contact and verification purposes, and to communicate with the investigators with respect to clinical research trial activities.

PII (Employment Status, Employment History, Certificates and Education Records, Publications, Memberships, Honors, Medical Licenses, Clinical Trial Support History and Trainings) is collected for investigators participating in the clinical trials to enable sponsor to determine that investigators are qualified to participate on a clinical trial per US FDA CFR.

PII is collected for patients participating in the clinical trials for the following purposes:
(1) Patient Drug Orders: Patient identification (ID) and Patient Initial (two to three characters) are used for patient safety. Study drug repository prints patient specific study drug labels containing this information. Once study drug is labeled, it is shipped to the clinical network pharmacies where drug is dispensed/administered to the patients identified on the label. Patient ID and Patient Initials are used as a verification prior to dispensing/administering drug to the patients.
(2) Patient Safety Reporting: Patient ID and Patient Month/Year of Birth are used for adverse event reporting. The sponsor reviews this information in real-time to assure continuing patient safety for each clinical trial and meet US FDA CFR.
(3) For Demographics Analysis: Patient Zip Code and Patient Date of Birth to be able to answer demographic queries related to NCI/CTEP sponsored trials. Date of birth is only used to calculate exact patient age for demographic analysis. It is not displayed in any reports.

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

None

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

Public Health Service Act. (42 U.S.C. 241, 242, 248, 281, 282, 284, 285a-285q, 287, 287b, 287c, 289a, 289c, and 44 U.S.C. 3101).

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
- Hardcopy
- Online
- Telephone Interview
- Other

Non-Governmental Sources
- Private Sector
- Other

Identify the OMB information collection approval number and expiration date

0925-0753, expiration 5/31/2027

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.

CTEP-ESYS shares PII with the Clinical Trials Support Unit (CTSU), a CTEP/NCI sponsored project to increase participation in NCI sponsored cancer related clinical trials. A Memorandum of Understanding (MOU)/ Interconnection Security Agreement (ISA) is in place with CTSU that establishes procedures and safeguards for the information being shared.

Describe the procedures for accounting for disclosures.

CTEP-ESYS follows HHS/NIH/NCI security policies and procedures. MOU/ISA are maintained in accordance with NCI/NIH/HHS policies and procedures. Access to PII is restricted through authentication, authorization and role-based access. CTEP-ESYS Users go through security awareness trainings and acknowledge warning banners during login. More information on security controls has been provided in response to Q38.

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

Investigators and clinical trial support staff are notified prior to completing their on-line registration process.

Patients are notified as part of the informed consent process prior to participating in a clinical trial.

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.

Investigators and clinical trial support staff may opt out by not registering for the clinical trials.

Participation in the clinical trials by patients is voluntary.

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

Consent is obtained through an annual registration process, which is mandatory for all investigators and clinical trial support staff. These registered users receive system release notes/changes to the system when they are published.

As part of the informed consent process, patients are notified that their data may be used for additional research studies. If changes were to occur to the use of patients PII data other than what was agreed to in the signed informed consent document, the clinical trial sites would be notified so that re-consent can be obtained from the patients.

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.

Investigators and clinical trial support staff may contact CTEP Help Desk via phone or email should they have any questions or concerns about their PII. Patients should follow the contact information in their informed consent documents.

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

Investigators and clinical trial support staff must undergo a mandatory annual re-registration process.

Clinical networks where clinical trials are conducted perform audits to ensure integrity, availability, accuracy and relevancy of patients data. If any issues are found, the clinical networks re-submit data to CTEP-ESYS.

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.

CTEP-ESYS access requests are submitted through an automated system module for approval. All requests are reviewed and validated by the CTEP-ESYS direct contractor who obtains necessary authorizations from CTEP-ESYS system owners or designated officials before approving the access requests.

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.

CTEP-ESYS enforces approved access authorizations through database and application roles, restricting access to those applications that users are authorized to access. Application level data attributes further restrict access to PII.

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.

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

Instructor-led trainings, online documentation or phone trainings are provided to system users as appropriate.

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.

01-0004: FDA Regulated Research Records. Cut off annually after application is approved/disapproved, or if no new application is filed, after the study is completed/discontinued and FDA is notified of discontinuation or when no longer
needed for business and scientific use, whichever is longer. Destroy 3 years after cutoff (DAA-0443-2012-0007-0004).

07-203: System access records. Systems not requiring special accountability for access. Destroy when business use ceases (DAA-GRS-2013-0006-0003).

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

Administrative Controls: CTEP-ESYS maintains Authorization To Operate(ATO). CTEP-ESYS security controls are assessed by an independent auditor annually. Contingency/disaster recovery simulations are conducted. Security vulnerabilities, identified via Infrastructure and Application scans are re-mediated in accordance with NIH 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 Center for Information Technology (CIT) Computer Room 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.
Note: web address is a hyperlink.