Privacy Impact Assessment Form

v 1.43

Status Draft Form Number F-54643 Form Date 9/18/2013 10:56:01 AM

Question Answer

1. OPDIV: TEST
2. PIA Unique Identifier: P-5860043-506903

2a Name: Test 9-18-01

1. The subject of this PIA is which of the following?

3a Identify the Enterprise Performance Lifecycle Phase of the system.

3b Is this a FISMA-Reportable system?

Does the system include a Website or online

General Support System (GSS) Major Application

Minor Application (stand-alone) Minor Application (child) Electronic Information Collection Unknown

Operations and Maintenance

Yes No

Yes

1. application available to and for the use of the general

public? No

1. Identify the operator.

Agency

Contractor

POC Title Head of Clinical and Translational Informatics

1. Point of Contact (POC):

POC Name Jose Galvez, MD POC Organization NCI CBIIT

POC Email jose.galvez@nih.gov

POC Phone 240-276-5206

1. Is this a new or existing system?

New

Existing

1. Does the system have Security Authorization (SA)?

Yes

No

8a Date of Security Authorization 4/10/2014

1. Describe the purpose of the system.

The CTRP Database provides a comprehensive real-time view of the state of NCI-funded cancer clinical trials, which enables NCI to make informed prioritization decisions via disease- specific steering committees. Accordingly, this resource allows the NCI to manage its portfolio of cancer clinical research investments effectively; consolidate and streamline existing reporting to individual programs within the NCI by aggregating the information already collected and eliminating the need for redundant submissions to the NCI; comply with regulatory reporting requirements when acting as the sponsor of FDA-regulated clinical investigations; prepare the detailed performance, financial management and administrative accountability reports required of Executive Branch agencies, including those required by Executive Orders or OMB Circulars, Memoranda and Guidelines; and provide appropriate public access to cancer research information.

Describe the type of information the system will

Information collected includes the trial protocol document, the template informed consent document, and IRB approval documentation, and related protocol/lead organization information including NIH funding information, trial/ organization contact information, trial status information, and IND/IDE information.

Throughout a trial, ongoing trial status information is collected as well as study subject accrual information including demographic data.

1. collect, maintain (store), or share. (Subsequent questions will identify if this information is PII and ask

about the specific data elements.)

Provide an overview of the system and describe the

The Clinical Trials Reporting Program (CTRP) is a web-based program to submit data about cancer-related clinical trials and to search for data concerning cancer-related clinical trials. The CTRP system is an electronic resource that is intended to serve as a single, definitive source of information about all NCI- supported clinical research. Deployment of this resource will allow the NCI to consolidate reporting, aggregate information and reduce redundant submissions. Information will be submitted by clinical research coordinators as designees of clinical investigators who conduct NCI-supported clinical research.

1. information it will collect, maintain (store), or share, either permanently or temporarily.

1. Does the system collect, maintain, use or share **PII**?

Yes No

1. Indicate the type of PII that the system will collect or maintain.

Social Security Number Date of Birth

Name Photographic Identifiers Driver's License Number Biometric Identifiers Mother's Maiden Name Vehicle Identifiers

E-Mail Address Mailing Address

Phone Numbers Medical Records Number

Medical Notes Financial Account Info

Certificates Legal Documents

Education Records Device Identifiers

Military Status Employment Status

Foreign Activities Passport Number Taxpayer ID

Zip code

Gender

Ethnicity

Race

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

Employees Public Citizens

Business Partners/Contacts (Federal, state, local agencies) Vendors/Suppliers/Contractors

Patients

Other

1. How many individuals' PII is in the system? 100,000-999,999
2. For what primary purpose is the PII used?

The information is collected for purposes of portfolio management, compliance with regulatory and administrative reporting obligations and appropriate dissemination of cancer research information to the public.

1. Describe the secondary uses for which the PII will be used (e.g. testing, training or research)

The PII collected is part of a set of study subject information which the NCI will use to determine accrual demographics across the NCI portfolio, helping to ensure equal access to NCI trials.

1. Describe the function of the SSN.

N/A

20a Cite the **legal authority** to use the SSN.

N/A

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

Are records on the system retrieved by one or more

Yes

N/A

1. PII data elements? No

22a

Identify the number and title of the Privacy Act System of Records Notice (SORN) that is being used to cover the system or identify if a SORN is being developed.

Published: Published: Published:

In Progress

Directly from an individual about whom the information pertains

1. Identify the sources of PII in the system.

Government Sources

Non-Government Sources

In-Person Hard Copy: Mail/Fax

Email Online Other

Within the OPDIV Other HHS OPDIV State/Local/Tribal

Foreign Other Federal Entities

Other

Members of the Public

23a Identify the OMB information collection approval number and expiration date.

Commercial Data Broker Public Media/Internet

Private Sector

Other

OMB Approval #: 0925-0600. Expiration Date: 05/31/2016

1. Is the PII shared with other organizations?

Yes No

Within HHS

24a Identify with whom the PII is shared or disclosed and for what purpose.

Only designated, appropriate NCI program and administrative employee and contractor staff will have full access to the data within the CTRP Database for purposes of portfolio management and compliance with regulatory and administrative reporting obligations. Access will be limited to those with a direct need to access the data. Access will be granted to non-Federal staff under a non-disclosure agreement and staff will be given mandatory privacy and security training

Individual submitters to the CTRP Database will have full access to information they have submitted.

Other Federal Agency/Agencies

State or Local Agency/Agencies

Private Sector

N/A

24b

Describe any agreements in place that authorizes the information sharing or disclosure (e.g. Computer Matching Agreement, Memorandum of Understanding (MOU), or Information Sharing Agreement (ISA)).

24c

Describe the procedures for accounting for disclosures

Describe the process in place to notify individuals

Study Subject PII is collected from the Principal Investigator or Study Coordinator, and not supplied directly by the study subject. The Principal Investigator and/or Study Coordinator are notified by posted notices on the website.

NCI will post written notices on the web site portal for the CTRP system to inform clinical investigators/research coordinators of:

1. major changes that occur to the CTRP system that affect disclosure and/or uses of PII in the CTRP system;
2. changes in the type of PII to be collected from study subjects; and
3. any changes to how PII is used or shared (from current practice of making PII collected from study subjects available only to designated, appropriate NCI employee and contractor staff on a “need to know” basis for purposes of portfolio management and compliance with regulatory and administrative reporting obligations).
4. that their personal information will be collected. If no prior notice is given, explain the reason.
5. Is the submission of PII by individuals voluntary or mandatory?

Describe the method for individuals to opt-out of the

1. collection or use of their PII. If there is no option to object to the information collection, provide a

reason.

Voluntary Mandatory

PII is not collected directly from individuals, but from the Principal Investigator or Study Coordinator. The information required from the individual is agreed upon during the Informed Consent process of enrollment.

Describe the process to notify and obtain consent from the individuals whose PII is in the system when major changes occur to the system (e.g., disclosure

1. and/or data uses have changed since the notice at the time of original collection). Alternatively, describe why they cannot be notified or have their consent obtained.

Describe the process in place to resolve an individual's concerns when they believe their PII has

1. been inappropriately obtained, used, or disclosed, or that the PII is inaccurate. If no process exists, explain why not.

Describe the process in place for periodic reviews of

1. PII contained in the system to ensure the data's integrity, availability, accuracy and relevancy. If no

processes are in place, explain why not.

NCI has no means to identify or contact the individuals whose PII is in the system. The Principal Investigator and/or Study Coordinator would be notified via the CTRP website and could contact the individuals.

If individuals believe their PII has been inappropriately obtained, used or disclosed, they can file a complaint to the Office of Civil Rights (OCR) within 180 days of the alleged violation. This complaint must be in writing and submitted either by e-mail, postal mail, or fax.

The system owner checks the PII in the system. The agency will request annual self-assessment to ensure confidentiality, integrity, and availability.

Personally identifiable information will be made available to designated, appropriate NCI employee and contractor staff for purposes of

1. Identify who will have access to the PII in the system and the reason why they require access.

Users

portfolio management and compliance with regulatory and administrative reporting obligations. Individual submitters will have full access to information they have submitted.

Administrators System Administration

Developers

Contractors

Perform services as required, primarily management of submitted data by clinical protocol abstraction staff

Others

Describe the procedures in place to determine which

Access will be limited to those with a direct need to access the data. Access will be granted to non-Federal staff under a non- disclosure agreement and staff will be given mandatory privacy and security training.

1. system users (administrators, developers, contractors, etc.) may access PII.

Describe the methods in place to allow those with

Level of access to PII will depend on role and users will be required to undergo training for the role responsibility. System audit logs will facilitate accountability enforcement for user transactions.

1. access to PII to only access the minimum amount of information necessary to perform their job.

Identify training and awareness provided to personnel (system owners, managers, operators,

1. contractors and/or program managers) using the system to make them aware of their responsibilities

for protecting the information being collected and maintained.

Describe training system users receive (above and

1. beyond general security and privacy awareness training).

All personnel take mandatory NIH IT Security Training to ensure they are aware of their responsibility for protecting the information collected.

N/A

Do contracts include Federal Acquisition Regulation

1. and other appropriate clauses ensuring adherence to privacy provisions and practices?

Describe the process and guidelines in place with

National Institutes of Health, NIH System Life Cycle requirements require destruction of PII upon the termination of the system.

1. regard to the retention and destruction of PII. Cite specific records retention schedules.

Yes No

Describe, briefly but with specificity, how the PII will

The PII will be secured by management, operational, and technical controls. Some of these controls include user identification and authentication, the concept of least privilege, and firewalls. Infrastructure product, username and password, annual risk assessments, background checks on administrative employees, key locks and keycards necessary to enter server rooms.

1. be secured in the system using administrative, technical, and physical controls.
2. Identify the publicly-available URL:

[http://trials.nci.nih.gov](http://trials.nci.nih.gov/)

1. Does the website have a posted privacy notice?

Is the privacy policy available in a machine-readable

Yes No

Yes

40a

41

format?

Does the website use web measurement and customization technology?

No Yes No

Technologies Collects PII?

Yes

41a

Select the type of website measurement and customization technologies is in use and if it is used to collect PII. (Select all that apply)

Web beacons

Web bugs Session Cookies

Persistent Cookies

Other...

No Yes No Yes No Yes No Yes No

1. Does the website have any information or pages directed at children under the age of thirteen?
2. Does the website contain links to non- federal government websites external to HHS?

Yes No

Yes No

**REVIEWER QUESTIONS:** The following section contains Reviewer Questions which are not to be filled out unless the user is an OPDIV Senior Officer for Privacy.

Reviewer Questions Answer

Yes

1 Are the questions on the PIA answered correctly, accurately, and completely?

No

*Reviewer*

*Notes*

Reviewer Questions Answer

2

*Reviewer*

*Notes*

3

*Reviewer*

*Notes*

Does the PIA appropriately communicate the purpose of PII in the system and is the purpose justified by appropriate legal authorities?

Do system owners demonstrate appropriate understanding of the impact of the PII in the system and provide sufficient oversight to employees and contractors?

Yes No

Yes No

Yes

1. Does the PIA appropriately describe the PII quality and integrity of the data?

*Reviewer*

*Notes*

1. Is this a candidate for PII minimization?

*Reviewer*

*Notes*

1. Does the PIA accurately identify data retention procedures and records retention schedules?

*Reviewer*

*Notes*

1. Are the individuals whose PII is in the system provided appropriate participation?

*Reviewer*

*Notes*

1. Does the PIA raise any concerns about the security of the PII?

*Reviewer*

*Notes*

No

Yes No

Yes No

Yes No

Yes No

9

*Reviewer*

*Notes*

Is applicability of the Privacy Act captured correctly and is a SORN published or does it need to be?

Yes No

Yes

1. Is the PII appropriately limited for use internally and with third parties?

*Reviewer*

*Notes*

1. Does the PIA demonstrate compliance with all Web privacy requirements?

*Reviewer*

*Notes*

No

Yes No

HHS Senior Agency Official for Privacy

OPDIV Senior Official for Privacy Signature

General Comments

*Reviewer*

*Notes*

Yes

No

Were any changes made to the system because of the completion of this PIA?

12

Answer

Reviewer Questions