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Privacy Impact Assessment Form

v 1.43

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	Question	Answer
1	OPDIV:	TEST
2	PIA Unique Identifier:	P-5860043-506903
2a	Name:	Test 9-18-01
3	The subject of this PIA is which of the following?	○ General Support System (GSS) ○ Major Application ○ Minor Application (stand-alone) ● Minor Application (child) ○ Electronic Information Collection ○ Unknown
3a	Identify the Enterprise Performance Lifecycle Phase of the system.	Operations and Maintenance
3b	Is this a FISMA-Reportable system?	○ Yes ● No
4	Does the system include a Website or online application available to and for the use of the general public?	● Yes ○ No
5	Identify the operator.	● Agency ○ Contractor
6	Point of Contact (POC):	POC Title: Head of Clinical and Translational Informatics POC Name: Jose Galvez, MD POC Organization: NCI CBIIT POC Email: jose.galvez@nih.gov POC Phone: 240-276-5206
7	Is this a new or existing system?	○ New ● Existing
8	Does the system have Security Authorization (SA)?	○ Yes ○ No
8a	Date of Security Authorization	4/10/2014

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11	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.
12	Describe the type of information the system will collect, maintain (store), or share. (Subsequent questions will identify if this information is PII and ask about the specific data elements.)	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.
13	Provide an overview of the system and describe the information it will collect, maintain (store), or share, either permanently or temporarily.	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.
14	Does the system collect, maintain, use or share **PII**?	◉ Yes ○ No

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15 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

16 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

17 How many individuals' PII is in the system?

100,000-999,999

18 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.

19 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.

20 Describe the function of the SSN.

N/A

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

N/A

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

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

- ( ) Yes
- (•) No

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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

23 Identify the sources of PII in the system.

Directly from an individual about whom the information pertains

☐ In-Person
☐ Hard Copy: Mail/Fax
☐ Email
☐ Online
☐ Other

Government Sources

☐ Within the OPDIV
☐ Other HHS OPDIV
☐ State/Local/Tribal
☐ Foreign

Non-Government Sources

☐ Other Federal Entities
☐ Other
☐ Members of the Public
☐ Commercial Data Broker
☐ Public Media/Internet
☐ Private Sector
◉ Other

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

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

24 Is the PII shared with other organizations?

○ Yes
○ No

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24a	Identify with whom the PII is shared or disclosed and for what purpose.	☐ Within HHS 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
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)).	N/A
24c	Describe the procedures for accounting for disclosures	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).
25	Describe the process in place to notify individuals that their personal information will be collected. If no prior notice is given, explain the reason.	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
26	Is the submission of PII by individuals voluntary or mandatory?	○ Voluntary ◉ Mandatory
27	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.	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.

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28	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 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.	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.
29	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. If no process exists, explain why not.	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.
30	Describe the process in place for periodic reviews of PII contained in the system to ensure the data's integrity, availability, accuracy and relevancy. If no processes are in place, explain why not.	The system owner checks the PII in the system. The agency will request annual self-assessment to ensure confidentiality, integrity, and availability.
31	Identify who will have access to the PII in the system and the reason why they require access.	☐ Users — Personally identifiable information will be made available to designated, appropriate NCI employee and contractor staff for purposes of 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
32	Describe the procedures in place to determine which system users (administrators, developers, contractors, etc.) may access PII.	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.
33	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.	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.
34	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.	All personnel take mandatory NIH IT Security Training to ensure they are aware of their responsibility for protecting the information collected.
35	Describe training system users receive (above and beyond general security and privacy awareness training).	N/A

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36	Do contracts include Federal Acquisition Regulation and other appropriate clauses ensuring adherence to privacy provisions and practices?	Yes / No
37	Describe the process and guidelines in place with regard to the retention and destruction of PII. Cite specific records retention schedules.	National Institutes of Health, NIH System Life Cycle requirements require destruction of PII upon the termination of the system.
38	Describe, briefly but with specificity, how the PII will be secured in the system using administrative, technical, and physical controls.	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.
39	Identify the publicly-available URL:	http://trials.nci.nih.gov
40	Does the website have a posted privacy notice?	Yes / No
40a	Is the privacy policy available in a machine-readable format?	Yes / No
41	Does the website use web measurement and customization technology?	Yes / No
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)	Technologies — Collects PII? ☐ Web beacons — Yes / No ☐ Web bugs — Yes / No ☐ Session Cookies — Yes / No Persistent Cookies — Yes / No Other... — Yes / No
42	Does the website have any information or pages directed at children under the age of thirteen?	Yes / No
43	Does the website contain links to non-federal government websites external to HHS?	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
1	Are the questions on the PIA answered correctly, accurately, and completely?	Yes

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No

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	Reviewer Questions	Answer
	Reviewer Notes	
2	Does the PIA appropriately communicate the purpose of PII in the system and is the purpose justified by appropriate legal authorities?	Yes No
	Reviewer Notes	
3	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
	Reviewer Notes	
4	Does the PIA appropriately describe the PII quality and integrity of the data?	Yes No
	Reviewer Notes	
5	Is this a candidate for PII minimization?	Yes No
	Reviewer Notes	
6	Does the PIA accurately identify data retention procedures and records retention schedules?	Yes No
	Reviewer Notes	
7	Are the individuals whose PII is in the system provided appropriate participation?	Yes No
	Reviewer Notes	
8	Does the PIA raise any concerns about the security of the PII?	Yes No
	Reviewer Notes	
9	Is applicability of the Privacy Act captured correctly and is a SORN published or does it need to be?	Yes No
	Reviewer Notes	
10	Is the PII appropriately limited for use internally and with third parties?	Yes No
	Reviewer Notes	
11	Does the PIA demonstrate compliance with all Web privacy requirements?	Yes No
	Reviewer Notes	

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	Reviewer Questions	Answer
12	Were any changes made to the system because of the completion of this PIA?	○ Yes ○ No
Reviewer Notes		
General Comments		
OPDIV Senior Official for Privacy Signature		HHS Senior Agency Official for Privacy