Privacy Impact Assessment Form

v 1.47.4

Status		Form Number		Form Date	

	Question	Answer
1	OPDIV:	NIH
2	PIA Unique Identifier:	
2a	Name:	NIH Office of Clinical Research (OCR) Clinical Research Training Application

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.	Development
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	◉ Accept ○ Reject
5	Identify the operator.	◉ Agency ○ Contractor	

6	Point of Contact (POC):	POC Title — Medical Officer POC Name — Anne Zajicek POC Organization — Office of the Director (OD) Office of Clinical Research (OCR) POC Email — zajiceka@mail.nih.gov POC Phone — 301-480-9913	◉ Accept ○ Reject

7	Is this a new or existing system?	◉ New ○ Existing
8	Does the system have Security Authorization (SA)?	○ ◉	◉ ○
		☐ Yes ... No	Accept Reject

8b Planned Date of Security   Authorization

September 1, 2019

Not Applicable

11	Describe the purpose of the system.	The purpose of the system is to provide a redesigned and modernized version of the existing NIH Clinical Research Training Application. This application is a Learning Management system built leveraging Drupal Key features which include: - Administrative ability to create and manage courses - Course registration for NIH and non-NIH (public) users - Access to course materials for registered users - Taking an exam and earning a certificate upon achieving a predetermined passing grade - Course and lecture evaluation - Discussion boards, calendars, and dashboards for each course created - Reporting features for user and usage statistics	⦿ Accept 　Reject
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.)	Users are required to create an account with a login ID and password to log into the system. Registration is then required to access course materials. The registration form collects the following information:	⦿ Accept 〇 Reject
13	Provide an overview of the system and describe the information it will collect, maintain (store), or share, either permanently or temporarily.	The information listed in Question 12 is collected and stored temporarily to provide login accounts for students taking courses within the system and to allow the OCR administrative 　　　　　⦿	⦿ Accept 〇 Reject ⦿
14	Does the system collect, maintain, use or share **PII**?	Yes 〇 No	Accept Reject
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 Degree ORCiD State/Territory Country Affiliation (NIH/Non-NIH, I/C, Institute/Company/ Organization, Department)	⦿ 〇 Accept Reject

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 [ ]	◉ Accept ○ Reject
17	How many individuals' PII is in the system?	5,000-9,999	◉ Accept ○ Reject
18	For what primary purpose is the PII used?	To provide identification for login accounts, emailing notifications, and placing students' names on passing exam certificates.	◉ Accept ○ Reject
19	Describe the secondary uses for which the PII will be used (e.g. testing, training or research)	To allow the OCR administrative team to analyze and report demographic data and statistics for all course students to provide metrics and help improve future course offerings, for use within OCR.	◉ Accept ○ Reject
20	Describe the function of the SSN.	N/A - SSN is not collected.	◉ Accept ○ Reject
20a	Cite the **legal authority** to use the SSN.	N/A - SSN is not collected.	
21	Identify **legal authorities** governing information use and disclosure specific to the system and program.	Privacy Act of 1974, as amended (5 U.S.C. Section 552a)	◉ Accept ○ Reject
22	Are records on the system retrieved by one or more PII data elements?	○ Yes ◉ No	◉ Accept ○ Reject

| 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 ☐
Other Federal Entities
☒
Other Non-Government Sources
Members of the Public ☐   Commercial
Data Broker ☐   Public
Media/Internet
☐   Private Sector
☐   Other | ◉ Accept
○ Reject |

23a	Identify the OMB information collection approval number and expiration date.	OMB Number 0925-XXXX Application for new OMB Number under review and to be received by October 15, 2019.	
24	Is the PII shared with other organizations?	○ Yes ◉ No	◉ Accept Reject
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.	The following OMB notice is placed at the top of the course registration form: OMB Notice Form approved | OMB Number 0925-XXXX | Expiration Date XX/XX/XX Public reporting burden for this collection of information is estimated to average (10) minutes per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to: NIH, Project Clearance Branch, 6705 Rockledge Drive, MSC 7974, Bethesda, MD 20892-7974, ATTN: PRA (0925-xxxx). Do not return the completed form to this address.	◉ Accept ○ Reject
26	Is the submission of PII by individuals voluntary or mandatory?	○ Voluntary ◉ Mandatory	◉ Accept ○ Reject
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.	Basic information is needed to create a login account for the system: First Name, Last Name, Email Address, and Username.	◉ Accept Reject
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.	If notification is required, individuals can be notified via email.	◉ Accept Reject
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.	Individuals may send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to: NIH, Project Clearance Branch, 6705 Rockledge Drive, MSC 7974, Bethesda, MD 20892-7974, ATTN: PRA (0925-xxxx). Do not return completed form to this address.	◉ Accept ○ Reject ◉
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.	A process will be in place for OCR administration to monitor the data collection annually.	Accept Reject

#	Question	Response	Accept/Reject
31	Identify who will have access to the PII in the system and the reason why they require access.	☐ Users — ☒ Administrators — Troubleshoot access issues; metrics reporting ☒ Developers — Troubleshoot access and system issues ☒ Contractors — Troubleshoot access and system issues (the development team consists of contractors) ☐ Others —	⦿ Accept ◯ Reject
32	Describe the procedures in place to determine which system users (administrators, developers, and contractors, etc.) may access PII. Services	The procedure to determine which system users may access PII is granted through a request to the system owner, along with a proper reason for needing access to the PII. NIH login is required. Following login, the system user's privileges are verified through the use of the NIH Identity, Credential, Access Management Services: Identity Management (IMS), formally known as the Active Directory (AD), and has its own approved PIA on record, including all legal authorities documented.	⦿ Accept ◯ Reject
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.	The procedure to determine which system users may access PII is granted through a request to the system owner, along with a proper reason for needing access to the PII. NIH login is required. Following login, the system user's privileges are verified through the use of the NIH Identity, Credential, and Access Management Services: Identity Management Services (IMS), formally known as the Active Directory (AD), and has its own approved PIA on record, including all legal authorities documented.	⦿ ◯ Accept Reject
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.	The NIH Security Awareness Training course is used to satisfy this requirement. According to NIH policy, all personnel who use NIH applications must attend security awareness training every year. There are four categories of mandatory IT training (Information Security, Counterintelligence, Privacy Awareness, and Records Management). Training is completed on the http://irtsectraining.nih.gov site with valid NIH credentials. All NIH personnel, contract personnel, and non-NIH users with authorized access to NIH-owned information system resources are required to complete NIH's on-line security awareness training course. Procedures, deadlines, and instructions are found within the NIH Security Awareness and Training policy document.	⦿ ◯ Accept Reject
35	Describe training system users receive (above and beyond general security and privacy awareness training).	Administrative users are provided training in the form of standard operating procedures. These trainings cover navigating the system, Shopping cart workflows and how to review and process publication orders.	⦿ Accept ◯ Reject
36	Do contracts include Federal Acquisition Regulation and other appropriate clauses ensuring adherence to privacy provisions and practices?	◯ Yes ◯ No	Accept Reject

37	Describe the process and guidelines in place with regard to the retention and destruction of PII. Cite specific records retention schedules.	6.5 Public Customer Service Records This schedule covers records an agency creates or receives while providing customer service to the public. Federal agencies that provide direct services to the public operate customer call centers or service centers to assist external customers. They may provide customer support through telephone discussions (toll free numbers), dialogue (via chat), and email. Item 020: Customer/client records. Distribution lists used by an agency to deliver specific goods or services. Records include: • contact information for customers or clients • subscription databases for distributing information such as publications and data sets produced by the agency • files and databases related to constituent and community outreach or relations • sign-up, request, and opt-out forms Record Type: Temporary Disposition Instructions: Delete when superseded, obsolete, or when customer requests the agency to remove the records. Disposition Authority: DAA-GRS-2017-0002-0002	⊙ Accept ○ Reject
38	Describe, briefly but with specificity, how the PII will based on be secured in the system using administrative, report. All technical, and physical controls.	Administrative Controls: Access requests are managed, validated, and audited by the OCR Support Team and scheduled audits are performed to ensure accounts are validated and/or revoked if needed. Access Disclosure Agreements are required for all users. 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 user, role, organizational unit, and status of the 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.	⊙ Accept ○ Reject ⊙
39	Identify the publicly-available URL:	ocrtraining.cit.nih.gov (expected URL; pending configuration of production site)	⊙ Accept Reject
40	Does the website have a posted privacy notice?	⊙ Yes ○ No	Accept Reject
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	◉ Accept ○ Reject

		Technologies	Collects PII?	
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	○ Yes ○ No	
		☐ Web bugs	○ Yes ○ No	
		☒ Session	○ Yes ◉ No	
		☒ Cookies	○ Yes ◉ No	
		Persistent Cookies	○ Yes ○ No	
		Other...		◉

42	Does the website have any information or pages directed at children under the age of thirteen?	◉ ○ ◉ Yes No	○ Accept ◉ Reject
43	Does the website contain links to non- federal government websites external to HHS?	◉ Yes ○ No	Accept ○ Reject
43a	Is a disclaimer notice provided to users that follow external links to websites not owned or operated by 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
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#	Question	Answer	Decision
1	Are the questions on the PIA answered correctly, accurately, and completely?	Yes / No	Accept ◉ Reject
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	Accept ◉ Reject
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	Accept ◉ Reject
Reviewer Notes			
4	Does the PIA appropriately describe the PII quality and integrity of the data?	Yes / No	Accept ◉ Reject
Reviewer Notes			
5	Is this a candidate for PII minimization?	Yes / No	Accept ◉ Reject
Reviewer Notes			
6	Does the PIA accurately identify data retention procedures and records retention schedules?	Yes / No	Accept ◉ Reject
Reviewer Notes			

	Reviewer Questions	Answer
7	Are the individuals whose PII is in the system provided appropriate participation?	○ Yes ● Accept ○ No ○ Reject
Reviewer Notes		
8	Does the PIA raise any concerns about the security of the PII?	○ Yes ● Accept ○ No ○ Reject
Reviewer Notes		
9	Is applicability of the Privacy Act captured correctly and is a SORN published or does it need to be?	○ ● ○ Yes ○ Accept No Reject
Reviewer Notes		
10	Is the PII appropriately limited for use internally and with third parties?	○ ● ○ Yes ○ Accept No Reject
Reviewer Notes		
11	Does the PIA demonstrate compliance with all Web privacy requirements?	○ ● ○ Yes ○ Accept No Reject
Reviewer Notes		
12	Were any changes made to the system because of the completion of this PIA?	○ ● ○ Yes ○ Accept No Reject
Reviewer Notes		
General Comments		

OPDIV Senior Official for Privacy Signature	HHS Senior Agency Official for Privacy

Third-Party Website Assessment PIA Form

v 1.47.4

Status	Form Number	Read Only	Form Date	Read Only

	Question	Answer
1	OPDIV:	Read Only - OPDIV
2	TPWA Unique Identifier (UID):	Read Only - TPWA UID

3	TPWA Name: Name	Read Only - TPWA	
4	Is this a new TPWA?	Yes No	
4a	Please provide the reason for revision		
5	Will the use of a third-party Website or application create a new or modify an existing HHS/OPDIV System of Records Notice (SORN) under the Privacy Act?	Yes No	Accept Reject
5a	Indicate the SORN number (or identify plans to put one in place.)	SORN Number: If not published:	
6	Will the use of a third-party Website or application create an information collection subject to OMB clearance under the Paperwork Reduction Act (PRA)?	Yes No OMB Approval Number Expiration Date	Accept Reject
6a	Indicate the OMB approval number and approval number expiration date (or describe the plans to obtain OMB clearance.)	Explanation Yes No	Accept Reject
7	Does the third-party Website or application contain Federal Records?		
8	Point of Contact (POC):	POC Title POC Name POC Organization POC Email POC Phone	Accept Reject
9	Describe the specific purpose for the OPDIV use of the third-party Website or application:		Accept Reject
10	Have the third-party privacy policies been reviewed to evaluate any risks and to determine whether the Website or application is appropriate for OPDIV use?	Yes No	Accept Reject
11	Describe alternative means by which the public can obtain comparable information or services if they choose not to use the third-party Website or application:		Accept Reject
12	Does the third-party Website or application have appropriate branding to distinguish the OPDIV activities from those of nongovernmental actors?	Yes No	Accept Reject
13	How does the public navigate to the third party Website or application from the OPIDIV?		

13a	Please describe how the public navigate to the third- party website or application:

13b	If the public navigate to the third-party website or application via an external hyperlink, is there an alert to notify the public that they are being directed to a nongovernmental Website?	○ Yes ○ No	
14	Has the OPDIV Privacy Policy been updated to describe the use of a third-party Website or application?	○ Yes ○ No	⦿ Accept ○ Reject
14a	Provide a hyperlink to the OPDIV Privacy Policy:		
15	Is an OPDIV Privacy Notice posted on the third-party Website or application?	○ Yes ○ No	⦿ Accept ○ Reject
15a	Confirm that the Privacy Notice contains all of the following elements: (i) An explanation that the Website or application is not government-owned or government-operated; (ii) An indication of whether and how the OPDIV will maintain, use, or share PII that becomes available; (iii) An explanation that by using the third-party Website or application to communicate with the OPDIV, individuals may be providing nongovernmental third-parties with access to PII; (iv) A link to the official OPDIV Website; and (v) A link to the OPDIV Privacy Policy	○ Yes ○ No	
15b	Is the OPDIV's Privacy Notice prominently displayed at all locations on the third-party Website or application where the public might make PII available?	○ Yes ○ No	⦿
16	Is PII collected by the OPDIV from the third-party Website or application?	○ Yes ○ No	Accept ⦿ Reject ○
17	Will the third-party Website or application make PII available to the OPDIV?	○ Yes ○ No	Accept ○ Reject ○ ⦿
18	Describe the PII that will be collected by the OPDIV from the third-party Website or application and/or the PII which the public could make available to the OPDIV through the use of the third-party Website or application and the intended or expected use of the PII:		Accept ○ Reject ⦿
19	Describe the type of PII from the third-party Website or application that will be shared, with whom the PII will be shared, and the purpose of the information sharing:		Accept ○ Reject
19a	If PII is shared, how are the risks of sharing PII mitigated?		⦿
20	Will the PII from the third-party Website or application be maintained by the OPDIV?	○ Yes ○ No	Accept ○ Reject
20a	If PII will be maintained, indicate how long the PII will be maintained:		⦿
21	Describe how PII that is used or maintained will be secured:		Accept ○ Reject

22	What other privacy risks exist and how will they be mitigated?		○ Accept
			○ Reject

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 responses accurate and complete?	○ Yes ○ No	◉ Accept ○ Reject
Reviewer Notes			
2	Is the TPWA compliant with all M-10-23 requirements, including appropriate branding and alerts?	○ Yes ○ No	◉ Accept ○ Reject
Reviewer Notes			
3	Has the OPDIV posted an updated privacy notice on the TPWA and does it contain the five required elements?	○ Yes ○ No	◉ Accept ○ Reject
Reviewer Notes			
4	Does the PIA clearly identify PII made available and/or collected by the TPWA?	○ Yes ○ No	◉ Accept ○ Reject
Reviewer Notes			
5	Is the handling of PII appropriate?	○ Yes ○ No	◉ Accept ○ Reject
Reviewer Notes			
General Comments			
OPDIV Senior Official for Privacy Signature		HHS Senior Agency Official for Privacy	