US Department of Health and Human Services

Privacy Impact Assessment

Date Signed:

09/29/2016

OPDIV:

FDA

Name:

FDA CDER Continuing Education

PIA Unique Identifier:

P-2888574-905507

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?

Yes

Identify the operator.

Contractor

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

New PIA

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

Not Applicable (N/A).

Describe the purpose of the system.

The Continuing Education/Oak Ridge Institute for Science and Education (CE-ORISE) system supports the work of FDA's Continuing Education (CE) Program, which provides continuing educational activities for FDA employees that are physicians, pharmacists, nurses, and clinical and non-clinical scientists.

The CE-ORISE system permits individuals to apply for continuing education approval for their educational activities by providing necessary information. It also maintains a record of continuing education activities approved for continuing education credit, and provides evidence that specific individuals have earned continuing education credits.

This system automates manual processes and eliminates the need for double entry when using online forms thereby reducing errors and improving data accuracy. It permits online document management; integrates business processes with existing e-mail systems; and provides automatic notifications to individuals regarding upcoming continuing education opportunities. The system also provides continuing education developers and participants a tool that allows them to view the status of their individual profiles and/or projects (although individuals who are the subjects of the records do not have direct or "write" access to their records).

Alternatively, the use of paper-based systems to track continuing education results in inefficiencies involving transcription errors, missing documents, and missed deadlines. Automating these processes has increased staff productivity by automating reports that were formerly generated manually and providing new reporting capabilities. The office also uses the system to generate and track Statements of Credit (for continuing education only). Although only staff with CE-ORISE administrative privileges can use the system to record and report continuing education credits, data subjects may request copies of their transcripts, and these are made available to these individuals in an appropriate format (e.g., a Word document or PDF).

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

The system will collect individuals' names and contact information such as addresses, e-mails, telephone numbers, and educational records. Individuals provide this information to a system administrator by phone or e-mail; administrators are the only parties with direct access to the system, and who can open accounts or enter information about continuing education activities scheduled or completed. No personal identification numbers will be required such as the Social Security number (SSN), passport number, or driver's license number.

Individuals with records in the system cannot alter their accounts directly. They must submit continuing education information to an administrator, who can enter the data or send certificates. Individuals can receive their records from the system on request, but personally identifiable information (PII) will not be available for public viewing through the system, even by the individual data subjects themselves.

Administrators retrieve system records by PII (name of the subject employee) and send the records to the individual.

The system holds authentication and access control information for system operation personnel (permanent and contract employees), i.e., administrators have a login identification name (created by the administrator) and password (initially created by the administrator but changed by the user after first use).

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

The CE Program provides continuing educational activities for FDA employees who are physicians, pharmacists, nurses, and clinical and non-clinical scientists by tracking the availability of training activities and assisting individuals with registering for these activities. The CE-ORISE system will: Increase efficiency by allowing administrators to create accounts on behalf of individuals; automate manual processes for recording and updating completion of continuing education classes or activities; eliminate the need for double-entry by using online forms (available to administrators only, not the data subjects); provide online document management; integrate with current e-mail systems; and provide automatic notifications of upcoming continuing education events. Training is not delivered through this system itself. The system just records information about completed training.

The system is maintained under contract with Swift Software of Frederick, Maryland.

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

Education Records

Educational records are limited to the information concerning continuing education activities planned

Note that individuals are expected to provide professional contact information (work e-mail, work phone), but may choose to provide home contact information instead or in addition.
Access credentials (user name and user created password)

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

Employees

Vendor/Suppliers/Contractors

Some administrator activities may be conducted by contract employees.

How many individuals' PII is in the system?

100-499

For what primary purpose is the PII used?

The primary purpose for the PII is to create accounts, maintain records of continuing education activities planned or completed, and to issue certificates.

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.

FDA conducts training as required under 21 U.S.C. §379l(a), which states, "In general... The Secretary shall conduct training and education programs for the employees of the Food and Drug Administration relating to the regulatory responsibilities and policies established by this chapter, including programs for scientific training; training to improve the skill of officers and employees authorized to conduct inspections under section 374 of this title; training to achieve product specialization in such inspections; and training in administrative process and procedure and integrity issues."

This system does not itself provide training. It assists in connecting FDA staff with training opportunities, and further assists staff in applying that training to maintaining credentials and qualifications relevant to FDA purposes. The system gathers the minimum amount of PII necessary to conduct these activities.

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.

09-90-0018, Personnel Records in Operating Offices, HHS/OS/ASPER.

Identify the sources of PII in the system.

Email

Online

Government Sources

Within OpDiv

Non-Governmental Sources

Private Sector

Identify the OMB information collection approval number and expiration date

Not Applicable.

Is the PII shared with other organizations?

No

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

Records subjects (i.e., those whose records of continuing education activities are contained in the system but who do not have system access) are aware that this information is being collected because they voluntarily supply the information to system users. Those who have direct access to the system (i.e., staff from FDA's continuing education program who operate and administer the system) are aware of the collection of the information needed to permit access because they supply that PII themselves. When an account is created for one of these users, they will be asked to provide information, mainly name and contact information.

This system does not require data subjects to complete paper forms, electronic forms or online submission (web page) processes. Administrators only use electronic forms to prepare the information for entry. If CDER uses any of these methods of data collection in the future, CDER will provide Privacy Act Notice statements on the form and/or web page.

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.

Use of the system is not mandatory, but is necessary to supply individuals with certificates used as evidence of having completed continuing education activities. Certificates are sent to them via e-mail. Only FDA staff involved in planning log into the system.

If records subjects have questions they can contact the same system administrators to whom they provide continuing education information. Administrators have access to the vendor's help desk, which provides support 24 hours per day, seven days per week. Non-emergency requests are addressed between 10AM to 8PM (EST).

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

No such major changes are anticipated, but users and records subjects could be informed through notices on the landing page, through e-mail, or through other FDA communications channels. They could also view FDA's web site and privacy policies permanently available on FDA.gov.

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 records subjects have questions or concerns they can contact the same system administrators to whom they provide continuing education information. Administrators have access to the vendor's help desk, which provides support 24 hours per day, seven days per week. Non-emergency requests are address between 10AM to 8PM (EST).

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

Data accuracy is the responsibility of individual data subjects, who can contact a system administrator if they detect a discrepancy or inaccuracy. Given the relatively low sensitivity of the data, no periodic reviews of records are planned, although random reviews of user accounts may be conducted. However, system administrators are aware of records retention requirements, and will implement a process of identifying unused accounts that are scheduled for disposal, and dispose of these as is appropriate.

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

Users:

The "users" of the system are Administrators who view and edit profiles and run reports.

Administrators:

All users have the same access type, and are in effect co-administrators who have read/write/delete access to all records. This is necessary for the business process the system supports.

Developers:

Will have access during the design phase only, then no further access after the implementation phase.

Contractors:

Hosting program site

Others:

Subjects of the data records may receive outputs of their own records on request but do not have direct access to the system.

Describe the procedures in place to determine which system users (administrators, developers, contractors, etc.) may access PII.

Access is restricted based on job duties. Only specific individuals whose duties require it have access to PII. Authorized system administrators and users from the FDA's continuing education program staff can access account information for the individuals who are subjects of the data (i.e., those personnel who report and track their continuing education credits in this system). Access is needed to create and update accounts. These administrators and users include employees of contractor Swift, who can access the information they need to add information to records and generate reports on behalf of the subjects of the records.

Individuals reporting continuing education information cannot create accounts on their own without the help of continuing education program staff. Data subjects may request and receive copies of their own records.

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.

All users including administrators and developers are granted the minimal account privileges that they need to perform their job function. Administrators from the continuing education program can only access the minimal amount of PII to create and update accounts. Registered users cannot view the tasks or data from other registered users for the continuing education program. Employees from the contractor Swift are restricted to accessing data only when FDA staff approves and requires reports generated or information added to records.

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 contractor requires system administrators and all employees working on this system to take FDA's annual security and privacy awareness training. Material covered in this training includes policies and requirements to protect data, proper access of data and systems, incident response procedures and security training.

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

In addition to general privacy and security awareness training, system users have received training specific to CE/ORISE from the vendor's training administrators. System training includes account management procedures and promotes privacy principles such as "least access" and "minimum necessary." FDA's specialized privacy training is also available to contractor personnel.

Do contracts include Federal Acquisition Regulation and other appropriate clauses ensuring adherence to privacy provisions and practices?

No

Describe the process and guidelines in place with regard to the retention and destruction of PII.

Government-wide General Records Schedule 1, Item 29: Training Records, Sub-point b Employee Training. The retention schedule calls for destruction of records "...when 5 years old or when superseded or obsolete."

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

Access to the data center is controlled by radio-frequency identification (RFID) devices assigned only to authorized staff. All authorized staff must also sign in and out of the data center and state purpose of access. All data center access is monitored via motion triggered camera monitoring. When triggered, a recording device transfers recorded images to a remote storage location (not part of this system).

Usernames and passwords (access credentials) are employed as technical measures to control access. Administrative task/role assignment procedures ensure only individuals who require access are granted access.

The contractor requires all its employees to take their security education and awareness training annually. The training includes policies to protect data, proper access of data and systems, incident response procedures and security training.

Also, when requested, FDA will review contractor facilities, installations, technical capabilities, operations, documentation, records, databases and devices to ensure compliance with privacy and security requirements.

Identify the publicly-available URL:

https://fda.jobtraq.net/

Note: web address is a hyperlink.

Does the website have a posted privacy notice?

No

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.

Session Cookies that do not collect PII.

Persistent Cookies that do not collect PII.

Does the website have any information or pages directed at children under the age of thirteen?

No

Does the website contain links to non- federal government websites external to HHS?

No

Is a disclaimer notice provided to users that follow external links to website not owned or operated by HHS?

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