US Department of Health and Human Services

Privacy Impact Assessment

Date Signed:

09/12/2016

OPDIV:

FDA

Name:

Administrative Applications: Office of Health and Constituent Affairs (OHCA) Tracking System

PIA Unique Identifier:

P-1865580-832892

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?

New

Does the system have Security Authorization (SA)?

Yes

Indicate the following reason(s) for updating this PIA.

Describe the purpose of the system.

Note that FDA previously prepared a single Privacy Impact Assessment (PIA) for the Agency's Administrative Applications system (AdminApps or "the system"). This PIA assesses the Office of Health and Constituent Affairs (OHCA) Tracking System (TS) which is one of many applications that make up AdminApps. Other applications within AdminApps are also addressed in separate PIAs.

The purpose of OHCA TS is to support FDA’s satisfaction of the statutory requirement to engage patients in regulatory activities and decision-making processes. Section 1137 of the Food and Drug Administration Safety and Innovation Act (FDASIA) requires OHCA to work with FDA’s Centers to include the patient perspective earlier in the medical product review process. FDA employs OHCA TS in the various steps involved in identifying and recruiting potential candidates for the Patient Representative Program and in its efforts to establish relationships with health professionals. OHCA must track these activities and ultimately report them if Congress requests an implementation status report.

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

OCHA TS maintains contact information and records the roles of individuals as relevant to their participation in the Patient Representative and Health Professional programs. The system contains the following information on Patient Representatives and applicants to be Patient Representatives: Medical information (i.e., experience of Patient Representatives with certain diseases, with a strong implication they may have had or have these diseases), name, address, phone numbers, e-mail addresses, past and present service on Advisory Committees and divisional assignments, training received, and special government employee (SGE) appointment dates. The system uses a single sign-on multi-factor authentication approach to authentication and no usernames or passwords are saved in the system.

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

The FDA Patient Representative Program gives patients a voice at the highest levels of the FDA product development and regulatory process. For example, the Program recruits patients and primary caregivers for patients with various diseases and conditions as SGEs to serve on FDA Advisory Committees and participate in divisional assignments and consultation meetings between review divisions and product sponsors.

OHCA is charged to work with patients, patient advocates, and health care professional organizations to ensure meaningful, broad-based participation in forming FDA regulatory policy and disseminating safety and regulatory information. OHCA TS improves management and coordination of Patient Representatives' (and applicants') activities involved with the OHCA's Patient Representative Program, and the associated Health Professional Program, such as identifying Patient Representatives to serve on Advisory Committees, accept divisional assignments, and attend other FDA meetings and workshops.

Note that this system is accessed and used by OHCA staff only. Applicants to the Patient Representative program send information to OHCA using a dedicated e-mail address, PatientRepProgram@fda.hhs.gov. Once application materials are reviewed, OHCA staff enter all the information provided in application materials relevant to managing Patient Representative assignments (which may include any and all PII provided, such as contact information and expertise) into OHCA TS; Patient Representatives have no access to this information themselves. Business process managers are also aware of privacy requirements that are relevant to the application process, such as the need to provide applicants with a Privacy Act notice, and the need to mitigate risks to application materials transmitted via e-mail.

Retrieval of records from this system will include retrieval using PII, specifically, individual patient representatives' names.

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

Phone Numbers

Medical Notes

Employment Status

Experience with specific diseases

Special Government Employee status (thus "employment status" indicated above; applicants may also provide additional employment information in the course of providing information about qualifications to serve as a patient advisor)
Note that applicants may choose to include other information, beyond what has been solicited or requested. FDA discourages submission of sensitive information that is not needed, such as a Social Security number.
Advisory Committee and divisional assignments

Training Received

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

Public Citizens

Patients

The only categories of individuals whose PII is in the system are Patient Advocates and applicants to be Patient Advocates. "Patients" above refers to individuals who have experience as a patient and are applying to be Patient Representatives. "Public Citizens" refers to all applicants and Patient Representatives. Using this designation is a somewhat grey area because these individuals are executing activities on behalf of the FDA, like employees, but are doing so in their individual capacities as members of the public.

How many individuals' PII is in the system?

100-499

For what primary purpose is the PII used?

The PII is used to identify the most appropriate Patient Representative to serve on an Advisory Committee or divisional assignment.

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.

Food and Drug Administration Safety and Innovation Act (FDASIA), Public Law 112-144 (enacted as an amendment to the Federal Food, Drug and Cosmetic Act, 21 U.S.C. 301). Section 1137 of FDASIA requires FDA to find ways to include the patient perspective early in the medical product review process.

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.

SORN 09-90-0059, Federal Advisory Committee Membership Files, HHS/OS/ASPER.

Identify the sources of PII in the system.

Email

Identify the OMB information collection approval number and expiration date

This system does not include forms used to collect information from the public. FDA will confirm and maintain awareness as to whether OHCA the application process may nevertheless require an OMB information collection approval number.

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.

Individuals initiate the process by contacting FDA. When a candidate expresses interest in becoming an FDA Patient Representative, OHCA sends him or her a resume template to complete and return (all transmitted via e-mail). Individuals will observe that elements of the template request PII information. Although the OHCA TS is not used during the application submission process, program management works to ensure that process is consistent with the Privacy Act and the Paperwork Reduction Act. No online form is used, but information about the Privacy Act and its application to this system is available on the FDA web site.

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.

Submission of PII is entirely voluntary, but necessary if the individual wishes to apply to be a Patient Representative in order to contact and coordinate with the individual.

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

No major changes to the system are anticipated. If major changes occur, these could be communicated directly using the contact information provided by phone or e-mail and more broadly by broadcast e-mail and amended notice statements.

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.

Any individual who believes their information has been misused or is inaccurate may contact the Program Manager directly. If necessary, the Program Manager could initiate a security or privacy incident report, update PII, or correct errors. Individuals may also contact the Privacy Office.

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

Accuracy and relevancy are protected by updating the PII at regular intervals. OHCA annually asks the Patient Representatives to review their resumes and submit updated versions reflecting any changes that may have occurred. Integrity and availability are protected by appropriate security controls selected from the National Institute of Standards and Technology’s (NIST’s) Special Publication 800-53, as determined using Federal Information Processing Standard (FIPS) 199.

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

Users:

Users (FDA personnel) have access so that they can contact Patient Representatives and applicants for Patient Representative positions and coordinate activities and projects. Patient Representatives and applicants are not users and do not have direct access to their records.

Administrators:

Administrators have access to ensure tracking information is current and correct.

Developers:

Developers have access for the purposes of operations and maintenance.

Contractors:

Direct contractors have access when and if they act as system developers.

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

System management must authorize access on an individual basis. Access is restricted to OHCA staff (administrator and standard users) whose duties will require accessing PII for identifying a Patient Representative for an FDA meeting or assignment. Each OHCA staff member user and administrator may require access to any and all stored PII to identify and reach out to potentially-suited patient representatives for specific projects.

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.

Each OHCA staff member user and administrator may require access to any and all stored PII to identify and reach out to potentially-suited patient representatives for specific projects. Although all such staff have and require access to all records, those records contain only the minimum necessary 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.

All personnel are FDA employees and must complete the FDA's annual Security Awareness Training and Privacy Training modules.

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

New users receive training on how to use the system and have training manuals to reference.

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.

Records are currently retained under FDA Records Schedule 4110, Program Management Files (NARA approved citation N1 088-04-5). This schedule is intended to include applications explicitly, along with any related program related materials. Disposition for these files is temporary. Document retention dates are cut off at end of each calendar year, and documents are to be destroyed or deleted ten years after the cut off date.

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

Administrative: As noted, users receive annual Security Awareness Training, and are subject to Rules of Behavior. Role-based access is determined on an individual basis.

Technical: The system uses single-sign on multi-factor authentication for user authentication.

Physical: The system is located in a secure facility with guards, locked rooms, and climate controls.