US Department of Health and Human Services

Privacy Impact Assessment

Date Signed:

08/16/2016

OPDIV:

FDA

Name:

Employee Invention Report

PIA Unique Identifier:

P-5604565-021261

The subject of this PIA is which of the following?

Minor Application (stand-alone)

Identify the Enterprise Performance Lifecycle Phase of the system.

Development

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)?

No

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

Describe the purpose of the system.

The purpose of the FDA collection of Employee Invention Reports (EIR) and storage within an electronic technology transfer knowledge management system is to provide a database for FDA to house, manage, track, and report information concerning FDA inventions and related agency patent and licensing activities that are mandated by law. The government has rights to any invention made by federal employees (see 37 C.F.R. 501) and its employees have a duty to report all inventions (see 45 CFR Part 7 “Employee Inventions” and Executive Order 10096 for more information). The invention information in the system originates from FDA employee inventors when they complete and submit the EIR form to notify the FDA about new or improved inventions developed in the course of their work for FDA.

Inventors who are federal employees have a legal obligation to submit an invention report to their employing federal agency; employees of regulated entities or other members of the public are not required to submit a report. The FDA inventor reports the invention by completing and submitting the EIR to the FDA Technology Transfer Program (TTP). In the report the FDA inventor lists those Collaborators who may have contributed to the invention as possible co-inventors.

Co-inventors may or may not be FDA/federal employees, and may include other Public Health Service (PHS) employees, grantees, fellowship recipients, or independent contractors.

The information collected is necessary to obtain patent protection for reported inventions and to accurately and effectively:

Grant licenses to use patented and non-patented inventions;

Make royalty payments and awards to inventors, and provide documentation needed for related financial management and fee collection functions, such as disbursing royalties, awards, and payments to co-inventors;

Benefit from the technology transfer process (e.g., have inventions marketed, provide statistics, and permit FDA to generate technology abstracts for scholarly and other activities); and

Share relevant information with the HHS office that manages grants, contracts, and other personnel matters associated with an invention.

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

The electronic technology transfer knowledge management system maintains EIR information concerning each inventor, invention, and the inventor's employment. FDA does not collect or use Social Security numbers in this system. To the extent FDA requires an individual identifier, FDA uses an employee identification number as an identifier for federal employees at the FDA. The FDA will not collect or generate any numeric or alphanumeric identifier for co-inventors who are not FDA employees. Non-employee co-inventors are identified by name in the invention record. If the name of the co-inventor is not found, FDA searches either by the employee inventor name or by the name of the co-inventing organization. FDA then examines the retrieved report to find the name of any non-employee co-inventor. Alternatively, FDA finds the employee inventor name and non-employee co-inventor name by searching using the title or subject of the invention and reviewing the resulting record for the names.

The information in the system includes the following information for federal employee and non-employee inventors and co-inventors which is required data: name, citizenship, FDA employee ID number , current employer, current work contact information (organization name, position title, full mailing address, e-mail address), home contact information (full mailing address, e-mail address, phone). The following information for federal employee and non-employee inventors and co-inventors are optional: degree and employment status, (federal employees only).

Information stored in the system that is tied to the invention includes an EIR number, license number (for royalties and payment) prior history of invention and serial numbers if reported. The EIR form also provides for including details about the invention itself such as the material used.

The system also contains descriptions of each invention, including an EIR number assigned by the system for tracking the status of the invention, patents or patent applications related to the invention, license number (if the invention is licensed), and information about inventor royalties. The EIR number is auto-assigned by the system based upon the fiscal year the EIR is submitted, received and letter codes for the type of patent filed (e.g., United States, or Patent Cooperation Treaty (PCT)).

Only FDA employees have access to the system and this access is provided by a system administrator. The system administrator provides the unique username and password for Tech Transfer staff who access the database directly. All requests by users for password resets go through the system administrator. Users cannot independently change their username or password. Access can be read-only, or full rights.

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

FDA employees obtain the EIR form via an internal intranet page link. Non-employee co-inventors such as members of the scientific community do not have access to this web page; an FDA employee completes the form and provides it to any relevant co-inventor to review and sign. The process is designed to use a single form with multiple signature lines for FDA employee inventor and non-employee co-inventors who contribute to the subject invention. The FDA employee inventor submits the completed form to the FDA Technology Transfer Program (TTP) staff via in person, online (via online intranet submission portal), e-mail or fax. TTP staff manually enter the content into the electronic tech transfer knowledge management system.

Information related to the marketing and licensing potential of reported inventions is also collected on the EIR form and entered into the system. Information about each inventor's contribution is maintained in order to perform accurate assessment of inventorship in accordance with US patent law. TTP staff updates records during the course of any patent prosecution regarding the status of the related patenting work. To update records, TTP staff search by either employee inventor name or by the system generated number assigned to the invention when the initial record is created. The record is used to determine proper royalty payments to disburse to relevant inventors; the disbursement of royalties is performed with the assistance of FDA's Office of Financial Management (OFM). Inventor names are by necessity shared with OFM to identify the proper payment recipient and the total amount of royalty payments owed. Any other information OFM requires in order to pay the inventor royalties resides in separate OFM administered systems and is not stored within the TTP System.

TTP staff typically retrieve records in this system using the FDA employee inventor's name. If TTP staff has a specific need to look up a record that concerns a non-employee co-inventor, they may use (e.g., search by) the non-employee name to look up the invention record. For FDA employee co-inventors, TTP staff may also look up records using employee ID number or name.

With regard to licensing activities, the Technology Transfer Office is responsible for finding organizations interested in licensing FDA technologies (see 15 U.S.C. 3710). The licensees will in turn pay royalties to the FDA for any licensed technologies. All royalties that FDA receives from licensing out its inventions are paid to the FDA (see 37 CFR 404 and 35 U.S.C. 207-209). FDA is then required by law to pay a certain percentage of royalties to the inventors (see 15 U.S.C. 3710c). FDA uses any remainder of received royalties in accordance with legal authorizations.

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

Legal Documents

Education Records

Employment Status

Royalty share, if applicable

Employee ID Number

User Credentials

Citizenship status

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

Employees

Business Partner/Contacts (Federal/state/local agencies)

Vendor/Suppliers/Contractors

All individuals are inventors or co-inventors. "Employees" includes Fellows. Partners include federal agencies or universities.

How many individuals' PII is in the system?

500-4,999

For what primary purpose is the PII used?

PII is used to obtain patent protections for inventions, license patented and non-patented inventions, grant licenses, and to provide royalty payments to relevant Public Health Service (PHS) employees, former PHS employees, co-inventor contractors, and non-profit and educational institutions.

Describe the secondary uses for which the PII will be used.

Potential secondary uses for PII include using the information during award processing, litigation, leveraging of invented technology and use promotion of the government supported invention, reporting of inventions, and licensing activity.

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

15 U.S.C. §§ 3701-10d, 3710, 3710a, 3710c and 3710d; 35 U.S.C. § 200-212; 42 U.S.C. §§ 241, 282 and 284; Executive Orders 9865 and 10096.

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.

09-25-0168, Invention, Patent, and Licensing Documents Submitted to the Public Health Service by

Identify the sources of PII in the system.

Directly from an individual about whom the information pertains

In-Person

Hardcopy

Email

Online

Government Sources

Within OpDiv

Other HHS OpDiv

State/Local/Tribal

Foreign

Other Federal Entities

Non-Governmental Sources

Private Sector

Other

Identify the OMB information collection approval number and expiration date

Not applicable.

Is the PII shared with other organizations?

Yes

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

Within HHS

Shared with non-FDA co-inventors within HHS for the purpose of obtaining patent protection for inventions, granting licenses to patented and non-patented inventions, and providing royalty payments to relevant inventors. Records may be used during grant and award processing, and activities related to the use promotion of the government supported invention.

Other Federal Agencies

Shared with such non-FDA co-inventors for the purpose of obtaining patent protection for inventions, granting licenses to patented and non-patented inventions, and providing royalty payments to relevant inventors. Records may be used during grant and award processing, and activities related to the use promotion of the government supported invention.

State or Local Agencies

Shared with any such co-inventors for the purpose of obtaining patent protection for inventions, granting licenses to patented and non-patented inventions, and providing royalty payments to relevant inventors. Records may be used during grant and award processing, and activities related to the use promotion of the government supported invention.

Private Sector

Shared with non-federal employee co-inventor for the purpose of obtaining patent protection for inventions, granting licenses to patented and non-patented inventions, and providing royalty payments to relevant inventors. Records may be used during grant and award processing, and activities related to the use promotion of the government supported invention. To contract patent counsel and their employees retained by the Department for patent searching and prosecution in the US and foreign patent offices.

Describe any agreements in place that authorizes the information sharing or disclosure.

For PII exchange with other Federal Agencies, State/Local Agencies, and private sector, there are legal terms under Cooperative Research and Development Agreements, Research Collaboration Agreements, or Confidential Disclosure Agreements that authorize the information sharing and impose data protection obligations.

Describe the procedures for accounting for disclosures.

In the event of a disclosure requiring an accounting, the FDA's disclosing office maintains a log containing the statutorily required information about each disclosure. The disclosing office seeks guidance from FDA's Privacy Act Officer as needed.

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

Notice statements are provided on the Employee Invention Report form. The published system of records notice (SORN) also provides notice, as does this assessment when published. Scientists are made aware of their obligation to submit their PII in the context of the EIR and the availability of patent protection for new technologies through training and other outreach activities. The Technology Transfer Program website contains information for inventors including links to the EIR form and frequently asked questions for completing the document. Supervisors also provide staff with information concerning the requirement to report federal inventions and the patent/EIR process.

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.

There is no opt-out method. Federal employees are required under 15 U.S.C. §§ 3701-10d, 3710, 3710a, 3710c and 3710d; 35 U.S.C. § 200-212; 42 U.S.C. §§ 241, 282 and 284; and Executive Orders 9865 and 10096 to report all inventions.
Patent offices require the identification of all potential inventors on any patent application. The reporting inventor is responsible for providing this information.

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

In the event of such changes to the system, FDA will notify individuals via updated notice statements on forms and web pages, an updated SORN, an updated Privacy Impact Assessment, the e-mail address provided by each reporter and/or the mailing address on file.

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.

Individuals may notify the System Manager and/or Director of the FDA Technology Transfer Program. Other avenues include FDA's 24-hour technical assistance phone line, contacting the Technology Transfer Office, contacting the Privacy Office, or reporting any suspicion of privacy and security breaches to FDA's Systems Management Center.

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

Staff will be trained in proper use of the database and procedures for entering accurate information, including PII. The database tracks the date a record is created or modified and identifies the person who created or modified the record. Only a limited number of people will have administrative privileges for the database. Administrative privileges are required for the deletion of data which limits the chance for inappropriate modification or destruction of PII. Staff with administrative privileges will also review records to insure their accuracy. The removal of any records from the database will be in accordance with the appropriate records retention schedules.

Federal employees are required under 5 U.S.C. §§ 3701-10d, 3710, 3710a, 3710c and 3710d; 35 U. S.C. § 200-212; 42 U.S.C. §§ 241, 282 and 284; and Executive Orders 9865 and 10096 to report all inventions. Patent offices require the identification of all potential inventors on any patent application. The reporting inventor is responsible for providing this information therefore individuals who provide PII cannot repudiate that action.

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

Users:

Technology Transfer Office will use PII for patenting, marketing and licensing activities. Inventors will have access to their own patents and co-inventor information. Technology Transfer Office staff will have access to manage the marketing of inventions and the patenting and licensing process. FDA financial office users will access information in support of royalty distribution activities.

Administrators:

Administrators will have access in order to monitor and troubleshoot the system.

Developers:

Direct contractor and FDA staff responsible for the database may access information for monitoring and troubleshooting of the system.

Contractors:

Contract patent law firm staff who are responsible for patent and licensing issues may have access to relevant PII.

Others:

Potential licensors, co-inventors and their employers may access PII in order to discuss the technology and patent prosecution activities.

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

Only authorized users whose official duties require the use of the information will be provided access by management. TTP management confirms these role-based user characteristics and position role before access is granted to the system.

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.

Authorized users of the system will require access to all information in the EIR system in order to perform their duties. Access credentials are controlled by the system administrators.

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 users will be required to complete FDA training on IT Security and Privacy Awareness, Ethics Awareness, Records Management, and Safeguards against Breach of Personally Identifiable Information. Applicable Privacy Act Federal Acquisition Regulation clauses are inserted in solicitations and contracts with contractors.

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

Users are trained on the system, review the HHS Rules of Behavior, and may complete specialized role-based privacy training as appropriate in accordance with their information handling duties.

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.

FDA is developing a record schedule to manage the disposition of the record types listed in this PIA. FDA did not previously maintain such records. Records will be maintained indefinitely until a record schedule has been written and approved by the National Archives and Records Administration (NARA).

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

Administrative safeguards include user training, system documentation that advises on proper use, implementation of Need to Know and Minimum Necessary principles when awarding access, and others. Technical Safeguards include usernames, passwords, use of SSL and others. Physical controls include that all system servers are located at FDA facilities protected by guards, locked facility doors, and climate controls. Other appropriate controls have been 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.