US Department of Health and Human Services

Privacy Impact Assessment

Date Signed:

10/06/2016

OPDIV:

FDA

Name:

FDA NCTR Research Management System

PIA Unique Identifier:

P-8086954-382822

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?

Existing

Does the system have Security Authorization (SA)?

Yes

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

PIA Validation

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

No change.

Describe the purpose of the system.

The mission of the Food and Drug Administration’s (FDA) National Center for Toxicological Research’s (NCTR) is to conduct peer-reviewed scientific research that supports and anticipates the FDA's current and future regulatory needs. To maximize return on investment and to manage its resources efficiently and effectively, NCTR has implemented an internal research protocol tracking and approval process, and, an activity-based costing regimen which requires significant data collection and internal reporting.

The Research Management System (RMS) is an information technology (IT) resource which supports NCTR's Strategic Research activities in Knowledge-Based, Method-Driven, Agent-Driven, Concept-Driven and New Strategies for the Prediction of Toxicology research areas.

In order to ensure that research resources are directed toward activities which are in alignment with NCTR/FDA goals, NCTR has implemented a protocol development and approval concept.

RMS provides the essential tools for gathering these data and for providing the necessary decision support mechanisms used to allocate available resources to new and ongoing research efforts.

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

The RMS collects data required for NCTR research protocol approval and tracking efforts as well as data needed to conduct activity-based cost analysis functions. The types of data collected for these functions include protocol review and approval information, document production and publishing, cost factors, training requirements, and, full-time equivalent (FTE) availability and resource (labor hour and dollar) costs estimated for and consumed in support of specific projects (e.g., protocol approval and tracking).

RMS collects Personally Identifiable Information (PII) about two categories of individuals: (1) FDA employees (including direct contractors) who are authors or co-authors of published articles listed within the system and (2) non-FDA personnel credited as co-authors of listed articles. The second category of individuals is scientists who willingly and knowingly are contributing to scientific research.

The expected result of individuals' participation is publication of the research results with their name listed as authors or co-authors. All authors willingly provide their names and e-mail address in order to be associated with the research and related publication(s). The system does not receive or store complete articles. It holds only reference level information such as journal title, article title, and author name for research articles for which NCTR staff are an author or co-author.

Non-FDA personnel who are co-authors do not have access to the system. Only FDA NCTR staff with access permissions can access RMS. They access the system via a single-sign-on process using multi-factor authentication. RMS does not require, use, collect or maintain system-specific logon credentials (e.g., username and password).

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

The Research Management System (RMS) software provides high quality research management. It contains software that provides functions such as: project planning, decision support, management of animal utilization, employee time collection, laboratory and environmentally controlled area usage, animal dietary requirements and tracking of other resource usage required for toxicological and regulatory research.

FDA uses the data collected to ensure agency resources are employed to perform research that supports FDA's ability to make science-based regulatory decisions. No regulatory data is collected or stored in RMS and no information within RMS can be retrieved by authors name or any other PII.

The following information is collected from FDA personnel (authors or co-authors) who may submit their PII directly in person, in hard copy or by email: name, email address, division or office, title, number of hours spent on a particular research concept, training courses and/or classes completed.

The following information collected from non-FDA personnel (co-authors) who may submit their PII in hard copy or by email: name, email address.

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

Education Records

Office and title

Educational Records refers to training or classes completed.

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

Employees

Public Citizens

"Employees" above refers to all FDA personnel including direct contractors. "Public Citizens" refers to research article co-authors or who are non-FDA personnel.

How many individuals' PII is in the system?

500-4,999

For what primary purpose is the PII used?

The purpose of PII collection is track resources and work, and, to associate research manuscripts with authors and give them credit for their work (manuscript and author is publicly available information).

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.

21 U.S.C. 301 (Federal Food, Drug and Cosmetic Act), 5 U.S.C. 301 and 21 U.S.C. 393 (general authority to prescribe procedures and use of information and records).

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

No

N/A. Although records in the system are retrieved by a name search, they do not contain any other

Identify the sources of PII in the system.

Directly from an individual about whom the information pertains

In-Person

Hardcopy

Email

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.

Research article authors willingly attach their name to the published articles listed in the system. Those authors who are FDA personnel are also notified at the time of hire via written statements on employment forms, within orientation programs, and through completion of FDA's Computer Security Awareness Training completed prior to reporting for duty, and, as a condition of employment consent to the agency's use of their professional contact information in relation to their work for HHS/FDA.

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 PII is voluntary; there is no dedicated opt-out process. Authors and co-authors willingly provide their PII for contact purposes and in order to be associated with their research and related publication(s).

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

Authors of scientific manuscripts willingly attach their name to the published articles listed in the system. If the agency changes the collection, use, or sharing of PII data in this system, the affected individuals will be notified by the most efficient and effective means available and appropriate to the specific change(s). This may include a notice on an FDA web site, or e-mail notice to the individuals.

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 raise any concerns by contacting NCTR/FDA via phone, e-mail or mail information provided on FDA.gov. FDA authors may self-correct errors related to their PII (e.g., spelling of name) and may also address concerns through a number of available channels including FDA's Employee Resource and Information Center (ERIC), IT Security, and their office management. Where inaccuracies result from the article publisher (journal publisher) authors may contact the publisher directly.

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

Personnel are responsible for maintaining accurate work contact information and if needed may use internal processes to update or correct inaccuracies in their work contact information. Information may also be corrected if errors are identified in the course of the quarterly review of system access permissions. Where inaccuracies result from the article publisher (journal publisher) authors may contact the publisher directly.

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

Users:

Users: FDA employees (including direct contractors) access and analyze data in the system in the performance of duties.

Administrators:

Manage the system and associated workflow; control access.

Developers:

Maintain and update the software/database as needed to ensure applications are operational.

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

Users who require access to the information system are NCTR staff and they must have supervisor approval and signature confirming their need for access before access is granted.

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 user's supervisor will establish the minimum information system access that is required in order for the user to complete his/her job. The access list for the information system is reviewed on a quarterly basis during which time users' access permissions are reviewed/adjusted, and unneeded accounts are purged from the system.

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 required to complete FDA's security and privacy awareness training at least annually.

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

Users are instructed on the proper system use by research division staff and/or management staff. A user guide is available.

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.

RMS database records are retained/destroyed under FDA file code 4200, and National Archives & Records Administration (NARA) approved citation N1-088-07-001. This covers data fields supporting various applications such as project planning, protocol tracking, pathology tracking for animal utilization and animal dietary requirements, laboratory and environmentally controlled area usage, employee and contractor tasks and approvals, procurement tracking, document tracking, personnel data and other related information.

The above records control schedules specify disposition is temporary and direct disposition as authorized under relevant subject records series for information in data fields. If data is used to support other projects or modules within RMS, it may be deleted after the completion of the project or the deletion of this module or 15 years after the research experiment is completed, whichever is shortest.

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 use of multi-factor access authentication, firewalls, and network monitoring and intrusion detection tools. Physical controls include that all system servers are located at 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.

This information system is installed on servers located in FDA Data Centers, which have physical security controls in place.