US Department of Health and Human Services

Privacy Impact Assessment

Date Signed:
10/07/2016

OPDIV:
OS

Name:

Annual Report on Possible Research Misconduct System

PIA Unique Identifier:
P-6212385-967309

The subject of this PIA is which of the following?
Minor Application (child)

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.
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.
N/A

Describe the purpose of the system.
The Annual Report on Possible Resource Misconduct System (ARPRM) is a mandatory report which is completed by all institutions which receive research funding from the U.S. Department of Health & Human Service (HHS).

Each Institution that applies for research, research-training, or research related grants or cooperative agreements under the Public Health Service (PHS) Act is required to maintain compliance with the PHS Policies on Research Misconduct (42 C.F.R. 93).

First, each institution is required to establish an administrative process for reporting and investigating instances of alleged or apparent misconduct, when such research involves PHS funding.

This function is supported by ARPRM system so an institution can upload/update an electronic copy of institution policy document on research misconduct with a browser.   The system accepts policy document in Word or Portable Document Format (PDF) file formats. For sample policies, see http: //ori.hhs.gov/sample-policy-procedures-responding-research-misconduct-allegations.

Second, an annual report of misconduct related activities to the Office of Research Integrity (ORI) must be completed by an institutional representative each year between January and April. This function is supported by the system so institution officials can submit an electronic form containing numerical data of the instances and points of contact for the certifying officials.

The system supports the function by allowing institutions officials to upload a copy of institution policy and annual report on possible misconducts. The annual report is due on April 30th. The annual reports contain the name of the institutional official responsible for filing the report; contact information for that individual; and statistical data such as numbers of allegations received broken out into one of three categories: fabrication, falsification, or plagiarism.

For institution's first use of ARPRM, an account must be created by ARPRM administrator. ARPRM administrator creates an account when an institution's grant application can be awarded by the National Institutes of Health (NIH) and notifies the institution. The institution is required to create their password upon the first time accessing the system. The institution is required to login to the system every time to update their contact information or submit their reports.

Institution accounts are created base on the Institutional Profile File (IPF) information provided by NIH. The IPF information consist of institution name, Institution's address, institution representative officials' titles, names and their official contact information such as email addresses and phone numbers.   No other Personally identifiable information (PII) is collected in the institution account information.

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

Reports contain the institution name, Institution's address, institution representative officials' titles, names and their official contact information such as email addresses and phone numbers, and statistical data such as number of allegations received broken out into one of three categories: fabrication, falsification, or plagiarism. See Form PHS-6349 for the content of the report at http://ori. hhs.gov/images/ddblock/PHS-6349.pdf

The Office of Research Integrity (ORI) analyzes this data, aggregates it, and makes a public annual report in forms of a PDF document to show a summary of statistical data and accomplishments. The annual reports can be found at http://ori.hhs.gov/annual_reports.

PII is limited to contact information of the person who sends the report and the Research Integrity Officer (RIO) and Responsible Conduct of Research (RCR) Coordinator. RIO and RCR contacts were added in 2013.

PII is also limited to login credentials of the internal users, such as user name, password, and email address, so system can authenticate employees and direct contractors of ORI to access the system. No other PII is collected on internal user accounts.

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

Federal regulations require institutions receiving federal grants from HHS to report allegations of misconduct to HHS's Office of Research Integrity (ORI). The ARPRM system permits grantees of the National Institutes of Health (NIH) and the Public Health Service (PHS) to make these reports directly as opposed to mailing or fax in the reports in paper format which would create the burden of data entry.

This reporting system is essential for the over 5000 institutions that receive federal research funding from HHS, and which are mandated to complete this report annually between January and April Failing to make this report will result in withholding funds until the report is made.

Further details on individual allegations are not recorded by the system. Reports do not reflect the names of the parties making the allegations, nor those against whom allegations are made. To see what information are being collect, please see Form PHS-6349 at http://ori.hhs. gov/images/ddblock/PHS-6349.pdf.   While the ORI does work directly with institutions to advise them how such allegations should be handled, this is not done through the ARPRM, but other business processes.   To learn about the process of handling allegations, please see http://ori.hhs. gov/handling-misconduct.

The contact information collected from the annual report are used for administrative purposes such as addressing allegations of research misconduct that meet the requirements, and or provide guidance on submitting annual report and policies in general. These contact information are necessary for ORI to establish communication with the proper representatives of the institutions.

The ARPRM system maintains internal user account information so employees and direct contractors of ORI can access the system, with proper role and permissions, to perform functions related to assurance program such as validating submissions of annual reports and policy review. The internal user (employees and direct contractors) account information/credentials are stored on the system which consist of only user name, password, role, and email address. No other PII is collected for the internal user accounts.

The ARPRM system also maintains institution user information which includes name, job title, mailing address, phone number, and email address. Institution users can only access their own contact information so they can update the contact information if changed.

The ARPRM internal users (employees and direct contractors) can access all institution's contact information so ORI can reach out to the appropriate institution representatives regarding matters in research integrity and possible misconduct.

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

Job Title

Fax Number

User Credentials

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

Employees

Public Citizens

Institutional Official responsible for completing assurance

How many individuals' PII is in the system?

10,000-49,999

For what primary purpose is the PII used?

PII is limited to contact information of the person who sends the report and the ORI employees and direct contractors.   ORI employees and direct contractors can access all institution's contact information so ORI can reach out to the appropriate institution representatives regarding matters in research integrity and possible misconduct.

42 C.F.R. Part 93 requires all institutions that receive PHS funding to have an official responsible for handling allegations of research misconduct (a RIO) and for fostering a research environment that promotes the responsible conduct of research (an RCR Coordinator). These contact information of RIO and RCR coordinator are necessary for ORI to establish communication with the proper representatives of the institutions that fulfills the regulatory requirements.

The contact information of employees and direct contractors are collected so proper roles and permissions can be assigned to the user accordingly to perform their respective functions related to assurance program.

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

Not Applicable

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

ORI gets its statutory authority from 42 U.S.C. § 289b. This activity is mandated by Section (b), which requires that "the Secretary [of HHS] shall by regulation require that each entity that applies for financial assistance under this chapter for any project or program that involves the conduct of biomedical or behavioral research submit in or with its application for such assistance (1)assurances satisfactory to the Secretary that such entity has established and has in effect (in accordance with regulations which the Secretary shall prescribe) an administrative process to review reports of research misconduct in connection with biomedical and behavioral research conducted at or sponsored by such entity (2) an agreement that the entity will report to the Director any investigation of alleged research misconduct in connection with projects for which funds have been made available under this chapter that appears Substantial ...."Regulations concerning this activity can be found at 42 CFR Part 93."

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

No

Reference: 09-37-0021Rcrds R/t Misconduct

Proceedings

Identify the sources of PII in the system.

    Directly from an individual about whom the information pertains
      Hardcopy

      Online

    Government Sources
      Within OpDiv

    Non-Governmental Sources
      Public

    Identify the OMB information collection approval number and expiration date
      OMB No. 0937-0198; Expires: 05/31/17

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.
    Not necessary as the only PII collected is from the person filing the report.

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.
    Individuals consent in the course of supplying the information directly. No individual is required to submit PII, but the institution is required to identify an individual willing to be identified as a point of contact responsible for handling allegations of research misconduct (a RIO) and for fostering a research environment that promotes the responsible conduct of research (an RCR Coordinator).

    In order to comply with 42 C.F.R. Part 93 to receive PHS funding, there is no option to object to the information collection.   These contact information of RIO and RCR coordinator are necessary for ORI to establish communication with the proper representatives of the institutions that fulfills the regulatory requirements.

Process to notify and obtain consent from individuals whose PII is in the system when major changes occur to the system.
    No major changes affecting the rights or interests of the individual are anticipated. If necessary, the individual could be contacted using the information submitted with the annual report.

    The institution may supply the name of any willing individual to serve as point of contact.

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.
    Information is used transactionally, and does not affect the rights or benefits of the individual.

    If an individual has concern about their PII was inappropriately obtained, used, or disclosed by using ARPRM, the individual may contact ORI via email or phone number displayed on the system.

Describe the process in place for periodic reviews of PII contained in the system to ensure the data's integrity, availability, accuracy and relevancy.
    Information is used transactionally, and does not affect the rights or benefits of the individual.

    Institution records are periodically reviewed and inactive records are deactivated.

A user account is deactivated/deleted upon separation of his/her role to the system. Database schema is modeled with mandatory constrains to ensure data integrity, availability, accuracy and relevancy.

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

Users:

Data entry for reporting purposes

Administrators:

Reporting purposes

Developers:

Troubleshoot and maintain the system

Contractors:

System administration

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

All ORI staff who have access to the ARPRM will have access to the PII in 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.

Depending on the roles and permissions of the internal users, different type of access to PII can be controlled, such as read-only access, reports generation, and communicating with institutions.

Note: The PII collected can easily be found on the websites of institutions that file reports; therefore, the level of risk is extremely nominal.

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 employees and direct contractors complete both mandatory training annually (HHS Privacy Awareness Training; and HHS Information Systems Security Awareness Training).

The grantees or the certifying official, whom the institutions had identified to use the system to complete the report, can only access their own records with data they have submitted.

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

New employees receive one-on-one training related to this activity. If any major changes are made, group training is provided.

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.

National Archives and Records Administration (NARA) retention schedule: Job citation# N1-514-93-1.

The Annual Report on Possible Research Misconduct data that is kept in an electronic database (required by institutions to maintain their assurance). See answers for question 11 and 12 for description of the PII information which ARPRM system maintains.

Disposition: Retain for 1 year, or when no longer needed administratively for reference, whichever is longer.

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

The following administrative, technical, and physical controls are in place for ARPRM:

Administrative Controls
Certification and Accreditation (completed May 7, 2012)
System security plan
Contingency (or backup) plan
File backup
Backup files stored offsite
User manuals
Security Awareness Training
Least Privilege Access

Technical Controls
User Identification and Passwords
Firewall
Intrusion Detection System (IDS)

Physical Controls
Guards
Identification Badges
Key Cards
Closed Circuit TV

Identify the publicly-available URL:

https://ori.hhs.gov/arprm/Login.php

Note: web address is a hyperlink.

Does the website have a posted privacy notice?

Yes

Is the privacy policy available in a machine-readable format?

Yes

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.

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 websites not owned or operated by HHS?

No