Privacy Impact Assessment (PIA): OS - ARPRM-Cloud - QTR4 - 2021 - OS1118294

Date Signed: 2/17/2022

Acronyms

ATO - Authorization to Operate
CAC - Common Access Card
FISMA - Federal Information Security Management Act
ISA - Information Sharing Agreement
HHS - Department of Health and Human Services
MOU - Memorandum of Understanding
NARA - National Archives and Record Administration
OMB - Office of Management and Budget
PIA - Privacy Impact Assessment
PII - Personally Identifiable Information
POC - Point of Contact
PTA - Privacy Threshold Assessment
SORN - System of Records Notice
SSN - Social Security Number
URL - Uniform Resource Locator

General Information

Status:	Approved	**PIA ID:**	1423618
PIA Name:	OS - ARPRM-Cloud - QTR4 - 2021 - OS1118294	**Title:**	OS - Annual Report on Possible Research Misconduct System – Cloud
OpDiv:	OS		

PTA

PTA - 1A:	Identify the Enterprise Performance Lifecycle Phase of the system	Initiation
PTA - 1B:	Is this a FISMA-Reportable system?	Yes
PTA - 2:	Does the system include a website or online application?	Yes

URL Details

Type of URL	List Of URL
Internet (publicly available)	https://ori.hhs.gov
HHS Intranet (HHS Internal)	https://ori.hhs.gov/intranet
Publicly accessible website with log in	https://ori.hhs.gov/arprm

PTA - 3A:	Is the data contained in the system owned by the agency or contractor?	Both
PTA - 5:	Does the system have or is it covered by a Security Authorization to Operate (ATO)?	No
PTA - 5B:	If no, Planned Date of ATO	4/25/2022
PTA - 6:	Indicate the following reason(s) for this PTA. Choose from the following options.	Significant System Management Change
PTA - 7:	Describe in further detail any changes to the system that have occurred since the last PIA	Adding Two Factor Authentication on login page

		Adding sub system that is only accessible in HHS network
PTA - 8:	Please give a brief overview and purpose of the system by describing what the functions of the system are and how the system carries out those functions?	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 own 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 based 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.

Another purpose of the system is to continue ORI's mission per regulation as stated in Public Health Service Policies on Research Misconduct - 42 C.F.R. Part 50, Subpart A. A subsystem, Case Tracking System (CTS), is integrated with ARPRM that provides the functionality for ORI's Division of Investigative Oversight to: 1) review and monitor investigations conducted by applicant and awardee institutions and intramural research programs; 2) evaluate investigations and investigatory findings of awardee and applicant institutions, intramural research programs, and the Office of Inspector General and develop and recommend to the ORI Director, findings of research misconduct and proposal administrative actions against those who committed misconduct; 3) assist the Office of the General Counsel (OGC) in preparing and presenting cases in hearings before the Research Integrity Adjudications Panel of the DHHS Department Appeals Board; 4) provide information on DHHS policies and procedures, as requested, to individuals who have made an allegation or have been accused of research misconduct; and 5) establish and implement a program of advice and technical assistance to entities that conduct inquiries and investigations, or otherwise respond to allegations of research misconduct.

PTA - 9:	List and/or describe all the types of information that are collected (into), maintained, and/or shared in the system regardless of whether that information is PII and how long that information is stored.	ARPRM annual 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. In CTS, respondents and institution representative officials' titles, names and their official contact information such as email addresses and phone numbers are also collected for communication purpose regarding allegations and investigations.
PTA -9A:	Are user credentials used to access the system?	Yes
PTA - 9B:	Please identify the type of user credentials used to access the system.	HHS User Credentials HHS Email Address HHS Password HHS Username HHS/OpDiv PIV Card Non-HHS User Credentials Email address Password Username
PTA - 10:	Describe why all types of information is collected (into), maintained, and/or shared with another system. This description should specify what information is collected about each category of individual	Federal regulations require institutions receiving federal grants from HHS to report allegations of misconduct to HHS 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 6000 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 https://ori.hhs.gov/assurance-program. 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 https://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.

PTA - 10A:	Are records in the system retrieved by one or more PII data elements?	No

PTA - 10B:	Please specify which PII data elements are used.	The PII data elements are used include respondent's name, respondents' titles, institution representative officials' titles, names and their official contact information such as email addresses and phone numbers.
PTA - 11:	Does the system collect, maintain, use or share PII?	Yes

PIA

PIA - 1:	Indicate the type of PII that the system will collect or maintain	Name E-Mail Address Phone numbers Mailing Address User Credentials Others - Title, Institution Name
PIA - 2:	Indicate the categories of individuals about whom PII is collected, maintained or shared	Business Partners/Contacts (Federal, state, local agencies) Employees/ HHS Direct Contractors Public Citizens
PIA - 3:	Indicate the approximate number of individuals whose PII is maintained in the system	Above 2000
PIA - 4:	For what primary purpose is the PII used?	Personal Identifiable Information (PII) is limited to contact information of the person who sends the report and the Office of Research Integrity (ORI) employees and direct contractors. ORI employees and direct contractors ca 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 Public Health Service (PHS) funding to have an official responsible for handling allegations of research misconduct (a Research Integrity Officer (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. The PII of the public citizens are collected for the purpose of research misconduct investigation.
PIA - 5:	Describe any secondary uses for which the PII will be used (e.g. testing, training or research)	The Office of Research Integrity uses this PII for research to identify scientific publications that are impacted by possible research misconducts.
PIA - 7:	Identify legal authorities,	ORI gets its statutory authority from 42 U.S.C. 289b. This

	governing information use and disclosure specific to the system and program	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. and 42 C.F.R. Part 50, Subpart A.
PIA - 8:	Provide the number, title, and URL of the Privacy Act System of Records Notice (SORN) that is being used to cover the system or indicate whether a new or revised SORN is in development.	Assigned SORN number: 09-37-0021 Title: HHS Records Related to Research Misconduct Proceedings, HHS/OS/ORI URL: https://www.hhs.gov/foia/privacy/sorns/exempt-systems/59fr36717.html
PIA - 9:	Identify the sources of PII in the system	Directly from an individual about whom the information pertains Hard Copy Mail/Fax Email Online Government Sources Within the OPDIV Other HHS OPDIV Non-Government Sources Members of the Public
PIA - 9A:	Identify the OMB information collection approval number or explain why it is not applicable.	Annual report form PHS-6349 OMB No. 0937-0198
PIA - 9B:	Identify the OMB information collection expiration date.	8/31/2023

PIA - 10:	Is the PII shared with other organizations outside the system's Operating Division?	No
PIA - 11:	Describe the process in place to notify individuals that their personal information will be collected. If no prior notice is given, explain the reason	All institutions that receives PHS funding are require to provide point of contacts to ORI for possible research misconduct matters in their annual reports. The point of contacts are the institutions Research Integrity Officers, or RIOs. During an investigation, an ORI scientist investigator may requests reports from the RIO via email. The RIOs may be required to submit the reports pertaining to institutions' investigations on possible research misconducts by email or ORI's File Transfer System (ORI-FTS). Once ORI receives the requested reports and evidence, ORI can conduct investigation oversight base on those artifacts.
PIA - 12:	Is the submission of PII by individuals voluntary or mandatory?	Voluntary
PIA - 13:	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. During investigations on possible research misconducts, the individuals involved in the investigation will have no option to opt-out because they are either the subject being investigated or the interviewers or experts who provided the analysis.
PIA - 14:	Describe the process to notify and obtain consent from the individuals whose PII is in the system when major changes occur to the system (e.g., disclosure and/or data uses have changed since the notice at the time of original collection). Alternatively, describe why they cannot be notified or have their consent obtained	Under their assurance, institutions are obligated to follow the policy they established for responding to allegations of research misconduct that complies with the PHS Policies on Research Misconduct (42 C.F.R. 93). The institutions are required to submit research documents and evidence upon request as part of compliance to PHS policy. The only function Office of Research Integrity - File Transfer System (ORI-FTS) provides is to collaborate with institutions so they can transfer the requested information to ORI to support the PHS Policies.. It will not change the use of the PIIs that were originally collected.

PIA - 15:	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 no process exists, explain why not	Under their assurance, institutions are obligated to follow the policy they established for responding to allegations of research misconduct that complies with the PHS Policies on Research Misconduct (42 C.F.R. 93). All PIIs in the reports and related artifacts are submitted by the institutions. If an individual has concern about their PII was inappropriately obtained, used, or disclosed by using Annual Report on Possible Resource Misconduct System (ARPRM), the individual may contact ORI via email or phone number displayed on the system.
PIA - 16:	Describe the process in place for periodic reviews of PII contained in the system to ensure the data's integrity, availability, accuracy and relevancy. Please address each element in your response. If no processes are in place, explain why not	Information is used transactional, 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. Investigative records are also periodically reviewed and closed cases are dispositioned per established retention schedule. Database schema is modeled with mandatory constrains to ensure data integrity, availability, accuracy and relevancy.
PIA - 17:	Identify who will have access to the PII in the system and the reason why they require access	Users Administrators Developers Contractors
PIA - 17A:	Provide the reason of access for each of the groups identified in PIA-17	1) Institution users, who will submit annual reports and maintain institution information. ORI staff users, who will request institutions for reports and accepting the electronic submissions for analysis and investigation 2) The Administrators manage the system configuration and user accounts; 3) The Developers maintain the system and provide IT support on database enhancement. 4) The contractor analyze reports and provides subject matter expertise in regulatory compliance.
PIA - 17B:	Select the type of contractor	HHS/OpDiv Direct Contractor

PIA - 18:	Describe the administrative procedures in place to determine which system users (administrators, developers, contractors, etc.) may access PII	1) Institution users can only access their own PII information that they had voluntarily provided and maintained in the system. ORI staff users, such as annual report reviewers, record management specialist, investigators and analysts would have access to PII to perform their jobs. 2) The system administrator or co-admin are assigned to designated ORI staff in order to administer user accounts. 3) The Developers may be granted temporary access to records with PII only when debugging or testing are needed for system upgrades or enhancements 4) Subject matter experts or contractors are administered to access PII in order to analyze reports and perform their investigations.
PIA - 19:	Describe the technical methods in place to allow those with access to PII to only access the minimum amount of information necessary to perform their job	Roles and responsibilities are defined within ORI. 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. Based on the conditions of the established roles as mentioned in the previous question, access are provided by creations of user accounts.
PIA - 20:	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 ORI personnel and contractors are required to complete the mandatory annual record management training, security and privacy awareness trainings.
PIA - 21:	Describe training system users receive (above and beyond general security and privacy awareness training).	The record management specialists have completed advanced record management training offered by National Archives and Records Administration (NARA). Users who are granted access to the system will also receive the system specific training for best practices of handling the collected information. The system administrator or ORI's IT Specialist received GIAC security essentials training and certification.
PIA - 23:	Describe the process and guidelines in place with regard to the retention and destruction of PII. Cite specific NARA records retention schedule(s) and include the retention period(s)	ORI has established retention schedule pertaining to this system as the following: (N1-514-93-1) Outline of Records Schedule Items for DAA-0514-2020-0001

		1 Inquiry and Investigative Case Files 1.1 Misconduct/Administrative Action Files Disposition Authority Number: DAA-0514-2020-0001-0001 Cutoff at the end of the fiscal year in which the case closed. Destroy 10 years after cutoff. 1.2 Misconduct Internal Summary Report (ISR) and Director's Memo (DM) - Final Report and Summary Disposition Authority Number: DAA-0514-2020-0001-0002 Cutoff at the end of the fiscal year in which the case closed. Transfer to the National Archives 15 year(s) after cutoff. Frequency of transfer is 1 year. 1.3 No misconduct/Administrative Action Files Disposition Authority Number: DAA-0514-2020-0001-0003 Cutoff at the end of the fiscal year in which the case closed. Destroy 5 years after cutoff. 2 Assurance Program Records 2.1 Initial Assurance Regarding Procedures for Dealing with and Reporting Possible Misconduct in Science Form (PHS 6315) Disposition Authority Number: DAA-0514-2020-0001-0004 Cutoff at the end of the calendar year in which the form is submitted. Destroy 3 years after cutoff. 2.2 The Annual Report on Possible Research Misconduct Form (PHS 6349) Disposition Authority Number: DAA-0514-2020-0001-0005 Cut-off at close of the calendar year of last agency action. Destroy 5 years after cutoff.
PIA - 24:	Describe how the PII will be secured in the system using administrative, technical, and physical controls. Please address each element in your response	The following administrative, technical, and physical controls are in place for ARPRM-Cloud: Administrative Controls: Certification and Accreditation

		System security plan Contingency (or backup) plan User manuals Security Awareness Training Access control policy Technical: Access Enforcement Use of External Information Systems Publicly Accessible Content. Authenticator Feedback Identifier Management Acceptance of PIV credentials Cryptographic key establishment and management Operational: Configuration Management Plan (CMP) Information System Monitoring Media storage, Media Sensitization Unauthorized software backlisting Error Handling Baseline Configuration Role-based Security Training Security Impact Analysis Management: Security Assessment System Interconnections Restriction on External Systems Connections Continuous Monitoring
PIA - 25:	Describe the purpose of the web site, who has access to it, and how users access the web site (via public URL, log in, etc.). Please address each element in your response	The purpose of the website is to provide institutions to submit their annual report on possible research misconduct. These institutions are required to establish an administrative process for reporting and investigating instances of alleged or apparent misconduct when such research involves PHS funding.

		The website is consist of a public facing website, which provides information about ORI; and ARPRM for institution users to submit misconduct reports; and the case tracking system to support investigation on research misconduct cases. Only permitted users have access to the system. The ORI staff users are consist of 1) the ARPRM specialist, who manages assurance data and user accounts; 2) ORI staff users, which includes investigators and record management specialists. Users can only access the website via a browser with login credentials.
PIA - 26:	Does the website have a posted privacy notice?	Yes
PIA - 27:	Does the website use web measurement and customization technology?	Yes
PIA - 27A:	Select the type of website measurement and customization technologies is in use and if it is used to collect PII	Session Cookies - Collect PII
PIA - 28:	Does the website have any information or pages directed at children under the age of thirteen?	No
PIA - 29:	Does the website contain links to non-federal government websites external to HHS?	No