Privacy Impact Assessment (PIA): FDA - AIRRS - QTR1 - 2023 - FDA2084392

Date Signed: 2/21/2023

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:**	1617710
PIA Name:	FDA - AIRRS - QTR1 - 2023 - FDA2084392	**Title:**	CTP Electronic Submissions
OpDiv:	FDA		

PTA

PTA - 2:	Indicate the following reason(s) for this PTA. Choose from the following options.	New
PTA - 3:	Is the data contained in the system owned by the agency or contractor?	Agency
PTA - 4:	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 Advanced Information Retrieval Research System (AIRRS) is a suite of applications serving the information and retrieval needs of members of the Office of Science (OS) within the Center of Tobacco Products (CTP). AIRRS supports domain-specific scientific and business analyses associated with CTP's regulatory and research mission. AIRRS consists of multiple applications that together make up the

		overall system. Specific applications are described below: The CTP Integrated Research Data System (CIRDS) is a digital information retrieval hub that pulls data from internal and external into one centralized platform. CIRDS allows users to easily share findings with each other to support the CTP mission of tobacco regulation. The Research Tracking System (RTS) supports the management of research study projects and is used to track all the Office of Science (OS) and Office of Health Communication and Education (OHCE) research projects funded by CTP. The tracking system includes CTP funded research projects since 2010. Currently, it does not include projects that support infrastructure purchases (e.g., office equipment, scientific equipment). Application Review Resources Tool (ARRT) is a Microsoft Power Apps Tool that helps reviewers quickly find resources to guide them in completing tobacco product marketing application reviews. Resources include Reviewer Guides, Job Aids, Templates, Policy Memos, and frequently used websites. ARRT only provides hyperlinks to the review resources at their source location, none of the documents are stored within the tool. The data / hyperlinks for ARRT are pulled from Protégé, a commercial off-the shelf ontology editor desktop application (FDA approved). Resource hyperlinks include links to external, non-government webpages. The Self-Service Text Analytics Tool (SSTAT) allows users to explore contents of a document using Advanced Text Analytics (ATA) and Latent Dirichlet Allocation (LDA) topic modelling. Documents are uploaded to the tool for analysis. A visual listing of the documents and their associated topics or keywords is automatically produced to help quickly snapshot contents of the documents. Once a user exits their session, all documents are removed.
PTA - 5:	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.	CIRDS handles health and research related documents submitted by tobacco industry at CTP's request, documents and data that aid in conducting, finding, using, synthesizing, and teaching qualitative research in the health sciences (UCSF); chemical attributes and routes of exposure data (from TCKB), details on CTP research projects (from RTS); scientific review articles CP uses to inform regulatory decisions (from EES and DPS). PII in the CIRDS collection includes author contact information found in research documents for official use. This includes first name, last name, work email

address, and work phone number. CTP operates CIRDS employing the FDA Single Sign-On (SSO) process for identity authentication and access control. health and research related documents submitted by tobacco industry CIRDS pulls documents from internal CTP SharePoint sites including the Tobacco Constituents Knowledge Base (TCKB); the Evidence Extraction System (EES) and Evidence Extraction System Archive (EESA) sites; and the Division of Product Science (DPS) site. CIRDS also pulls documents from internal CTP databases, including Research Tracking System (RTS) data from RTS database; 904(a)(4) Health-Related Documents and 904(b) Research-Related Documents related to toxicological, behavioral, or physiologic effects of current or future tobacco products, their constituents (including smoke constituents), ingredients, components, and additives. In addition, CIRDS pulls research articles from external sources including the University of California San Francisco (UCSF) publications.

RTS also employs the FDA Single Sign-On (SSO) process for identity authentication and access control. Data within RTS is entered by CTP users and includes research concepts, research documents and protocols, funding mechanisms, funding IDs, project funding details, and administrative project documents. All data is internal to CTP. PII collected in RTS includes first and last names, work phone numbers and email addresses of researchers and scientists. PII is used for official business such as author information included in research articles. RTS also stores first and last name, email address and phone numbers of users for tracking in the research workflow process, such as when projects are approved.
ARRT Uses Microsoft O365/Active Directory Credentials for access. ARRT contains hyperlinks to documents stored within other CTP repositories. No personally identifiable information (PII) is collected (into), maintained in, and/or shared out of ARRT Users must already have access to the source repositories for hyperlinks to work.

SSTAT Users must be logged on to their Government Issued devices and FDA network (VPN) to access this tool. SSTAT retains only analytic topic model information. No PII is collected (into), maintained in, and/or shared out of SSTAT. No documents are stored in SSTAT.

PTA - 5A:	Are user credentials used to access the system?	Yes
PTA - 6:	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.	CTP uses CIRDS to collect and maintain health and research related documents submitted by tobacco industry, data about teaching qualitative research in the health sciences, chemical attributes and routes of exposure data, scientific review articles are collected to support well-informed regulatory analysis and decision making by CTP. PII in the CIRDS collection consists of author contact information found in research documents for official use. This includes first name, last name, work email address, and work phone number. This PII is necessary for analysis and comprehensive understanding of the article. RTS holds project funding details, administrative project documents and research project documents such as research protocols. PII collected in RTS includes first and last names, work phone numbers and email addresses of researchers and scientists. PII is used for official business such as author information included in research articles. RTS also stores first and last name, email address and phone numbers of users for tracking in the research workflow process, such as when projects are approved. ARRT contains hyperlinks to documents stored so users can be directed to the source repository for documents. SSTAT retains only analytic topic model information to help improve results on future analyses.
PTA - 7:	Does the system collect, maintain, use or share PII?	Yes
PTA - 7A:	Does this include Sensitive PII as defined by HHS?	No
PTA - 8:	Does the system include a website or online application?	Yes
PTA - 8A:	Are any of the URLs listed accessible by the general public (to include publicly accessible log in and internet websites/online applications)?	No
PTA - 9:	Describe the purpose of the website, 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.	https://airrs.fda.gov/ - This is the landing page for AIRRS suite of applications, it contains links to all applications under AIRRS and can only be accessed internally using FDA Single Sign-On (SSO). https://airrs.fda.gov/cirds - This is the URL for the CIRDS application which can only be

		accessed internally using FDA SSO. https://airrs.fda.gov/rts - This is the URL for the RTS application which can only be accessed internally by personnel using FDA SSO. https://apps.gov.powerapps.us/play/4b6f773f-5b15-4940-bbc9-8282a9fa5c08 - This is the URL for ARRT which can only be accessed internally by individuals using their FDA issued personal identity verification (PIV) Card. https://airrs.fda.gov/lda - This is the URL for SSTAT which can only be accessed internally by individuals using their FDA PIV Card.
PTA - 10:	Does the website have a posted privacy notice?	Yes
PTA - 11:	Does the website contain links to non-federal government websites external to HHS?	Yes
PTA - 11A:	Is a disclaimer notice provided to users that follow external links to websites not owned or operated by HHS?	No
PTA - 12:	Does the website use web measurement and customization technology?	Yes
PTA - 13:	Does the website have any information or pages directed at children under the age of thirteen?	No
PTA - 14:	Does the system have a mobile application?	No
PTA - 20:	Is there a third-party website or application (TPWA) associated with the system?	No
PTA - 21:	Does this system use artificial intelligence (AI) tools or technologies?	No

PIA

PIA - 1:	Indicate the type(s) of personally identifiable information (PII) that the system will collect, maintain, or share.	Email Address Name

		Phone numbers
PIA - 2:	Indicate the categories of individuals about whom PII is collected, maintained or shared.	Employees/ HHS Direct Contractors Members of the public
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?	The PII is stored as part of research documents where authors provide their contact information within the documents. FDA uses other employee PII as part of tracking information in research approval workflow.
PIA - 5:	Describe any secondary uses for which the PII will be used (e.g. testing, training or research).	The FDA makes no secondary use of the PII.
PIA - 7:	Identify legal authorities governing information use and disclosure specific to the system and program.	21 U.S.C. 301, Subchapter IX – Tobacco Products, and Sections 904(a) and 904(b) of the Federal Food, Drug, and Cosmetic Act, as amended by the Family Smoking Prevention and Tobacco Control Act (Pub. L. 111-31, 123 Stat. 1776), incorporated at 18.U.S.C. 1001.
PIA - 8:	Are records in the system retrieved by one or more PII data elements?	No
PIA - 9:	Identify the sources of PII in the system.	Government Sources Within the OPDIV Non-Government Sources Public Media/Internet
PIA - 10:	Is there an Office of Management and Budget (OMB) information collection approval number?	No
PIA - 10C:	Explain why an OMB information collection approval number is not required.	The data in the system is collected from other systems not from individuals and/or is publicly available.
PIA - 11:	Is the PII shared with other organizations outside the system's Operating Division?	No
PIA - 11A:	Identify with whom the PII is shared or disclosed.	

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	There is no option to object to or opt-out of the information collection. FDA does not collect the information directly from individuals; any opting out would occur at the original collection point which is not part of AIRRS and is beyond the scope of this assessment. The PII about external individuals is publicly available information embedded in documents (published research articles or collaborations). FDA employees are advised at the time of hire of the agency's collection, creation and use of PII about them for necessary work purposes.
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.	Individuals whose PII is in the system will be notified of a major change by the most efficient and effective means available and appropriate to the specific change(s). This may include a formal process involving written and/or electronic notice, updated notice and privacy policy language on FDA intranet and internet pages or less formal processes such as email notice to the individuals. If needed, consent will be obtained through the most effective and efficient means available such as via email and/or a webpage.
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.	Individuals who suspect their PII has been inappropriately obtained, used, or disclosed in any FDA and CTP system have several avenues available to resolve the situation using contact and reporting information available across FDA.gov including contacting or submitting concerns to the FDA Privacy Office. Employees aware of potential unauthorized use of PII are required to rapidly report the matter to FDA's Cybersecurity and Infrastructure Operations Coordination Center

		(CIOCC). They may also submit concerns to or request assistance from their supervisor, the FDA Privacy Office, or a 24-hour technical assistance line.
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.	PII in AIRRS (CIRDS) is not specifically reviewed. It is already embedded in documents and aggregated from internal and external sources. These sources are responsible for the integrity, availability, accuracy, and relevancy of the data. Inaccurate PII found in the course of use of AIRRS is corrected as discovered.
PIA - 17:	Identify who will have access to the PII in the system.	Users Developers Contractors
PIA - 17A:	Select the type of contractor.	HHS/OpDiv Direct Contractors
PIA - 17B:	Do contracts include Federal Acquisition Regulation (FAR) and other appropriate clauses ensuring adherence to privacy provisions and practices?	Yes
PIA - 18:	Provide the reason why each of the groups identified in PIA - 17 needs access to PII.	**Users** have access to PII as part of their everyday use for example, to identify the author of an article, or approver of a research project. **Developers** have access to PII for data ingestion, system development, system upkeep and system troubleshooting. **Contractors** have access to PII for data ingestion, system development, system upkeep, system troubleshooting. No PII is collected or stored for contractors.
PIA - 19:	Describe the administrative procedures in place to determine which system users (administrators, developers,	A System Access Request (SAR) form is used to grant different levels of system access based on an individual employee's work need and role. The relevant supervisor will indicate on the SAR form the minimum access that is required and provide justification for the selected access. The scope of access is restricted based on role-based criteria.

	contractors, etc.) may access PII.	Access is restricted to CTP employees and Direct Contractors with valid network accounts. All users are authenticated.
PIA - 20:	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.	The scope of access to different content is restricted based on role-based criteria and using internal technical controls and applying identity authentication standards.
PIA - 21:	Identify the general security and privacy awareness training provided to system users (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 system users at FDA take annual mandatory computer security and privacy awareness training. This training includes guidance on Federal laws, policies, and regulations relating to privacy and data confidentiality, integrity, and availability, as well as the handling of data (including any special restrictions on data use and/or disclosure). The FDA Office of Digital Transformation (ODT) verifies that training has been successfully completed.
PIA - 22:	Describe the training system users receive (above and beyond general security and privacy awareness training).	Personnel are trained on the use of the system and review the HHS/FDA Rules of Behavior. Additional role-based training on privacy is available via FDA's Privacy Office. Users also have access to user guides for the different AIRRS components via the AIRRS website.
PIA - 23:	Describe the process and guidelines in place with regard to the retention and destruction of PII. Cite specific National Archives and Records Administration (NARA) records retention schedule(s) and include the retention period(s).	The electronic data captured or stored within AIRRS is currently retained indefinitely, pending receipt of the requested FDA file code consistent with the National Archives and Records Administration (NARA) guidelines.

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.	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 user access authentication, firewalls, and network monitoring. 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.