PTA / PIA: FDA - CASPER - QTR2 - 2025 - FDA4919092

Created Date: 4/29/2025 12:50 PM Last Updated: 5/7/2025 12:25 PM

General Information

PTA / PIA Name:	FDA - CASPER - QTR2 - 2025 - FDA4919092	**PTA / PIA ID:**	3114944
Component Name:	FDA - HFP Common Automated Submission Process Exchange and Reporting System	**ATO Boundary Name:**	CBER Office of Regulatory Operations
Overall Status:	Complete	**# of Days - Open:**	9
Submitter:		**Submit Date:**	5/5/2025
Next Assessment Date:	N/A	**Expiration Date:**	1/1/2100
Office:		**OpDiv:**	FDA
Security Categorization:	Low		
Make PIA available to Public?:	No	**PIA Required:**	Yes

General 01:	Identify the Enterprise Performance Lifecycle Phase of the system.	Operations and Maintenance
General 02:	Is this a FISMA-Reportable system?	No
General 03:	Does the system have or is it covered by a Security Authorization to Operate (ATO)?	No
General 04:	ATO Date or Planned ATO Date.	12/23/2022
General 05:	Is the system or electronic information collection, agency or contractor operated?	Agency
History Log:	View History Log	

Privacy Threshold Analysis

Privacy Threshold Analysis

PTA 01:	Point of Contact (POC) Name	Wenmin Chen
PTA 01A:	POC Title and Organization	Sup Analyst, OC/FDA
PTA 01B:	POC Email Address	wenmin.chen@fda.gov
PTA 01C:	POC Phone Number	240-402-0730
PTA 02:	Indicate the following reason(s) for this PTA. Choose from the following options.	New
PTA 03:	Is the data contained in the system owned by the agency or contractor?	Agency

PTA 04:	Please give a brief overview of the purpose of the system by describing what the functions of the system are and how the system carries out those functions in support of HHS.	The Common Automated Submission Process Exchange and Reporting (CASPER) is an electronic workflow tracking and information system designed to automate common business practices of receiving, tracking, processing, reporting, storage, and retrieval of submissions. CASPER provides a needed tool that replaces the manual, decentralized receipt, and processing of submissions with one that supports an online single system with a centralized entry point for potentially all business process submissions. CASPER provides imaging, database, workflow, Optical Character Recognition (OCR) functionality that allows managers, analysts, and reviewers to electronically access, assign, capture, and retrieve information needed to conduct business. CASPER contains business process data, including employee names and e-mail addresses. Business process data defines the work activities, tasks, events, rules, people, and the automated systems engaged in delivering goods, services or information to an organization's employees, external customers, and partners. It is the flow or progression of activities, each of which represents the work of a person, an internal system, or the process of a partner company, toward some business goal. All information is internal to the FDA. Users have the ability to add notes to their work activities to record comments, problems and their resolution, or other associated issues. The system collects business contact information, which is considered PII. CASPER collects the following PII information: (a) names of FDA employees and business partners/contacts; (b) work email addresses; (c) telephone numbers; and (d) mailing addresses. The PII data is not shared with any other system or organization. CASPER also collects the following non-PII data: (a) travel and (b) program evaluation and monitoring.

PTA 05:	List and/or describe all the types of information that are collected, maintained, and/or shared by the system regardless of whether that information is PII and how long that information is stored.	The types of information collected into the system are: CASPER collects and maintains the following PII from FDA employees and business partners/contacts: (a) names of FDA employees and business partners/contacts; (b) work email addresses; (c) telephone numbers; and (d) mailing addresses. The types of data that are maintained in and/or shared from the system is/are: The FDA system providing employee data is the Enterprise Administrative Support Environment (EASE) system (the subject of a separate assessment). Employee data is used to log on authorized users automatically and securely. The amount of time the PII is stored in the system is: CASPER is Single Sign On (SSO) and PIV enabled. The system has implemented a multifactor authentication via alternate PIV cards for network access to privileged accounts. The FDA uniquely identifies and authenticates organizational users. For PIV authenticated system, PIV credentials are based on user's certification which are also unique. CASPER also collects the following non-PII: (a) travel and (b) program evaluation and monitoring.
PTA 05A:	Are user credentials used to access the system?	Yes
PTA 05B:	Please identify the type of user credentials used to access the system.	HHS User Credentials HHS/OpDiv PIV Card

PTA 06:	Describe why each type of information is collected, maintained, and/or shared by the system. Specify what information is collected about each category of individual.	The information about managers, analysts, and reviewers is collected and/or maintained in order to electronically access, assign, capture and retrieve information needed to conduct business. FDA employees and Direct Contractors who access or use these applications do not use any personal identifiers to retrieve records held in the CASPER application. The Common Automated Submission Process Exchange and Reporting (CASPER) is an electronic workflow tracking and information system designed to automate common business practices of receiving, tracking, processing, reporting, storage and retrieval of submissions. CASPER provides a needed tool that replaces the manual, decentralized receipt and processing of submissions with one that supports an online single system with a centralized entry point for potentially all business process submissions. CASPER provides imaging, database, workflow, Optical Character Recognition (OCR) functionality that allows managers, analysts and reviewers to electronically access, assign, capture and retrieve information needed to conduct business. CASPER contains business process data, including employee names and e-mail addresses. Business process data defines the work activities, tasks, events, rules, people and the automated systems engaged in delivering goods, services or information to an organization's employees, external customers and partners. It is the flow or progression of activities, each of which represents the work of a person, an internal system, or the process of a partner company, toward some business goal. All information is internal to the FDA. The CASPER system is Single Sign On (SSO) and PIV enabled. The system has implemented a multifactor authentication via alternate PIV cards for network access to privileged accounts. The FDA uniquely identifies and authenticates organizational users. For PIV authenticated system, PIV credentials are based on user's certification which are also unique. Users of the system include administrators and investigators (FDA Employees) and developers (FDA Direct Contractors). CASPER utilizes PIV cards and Single Sign On (SSO). The authenticator is managed by Active Directory and all access is managed and granted through PIV/SSO.
PTA 07:	Does the system collect, maintain, use, or share PII?	Yes
PTA 08:	Does the system include a website or online application?	Yes
PTA 08A:	Provide the URL(s).	**https://cfsanappsinternal.fda.gov/scripts/CASPER/**

PTA 08B:	Are any of the website or online applications accessible by the public (including publicly accessible log in pages)?	No
PTA 09:	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.	The purpose of the website is for internal access for employees/direct contractors Users access the website via login.
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?	No
PTA 12:	Does the website use web measurement and customization technology?	Yes
PTA 12A:	Select the type(s) of website measurement and customization technologies in use and if it is used to collect PII.	Session Cookies- Does Not Collect PII
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:	Are any third-party websites or applications (TPWA) associated with the system?	No
PTA 21:	Does this system use artificial intelligence (AI) tools or technologies?	No

Privacy Impact Assessment

Privacy Impact Assessment

PIA 22:	Indicate the type(s) of personally identifiable information (PII) that the system will collect, maintain, or share.	Biographical Information Name Contact Information Mailing Address (Business) Phone Numbers (Business)
PIA 23:	Indicate the categories of individuals about whom PII is collected, maintained, or shared.	Employees/HHS Direct Contractors
PIA 24:	Indicate the approximate number of individuals whose PII is maintained in the system.	500 – 4,999
PIA 25:	For what primary purpose is the PII used?	The FDA uses the PII for the primary purpose to track, process, report, and store, retrieve submissions, and manage work activities.
PIA 26:	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 28:	Identify legal authorities, governing information use and disclosure specific to the system and program.	The legal authorities that govern information use and disclosures specific to the system and program are: Federal Information Processing Standards (FIPS) 199 and NIST SP 800-60 Rev. 1, Volumes I and II.
PIA 29:	Are records in the system retrieved by one or more PII data elements?	No
PIA 30:	Identify the sources of PII in the system.	Directly from an individual about whom the information pertains Online Government Sources Within the OPDIV

PIA 31:	Is there an Office of Management and Budget (OMB) information collection approval number?	Yes
PIA 31A:	Provide the information collection approval number(s) and expiration date(s).	0910-0832 06/30/2026
PIA 32:	Is the PII in the system shared directly with other organizations outside the system's Operating Division?	No
PIA 33:	Is the submission of PII by individuals voluntary or mandatory as defined in the Privacy Act?	Voluntary
PIA 34:	Describe the method in place to notify and obtain consent from individuals whose PII will be collected. If no prior notice is given or consent cannot be obtained, explain why.	Individuals may opt-out of the collection or use of their PII by: Users of CASPER may ask the agency to remove name and e-mail information from a business process by contacting the system administrator.
PIA 35:	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). If they cannot be notified or have their consent obtained, explain why.	When major changes occur to the system, the process in place to notify: If FDA changes its practices with regard to the collection or handling of PII related to the website, the Agency will adopt measures to provide any required notice and obtain consent from individuals regarding the collection and/or use of PII. This may include email to individuals, adding or updating online notices or forms, or other available means to inform the individual.
PIA 36:	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.	The processes in place to resolve an individual's concerns when they PII has been inappropriately obtained, used or disclosed include: Individuals who suspect their PII has been inappropriately obtained, used, or disclosed in any FDA system have many avenues available for assistance. These individuals may contact FDA offices, including the Privacy Office, the Employee Resource and Information Center (ERIC), the Cybersecurity and Infrastructure Operations Coordination Center (CIOCC) and other agency offices, via email, phone and standard mail avenues (all listed on fda.gov and the FDA intranet). In the event of a suspected incident or data breach, FDA personnel must report without delay to FDA's Cybersecurity and Infrastructure Operations and Coordination Center (CIOCC).

PIA 37:	Describe the process in place for periodic reviews of the system to ensure the integrity, availability, accuracy, and relevancy of the PII in the system. Please address each element in your response. If no processes are in place, explain why not.	The process in place for periodic reviews of PII to ensure the data integrity and data availability is: Integrity and availability are protected by privacy and security controls selected and implemented in the course of providing the system with an authorization to operate (ATO). Controls are selected based on National Institute of Standards and Technology (NIST) guidance concerning the ATO process, appropriate to the system's level of risk as determined using NIST's Federal Information Processing Standards (FIPS) 199. CFSAN performs annual reviews to evaluate user access. The process in place for periodic reviews of PII to ensure data relevancy is: PII relevancy is supported through the design of the system to require and collect only the PII elements necessary to administer the system and enable its intended use. Access is granted and restricted at the individual level as appropriate to the individual's duties (role-based access). Accuracy of PII is ensured: Individuals voluntarily provide their PII. The individual is responsible for providing accurate information. Accuracy is ensured by individual review at the time of reporting. FDA personnel may correct/update their information themselves and their PII is relevant and necessary to be granted access to the system. The limited amount of PII involved is reviewed during the approval and certification process conducted for all submitted CASPER forms.
PIA 38:	Identify who will have access to the PII in the system.	Users Administrators Developers Contractors
PIA 38A:	Select the type of contractor.	HHS/OpDiv Direct Contractors
PIA 38B:	Do contracts include Federal Acquisition Regulation (FAR) and other appropriate clauses ensuring adherence to privacy provisions and practices?	Yes
PIA 39:	Provide the reason why each of the groups identified in 38 needs access to PII.	Employees (also considered the Users) require access so their work product can be tracked. Direct Contractors (listed as admin/developers) require access to perform system specific related duties.

PIA 40:	Describe the administrative procedures in place to determine which system users (administrators, developers, contractors, etc.) may access PII.	The administrative procedures in place to determine which system users may access PII are: Users who require access to the PII in the system need to have supervisor approval before access is granted. There are two ways to request access to the applications: the user emails the business owner/IT Technical Lead or submits a request online through the 'Request Access' application option. The users' supervisor will indicate on the account creation form the minimum information system access that is required for the user to complete his/her job. The agency reviews the access list for the information system on a quarterly basis. During this process users' access permissions are reviewed/adjusted, and unneeded accounts are purged from the system.
PIA 41:	Describe the technical methods in place to allow those with access to PII to access only the minimum amount of information necessary to perform their job.	The following technical methods are in place to allow those with access to PII to only access the minimum amount of information necessary to perform the job: For CASPER, the user's supervisor indicates on the account creation form the minimum necessary system access that is required for the user to complete his/her job. The agency reviews the information system access list semi-annually. During this review the agency reviews/adjusts users' access permissions and removes unneeded accounts from the system.
PIA 42:	Identify the general security and privacy awareness training provided to system users (system owners, managers, operators, contractors and/or program managers) 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 individuals successfully complete the training.
PIA 43:	Describe the training system users receive above and beyond general security and privacy awareness training.	System/system component/information collection users also receive the following additional training: No additional system-specific training is received by users, however: CASPER has an online help guide that is available from within the application and users may email questions to the system administrator.

PIA 44:	Describe the process and guidelines in place for 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 following process and guidelines are in place for the retention and destruction of PII: Records Schedules numbered File Code 020 and 051 GRS 5.2 DAA-GRS-2017-0003- 0002 (Input Records): Temporary. Destroy upon verification of successful creation of the final document or file, or when no longer needed for business use, whichever is later. The specific NARA records schedule is… and the retention schedule and retention period(s) is/are: GRS 3.1 DAA-GRS-2013-0005- 0003 (All other documentation): Destroy 5 years after the project/activity/ transaction is completed or superseded, or the associated system is terminated, or the associated data is migrated to a successor system, but longer retention is authorized if required for business use.
PIA 45:	Describe how the PII will be secured in the system using administrative, technical, and physical controls. Please address each element in your response.	FDA secures PII in the system using the following administrative 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. FDA secures PII in the system using the following technical controls: Technical Safeguards include use of multi-factor access authentication, firewalls, and network monitoring and intrusion detection tools. FDA secures PII in the system using the following physical controls: 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 NIST's Special Publication 800-53, as determined using Federal Information Processing Standard (FIPS) 199.

Review and Comments

OpDiv Privacy Analyst Review

Privacy Analyst Review Decision:	Approved	**Privacy Analyst Review Date:**	5/5/2025
Privacy Analyst Review Comments:		**# of Days - PA Review:**	0

SOP Review

SOP Review Decision:	Approved	**SOP Review Date:**	5/6/2025
SOP Review Comments:		**# of Days - SOP Review:**	1

Agency Privacy Analyst Review

Agency Privacy Analyst Review Decision:	Approved	**Agency Privacy Analyst Review Date:**	5/6/2025
Agency Privacy Analyst Review Comments:	Reviewer: Crystal Bland 5/6/2025 All comments seems to be address. This PIA is ready for SAOP review and approval. 5/2/2025 Please see comments and update accordingly. PTA-1-1C: Must list the POC information prior to PIA and ATO approval. PIA-22: Per PTA-5, please select work email (Email (Business)) and are Phone numbers and mailing address Personal or Business? If Business then update the selection to Phone numbers (Business) and mailing address (Business). PIA-39: Please provide the reason Administrators and Developers have access to PII. If contractors are Administrators and/or Developers please state that in your response. Also if Employees are considered Users then please state that in your response. We need to have a clear distinction between the roles and their access to PII.	**# of Days - APA Review:**	0

SAOP Review

SAOP Review Decision:	Approved	**SAOP Review Date:**	5/7/2025
SAOP Review Comments:		**# of Days - SAOP Review:**	1

SAOP Signature

Date	User	Type	Name	Original Value	New Value
5/7/2025 11:01 AM	GUENTHER, BRIDGET	Signature	SAOP (Email PIN)		Content Signed

Supporting Document(s)

Name	Size	Type	Upload Date	Downloads
No Records Found				

Comments

Question Name	Submitter	Date	Comment	Attachment
PTA 01	BLAND, CRYSTAL	5/1/2025	5/1/2025 Couldn't attached email or copy of PIA, received error that it was an invalid size. Per email, The PIA is experiencing an Archer error with Question #3 of the general information. Q-3 “Does the system have or is it covered by a Security Authorization to Operate (ATO)?” The FDA instance of Archer is automatically entering the answer “No,” which is incorrect. The ATO date is 12/23/2022. At this time, we are unable to update Archer to reflect the correct answer “Yes.” The FDA Archer Team is aware of this occurrence and is working on a solution.	
PTA 01	BLAND, CRYSTAL	5/2/2025	Must list the POC information (Name) prior to PIA and ATO approval.	
PTA 01A	BLAND, CRYSTAL	5/2/2025	Must list POC title and Organization prior to PIA and ATO approval.	
PTA 01C	BLAND, CRYSTAL	5/2/2025	Must list POC phone number prior to PIA and ATO approval.	
PIA 22	BLAND, CRYSTAL	5/2/2025	Per PTA-5, please select work email (Email (Business)) and are Phone numbers and mailing address Personal or Business? If Business then update the selection to Phone numbers (Business) and mailing address (Business).	
PIA 39	BLAND, CRYSTAL	5/2/2025	Please provide the reason Administrators and Developers have access to PII. If contractors are Administrators and/or Developers please state that in your response. Also if Employees are considered Users then please state that in your response. We need to have a clear distinction between the roles and their access to PII.	