Privacy Impact Assessment (PIA): FDA - MIA - QTR1 - 2025 - FDA4914004

Created Date: 2/24/2025 7:33 PM Last Updated: 3/10/2025 1:55 PM

Copy PIA (Privacy Impact Assessment)

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Instructions

Review the following steps to complete this questionnaire:

1) Answer questions. Select the appropriate answer to each question. Question specific help text may be available via the icon. If your answer dictates an explanation, a required text box will become available for you to add further information.

2) Add Comments. You may add question specific comments or attach supporting evidence for your answers by clicking on the icon next to each question. Once you have saved the comment, the icon will change to the icon to show that a comment has been added.

3) Change the Status. You may keep the questionnaire in the "In Process" status until you are ready to submit it for review. When you have completed the assessment, change the Submission Status to "Submitted". This will route the assessment to the proper reviewer. Please note that all values list questions must be answered before submitting the questionnaire.

4) Save/Exit the Questionnaire. You may use any of the four buttons at the top and bottom of the screen to save or exit the questionnaire. The button allows you to complete the questionnaire. The button allows you to save your work and close the questionnaire. The button allows you to save your work and remain in the questionnaire. The button closes the questionnaire without saving your work.

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

PIA Name:	FDA - MIA - QTR1 - 2025 - FDA4914004	**PIA ID:**	2804705
Name of Component:	FDA - CTP RTI Monthly Implementation Assessment	**Name of ATO Boundary:**	CTP RTI International
Overall Status:		**PIA Queue:**	
Submitter:		**# Days Open:**	14
Submission Status:	Submitted	**Submit Date:**	3/5/2025
Next Assessment Date:	03/09/2028	**Expiration Date:**	3/9/2028
Office:		**OPDIV:**	FDA
Security Categorization:	Not Rated	**OpDiv PIA ID:**	FDA4914004
Legacy PIA ID:		**Make PIA available to Public?:**	Yes

1:	Identify the Enterprise Performance Lifecycle Phase of the system.	Initiation
2:	Is this a FISMA-Reportable system?	No
3:	Does the system have or is it covered by a Security Authorization to Operate (ATO)?	No
4:	ATO Date or Planned ATO Date.	11/1/2022
5:	Is the system or electronic information collection, agency or contractor operated?	

PTA

PTA

PTA - 2:	Indicate the following reason(s) for this PTA. Choose from the following options.	PIA Validation (PIA Refresh)
PTA - 2A:	Describe in further detail any changes to the system that have occurred since the last PIA.	This PIA was updated to include website collection.
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 Real Cost" Campaign Monthly Implementation Assessment (MIA) is an electronic information collection subject to the Paperwork Reduction Act (PRA) being conducted by FDA's Center for Tobacco Products (CTP). The term study is used in this assessment instead of system. The purpose of the Monthly Study is to evaluate the implementation of "The Real Cost" campaign. The Monthly Study is a cross-sectional study consisting of monthly data collection, spanning 2 years. The Monthly Study will use an online survey to collect data from up to 2,000 youth ages 12-20 in the United States each month. All surveys will be self-administered online. The survey is estimated to take approximately 25 minutes to complete for each respondent. The external contractor analyzing the data on behalf of the FDA is Research Triangle Institute International (RTI). The external sub-contractor collecting and storing the data on behalf of the FDA is Ipsos. The Ipsos Knowledge Panel, an established national online panel of adults is solely maintained by Ipsos. Data from the voluntary respondents (adults participating on the Ipsos Knowledge Panel) will be processed by Ipsos to de-identify it before being shared to either RTI or FDA. This Knowledge Panel system is maintained solely by Ipsos in the Ipsos Amazon Web Services (AWS) platform and accessed solely by employees of Ipsos who are designated as requiring access based on their role and duties. Ipsos does not allow external third-party access to the Knowledge Panel system. Neither RTI nor FDA will access it directly. Ipsos will de-identify data shared from the Knowledge Panel before providing it to RTI. Data will be transmitted by standard SSH File Transfer Protocol (SFTP) or Liquid Files that limit the number of people who receive the information and the period it is accessible.
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.	This information collection will rely on an online survey to be self-administered to children of respondents in the Ipsos Knowledge Panel sample, an established national online panel of adults. All Knowledge Panel participants/respondents are adults, 18 years and older. As the respondents are already part of Ipsos's internal Knowledge Panel, having given consent for Ipsos to contact them, and the method they wish to be contacted, no additional PII is required to facilitate study recruitment. The respondents have already consented and approved Ipsos to possess and maintain the information they voluntarily submit. Data collection for the Monthly Study will consist of a monthly online survey. Ipsos will send out a request through their Knowledge Panel to parents of youth ages 12-20 asking interested parents to complete a brief screener to determine eligibility for their child (youth) to participate, through their parent, in the Monthly Study. Ipsos will screen Knowledge Panel participants that are 18 years or older directly into the Monthly Study. Ipsos will not collect any personally identifiable information (PII)

from adults on behalf of the Monthly Study. Ipsos already has the following PII for adult Knowledge Panel participants: first and last names, mailing address, email addresses, phone numbers, and date of birth. Ipsos will not share this PII with RTI or FDA.

The Monthly Study will also collect the following non-PII data: (1) youth age; (2) Youth's race/ethnicity; (3) Youth's acculturation; (4) Youth's gender identity; (5) Youth's sexual orientation; (6) Youth's perceived financial situation; (7) Youth's tobacco use; (8) Youth's media campaign awareness; (9) Youth's awareness of other media campaigns; (10) Youth's attention and processing of the media campaign advertisements; (11) Youth's receptivity and comprehension of the media campaign advertisements; (12) Youth's belief and knowledge tracking; and (13) Youth psychographic information (attitudes, interests, personality, values, opinions).

Additional PII may be gathered from the Ipsos Knowledge Panel, depending on the specific questions that are asked. Survey response data gathered through the adult Knowledge Panel will be de-identified prior to transmission to RTI International, the data analyst contractor.

Delivered survey data includes only survey data, non-PII demographics and surveys weights.

As the relationship with Ipsos Knowledge Panel respondents is wholly between Ipsos and the individual respondents, at no time will either RTI International or FDA have access to any of the respondent information, including PII. Only Ipsos employees are permitted access to respondent information. Neither FDA CTP nor RTI will have access to survey data files containing PII (respondent name, email address, date of birth, and phone numbers).

RTI study staff will be provided de-identified data and will store it on a secure RTI share drive. The data will remain and be stored on RTI's secure shared drive for three years after the project has ended. RTI will also securely share de-identified datasets with relevant FDA staff through a restricted SharePoint site. Only staff who are granted access to the SharePoint site by the RTI SharePoint manager will have access to the data files. FDA will store these data on a secure drive. Only the necessary RTI and FDA study staff will have access to de-identified survey data. Only RTI and FDA project staff directly involved in analysis will have access to the de-identified survey data. No respondent identifiers will be contained in data delivery and reports to FDA and results will only be presented in aggregate form.

The Ipsos Knowledge Panel system and Ipsos overall operations are governed and certified under ISO (International Organization for Standardization, information security standard) 27001, the European Union General Data Protection Regulation (GDPR) when appropriate and complies with all applicable US Federal regulations. Terms of the contract issued by the FDA also specify data security and privacy

		standards and requirements and are binding on RTI and Ipsos.
PTA - 5A:	Are user credentials used to access the system?	No
PTA - 5B:	Please identify the type of user credentials used to access the system.	
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.	The Monthly Implementation Assessment is a cross-sectional study designed to evaluate and understand youth awareness; attention; processing; and receptivity and comprehension of The Real Cost ads airing across various digital media platforms. FDA's The Real Cost is a national public education campaign to prevent youth tobacco use. The Monthly Study will consist of online surveys that are self-administered on personal computers or web enabled mobile devices. FDA will use an Ipsos Knowledge Networks Panel to collect rapid data on The Real Cost ads. The Monthly Implementation Assessment will ask youth participants, through their penal-participating parent(s), to answer survey questions on ad awareness, attention, processing, and ad receptivity. At no point in the survey process is information gathered directly from individuals under age 18. To ensure data security, all RTI and Ipsos project staff will be required to adhere to strict standards and to sign a non-disclosure agreement as a condition of employment on this project. RTI maintains restricted access to all data preparation areas (i.e., receipt and coding). All data files on multi-user systems will be under the control of an Ipsos database manager, with access to the data restricted to only project staff specifically authorized to work on this project. Survey responses are written in real-time directly to Ipsos's server and are then stored in a local MS-SQL database. Ipsos has developed a secure transmission and collection protocol, including the use of system passwords, encryptions, and firewalls to prevent unauthorized access to the data collection system. Ipsos will use the parents' first and last name and address so that they can provide incentives to promote survey responses. Ipsos will not share this information with RTI or CTP. RTI and CTP will not have access to any data that could be combined to identify respondents. All information held by Ipsos is given voluntarily by the respondents and their parents as part of an agreement solely between Ipsos and the youth respondents' parents. On Ipsos's secure server, survey responses will be distinguished by assigned unique identifiers. Only Ipsos project staff will have access to the database that links the Case ID (specific to a response) with identifying information. Only study participants will be assigned a Case ID and password by Ipsos. Case ID and passwords are required to access the online questionnaire; access will not be available to the public. Parent names, email addresses, phone

		numbers, youth date of birth, Case ID, IP addresses, and mailing addresses, which are considered PII and are controlled by Ipsos, will not be shared by Ipsos with RTI nor FDA. FDA CTP employees must use the Single Sign On process with their personal identity verification (PIV) cards to access the de-identified data, which will be stored on secure internal shared drives at CTP. The FDA will not store or maintain PII internally (within the FDA network), nor will it have access to any PII collected from this study. Data collection will be conducted by Ipsos on behalf of FDA and RTI. RTI will maintain all non-PII collected data, within RTI's or its subcontractors'/service providers' environment. Ipsos, RTI, and FDA, including any vendors or subcontractors, will use Case ID, but no other personal identifiers, to retrieve records held in the system during this study.
PTA - 7:	Does the system collect, maintain, use or share PII?	Yes
PTA - 7A:	Does this include Sensitive PII as defined by HHS?	Yes
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)?	Yes
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.	The purpose of the website is to collect survey data. Only panel members or their children with a unique personalized link will have access to the survey. They will access the data one of two ways, through the link in their emailed invite or through the Knowledge Panel portal. Each panelist has a unique log-in for the survey. It is a one-time use log-in.
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 - 11A:	Is a disclaimer notice provided to users that follow external links to websites not owned or operated by HHS?	
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 - 13A:	Does the website collect PII from children under the age thirteen?	
PTA - 13B:	Is there a unique privacy policy for the website and does the unique privacy policy address the process for obtaining parental consent if any information is collected?	
PTA - 14:	Does the system have a mobile application?	No
PTA - 14A:	Is the mobile application HHS developed and managed or a third-party application?	
PTA - 15:	Describe the purpose of the mobile application, who has access to it, and how users access it. Please address each element in your response.	
PTA - 16:	Does the mobile application/ have a privacy notice?	

PTA - 17:	Does the mobile application contain links to non-federal government websites external to HHS?	
PTA - 17A:	Is a disclaimer notice provided to users that follow external links to resources not owned or operated by HHS?	
PTA - 18:	Does the mobile application use measurement and customization technology?	
PTA - 18A:	Describe the type(s) of measurement and customization technologies or techniques in use and what information is collected.	
PTA - 19:	Does the mobile application have any information or pages directed at children under the age of thirteen?	
PTA - 19A:	Does the mobile application collect PII from children under the age thirteen?	
PTA - 19B:	Is there a unique privacy policy for the mobile application and does the unique privacy policy address the process for obtaining parental consent if any information is collected?	
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

PIA - 1:	Indicate the type(s) of personally identifiable information (PII) that the system will collect, maintain, or share.	Name Email Address Phone numbers Date of Birth Mailing Address Other - Free text Field
PIA - 2:	Indicate the categories of individuals about whom PII is collected, maintained or shared.	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?	For the Monthly Study, Ipsos will not collect any PII from parents of youth. Ipsos already has PII for adult Knowledge Panel participants; this information will not be collected for the Monthly Study. Ipsos collects parent/adult first and last names, mailing addresses, email addresses, telephone number and date of birth during the initial screening process for participation in the Ipsos Knowledge Panel and does not need to collect it again for this study. Ipsos will use the mailing addresses and email addresses to send the study participation incentives to the parents of the youth participants and to those participants who are 18 years or older.
PIA - 5:	Describe any secondary uses for which the PII will be used (e.g. testing, training or research).	Not applicable. The collected PII is not used for secondary purposes.
PIA - 6:	Describe the function of the SSN, Truncated SSN, and/or Taxpayer ID.	
PIA - 6A:	Cite the legal authority to use the SSN, Truncated SSN, and/or Taxpayer ID.	

PIA - 7:	Identify legal authorities governing information use and disclosure specific to the system and program.	The 2009 Family Smoking Prevention and Tobacco Control Act (Tobacco Control Act) (Pub. L. 111-31) amends the Federal Food, Drug, and Cosmetic Act (the FD&C Act) to grant FDA authority to regulate the manufacture, marketing, and distribution of tobacco products to protect public health and to reduce tobacco use. Section 1003(d)(2)(D) of the FD&C Act (21 U.S.C. 393(d)(2)(D)) supports the development and implementation of FDA public education campaigns related to tobacco use. Accordingly, FDA conducts evaluations of public education campaigns to determine their effectiveness in preventing and reducing tobacco use among youth.
PIA - 8:	Are records in the system retrieved by one or more PII data elements?	No
PIA - 8A:	Please specify which PII data elements are used to retrieve records.	
PIA - 8B:	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.	
PIA - 9:	Identify the sources of PII in the system.	Directly from an individual about whom the information pertains Email Online Non-Government Sources Members of the Public
PIA - 10:	Is there an Office of Management and Budget (OMB) information collection approval number?	No
PIA - 10A:	Provide the information collection approval number.	
PIA - 10B:	Identify the OMB information collection approval number expiration date.	
PIA - 10C:	Explain why an OMB information collection approval number is not required.	An OMB collection number is acquired, but it has not yet been assigned. This is a new data collection. CTP expects to receive OMB approval by July 2025. We will provide the OMB control number and expiration date once OMB issues the Notice of Action.
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 - 11B:	Please provide the purpose(s) for the disclosures described in PIA - 11A.	
PIA - 11C:	List any agreements in place that authorizes the information sharing or disclosure (e.g., Computer Matching Agreement (CMA), Memorandum of Understanding (MOU), or Information Sharing Agreement (ISA)).	
PIA - 11D:	Describe process and procedures for logging/tracking/accounting for the sharing and/or disclosing of PII. If no process or procedures are in place, please explain why not.	
PIA - 12:	Is the submission of PII by individuals voluntary or mandatory?	Voluntary
PIA - 12A:	If PII submission is mandatory, provide the specific legal requirement that requires individuals to provide information or face potential civil or criminal penalties.	

PIA - 13:	Describe the method for notifying individuals that their information will be collected and how they can opt-out of the collection or use of their PII. If there is no option to object to the information collection, provide a reason.	Respondents are provided a study consent/assent form that describes the voluntary nature of all data they provide, including PII. Respondents may choose to not join the study, and are free to withdraw at any time, including while responding to the survey questions. To withdraw from the study, respondents can contact Ipsos.
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.	No such changes are anticipated. If Ipsos changes its practices regarding the collection or handling of PII related to this study, they will adopt measures to provide any required notice and obtain consent from individuals regarding the collection and/or use of PII. This may include contacting participants by phone, e-mail, or mail to request their consent or assent.
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.	Participants can use a variety of avenues to seek assistance with concerns about their PII. All materials and communications include a toll-free phone number and project email address which will allow them to reach a helpdesk maintained by Ipsos. Study materials will also include the phone number for the Ipsos Institutional Review Board which oversees protection of human subjects who participate in this research study. Individuals may also contact RTI and/or the FDA for assistance with concerns about their PII. All FDA and contractor personnel are required to rapidly report suspected PII incidents/breaches.
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.	Respondent (adult over age 18, parent, youth under age 18 through parent) PII will be provided voluntarily by the individual subject. The individual is responsible for providing accurate information. Accuracy is ensured by individual review at the time of data review. Periodic reviews of PII are conducted at the systems level at Ipsos, not at the project level. These reviews evaluate the need to know of anyone beyond Panel Management and Statistics personnel at Ipsos. All access to PII is by functional necessity and addressed through password protection. PII will not be transmitted to the FDA or RTI. Relevancy is ensured by the design of the study and survey questions. PII de-identification by Ipsos further supports relevancy by limiting data provided to RTI and FDA to non-PII. Standards and processes required under contract terms and applied by RTI and Ipsos also support appropriate PII integrity and availability.
PIA - 17:	Identify who will have access to the PII in the system.	Contractors
PIA - 17A:	Select the type of contractor.	Third-Party Contractor (Contractors other than HHS 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.	Ipsos requires access to email addresses and phone numbers for the necessary purpose of contacting respondents for recruitment into the Monthly Implementation Assessment. Ipsos Panel Relations staff manage incentive fulfillment (physical checks mailed to the respondent's address). Panel Relations staff handle PII data from Knowledge Panel members but have no access to survey data. Ipsos statistics staff have access survey data but no PII. Neither FDA nor RTI will have access to survey data files containing PII (respondent name, email address, date of birth, and phone numbers).
PIA - 19:	Describe the administrative procedures in place to determine which system users (administrators, developers, contractors, etc.) may access PII.	Ipsos has individual level administrative approval procedures in place to restrict staff access to PII. Specifically, Statistics staff who have access to survey data cannot also access Knowledge Panel member PII, while Project Managers and Panel Relations staff who access Knowledge Panel member PII as part of their job function (e.g., to address member inquiries, incentive fulfillment) cannot also access survey data. Statistics staff do not have access to Knowledge Panel member PII. PII is removed and aggregate data is used for sampling and weighting.
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.	Ipsos uses role-based access controls to ensure appropriate access commensurate with the role everyone is required to perform. "Roles" are job functions in which certain permissions are granted according to the actual need of the person's project responsibilities. Those who need access to PII for purposes of panel management (survey invitations, incentive distributions, etc.) have no access to respondent survey data, while those with access to survey data have no access to PII. Technical processes and steps are applied to confirm roles, associate data access with the role, authenticate user identity.
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.	Project Managers complete certification (e.g., CITI Program Research Ethics and Compliance Training), with the certification being renewed as required by the organization.
PIA - 22:	Describe the training system users receive (above and beyond general security and privacy awareness training).	CITI Program Research Ethics and Compliance Training focuses on human subjects' protections.

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).	Currently there are no record schedules in place to provide guidance on PII gathered and retained by RTI/Ipsos on behalf of FDA. FDA itself will not receive or maintain PII and PII retention is not an issue. FDA will archive the de-identified data containing no PII indefinitely and provide access to approved personnel. FDA records that do not have an approved disposition schedule will be retained until disposition authority is obtained from NARA in accordance with Implementing Schedules under 36 CFR 1226.14. Ipsos does not provide PII to RTI. In accordance with Federal Acquisition Regulation (FAR) Subpart 4.7, RTI will retain all documents and data for at least three years after final payment of the contract, unless a shorter period is specified. FDA and RTI will not have hard copy materials and will not have access to sensitive data. Ipsos will retain the survey-specific response data and metadata in its secure database after a project is completed. These data are retained for purposes of operational research, such as studies of response rates and for the security of our customers who might request additional analyses later or statistical adjustments. All PII are housed in a separate database from survey data, with restricted access granted to those with a need to know. No PII will be sent to or accessible by RTI and FDA at any time.

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.	Ipsos maintains all PII exclusively, and applies administrative, technical, and physical controls to secure the data. All records containing PII, such as names, addresses, and emails, are kept on Ipsos' physically secure password-protected encrypted data storage systems within actively monitored network firewalls. All data transfers from web-enabled devices (PCs and laptops used for survey administration) to the main servers are protected by data encryption and a network firewall. Ipsos never provides any respondent's PII to any external client or agency without the respondent's explicit and informed consent, and the client or agency must also sign a non-disclosure agreement. Any subcontractors or service providers who handle PII and/or survey response data are subject to confidentiality and non-disclosure agreements. Ipsos uses organizational controls including pseudonymous identifiers to segregate data and restrict access on a need-to-know basis. A master file linking research participants' names and addresses with their corresponding internally generated ID numbers is kept secure with access limited to Panel Management staff members and IT administrators who must have access to maintain the computer systems. Thus, researchers, data processing, or coding staff who have a business need to analyze participant-level survey data can do so without seeing participants' PII. Ipsos' databases contain field-specific permissions that restrict access to data by type of user, as described above, thus preventing unauthorized access.

Review & Comments

Privacy Analyst Review

OpDiv Privacy Analyst Review Status:	Approved	**Privacy Analyst Review Date:**	3/5/2025
Privacy Analyst Comments:		**Privacy Analyst Days Open:**	

SOP Review

SOP Review Status:	Approved	**SOP Signature:**	
SOP Comments:	The FDA's Senior Official for Privacy (SOP) has: (a) approved the Privacy Threshold Analysis (PTA)/Privacy Impact Assessment (PIA) conducted for the subject system/component; (b) reviewed and approved the associated security categorization; and (c) reviewed and confirmed acceptable implementation status of the assigned privacy controls.	**SOP Review Date:**	3/5/2025
		SOP Days Open:	0

Agency Privacy Analyst Review

Agency Privacy Analyst Review Status:	Approved	**Agency Privacy Analyst Review Date:**	3/6/2025
Agency Privacy Analyst Review Comments:	Reviewer: Shanai Shobowale 3/6/2025 There was a sync issue and they the fixed the issue of the word gender on the document we reviewed outside the tool but it still appears in PTA-5. I have attached the correct PIA to Supporting Documentation. They could fix this issue during the 508 process prior to posting. 2/28/2025 PTA-5: Per the Executive Order - Defending Women From Gender Ideology Extremism And Restoring Biological Truth To The Federal Government. The term "gender" need to be removed and replace with the term "sex." Please remove "(4) Youth's gender" and replace with "(4) Youth's sex."	**Agency Privacy Analyst Days Open:**	1

SAOP Review

SAOP Review Status:	Approved	**SAOP Signature:**	Archer Signature_Bridget Guenther.docx
SAOP Comments:		**SAOP Review Date:**	3/10/2025
		SAOP Days Open:	4

Supporting Document(s)

Name	Size	Type	Upload Date	Downloads
CTP RTI Monthly Implementation Assessment_3.5.2025_SMS_PA Approved.rtf	758741	.rtf	3/6/2025 8:57 AM	0
CTP RTI Monthly Implementation Assessment_SOP Approved.pdf	189800	.pdf	2/25/2025 12:31 PM	0
PIA in Queue (CTP RTI Monthly Implementation Assessment).pdf	418493	.pdf	2/25/2025 12:31 PM	0

Comments

Question Name	Submitter	Date	Comment	Attachment
PIA - 1	BLAND, CRYSTAL	2/28/2025	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 11/1/2022. 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.	
PIA - 1	BLAND, CRYSTAL	2/28/2025	PTA-5: Per the Executive Order - Defending Women From Gender Ideology Extremism And Restoring Biological Truth To The Federal Government. The term "gender" need to be removed and replace with the term "sex." Please remove "(4) Youth's gender" and replace with "(4) Youth's sex."	

Admin Section

Is OpDiv Privacy Analyst Approved ?:	1	**Is OpDiv Privacy Analyst Return ? :**	0
		Is SOP Return ?:	0
Is Agency Privacy Analyst Approve ?:	1	**Is Agency Privacy Analyst Return ?:**	0
Is SAOP Approved?:	1	**Is SAOP Return ?:**	0
Total Approved:	4	**Total Return:**	0
Total Approval Required:	4		

Miscellaneous Fields

Last Updated:	3/10/2025 1:55 PM	**History Log:**	View History Log