Privacy Impact Assessment (PIA): FDA - ExPECTT III - QTR2 - 2022 - FDA2061002

Date Signed: 7/11/2022

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:**	1457399
PIA Name:	FDA - ExPECTT III - QTR2 - 2022 - FDA2061002	**Title:**	FDA - CTP RTI International
OpDiv:	FDA		

PTA

PTA - 1A:	Identify the Enterprise Performance Lifecycle Phase of the system	Initiation
PTA - 1B:	Is this a FISMA-Reportable system?	No
PTA - 2:	Does the system include a website or online application?	No
PTA - 3:	Is the system or electronic collection, agency or contractor operated?	Contractor
PTA - 3A:	Is the data contained in the system owned by the agency or contractor?	Agency
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	6/25/2021
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 Outcomes Study 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. To continue assessing the impact of the "The Real Cost" campaign, the FDA will implement the Outcomes Study. The purpose of the Outcomes Study is to evaluate The Real Cost campaign being conducted by CTP in support of its mandate to positively impact public health by reducing and preventing tobacco use among youth.

The Outcomes Study is a longitudinal study with a main data collection consisting of four waves: a baseline wave and three follow-up waves. The external contractor collecting and storing the data on behalf of the FDA is RTI International (RTI). For the main data collection, a national probability sample of approximately 8,500 U.S. households with a child aged 11-17 will be used for this study. Addresses from a probability sample of U.S. households will be obtained from RTI's Address Based Sampling (ABS) Frame; acquired from the U.S. Postal Service Computerized Delivery Sequence file, which does not contain names. Recruitment will be done by contacting selected households by mail describing the purpose of the study and requesting that the parent/guardian complete and return to RTI a brief online or mail screener confirming they are eligible (have a child aged 11-17 living in the household). Approximately 6,000 youth ages 11-17 will complete the baseline survey online. To adhere to Children's Online Privacy Protection Act (COPPA), RTI has a privacy policy that addresses the collecting of data from minors under 13 as well as procedures to collect and store parental consent for the minor's personal information. With approval from the Institutional Review Board overseeing the study, we will waive parental permission for those ages 14 to 17 for both the main and supplemental data collection (or 14 to 18 in Alabama and Nebraska as required by state law), and instead ask youth respondents to provide assent of their own accord.

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.	The main data collection for the Outcomes Study will consist of an online or mail screener, online baseline survey, and three online follow-up

surveys. The following PII will be collected (but will not be shared with FDA): (a) parent's first/last name; (b) parent's mailing address; (c) parent's email address; (d) parent's phone number; (e) youth's first/last name; and (f) youth's date of birth. The Outcomes Study will collect additional PII for youth with a waiver of parental permission, including: (g) youth's phone number; (h) youth's email address; and (i) youth's mailing address.

The supplemental data collection will consist of an online screener, online baseline survey, and three online follow-up surveys. The following PII will be collected for the supplemental data collection (but will not be shared with FDA): (e) youth's first/last name; (f) youth's date of birth; (g) youth's phone number; (h) youth's email address; (i) youth's mailing address; (j) Facebook unique ID; and (k) IP address.

PII data, including the youth's first and last name, and mailing address for both the main and supplemental data collections will be shared with the incentive provider group at RTI (Division of Research Services Respondent Incentive Group) so that they can distribute incentives.

For the main data collection, parent's first and last name, mailing address, and youth's first name will be shared with the print vendor for mailing lead letters, study information sheets, paper and pencil interview screeners when necessary, and reminder letters. The batch tracing vendor (LexisNexis) receives parent first and last names and addresses at follow-ups to conduct an initial round of automated tracing for respondents that have moved since the prior study. For respondents who are 18+, the batch tracing vendor will also receive respondent first and last names and address to conduct automated tracing. Call center staff (HR Directions, subcontractor) will receive parent first and last names, phone numbers, and login credentials (Case ID and password) at baseline to contact households and confirm eligibility and invite them to the study. Call center staff (HR Directions, subcontractor) will also receive parent first and last names, phone numbers, and mailing addresses at follow-ups, for use in locating updated contact information for cases where we are unable to locate the respondent at the address currently on file. For respondents who are 18+, call center staff will also receive respondent first and last names and address for use in locating updated contact information for cases where we are unable to locate the respondent at the address currently on file. Additionally, the call center staff will conduct study reminder phone calls to the households at follow-ups.

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	The Outcomes Study is a longitudinal study designed to evaluate the effectiveness of FDA's The Real Cost national public education

campaign to prevent youth tobacco use. The Outcomes Study will consist of an online or mail screener, an online baseline survey, and three online follow-up surveys for both the main and supplemental samples. Results of the evaluation will be used to document awareness of anti-tobacco messaging among youth in the U.S. and the extent to which the messaging has been effective in changing tobacco-related outcomes, including cigarettes and e-cigarettes.

All information collected will be securely maintained on RTI's network servers for the duration of the study. RTI implements security in alignment with the NIST 800-53 controls to secure the network. Paper and pencil interview (PAPI) screeners returned by mail by potential participants will be scanned and the data stored on a secure RTI server. Hard copies of screeners will be shredded and disposed of after scanning.

Baseline and follow-up waves of data collection will be conducted online using the youth's own device (computer or tablet). When the survey is completed, the data will be transmitted from Qualtrics and RTI's Blaise account directly into the Outcomes Study database on RTI's servers. Names, email addresses, phone numbers, Facebook unique ID, IP address, date of birth, and mailing addresses, all considered PII, will never be transmitted to FDA/CTP.

RTI study staff will provide a password-protected file to the RTI Division of Research Services Respondent Incentive Group containing the participants' first and last name and address so that they can provide incentives to respondents. The same will be done for call center staff (HR Directions, subcontractor) for the files for invitation calls at baseline and interactive tracing and reminder phone calls at follow-ups. RTI will not share this information with CTP.

The PII shared with the incentive provider and call center staff will not be linked to any study data and CTP will not have access to any data that could be combined to identify respondents. On RTI's secure server, survey responses will be distinguished by the unique identifiers. Only RTI project staff will have access to the database that links the Case ID with identifying information. Only study participants will be assigned a Case ID and password by RTI. Case ID and passwords are required to access the online questionnaire; access will not be available to the general public. RTI will only provide de-identified data to CTP at the conclusion of data collection. Names, email addresses, phone numbers, date of birth, Case ID, Facebook unique IDs, IP addresses, and mailing addresses, which are considered PII, are never transmitted to CTP. 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 RTI on behalf of FDA and RTI will maintain all collected data, including PII, within RTI's or its subcontractors'/service providers' environment.

RTI, including its vendors and subcontractors, will use Case ID, but no other personal identifiers, to retrieve records held in the system during this study.

PTA - 10A:	Are records in the system retrieved by one or more PII data elements?	No
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 Date of Birth Mailing Address Others - Case ID Password Facebook unique IDIP address Respondents are requested to provide an email address. They may choose to provide personal or professional email addresses.
PIA - 2:	Indicate the categories of individuals about whom PII is collected, maintained or shared	Public Citizens
PIA - 4:	For what primary purpose is the PII used?	For the main data collection baseline survey, parents/guardians are asked to provide their first and last names, email addresses, and phone numbers so RTI can contact them for follow-up waves. Parents are asked to provide their mailing address in order to send the respondent their incentives. At each follow-up wave of the main data collection, parents are asked to provide their first and last names, mailing address, email addresses, and phone numbers. We will also collect first and last names, mailing address, email addresses, and phone numbers from any youth respondents for which we have a parental waiver of permission or who are of the age of majority in both the main and supplemental data collections. Mailing addresses are collected from parents, and youth for which we have a parental waiver of permission or who are of the age of majority in order to send the incentives. Parents are asked to provide their first and last names, phone numbers, and email addresses in order to provide permission for their children, not covered under a waiver, to participate. Email addresses and mailing addresses are collected from youth for which we have a parental waiver of permission to communicate with them directly since parental permission is not required. Date of birth (from all youth participants) is used to confirm that respondents are eligible to participate in the survey. RTI requires access to email addresses, Facebook unique IDs, and IP addresses to prevent duplicate and fraudulent responses in the supplemental data collection recruited through social media.
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 is currently developing and implementing youth-targeted public education campaigns to help prevent tobacco use among youth ages 11-18.
PIA - 9:	Identify the sources of PII in the system	Directly from an individual about whom the information pertains Hard Copy Mail/Fax Online Non-Government Sources Members of the Public
PIA - 9A:	Identify the OMB information collection approval number or explain why it is not applicable.	This is a new data collection. CTP expects to receive OMB approval in early 2023. We will provide the OMB control number and expiration date once OMB issues a Notice of Action.
PIA - 10:	Is the PII shared with other organizations outside the system's Operating Division?	Yes
PIA - 10A:	Identify with whom the PII is shared or disclosed and for what purpose	Private Sector
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	After completing the parent screener, parents will read the parent permission and informed consent language displayed on their personal laptop,

		mobile device, or tablet informing them that personal information will be collected as part of the study. At the end of the parent permission/consent process, the parent will click a radio button indicating they understand and agree or do not agree to allow their child to participate. For households that complete the screener by mail, they will be directed to complete the survey, including the parent permission and informed consent language, on their personal laptop, tablet, or mobile device, similar to those who complete the screener online. Once parent permission is obtained, youth will be presented the informed assent language online via a personal laptop or tablet informing them that personal information will be collected as part of the youth survey. Youth who fall under the waiver of parental permission in both the main and supplemental sample, will receive the informed assent language online via a personal laptop or tablet informing them that personal information will be collected as part of the youth survey. At the end of the assent language, the youth will click a radio button indicating they understand and agree or do not agree to participate. Participants will also complete the parent permission and youth assent process online via a personal laptop or tablet prior to completing the follow-up surveys. We will be waiving parental permission for those ages 14 to 17 (or 14 to 18 in Alabama and Nebraska), and instead ask the youth respondents to provide assent of their own accord for both the main and supplemental data collections. Youth 18 or older at follow-up will complete the informed consent process by providing their own consent
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	Participation in the Outcomes Study is entirely voluntary. Parents and youth may choose to not join the study, and are free to withdraw at any

		time, including while responding to the survey questions. To withdraw their child from the study, parents can call the ExPECTT Helpdesk Manager at RTI. PII provided by parents and youth will be used to contact them for follow-up waves of data collection.
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 FDA changes its practices regarding to the collection or handling of PII related to this study, RTI 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	Individuals can use a variety of avenues to seek assistance with concerns about their PII. All survey invitation letters, reminder postcards, panel maintenance letters, screeners, study information documents, and electronic communications include a toll-free phone number and project email address which will allow them to reach a helpdesk maintained by RTI. Requests received via the helpdesk (either through telephone or email inquiries) will be routed to the appropriate member of RTI's data collection management team. The letters, postcards, and electronic communications also provide the phone number for the Institutional Review Board which oversees protection of human subjects who participate in this research study. Individuals may also contact FDA's Privacy Office via contact information provided on FDA.gov.
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 PII will be provided voluntarily by the individual subject. The individual will be responsible for providing accurate information. Accuracy will be ensured by individual review at

		the time of data review at the end of each wave of data collection. Respondents will be able to correct/update their information themselves by responding to the panel maintenance letter, providing new information during the survey data collection, or by contacting RTI's project specific toll-free phone number or email address. Respondent PII is relevant and necessary to participate in the survey. Access to PII by RTI staff and subcontractors will be granted and restricted at the individual level as appropriate to the individual's duties (role-based access). Integrity and availability will be protected by privacy and security controls selected and implemented in the course of providing the system with an authority to operate (ATO). Controls will be selected based on National Institute of Standards and Technology's (NIST's) guidance concerning the ATO process, appropriate to the system's level of risk as determined using the NIST's Federal Information Processing Standards (FIPS) 199.
PIA - 17:	Identify who will have access to the PII in the system and the reason why they require access	Contractors Others
PIA - 17A:	Provide the reason of access for each of the groups identified in PIA-17 **Contractors:** RTI requires access to email addresses and phone numbers to contact participants for future waves of the study. The print vendor (NPC, Inc) has access to parent first and last names, child first names, mailing addresses, and Case ID and passwords in order to print and mail study materials. Case ID, names, and passwords are included in the invitation letters, and reminder letters/postcards sent to households. RTI requires access to email addresses, Facebook unique IDs, and IP addresses to prevent duplicate and fraudulent responses in the supplemental data collection recruited through social media. **Others:** The internal RTI incentive group (Division of Research Services Respondent Incentive Group) will receive mailing addresses and Case IDs of participants to distribute incentives.	
PIA - 17B:	Select the type of contractor	Third-Party Contractor (Contractors other than HHS Direct Contractors)
PIA - 18:	Describe the administrative procedures in place to determine which system users (administrators, developers, contractors, etc.) may access PII	System roles are reviewed and authorized by project management and granted by the appropriate administrator. Role-based access

		controls are applied for all PII. Contractor system administrators for the project have role-based access to PII and utilize only the PII necessary to perform job duties identified with their role. Other RTI employees (i.e., project director, data collection task leader, programming task leader, programming team, data collection managers, data collection supervisors, data collectors, analysts) are provided with access to the secure project share to access PII or survey data to perform role-based programming, data management, data collection, analysis, and/or reporting job duties. Role-based access control is employed so that users only have "need-to-know" access to the data necessary to perform their job duties.
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	The data collection system employs data access through the use of controls advised by NIST Special Publication 800-53 that are deployed in RTI's network to ensure that access to any data is restricted by role. Unaffiliated with the project team, RTI Global Technology Solutions (GTS) maintains all role-based access controls independently from project staff. Inclusion of project staff users in role groups must be formally requested to RTI GTS and specifically approved by the RTI project director or project manager for any user to obtain access to systems or data. Membership in specific role groups allows specific access to specific data and/or systems. Role-based access to PII is limited to the information needed to perform specific tasks. Role-based access controls are in place and authorized only for individuals who are or were involved in processing and managing data collection production, and for contacting study participants for the purposes of data collection, fulfillment, and telephone tracing or prompting activities.
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	RTI requires all personnel to complete company-wide, Information Security and GTS cyber awareness training before obtaining authorization to access RTI's information system. RTI conducts this training upon employment and

		a refresher course at least annually thereafter. Additionally, RTI provides company-wide Privacy Training. These trainings cover the same core components as the FDA privacy awareness training. Additional project-specific training on protecting the information being collected and maintained will be provided to the RTI project team, including call center staff. These staff members are also required to complete the Commitment to Protect Non-Public Information Employee Agreement (FORM FDA 3398 (10/10)).
PIA - 21:	Describe training system users receive (above and beyond general security and privacy awareness training).	All call center staff receive privacy training at the start of their employment and then annually through RTIUx. The training focuses on data security practices and how to protect the privacy of the data. This training mirrors the training RTI staff complete on an annual basis regarding data security and privacy. In addition, staff are required to sign a pledge regarding data security practices they are expected to follow while working remotely.
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)	Currently there are no record schedules in place to provide guidance on PII gathered and retained by the FDA. 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. 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. Hard copies of screeners will be shredded and disposed of after scanning. Until the date of destruction, hard copy materials will be stored in RTI's secure long-term storage facility. Hard copy materials will be securely shredded at the time of destruction. For electronic data and materials, file deletion is the only practical method of destroying records stored on hard drives or share drives that will remain in service following destruction of the information. Any hard drive that previously contained sensitive information will be reformatted and then physically destroyed when it is taken out of service. Sensitive records will be kept in a secure location described in question 13 until destruction occurs. Appropriate measures will be taken to ensure the security and confidentiality of recorded information during all phases of the destruction process, including pickup and transport of records from RTI's locations to the destruction site. PII will be stored at RTI for 5 years after the project has ended unless FDA requests it be retained for a longer period. De-identified data will be stored on RTI servers and delivered to FDA at the end of each wave of data collection. No PII will be sent to or accessible by 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	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 use of multi-factor access authentication, firewalls, and network monitoring and intrusion detection tools.

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.