US Department of Health and Human Services

Privacy Impact Assessment

Date Signed:

07/17/2025

OPDIV:

NIH

Name:

NIAAA Qualtrics

PIA Unique Identifier:

P-6071106-934790

The subject of this PIA is which of the following?

Minor Application (child)

Identify the Enterprise Performance Lifecycle Phase of the system.

Operations and Maintenance

Is this a FISMA-Reportable system?

No

Does the system include a Website or online application available to and for the use of the general public?

No

Identify the operator.

Agency

Is this a new or existing system?

New

Does the system have Security Authorization (SA)?

Yes

Indicate the following reason(s) for updating this PIA.

Describe the purpose of the system.

The National Institute on Alcohol Abuse and Alcoholism (NIAAA) has contracted with the vendor Qualtrics to conduct NIH scientific research surveys.

The Qualtrics Survey System is a web-based application that provides the functionality for NIAAA staff to create and disseminate custom surveys, notifications, and other messages.

The NIAAA Qualtrics Team generates specific survey Uniform Resource Locator (URLs) to be used by individual study participants to access and provide survey responses. Collected survey data is transferred from the web and stored within a secure NIAAA on-premises database within the NIAAA Clinical Research Database (CRDB) system boundary and covered under the CRDB Privacy Impact Assessment (PIA).

Describe the type of information the system will collect, maintain (store), or share.

NIAAA Qualtrics collects information from members of the public who become Study participants

(survey takers) for clinical research purposes. Study participants provide answers to survey questions focused on the area of research being investigated.

A Quick Response (QR) code or URL is provided to members of the public (potential survey takers) to provide information for pre-screening. Not all studies use pre-screening. If pre-screening results indicate acceptance into a Study, or if no pre-screening is used, the potential survey taker accesses the web-based tool and is required to provide consent for the collection of personally Identifiable Information (PII) and to participate in the Study prior to taking a survey.

The following PII is collected when a participant consents to a Study and is used only for authentication and contact purposes: name, email, and phone number. Clinical survey responses are separate and not kept with the PII that is collected for authentication and contact purposes. The PII for authentication and contact purposes is maintained in the system within a contact list database. PII is used only to allow authentication with a phone number when a Study participant logs into their specific survey and, if need be, is used to contact the Study participant. Study participants (survey takers) are provided with a specific survey link via email and log in to their survey with their cell-phone number.
Clinical survey forms collect the Principal Investigators name, organizational email, and organizational phone number. This information is made available should there be a change in contact information, or if the study participant needs to contact the study coordinator.

Authorized NIAAA staff access the application using the NIH Identity, Credential, and Access Management (IAM) Services which maintains its own unique privacy impact assessment (PIA) on record, with all legal authorities documented. The purpose of IAM Services is to authenticate and authorize all users and computers in a Windows domain type network assigning and enforcing information security policies for all computers and installing or updating software. The IAM Services collects unique user credentials and stores them in an encrypted format. The IAM Service is an essential service which facilitates and governs network access to various resources. Access is through a Virtual Private Network (VPN) connection or while on NIH Net to create, maintain, and update surveys, and assign permissions/user roles.

Qualtrics Experience Management (XM) Software as a Service (SaaS) application and Federal Risk and Authorization Management Program (FedRAMP) approved.

Provide an overview of the system and describe the information it will collect, maintain (store), or share, either permanently or temporarily.

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Does the system collect, maintain, use or share PII?

Yes

Indicate the type of PII that the system will collect or maintain.

Name
E-Mail Address
Phone Numbers

Indicate the categories of individuals about whom PII is collected, maintained or shared.

Employees
Public Citizens
Patients

How many individuals' PII is in the system?

500-4,999

For what primary purpose is the PII used?

PII is used for contacting Study participants should there be a need, and to provide a mechanism to authenticate with a phone number when a Study participant logs into their specific survey.

Describe the secondary uses for which the PII will be used.

No secondary uses.

Identify legal authorities governing information use and disclosure specific to the system and program.

The legal authority to collect information and maintain this system is: 5.U.S.C. 301; 42 U.S.C. 217a, 241, 242, 281, 282, 284, 284a, 285, 285b-t; 286, 287, 287b, 287c-11, 287c-21, 287d, 288; 44 U.S.C. 3101; 35 U.S.C. 200-212; 48 CFR Subpart 15.3, and; 37 CFR 401.1-18.

Are records on the system retrieved by one or more PII data elements?

Yes

Identify the number and title of the Privacy Act System of Records Notice (SORN) that is being use to cover the system or identify if a SORN is being developed.

09-25-0200; Clinical, Basic and Population-based Research Studies of the National Institutes of

Identify the sources of PII in the system.

Directly from an individual about whom the information pertains

Online

Non-Governmental Sources

Identify the OMB information collection approval number and expiration date

Public Law 114-255, Section 2035, exempts research conducted by NIH from Paperwork Reduction Act (PRA) requirements.

Is the PII shared with other organizations?

No

Describe the process in place to notify individuals that their personal information will be collected. If no prior notice is given, explain the reason.

An email is sent to the potential survey taker to provide consent. The email includes a Study contact email address (research@niaaa.nih.gov) as well as the Principal Investigators name, email, and phone number to be used should there be a change in contact information, or if the Study participant believes their PII has been inappropriately obtained, used, or disclosed, or that the PII is inaccurate.

Is the submission of PII by individuals voluntary or mandatory?

Voluntary

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.

If a user decides to opt-out of the collection or use of their PII, then they will not be able to take the survey and be a Study participant.

Process to notify and obtain consent from individuals whose PII is in the system when major changes occur to the system.

In the unlikely event that major changes occur to the system and/or PII use requires updated consent, the Study participant will be contacted using the information stored in the NIAAA Qualtrics Study participant contact list.

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.

An email is sent to the potential survey taker to provide consent prior to providing their PII. The email includes the Study contact email address (research@niaaa.nih.gov) as well as the Principal Investigators name, email, and phone number, to be used should there be a change in contact information, or if the Study participant believes their PII has been inappropriately obtained, used, or disclosed, or that the PII is inaccurate.

Describe the process in place for periodic reviews of PII contained in the system to ensure the data's integrity, availability, accuracy and relevancy.

The System Owner and the Study Principal Investigator review PII contained in the contact list, on a regular basis, or at least annually. If PII is not accurate it will affect the ability of a Study participant

to access the survey which will be reflected in the survey data collection.

Identify who will have access to the PII in the system and the reason why they require access.

Describe the procedures in place to determine which system users (administrators, developers, contractors, etc.) may access PII.

Determination is made based on Role Based Access Controls and least privilege. User rights are provisioned based on controls within the system, allowing users only access to the minimum amount of PII necessary to perform their job function.

Describe the methods in place to allow those with access to PII to only access the minimum amount of information necessary to perform their job.

The roles established for permitting access are based on the principle of least privilege. The Principal Investigator maintains a list of authorized users at the individual study level, and access to study level records is restricted to authorized study level users.

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.

According to NIH policy, all personnel who manage or operate NIH applications must successfully complete annual security and privacy awareness training.

Describe training system users receive (above and beyond general security and privacy awareness training).

Individuals with elevated privileges, such as Administrators, are additionally required to take Role-Based Training Courses specific to their roles and responsibilities.

Do contracts include Federal Acquisition Regulation and other appropriate clauses ensuring adherence to privacy provisions and practices?

Yes

Describe the process and guidelines in place with regard to the retention and destruction of PII.

01-003, Records of All Other Intramural Research Projects. Cut off annually at termination of project/program or when no longer needed for scientific reference, whichever is longer. Destroy 7 years after cutoff (DAA-0443-2012-0007-0003).

Describe, briefly but with specificity, how the PII will be secured in the system using administrative, technical, and physical controls.

Administrative Controls allow securing the PII by the following mechanisms: administrative personnel are all NIAAA employees or direct-badged contractors that are bound by the annually affirmed Rules of Behavior and Non-Disclosure Agreements.

Technical Controls allow securing the PII by the following mechanisms: access is based on roles and groups established for the user and administrative privileges and uses multi-factor authentication.

Physical controls allow securing the PII by the following mechanisms: implementation of the full complement of 23 NIST 800-53 r5 physical controls aligned to Moderate systems are inherited from the Qualtrics Experience Management (XM) Platform Software as a Service (SaaS) cloud platform which is Federal Risk and Authorization Management Program (FedRAMP) authorized at the Moderate impact level. (FedRAMP identification (ID) F1606097904).
Qualtrics XM is a registered trademark.