# US Department of Health and Human Services

## Privacy Impact Assessment

### Date Signed:

07/23/2025

### OPDIV:

NIH

### Name:

NIAAA Clinical Research Database System

**PIA Unique Identifier:**

P-7988386-336868

**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) Clinical Research Database (CRDB) is used for ongoing clinical research data collection during protocol studies conducted by the Division of Intramural Clinical and Biological Research (DICBR).

The CRDB acquires data from the Biomedical and Translational Research Information System (BTRIS) and collects data from intramural laboratories, patients in the NIH Clinical Center, principal investigators (PIs), and from external research participants via the NIAAA Qualtrics cloud survey tool. Data is analyzed and presented in numerous report formats for clinical study analyses. BTRIS and NIAAA Qualtrics maintain their own PIAs.

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

The types of information the system collects and maintains (stores) is specific to research and analysis of alcohol use disorders and related topics. Clinical research study patient personally identifiable information (PII) is collected, including patient name, email address, mailing address,

date of birth, phone number(s), and NIAAA Identifier (NIAAA ID).

Those requiring access to this system log in 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.

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

The National Institute on Alcohol Abuse and Alcoholism (NIAAA) Clinical Research Database (CRDB) is used for ongoing clinical research data collection during protocol studies conducted by the Division of Intramural Clinical and Biological Research (DICBR).

The CRDB acquires data from the Biomedical and Translational Research Information System (BTRIS) and collects data from intramural laboratories, patients in the NIH Clinical Center, principal investigators (PIs), and from external research participants via the NIAAA Qualtrics cloud survey tool. Data is analyzed and presented in numerous report formats for clinical study analyses. BTRIS and NIAAA Qualtrics maintain their own PIAs.

The types of information the system collects and maintains (stores) is specific to research and analysis of alcohol use disorders and related topics. Clinical research study patient PII is collected, including patient name, email address, mailing address, date of birth, phone number(s), and NIAAA Identifier (NIAAA ID).

Those requiring access to this system log in 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.

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

Yes

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

Date of Birth
Name
E-Mail Address
Mailing Address
Phone Numbers
NIAAA ID

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

Employees
Public Citizens

**How many individuals' PII is in the system?**

500-4,999

**For what primary purpose is the PII used?**

PII is primarily used to uniquely identify each patient within a clinical research study.

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

PII may be secondarily used to contact a patient should there be a requirement to do so.

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

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 401.1-16.

**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

In-Person

Online

Government Sources

Within OpDiv

Non-Government Sources

Public

**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.**

CRDB is not the source system. For information that is derived from NIAAA Qualtrics and BTRIS, those systems maintain their own PIAs, including process for notification.

For imaging data in the system, PIs upload that data. Consent is handled by a consent form when individuals start thier clinical trial.

**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.**

There is no opt-out option. The collection of PII is required to participate in a clinical study. If one chooses not to provide PII, they cannot participate in the protocol.

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

CRDB is not the source system. BTRIS and NIAAA Qualtics maintain their own PIAs, including process to notify and obtain consent when major changes occur.

For imaging data, PIs handle the process of obtaining consent.

**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.**

Individuals can contact the NIH Senior Official for Privacy at 6705 Rockledge Dr., Suite 601, Bethesda, MD 20892 (Phone: 301-496-4606) and reasonably identify the record, specify the information being contested, and state corrective action sought, with supporting information to show how the record is inaccurate, incomplete, untimely, or irrelevant.

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

Patient data is reviewed for relevancy and accuracy by intramural PIs and data integrity and availability is validated by the database administrator through automated database integrity software.

For data that comes from BTRIS and NIAAA Qualtrics, each maintain their own PIAs, including process for period reviews of PII.

**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.**

Determinations are 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.

**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.**

Access to PII is assigned to personnel based upon current job responsibilities. The system uses NIH IAM Services to assign permissions/user roles which is considered PII. IAM maintains its own PIA.

**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. Training is completed on the http://irtsectraining.nih.gov site with valid NIH credentials.

**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. Individuals supporting Intramural studies that involve patient data are additionally required to take Intramural Sensitive Information Training for each study they support.

**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:  The website login page includes a standard government system warning banner; 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: PII is secured by the following mechanisms: access is based on roles and groups established for the user and administrative privileges and uses Multi-Factor authentication via NIH IAM.

Physical Controls: All computing infrastructure (e.g., Servers) housing PII are required to be maintained within a data center that has controlled access through Personal Identity Verification(PIV) credentials, cypher locks, and/or keys: access is provided to system administrators based on need: paper records are located in locked file cabinets or in secured rooms with access limited to those personnel whose official duties require access.