

# US Department of Health and Human Services

## Privacy Impact Assessment

**Date Signed:**

03/27/2026

**OPDIV:**

NIH

**Name:**

Information Management Services - BioShare

**PIA Unique Identifier:**

P-1243339-861283

**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?**

Yes

**Identify the operator.**

Contractor

**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 Information Management Services (IMS) BioShare provides a central location for researchers to search available collections and submit requests for specimens and data of interest. BioShare provides a comprehensive and coordinated site to track the full life cycle of a request from initial submission, through review, approval, resource delivery and long-term study follow up.

BioShare maintains three Controlled Access Data Repositories (CADRs), which are:

Surveillance, Epidemiology, and End Results (SEER) - Consumer Assessment of Healthcare Providers and Systems (CAHPS) or SEER-CAHPS: A web-based system for requesting access to data linking NCI cancer registry data (SEER) with Medicare beneficiary surveys to evaluate patient experience with care.

SEER Specialized Databases: A web-based system for requesting access to data derived from the SEER/National Cancer Institute (NCI) program which supports cancer surveillance and research.

AgingResearchBioBank: A web-based system for requesting access to data, images, and biospecimens related to aging studies by the National Institute on Aging (NIA). The system facilitates review of requests, data and biospecimen delivery, and study approval for various research interests.

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

BioShare is a subsystem within the Information Management Services Application Support Environment (IMS ASE). The IMS ASE maintains its own PIA on record. BioShare maintains the following personally identifiable information within its instances and CADR for the purpose of supporting cancer and other research across the nation to advance scientific knowledge.

Name, email, phone number, mailing address, login credentials (usernames), and Census tract information (state, country) of users for the purpose of contacting them about their requests; partial dates (month, year) for diagnostic tests and treatments in the individual subjects' data.

BioShare uses specific login information to assign permissions/user roles which are considered Personally Identifiable Information (PII).

However, this is done by using the following access tools and processes:

Developer and system maintainer login information is stored within an IMS ASE MS Active Directory (AD) service that is used for authorizing computers, users, and applications for use within the IMS ASE. The AD service governs network access to all resources inside the IMS ASE.

NIH Login, a module of the NIH Identity, Credential, and Access Management (IAM) Services. IAM maintains its own Privacy Impact Assessment and is used to grant access to NIH users to the IMS BioShare instances.

Login.gov, a publicly available secure online Government resource which allows a safe way to sign into U.S. government websites using just one account.

ID.me, a publicly available secure online resource which allows a safe way to sign into U.S. government websites using just one account.

Federated login, a centralized authentication for web-based applications. Instead of storing a user's login credentials, federated login enables users to use a single authentication method via an individual's parent organization.

**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

Mailing Address

Phone Numbers

User Credentials, Census tract information (state, country), partial dates (month, year) for diagnostic tests and treatments

**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?**

1,000,000 or more

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

The primary purpose of the collected PII is to support a broad range of research, training, and information dissemination activities across the entire country and with research partners.

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

PII is used secondarily to assign permissions within the site. Limiting PII access to vetted and approved users.

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

Public Health Service Act. (42 U.S.C. 241, 242, 248, 281, 282, 284, 285a-285q, 287, 287b, 287c, 289a, 289c, and 44 U.S.C. 3101)

**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.**

09-90-0777 Facility and Resource Access Control Records

09-25-0200 - SORN for Clinical, Basic and Population-based Research Studies of the National

**Identify the sources of PII in the system.**

Directly from an individual about whom the information pertains

Online  
Government Sources

**Identify the OMB information collection approval number and expiration date**

Not Applicable  
The collection of PII to create an account solely for access is exempt from the Non-Governmental Sources Paperwork Reduction Act, or Public Law 114-255, Section 2035, exempts Public research conducted by NIH from Paperwork Reduction Act (PRA) requirements.

**Is the PII shared with other organizations?**

Yes

**Identify with whom the PII is shared or disclosed and for what purpose.**

**Describe any agreements in place that authorizes the information sharing or disclosure.**

Individuals that have access to PII within BioShare repositories, and CADRs must sign data

use agreements (DUAs) after submitting their application forms for review and approval.

**Describe the procedures for accounting for disclosures.**

BioShare repositories, and CADR's account for disclosures by limiting data access to approved users. DUAs are kept and outline which datasets users have access to PII in.

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

BioShare repositories, and CADR's are not the sources of PII collection from individuals whose data are held. These partnered systems, including research studies and state cancer repositories, maintain their own processes to notify individuals that their PII is being collected.

For PII that is used for access control and permissions, users are notified when they fill out their applications for access to the system.

**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.**

BioShare is not the source system. Opt-out methods are handled at the time of PII collection. This includes by Principal Investigators (PIs), state cancer registries, and clinical research partners.

For PII used for access and permissions, there is no opt-out option. Users may decide to not provide their PII during the application process, but that would result in individuals not being granted access to BioShare repositories, and CADR's.

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

BioShare is not the source system. Processes to notify and obtain consent when major changes occur are handled at the time of PII collection. This includes by Principal Investigators (PIs), state cancer registries, and clinical research partners.

For PII used for access and permissions, there is no opt-out option. Users are notified by email and webpage notifications when major changes occur.

**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.**

There is a "Contact Us" page on BioShare website that users can use to submit concerns about how PII has been obtain, used, or disclosed, or if it is inaccurate. Upon submitting the concern, a member of the appropriate BioShare Help Desk responds to the reporting individual by their preferred method of communication.

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

BioShare is not the source system. Periodic reviews are handled at the time of PII collection. This includes by Principal Investigators (PIs), state cancer registries, and clinical research partners.

For PII used for access and permissions, user accounts are periodically reviewed by BioShare administrators to ensure compliance with all BioShare policies and procedures.

**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 access to only 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.**

Determinations are made based on role-based access controls and least privilege. User rights are provisioned based on controls within the system, allowing users access to only the minimum amount of PII necessary to perform their job.

**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 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).**

Administrators of BioShare are required to participate in role-based training for their job functions.

**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.**

07-203, System access records. Systems not requiring special accountability for access. Destroy when business use ceases (DAA-GRS-2013-0006-0003).

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: Access level and permissions are controlled by the system and based on approval by NCI, NIA, or other government organization utilizing BioShare during the organization's review of the data access requests.

Technical Controls: Access to the system is controlled by login authentication of users prior to granting access. All servers have been configured to remove all unused applications and system files and all local account access except when necessary to manage the system and maintain integrity of data.

Physical Controls: The data is stored within the Information Management Services Application Support Environment, a Federal Information Security Modernization Act (FISMA) of 2014 moderate audited system which is hosted in co-location facilities in Sterling, VA and Baltimore, MD. The facilities provide secure infrastructure and restricted physical access to servers and administrative systems, ensuring that only authorized personnel can manage or maintain the environment.

**Identify the publicly-available URL:**

<https://healthcaresdelivery.cancer.gov/acccsis/datashare>

<https://dceg2.cancer.gov/dups>

<https://epi.grants.cancer.gov/cohort-consortium/projecthub>

<https://dceg2.cancer.gov/gemshare>

<https://samples.moonshotbiobank.cancer.gov/>

<https://neurobiobank.nih.gov/>

<https://agingresearchbiobank.nia.nih.gov/>

<https://healthcaresdelivery.cancer.gov/prospr/datashare>

<https://healthcaresdelivery.cancer.gov/seer-cahps/application>

<https://healthcaresdelivery.cancer.gov/seermedicaid/application/>

<https://seer.cancer.gov/data/specialized/>

<https://seer.cancer.gov/vtr/>

Note: web address is a hyperlink.

**Does the website have a posted privacy notice?**

Yes

**Is the privacy policy available in a machine-readable format?**

Yes

**Does the website use web measurement and customization technology?**

Yes

**Select the type of website measurement and customization technologies is in use and if it is used to collect PII.**

**Does the website have any information or pages directed at children under the age of thirteen?**

No

**Does the website contain links to non- federal government websites external to HHS?**

Yes

**Is a disclaimer notice provided to users that follow external links to websites not owned or operated by HHS?**

Yes