US Department of Health and Human Services

Privacy Impact Assessment

Date Signed:

04/16/2025

OPDIV:

NIH

Name:

Histotrac

PIA Unique Identifier:

P-2285847-876016

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?

Existing

Does the system have Security Authorization (SA)?

Yes

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

PIA Validation

Describe in further detail any changes to the system that have occurred since the last PIA.

The PIA has been updated to meet the requirements of Executive Order - Defending Women from Gender Ideology Extremism and Restoring Biological Truth to the Federal Government.

Describe the purpose of the system.

The Histotrac system collects, maintains and disseminates blood types, HLA (Human Leukocyte Antigen) testing results, and related medical information collected from donors and potential transplant recipients.

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

Information required by the Division of Transfusion Medicine (DTM) staff and intramural research teams to make clinical decisions regarding potential transplantation. The information contains Personally Identifiable Information (PII), including: Name, Medical Notes, Date of Birth (DoB), and Medical Records Number (MRN).

The system contains minimal demographic data (sex and race) which crosses the Clinical Research Information System (CRIS) to Soft interface into the Histotrac incoming orders utility where it is verified for accuracy. Patient testing is performed and results are transmitted back across the interfaces. This system is a process management system in addition to a database storage system for multiple facets of HLA and demographic information. CRIS maintains its own Privacy Impact Assessment (PIA), including all legal authorities documented.

Those requiring access to this system log in using the NIH Identity, Credential, and Access Management (IAM) Services which maintains its own unique 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 Histotrac system collects, maintains and disseminates blood types, HLA testing results, and related medical information collected from donors and potential transplant recipients.

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Those requiring access to this system log in using the NIH IAM Services which maintains its own unique PIA on record, with all legal authorities documented.

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
Medical Records Number
Medical Notes
Demographic data

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?

50,000-99,999

For what primary purpose is the PII used?

PII is used and limitedly shared with the NIH intramural research transplant program staff from National Heart, Lung, and Blood Institute (NHLBI) and National Cancer Institute (NCI) for the purposes of clinical care and research at NIH.

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

There are no secondary uses.

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

The legal authority to operate and maintain this Privacy Act records system is 42 U.S.C. §§ 241, 248, 282 and 284

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.

09-25-0099, Clinical Research: Patient Medical Records

Identify the sources of PII in the system.

Directly from an individual about whom the information pertains

In-Person

Online

Government Sources

Within OpDiv

NIH

Identify the OMB information collection approval number and expiration date

N/A

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.

Individuals are notified that their personal information will be collected when they present for donation at the Clinical Center (CC) for blood donation. Each individual is provided a formal notification of Information Practices and must certify that they have been so advised.

Every patient must voluntarily execute a protocol consent and authorization prior to entry onto an intramural research protocol and treatment at the CC. In addition, each patient is provided a formal notification of Information Practices and must certify that they have been so advised.

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.

General admission and protocol consent forms are signed by each patient. Additionally, an information practices notification form is reviewed and acknowledged in writing by each patient at the time of initial admission to the CC. Enrollment in a clinical research trial is voluntary and the collection of PII and medical notes is necessary to conduct research and provide clinical care. Therefore, a patient may not opt out of the collection or use of their PII while participating in research at the CC.

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

General admission and protocol consent forms are signed by each patient. Additionally, an information practices notification form is reviewed and acknowledged in writing by each patient at the time of initial admission to the CC. Enrollment in a clinical research trial is voluntary and the collection of PII and medical notes is necessary to conduct research and provide clinical care. Therefore, a patient may not opt out of the collection or use of their PII while participating in research at the CC.

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.

A Privacy Rights Complaint Form is available to individuals when they believe that their PII has been inappropriately used or disclosed. The Clinical Center's Privacy Office will review the complaint and respond to the concern within 30 business days. Complaints could also be submitted to the System Manager, who would investigate and share findings with CC Information Systems Security Officer (ISSO) and CC Privacy Officer.

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

Modifications to patient PII such as name, MRN, visit number or medication order number are sent via interfaces from CRIS to the system to keep the patient PII in synchronization across the ancillary clinical information systems.

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.

Access to PII is assigned to personnel based upon current job responsibilities. A standard NIH IAM System account login is required to gain access to the stored PII data.

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.

Appropriate access is granted to the system based on predefined roles and job descriptions, and administrative access is limited to authorized employees based on current roles. Authentication with NIH Personal Identity Verification (PIV) card will occur at time of login to the NIH Network. System owners are responsible for creating the proper security groups within their systems with the applicable permissions for group members to enforce least privilege.

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.

Administrators and Privileged Users require additional training specific to their roles and responsibilities.

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

Application specific peer training is available.

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

No

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

Records are retained and disposed of under the authority of the NIH Intramural Records Retention Schedule.

Item 03-005: Patient Medical Records.
These records document admissions and medical treatment for a patient accepted in a research project.
Disposition: Cut off patient case file annually after 5 years of inactivity. Destroy when case file is no longer needed for scientific reference. DAA-0443-2012-0007-0010

Item 03-003 - Blood Donor and Receiving Records
These records relate to blood and its components that are collected, processed, compatibility tested, stored, and distributed by NIH. These records identify blood donors, document donor deferrals, and identify and describe blood products received from other collection facilities. These records shall be retained for such intervals beyond the expiration date for the blood or blood component as necessary to facilitate the reporting of any unfavorable clinical reactions as required by 21 CFR 606.
Disposition: Cut off annually after 50 years or annually after expiration of the patient/subject, whichever is longer. Transfer to inactive storage 1 year after cutoff. Destroy 30 years after cutoff. DAA-0443-2012-0007-0008

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

Administrative Controls: All technical personnel who access Information Technology (IT) systems which contain protected information have met background investigation criteria for Public Trust positions. All personnel have taken mandatory security training and awareness classes and refreshers. Personnel accessing these systems use privileged and separate accounts for administrative access to systems.

Technical Controls: The IT hardware and software used to host information is segregated from default commodity public networks to prevent unauthorized or malicious access. Access controls lists and event logs are maintained and monitored to detect unauthorized, suspicious or malicious activity. Access lists are restricted to approved IT technical personnel. Two factor authentication must be used for access. File integrity and auditing software are employed on hardware.

Physical Controls: The servers reside in the Center for Information Technology (CIT) Computer Room where policies and procedures are in place to restrict access to the machines. This includes guards at the front door and entrance to the machine room. Each discrete ingress and egress event is logged. The facility is under 24-hour surveillance by facilities security for security and environmental hazards.