PTA / PIA: HRSA - CIBMTR - QTR3 - 2025 - HRSA1446036

Created Date: 10/20/2025 12:23 PM Last Updated: 3/6/2026 3:22 PM

General Information

PTA / PIA Name:	HRSA - CIBMTR - QTR3 - 2025 - HRSA1446036	**PTA / PIA ID:**	3924304
Component Name:	HRSA - Stem Cell Therapeutic Outcomes Database (new)	**ATO Boundary Name:**	Stem Cell Therapeutic Outcomes Database
Overall Status:	Complete	**# of Days - Open:**	248
Submitter:		**Submit Date:**	12/16/2025
Next Assessment Date:	03/05/2029	**Expiration Date:**	3/5/2029
Office:		**OpDiv:**	HRSA
Security Categorization:	Low		
Make PIA available to Public?:	Yes	**PIA Required:**	Yes

General 01:	Identify the Enterprise Performance Lifecycle Phase of the system.	Operations and Maintenance
General 02:	Is this a FISMA-Reportable system?	Yes
General 03:	Does the system have or is it covered by a Security Authorization to Operate (ATO)?	Yes
General 04:	ATO Date or Planned ATO Date.	8/24/2024
General 05:	Is the system or electronic information collection, agency or contractor operated?	Contractor
History Log:	View History Log	

Privacy Threshold Analysis

Privacy Threshold Analysis

PTA 01:	Point of Contact (POC) Name	Reginald Ralph
PTA 01A:	POC Title and Organization	ISSO (HRSA)
PTA 01B:	POC Email Address	rralph@hrsa.gov
PTA 01C:	POC Phone Number	N/A
PTA 02:	Indicate the following reason(s) for this PTA. Choose from the following options.	PIA Validation (PIA Refresh)
PTA 02A:	Describe in further detail any changes to the system that have occurred since the last PIA.	No Changes have been made.
PTA 03:	Is the data contained in the system owned by the agency or contractor?	Contractor

PTA 04:	Please give a brief overview of the purpose of the system by describing what the functions of the system are and how the system carries out those functions in support of HHS.	One purpose of this system is to maintain the Stem Cell Therapeutic Outcomes Database (SCTOD), a component of the C.W. Bill Young Cell Transplantation Program (Program). The SCTOD is a subset of the Center for International Blood and Marrow Transplant Research (CIBMTR) Research Database (the System) that includes, in a standardized electronic format, information related to patients who have received stem cell therapeutic products. This information is defined as the information necessary to conduct an ongoing evaluation of the scientific and clinical status of transplantation involving recipients of a stem cell therapeutic product from a donor.
PTA 05:	List and/or describe all the types of information that are collected, maintained, and/or shared by the system regardless of whether that information is PII and how long that information is stored.	Data on all allogeneic (related and unrelated) hematopietic cell transplant. These data include demographic, disease, treatment and outcomes. Examples of demographic data include--date of birth, gender, race, and ethnicity. Examples of disease data include primary diagnosis and disease status. Examples of treatment data include preparatory regimen administered, transplant data and date of treatment. Outcomes data include but are not limited to--relapse, secondary malignancies and survival. The system does not collect information about HHS system users or contractors. Access to the system is tightly controlled and limited to internal CIBMTR Medical College of Wisconsin (MCW) users using an MCW identity management system. PII Elements: Name Employment Email (Personal) Phone Number (Personal) Medical Records Date of Death Medical Records Sex
PTA 05A:	Are user credentials used to access the system?	Yes
PTA 05B:	Please identify the type of user credentials used to access the system.	Non-HHS User Credentials Username Password Email Address

PTA 06:	Describe why each type of information is collected, maintained, and/or shared by the system. Specify what information is collected about each category of individual.	The CIBMTR-MCW (Center for International Blood & Marrow Transplant Research - Medical College of Wisconsin) collects, maintains and shares information and data on allogeniec and autologous stem cell transplants and cellular therapies. As the Government contractor, the CIBMTR-MCW (Center for International Blood & Marrow Transplant Research - Medical College of Wisconsin) will also provide aggregated public information to increase availability, safety, and effectiveness of stem cell therapies. Using a subset of these data, the CIBMTR-MCW will report to the Government regarding activity of the C.W. Bill Young Cell Transplantation Program and transplant outcomes. The submission is voluntary, and contains data elements that include DOB, date of death, and treatment prescribed, but are not linkable to any particular individuals (the information gathered is de-identified, assigned a randomly generated number and used for statistical purposes). The CIBMTR-MCW also collects contact information from requestors via its public website for distribution of information or data. The contact information (name, phone and email address) collected, on the public website, from those who request data is not stored in or used by the CIBMTR data system. The contact information collected is solely used for the purpose of the transaction of responding to requests for information.
PTA 07:	Does the system collect, maintain, use, or share PII?	Yes
PTA 08:	Does the system include a website or online application?	Yes
PTA 08A:	Provide the URL(s).	https://portal.cibmtr.org https://bi.cibmtr.org/qlikview/
PTA 08B:	Are any of the website or online applications accessible by the public (including publicly accessible log in pages)?	Yes
PTA 09:	Describe the purpose of the website, who has access to it, and how users access the web site (via public URL, log in, etc.). Please address each element in your response.	The CIBMTR portal provides centralized method for authorized users from centers, cord blood banks and research partners to securely access integrated applications that support specific operational functions, such as data visualization, data file access, and feature access.
PTA 10:	Does the website have a posted privacy notice?	No
PTA 11:	Does the website contain links to non-federal government websites external to HHS?	Yes
PTA 11A:	Is a disclaimer notice provided to users that follow external links to websites not owned or operated by HHS?	Yes
PTA 12:	Does the website use web measurement and customization technology?	Yes
PTA 12A:	Select the type(s) of website measurement and customization technologies in use and if it is used to collect PII.	Session Cookies- Does Not Collect PII
PTA 13:	Does the website have any information or pages directed at children under the age of thirteen?	No
PTA 14:	Does the system have a mobile application?	No

PTA 20:	Are any third-party websites or applications (TPWA) associated with the system?	Yes
PTA 20A:	What TPWAs are used?	Onelogin (Supports URL login)
PTA 20B:	Do the TPWAs have an approved TPWA PIA?	No
PTA 21:	Does this system use artificial intelligence (AI) tools or technologies?	No

Privacy Impact Assessment

Privacy Impact Assessment

PIA 22:	Indicate the type(s) of personally identifiable information (PII) that the system will collect, maintain, or share.	Biographical Information Name Date of Birth User Credentials Employment Status/History Contact Information Email Address (Personal) Phone Numbers (Personal) Medical Information Medical Records Other Other
PIA 22A:	Identify the “other” type(s) of personally identifiable information (PII) not mentioned in the above list.	Dates of Service for Treatment; Date of Death; Sex, Race, & Ethnicity
PIA 23:	Indicate the categories of individuals about whom PII is collected, maintained, or shared.	Business Partners/Contacts (Federal state, local agencies)
PIA 24:	Indicate the approximate number of individuals whose PII is maintained in the system.	500 – 4,999
PIA 25:	For what primary purpose is the PII used?	The primary purpose for which the limited PII is used is to compute outcomes variables for research, including--patient age at time intervals, time intervals since transplant, time since last clinical follow-up, and for analysis of other specific outcomes. The contact information collected is solely used for the purpose of the transaction of responding to requests for information.
PIA 26:	Describe any secondary uses for which the PII will be used (e.g., testing, training, or research).	N/A
PIA 28:	Identify legal authorities, governing information use and disclosure specific to the system and program.	Public Law 109-129 establishes the C.W. Bill Young Cell Transplantation Program, authorizing the Department to establish by contract a system for identifying, matching, and facilitating bone marrow and cord blood transplants, including recruitment, patient advocacy and maintenance of a stem cell therapeutic outcomes database.
PIA 29:	Are records in the system retrieved by one or more PII data elements?	Yes

PIA 29A:	Please specify which PII data elements are used to retrieve records.	This action is not routinely performed, however if a research subject were to have multiple transplants their date of birth may be used to support data consistency.
PIA 29B:	Provide the number, title, and URL of the Privacy Act System of Records Notice (SORN) that is being used to cover the system or indicate whether a new or revised SORN is in development.	09-15-0068. Dated: 02/14/2018 History: 74 FR 23869 Dated: 5/21/2009 www.federalregister.gov
PIA 30:	Identify the sources of PII in the system.	Non-Government Sources Members of the Public Private Sector
PIA 31:	Is there an Office of Management and Budget (OMB) information collection approval number?	Yes
PIA 31A:	Provide the information collection approval number(s) and expiration date(s).	OMB No: 0915-0310 Expiration: 09/30/2028 per reginfo.gov.
PIA 32:	Is the PII in the system shared directly with other organizations outside the system's Operating Division?	Yes
PIA 32A:	Identify with whom the PII is shared or disclosed.	Private Sector Within HHS
PIA 32B:	For each disclosure, name the organizations/systems the system shares PII with and the purpose(s) of the disclosure.	Private Sector: Transplant Centers who provided the data to CIBMTR and very rarely, private sector research partners on a specific research protocol with whom an Agreement has been executed. Within HHS: HRSA
PIA 32C:	List any agreements in place that authorize the information sharing or disclosure (e.g., Computer Matching Agreement (CMA), Memorandum of Understanding (MOU), or Information Sharing Agreement (ISA)).	CIBMTR/MCW uses different agreements to govern information sharing and disclosure: Master Healthcare Data and Sample Submission Agreement (MHA) - an agreement between the CIBMTR and centers that formalizes lawful terms and transfer of data for mandated reporting under the C.W. Bill Young Cell Transplantation Program, as well as data and samples with informed consent submitted under CIBMTR protocols. Letter of Commitment for the Use of CIBMTR Datasets -- often simply referred to as the Data Use Agreement (DUA) -- delineates for a principal investigator, the purposes for permissible use of CIBMTR data and the obligates the data recipient (and their institution) to protect privacy, prevent unauthorized data sharing or attempts to re-identify centers or patients(unless previously authorized to do so), data retention periods or destruction of datasets at the completion of the proposed work (where relevant). Research Services Agreement (RSA)- outlines CIBMTR services and data set ownership and incorporates data use language when contracting with commercial, private sector organizations.

PIA 32D:	Describe process and procedures for logging/tracking/accounting for the sharing and/or disclosing of PII. If no process or procedures are in place, please explain why not.	In accord with the CIBMTR Data Use and Processing Policy, CIBMTR will only use personal data/PII to fulfill its obligations under formal agreements with third parties. In any case where personal data is shared, such as to facilitate computerized matching of CIBMTR data with other data sources under a specific research protocol for consented persons only, CIBMTR requires a fully executed DUA and maintains complete and accurate records of any disclosure of PII or Personal Data in accord with SOP-0100, PII Use and Disclosure Accounting. This disclosure log minimally includes identification of external party, dates of transfer or disclosure, study protocol or project name under which the disclosure is conducted as well as documented approval from a senior CIBMTR leadership. When disclosure is conducted as part of a research proposal, documented approval by the National Marrow Donor Program (NMDP) centralized Institutional Review Board (IRB) is required
PIA 33:	Is the submission of PII by individuals voluntary or mandatory as defined in the Privacy Act?	Voluntary
PIA 34:	Describe the method in place to notify and obtain consent from individuals whose PII will be collected. If no prior notice is given or consent cannot be obtained, explain why.	Submission of PII by individuals is voluntary. While patients may not opt out of collection of PII for the purposes of the public health requirements of the Stem Cell Therapeutic Outcomes Database (SCTOD) contract. Patients who have given consent for research uses of their PII may subsequently opt out of those uses by contacting their treatment center and request a change in their consent status. CIBMTR will also notify treatment centers of any communication from a patient, if the patient provides this information to CIBMTR. Centers are instructed to update their reporting to CIBMTR, and the patient's record will be excluded for any other non-SCTOD related matters from that date forward.
PIA 35:	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). If they cannot be notified or have their consent obtained, explain why.	Major changes to the system are communicated to the public in the following ways: Updates to the CIBMTR System of Records Notice (SORN) publication in the Federal Register in accord with the US Privacy Act. Updates to the CIBMTR Privacy Impact Assessment (PIA) as warranted upon implementation of new systems. Publication of updates to the CIBMTR Data Use and Processing Policy (DUPP) on the CIBMTR public website and notification is provided to treatment centers that provide data to CIBMTR in accord with our standard procedure.

PIA 36:	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.	CIBMTR's personal data protection statement--published on its public website--summarizes the rights of those individuals for whom data has been collected and provides instructions on how to contact CIBMTR to exercise any of these rights. This link can be found at the following URL: https://cibmtr.org/CIBMTR/About/Data-Protection-Privacy
PIA 37:	Describe the process in place for periodic reviews of the system to ensure the integrity, availability, accuracy, and relevancy of the PII in the system. Please address each element in your response. If no processes are in place, explain why not.	PII and other data collected by CIBMTR undergoes ongoing review to ensure its integrity, availability, accuracy and relevancy. Data collected, including any PII, undergoes regular updating and revision by CIBMTR data operations staff and scientific directors and receives input from the wider transplant community to collectively maintain ongoing relevance. PII collected by CIBMTR undergoes ongoing validation and verification for integrity, availability, accuracy and completeness both at the of capture and throughout the data life cycle. Ongoing processes are in place to assess data quality and as discovered correct inaccurate PII data at the source. Additionally, CIBMTR conducts random audits of key data fields that include PII for specific centers. PII and other data that is extracted from the system for use undergoes additional validation for integrity and availability prior to analysis, sharing these data back with treatment centers or prior to fulfilling reporting obligations with third parties, including HRSA. Annual inventories of PII stores are conducted to ensure that systems that maintain these inventories are known and protected.
PIA 38:	Identify who will have access to the PII in the system.	Users Administrators Developers Contractors
PIA 38A:	Select the type of contractor.	Third-Party Contractor (Contractors other than HHS Direct Contractors)
PIA 38B:	Do contracts include Federal Acquisition Regulation (FAR) and other appropriate clauses ensuring adherence to privacy provisions and practices?	No

PIA 39:	Provide the reason why each of the groups identified in 38 needs access to PII.	Users - Users are assigned access to PII based on job function and legitimate business purpose to access data. Generally, these users will be provided access on least privileges basis and have read only permissions. These roles include Clinical research coordinators, statisticians and scientific directors. Administrators - Administrators represent a limited, special class of user with privileged access, and must have responsibilities that include maintaining systems and data. These users will undergo role-based training for configuration and change management, and include system administrators, database administrators, and data engineers. Developers - Represent a limited, special class of user with privileged access, and must have responsibilities that include maintaining systems and data. These users will undergo role-based training for configuration and change management. Contractors - Only contractors engaged directly by CIBMTR MCW or NMDP Be The Match, and who have executed a Business Associate Addendum, and have a legitimate business purpose to access PII will be so authorized and only on a least privileges basis. These personnel may be functioning in the capacity of one of the roles above or might be engaged to perform a specific scope of work, under temporary time frame and direct supervision of CIBMTR or NMDP Be The Match.
PIA 40:	Describe the administrative procedures in place to determine which system users (administrators, developers, contractors, etc.) may access PII.	Administrative: Access to PII is limited to only those staff members who have a legitimate business purpose to access the PII. CIBMTR has identified a limited set of users who have access to the systems and even smaller number of users with privileged accounts. CIBMTR adheres to the data minimization principle, using only the minimum sensitive data needed to complete a task. All personnel who have access to and/or use PII receive training and are obliged to keep the PII confidential. CIBMTR regularly tests key processes and perform annual risk assessments against reasonably foreseeable information security risks.

PIA 41:	Describe the technical methods in place to allow those with access to PII to access only the minimum amount of information necessary to perform their job.	Technical: For systems included within its boundary, CIBMTR employs multiple and overlapping layers of security controls on systems. Access controls, enforce long and complex passwords, Multi-Factor Authentication (MFA), forced session time outs, and preauthorized access for physical access to internal networks. At the network layer, CIBMTR implements logical and physical separated network design, Intrusion Detection System (IDS) in line with internal firewalls, Demilitarized Zones (DMZ) for externally accessible servers, and workstation network level authentication and authorization. At the management/operational layer CIBMTR utilizes a configuration baseline for system constitution and hardening, change management processes, vulnerability management processes, continuous monitoring plans, and System Incident and Event Monitoring
PIA 42:	Identify the general security and privacy awareness training provided to system users (system owners, managers, operators, contractors and/or program managers) to make them aware of their responsibilities for protecting the information being collected and maintained.	All staff and contractors receive information security and data privacy training and must agree to rules of behavior for systems and data at point of hire and annually thereafter. Staff also receive periodic specialized training that includes data privacy topics for protecting the information being collected and may receive additional functional or role-based training related to their position. For example, CIBMTR staff are trained to follow a standard procedure for creation and double checking by a second person of anonymized, pseudonymized or de-identified datasets that specifies the removal of all patients, donor, and center identifiers, which could lead to the identification of a patient or center from data files.
PIA 43:	Describe the training system users receive above and beyond general security and privacy awareness training.	All users receive ethics training in the handling of data for Human Subjects Research through the Collaborative Institutional Training Initiative (CITI) upon hire and at least every 3 years thereafter.
PIA 44:	Describe the process and guidelines in place for the retention and destruction of PII. Cite specific National Archives and Records Administration (NARA) records retention schedule(s) and include the retention period(s).	According to the SCTOD Performance Work Statement established with the HRSA, CIBMTR will retain records permanently throughout the duration of the SCTOD contract or a HRSA Records Schedule has been approved by National Archives & Records Administration (NARA) to obtain the appropriate retention value of these records.

PIA 45:	Describe how the PII will be secured in the system using administrative, technical, and physical controls. Please address each element in your response.	Administrative Access to PII is limited to only those staff members who have a legitimate business purpose to access the PII. CIBMTR has identified a limited set of users who have access to the systems and even smaller number of users with privileged accounts. CIBMTR adheres to the data minimization principle, using only the minimum sensitive data needed to complete a task. All personnel who have access to and/or use PII receive training and are obliged to keep the PII confidential. CIBMTR regularly tests key processes and perform annual risk assessments against reasonably foreseeable information security risks. Physical Physical access to the CIBMTR office space requires users present an authorized physical security badge Physical access to the Data Center that hosts the System is permitted only to specific, authorized personnel using a physical security badge and biometric controls. All other personnel, maintenance contractors or visitors must be logged and escorted by authorized personnel. Certain system components are segmented by a dual redundant firewall within a subnetwork of the Medical College of Wisconsin (MCW) parent enterprise network domain and identity management and access is maintained locally within this subnetwork. Technical For systems included within its boundary, CIBMTR employs multiple and overlapping layers of security controls on systems. Access controls, enforce long and complex passwords, Multi-Factor Authentication (MFA), forced session time outs, and preauthorized access for physical access to internal networks. At the network layer, CIBMTR implements logical and physical separated network design, Intrusion Detection System (IDS) in line with internal firewalls, Demilitarized Zones (DMZ) for externally accessible servers, and workstation network level authentication and authorization. At the management/operational layer CIBMTR utilizes a configuration baseline for system constitution and hardening, change management processes, vulnerability management processes, continuous monitoring plans, and System Incident and Event Monitoring

Review and Comments

OpDiv Privacy Analyst Review

Privacy Analyst Review Decision:	Approved	**Privacy Analyst Review Date:**	2/26/2026
Privacy Analyst Review Comments:	PTA 6 states that the "CIBMTR-MCW also collects contact information from requestors via its public website ..." and the CIBMTR Portal URL (https://portal.cibmtr.org) is publicly accessible but question PTA 8B "Are any of the website or online applications accessible by the public (including publicly accessible log in pages)?" is answered No - please review and update accordingly and resubmit.	**# of Days - PA Review:**	72

SOP Review

SOP Review Decision:	Approved	**SOP Review Date:**	3/2/2026
SOP Review Comments:		**# of Days - SOP Review:**	4

Agency Privacy Analyst Review

Agency Privacy Analyst Review Decision:	Approved	**Agency Privacy Analyst Review Date:**	3/2/2026
Agency Privacy Analyst Review Comments:	Reviewer: Crystal bland 3/2/2026 We will have to remove "gender" and replace with "sex" during the 508 process for PTA-5. We've sent this PIA back several times already. This PIA is ready for SAOP review and approval. Reviewer: Nestor Villafuerte 12/10/2025 Please see comments and update accordingly: PTA-5: Per PIA-22, please include following PII elements "Name, employment, email and phone number (personal), Medical records, Other: Date of treatment, Date of Death," and Per EO 14168, please change "gender" to "sex". PIA-22A: Please change "Gender" to "Sex". PIA-31A: Please include the expiration date 09/30/2028 per reginfo.gov.	**# of Days - APA Review:**	0

SAOP Review

SAOP Review Decision:	Approved	**SAOP Review Date:**	3/6/2026
SAOP Review Comments:		**# of Days - SAOP Review:**	4

SAOP Signature

Date	User	Type	Name	Original Value	New Value
3/6/2026 1:32 PM	BAUR, VANESSA	Signature	SAOP (Email PIN)		Content Signed

Supporting Document(s)

Name	Size	Type	Upload Date	Downloads
No Records Found				

Comments

Question Name	Submitter	Date	Comment	Attachment
PTA 05	VILLAFUERTE, NESTOR	10/21/2025	Per EO 14168, please change "gender" to "sex".	
PIA 22A	VILLAFUERTE, NESTOR	10/21/2025	Please change "Gender" to "Sex".	
PIA 31A	VILLAFUERTE, NESTOR	10/21/2025	Please include the expiration date 09/30/2028 per reginfo.gov.	
PTA 05	BLAND, CRYSTAL	12/10/2025	Per PIA-22, please include following PII elements "Name, employment, email and phone number (personal), Medical records, Other: Date of treatment, Date of Death," and Per EO 14168, please change "gender" to "sex".	