

**Supporting Statement A**  
**Stem Cell Therapeutic Outcomes Database**  
**OMB Control No. 0915-0310**  
**Revision**

**Terms of Clearance:** None.

**A. BACKGROUND**

The Stem Cell Therapeutic and Research Act of 2005 (Public Law 109-129) as amended and codified in Section 379 of the Public Health Service Act (42 U.S.C. 247k) requires “The Secretary, acting through the Administrator of the Health Resources and Services Administration, shall by one or more contracts establish and maintain a C.W. Bill Young Cell Transplantation Program...that has the purpose of increasing the number of transplants for recipients suitably matched to biologically unrelated donors of bone marrow and cord blood, and that meets the requirements of this section.”<sup>1</sup> On behalf of the Secretary of Health and Human Services (“the Secretary”), the Health Resources and Services Administration (HRSA) provides oversight and management of the C.W. Bill Young Cell Transplantation Program (CWBYCTP).<sup>2</sup>

The CWBYCTP was reauthorized by the Stem Cell Therapeutic and Research Reauthorization Act of 2010 (Public Law 111-264), 2015 (Public Law 114-104) and the Transplant Act of 2021 (Public Law 117-15). These pieces of legislation also reauthorized other related programs, including the National Cord Blood Inventory (NCBI) and the Advisory Council on Blood Stem Cell Transplantation (ACBSCT).

**1. C.W. Bill Young Cell Transplantation Program (CWBYCTP)**

CWBYCTP provides an infrastructure for identifying, matching, and facilitating the distribution of bone marrow and cord blood from unrelated donors to individuals in need of hematopoietic stem cell transplants (HCT).<sup>3</sup> The transplantation of blood-forming cells from unrelated donors can improve patient-centered outcomes for individuals with life-threatening diseases, such as leukemia, lymphoma, sickle cell anemia, or other metabolic or immune system disorders.

The CWBYCTP includes the following functions: Bone Marrow Coordinating Center, Cord Blood Coordinating Center, Single Point of Access, Office of Patient Advocacy,

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<sup>1</sup> The Stem Cell Therapeutic and Research Act of 2005 (Public Law 109-129, December 20, 2005) as amended and codified in Section 379A of the Public Health Service Act (42 U.S.C. 247l) also requires that the Secretary, by contract, “establish and maintain a scientific database of information relating to patients who have been recipients of a stem cell therapeutics product (including bone marrow, cord blood, or other such product) from a donor.”

<sup>2</sup> Health Resources and Services Administration (HRSA), Healthcare Systems Bureau, Division of Transplantation

<sup>3</sup> Various acronyms refer to hematopoietic stem cell transplantation, including HPSCT, HSCT, or the current usage of HCT. Unless quoting statute, regulations, or other official documents, HCT is used throughout this statement.

and Stem Cell Therapeutic Outcomes Database. In 2017, HRSA reorganized these five functions into three major contracts as described below:

- **Single Point of Access- Coordinating Center (SPA-CC).** This contract coordinates a network of organizations to recruit potential adult donors, with an emphasis on recruiting individuals from genetically varied populations. This network collectively provides access to bone marrow transplants, provides tissue typing to match patients and donors, and engages in public and professional educational activities. The SPA-CC also contains a network of cord blood banks (CBBs) that list their cord blood units (CBUs) and make them available for transplantation. The SPA-CC maintains a single, searchable electronic system for health care professionals and physicians searching on behalf of patients for cells derived from adult bone marrow donors and cord blood units (CBUs) through a single point of access.
- **Office of Patient Advocacy (OPA).** This contract supports patient advocacy and case management specific to bone marrow and blood stem cell transplantation, as well as histocompatibility and search expertise, providing guidance for patients and physicians. The OPA provides public and professional education, information, resources, and support for transplant patients and families from diagnosis through long-term survivorship.
- **Stem Cell Therapeutic Outcomes Database (SCTOD).** This contract provides a repository of donor and patient samples for research and supports an electronic database of blood stem cell transplantation products, processes, and outcomes for use by researchers, health care professionals, and the public. The SCTOD produces data on clinical outcomes (e.g., by transplant facility and treatment method) that supports patient decision-making and fosters continuous quality improvement efforts among health care professionals and transplant facilities.

As part of its oversight responsibilities, HRSA submits an annual Report to Congress on the performance and activities of these contractors in supporting the CWBYCTP.<sup>4</sup>

## **2. National Cord Blood Inventory (NCBI)**

The NCBI Program contracts with CBBs to meet the statutory goal of building a public inventory of at least 150,000 new, high-quality, and genetically varied CBUs. These CBUs are available for transplantation through the CWBYCTP.

## **3. Advisory Council on Blood Stem Cell Transplantation (ACBSCT)**

The role of the ACBSCT is to advise, assist, consult with, and make recommendations to the Secretary of Health and Human Services (HHS) and the Administrator of HRSA on matters conducted by both the CWBYCTP and the NCBI Program.<sup>5</sup>

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<sup>4</sup> <https://bloodstemcell.hrsa.gov/about/legislation/reports-congress>

<sup>5</sup> <https://bloodstemcell.hrsa.gov/about/advisory-council>

## **B. JUSTIFICATION**

### **1. Circumstances Making the Collection of Information Necessary**

The Stem Cell Therapeutic and Research Act of 2005 (Public Law 109-129, December 20, 2005) as amended and codified in Section 379A of the Public Health Service Act (42 U.S.C. 247l) requires that the Secretary, by contract, “establish and maintain a scientific database of information relating to patients who have been recipients of a stem cell therapeutics product (including bone marrow, cord blood, or other such product) from a donor.” Based on this authority, HRSA requests that the Office of Management and Budget (OMB) continue approval of the collection of information for the SCTOD, a component of the C.W. Bill Young Cell Transplantation Program (CWBYCTP). The collection of these data fulfills the statutory requirements at 42 U.S.C. 247l.

### **2. Purpose and Use of Information**

The overall purpose of the data collection is to improve the treatment and outcome for patients who may benefit from cellular therapies. It does so by fulfilling the legislative requirement at 42 U.S.C. 247l(a) to establish and maintain a scientific database of information relating to donors and recipients of a stem cell therapeutics product. Per 42 U.S.C. 247l(b), the outcomes database shall include information regarding “diagnosis, transplant procedures, results, long-term follow-up, and such other information as the Secretary determines to be appropriate” to conduct an ongoing evaluation of the scientific and clinical status of HCT transplantation. HRSA, through its SCTOD contractor, maintains the scientific database and fulfills the statutory requirements to provide information for two primary purposes:

- The submission of an annual report to the Secretary “concerning patient outcomes with respect to each transplant center” under 42 U.S.C. 247l(c) and
- The provision of relevant and de-identified scientific information to the public in the form of summaries and data sets under 42 U.S.C. 247l(d).

To meet these requirements, the SCTOD contractor supports HRSA’s production of annual reports, including a U.S. Patient Survival Report, U.S. Transplant Data by Center Report, U.S. Transplant Data by Disease Report, and a Transplant Activity Report.<sup>6,7</sup> These reports and their datasets contain center-specific transplant patient-, disease-, and procedure-related characteristics and outcomes for nearly all allogeneic and a majority of autologous HCTs performed in the U.S.

Much like Medicare’s CareCompare website for hospitals,<sup>8</sup> these reports include transplant center-specific data that provide potential HCT recipients, their families, and the general public with a comparison of survival rates among the centers in the CWBYCTP network. Also, like Medicare’s CareCompare website, some of the

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<sup>6</sup> <https://bloodstemcell.hrsa.gov/data>

<sup>7</sup> <https://bloodstemcell.hrsa.gov/data/donation-and-transplantation-statistics/transplant-activity-report#summary>

<sup>8</sup> <https://www.medicare.gov/care-compare/>

transplant center-specific data (e.g., survival rates) are based on transparent statistical models that adjust for several important risk factors. And finally, like Medicare's CareCompare website, the SCTOD contractor intends to continually improve the value of its models and public reporting. Thus, in consultation with stakeholders, it may update some of its models and their required data on a more frequent basis than every three years, to reflect the most up-to-date evidence on clinical care and statistical modeling.<sup>9</sup>

To help meet the second statutory requirement, the SCTOD contractor also produces study summaries for patients, de-identified data for original and secondary analysis, and a highly detailed report on survival statistics that describes the use and outcome of autologous and allogeneic HCT in more than 500 transplant centers that have participated in the program.<sup>10,11,12,13</sup> These reports, summaries, and data are made available to assist with program operation; to encourage medical research; and to provide relevant, timely, and actionable information to transplant programs, physicians, patients, certain donor registries,<sup>14</sup> and cord blood banks.

As part of its ongoing efforts to provide transparency, demonstrate value, and welcome research, the SCTOD contractor maintains a Working Committee Research Portfolio that lists recently published and current studies for each Working Committee, and it provides information regarding the committee structure and contact information for those who may wish to participate in or lead studies.<sup>15</sup> The data, resources, and support provided by the entity currently serving as the SCTOD contractor have resulted in over 1,750 peer-reviewed publications, including more than 70 journal articles in 2024.<sup>16,17,18</sup>

The SCTOD contractor also supports decision-making for other parts of the Government. For example, the SCTOD contractor recently completed two clinical studies, while also sponsoring three separate clinical studies to support the Centers for Medicare and Medicaid Services (CMS) in its coverage with evidence development (CED) process. These clinical studies aim to develop evidence to support coverage

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<sup>9</sup> Transplant center-specific survival rates are based on one-year overall survival and estimated using a censored data logistic regression model that adjusts for several risk factors: <https://cibmtr.org/CIBMTR/Resources/Summary-Slides-Reports/Center-Specific-Survival-Analysis-Methodology>

<sup>10</sup> <https://www.cibmtr.org/ReferenceCenter/Patient/PatientSummaries/pages/index.aspx>

<sup>11</sup> [https://www.cibmtr.org/Data/Available/Pages/index.aspx#data\\_request](https://www.cibmtr.org/Data/Available/Pages/index.aspx#data_request)

<sup>12</sup> <https://cibmtr.org/CIBMTR/Resources/Publications>

<sup>13</sup> <https://www.cibmtr.org/ReferenceCenter/SlidesReports/StatReport/Pages/index.aspx>

<sup>14</sup> Donor registries awarded a contract under section 379 of the Public Health Service Act (42 U.S.C. 274k).

<sup>15</sup> Study lists are available at: <https://www.cibmtr.org/Studies/Observational/StudyLists/Pages/index.aspx>

<sup>16</sup> The publication list is available at: <https://www.cibmtr.org/ReferenceCenter/PubList/Pages/index.aspx>

<sup>17</sup> All disclosures by the SCTOD contractor are governed by Privacy Act System of Records Notice #09-15-0068 (notification of an altered system of records was published on February 14, 2018, at 83 FR 6591).

<sup>18</sup> Though the collection of data for the SCTOD is not a research project, the SCTOD contractor submitted for ethical review to the NMDP Institutional Review Board (IRB) and was approved. The NMDP IRB is registered with the HHS Office of Human Research Protections (Registration IRB00001253) and has an approved Federal wide Assurance (FWA00000441) [<https://ohrp.cit.nih.gov/search/IrbDtl.aspx>]. All HCT facilities must obtain IRB-approved informed consent from recipients to allow SCTOD data to be used for research studies.

decisions regarding stem cell transplantation as a treatment for Myelodysplastic Syndrome (MDS), Sickle Cell Disease, Myelofibrosis, and Multiple Myeloma.<sup>19,20,21,22,23,24</sup>

### **3. Use of Improved Information Technology**

The SCTOD has integrated electronic records and data that are submitted to the database through one of two primary methods: a secure Web-based application known as FormsNet and an open-source messaging system specifically designed to exchange HCT data using a secure, standards-based system, known as AGNIS® (A Growable Network Information System). The SCTOD contractor also implemented an application that uses an HHS-approved application programming interface (API) known as the HL7 Fast Healthcare Interoperability Resources® (FHIR®) standard that enables automated acquisition of data from electronic medical records and other real-world evidence source systems deployed within reporting centers.<sup>25,26</sup>

The SCTOD contractor's current default method for data collection is FormsNet, a single Web-based application for data entry, viewing, and auditing of electronic data. This application allows remote data entry of all transplant baseline and follow-up data by transplant centers.<sup>27</sup> Important features included in the current version of the FormsNet application (v3) are:

- 24/7 accessibility;
- create/edit data collection instruments and inserts;
- create/edit all contractor-specific inserts;
- create/edit confirmation of Human Leukocyte Antigen (HLA) typing and product data;
- audit trail and user interface;
- data entry and data reconciliation; and
- tools for monitoring accuracy and processes.

FormsNet also includes: automated validation checks within and between data collection instruments; automatically generated error reports; field-level saving and field-level audit trails; review functions for center supervisors; forms due reporting; and the flexibility to add additional features. And finally, FormsNet provides additional functionality that can reduce the burden and increase data quality (e.g., modifying

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19 <https://www.cms.gov/medicare-coverage-database/view/ncd.aspx?NCID=366&DocID=110.23>

20 <https://clinicaltrials.gov/ct2/show/NCT01166009>

21 <https://clinicaltrials.gov/ct2/show/NCT02766465>

22 <https://clinicaltrials.gov/ct2/show/NCT02934477>

23 <https://clinicaltrials.gov/ct2/show/NCT01166009>

24 <https://clinicaltrials.gov/ct2/show/NCT03127761>

25 <https://fhir.nmdp.org/ig/cibmtr-reporting/>

26 The Office of the National Coordinator for Health Information Technology adopted a new standardized Application Programming Interface (API) certification criterion for patient and population services that requires the use of the FHIR® standard and references several standards and implementation specifications adopted in 45 CFR §170.213 and 45 CFR §170.215 to support interoperability (85 FR 25642)

27 <https://cibmtr.org/CIBMTR/Data-Operations/Support-Resources/CIBMTR-System-Applications>

response options in drop-down boxes to align with current medical evidence and modifying question paths to align with respondent workflow).

FormsNet is fully compliant with Federal database security requirements as established by HRSA's Office of Information Technology (OIT) and the Food and Drug Administration (FDA) *21 CFR Part 11; Electronic Records; Electronic Signatures Maintenance of Electronic Records and Computerized Systems Used in Clinical Trials*.

To continually improve its data collection process, the SCTOD contractor performed an analysis to identify the gaps between the current state and desired future state for collecting data that (1) reduces burden and (2) results in data that is timely, meaningful, and actionable. Based on this analysis, the SCTOD contractor implemented its Data Transformation Initiative (DTI), whose vision is "to optimize the acquisition and utilization of entrusted data assets to accelerate breakthroughs that transform patient experiences."<sup>28</sup> To support the Initiative, the SCTOD contractor took two simultaneous paths to improving data quality and reducing burden:

- Development and implementation of an Epic®-based Center for International Bone Marrow Transplant and Research [CIBMTR] Reporting Application (CRA) that auto-populates fields in the FormsNet application using data from the HCT facility's electronic health record and
- Development and release of tools, performance of voluntary pilots, and enrollment of interested facilities into a program to submit data using the HL7 Fast Healthcare Interoperability Resources® (FHIR®) standard.<sup>29,30,31,32</sup>

With further development and refinement of these interoperability tools, HRSA and its contractor intend to continually refine and improve their data collection to reflect the most up-to-date medical evidence, while simultaneously reducing the burden on HCT facilities.

#### **4. Efforts to Identify Duplication and Use of Similar Information**

The SCTOD data system is the only nationwide data collection effort specifically targeting donors and recipients of stem cell therapeutics products (including bone marrow, cord blood, or other similar products). The system's unique and robust data collection efforts, which utilize internationally recognized instruments, make it a valuable

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<sup>28</sup> <https://cibmtr.org/CIBMTR/Data-Operations/Support-Resources/CIBMTR-System-Applications>

<sup>29</sup> <https://apporcard.epic.com/Gallery?id=754>

<sup>30</sup> <https://cibmtr.org/CIBMTR/Data-Operations/Support-Resources/CIBMTR-System-Applications>

<sup>31</sup> In October 2020, the SCTOD contractor began testing a proof-of-concept pilot for use of the HL7® FHIR® standard. In six months, four different transplant centers successfully completed the pilot. As of March 2022, eighteen HCT facilities are submitting data via the HL7® FHIR® standard, ten are in the implementation process and another sixty have expressed interest.

<sup>32</sup> As described by the Office of the National Coordinator for Health Information Technology, "The HL7® FHIR® standard defines how healthcare information can be exchanged between different computer systems regardless of how it is stored in those systems. It allows healthcare information, including clinical and administrative data, to be available securely to those who have a need to access it, and to those who have the right to do so for the benefit of a patient receiving care." See: <https://www.healthit.gov/sites/default/files/2019-08/ONCFHIRFSWhatIsFHIR.pdf>

resource for research, education, and policy development purposes. The Federal government contracts with no other entity to gather similar data related to HCT.

## **5. Impact on Small Businesses or Other Small Entities**

This project will not collect any data from small businesses, as defined by the OMB. The data collected will not have any significant impact on small businesses or other small entities.

## **6. Consequences of Collecting the Information Less Frequently**

The information collection activity outlined in this request is required under the Stem Cell Therapeutic and Research Act of 2005, as amended and codified in Section 379A of the Public Health Service Act (42 U.S.C. 247I). These data, along with their corresponding data collection periods, represent a consensus-based solution to balancing the reporting burden with statutory requirements. Additionally, facilities that submit data to the SCTOD are regularly consulted regarding any improvements and changes in data collection [See Section B.3. Use of Improved Information Technology]. For example, the SCTOD contractor hosts an annual Clinical Research Professionals/Data Management conference and a biannual Center Outcomes Forum. At these conferences, transplant physicians, center directors, representatives from the American Society for Transplantation and Cellular Therapy (ASTCT), governmental funding agencies, patients, private payers, and statisticians are consulted regarding data collection and outcomes reporting.<sup>33</sup>

The requirements for data collection include the number of transplants facilitated by the CWBYCTP, the number of transplants performed annually in the United States, the outcomes of those transplant procedures, the long-term outcomes of blood stem cell transplantation, and the effective use of cord blood units for transplantation. Additionally, these requirements include annual Transplant Center-Specific Survival Reports that are made available to patients, physicians, and the public.

To meet these requirements, HRSA requests continuation of the current data collection schedule:

### **Pre-transplant Data (within 30 days of transplant)**

- Baseline recipient data including patient demographics, pertinent medical history, disease characteristics and status, and co-morbidities;
- Procedure characteristics, including preparative regimen, and
- Donor data.

### **Transplant Data (within 60 days of transplant)**

- Graft-vs-Host Disease (GVHD) prophylaxis, graft source, donor type, and degree of HLA matching, and graft manipulation;
- Graft characteristic data for cord blood units, including infused cell dose, and

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<sup>33</sup> <https://www.cibmtr.org/Meetings/Materials/Pages/index.aspx>

- Product information.

Post-Transplant Data (100 days after transplant, 6 months after transplant, 1 year after transplant, annually for 6 years after transplant, and then biennially thereafter)<sup>34</sup>

- Hematopoietic recovery and engraftment,<sup>35</sup> serious complications including GVHD and second cancers, disease status, survival status, and cause of death; and
- Subsequent procedures.

These expectations and timelines for data submission are the result of ongoing input from the transplant community and the facilities that provide the data. To meet statutory requirements under 42 U.S.C. 247l, the SCTOD contractor will continue to work with stakeholders to improve the quality of data used for clinical research and outcomes reporting (e.g., disease classification, risk factors, and risk adjustments).

Collecting data at the proposed time points is not only essential for understanding outcomes at various stages of the transplant process, but it also represents standard assessment time points for allogeneic transplant recipients. These time points are also intended to emphasize the importance of follow-up assessments by transplant centers to prevent losing contact with transplant recipients, as recipients gradually become more distant from the tertiary care centers where allogeneic transplantation is performed.

If the information required by statute is not collected at the designated time points, HRSA will not be in compliance with the authorizing legislation. Additionally, collecting less information at each time point than that which is proposed would also be contrary to statutory direction and community consensus.<sup>36</sup> These data are also required by the Secretary to report the following:

- Whether program funds for the SCTOD are fulfilling the mission of the CWBYCTP;
- The indications for and outcomes from various types of transplants performed in the U.S.; and
- Facility-specific HCT outcomes.

The legal obstacles to reducing the burden are the authorizing statutes at 42 U.S.C. 247k and 247l.

## **7. Special Circumstances Relating to the Guidelines at 5 CFR 1320.5(d)(2)**

As described above, HCT facilities may report data to HRSA's contractor more often than quarterly. The HCT data reporting schedule is patient-based as opposed to facility-based. It follows a standardized schedule: baseline (within 30 days of HCT), 100 days

<sup>34</sup> In the circumstance that a patient dies, cause of death data will be collected as soon as possible after death.

<sup>35</sup> The process in which transplanted hematopoietic cells begin to grow in the bone marrow of the host and to produce new white blood cells, red blood cells and platelets.

<sup>36</sup> For example, the Foundation for Accreditation of Cellular Therapy (FACT), which accredits HCT facilities, coordinates with the SCTOD contractor on data quality and announced on March 1, 2017, that it will no longer include verification of clinical data against source data as FACT clinical inspectors have access to CIBMTR data audit results.

after HCT, 6 months after HCT, 1 year after HCT, annually for 6 years after HCT, and biennially thereafter, as well as cause of death data if the patient dies. The reason for this scheduling is that the timeliness of pre- and post-transplant data collection is essential to improving patient outcomes and advancing transplantation policy and science.

HRSA's contractor is making changes per OMB new guidance for race and ethnic categories as outlined in SPD-15; however, the contractor's classifications do not exactly align with OMB classification. There are some minor discrepancies as certain additional detailed subcategories were developed that align with geographic ancestry classification. This classification is necessary for work that involves genetic HLA matching for patients and donors. There is a mechanism to roll up the ancestry classification developed by the contractor to the OMB overall classification for race and ethnicity categories.

Other than this special circumstance described above regarding 5 CFR 1320.5(d)(2)(i), there are no other special circumstances that would require an information collection to be conducted in a manner that requires respondents to:

- Prepare a written response to a collection of information in less than 30 days after receipt;
- Submit more than an original and two copies of any document;
- Retain records, other than health, medical, government contract, grant-in-aid, or tax records for more than 3 years;
- Collect data in connection with a statistical survey that is not designed to produce valid and reliable results that can be generalized to the universe of study;
- Use a statistical data classification that has not been reviewed and approved by OMB;
- Include a pledge of confidentiality that is not supported by authority established in statute or regulation that is not supported by disclosure and data security policies that are consistent with the pledge, or which unnecessarily impedes sharing of data with other agencies for compatible confidential use; or
- Submit proprietary trade secret, or other confidential information unless the agency can demonstrate that it has instituted procedures to protect the information's confidentiality to the extent permitted by law.

## **8. Comments in Response to the Federal Register Notice/Outside Consultation**

### **Section 8A:**

The 60-day notice required in 5 CFR 1320.8(d) was published in the *Federal Register* on May 16, 2025 (Volume 90, Number 94, Pages 21049-21051). No comments were received.

The 30-day notice required in 5 CFR 1320.8(d) was published in the *Federal Register* on July 30, 2025 (Volume 90, Number 144, Pages 35913-35914).

## **Section 8B:**

HRSA and its SCTOD contractor regularly consult with outside persons to obtain their views on the data collected, including consideration of data availability, data frequency, instructions, data dictionaries, reporting, and disclosures. These data, along with their corresponding data collection periods, represent a consensus-based solution to balancing the reporting burden with statutory requirements. Facilities that submit data to the SCTOD are regularly consulted regarding any improvements and changes in data collection [See Section B.3. Use of Improved Information Technology].

The SCTOD contractor holds an annual Clinical Research Professionals / Data Management conference and a bi-annual Center Outcomes Forum. At these conferences, transplant physicians and center directors, the ASTCT, governmental funding agencies, patients, private payers, and statisticians are consulted regarding data collection and outcomes reporting.<sup>37</sup>

Data collection instruments are reviewed on an established timeline, at least once every three years, to ensure that the most relevant data are being collected. Broad stakeholder participation in this process is accomplished through engagement of data professionals at participating centers and the Working Committees established by the SCTOD contractor, which include cord blood banks, other CWBYCTP contractors, HCT facilities, and other stakeholders such as the European Group for Blood and Marrow Transplantation (EBMT), the Worldwide Network for Blood and Marrow Transplantation (WBMT), ASTCT, and the Foundation for the Accreditation of Cellular Therapy (FACT).

HRSA and its SCTOD contractor promote international harmonization of HCT data standards by participating in periodic data standards reviews with other international registries, including the European Blood and Marrow Transplantation (EBMT). The broad acceptance of these standards facilitates the acquisition of data regarding HCTs conducted outside the U.S. using U.S. products. The SCTOD contractor will also continue to work with ASTCT, EBMT, other international registries, cord blood banks (using the Cord Blood Data Working Group), and other CWBYCTP members to achieve consensus on any revisions to the standard dataset. Finally, the SCTOD contractor will continue to coordinate with the SPA-CC contractor to ensure that HLA data reflect current matching algorithms.

### **9. Explanation of Any Payment/Gift to Respondents**

Respondents will not receive any payments or gifts associated with completing these forms for the CWBYCTP.

### **10. Assurance of Confidentiality Provided to Respondents [respondents are facilities]**

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<sup>37</sup> <https://www.cibmtr.org/Meetings/Materials/Pages/index.aspx>

All data collected will be subject to Privacy Act protection (Privacy Act System of Records #09-15-0068). Data collected under the SCTOD contract is also well protected within the contractor's robust cybersecurity program, which is aligned with NIST 800-53, Security and Privacy Controls for Federal Information Systems and Organizations. It is assessed annually by a qualified, independent third-party auditor to ensure that it meets or exceeds the requirements as prescribed by OMB Circular A-130, Appendix III, Security of Federal Automated Information Systems, and the Department's Automated Information Systems Security Program Handbook. These security features are implemented within a comprehensive System Security Plan that addresses administrative, operational, and technical controls, including but not limited to:

- Annual risk assessment;
- System and component inventories;
- Annual security awareness & data privacy training;
- System and data access control and entitlement reviews;
- System event auditing and accountability;
- Configuration and change management;
- Threat and vulnerability management and remediation;
- Incident response and management;
- Contingency planning;
- Annual privacy impact assessment;
- Physical and facilities access and security; and
- Continuous monitoring.

The SCTOD contractor utilizes a unique identification (ID) registration system for transplant recipients to prevent redundant reporting across transplant centers and over time. This unique ID registration system exists within an isolated server. It uses identifying information about transplant recipients provided by the transplant center to assign a unique ID number that does not contain personal identifiers. Subsequently, this unique number is used by the transplant center and other CWBYCTP components to exchange data regarding transplant recipients for purposes of reporting outcomes to the Government.

The ID registration system and the exchange of data between entities exists within the context of the designation of the SCTOD contractor, CIBMTR, as a public health authority for purposes of the Health Insurance Portability and Accountability Act (HIPAA) as determined by the HHS Office of General Counsel (OGC) and Office of Civil Rights (OCR) in fulfillment of the contract requirements (PHA letter attached). The OGC has determined, and OCR concurs, that the SCTOD contractor meets the Privacy Rule's definition of a public health authority and is authorized by law to collect the information necessary for the SCTOD to fulfill its statutory purpose and functions. Under this analysis, transplant centers that are covered entities may disclose to the SCTOD contractor the individually identifiable health information collected by the SCTOD to comply with its statutory purposes. Additionally, the electronic systems used to create and maintain the unique ID system exist under the auspices of HRSA's OIT Certification and Accreditation system.

Although the data collection instruments do not request direct identifiers, due to the nature of reporting transplant outcomes required for the SCTOD contract, they do request birth dates, procedure dates, complication and event dates, and death dates. These data are housed in secure electronic data systems under the certification and accreditation by HRSA OIT.

Data will be kept private to the extent allowed by law. This data collection is covered by a Certificate of Confidentiality from the National Institutes of Health. The researchers with this Certificate may not disclose or use information, documents, or biospecimens that may identify a patient in any federal, state, or local civil, criminal, administrative, legislative, or other action, suit, or proceeding, or be used as evidence, for example, if there is a court subpoena, unless the patient has consented for this use. Information, documents, or biospecimens protected by this Certificate cannot be disclosed to anyone else who is not connected with the research except, if there is a federal, state, or local law that requires disclosure (such as to report child abuse or communicable diseases but not for federal, state, or local civil, criminal, administrative, legislative, or other proceedings, see below); if the patient has consented to the disclosure, including for medical treatment; or if it is used for different scientific research, as allowed by federal regulations protecting research subjects.

The Certificate cannot be used to refuse a request for information from personnel of a United States federal or state government agency sponsoring the project that is needed for auditing or program evaluation by Federal funding agencies, or for information that must be disclosed to meet the requirements of the FDA.

## **11. Justification for Sensitive Questions**

There are no questions of a possible sensitive nature, except for race and ethnicity. These data are necessary to support analysis of demographic subgroups and improve access. The only patient-level identifying information is birth date, procedure and complication dates, and death dates. These are required for outcomes reporting for the SCTOD. However, as detailed above, these data are maintained in secure and protected systems. Only aggregate data summarizing transplant activity and outcomes are included in reports published by the SCTOD.

## **12. Estimates of Annualized Hour and Cost Burden**

The estimate of annualized respondent burden hours and costs to complete data collection instruments is shown in Tables 1 and 2. As shown in Table 1, the SCTOD contractor collects transplant data from 182 U.S. transplant centers using these reporting instruments. Over time, there is an expected increase in the number of recipients for whom data are reported, as the number of transplants performed annually increases and survivorship after transplantation improves. The burden of data collection

and reporting will vary by transplant center, as HCT facilities exhibit a significant variation in the number of allogeneic transplants performed.

The Department of Labor rate was used for estimating respondent's hourly wage rate. The Bureau of Labor Statistics occupation code 29-2072 Medical Records Specialists was used, as it is the closest representation of the required activities for information collection. The hourly wage rate has been doubled to account for overhead costs. The median hourly rate is used, as opposed to adjusting for locality, since award recipients are spread across the country.

## 12A. Estimated Annualized Burden Hours

Form Name <sup>38</sup>	Number of Respondents <sup>39</sup>	Number of Responses per Respondent <sup>40</sup>	Total Responses	Average Burden per Response (in hours)	Total Burden Hours <sup>41</sup>
Pre-Transplant Information Collection	182.00	53.78	9,788.00 <sup>42</sup>	2.24 <sup>43</sup>	21,902.61
Transplant Procedure and Product Information	182.00	53.78	9,788.00 <sup>44</sup>	0.75 <sup>45</sup>	7,356.66
Post-Transplant Periodic Information Collection based on Predetermined Schedule	182.00	418.86	76,232.00 <sup>46</sup>	0.57 <sup>47</sup>	43,810.53
<b>Total</b>	<b>182.00</b>		<b>95,808.00</b>		<b>73,069.80</b>

Note: The Number of Responses Per Respondent is slightly different from on the 30-day FRN. This is because the Number of Responses Per Respondent was adjusted to be the Total Respondents/Number of Responses Per Respondent and not rounded to the nearest 100<sup>th</sup> as to match ROCIS rounding rules.

## Estimated Annualized Burden Costs

Type of Respondent	Total Burden Hours	Hourly Wage Rate (\$) <sup>48</sup>	Total Respondent Costs (\$)
Data Manager	73,069.80	48.32	\$3,530,732.74
<b>Total</b>	<b>73,069.80</b>	<b>48.32</b>	<b>\$3,530,732.74</b>

38 This burden estimate table refers to data collections at different time periods consistent with approved practice. The SCTOD contractor is working with respondents to reduce burden by submitting data using interoperability standards. These data collections may include OMB-approved forms.

39 The total number of U.S. transplant centers that submit data to the SCTOD is 182 as of 4/14/2025. The number of centers providing data may change intermittently based on opening or closure of centers.

40 The Number of Responses per Respondent was calculated by dividing the Total Responses by the Number of Respondents.

41 The total in ROCIS is 73070, which is 73,069.80 rounded up.

42 Total responses for Pre-Transplant Information Collection equals estimated number of new transplant patients in 2024.

43 Pre-transplant Data includes baseline recipient data including patient demographics, pertinent medical history, disease characteristics and status, and co-morbidities, transplant data procedure characteristics, including preparative regimen, and donor data. This number is rounded to the nearest hundredth. The actual burden estimate for these data is 2.2377.

44 Transplant Procedure and Product Information equals estimated number of new transplant patients in 2024.

45 Transplant Procedure and Product Information includes Graft-vs-Host Disease prophylaxis, graft source, donor type and degree of HLA matching and graft manipulation; graft characteristic data for cord blood units, including infused cell dose; and product information. This number is rounded to the nearest hundredth. The actual burden estimate for these data is 0.7516.

46 The number of responses for Post-Transplant Periodic Information Collection is based on a predetermined schedule: 100 days after transplant, 6 months after transplant, 1 year after transplant, annually for 6 years after transplant and then biennially thereafter. In any given year the number of responses is a function of the number of transplants in that year, the number of transplants in previous years, and expected patient survival between the time of transplant and any follow-up activity.

47 Post-Transplant Data Collection includes hematopoietic recovery and engraftment, serious complications including Graft-vs-Host Disease and second cancers, disease status, survival status, and cause of death; and subsequent procedures. This number is rounded to the nearest hundredth. The actual burden estimate is 0.5747.

48 Source: Hourly Median Wage for Medical Records Specialists, United States Department of Labor, Bureau of Labor Statistics, May 2024. <https://data.bls.gov/oesprofile/>. Median wage of \$24.16 has been multiplied by 2 to account for overhead costs.

### **13. Estimates of other Total Annual Cost Burden to Respondents or Recordkeepers/Capital Costs**

Other than their time, there is no cost to respondents.

### **14. Annualized Cost to the Federal Government**

The cost of the study for government personnel is estimated for one person working on this ICR for two years for an estimated annualized cost per year of \$22,910.37 (10 percent full time equivalent; GS-13, Step-09 salary level with 33.94% locality payment included, total costs are multiplied by 1.5 percent to account for overhead costs).

The annual estimated government cost for carrying out this study is approximately \$5.9 million annually to be spent on all the activities of the contract and the operation of the SCTOD.

### **15. Explanation of Program Changes or Adjustments**

This is a revised collection of information with an estimated increase to the overall hour burden inventory to 73,069.80. The increase in average burden per response for the Pre-Transplant Information Collection reflects the effort required for assembling the information for the most complex indications for transplant, which are the most common. The overall burden increased due to the higher number of transplants being performed and improved survival rates, necessitating more follow-up forms. The decrease in average burden per response for the Transplant Procedure and Product Information and Post-Transplant Information Collection reflects the removal of questions that are no longer relevant, as well as improvements in entry options and other efficiencies, such as checkboxes and auto-population from previously completed questions.

### **16. Plans for Tabulation, Publication, and Project Time Schedule**

The data collected using the instruments outlined above are populated in a database for the SCTOD and are used for numerous analyses, reports, and publications. Data collected for the SCTOD are shared with other components of the CWBYCTP in fulfillment of the goals and statutory charge of the CWBYCTP. The data collected is shared with HRSA, and reports from the data are shared with umbilical cord blood banks and the transplant programs themselves. The outcomes database is also used to prepare reports about the CWBYCTP for the Secretary, the Advisory Council on Blood Stem Cell Transplantation, HRSA, and the public. One of the main reports produced under SCTOD is the Transplant Center-Specific Survival Report, which outlines the specific survival rates for allogeneic recipients at all transplant centers in the U.S. This is a critical report for patients and physicians, both for improving quality of care at transplant centers and for helping patients and their physicians make well-informed choices about which transplant centers are most appropriate for each patient.

In addition, as required in section 379A(d) of the Act, the outcomes database makes relevant scientific information that does not contain individually identifiable information available to the public. This information is provided by CIBMTR in the form of summaries and data sets to encourage medical research and to provide information to transplant programs, physicians, patients, and cord blood banks. The Transplant Center-Specific Survival Report and the U.S. Transplant Activity Report are available through the HRSA website.

The center-specific survival analysis report is delivered to HRSA annually in the fall and made available to the public each December. The data collection is ongoing, and the maximum number of years for clearance (3 years) is requested.

**17. Reason(s) Display of Expiration Date is Inappropriate**

The OMB number and Expiration date will be displayed on every page of every form/instrument.

**18. Exceptions to Certifications for Paperwork Reduction Act Submissions**

There are no exceptions to the certification.