



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Agency Information Collection Activities: Submission to OMB for Review and Approval; Public Comment Request; The Stem Cell Therapeutic Outcomes Database

AGENCY: Health Resources and Services Administration (HRSA), Department of Health and Human Services (HHS).

ACTION: Notice.

SUMMARY: In compliance with the Paperwork Reduction Act of 1995, HRSA submitted an Information Collection Request (ICR) to the Office of Management and Budget (OMB) for review and approval. Comments submitted during the first public review of this ICR will be provided to OMB. OMB will accept further comments from the public during the review and approval period. OMB may act on HRSA's ICR only after the 30-day comment period for this notice has closed.

DATES: Comments on this ICR should be received no later than **[INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*]**.

ADDRESSES: Written comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to www.reginfo.gov/public/do/PRAMain. Find this particular information collection by selecting "Currently under Review - Open for Public Comments" or by using the search function.

FOR FURTHER INFORMATION CONTACT: To request a copy of the clearance requests submitted to OMB for review, email Samantha Miller, the HRSA Information Collection Clearance Officer, at paperwork@hrsa.gov or call (301) 443-3983.

SUPPLEMENTARY INFORMATION:

Information Collection Request Title: The Stem Cell Therapeutic Outcomes Database

OMB No. 0915- 0310 – Revision

Abstract: 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. 2471), provides for the collection and maintenance of human blood stem cells for the treatment of patients and research. The Public Health Service Act requires the Secretary of HHS to contract for the establishment and maintenance of information related to patients who have received stem cell therapeutic products and to do so using an electronic format. HRSA has established the Stem Cell Therapeutic Outcomes Database (SCTOD), a component of the C.W. Bill Young Cell Transplantation Program (Program), which necessitates certain electronic record-keeping and reporting requirements to perform functions related to hematopoietic stem cell transplantation (HCT) under contract to HHS. Data are collected from transplant centers by the Center for International Blood and Marrow Transplant Research. They are used for ongoing analysis of transplant outcomes to improve treatment and survival for patients who may benefit from cellular therapies.

The proposed revisions to this ICR reflect the most up-to-date medical evidence while also reducing the burden on hematopoietic stem cell transplantation facilities. Revisions fall into several categories: consolidating questions, implementing interactive requests (such as electronic check boxes, "check all that apply," and pull-down menus) to reduce data entry time, adding necessary information fields, clarifying information requests, and removing items that are no longer clinically significant.

Over time, there is an expected increase in the information reported as the number of transplants performed annually increases and survivorship after transplantation improves. Similarly, because of the ongoing rapid evolution in transplant indications, methods to establish diagnoses, disease prognostic factors, treatments provided before HCT, methods to determine

donor matching, and transplantation techniques, the Program anticipates incremental changes in the information collected by the SCTOD after OMB approval to reflect current clinical care, facilitate statistical modeling throughout the approval period to fulfill Program requirements, keep pace with changes in the field, and to enhance the ability to collect information in an automated fashion from respondent source systems, such as electronic health records. Interim updates to the information collected about disease indications, disease definitions, and disease prognostic factors will be triggered by the publication of peer-reviewed scientific articles or public reference materials of updated criteria by organizations such as the World Health Organization, national or international scientific consensus panels (e.g., European LeukemiaNet, International Working Group for Prognosis in MDS), or similar. The updates mentioned above are anticipated to be reflected as changes in response options to existing information collection and will represent non-substantive changes without additional public notice. Such small incremental changes will not significantly affect the burden.

A 60-day notice published in the **Federal Register** on May 16, 2025, vol. 90, No. 94; pp. 21049-51. There were no public comments.

Need and Proposed Use of the Information: Per statutory responsibilities, the collection of information outlined in the “Total Estimated Annualized Burden Hours” section below is needed to collect, analyze, and publish stem cell transplantation-related data, including patient outcomes data, and provide the Secretary of HHS with an annual report of transplant center-specific survival data.

Likely Respondents: Transplant centers.

Burden Statement: Burden in this context means the time expended by persons to generate, maintain, retain, disclose, or provide the information requested. This includes the time needed to review instructions; to develop, acquire, install, and utilize technology and systems for the purpose of collecting, validating, and verifying information, processing and maintaining information, and disclosing and providing information; to train personnel and to be able to

respond to a collection of information; to search data sources; to complete and review the collection of information; and to transmit or otherwise disclose the information. The total annual burden hours estimated for this ICR are summarized in the table below.

Total Estimated Annualized Burden Hours:

Form Name ¹	Number of Respondents ²	Number of Responses per Respondent ³	Total Responses	Average Burden per Response (in hours)	Total Burden Hours ⁴
Pre-Transplant Information Collection	182.00	53.80	9,788.00 ⁵	2.24 ⁶	21,902.61
Transplant Procedure and Product Information	182.00	53.80	9,788.00 ⁷	0.75 ⁸	7356.66
Post-Transplant Periodic Information Collection based on Predetermined Schedule	182.00	418.90	76,232.00 ⁹	0.57 ¹⁰	43,810.53
Total	182.00		95,808.00		73,069.80

Maria G. Button,

Director, Executive Secretariat.

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¹ 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.

² The total number of U.S. transplant centers that submit data to the SCTOD is 182 as of April 14, 2025. The number of centers providing data may change intermittently based on opening or closure of centers.

³ The Number of Responses per Respondent was calculated by dividing the Total Responses by the Number of Respondents and rounding to the nearest hundredth.

⁴ The numbers in this column have been rounded to the nearest hundredth and do not sum precisely due to rounding adjustments throughout the table.

⁵ Total responses for Pre-Transplant Information Collection equals the estimated number of new transplant patients in 2024.

⁶ Pre-transplant Data includes baseline recipient data including patient demographics, pertinent medical history, disease characteristics and status, 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.

⁷ Transplant Procedure and Product Information equals estimated number of new transplant patients in 2024.

⁸ 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.

⁹ 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.

¹⁰ Post-Transplant Data Collection includes hematopoietic recovery and engraftment, serious complications including Graft-vs-Host Disease and second cancers, disease status, survival status, cause of death, and subsequent procedures. This number is rounded to the nearest hundredth. The actual burden estimate is 0.5747.