



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Agency Information Collection Activities: Proposed Collection: Public Comment Request; Information Collection Request Title: 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 requirement for opportunity for public comment on proposed data collection projects of the Paperwork Reduction Act of 1995, HRSA announces plans to submit an Information Collection Request (ICR), described below, to the Office of Management and Budget (OMB). Prior to submitting the ICR to OMB, HRSA seeks comments from the public regarding the burden estimate, below, or any other aspect of the ICR.

DATES: Comments on this ICR should be received no later than **[INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*]**.

ADDRESSES: Submit your comments to paperwork@hrsa.gov or mail the HRSA Information Collection Clearance Officer, Room 14NWH04, 5600 Fishers Lane, Rockville, Maryland 20857.

FOR FURTHER INFORMATION CONTACT: To request more information on the proposed project or to obtain a copy of the data collection plans and draft instruments, email paperwork@hrsa.gov or call Samantha Miller, the HRSA Information Collection Clearance Officer, at (301) 443-3983.

SUPPLEMENTARY INFORMATION: When submitting comments or requesting information, please include the ICR title for reference.

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), one component of the C.W. Bill Young Cell Transplantation Program (Program) which necessitates certain electronic record keeping and reporting requirements to perform the functions related to hematopoietic stem cell transplantation (HCT) under contract to HHS. Data is collected from transplant centers by the Center for International Blood and Marrow Transplant Research and is used for ongoing analysis of transplant outcomes to improve the treatment, survival, and quality of life for patients who may benefit from cellular therapies.

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.

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 with an annual report of transplant center-specific survival data. The proposed revisions of this information collection reflect the most up-to-date medical evidence while simultaneously reducing the HCT facility burden. Revisions fall into several categories: consolidating questions, implementing interactive requests (electronic check boxes, check all that apply, and pull-down menus) to reduce data entry time, adding necessary information fields, adding clarity to information requests and removing items no longer clinically significant (e.g., discontinued or re-named medications).

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. The estimated total annual burden hours for this submission is 52,469.66.

Total Estimated Annualized Burden Hours:

Form Name ¹	Number of Respondents ²	Number of Responses per Respondent ³	Total Responses ⁴	Average Burden per Response (in hours)	Total Burden Hours
Pre-Transplant Information Collection	177.00	52.63	9,315.51 ⁵	1.42 ⁶	13,228.02
Transplant Procedure and Product Information	177.00	52.63	9,315.51 ⁷	1.06 ⁸	9,874.44
Post-Transplant Periodic Information Collection based on Predetermined Schedule	177.00	319.07	56,475.39 ⁹	0.52 ¹⁰	29,367.20
Total	177.00		75,106.41		52,469.66

HRSA specifically requests comments on: (1) the necessity and utility of the proposed information collection for the proper performance of the agency’s functions; (2) the accuracy of the estimated burden; (3) ways to enhance the quality, utility, and clarity of the information to be

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 177 as of March 29, 2022. 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 total number of responses is less than previous calculations because of improvements in estimation. Previous estimates assumed all years had the same number of transplants. This improved estimate includes accurate transplant counts from prior years, which are often less than the current year leading to less follow-up activity.

⁵ Total responses for Pre-Transplant Information Collection equals estimated number of new transplant patients in 2021.

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 1.4175.

⁷ Transplant Procedure and Product Information equals estimated number of new transplant patients in 2021.

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 1.0616.

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, and cause of death; and subsequent procedures. This number is rounded to the nearest hundredth. The actual burden estimate is 0.5247.

collected; and (4) the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

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