

Most important, the Activity Scorecard provides incentive for hospitals to conduct activities that will increase the number of registered donors throughout the nation. A list of hospitals that reach these levels will be shared with all campaign participants during monthly webinars, in monthly campaign e-newsletters from HRSA, and in communications pieces sent out by the campaign's ten national partners, which include the American Hospital Association, the Association of Organ Procurement Organizations, and the American Society of Transplant Surgeons. In addition, OPOs, DLA affiliates, participating state hospital

associations, HRSA, and the national partners can use the results to recognize hospital participation and successes. The "write-in" option that allows hospitals to list additional activities will help to identify best practices that can be shared with all hospital partners on monthly webinars.

Likely Respondents: A hospital representative, most often the organ donation champion identified by the OPO, can download the form from organdonor.gov or receive it from their OPO or Donate Life America (DLA) affiliate.

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	Number of respondents	Number of responses per respondent	Total responses	Average burden per response (in hours)	Total burden hours
National Hospital Organ Donation Campaign's Activity Scorecard	1000	1	1000	0.36	360

Dated: September 20, 2013.

Bahar Niakan,
Director, Division of Policy and Information Coordination.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Agency Information Collection Activities: Proposed Collection: Public Comment Request

AGENCY: Health Resources and Services Administration, HHS.

ACTION: Notice.

SUMMARY: In compliance with the requirement for opportunity for public comment on proposed data collection projects (Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995), the Health Resources and Services Administration (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 Information Collection Request must be received within 60 days of this notice.

ADDRESSES: Submit your comments to paperwork@hrsa.gov or mail the HRSA Information Collection Clearance Officer, Room 10-29, Parklawn Building, 5600 Fishers Lane, Rockville, MD 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 the HRSA Information Collection Clearance Officer at (301) 443-1984.

SUPPLEMENTARY INFORMATION: When submitting comments or requesting information, please include the information request collection 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 (Pub. L.) 109-129, as amended by the Stem Cell Therapeutic and Research Reauthorization Act of 2010, Public Law 111-264 (the Act), provides for the collection and maintenance of human blood stem cells for the treatment of patients and research. HRSA's Healthcare Systems Bureau has established the Stem Cell Therapeutic Outcomes Database. Operation of this database necessitates certain record keeping and reporting requirements in order to perform the functions related to hematopoietic stem cell transplantation under contract to the U.S. Department of

Health and Human Services (HHS). The Act requires the Secretary to contract for the establishment and maintenance of information related to patients who have received stem cell therapeutic products and to do so using a standardized, electronic format. 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. HRSA uses the information in order to carry out its statutory responsibilities. Information is needed to monitor the clinical status of transplantation and to provide the Secretary of HHS with an annual report of transplant center-specific survival data. The increase in burden is due to an increase in the annual number of transplants and increasing survivorship after transplantation.

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 Information

Collection Request are summarized in the table below.

TOTAL ESTIMATED ANNUALIZED BURDEN HOURS

Form Name	Number of respondents	Number of responses per respondent	Total responses	Average burden per response (in hours)	Total burden hours
Baseline Pre-TED (Transplant Essential Data)	200	38	7,600	1	7,600
Product Form (includes Infusion, HLA, and Infectious Disease Marker inserts)	200	29	5,800	1	5,800
100-Day Post-TED	200	38	7,600	0.85	6,460
6-Month Post-TED	200	31	6,200	1	6,200
12-Month Post-TED	200	27	5,400	1	5,400
Annual Post-TED	200	104	20,800	1	20,800
Total	200	53,400	52,260

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

Dated: September 20, 2013.

Bahar Niakan,

Director, Division of Policy and Information Coordination.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Submission for OMB Review; 30-Day Comment Request; Interactive Informed Consent for Pediatric Clinical Trials

SUMMARY: In compliance with the requirement of Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, for opportunity for public comment on proposed data collection projects, the National Institute Heart, Lung, and Blood Institute (NHBLI), the National Institutes of Health (NIH) will publish periodic summaries of proposed projects to be submitted to the Office of Management and Budget (OMB) for review and approval. The 60-day FRN was published 05/9/2013 (Vol. 78, No.

90, page 27243). No public comments were received. The purpose of this notice is to allow an additional 30 days for public comment. The National Institute of Dental and Craniofacial Research (NIDCR), National Institutes of Health, may not conduct or sponsor, and the respondent is not required to respond to, an information collection that has been extended, revised, or implemented on or after October 1, 1995, unless it displays a currently valid OMB control number.

Direct Comments to OMB: Written comments and/or suggestions regarding the item(s) contained in this notice, especially regarding the estimated public burden and associated response time, should be directed to the: Office of Management and Budget, Office of Regulatory Affairs, *OIRA_submission@omb.eop.gov* or by fax to 202-395-6974, Attention: NIH Desk Officer.

Comment Due Date: Comments regarding this information collection are best assured of having their full effect if received within 30-days of the date of this publication.

FOR FURTHER INFORMATION CONTACT: To obtain a copy of the data collection plans and instruments or request more information on the proposed project contact: Victoria Pemberton, Clinical Trials Specialist, NHLBI, 6701 Rockledge Drive, Room 8102, MSC 7940, Bethesda, MD 20892 or call non-toll-free number (301) 435-0510 or Email your request, including your address to: *pembertonv@nhlbi.nih.gov*. Formal requests for additional plans and

instruments must be requested in writing.

Proposed Collection: Interactive Informed Consent for Pediatric Clinical Trials, 0925-New, National Heart, Lung, and Blood Institute (NHLBI), National Institutes of Health (NIH).

Need and Use of Information Collection: This study will compare parents' and children's understanding of information about a hypothetical clinical trial presented using either a standard paper consent document or an interactive computer-based consent program. Parents' and children's understanding, regardless of whether they received the standard consent or the interactive computer-based program, will be assessed by face-to-face interview. In addition, parents' and children's perceptions of, and satisfaction with, the information presented will be evaluated by completion of a short questionnaire. The primary hypothesis to be tested is that interactive computer-based research consent information is better understood and accepted by parents and children compared with the standard paper consent document. Given that many individuals have difficulty reading and interpreting standard written consent documents, this technology holds promise as a means to optimize the consent and assent process particularly among individuals with low literacy and numeracy skills.

OMB approval is requested for 18 months. There are no costs to respondents other than their time. The total estimated annualized burden hours are 190.