



Billing Code 4165-15

## **DEPARTMENT OF HEALTH AND HUMAN SERVICES**

### **Health Resources and Services Administration**

**Agency Information Collection Activities: Proposed Collection: Public Comment Request**

**Information Collection Request Title: Scientific Registry of Transplant Recipients**

**Information Collection Effort for Potential Donors for Living Organ Donation - New**

**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 14N39, 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, pursuant to Section 3506(c)(2)(A), the Paperwork Reduction Act of 1995.

*Information Collection Request Title:* Scientific Registry of Transplant Recipients  
Information Collection Effort for Potential Donors for Living Organ Donation-New

*Abstract:* The Scientific Registry of Transplant Recipients (SRTR) is administered under contract with HRSA, an agency of HHS. HHS is authorized to establish and maintain mechanisms to evaluate the long-term effects associated with living donations (42 U.S.C. §273a) and is required to submit to Congress an annual report on the long-term health effects of living donation (42 U.S.C. §273b). The SRTR contractor will establish a pilot living donor registry in which 14 transplant programs will register all potential living donors who provide informed consent to participate in the pilot registry. The SRTR's authority to collect information

concerning potential living donors is set forth in the Organ Procurement and Transplantation Network final rule requiring Organ Procurement Organizations and transplant hospitals to submit to the SRTR, as appropriate, information regarding “donors of organs” and “other information that the Secretary deems appropriate” 42 CFR 121.11(b)(2).

*Need and Proposed Use of the Information:* The transplant programs will submit health information collected at the time of donation evaluation through a secure web-based data collection tool developed by the contractor. The SRTR contractor will maintain contact with registry participants and collect data on long-term health outcomes through surveys. The data collection will also include outcomes of evaluation including reasons for non-donation. The goal of the pilot registry is to develop data collection tools and survey instruments that can be used to expand the registry to include most, if not all, living donor transplant programs in the United States over time. Monitoring and reporting of long-term health outcomes of living donors post donation will provide useful information to transplant programs in their future donor selection process and will aid potential living donors in their decision to pursue living donation.

*Likely Respondents:* Potential living donors, transplant programs, medical and scientific organizations, and public organizations.

*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: (1) review instructions; 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; (2) train personnel to respond to a request for collection of information; (3) search data sources; (4) complete and review the collection of information; and (5) 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:

<b>Form Name</b>	<b>Number of Respondents</b>	<b>Average Number of Responses per Respondent</b>	<b>Total Number of Responses</b>	<b>Average Burden per Response (in hours)</b>	<b>Total Burden Hours</b>
Potential Living Donor Registration form	14	55	770	1	770
Potential Living Donor Follow-up form	776	1	776	.50	388
<b>Total</b>	<b>790*</b>		<b>1546</b>		<b>1158</b>

\*Number of respondents for potential living donor registration forms is based on the number of programs participating in the pilot registry. Number of respondents for potential living donor follow-up forms is based on the number of potential living donors evaluated at the 14 participating programs in 2015.

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.

Jason E. Bennett,

Director, Division of the Executive Secretariat.

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