



## 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 OMB No.**

#### **0906-0034 – Extension**

**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](mailto:paperwork@hrsa.gov) or mail the HRSA Information Collection Clearance Officer, Room 14N39, 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](mailto:paperwork@hrsa.gov) or call Joella Roland, the HRSA Information Collection Clearance Officer, at (301) 945-0232.

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

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

Information Collection Effort for Potential Donors for Living Organ Donation, OMB No. 0906-0034 – Extension

*Abstract:* The Scientific Registry of Transplant Recipients (SRTR) is administered under contract with HRSA, an agency within HHS. HHS is authorized to establish and maintain mechanisms to evaluate the long-term effects associated with living organ 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). In 2018, the SRTR contractor implemented a pilot living donor registry in which transplant programs registered all potential living organ donors who provided informed consent to participate in the pilot registry. The Organ Procurement and Transplantation Network final rule, 42 CFR part 121, requires organ procurement organizations and transplant hospitals, “as specified from time to time by the Secretary,” 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).

In 2018, a pilot living donor registry was implemented by the SRTR, and each participating transplant program registered all potential candidates for living donation who provided informed consent to enroll. In 2019, an updated version of the data collection instrument was approved, followed by the latest data collection forms which were approved on February 26, 2021. These data collection modifications were intended to improve the quality of the data and reduce the administrative burden for respondents. This federal register notice requests an extension of the last approved data collection forms (February 2021) with no changes to the total estimated annualized burden hours.

*Need and Proposed Use of the Information:* The transplant programs submit health information collected at the time of donation evaluation through a secure web-based data collection tool developed by the SRTR contractor. The SRTR contractor maintains contact with registry participants and collects data on long-term health outcomes through surveys. The data

collection includes outcomes of evaluation, including reasons for non-donation. The living donor registry is an ongoing effort, and the goal is to continue to collect data on living organ donor transplant programs in the United States over time. Monitoring and reporting of long-term health outcomes of living organ donors post-donation will continue to provide useful information to transplant programs for their future donor selection process and to aid potential living organ donors in their decision to pursue living donation.

*Likely Respondents:* Potential and actual living donors, transplant programs, medical and scientific organizations, and public organizations, including patient advocacy groups.

*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:

<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 minutes)</b>	<b>Total Burden Hours</b>
Potential Living Donor Registration form	16 <sup>a</sup>	112	1,792	0.27	484
Potential Living Donor Follow-up form	754 <sup>b</sup>	1	754	0.50	377
Reasons Did not Donate form (liver or kidney)	16 <sup>a</sup>	106	1,696	0.23	390
<b>Total</b>	<b>786</b>		<b>4,242</b>		<b>1,251</b>

<sup>a</sup> Number of respondents is based on the current number of transplant programs and is likely to increase as additional programs decide to participate.

<sup>b</sup> Number of living organ donor candidates submitting follow-up forms in 2019.

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.

**Maria G. Button,**

*Director, Executive Secretariat.*

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