: 4165-15-P

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 of the Paperwork Reduction Act of 1995, HRSA has 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 30-day 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 Lisa Wright-Solomon, the HRSA Information Collection Clearance Officer at paperwork@hrsa.gov or call (301) 443-1984.

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, a sub agency of 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 provide informed consent to participate in the pilot registry. The SRTR's authority to collect information concerning potential living organ donors is set forth in the HHS organ procurement and transplantation network regulation, 42 CFR part 121, 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)).

In 2018, an updated version of the data collection instrument was approved. The data collection modifications improve the quality of the data and reduce the administrative burden for respondents.

A 60-day notice published in the **Federal Register** on September 8, 2020, vol. 85, No. 174; pp. 55464-65. There were no public comments.

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 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 in their future donor selection process and aid potential living organ donors in their decision to pursue living donation.

There were minor revisions to the burden per response as it has decreased from the current amount due to improvements to the efficiency of the processes used by programs for data submission, as well as the tools provided for program use by SRTR.

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 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	Average Number of Responses per Respondent	Total Number of Responses	Average Burden per Response (in minutes)	Total Burden Hours
Potential Living Donor Registration form	16[a]	112	1,792	.27	484
Potential Living Donor Follow-up form	754[b]	1	754	.50	377
Reasons Did not Donate form (liver or kidney)	16[a]	106	1,696	.23	390

Total	**786**		**4,242**		**1,251**

[a] Number of respondents is based on the current number of transplant programs and is likely to increase as additional programs decide to participate.
[b] 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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