: 4165-15-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Agency Information Collection Activities: Submission to OMB for Review and Approval; Public Comment Request; 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 Paperwork Reduction Act of 1995, HRSA submitted an Information Collection Request (ICR) to the Office of Management and Budget (OMB) for review and approval. The initial notice was published on November 17, 2023, with a 60-day comment period. No comments were received. OMB will accept comments from the public during the 30-day comment period for this notice. 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 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 Joella Roland, the HRSA Information Collection Clearance Officer, at paperwork@hrsa.gov or call (301) 443-3983.

SUPPLEMENTARY INFORMATION:

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). The Organ Procurement and Transplantation Network final rule, 42 CFR part 121.11(b)(2), 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."

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.

A 60-day notice published in the **Federal Register** on November 17, 2023, vol. 88, No. 221; pp. 80318-19. 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 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:

Form Name	Number of Respondents	Number of Responses per Respondent	Total Responses	Average Burden per Response (in hours)	Total Burden Hours
Potential Living Donor Registration Form	16[a]	112[c]	1,792[c]	0.27[e]	484

Potential Living Donor Follow-up Form	754[b]	1	754[d]	0.50[f]	377
Reasons Did Not Donate Form (Liver or Kidney)	16[a]	106[c]	1,696[c]	0.23[g]	390
Total	**786[a]**		**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 donor candidates that submitted follow-up forms in 2019.
[c] Derived from the number of forms submitted by transplant programs in 2019.
[d] Total number of Living Donor Collective follow-up forms submitted by living donor candidates in 2019.
[e] Based on a 2019 survey of transplant programs submitting data to the Living Donor Collective.
[f] Based on internal testing and user feedback.
[g] Based on discussion and interviews with staff at participating transplant programs in 2019-2020.

Maria G. Button,

Director, Executive Secretariat.

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