Billing Code 4165-15

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; Information Collection Request Title: Scientific Registry of Transplant Recipients Information Collection Effort for Potential Donors for Living Organ Donation,

[OMB No. 0906-xxxx - New]

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 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.

DATES: Comments on this ICR should be received no later than [**INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER**].

ADDRESSES: Submit your comments, including the ICR Title, to the desk officer for HRSA, either by email to *OIRA_submission@omb.eop.gov* or by fax to 202-395-5806.

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 information request collection title for reference, in compliance with Section 3506(c)(2)(A) of 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
OMB No. 0906-xxxx – 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 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 hours)	Total Burden Hours
Potential Living Donor Registration form	14	55.43	776	1	776
Reasons Did not Donate Form (liver or kidney)	14	27.71	388	.50	194
Potential Living Donor Follow-up form	776	1	776	.50	388
Total	**804***		**1940**		**1358**

*Number of respondents for potential living donor registration and reasons did not donate forms based on number of programs participating in the pilot registry. Number of respondents for potential living donor follow-up forms based on 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.

Amy McNulty,

Acting Director, Division of the Executive Secretariat.

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