

Health Resources and Services Administration
SUPPORTING STATEMENT A
Scientific Registry of Transplant Recipients Living Organ Donation Registry Data
Collection Surveys
OMB Control No. 0906-0034

A. Justification

1. Circumstances Making the Collection of Information Necessary

This is a request for an extension of the Scientific Registry of Transplant Recipients (SRTR) Information Collection Effort for Potential Donors for Living Organ Donation (OMB 0906-0034). These data collection instruments establish and maintain a national registry of living organ donors.

Since its approval in 2018, the registry's data collection efforts have been operated by the SRTR under contract with the Health Resources and Service Administration (HRSA). The registry, known as the Living Donor Collective (LDC), serves an essential public health purpose by collecting long-term data critical to understanding the risks and impacts of living organ donation, which are not regularly collected elsewhere.

This information collection is permitted under the U.S. Department of Health and Human Services (HHS) authority to establish and maintain mechanisms to evaluate the long-term effects associated with living organ donations (42 U.S.C. §273a). It is necessary to fulfill HHS's requirement to submit to Congress an annual report on the long-term health effects of living organ donation (42 U.S.C. §273b). The authority of the SRTR to collect information concerning potential living organ donors is outlined in the Organ Procurement and Transplantation Network (OPTN) Final Rule, which allows transplant centers to submit data to the OPTN and the SRTR (42 U.S.C. 121).

In 2019, OMB approved minor changes to the previously approved data forms. These changes were developed in consultation with experts in living donor transplantation to improve the quality of data collected by the registry and reduce the effort required of transplant programs to submit data to the registry. In 2020, HRSA contracted with SRTR for the continued operation of the registry.

The registry's objective is to collect longitudinal data on the health outcomes of living organ donors and a control group of potential donors who did not donate to try better to understand the long-term health effects of living organ donation.

2. Purpose and Use of Information Collection

Transplant programs submit health information on candidates for living organ donation collected at the time of their evaluation. Once it has been determined whether a candidate will donate, this outcome is reported, along with the reasons for non-donation, where applicable.

The contractor maintains contact with registry participants and collects data on long-term health outcomes through surveys. This follow-up includes both living organ donors and candidates

who do not go on to donate. In the future, additional data on these patients will be obtained via linkages to other registries and data sources.

Monitoring and reporting the long-term health outcomes of living organ donors will continue to provide useful information to transplant programs in their future donor selection process and help potential living organ donors decide to pursue living organ donation.

Long-term monitoring of candidates who are approved to donate but who do not donate for reasons unrelated to the health of the candidate will help establish a control group that can be used in future research on the effects of living organ donation.

3. Use of Improved Information Technology and Burden Reduction

Data is submitted to the registry through a secure web-based application developed by the contractor. The application supports data entry for individual records and the electronic batch upload of multiple records. Of transplant programs that participated in the registry's pilot phase of the registry, 40 percent developed processes for batch uploads of data extracted from electronic health records and other sources. These programs reported a significantly reduced burden of data entry. Several programs developed sophisticated automated processes for extracting and formatting data from multiple sources, resulting in an additional burden reduction.

The contractor consulted closely with programs to understand the data submission processes utilized. In the future, there is potential to further significantly reduce the overall burden across programs by promoting the use of automated methods for data submission and developing additional integration with data sources commonly used within transplant programs.

The contractor's web application can also automatically distribute follow-up surveys to registered candidates via e-mail at determined intervals and track the status and results of these surveys. There is potential to reduce the burden on programs if automated follow-up facilitated by the registry can accomplish some of the purpose currently served by manual follow-up conducted by programs.

4. Efforts to Identify Duplication and Use of Similar Information

The need to obtain more data on long-term outcomes for living organ donors has been discussed and acknowledged within the transplant community. Limited data are collected to support expanded knowledge in this area. Currently, the only centralized collection of data on living organ donors is undertaken by the OPTN for a limited donation period. The OPTN requires member programs to submit follow-up data on living organ donors at 6, 12, and 24 months post-donation. This data collection is not sufficient to study the long-term effects of living organ donation on the donor.

Moreover, the OPTN does not collect data on donor candidates who *do not* go on to donate. Data on candidates who are evaluated as donors and approved to donate but who do not go on to donate for reasons unrelated to their health (e.g., non-medical reasons or reasons related solely to the intended recipient) are valuable for studying the long-term effects of living organ donation. Approved living donor candidates who do not become donors can serve as a control/comparison group of individuals whose health is closely comparable to candidates who do go on to donate.

5. Impact on Small Businesses or Other Small Entities

No small businesses will be involved in this study.

6. Consequences of Collecting the Information Less Frequently

Transplant programs are asked to collect registration data on candidates for living organ donation at the time of their initial evaluation. The collection's timing is essential to capture both candidates who go on to donate and those who do not.

Programs are asked to report the outcome of a candidate's evaluation and donation decision when this decision is made. This is essential to capture the reasons for not donating (where applicable) since many programs do not systematically track this information.

Registered candidates are asked to reply to brief e-mail surveys at regular intervals (currently 1- and 2-years post-donation). While the optimal follow-up interval may be the subject of further discussion, sufficient regular follow-up is essential to supporting research on the long-term effects of living organ donation.

7. Special Circumstances Relating to the Guidelines of 5 CFR 1320.5

The request fully complies with the regulation.

8. Comments in Response to the Federal Register Notice/Outside Consultation

Section 8A:

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

Section 8B:

In 2020, the contractor held consultations with all programs participating in the registry regarding the burden of data collection, ways to improve the data submission process's efficiency, and possible future models for program participation in the registry. Below is a list of participating programs and e-mail contact information of the Principal Investigators who participated in the consultations.

Dr. Jeffrey Wang (Jeffrey.Wang@hcmcd.org) - Hennepin County Medical Center, Minneapolis, MN

Dr. James Trotter (James.Trotter@BSWHealth.org) - Baylor University Medical Center, Dallas, TX

Dr. Mary Amanda Dew (dewma@upmc.edu) - University of Pittsburgh, Pittsburgh, PA

Dr. Macey Henderson (maceyh@jhmi.edu) - Johns Hopkins University, Baltimore, MD

Dr. Krista Lentine (krista.lentine@health.slu.edu) - Saint Louis University, St. Louis, MO

Dr. Arthur Matas (matas001@umn.edu) - University of Minnesota, Minneapolis, MN

Dr. Kenneth Newell (kanewel@emory.edu) - Emory University, Atlanta, GA

Dr. Dianne LaPointe Rudow (dianne.lapointerudow@mountsinai.org) - Transplantation Institute, Mount Sinai Hospital, New York, NY

Dr. Sandra Taler (staler@mayo.edu) - Mayo Clinic, Rochester, MN

Dr. Amy Waterman (AWaterman@mednet.ucla.edu) - University of California at Los Angeles, Los Angeles, CA

In 2020, the contractor also consulted with the OPTN Living Donor Committee. Principal members of the committee and support staff included:

Committee Chair – Heather Hunt (heatherfhunt@gmail.com)

Committee Vice-Chair – Dr. Titte Srinivas, University Hospitals of Cleveland

OPTN Liaison – Lindsay Larkin (lindsay.larkin@unos.org)

9. Explanation of any Payment/Gift to Respondents

Respondents will not receive any payments or gifts.

10. Assurance of Confidentiality Provided to Respondents

Data will be kept private to the extent allowed by law. Information proposed to be collected is considered to be protected health information. SRTR is recognized as a public health authority under the HIPAA Privacy Rule (42 CFR 164.512(b)).

11. Justification for Sensitive Questions

Potentially sensitive information included in this data collection includes:

- Race/Ethnicity – This information is essential to analyzing observed health outcomes relative to expected risk since risk factors are prevalent to different degrees within different racial and ethnic groups. This data is also relevant to the interpretation of psychosocial factors that may influence how candidates for living organ donation are evaluated and their decision whether or not to donate.
- Use of Drugs/Alcohol/Tobacco – Transplant programs use this information as a factor in determining the fitness of candidates for living organ donation.
- Social Security Number – This information will be used to obtain additional data on long-term outcomes of individuals by matching with data obtained from other registries or sources. Given this limited and centrally important use case, there is justification for using social security number as an identifier rather than a composite of non-unique factors (e.g., name, date of birth).

12. Estimates of Annualized Hour and Cost Burden

12A. 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	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

12B.

Type of Collection	Number of Respondents	Average Number of Responses per Respondent	Total Number of Responses	Average Burden per Response (in hours)	Total Burden Hours	Wage Rate	Total Hour Cost
Potential Living Donor Registration Form	16 ^a	112 ^c	1,792 ^c	0.27 ^e	484	\$37.77 ^h	\$18,054
Potential Living Donor Follow-up Form	754 ^b	1	754 ^d	0.50 ^f	377	-	-
Reasons Did Not Donate Form (Liver or Kidney)	16 ^b	106 ^c	1,696 ^c	0.23 ^g	390	\$37.77 ^h	\$14,730
Total	786^a		4,242		1,251		\$32,784

a. Number of respondents for potential living donor registration forms based on the number of programs participating in the pilot registry. Number of respondents for potential living donor follow-up forms based on the number of potential living donors evaluated at the 14 participating programs in 2015. Total number of transplant programs submitting data to LDC in 2019. We anticipate an increase of 30 additional programs submitting data to LDC over the three years from September 2020 to September 2023, with the goal of all U.S. transplant programs submitting data to LDC by September 2025.

b. Total number of living donor candidates submitting LDC follow-up forms in 2019.

c. Derived from the number of forms submitted by transplant programs in 2019.

- d. Total number of LDC follow-up forms submitted by living donor candidates in 2019.
- e. Based on a 2019 survey of transplant programs submitting data to LDC.
- f. Based on internal testing and user feedback.
- g. Based on discussion and interviews with staff at participating transplant programs in 2019-2020.
- h. Based on 2019 mean hourly rate for registered nurses in the Minneapolis-St. Paul-St. Cloud area in Minnesota (accessed here: https://www.bls.gov/oes/current/oes_mn.htm#29-0000).

13. Estimates of other Total Annual Cost Burden to Respondents or Recordkeepers/Capital Costs

Other than their time, there is no cost to respondents.

14. Annualized Cost to Federal Government

The federal government's annual cost consists of those costs allocated to the registry under the HRSA contract for the SRTR. There is also the government's cost to monitor the registry, which will be .025 FTE (project officer) at \$57.13 per hour (\$2,970.76 per year).

15. Explanation for Program Changes or Adjustments

The current burden inventory for this information collection request is 1358 hours. This extension request is for 1251 hours due to improvements to the efficiency of the processes used by programs for data submission.

16. Plans for Tabulation, Publication, and Project Time Schedule

Data collected for the registry may be tabulated in several forms:

1. Living Donor Registry Data Files - Produced at regular intervals and made available to the scientific community for research
2. Site-specific Reports - Shared securely with participating transplant programs.
3. Quarterly Project Reports – Shared directly with HRSA

These data may be shared electronically through e-mail, secure file transfer, and/or publication on a website maintained by LDC for this purpose. The final content and statistical methods used in these reports remain to be determined. A formal analysis plan was submitted to HRSA in the initial phase of the project and modified as necessary.

The registry will be expanded through the addition of participating transplants over the next 3-5 years, with the ultimate goal of including all U.S living donor transplant programs. Per requirements, the contractor will submit to HRSA a plan for expanding the registry within 90 days of the effective date of the SRTR contract beginning in September 2020.

17. Reason(s) Display of OMB Expiration Date is Inappropriate

The OMB number and expiration date will be displayed on every page of every form/instrument.

18. Exceptions to Certification for Paperwork Reduction Act Submissions

There are no exceptions to the certification.