

Supporting Statement A

Scientific Registry of Transplant Recipients Living Organ Donation Registry Data Collection Surveys

OMB Control No. 0906-XXXX

Terms of Clearance: None

A. Justification

1. Circumstances Making the Collection of Information Necessary

The Department of Health and Human Services (HHS) is required to submit to Congress an annual report on the long-term health effects of living donation (42 U.S.C. §273b). However, there is relatively little data available to inform this report and improve data-driven decision-making. Therefore, the Health Resources and Services Administration (HRSA), based on HHS' authority to establish and maintain mechanisms to evaluate the long-term effects associated with living donations (42 U.S.C. §273a), modified the Scientific Registry of Transplant Recipients (SRTR) contract to establish a pilot living donor registry to follow health outcomes of donors who volunteer to participate.

Current Organ Procurement and Transplantation Network (OPTN) policy requires organ transplant programs to report living donor outcome information at three points in time: 6 months, 1 year, and 2 years. The information gained from these reports is insufficient to track the long-term health of living donors. For over a decade, the HHS Secretary's Advisory Committee on Organ Transplantation (ACOT) and other relevant stakeholders have recommended that HRSA create a living donor registry. Specifically, in 2002, ACOT unanimously recommended that "serious consideration" be given to the establishment of a living donor registry to provide potential donors with complete information about living organ donation. In 2010, a meeting of stakeholders, including living donors, family members, transplant surgeons, and medical ethicists, concluded that a need for a living donor registry exists and provided expert opinion on the data to collect in such a registry. This group of stakeholder experts also recommended that HRSA establish and support such a registry to improve living donation by increasing the information available to researchers and potential living donors about the long-term health effects of living organ donation.

2. Purpose and Use of Information Collection

Through the living organ donor registry, SRTR will collect baseline information on all potential living donor candidates who begin the evaluation process at participating transplant centers. The SRTR will collect information from donor candidates who become living donors as well as those who end up not donating an organ, and it will

collect follow-up data at 1 year from all participants in the registry. The registry will ascertain long-term health status by maintaining contact with the participants over time and conducting surveys (which will be submitted for OMB approval in the future) every 5 or 10 years. The SRTR will also link with other national data sources (such as the National Institutes of Health-funded U.S. Renal Data System and the Centers of Disease Control and Prevention-funded National Death Index) to obtain relevant clinical information on participants without the burden of additional data collection. By collecting information on both the donor candidates that became living donors as well as the candidates who were evaluated but chose not to become living donors, the SRTR will be able to compare the long-term differences in health outcomes between the two groups. The registry will also collect information regarding the reasons why some potential living donors ultimately choose not to donate.

Consumers of the information provided by the registry will include potential donors, patients, caregivers, transplant programs, the general public, investigators, HRSA and other federal agencies. See the attached article (Attachment A) for more details on the purpose of the registry.

3. Use of Improved Information Technology and Burden Reduction

Registration information will be collected using a secure online data collection system built specifically for the registry. Volunteer transplant programs will register each donor candidate at the time of initial evaluation. The program will ultimately report whether or not the donor candidate donated his/her organ, and if not, the reasons for not donating. Data collection will be implemented in a manner fully consistent with 5 CFR 1320.5(d) (2). Participating volunteer programs will only be responsible for entering the initial registration, whether the candidate became a donor, and if not, why not. The SRTR will perform all subsequent follow-up through direct patient contact at the one-year mark, and subsequently through electronic linkages with other data sources, such as pharmacy claims data and the National Death Index. This will eliminate any burden on transplant programs for providing any follow-up information on donors or candidates for donation.

4. Efforts to Identify Duplication and Use of Similar Information

Components of the initial registration data collected by the registry will duplicate some data currently collected by the OPTN. However, the registry will be collecting information beyond that collected by the OPTN, e.g., registration information on individuals who do not ultimately donate their organ along with the reason(s) those individuals do not become donors. Ultimately, if the registry is successful, SRTR will work with HRSA's Division of Transplantation to explore whether or not the registry can supplant the OPTN's collection of data on living donors, particularly the follow-up requirements through the first two years post-donation. This would greatly reduce the burden of data collection currently borne by transplant programs.

5. Impact on Small Businesses or Other Small Entities

The data collected by the registry were selected by a steering committee of professionals in the fields of kidney and liver transplantation, including professionals from both large and small transplant programs. All data elements were carefully selected and limited to those needed to fulfill the purpose of the registry. The same data will be collected on each donor candidate, and therefore the burden of the data collection on organ transplant programs (for the initial intake of potential living donors) will be proportional to the number of donors and donor candidates seen by the program. Small programs will collect less data and vice versa.

We anticipate that the data collection will minimally impact two (2) small businesses/entities for the Potential Living Donor Registration form and two (2) small businesses/entities for the Reasons Didn't Donate form.

6. Consequences of Collecting the Information Less Frequently

If this information collection request is not approved, the SRTR program will be unable to monitor and report the long-term health outcomes of living donors post donation. This information will be useful to transplant programs in their future donor selection process and to aiding potential living donors in their decision to pursue living donation.

The proposed pilot registry will consist entirely of transplant programs that have volunteered to participate. The registry will demonstrate the feasibility and burden of collecting a minimum amount of data that will then allow the SRTR to collect the follow-up information needed for donors and candidates that did not donate. Organ transplant programs will not be burdened with collecting follow-up information. The ultimate goal of this pilot project is to establish a registry of minimal burden so that other organ transplant programs will want to participate after this pilot is completed.

The data collection for participating transplant programs will be only once, at the time of initial registration and when it is determined whether the donor candidate has become a donor, and if not, why not. The SRTR will follow-up with donors and donor candidates. To determine the feasibility of this registry during this pilot project, the SRTR will contact all donors and donor candidates at 1 year after donation or after the decision that the candidate will not donate. The initial survey that the SRTR will conduct (by telephone or email) will require less than 5 minutes of the participant's time. It will be voluntary; donors and donor candidates may opt out of any contact with the SRTR if they wish.

This pilot program and any data collection burden are voluntary. There are no legal obstacles to reduce the burden.

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

This request fully complies with the regulation.

The HHS Office of General Counsel determined the information collection is authorized under the OPTN Final Rule, which allows transplant centers to submit data to the OPTN and the SRTR. (42 U.S.C. 121). 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)).

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

Section 8A:

A 60-day Federal Register Notice (82 Fed Reg. 22836) was published in the *Federal Register* on May 18, 2017. There were no public comments.

Section 8B:

SRTR and HRSA sought feedback from transplant professionals, physicians, surgeons, organ donation researchers, living donor advocacy organizations and professional organizations in developing the elements to be collected by the registry. Several meetings to discuss the draft forms and instructions took place between December 2016 and April 2017 to help staff refine the data elements in the forms and provide clear accompanying instructions.

The participating transplant programs in this pilot project include:

1. Hennepin County Medical, Center, Minneapolis, MN
2. Baylor University Medical Center, Dallas, TX
3. University of Pittsburgh, Pittsburgh, PA
4. Johns Hopkins University, Baltimore, MD
5. Saint Louis University, St. Louis, MO
6. University of Minnesota, Minneapolis, MN
7. Emory University, Atlanta, GA
8. Transplantation Institute, Mount Sinai Hospital, New York, NY
9. Mayo Clinic, Rochester, MN
10. University of California at Los Angeles, Los Angeles, CA

9. Explanation of any Payment/Gift to Respondents

Donors and donor candidates will not receive any payments or gifts. The transplant programs participating in the pilot will have the cost of their data entry time and effort reimbursed by the SRTR contract.

10. Assurance of Confidentiality Provided to Respondents

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)). See also Section 7, above.

11. Justification for Sensitive Questions

This collection of information contains some questions that some may consider being of a sensitive nature, including protected health information. This information is already collected by the transplant centers for tracking purposes, and the SRTR will use this information for follow-up purposes, e.g., to find follow-up information from data sources such as the National Death Index.

12. Estimates of Annualized Hour and Cost Burden

12A. Estimated Annualized Burden Hours

The total estimated annualized burden for this information collection request is 1,358.

Type of Respondent	Form Name	No. of Respondents	Average No. of Responses per Respondent	Total Number of Responses	Average Burden per Response (in hours)	Total Burden Hours
Private Sector (Organ Transplant Centers)	Potential Living Donor Registration form	14	55.43	776	1	776
Private Sector (Organ Transplant Centers)	Reasons Didn't Donate form (liver or kidney)	14	27.71	388	.50	194
Individual/Household (Living Donors)	Potential Living Donor Follow-up form	776	1	776	.50	388
Total		804*		1,940		1,358

*The number of respondents for the Potential Living Donor Registration and Reasons Didn't Donate forms are based on a number of programs participating in the pilot registry. The number of respondents for Potential Living Donor Follow-up forms are based on a number of potential living donors evaluated at the 14 participating programs in 2015.

12B.

The total estimate of annualized cost to respondents for this information collection request is \$43,742.

Type of Respondent	Form Name	Total Burden Hours	Wage Rate	Total Hour Cost
Private Sector (Organ Transplant Centers)	Potential Living Donor Registration form	776	\$35.55	\$27,587
Private Sector (Organ Transplant Centers)	Reasons Didn't Donate Form (liver or kidney)	194	\$35.55	\$6,897
Individual/ Household (Living Donors)	Potential Living Donor Follow-up form	388	\$23.86	\$9,258
	Total	1,358		\$43,742

The wage rate for Organ Transplant Centers is based on the 2016 mean hourly rate for Registered Nurses in the Minneapolis-St. Paul-St. Cloud area in Minnesota for our estimate (accessed here: https://www.bls.gov/oes/current/oes_MN.htm). The wage rate for Living Donors is based on the 2016 mean hourly rate for all occupations (accessed here: https://www.bls.gov/oes/2016/may/oes_nat.htm).

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 pilot living donor registry is funded through SRTR contract by HRSA. The annual cost to Federal Government is \$838,386.41 for FY2018, \$932,716.57 for FY2019, and \$1,010,044.68 for FY2020. Monitoring the information collection will be part of the existing responsibilities of the Contract Officer Representative (COR) of the SRTR contract, the Federal staff monitoring the performance of the SRTR contract. The COR's level of effort on this project is 10% at a GS-14, Step 10 salary (\$145,629) for a cost of \$14,563.

15. Explanation for Program Changes or Adjustments

This is a new request. There are no changes or adjustments at this time.

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

Data collection will begin following OMB approval and will be collected over a period of 2 years. The results will be presented in a report to HRSA on an ongoing basis (progress reports due every 3 months) and in a final report at the end of the pilot period (approximately September 2020).

At this time, there are no plans to conduct statistical analyses with the information collected or to publish the information collected.

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

This information collection activity will comply with the requirements in 5 CFR 1320.9.