

Supporting Statement A

National Survey of Organ Donation Attitudes and Practices

OMB Control No. 0915-0290 Reinstatement

Terms of Clearance: None

A. Justification

1. Circumstances Making the Collection of Information Necessary

Patients in need of organ transplantation in the United States face a longstanding critical shortage of organs. Approximately 115,000 Americans were on the waiting list for transplantation by the end of 2017, but only 34,771 transplants were performed, which only meets 30 percent of the national need. While this represents a 20 percent increase over the number of transplants performed in 2012, and is the fifth annual increase in transplants in as many years, the organ shortage is still severe across the nation. Understanding the attitudes of the American public in regards to organ donation and transplantation is critical in this ongoing effort to encourage more Americans to donate their organs to close the gap before the number of individuals on the organ transplant waiting list and the supply of available organs.

The National Survey of Organ Donation Attitudes and Practices is sponsored by the Department of Health and Human Services (HHS) Health Resources and Services Administration's (HRSA) Division of Transplantation (DoT). It provides for the larger donation community and consistent with its legal authority to establish a public education and awareness program (section 377A of the Public Health Service Act, 42 USC 274f-1). This type of information is essential for planning, targeting, and implementing outreach efforts to increase public donation commitment as well as for tracking the results of such efforts over time. Members of the donation and transplantation community also make use of the findings of these national surveys in their outreach and research efforts. Three national donation attitudes/practices surveys have been conducted to date (1993, 2005, and 2012) using a similar survey instrument and thereby enabling tracking over time. The 2019 survey will extend and expand upon prior surveys about organ donation and practices.

HRSA is improving the quality and relevance of the data collected by making several changes. The revised survey will produce results that are representative of U.S. adults 18 and older with enough responses from racial/ethnic sub-groups and adults over the age of 65 to make reliable statistical comparisons. The survey will consist of at least 10,000 respondents. The survey will be online and telephone modes in English and Spanish with interviews lasting about 17.4 minutes on average compared to the 18-minute length of survey in 2012. The survey will include many questions asked in prior years to facilitate assessment of changes over time.

The 2019 survey will also replace some questions to address current, emerging issues. A first-time element of the design will incorporate an online panel of representative U.S. adults and adults contacted via address-based sampling. This methodology change is in keeping with

current trends in survey research and the widespread level of internet access across all levels of the U.S. population. Following the survey interviewing and data processing, a detailed analysis and report will be prepared and presented to HRSA along with an electronic copy of the database (the survey data file).

2. Purpose and Use of Information Collection

The overall purpose of this study is to conduct an independent multi-mode (web and telephone) survey of public opinion regarding various issues related to organ donation. The survey will measure public opinion on issues such as willingness to become an organ donor, financial incentives for donation, living donation, impediments to donation, and level of public knowledge about donation. The goal is to complete 10,000 interviews with adults (18 years of age or older) nationwide. Specifically, this will include 1,000 equal-probability of selection method computer-assisted telephone interviewing (CATI) interviews, 1,000 ethnic oversamples CATI interviews, and a supplemental web panel of 8,000 respondents. The final sample will include 1,000 interviews each with African Americans, Asians, Hispanics, and Native Americans, and statistically sufficient sample for meaningful comparisons across demographic levels of age group, education, and income groups. The total sample of 10,000 is necessary to achieve sufficiently large subgroups for statistical analysis across demographic groups.

The survey will replicate a number of questions asked in the 2012 and 2005 surveys and will provide HRSA, as well as the transplant community at large, with updated information on public opinion surrounding organ donation and transplantation. These updates to the survey will keep HRSA and the transplant community informed of trends in public attitudes towards organ donation over time, and better inform national strategies for promoting organ donation.

Additionally, conducting a survey to assess national attitudes about donation and obtaining public input regarding newer, and in some cases untried, ways to increase donation is useful as the transplant community continues to engage in numerous and increasingly sophisticated efforts to generate public support for donation. The data from this study will provide an overall assessment of the impact of previous outreach efforts and directions, and guidance for populations to target and for the creation of additional campaign messages and intervention strategies. Data will inform the development of policy related to organ donation and transplantation.

3. Use of Improved Information Technology and Burden Reduction

The modes of data collection are web survey and CATI interviews and include both landline and cell phones. Respondent burden is minimized by having automatic data entry either electronically by the respondent answering the online survey or by a trained CATI interviewer for a telephone survey that includes no additional requirements for respondents. The survey will capture only the minimum necessary information for analysis and will take only about 22 minutes of the respondent's time for the CATI survey and 16 minutes for the web survey. The questions are the same in both the CATI and web surveys, but prior research experience by the contractor has found web surveys takes 25 percent less time to complete as the same survey

conducted via phone, because respondents can read and click faster than a phone interviewer can read survey questions.

4. Efforts to Identify Duplication and Use of Similar Information

HHS is the primary federal entity authorized to oversee the national system of organ transplantation and the initiatives to increase organ donor registration and donation in the United States. Within HHS, HRSA DoT is responsible for administering the national organ transplantation program including efforts to increase organ donation. To the best of our knowledge, no other entity within the federal government has implemented or will implement a national representative survey of the public's knowledge, attitudes, and behaviors related to organ donation and transplantation. Similarly, we are not aware of any private sector group that has implemented or will implement a nationally representative survey with a similar oversampling strategy as proposed for this survey.

5. Impact on Small Businesses or Other Small Entities

The survey is of a representative sample of the U.S. population over the age of 18. No small businesses will be involved in this study.

6. Consequences of Collecting the Information Less Frequently

This is an infrequent survey that HRSA anticipates supporting approximately every 5 years. The previous administration of this survey took place in 2012 and before that in 2005. In addition to the 2019 survey, we anticipate that another survey will be conducted in 2023.

Less frequent administration of this survey would have a negative impact on practice and policy. The data from this survey are crucial for understanding in a rapidly changing health environment how to develop messages to the public regarding organ donation to encourage more individuals to register as organ donors and create or modify public policy related to donation and transplantation. Specifically, a longer time between administrations would preclude evidence-based decision-making. Current decisions would be made, and programs would be created and implemented based on old data; it would be difficult to associate any changes in public attitudes and behaviors with specific outreach efforts and campaigns, and it would impede the timely identification of, and proactive attention to, population trends and circumstances that may impact public willingness to donate.

There are no legal obstacles to reduce the burden.

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

The request fully complies with the regulation.

Comments in Response to the Federal Register Notice/Outside Consultation

Section 8A:

A 60-day *Federal Register* notice (FRN) was published on February 9, 2018, vol. 83, No. 28; pp. 5793-94 (see attachment 60-day FRN). Two comments were received as described below in section 8B.

Section 8B:

Before submitting to the 60-day FRN, in November 2017, HRSA solicited feedback for the survey from approximately 40 organ donation stakeholders, including advocates, physicians, and researchers. Organizations solicited included the American Society of Transplant Surgeons, American Society of Transplantation, Association of Organ Procurement Organizations, Chronic Disease Research Group, Donate Life America, National Living Donor Assistance Center, New England Donor Bank, Organ Donation and Transportation Alliance, Scientific Registry of Transplant Recipients, and the National Kidney Foundation, and 17 DoT research grantees. Several stakeholders expressed interest in the data being collected and made specific recommendations for questions to update, add, or delete.

Public comments were received from the Organ Procurement and Transplantation Network (OPTN) and Donate Life America (DLA). Both OPTN and DLA comments are included as attachments (60-day public comment – OPTN and 60-day public comment – DLA) in 2018.

The OPTN supported several of the current changes, including less formal language, such as in Q14C, revisions to questions about minority access to organ transplants, simpler language, and less confrontation and formal. We followed through on this recommended change. Cognitive interviewing was performed on the survey instrument to understand the respondent's ability to recall relevant information, bias, and comprehension and the final survey incorporated recommendations from these interviews as well. OPTN also recommended including a definition of Hispanic and Latino. We kept the Office of Management and Budget (OMB) approved a shorter version of the Hispanic question to keep the survey short. OPTN also recommended adding "Unsure," "N/A," or "Decline to Answer" as the multiple-choice option. All responses are voluntary, and respondents can choose not to answer a question. However, response choices were kept as is to ensure longitudinal comparability with the prior surveys. We considered the suggestion to clarify if the question pertains to deceased versus living donation. We clarified this as deemed appropriate when the question pertained specifically to deceased or living donation. OPTN also recommended that the survey be shortened where possible. The questions that considered to be no longer relevant were removed, and the survey will be of a similar length as the prior surveys.

DLA made several recommendations including several wording changes to improve clarity. Many of these minor wording changes could not be implemented because these questions are adopted verbatim from prior surveys, and changing the question's text would disrupt longitudinal comparability. Some wording changes could be implemented, such as changing "where" to "how" in Q2. DLA also recommended that questions 17, 17A, and 17C regarding presumed

consent be removed from the survey because of concerns that results from these questions might be used by others to advocate for a presumed consent system. These questions were kept in the survey as this topic periodically comes up, and the purpose of this survey is to provide public opinion data on a broad range of topics related to organ donation, although we did update the wording to increase clarity. Response to the DLA comments on specific questions are included as an attachment (see attachment “60-day public comment DLA with HRSA response”).

8. Explanation of any Payment/Gift to Respondents

Respondents will not receive any payments or gifts.

9. Assurance of Confidentiality Provided to Respondents

In accordance with the Privacy Act of 1974 all potential respondents will either see (if replying via web) or hear (if replying via telephone) a statement of the data authority, cooperation is voluntary, responses will be used to produce statistical summaries only, and it will be impossible to identify individuals from their responses. We will inform respondents “data will be kept private to the extent allowed by law.”

The file system for this study will provide maximum protection for confidentiality. At the completion of the data collection, the respondent’s telephone number and address (the only identifying information) will be separate from the answers to the survey questionnaire.

The file(s) of survey results are for statistical purposes only. The files will be sent to the government at the conclusion of the study and will allow for summary data analysis and for proper estimation of sampling errors.

10. Justification for Sensitive Questions

There are no questions of a sensitive nature, except for race and ethnicity. These questions are required to support analysis of demographic subgroups. Because organ transplantation attitudes vary across racial and ethnic categories, and race/ethnicity is a key sample stratification, this is an essential question for this research. Respondents are anonymous and are free to decline to answer any questions they choose.

11. Estimates of Annualized Hour and Cost Burden

The survey will minimize the burden on respondents (respondents in this study are individuals.) The time that a respondent takes to complete a survey has been carefully considered, and only the most important issues are being surveyed. The majority of the items are the same items that were included in the 2012 survey, with some minor edits, to enable analysis of trends over time. The total number of completed surveys will be 10,000 including the oversamples, and survey completion will average about 17.4 minutes. The 10,000 completed surveys include 2,000 phone respondents with an estimated average of 22 minutes (.37 hours) and 8,000 web cases with an estimated completion time of 16 minutes (.27 hours). Together, this would average to 17.4 minutes, totaling 2,900 hours. The estimated burden is slightly higher than the estimate given in

the 60-day FRN because additional questions were added to the survey since then.

12A.

Estimated Annualized Burden Hours

Type of Respondent	Form Name	No. of Respondents	No. Responses per Respondent	Average Burden per Response (in hours)	Total Hours
Adults over the age of 18	National Survey of Organ Donation Attitudes and Practices –Telephone (English and Spanish Versions)	2,000	1	.37	740
Adults over the age of 18	National Survey of Organ Donation Attitudes and Practices –Web Online Panel (English and Spanish Versions)	8,000	1	.27	2,160
Total		10,000			2900

12B.

Estimated Annualized Burden Costs

Type of Respondent	Total Burden Hours	Hourly Wage Rate	Total Respondent Costs
Adults over the age of 18	2900	\$ 36.32	\$105,328
Total	2900		\$105,328

Hourly Wage Rate based on the United States Department of Labor, Bureau of Labor Statistics: (https://www.bls.gov/news.release/archives/ecec_06082018.htm)

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

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

13. Annualized Cost to Federal Government

The cost of the study for government personnel is estimated at \$36,180 for two years for an estimated annualized cost per year of \$18,090 (10 percent full time equivalent at \$180,900= \$18,090 per year; GS-14, Step 3 salary level with 48% fringe benefit included [<https://www.opm.gov/policy-data-oversight/pay-leave/salaries-wages/salary-tables/18Tables/html/DCB.aspx>]). The estimated government cost for a contract to carry out this study is

\$562,235. This cost is for roughly 8,228 person hours, of which 25 percent are professional hours, and 75 percent are supporting hours (of which 55 percent are interviewing hours).

14. Explanation for Program Changes or Adjustments

As this is a reinstatement, there is currently no burden inventory.

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

Time Schedule: The final report will be delivered to HRSA by September 2019 and be available to the public after September 2019. The survey will be fielded approximately four weeks after OMB approval, and be completed within ten weeks of the start of fielding (14 weeks after OMB approval).

Publication: The final report will be available on HRSA website, and the de-identified dataset will be available upon request. HRSA DoT will use these data in ongoing activities of analyzing and responding to issues on organ donation.

Analysis Plan: The report will provide tabulations at the national level, and for relevant subpopulations, including age groups, gender, racial and ethnic groups, education level, income level, and large geographic regions, such as states or groups of states. It will include an executive summary along with detailed findings about factors related to donation practices, willingness to donate, and attitudes toward organ donation broken out by important demographic categories. Survey data will be weighted to minimize bias in the survey-based estimates, and the analysis will be based on weighted data. A full description can be found in supporting statement B.

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

The OMB number and expiration date are on every page of every form/instrument.

17. Exceptions to Certification for Paperwork Reduction Act Submissions

There are no exceptions to the certification.

OMB control number 0915-0290 Expiration XX/XX/XXXX

**NATIONAL SURVEY OF ORGAN DONATION ATTITUDES AND PRACTICES
Computer-Assisted-Telephone-Interviewing (CATI) Script (English Version)**

Public Burden Statement: An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. The OMB control number for this project is 0915-0290. Public reporting burden for this collection of information is estimated to average 0.29 hours per response, including the time for reviewing instructions, searching existing data sources, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to HRSA Reports Clearance Officer, 5600 Fishers Lane, Room 14N-39, Rockville, Maryland, 20857.