

Supporting Statement A

The National Survey of Organ Donation Attitudes and Practices (NSODAP)

OMB Control No. 0915-0290

Note: OMB control number prefix will change to 0906- after OMB approval.

Terms of Clearance: None.

A. Justification

1. Circumstances Making the Collection of Information Necessary

The Division of Transplantation (DoT), within the Health Systems Bureau of the Health Resources and Services Administration (HRSA) at the U.S. Department of Health and Human Services (HHS), is the primary federal entity responsible for oversight of the solid organ and blood stem cell transplant systems in the United States and for initiatives to increase organ donor registration and donation. Sponsorship of a national survey on the American public's donation attitudes and practices is one of the services that DoT provides for the larger donation community, 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).

Patients in need of organ transplantation in the United States face a longstanding critical shortage of organs. More than 103,000 Americans were on the waiting list for transplantation in December 2023, but only 46,000 transplants were performed that same year—meeting only two-fifths of the national need. While this represents an increase in the number of transplants performed in 2022, the organ shortage remains. Understanding public attitudes about organ donation and how the attitudes change over time is critical to addressing organ shortage through public awareness and education efforts.

Data from the National Survey of Organ Donation Attitudes and Practices (NSODAP) 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 use the findings of these national surveys in their outreach and research efforts.

Previous national surveys of the public's donation attitudes and practices were conducted in 1993, 2005, 2012, and 2019 using a similar survey instrument thereby enabling tracking over time. HRSA sponsored the last three national surveys but did not sponsor the first one conducted in 1993. The 2024 survey will replace some questions to address current, emerging organ donation and transplantation issues, but will otherwise follow the same fielding protocol and sampling plan as the 2019 survey, which was approved under OMB control number 0915-0290.

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 (CACTI) interviews, 1,000 ethnic oversamples CACTI interviews, and a supplemental web panel of 8,000 respondents. The final sample will include 1,000 interviews each with Black or African Americans, Asian Americans, Hispanic/Latino Americans, and American Indian/Alaskan Natives, and statistically sufficient samples for meaningful comparisons across demographic levels of age group, education, and income groups. A total sample of 10,000 is necessary to achieve sufficiently large subgroups for statistical analysis across demographic groups.

The survey will replicate some questions asked in the 2012 and 2019 surveys and will provide HRSA, as well as the transplant community at large, with updated information on public opinion surrounding organ donation and transplantation. This 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. Examples of how the data will be used are provided in Table 1.

Table 1: Use of Information Collection - Examples

<p>Research</p>	<ul style="list-style-type: none"> - Investigators rely upon the survey data to (a) understand the gaps, barriers, and opportunities in organ donation attitudes and registry enrollment, to design studies (b) examine data trends in a more granular manner (e.g., racial disparities in donor registration rates), and (c) develop, implement, and evaluate novel interventions to increase favorable attitudes and registry enrollment in targeted populations (e.g., interventions with men >60 years old). Effective interventions are then disseminated more broadly by Organ Procurement Organizations and other entities as part of their mandate to educate the general public about organ donation. - Agencies that provide research grants also rely upon these data for targeted request for applications (RFAs). For instance, HRSA previously funded grant projects designed to evaluate innovative strategies to increase organ donation awareness and registry enrollment. The National Institutes of Health continues to offer a special RFA every 5 years to fund studies evaluating strategies to promote organ and tissue donation among health disparity populations (e.g., RFA-DK-22-003)
<p>Education</p>	<ul style="list-style-type: none"> - HRSA’s DoT, Organ Procurement Organizations (e.g., New England Donor Services, One Legacy), national advocacy organizations (e.g., Donate Life America, National Kidney Foundation), and regional nonprofit organizations (e.g., American Transplant Foundation, John Brockington Foundation) use the data to identify targeted opportunities for new community-wide initiatives to increase awareness of the need for more organ donors and to facilitate registry enrollment. For example, New England Donor Services developed three priorities for increasing registry enrollment based on the 2019 NSODAP survey data. The priorities all focused on education initiatives designed to facilitate registry enrollment among those the survey identified as “non-registered supporters” of organ donation. - Organ Procurement Organizations will use the data for target media buys when developing Department of Motor Vehicles (DMV) brochures and posters, videos, and public service announcements.
<p>Policy and Practices</p>	<ul style="list-style-type: none"> - Organ Procurement Organizations will use the data to facilitate discussions with legislators, government agency officials, and relevant staff about organ donation and to recommend policy and/or legislative changes that facilitate organ donation education (e.g., requiring driver’s education programs to inform students about organ donation) and registry enrollment (e.g., requiring all

	<p>DMV transactions to ask customers about organ donor registration)</p> <ul style="list-style-type: none"> - The 2019 data informed the OPTN about the prioritization of transplantation based on medical need over geographic proximity based on overwhelming public preference over medical need.
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3. Use of Improved Information Technology and Burden Reduction

The modes of data collection are web surveys and Computer Assisted Telephone Interviewing (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 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 take 25 percent less time to complete than 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 nationally 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

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 2019 and before that in 2012. Respondents to the 2024 survey will only be asked to participate once.

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 survey 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 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 January 18, 2024, vol. 89, No. 12; pp. 3409-3410. There were no public comments. A 30-day Federal Register Notice was published in the *Federal Register* on May 22, 2024, vol. 89, No. 100; pp. 44998-44999.

Section 8B:

Before submitting to the 60-day FRN, in December 2023, HRSA solicited feedback (under OMB 0915-0212) for the survey from organ donation and transplantation stakeholders, including advocates, physicians, and researchers. Organizations that responded to the solicitation included the Organ Procurement and Transplantation Network – Patient Affairs Committee, The National Kidney Foundation, the American Society of Transplantation, National Living Donor Assistance Center, Donate Life, America Association of Multicultural Affairs in Transplantation, Eye Bank Association of America, Association of Organ Procurement Organizations, and American Association of Tissue Banks. Several stakeholders expressed interest in the data being collected and made specific recommendations for questions to update, add, or delete. HRSA also solicited feedback internally from the HRSA Office of Health Equity and the HRSA Office of Planning, Analysis, and Evaluation.

9. Explanation of any Payment/Gift to Respondents

Respondents will not receive any payments or gifts.

10. Assurance of Confidentiality Provided to Respondents

In accordance with the Privacy Act of 1974, all potential respondents will either see (if replying via the web) or hear (if replying via telephone) a statement of the data authority, that 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 to match the

promise made to respondents to encourage their response and to conform to Institutional Review Board standards for human subjects' protection. After 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. De-identified, case-level data files will be sent to the government at the conclusion of the study and will allow for summary data analysis and proper estimation of sampling errors.

11. Justification for Sensitive Questions

HRSA will include race and ethnicity questions in the survey as in prior iterations of the survey, updated to be align with new SPD-15 guidance. These questions are required to support the 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. New in 2024 will be a question about political ideology (conservative, moderate, and liberal). HRSA is including this question to evaluate whether organ donation attitudes and practices differ by political ideology. If they do, HRSA will adjust communication and outreach strategies to be most appropriate to a wide range of audiences while considering political ideology. Also new in 2024, the survey asks participants how long they have lived in the United States. This could potentially be a sensitive question for someone not born in the United States; however, the wording should alleviate concerns because it does not ask about citizenship. Results from these questions will be aggregated for reporting. Respondents are anonymous and are free to decline to answer any questions they choose.

12. 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 and 2019 surveys, 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. This includes 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 17.4 minutes, totaling 2,900 hours. At least 10,000 cases are needed to produce statistically valid results for sub-groups of interest that are in the sampling plan. They include Black African or African American, Hispanic/Latino Americans, Asian Americans, American Indian/Alaskan Natives, and persons 65 years and older. The estimated average survey completion time was determined in fielding the 2019 survey. The 2024 survey instrument is of comparable length, and we estimate a similar completion time.

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			2,900

12B. Estimated Annualized Burden Costs

Type of Respondent	Total Burden Hours	Median Hourly Wage Rate (x2)*	Total Respondent Costs
Adults over the age of 18	2,900	\$ 46.22	\$ 134,038
Total	2,900		\$ 134,038

* Hourly median wage across all occupations was \$23.11 per hour. The median hourly wage was multiplied by 2 to account for overhead costs (e.g., benefits). Source: https://www.bls.gov/oes/current/oes_nat.htm (All Occupations).

The median hourly wage across all occupation was used because the survey is not targeting any specific occupation.

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 cost of the study for government personnel is estimated at \$86,179.80 for 2 years for an estimated annualized cost per year of \$43,089.90. This consists of 20 percent of a full-time equivalent (FTE) GS-14 employee (20% of \$118,552.00, multiplied by 1.5 to adjust for overhead costs); as well as 5 percent of a GS-13 FTE at \$7,524.30 per year (5% of \$150,486.00, multiplied by 1.5 to adjust for overhead costs). The estimated government cost for a contract to carry out this study is \$597,826. This cost is for roughly 7,091 person hours of which 32 percent are professional hours, and 68 percent are supporting hours (of which 86 percent are interviewing hours). This brings the total annual cost to \$684,005.80.

15. Explanation for Program Changes or Adjustments

This is a request for revision with changes to an approved information collection because of edits to the existing NSODAP survey instrument. The success in executing this project will be measured by how useful, meaningful, and understandable the resultant data and report are. To that end, we sought input from the organ donation stakeholder community (as described in Section 8B) and relevant offices within HRSA on the 2024 survey questions. The edits include removing 26 questions and adding 18 new questions, for a net survey decrease of eight questions. Overall, even with a net decrease in questions, the survey is approximately the same length as the 2019 version due to the varying length of individual questions that were added and deleted. Thus, we expect no changes to respondent burden time compared to the last, approved collection.

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

Time Schedule: The contractor will deliver the final report to HRSA by July 2025 and HRSA will make the report available to the public after July 2025. The survey will be fielded approximately two weeks after OMB approval and completed within 5 months of the start of fielding (18 weeks after OMB approval).

Publication: The final report and the de-identified dataset will be available at <https://www.organdonor.gov/>. Additional datasets will be available at https://data.hrsa.gov/topics/health-systems/organ_donation_opinion_survey-data?hmpgdshbrd=1. HRSA DoT will use these data to inform its statutory requirements to establish a public education and awareness program to increase awareness about organ donation and ultimately the number of registered organ donors.

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. Results will be compared to prior surveys (1993, 2005, 2012, 2019) with more comprehensive comparisons within demographic levels of the 2019 survey results. A full description can be found in supporting statement B.

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.