

OMB SUPPORTING STATEMENT A

Organ and Tissue Donor and Recipient Life Stories Form

OMB Control No. 0915-XXXX

Submitted by:

Division of Transplantation
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Terms of Clearance: N/A

A. Justification

1. Circumstances Making the Collection of Information Necessary

As of March, 2013, more than 117,000 candidates were awaiting organs for transplantation in the United States. At current rates, approximately 28,000 transplants will occur this year, and about 14,000 organs will be recovered from living and deceased donors (<http://optn.transplant.hrsa.gov>). Although progress has been made in the past two decades, thousands continue to die each year because of the unavailability of suitable organs due to a lack of organs. Organs can be donated while the donor is alive or within several hours of death. In 2011, deceased donors (8,125) outnumbered live donors (6,020), which has been the case since 2004. Most deceased donors were in good health but died suddenly from fatal neurologic injuries, primary central nervous system events, cerebrovascular accidents, subarachnoid hemorrhage, brain tumors or injuries, accidents, drug overdose, smoke inhalation, suicide, or cardiac arrest. Living donors can donate bone marrow, a kidney, and portions of the lungs and liver. Most living-donor transplants are performed for a relative of the donor.

Section 377A of the PHS Act authorizes the Secretary of HHS to establish a public education program to increase awareness about organ donation and the need to provide for an adequate rate of such donations. Recent unpublished program evaluation results show that the true stories of organ and tissue donors and recipients are often the most compelling motivators for people to sign up as donors because they present the concept of organ transplantation in a manner that the reader can relate to in a personal way. Presenting multiple stories about regular people who have been saved by organ donation can also serve to refute myths many people hold about organ donation and allocation, such as the myth that celebrities and wealthy individuals can get to the top of the waiting list and be transplanted sooner than others.

Organdonor.gov is the primary tool used by DoT to present information about organ donation to the public. All outreach efforts, including print materials, social media messages and videos, lead the audience back to organdonor.gov for more information and ultimately to their state registries. Therefore, organdonor.gov must be maintained, kept up-to-date and dynamic. This requires frequently updating the site by posting new life stories. The proposed information collection will allow the development of an application that will streamline the collection of these stories by enabling recipients, living donors, deceased donor family members, and donation professionals to submit their stories directly to DoT.

2. Purpose and Use of Information Collection

The overall purpose of this effort is to develop an application that gives organ, eye, and tissue recipients and donor families the opportunity to voluntarily submit their stories to DoT via a standardized online form. The online form will be posted on organdonor.gov and will collect demographic and contact information, the individual's donation/transplant story up to 500 words, a high resolution photo and a signed authorization.

When an online form is completed, the information will automatically populate a secure database hosted on a HRSA server. DoT will then review the story for appropriateness, validate that the donation or transplantation occurred utilizing Organ Procurement and Transplantation Network (OPTN) data, and edit the story for length, grammar and other factors ensuring that it is appropriate for a government Web site. It will then be reviewed and may be posted to organdonor.gov. In addition to enabling story submission, the online application process will make the donor and recipient life stories posted on the site searchable by the public to enhance public viewing and understanding of the organ donation process.

It is anticipated that we will receive approximately 100 submissions each year.

3. Use of Improved Information Technology and Burden Reduction

This effort utilizes information technology to collect, process and host stories. All stories (100%) collected through this application will use the proposed automated, electronic system. Respondents will not be required to obtain any special software to complete the online form.

The collection of the stories using this new system is an effort to allow individuals who wish to share their story the opportunity to do so. It also will reduce the burden of collecting stories as it is currently done. The current time consuming process relies on DoT staff and contractors to contact organ procurement organizations (OPO) with requests for stories. The OPO staff respond with several recommendations and the DoT staff decides which stories to pursue. The OPO staff then contacts the donor/donor family or recipient to ask them if they are interested in participating. If they are, the OPO staff will send DoT the respondent's contact information and DoT will reach out to set up an interview. Setting up an interview can take some time as it requires coordination. Once the interview is complete DoT writes, edits and approves the story before posting it to organdonor.gov.

The new system eliminates most of the time consuming elements of the current process described above as donors and recipients are taking the initiative to reach out to DoT and write the first draft of their story. Thus it has the potential to greatly reduce the amount of time DoT must dedicate to the collection of stories and will allow DoT to post new stories more frequently. It also will enable anyone who wants to share his or her story to do so rather than relying on OPOs to identify a select few.

The information collected will include the minimum information necessary to post life stories on organdonor.gov. This includes the story, a picture, some descriptive items about the featured person, such as name, state, and type of organ or tissue received. Other information collected will include contact information so DoT can follow-up with the story submitter and the race/ethnicity of the featured person to ensure diversity on the site.

4. Efforts to Identify Duplication and Use of Similar Information

The Department of Health and Human Services is the only Cabinet Department with statutory responsibility for organ donation. Within the HHS, responsibility for implementing efforts to increase organ donation is delegated to HRSA/DoT. To the best of our knowledge, no entity

within the Federal Government, other than HRSA/DoT, is collecting or is planning to collect stories about organ and tissue donors and recipients. Similarly, we are not aware of any private sector group that has implemented or is planning to implement an organ and tissue donor and recipient story collection online tool.

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

A respondent will provide data only once. There are no legal obstacles to reduce the burden.

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

This information collection fully complies with 5 CFR 1320.5(d)(2).

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

A 60-day Federal Register Notice was published in the *Federal Register* on January 15, 2013, vol. 78, No. 10; pp. 3008-09. There were no public comments.

In February 2013, DoT utilized its Facebook page, www.facebook.com/organdonor.gov, to identify volunteer transplant recipients and donor families to test the Life Stories submission form. Nine of the volunteers who responded were asked to complete the form and to report the time it took them to complete it. They also were asked to indicate any issues they found with the form, such as instructions, questions, or statements that required clarification. A total of six (6) individuals completed the form and indicated the time it took to complete the form. Based on their responses, the estimated average time to complete the form is 41 minutes.

Crosby Marketing Communications has been working with DoT under contract for over 5 years to create and implement donor registration outreach campaigns, including the development of outreach materials. These efforts have included the collection of donor and recipient transplant stories to include in these outreach efforts. Crosby developed the first draft of the Life Stories collection form based on their experience collecting stories. The primary contact at Crosby is Maura McCarthy, mmccarthy@crosbymarketing.com, (301) 951-9200.

Several offices within HHS were consulted in the development of the form, including the HRSA Office of Information Technology, Division of IT Security and Records Management (OIT/DITSRM). OIT/DITSRM, in consultation with the HHS/Office of the Assistant Secretary for Public Affairs (OASPA), assisted DoT with limiting the collection of PII to include only the most essential items. They will continue working with DoT during the development of the database to ensure the database is sufficiently secure to protect the collected PII. The primary contact in OIT/DITSRM is Zena Clare, zclare@hrsa.gov, (301) 443-2854. Finally, the HHS Office of the General Counsel (OGC) was consulted to provide feedback on the Life Stories collection form and more specifically to develop the authorization statement on the

form. Rina Hakimian is DoT's primary contact in OGC, rina.hakimian@hhs.gov, (301)-443-7033.

9. Explanation of any Payment/Gift to Respondents

No remuneration will be given to respondents.

10. Assurance of Confidentiality Provided to Respondents

The collection of the life stories is for use on a public Web site as well as in other materials developed by DoT. People respond to the form because they wish to have their story published on the Web site. The DoT will make an effort to protect the privacy of these individuals by enabling the story submitter to choose whether to provide the featured person's first name or an alias to be published with the story. The published story will include only the first name or alias, organ(s)/tissue(s) received or donated, approximate age at transplant (collected and displayed as a 10 year range), picture and story. Other required information to be collected includes the story submitter's first name (this may differ from the featured person), email address (for contact purposes), and relationship to the featured person. These items were chosen in consultation with HRSA's OIT/DITSRM as sufficient to describe the individual telling the story while protecting his or her privacy. The story itself will be reviewed and edited to ensure that no additional identifying information is included and names of others mentioned in the story will be removed. The required picture will include only the featured individual.

A statement, developed in consultation with HHS/OGC, is included on the Life Stories submission form informing respondents of the ways DoT intends to use their story as well as the possibility that their published story may be used by non-Federal entities who access the Web site. It will not be possible for the respondent to transmit the form to HRSA unless the he or she has agreed to this statement.

In consultation with HRSA/OIT/DITSRM the file system for this study will be devised to provide maximum protection for confidentiality and the online form will include a Privacy Act statement.

11. Justification for Sensitive Questions

In consultation with HRSA/OIT/DITSRM, HHS/OGC, and HHS/OASPA, the sensitive questions were kept to the minimum required. This includes an email address for story submitters in the event that we need to follow up with any of these individuals or would like to inform them that their story will be published. The first names of the story submitter and the featured person will also be requested however, they are offered the option to submit an alias instead. Finally, the date of donation or transplant is requested but will not be published with this story. This date is used for verification purposes only to protect against false donation/transplantation stories being published.

The story itself may include sensitive information for some individuals. It is up to the individual whether or not to provide a story as well as what details to include. Prior to publishing any story, DoT will review it to ensure that all details to be posted on the Web site are appropriate for a government Web site. Respondents will also be informed that they can request removal of their story from DoT’s Web site and from database at any time.

12. Estimates of Annualized Hour and Cost Burden

12A. Estimated Annualized Burden Hours

The total number of completed forms is estimated to be 100 each year and form completion is expected to average about 41 minutes. Therefore, 100 respondents times .68 of an hour (i.e., 41 minutes) would equal a total of 68 hours. The average burden hour was estimated based on a sample of 5 potential respondents. These individuals were contacted via DoT’s Facebook page after a post was placed on the page asking for volunteers. They were asked to time how long it took them to answer the questions included on the form.

Organ donors and recipients come from all walks of life. To calculate the total respondent costs, the 50th percentile wage rate for full-time civilian workers was used (<http://www.bls.gov/ncs/ocs/sp/nctb1490.txt>).

Type of Respondent	Form Name	No. of Respondents	No. Responses per Respondent	Average Burden per Response (in hours)	Total Burden Hours	Hourly Wage Rate	Total Respondent Costs
Public	Life Stories Submission Form	100	1	0.68	68.0	\$18.10	\$1,231
Total		100	1	0.68	68.0	\$18.10	\$1,231

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

There are no operation and maintenance costs for respondents.

14. Annualized Cost to Federal Government

The cost of the study for Government personnel is estimated at \$13,918 for three years for an estimated annualized cost per year of \$4,639 (2 percent FTE @ \$136,771 = \$2,740 per year and 2 percent FTE @ \$94,969 = \$1,899 per year). The estimated government cost in contracts to carry out this collection and display the stories is \$273,940. This cost is \$42,000 per year for roughly 300 person hours at \$140 per hour for editing stories per year, \$99,940 to build the database in the first year, and \$24,000 for technical operations and maintenance of the database per year in years two and three.

The total cost to the government in year 1 is estimated at \$146,579 and an average of \$70,639 per year in the subsequent years. The annualized cost to the Federal Government is \$95,952.

15. Explanation for Program Changes or Adjustments

This is a new data collection.

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

The stories collected via the Life Stories form may be published on organdonor.gov as well as in other DoT educational materials. The information gathered will not be tabulated or manipulated.

In order for DoT to maintain and update organdonor.gov, it is important that collection of life stories is ongoing and that new stories are posted to the Web site frequently. Therefore, a 3-year clearance is requested to allow for continuous collection and processing of organ and tissue donor and recipient life stories.

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

The expiration date will be displayed.

18. Exceptions to Certification for Paperwork Reduction Act Submissions

There are no exceptions to the certification.