

SUPPORTING STATEMENT A

Data System for Organ Procurement and Transplantation Network

OMB Control No. 0915-0157
Revision

A. Justification

1. Circumstances of Information Collection

This is a request for OMB approval for the revision of the data system for the Organ Procurement and Transplantation Network (OPTN) and the following associated forms: 1) Deceased Donor Registration; 2) Living Donor Registration; 3) Living Donor Follow-Up; 4) Donor Histocompatibility; 5) Recipient Histocompatibility; 6) Heart Candidate Registration; 7) Heart Recipient Registration; 8) Heart Follow-Up (6-Month); 9) Heart Follow-Up (1-5 Year); 10) Heart Follow-Up (Post 5 Year); 11) Heart Post Transplant Malignancy; 12) Lung Candidate Registration; 13) Lung Recipient Registration; 14) Lung Follow-Up (6 Month); 15) Lung Follow-Up (1-5 Year); 16) Lung Follow-Up (Post 5 Year); 17) Lung Post Transplant Malignancy; 18) Heart/Lung Candidate Registration; 19) Heart/Lung Recipient Registration; 20) Heart/Lung Follow-Up (6 Month); 21) Heart/Lung Follow-Up (1-5 Year); 22) Heart/Lung Follow-Up (Post 5 Year) 23) Heart/Lung Post Transplant Malignancy 24) Liver Candidate Registration; 25) Liver Recipient Registration; 26) Liver Follow-Up (6 Month -5 Year); 27) Liver Follow-Up (Post 5 Year); 28) Liver Post Transplant Malignancy Form 29) Liver Recipient Explant Pathology Form 30) Intestine Candidate Registration; 31) Intestine Recipient Registration; 32) Intestine Follow-Up (6 Month -5 Year); 33) Intestine Follow-Up (Post 5 Year); 34) Intestine Post Transplant Malignancy Form; 35) Kidney Candidate Registration; 36) Kidney Recipient Registration Form; 37) Kidney Follow-Up (6 Month -5 Year); 38) Kidney Follow-Up (Post 5 Year); 39) Kidney Post Transplant Malignancy; 40) Pancreas Candidate Registration; 41) Pancreas Recipient Registration; 42) Pancreas Follow Up (6 Month -5 Year); 43) Pancreas Follow-Up (Post 5 Year); 44) Pancreas Post Transplant Malignancy; 45) Kidney/Pancreas Candidate Registration; 46) Kidney/Pancreas Recipient Registration; 47) Kidney/Pancreas Follow Up (6 Month – 5 Year); 48) Kidney/Pancreas (Post 5 Year); 49) Kidney/Pancreas Post Transplant Malignancy; 50) Vascularized Composite Allograft Candidate Registration; 51) Vascularized Composite Allograft Recipient Registration; 52) Vascularized Composite Allograft Recipient Follow Up; 53) Organ Labeling and Packaging System; 54) Organ Tracking and Validating System; 55) Kidney Paired Donation Candidate Registration; 56) Kidney Paired Donation Donor Registration; 57) Kidney Paired Donation Match Offer Management; 58) Disease Transmission Event; 59) Living Donor Event; 60) Safety Situation; 61) Potential Disease Transmission Report; 62) Request to Unlock Form. Forms 1-52 are currently approved under OMB No. 0915-0157, which expires on August 31, 2023. Forms 53-62 are new additions to the Information Collection.

Section 372 of the Public Health Service (PHS) Act (42 USC 274) requires that the Secretary, by

contract, provide for the establishment and operation of an Organ Procurement and Transplantation Network (OPTN). The OPTN, among other responsibilities, operates and maintains a national waiting list of individuals requiring organ transplants, maintains a computerized system for matching donor organs with transplant candidates on the waiting list, and operates a 24-hour system to facilitate matching organs with individuals included in the list.

The OPTN must assist organ procurement organizations (OPOs) in the distribution of organs equitably among transplant patients nationwide and adopt and use standards of quality for the acquisition and transportation of donated organs. In accordance with Section 372(b)(2)(I) of the PHS Act (42 U.S.C. §274 (b)(2)(I)), the OPTN must also collect, analyze and publish data concerning organ donation and transplants.

2. Purpose and Use of Information

Transplant hospitals, OPOs, and histocompatibility laboratories report data to the OPTN data system. The information is used to match donor organs with recipients, to monitor compliance of member organizations with OPTN policies and requirements to guide organ allocation policy development, and to report periodically on the clinical and scientific status of organ donation and transplantation in this country. OPTN members are assisted in these efforts by the Scientific Registry of Transplant Recipients (SRTR). The SRTR provides statistical and analytic support for the OPTN Board of Directors and committees, HRSA, and the Department of Health and Human Services (HHS) Advisory Committee on Organ Transplantation (ACOT). The SRTR contract currently is held by Hennepin Healthcare Research Institute (HHRI) Analyses of OPTN data by the OPTN and SRTR are used to develop transplant, donation and allocation policies, to determine if institutional members are complying with policy, to determine member specific performance, to ensure patient safety when no alternative sources of data exist and to fulfill the requirement of the OPTN Final Rule. Data are available for statistical analysis of the End Stage Renal Disease (ESRD) Program as required by Section 1881 of the Social Security Act (42 USC 1395(rr)(c)(2)).

The practical utility of the data collection is further enhanced by requirements that the OPTN database must be made available, consistent with applicable laws, for use by the OPTN members, the SRTR, HHS, and in many circumstances others, for evaluation, research, patient information, and other important purposes. This disclosure is governed by Privacy Act System of Records Notice #09-15-0055 (Notification of an altered system of records was published in the Federal Register, 83 Fed. Reg. 6591, (February 14, 2018)). The DoT must report a variety of data to the Secretary of HHS, including data on performance by organ and status category, program-specific data, OPO specific data, data by program size, and data aggregated by organ procurement area, OPTN region, States, the Nation as a whole, and other geographic areas (42 CFR section 121.8(c)(3) of the OPTN final rule). Much of these data are made available to DoT, OPTN members, and the general public via DoT's contracts for the OPTN and SRTR.

Under the requirements of the Final Rule, the OPTN also must develop organ allocation policies and performance indicators which will be used to indicate the goals of the proposed policies and to assess the effects of policy changes. Proposed allocation policies and performance indicators, including supporting materials such as computer models being developed by the SRTR, are premised on the availability of timely and accurate data and information. Records must be maintained and updated appropriately to assure program effectiveness and ongoing monitoring of transplant programs. Section 121.11(b) contains provisions that require the OPTN and SRTR to make available to the public timely and accurate information on the performance of transplant programs so the public can make well-informed decisions and health care professionals may conduct scientific and clinical research.

Data collected by the OPTN are transmitted monthly to HRSA and to HHRI (HRSA's SRTR contractor) by United Network for Organ Sharing (UNOS), the OPTN contractor. Section 372(b)(2)(L) of the PHS Act (42 U.S.C. § 274 (b)(2)(L)) requires that the OPTN provide an annual report on the scientific and clinical status of organ transplantation. Both UNOS and HHRI work collaboratively with HRSA to meet this requirement. Additionally, data collected by the OPTN are used by the DoT in monitoring the OPTN contract and in carrying out other statutory responsibilities. Information from these reports is made available to the public and is routinely used for public information purposes. The public may obtain these data, including transplant center- and OPO-specific performance data, on the SRTR Web site (www.srtr.org).

HRSA, Centers for Medicare and Medicaid Services (CMS), and National Institutes of Health (NIH) all require various kinds of information on transplants to satisfy statutory requirements. They have agreed that only one set of data collection instruments will be used to collect data on organ transplants. (The agencies' data need and the transition to a single data collection approach are more fully described under number 4, Efforts to Identify Duplication.) The data are collected by the OPTN contractor and are available weekly to CMS. The data also are provided to NIH for use in the United States Renal Data System (USRDS). Thus, two major additional data collection requirements are being satisfied by using this data system.

3. Use of Improved Information Technology

Since October 25, 1999, the OPTN has used an electronic data collection system to reduce the paperwork burden on the providers of the data (transplant programs, OPOs, and histocompatibility labs) and to minimize any intrusion into the immediate processes of organ procurement and transplantation. For example, transplant candidates can be registered and critical data regarding candidates updated through direct electronic access by transplant programs and OPOs with the central OPTN computer software which maintains the national waiting list.

All major reports issued under the OPTN contract are required to be available in electronic format. The Annual Data Report is available through the OPTN Web site, <http://optn.transplant.hrsa.gov>, and the SRTR website, www.srtr.org. Also, Program-Specific Graft and Patient Survival data are available on www.srtr.org.

Weekly and monthly, the OPTN provides data to CMS to aid in policy development and data

analyses for the ESRD Program.

4. Efforts to Identify Duplication

The OPTN data system is the only data collection effort in the U.S. encompassing living and deceased organ donors, transplant candidates and transplant recipients for all organ transplants (i.e., kidney, heart, heart-lung, lung, liver, pancreas, kidney-pancreas, intestines, vascularized composite allografts). This is the most comprehensive data analysis system for a single mode of therapy anywhere in the world. There are other single organ (e.g., kidney only) data collection efforts and these have been recognized under the contract in the development of the OPTN data systems and addressed as follows:

- CMS, as a condition of approval for Medicare reimbursement for heart transplant, requires those heart transplant programs which receive approval, to submit specified data on all their heart transplant recipients (not just those paid for by Medicare) to CMS. The data required by CMS are included in the OPTN data requirements.
- In fulfilling P.L. 95-292 in part, CMS collected kidney transplant data as part of the ESRD Program Management and Medical Information System (PMMIS) data system, encompassing all dialysis and kidney transplant patients covered by the Medicare ESRD program. Some of the transplant data collected by the ESRD Program were the same as that collected for the OPTN data systems. This duplication of effort was recognized as a redundant reporting burden to providers of transplant services. CMS and HRSA agreed to have the OPTN become the sole collector of patient-specific kidney transplant data for these two data systems. In July 1994, the two systems were merged and the OPTN contractor, became the sole collector of kidney data. Weekly, the data are transferred to CMS to be incorporated into the ESRD PMMIS.

The ESRD patient registry is known as the United States Renal Data System and is operated under contract awarded by NIH, National Institute of Diabetes and Digestive and Kidney Disease (NIDDK). Because the data for this patient registry come from the CMS ESRD PMMIS, the NIH/NIDDK also is considered an end user of this transplant data. Senior personnel of HRSA, CMS, and OPTN contractor meet on an ad hoc basis to review any problems with the data transmission.

5. Involvement of Small Entities

This project will not be collecting any data from small businesses as defined by OMB. The data collected will not have any significant impact on small business or other small entities.

6. Consequences if Information Collected Less Frequently

Data must be provided to the OPTN on a case-by-case basis, e.g., as each patient is placed on the waiting list, at the time an organ is procured, and when there is a donor organ-recipient match. Timeliness is critical because organ function will begin to deteriorate once cardiac and respiratory functions cease. If donor organs are not listed with the computer system as soon as they become available, organ function will be compromised and patient and graft survival rates will be lower. Timeliness of post-transplant data collection is essential to advancing organ

transplantation policy and science.

7. Consistency with the Guidelines in 5 CFR 1320.5(d)(2)

This data collection is consistent with the guidelines under 5 CFR 1320.5(d)(2).

8. Consultation Outside the Agency

The notice required by 5 CFR 1320.8(d) was published in the Federal Register, 86 Fed. Reg. 48743, (August 31, 2021). One comment was received. The commenter, the president of the Association of Organ Procurement Organizations, supported the necessity and utility of the proposed information collection and the use of automated collection techniques. The commenter recommended that HRSA account for anticipated increased staff hours and recommended emphasizing collecting data pertaining to race, ethnicity, social determinants of health, and any other characteristics that will help achieve equity in organ donation and transplantation. HRSA appreciates all feedback, and we will continue to review and evaluate all data collection efforts going forward in consultation with the OPTN.

Information Technology, Data Governance, Patient Safety, and Policy Development staff employed by the OPTN contractor have reviewed these forms extensively and may be contacted at the following address:

United Network for Organ Sharing (UNOS)
Contact Person: Maureen McBride
700 North 4th Street
Richmond, Virginia 23219
Phone: 804/782-4649
Fax: 804/782-4835

Specific OPTN contractor staff who provided considerable input on the development of the forms include the following:

Maureen McBride, PhD, Chief Operations Officer
Elizabeth Robbins, Associate General Counsel
Kimberly Uccellini, Manager, Data Governance
Lauren Mauk, Manager, Service Owners
Emily Womble, Manager, Patient Safety
Suhuan Wang, Data Governance Analyst
Kerrie Masten, Service Owner
Tory Boffo, Safety Analyst

The design and development of the OPTN data systems have involved consultation not only with the providers of the data, but also with other Federal government entities and members of the transplant community. The most significant collaborative efforts to date have been with CMS, the National Institute for Allergy and Infectious Diseases (NIAID) at the NIH which oversees the Tumor Registry; and the Office of Health Policy, Office of the Assistant Secretary for Planning and Evaluation, DHHS.

9. Remuneration of Respondents

There is no remuneration to respondents.

10. Assurances of Confidentiality

All data collected will be subject to Privacy Act protection (Privacy Act System of Records #09-15-0055). Data collected under the OPTN and SRTR contracts also are well protected by a number of the contractor's security features. HRSA certifies that OPTN's security system, operated by UNOS, meets or exceeds the requirements as prescribed by OMB Circular A-130, Appendix III, Security of Federal Automated Information Systems, and the Departments Automated Information Systems Security Program Handbook. These security features include:

Security Administration

All OPTN system accounts utilized by organ procurement organizations, transplant centers, or histocompatibility laboratories use a federated model for security administration. Access roles are assigned by the site administrators at each member organization, who are able to align access based on a user's business needs to have access to the information.

Once an authorized individual logs in to the OPTN contractor data collection system using their user credentials, that individual cannot execute any commands except those for which they are authorized.

Limited Access

The operating environment is located in two geographically dispersed facilities. These facilities require all individuals who enter the building to be permitted to do so explicitly by OPTN contractor, the business owner of the physical equipment. The facility requires an ID badge to get into the foyer and to pass through turn styles into the Data Center. Once in the Data Center, the contractor's physical systems are located in a locked cage.

Encrypted Identifiers

Web authentication and authenticated web sessions are encrypted using TLS 1.2 or higher as we migrate to TLS 1.3. Identifiers are protected at rest using a salted one-way hash.

Disaster Recovery

The contractor maintains an up-to-date Contingency Plan, which contains emergency operations, backup operations, recovery plans, and identifies roles and responsibilities of the recovery team to ensure continuous operation of the systems facility. Testing of this system occurs twice per year. The OPTN contractor uses two third party co-location sites as alternate processing centers to increase resiliency through load balancing, redundancy, and automated failover of systems.

Paper Documents

No paper data collection instruments are maintained.

Confidentiality Agreements

All of the contractor’s personnel have signed confidentiality agreements stating they will not reveal sensitive data to unauthorized individuals. The contractor has agreed to comply with the requirements of the Privacy Act as it pertains to the data in this system. A Privacy Act System of Records has been established for this project (09-15-0055). Notification of a modified system of records was published in the Federal Register on February 14, 2018 (83 FR 6591).

11. Questions of a Sensitive Nature

The Organ Procurement Organization’s final rule (42 CFR Parts 413, 441, et al. Medicare and Medicaid Programs; Conditions for Coverage for Organ Procurement Organizations [OPOs]; Final Rule) which was published by CMS on May 31, 2006, includes a requirement at 42 CFR § 486.344(b) (potential donor evaluation) that the OPO must “Determine whether there are conditions that may influence donor acceptance,” and “If possible, obtain the potential donor’s medical and social history.” Presumably, obtaining such information would require an OPO to ask the potential donor’s family questions of a sensitive nature, such as whether the potential donor’s social history included behavior that could have resulted in HIV infection.

Social security numbers are requested on a basis. It is a unique identifier that will facilitate data categorization and analysis. Without it, data on commonly named recipients could be erroneously attributed and, therefore, could adversely affect analyses and conclusions about organ disposition and transplant outcomes. The social security number is requested once a candidate or living donor is added to the OPTN database and then displayed on all forms except the Deceased Donor Registration form.

It is essential to ask questions regarding race and ethnicity for comparing the scientific and clinical outcomes among various minority populations, to evaluate access to transplantation, and to understand donation rates among various ethnic and racial populations. Race could be taken from existing donor or candidate records. In some donor cases the race may be provided by donor families; more than one race category may be indicated. Ethnicity/Race was modified to add subcategories for each of the defined main categories and to provide more specific data concerning ethnicity when communicating with specific groups concerning donation and transplantation.

12. Estimates of Annualized Hour Burden

The following is an estimate of the annual respondent burden.

Form Name	Number of Respondents	Number of Responses per Respondent	Total Responses	Average Burden per Response (in hours)	Total Burden Hours	Wage Rate	Total Hour Cost
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Deceased Donor Registration	57	188.26	10,731	1.10	11,804	\$36.30	\$428,485.20
Living Donor Registration	300	22.85	6,855	1.80	12,339	\$36.30	\$447,905.70
Living Donor Follow-up	300	62.23	18,669	1.30	24270	\$36.30	\$881,001.00
Donor Histocompatibility	147	123.99	18,226	0.20	3,645	\$36.30	\$132,313.50
Recipient Histocompatibility	147	225.1	33,090	0.40	13,236	\$36.30	\$480,466.80
Heart Candidate Registration	140	33.69	4,717	0.90	4,245	\$36.30	\$154,093.50
Heart Recipient Registration	140	24.33	3,406	1.20	4,087	\$36.30	\$148,358.10
Heart Follow Up (6 Month)	140	22.01	3,081	0.40	1,232	\$36.30	\$44,721.60
Heart Follow Up (1-5 Year)	140	90.61	12,685	0.90	11,417	\$36.30	\$414,437.10
Heart Follow Up (Post 5 Year)	140	153.97	21,556	0.50	10,778	\$36.30	\$391,241.40
Heart Post-Transplant Malignancy Form	140	12.77	1,788	0.90	1,609	\$36.30	\$58,406.70
Lung Candidate Registration	71	45.21	3,210	0.90	2,889	\$36.30	\$104,870.70
Lung Recipient Registration	71	35.66	2,532	1.20	3,038	\$36.30	\$110,279.40
Lung Follow Up (6 Month)	71	32.35	2,297	0.50	1,149	\$36.30	\$41,708.70
Lung Follow Up (1-5 Year)	71	118.85	8,438	1.10	9,282	\$36.30	\$336,936.60
Lung Follow Up (Post 5 Year)	71	116.49	8,271	0.60	4,963	\$36.30	\$180,156.90
Lung Post-Transplant Malignancy Form	71	19.72	1,400	0.40	560	\$36.30	\$20,328.00
Heart/Lung Candidate Registration	69	0.97	67	1.10	74	\$36.30	\$2,686.20
Heart/Lung Recipient Registration	69	0.46	32	1.30	42	\$36.30	\$1,524.60
Heart/Lung Follow Up (6 Month)	69	0.45	31	0.80	25	\$36.30	\$907.50
Heart/Lung Follow Up (1-5 Year)	69	1.14	79	1.10	87	\$36.30	\$3,158.10
Heart/Lung Follow Up (Post 5 Year)	69	3.3	228	0.60	137	\$36.30	\$4,973.10
Heart/Lung Post-Transplant Malignancy Form	69	0.3	21	0.40	8	\$36.30	\$290.40
Liver Candidate Registration	146	90.29	13,182	0.80	10,546	\$36.30	\$382,819.80
Liver Recipient Registration	146	56.55	8,256	1.20	9,907	\$36.30	\$359,624.10

Liver Follow-up (6 Month - 5 Year)	146	266.57	38,919	1.00	38,919	\$36.30	\$1,412,759.70
Liver Follow-up (Post 5 Year)	146	316.61	46,225	0.50	23,113	\$36.30	\$839,001.90
Liver Recipient Explant Pathology Form	146	10.58	1,545	0.60	927	\$36.30	\$33,650.10
Liver Post-Transplant Malignancy	146	16.35	2,387	0.80	1,910	\$36.30	\$69,333.00
Intestine Candidate Registration	20	6.95	139	1.30	181	\$36.30	\$6,570.30
Intestine Recipient Registration	20	5.2	104	1.80	187	\$36.30	\$6,788.10
Intestine Follow Up (6 Month - 5 Year)	20	26.2	524	1.50	786	\$36.30	\$28,531.80
Intestine Follow Up (Post 5 Year)	20	37.2	744	0.40	298	\$36.30	\$10,817.40
Intestine Post-Transplant Malignancy Form	20	2.1	42	1.00	42	\$36.30	\$1,524.60
Kidney Candidate Registration	237	168.77	39,998	0.80	31,998	\$36.30	\$1,161,527.40
Kidney Recipient Registration	237	89.43	21,195	1.20	25,434	\$36.30	\$923,254.20
Kidney Follow-Up (6 Month - 5 Year)	237	431.86	102,351	0.90	92,116	\$36.30	\$3,343,810.80
Kidney Follow-up (Post 5 Year)	237	449.4	106,508	0.50	53,254	\$36.30	\$1,933,120.20
Kidney Post-Transplant Malignancy Form	237	22.64	5,366	0.80	4,292	\$36.30	\$155,799.60
Pancreas Candidate Registration	133	2.77	368	0.60	221	\$36.30	\$8,022.30
Pancreas Recipient Registration	133	1.46	194	1.20	233	\$36.30	\$8,457.90
Pancreas Follow-up (6 Month - 5 Year)	133	7.87	1,047	0.50	524	\$36.30	\$19,021.20
Pancreas Follow-up (Post 5 Year)	133	15.93	2,119	0.50	1,060	\$36.30	\$38,478.00
Pancreas Post-Transplant Malignancy Form	133	0.73	97	0.60	58	\$36.30	\$2,105.40
Kidney/Pancreas Candidate Registration	133	9.75	1,297	0.60	778	\$36.30	\$28,241.40
Kidney/Pancreas Recipient Registration	133	7.73	1,028	1.20	1,234	\$36.30	\$44,794.20
Kidney/Pancreas Follow-up (6 Month - 5 Year)	133	32.8	4,362	0.50	2,181	\$36.30	\$79,170.30
Kidney/Pancreas Follow-up (Post 5 Year)	133	57.8	7,688	0.60	4,613	\$36.30	\$167,451.90
Kidney/Pancreas Post-Transplant Malignancy Form	133	2.2	293	0.40	117	\$36.30	\$4,247.10
VCA Candidate Registration	27	0.89	24	0.40	10	\$36.30	\$363.00

VCA Recipient Registration	27	1.59	43	1.30	56	\$36.30	\$2,032.80
VCA Recipient Follow Up	27	0.67	18	1.00	18	\$36.30	\$653.40
Organ Labeling and Packaging System	57	208.25	11,870	0.18	2,137	\$36.30	\$77,573.10
Organ Tracking and Validating System	34	169.06	5,748	0.08	460	\$36.30	\$16,698.00
Kidney Paired Donation Candidate Registration	160	1.38	221	0.29	64	\$36.30	\$2,323.20
Kidney Paired Donation Donor Registration	160	1.46	234	1.07	250	\$36.30	\$9,075.00
Kidney Paired Donation Match Offer Management	160	1.51	242	0.67	162	\$36.30	\$5,880.60
Disease Transmission Event	308	1.44	444	0.62	275	\$36.30	\$9,982.50
Living Donor Event	251	0.12	30	0.56	17	\$36.30	\$617.10
Safety Situation	450	0.48	216	0.56	122	\$36.30	\$4,428.60
Potential Disease Transmission Report	57	6.88	392	1.27	498	\$36.30	\$18,077.40
Request to Unlock Form	450	39.22	17,649	0.02	353	\$36.30	\$12,813.90
Total	8,290		604,519		430,267		\$15,618,692.10

Basis for Burden Estimates:

Forms 1-52 estimates are based on the number of OPTN members in each membership category (i.e. transplant center, OPO, histocompatibility laboratory) as of June 23, 2019. The number of members in each category will vary as new members are approved and/or members relinquish their OPTN membership when a member ceases activity related to organ transplantation.

As of June 23, 2019, there are 147 histocompatibility laboratories that are members of the OPTN and have responsibility for completing the Donor Histocompatibility form and the Transplant Recipient Histocompatibility form.

As of June 23, 2019, there are 140 transplant centers with heart programs, 69 transplant centers with heart-lung programs, 71 transplant centers with lung programs, 237 transplant centers with kidney programs, 146 transplant centers with liver programs, 20 transplant centers with intestine programs, and 133 transplant centers with pancreas programs. They each complete a different Transplant Candidate Registration form, Transplant Recipient Registration form and Transplant Recipient Follow-up forms. The Living Donor Registration (LDR) and Follow-up (LDF) forms are completed by the living donor components of the kidney and liver programs at transplant centers. There are a total of 300 living donor programs responsible for completing the LDRs and LDFs.

The Post-Transplant Malignancy form is completed by the organ specific programs at the transplant centers on a case by case basis. The liver explant pathology form is completed by

liver programs at various transplant centers.

As of June 23, 2019, there are 27 transplant centers with OPTN approved VCA programs. These programs will the VCA Candidate Registration, VCA Recipient Registration, and VCA Follow Up forms.

Forms 53-54 estimates are based on total number of OPTN Organ Procurement Organizations as of April 19, 2021; total number of deceased donors recovered between January 1, 2019 and December 31, 2019; and total number of deceased donor transplants between January 1, 2019 and December 31, 2019 at transplant centers actively using Organ Tracking and Validating System.

Forms 55-57 estimates are based on total number of eligible transplant centers participating in the OPTN KPD Pilot Program; total number of candidates added to the OPTN KPD system over the past 12 months; total number of donors added to the OPTN KPD system over the past 12 months; total number of match offers in the OPTN KPD system over the past 12 months as of August 25, 2020.

Forms 58-61 estimates are based on the numbers of organ procurement organizations, transplant centers, and histocompatibility laboratories with active OPTN membership; total number of disease transmission events reported to the OPTN Patient Safety system over the past 12 months; total number of living donor events reported to the OPTN Patient Safety system over the past 12 months; total number of safety situations reported to the OPTN Patient Safety system over the past 12 months; total number of potential disease transmission reports submitted to the OPTN over the past 12 months, as of January 27, 2021.

Forms 62 estimates based on total number of organ procurement organizations, transplant centers, and histocompatibility laboratories with active OPTN membership status as of April 19, 2021 and estimated total number of form submissions in the next 12 months.

The difference in burden hours among the different forms relates both to the number of items on the forms and the availability of data. For some, the respondent may simply copy the information from an existing hospital record. For others, two or more data sources are necessary.

Basis for Hour Costs:

Data collection and reporting is carried out at transplant centers, OPOs, and histocompatibility laboratories by a variety of personnel including transplant coordinators, nurses, laboratory technicians, medical record specialists, etc. The individual(s) responsible for filling out the data collection forms will vary among the respondents. Therefore, for purposes of estimating the cost to the respondents, the average hourly wage reflects the mean hourly wage of a Registered Nurse by United States Department of Labor - Bureau of Labor Statistics [website](#). The mean hourly wage as of December 12, 2019 for this position is \$36.30.

13. Estimates of Annualized Cost Burden to Respondents

Capital costs and start-up costs:

The OPTN system has been in place for many years; there are no capital or start-up costs for the basic network. The OPTN system is internet-based. Additionally, facilities are equipped with PCs and Internet connections and should incur no costs.

Operation and maintenance costs:

Users have computers for their normal business activities and, therefore, will not need to change maintenance practices for this purpose. Some users do have internal import/export systems that assist in the completion of these forms via their electronic medical record systems. Transplant centers are responsible for all of the proposed data collection modifications and are routinely responsible for a majority of the data collection volume.

14. Estimates of Annualized Cost to the Government

The annual cost to the Federal Government consists of those costs allocated to the data system under the HRSA contract for the OPTN. There also is the cost to the government to monitor the data system.

Listed below are costs from the OPTN Task #5 “Collect official OPTN data to support the operations of the OPTN” and OPTN Task #9 “The Contractor shall maintain and improve the OPTN website for dissemination of transplant information to the public and the transplant community”. These tasks do not include costs for development and maintenance of OPTN systems and maintaining OPTN security requirements.

A. OPTN contract (HRSA 250-2019-00001C)

Direct Cost	
1. Direct Salaries and Wages	\$3,757,650
2. Fringe Benefits	\$1,575,460
3. Travel	0
4. Other Direct Costs	\$931,240
Total Direct Costs	\$6,263,350
5. Indirect Costs	\$851,190
TOTAL ESTIMATED COST	\$ 7,114,540*

* The OPTN is a cost-share contract with the contractor contributing 89.9 percent of this cost from patient registration fees. Thus, the estimated net cost to the Federal government for the performance of the contract tasks for data collection and dissemination in fiscal year 2022 is \$718,569.

15. Changes in Burden

Currently, there are a total of 430,267 burden hours in the OMB inventory. The total burden hours has increased by 4,342 hours. This increase represents a change in adding 10 new forms to the existing Information Collection.

16. Time Schedule, Publication and Analysis Plans

The Scientific Registry of Transplant Recipients (SRTR) contractor uses data collected by the OPTN to produce updated program- and OPO-specific reports every six months. These reports are published online at www.srtr.org. In addition, the data are used to produce an Annual Report, also available at www.srtr.org.

Data also will be available for clinical, scientific effectiveness, and epidemiological research. All provisions of the Privacy Act of 1974 will be strictly enforced.

17. Exemption for Display of Expiration Date

The expiration date will be displayed.

18. Certifications

This information collection fully complies with the guidelines set forth in 5 CFR 1320.9. The certifications are included in the package.