

Health Resources and Services Administration

SUPPORTING STATEMENT

**Data System for Organ Procurement and
Transplantation Network**

OMB Control No. 0915-0157

A. Justification

1. Circumstances of Information Collection of Information Necessary

This is a request for OMB approval for the revision of the Data System for the Organ Procurement and Transplantation Network (OPTN) and the associated forms listed below in section 12. Sixty-two forms (Forms 1-62 on the burden table starting on page 6) were approved on March 22, 2022, and expire on March 31, 2025. Eight forms (Forms 63-70 on the burden table starting on page 6) 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 OPTN, which on behalf of the Health Resources and Services Administration (HRSA), oversees the U.S. donation and transplantation system. 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. 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 the Information

Transplant hospitals, organ procurement organizations (OPO), 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 (BOD) and committees, HRSA, and the Department of Health and Human Services (HHS) Advisory Committee on Organ Transplantation (ACOT). The SRTR contract is currently 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 1395rr(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 the OPTN Final Rule (42 C.F.R. §121.11). HRSA has also published a Privacy Act System of Records Notice #09-15-0055 (Notification of an altered system of records was published in the Federal Register on August 1, 2022 (87 Fed. Reg. 46967), governing some uses of the data. OPTN 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 § 121.8(c)(3)). Much of these data are made available to OPTN members and the general public

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) of the OPTN Final Rule 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 HRSA's SRTR contractor by 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 in the United States. These reports can be found at: <https://srtr.org/reports/optnsrtr-annual-data-report/>. Both the OPTN contractor and the SRTR contractor work collaboratively with HRSA to meet this requirement. Information from this report 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). Additionally, data collected by the OPTN are used by the DoT in monitoring the OPTN contract and in carrying out other statutory responsibilities.

3. Use of Improved Information Technology and Burden Reduction

Since October 25, 1999, the OPTN contractor has provided an electronic data collection system to reduce the paperwork burden on the respondents (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 contractor computer software, which maintains the national waiting list.

The contract requires the OPTN contractor to develop direct electronic data submission. As this direct connection transfers more of this data, the burden hours are expected to be revised. HRSA expects to see a reduction in burden hours as a result of this direct electronic data submission in a future revision of this package.

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 website, <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 Avoid Duplication and Use of Similar Information

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). CMS, as a condition of approval for Medicare reimbursement for a 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.

OPTN data also contribute to the United States Renal Data System (USRDS), which is operated under a contract awarded by NIH. Thus, two major additional data collection requirements are satisfied by using this data system.

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

Data must be submitted to the OPTN on a case-by-case basis. Frequency of collection varies by form and data submission requirements as specified in OPTN Policy 18. Timeliness in organ transplantation is critical because organ function will begin to deteriorate once cardiac and respiratory functions cease. For example, if donor organs are not listed within the OPTN Donor Data and Matching 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

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, “Data System for Organ Procurement and Transplantation Network, OMB No. 0915-0157- Revision” was published in the *Federal Register* on Thursday, September 29, 2022. 87 Fed. Reg. 59103-05. HRSA received one comment. The commenter supported the necessity and utility of the proposed information collection and the accuracy of the estimated burden. However, recommended that HRSA consider enhancements to the ‘currently-used United Network for Organ Sharing (UNOS) data system’, including the need for more real-time data for OPOs and a more advanced application programming interface which integrates with OPO’s electronic medical record platforms. Since the requested changes are to the ‘OPTN data system’, and not the forms themselves, HRSA is not making any changes to the information collection request as a result of this comment. However, HRSA appreciates all public feedback and will consider data system changes in consultation with the OPTN members and the public.

A 30-day Federal Register Notice, “Data System for Organ Procurement and Transplantation Network, OMB No. 0915-0157- Revision” was published in the *Federal Register* on Wednesday June 14, 2023. 88 Fed. Reg. 38873-76.

Section 8B:

The design and development of the OPTN computer system have involved consultation not only with the providers of the data, but also with OPTN expert Committees, the OPTN BOD, the SRTR contractor, and with Federal government entities and members of the transplant community. The most significant collaborative efforts to date with other HHS agencies have been with CMS, NIH, CDC, and the Office of the Secretary.

OPTN data collection undergoes a public comment period of 55 days, during which the general public can submit their comments through a dedicated web page. Comments are considered, and data collection may be revised before the policy proposals are submitted to the OPTN BOD for final review and approval.

9. Remuneration of any Payment/Gift to Respondents

Respondents will not receive any payments or gifts.

10. Assurance of Confidentiality Provided to Respondents

Data collected under the OPTN contract is well protected by a number of security features. HRSA certifies that OPTN contractor’ security systems meet or exceed the requirements in accordance with National Institute of Standards in Technology Special Publication (NIST SP) 800-53, Security and Privacy Controls for Federal Information Systems Organizations, and OMB Memorandum M-06-16, Protection of Sensitive Agency Information by securing it with a Federal Information Processing Standard (FIPS) 140-2 validated solution, as well as Information Security Continuous Monitoring (ISCM) in accordance with Federal Information Security Modernization Act (FISMA) and NIST SP 800-137. These security features include, but are not limited to:

- Captured Accounts
All accounts utilized by OPOs, transplant centers, or histocompatibility laboratories are captured accounts. This means that, once an authorized individual gains access to the contractor's computer system, he/she cannot execute any commands or access any data except those for which they are authorized. When an authorized user exits the contractor's software, he/she is automatically logged off the system. Authorized individuals are only able to access the OPTN Computer System using user id and password in conjunction with Multi-Factor Authentication token.
- Limited Access
The OPTN Computer System operating environment is hosted in multi-regional co-location facilities in a hybrid cloud configuration. All personnel entering the co-located facilities must be explicitly approved for access by the OPTN contractor, who are the business owner of the physical equipment. In addition, for each co-location site, an ID badge is required to enter the main building and is issued by the operator of the co-location facility. From that point, badge, fingerprint, and optical access is required to access the operating environment floor, and the OPTN contractor's physical systems which are located in a locked cage, with limited access to the cage.
- Encrypted Identifiers
The OPTN contractor employs FIPS 140-2 compliant encryption capabilities. The OPTN Computer System is a public-facing web application, and all users require appropriate credentials to remotely access the system using Transport Layer Security (TLS) 1.2 encrypted sessions. At each layer of the system including hosting, virtualization, and presentation, TLS 1.2 is used for securing data in transit and Advanced Encryption Standard (AES) 256 for securing data at rest. In addition, all system audit logs, and system backups also utilize TLS and AES for encrypting data in transit and at rest, respectively.
- 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 operations of the OPTN Computer System. Testing of the system occurs twice per year. As mentioned earlier, the contractor uses multi-regional co-location facilities in a resilient hybrid cloud configuration with load balancing, redundancy, and automated site-to-site failover of system workloads.

Destruction of information and/or data are performed in accordance with NIST SP 800-88, Guidelines for Media Sanitization.
- 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 August 1, 2022 (87 FR 46967).

11. Justification for Sensitive Questions

The CMS conditions for Coverage for OPOs (42 CFR §§486.301-348) includes a requirement 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.” This information is included in this data collection. 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 as needed. 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 Computer System database and then displayed on all forms except the Deceased Donor Registration form.

It is essential to ask questions regarding race and ethnicity to compare 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. Existing OPTN data collection forms that collect a single race and ethnicity variable will be revised to collect separate race and ethnicity variables, following the minimum standards for collecting and presenting data on race and ethnicity for all Federal agencies reporting found within *Revisions of Standards for the Classification of Federal Data on Race and Ethnicity*, OMB Statistical Policy Directive No. 15 in Federal Register, 62 FR 58782 (Oct. 30, 1997). Improving data collection around race and ethnicity information of donors and candidates aligns with Executive Order 13985, which calls on agencies to advance equity through identifying and addressing barriers to equal opportunity that underserved communities may face due to government policies and programs.

12. Estimates of Annualized Hour and Cost Burden

Annual burden estimates:

The numbers in Table 1 are slightly different than the 30 Day *Federal Register Notice* since total values are rounded up to the nearest whole number in this table (in the 30 Day, it was rounded to two decimal places).

Table 1: Annual Burden Estimates (Totals Rounded to Nearest Whole Number)

	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*
1	Deceased Donor Registration	57	243.56	13,883	1.2	16,660	\$39.78	\$662,735

	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*
2	Living Donor Registration	216	28.11	6,072	2.19	13,298	\$39.78	\$528,994
3	Living Donor Follow-up	216	90.55	19,559	1.52	29,730	\$39.78	\$1,182,659
4	Donor Histocompatibility	141	149.18	21,034	0.2	4,207	\$39.78	\$167,354
5	Recipient Histocompatibility	141	264.95	37,358	0.4	14,943	\$39.78	\$594,433
6	Heart Transplant Candidate Registration	145	34.59	5,016	0.9	4,514	\$39.78	\$179,567
7	Heart Transplant Recipient Registration	145	26.32	3,816	1.96	7,479	\$39.78	\$297,515
8	Heart Transplant Recipient Follow Up (6 Month)	145	24.4	3,538	0.4	1,415	\$39.78	\$56,289
9	Heart Transplant Recipient Follow Up (1-5 Year)	145	104.14	15,100	0.9	13,590	\$39.78	\$540,610
10	Heart Transplant Recipient Follow Up (Post 5 Year)	145	171.1	24,810	0.5	12,405	\$39.78	\$493,471
11	Heart Post-Transplant Malignancy Form	145	13.17	1,910	0.9	1,719	\$39.78	\$68,382
12	Lung Transplant Candidate Registration	72	42.97	3,094	0.9	2,785	\$39.78	\$110,787
13	Lung Transplant Recipient Registration	72	35.01	2,521	1.2	3,025	\$39.78	\$120,335
14	Lung Transplant Recipient Follow Up (6 Month)	72	33.63	2,421	0.5	1,211	\$39.78	\$48,174
15	Lung Transplant Recipient Follow Up (1-5 Year)	72	139.94	10,076	1.1	11,084	\$39.78	\$440,922

	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*
16	Lung Transplant Recipient Follow Up (Post 5 Year)	72	136.28	9,812	0.6	5,887	\$39.78	\$234,185
17	Lung Post-Transplant Malignancy Form	72	22.63	1,629	0.4	652	\$39.78	\$25,937
18	Heart/Lung Transplant Candidate Registration	70	0.96	67	1.1	74	\$39.78	\$2,944
19	Heart/Lung Transplant Recipient Registration	70	0.64	45	2.15	97	\$39.78	\$3,859
20	Heart/Lung Transplant Recipient Follow Up (6 Month)	70	0.6	42	0.8	34	\$39.78	\$1,353
21	Heart/Lung Transplant Recipient Follow Up (1-5 Year)	70	2.1	147	1.1	162	\$39.78	\$6,444
22	Heart/Lung Transplant Recipient Follow Up (Post 5 Year)	70	3.36	235	0.6	141	\$39.78	\$5,609
23	Heart/Lung Post-Transplant Malignancy Form	70	0.29	20	0.4	8	\$39.78	\$318
24	Liver Transplant Candidate Registration	143	96.92	13,860	0.8	11,088	\$39.78	\$441,081
25	Liver Transplant Recipient Registration	143	64.58	9,235	1.2	11,082	\$39.78	\$440,842
26	Liver Transplant Recipient Follow Up (6 Month - 5 Year)	143	320.27	45,799	1	45,799	\$39.78	\$1,821,884
27	Liver Transplant Recipient Follow Up (Post 5 Year)	143	384.32	54,958	0.5	27,479	\$39.78	\$1,093,115

	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*
28	Liver Recipient Explant Pathology Form	143	7.3	1,044	0.6	626	\$39.78	\$24,902
29	Liver Post-Transplant Malignancy	143	19.06	2,726	0.8	2,181	\$39.78	\$86,760
30	Intestine Transplant Candidate Registration	21	6.86	144	1.3	187	\$39.78	\$7,439
31	Intestine Transplant Recipient Registration	21	4.57	96	1.8	173	\$39.78	\$6,882
32	Intestine Transplant Recipient Follow Up (6 Month - 5 Year)	21	20.05	421	1.5	632	\$39.78	\$25,141
33	Intestine Transplant Recipient Follow Up (Post 5 Year)	21	40.19	844	0.4	338	\$39.78	\$13,446
34	Intestine Post-Transplant Malignancy Form	21	0.62	13	1	13	\$39.78	\$517
35	Kidney Transplant Candidate Registration	234	177	41,418	0.8	33,134	\$39.78	\$1,318,071
36	Kidney Transplant Recipient Registration	234	105.4	24,664	1.2	29,597	\$39.78	\$1,177,369
37	Kidney Transplant Recipient Follow Up (6 Month - 5 Year)	234	517.12	121,006	0.9	108,905	\$39.78	\$4,332,241
38	Kidney Transplant Recipient Follow Up (Post 5 Year)	234	525.1	122,873	0.5	61,437	\$39.78	\$2,443,964
39	Kidney Post-Transplant Malignancy Form	234	24.47	5,726	0.8	4,581	\$39.78	\$182,232

	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*
40	Pancreas Transplant Candidate Registration	120	2.65	318	0.6	191	\$39.78	\$7,598
41	Pancreas Transplant Recipient Registration	120	1.19	143	1.2	172	\$39.78	\$6,842
42	Pancreas Transplant Recipient Follow Up (6 Month - 5 Year)	120	6.68	802	0.5	401	\$39.78	\$15,952
43	Pancreas Transplant Recipient Follow Up (Post 5 Year)	120	17.82	2138	0.5	1,069	\$39.78	\$42,525
44	Pancreas Post-Transplant Malignancy Form	120	1.06	127	0.6	76	\$39.78	\$3,023
45	Kidney/Pancreas Transplant Candidate Registration	120	12.45	1,494	0.6	896	\$39.78	\$35,643
46	Kidney/Pancreas Transplant Recipient Registration	120	6.84	821	1.2	985	\$39.78	\$39,183
47	Kidney/Pancreas Transplant Recipient Follow Up (6 Month - 5 Year)	120	39.44	4,733	0.5	2,367	\$39.78	\$94,159
48	Kidney/Pancreas Transplant Recipient Follow Up (Post 5 Year)	120	69.41	8,329	0.6	4,997	\$39.78	\$198,781
49	Kidney/Pancreas Post-Transplant Malignancy Form	120	2.49	299	0.4	120	\$39.78	\$4,774
50	VCA Transplant Candidate Registration	21	0.33	7	0.4	3	\$39.78	\$119

	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*
51	VCA Transplant Recipient Registration	21	0.19	4	1.36	5	\$39.78	\$199
52	VCA Transplant Recipient Follow Up	21	1	21	1.31	28	\$39.78	\$1,114
53	Organ Labeling and Packaging	57	247.72	14,120	0.18	2,542	\$39.78	\$101,121
54	Organ Tracking and Validating	308	19.49	6,003	0.08	480	\$39.78	\$19,094
55	Kidney Paired Donation Candidate Registration	159	1.2	191	0.29	55	\$39.78	\$2,188
56	Kidney Paired Donation Donor Registration	159	1.56	248	1.08	268	\$39.78	\$10,661
57	Kidney Paired Donation Match Offer Management	159	1.52	242	0.67	162	\$39.78	\$6,444
58	Disease Transmission Event	308	1.81	557	0.62	345	\$39.78	\$13,724
59	Living Donor Event	251	0.156	39	0.56	22	\$39.78	\$875
60	Safety Situation	449	0.6	269	0.56	151	\$39.78	\$6,007
61	Potential Disease Transmission	57	8.72	497	1.27	631	\$39.78	\$25,101
62	Request to Unlock Form	449	42.4	19,038	0.02	381	\$39.78	\$15,156
63	Initial Donor Registration	57	335.72	19,136	3	57,408	\$39.78	\$2,283,690
64	OPO Notification Limit Administration	57	0.49	28	0.17	5	\$39.78	\$199
65	Potential Transplant Recipient	308	4718.48	1,453,292	0.05	72,665	\$39.78	\$2,890,614
66	Death Notification Registration	57	185.77	10,589	0.42	4,447	\$39.78	\$176,902
67	Deceased Donor Death Referral	57	53.84	3,069	0.5	1,535	\$39.78	\$61,062

	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*
68	Donor Hospital Registration	57	0.04	2	0.08	0**	\$39.78	\$0
69	Donor Organ Disposition	57	335.72	19,136	0.17	3,253	\$39.78	\$129,404
70	Transplant Center Contact Management	251	637.5	160,013	0.06	9,601	\$39.78	\$381,928
	Total = 70 forms	9,146		2,352,737		647,633		\$25,762,841

* Totals are rounded up to the nearest whole number.

** The actual average burden response is 0.16, which rounds down to 0.

Table 2 shows the original table, with Total Responses and Total Hour Cost not rounded to the nearest whole number. It is provided for reference.

Table 2: Annual Burden Estimates (Original Table Matching 30-Day)

	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
1	Deceased Donor Registration	57	243.56	13,883	1.2	16,659.60	\$39.78	\$662,718.89
2	Living Donor Registration	216	28.11	6,072	2.19	13,297.68	\$39.78	\$528,981.71
3	Living Donor Follow-up	216	90.55	19,559	1.52	29,729.68	\$39.78	\$1,182,646.67
4	Donor Histocompatibility	141	149.18	21,034	0.20	4,206.80	\$39.78	\$167,346.50
5	Recipient Histocompatibility	141	264.95	37,358	0.40	14,943.20	\$39.78	\$594,440.50
6	Heart Transplant Candidate Registration	145	34.59	5,016	0.90	4,514.40	\$39.78	\$179,582.83
7	Heart Transplant Recipient Registration	145	26.32	3,816	1.96	7,479.36	\$39.78	\$297,528.94
8	Heart Transplant Recipient Follow Up (6 Month)	145	24.40	3,538	0.40	1,415.20	\$39.78	\$56,296.66
9	Heart Transplant Recipient Follow Up (1-5 Year)	145	104.14	15,100	0.90	13,590.00	\$39.78	\$540,610.20

	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
10	Heart Transplant Recipient Follow Up (Post 5 Year)	145	171.10	24,810	0.50	12,405.00	\$39.78	\$493,470.90
11	Heart Post-Transplant Malignancy Form	145	13.17	1,910	0.90	1,719.00	\$39.78	\$68,381.82
12	Lung Transplant Candidate Registration	72	42.97	3,094	0.90	2,784.60	\$39.78	\$110,771.39
13	Lung Transplant Recipient Registration	72	35.01	2,521	1.20	3,025.20	\$39.78	\$120,342.46
14	Lung Transplant Recipient Follow Up (6 Month)	72	33.63	2,421	0.50	1,210.50	\$39.78	\$48,153.69
15	Lung Transplant Recipient Follow Up (1-5 Year)	72	139.94	10,076	1.10	11,083.60	\$39.78	\$440,905.61
16	Lung Transplant Recipient Follow Up (Post 5 Year)	72	136.28	9,812	0.60	5,887.20	\$39.78	\$234,192.82
17	Lung Post-Transplant Malignancy Form	72	22.63	1,629	0.40	651.60	\$39.78	\$25,920.65
18	Heart/Lung Transplant Candidate Registration	70	0.96	67	1.10	73.70	\$39.78	\$2,931.79
19	Heart/Lung Transplant Recipient Registration	70	0.64	45	2.15	96.75	\$39.78	\$3,848.72
20	Heart/Lung Transplant Recipient Follow Up (6 Month)	70	0.60	42	0.80	33.60	\$39.78	\$1,336.61
21	Heart/Lung Transplant Recipient Follow Up (1-5 Year)	70	2.10	147	1.10	161.70	\$39.78	\$6,432.43
22	Heart/Lung Transplant Recipient Follow Up (Post 5 Year)	70	3.36	235	0.60	141.00	\$39.78	\$5,608.98

	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
23	Heart/Lung Post-Transplant Malignancy Form	70	0.29	20	0.40	8.00	\$39.78	\$318.24
24	Liver Transplant Candidate Registration	143	96.92	13,860	0.80	11,088.00	\$39.78	\$441,080.64
25	Liver Transplant Recipient Registration	143	64.58	9,235	1.20	11,082.00	\$39.78	\$440,841.96
26	Liver Transplant Recipient Follow Up (6 Month - 5 Year)	143	320.27	45,799	1.00	45,799.00	\$39.78	\$1,821,884.22
27	Liver Transplant Recipient Follow Up (Post 5 Year)	143	384.32	54,958	0.50	27,479.00	\$39.78	\$1,093,114.62
28	Liver Recipient Explant Pathology Form	143	7.30	1,044	0.60	626.40	\$39.78	\$24,918.19
29	Liver Post-Transplant Malignancy	143	19.06	2,726	0.80	2,180.80	\$39.78	\$86,752.22
30	Intestine Transplant Candidate Registration	21	6.86	144	1.30	187.20	\$39.78	\$7,446.82
31	Intestine Transplant Recipient Registration	21	4.57	96	1.80	172.80	\$39.78	\$6,873.98
32	Intestine Transplant Recipient Follow Up (6 Month - 5 Year)	21	20.05	421	1.50	631.50	\$39.78	\$25,121.07
33	Intestine Transplant Recipient Follow Up (Post 5 Year)	21	40.19	844	0.40	337.60	\$39.78	\$13,429.73
34	Intestine Post-Transplant Malignancy Form	21	0.62	13	1.00	13.00	\$39.78	\$517.14
35	Kidney Transplant Candidate Registration	234	177.00	41,418	0.80	33,134.40	\$39.78	\$1,318,086.43

	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
36	Kidney Transplant Recipient Registration	234	105.40	24,664	1.20	29,596.80	\$39.78	\$1,177,360.70
37	Kidney Transplant Recipient Follow Up (6 Month - 5 Year)	234	517.12	121,006	0.90	108,905.40	\$39.78	\$4,332,256.81
38	Kidney Transplant Recipient Follow Up (Post 5 Year)	234	525.10	122,873	0.50	61,436.50	\$39.78	\$2,443,943.97
39	Kidney Post-Transplant Malignancy Form	234	24.47	5,726	0.80	4,580.80	\$39.78	\$182,224.22
40	Pancreas Transplant Candidate Registration	120	2.65	318	0.60	190.80	\$39.78	\$7,590.02
41	Pancreas Transplant Recipient Registration	120	1.19	143	1.20	171.60	\$39.78	\$6,826.25
42	Pancreas Transplant Recipient Follow Up (6 Month - 5 Year)	120	6.68	802	0.50	401.00	\$39.78	\$15,951.78
43	Pancreas Transplant Recipient Follow Up (Post 5 Year)	120	17.82	2138	0.50	1,069.00	\$39.78	\$42,524.82
44	Pancreas Post-Transplant Malignancy Form	120	1.06	127	0.60	76.20	\$39.78	\$3,031.24
45	Kidney/Pancreas Transplant Candidate Registration	120	12.45	1,494	0.60	896.40	\$39.78	\$35,658.79
46	Kidney/Pancreas Transplant Recipient Registration	120	6.84	821	1.20	985.20	\$39.78	\$39,191.26
47	Kidney/Pancreas Transplant Recipient Follow Up (6 Month - 5 Year)	120	39.44	4,733	0.50	2,366.50	\$39.78	\$94,139.37

	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
48	Kidney/Pancreas Transplant Recipient Follow Up (Post 5 Year)	120	69.41	8,329	0.60	4,997.40	\$39.78	\$198,796.57
49	Kidney/Pancreas Post-Transplant Malignancy Form	120	2.49	299	0.40	119.60	\$39.78	\$4,757.69
50	VCA Transplant Candidate Registration	21	0.33	7	0.40	2.80	\$39.78	\$111.38
51	VCA Transplant Recipient Registration	21	0.19	4	1.36	5.44	\$39.78	\$216.40
52	VCA Transplant Recipient Follow Up	21	1.00	21	1.31	27.51	\$39.78	\$1,094.35
53	Organ Labeling and Packaging	57	247.72	14,120	0.18	2,541.60	\$39.78	\$101,104.85
54	Organ Tracking and Validating	308	19.49	6,003	0.08	480.24	\$39.78	\$19,103.95
55	Kidney Paired Donation Candidate Registration	159	1.20	191	0.29	55.39	\$39.78	\$2,203.41
56	Kidney Paired Donation Donor Registration	159	1.56	248	1.08	267.84	\$39.78	\$10,654.68
57	Kidney Paired Donation Match Offer Management	159	1.52	242	0.67	162.14	\$39.78	\$6,449.93
58	Disease Transmission Event	308	1.81	557	0.62	345.34	\$39.78	\$13,737.63
59	Living Donor Event	251	0.156	39	0.56	21.84	\$39.78	\$868.80
60	Safety Situation	449	0.60	269	0.56	150.64	\$39.78	\$5,992.46
61	Potential Disease Transmission	57	8.72	497	1.27	631.19	\$39.78	\$25,108.74
62	Request to Unlock Form	449	42.40	19,038	0.02	380.76	\$39.78	\$15,146.63
63	Initial Donor Registration	57	335.72	19,136	3.00	57,408.00	\$39.78	\$2,283,690.24

	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
64	OPO Notification Limit Administration	57	0.49	28	0.17	4.76	\$39.78	\$189.35
65	Potential Transplant Recipient	308	4718.48	1,453,292	0.05	72,664.60	\$39.78	\$2,890,597.79
66	Death Notification Registration	57	185.77	10,589	0.42	4,447.38	\$39.78	\$176,916.78
67	Deceased Donor Death Referral	57	53.84	3,069	0.50	1,534.50	\$39.78	\$61,042.41
68	Donor Hospital Registration	57	0.04	2	0.08	0.16	\$39.78	\$6.36
69	Donor Organ Disposition	57	335.72	19,136	0.17	3,253.12	\$39.78	\$129,409.11
70	Transplant Center Contact Management	251	637.50	160,013	0.06	9,600.78	\$39.78	\$381,919.03
	Total = 70 forms	9,146		2,352,737		647,628.30		\$25,762,653.80

12A. Estimated Annualized Burden Hours:

Estimates are based on the number of OPTN members in each membership category (i.e., transplant center, OPO, histocompatibility laboratory) as of December 31, 2021, form submission volumes from January 1, 2021, to December 31, 2021, and average burden per response estimated by survey of OPTN members. 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 December 31, 2021, there are 251 transplant centers, 57 OPOs, 141 histocompatibility laboratories, 145 transplant centers with heart programs, 70 transplant centers with heart-lung programs, 72 transplant centers with lung programs, 234 transplant centers with kidney programs, 143 transplant centers with liver programs, 21 transplant centers with intestine programs, 120 transplant centers with pancreas programs, 21 transplant centers with vascularized composite allograft (VCA) programs, 216 living donor programs, and 159 transplant centers participating in the Kidney Paired Donation Pilot program.

12B. Estimated Annualized Burden 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 August 5, 2022, for this position is \$39.78.

Planned frequency of information collection:

Frequency of information collection varies by form and data submission requirements are specified in OPTN Policy 18.

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

(a) Total Capital costs and start-up costs component:

The OPTN Computer System has been in place for many years; there are no capital or start-up costs for the basic network. The system is internet-based and, therefore, does not carry capital or start-up costs. Additionally, facilities are equipped with PCs and Internet connections and should incur no costs.

(b) Total Operation and maintenance and purchase of services component:

Users have computers for their normal business activities and, therefore, will not need to change maintenance practices for this purpose. Some users have internal import/export systems that assist in the completion of these forms via their electronic medical record systems. These systems may require some cost to be developed, resulting in cost to respondents. Transplant centers are responsible for all of the proposed data collection modifications and are routinely responsible for a majority of the data collection volume. Majority of cost are attributable to respondents' staff time.

14. Annualized Cost to Federal 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	\$3,745,800
2. Fringe Benefits	\$1,584,900
3. Travel	0
4. Other Direct Costs	\$1,639,500
Total Direct Costs	\$6,970,200

5. Indirect Costs	\$918,700
TOTAL ESTIMATED COST	\$ 7,888,900*

* The OPTN is a cost-share contract with the contractor contributing 92.4 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 2023 is \$600,500.

15. Explanation for Program Changes or Adjustments

The burden estimates, reported in Section 12, are derived from Burden Surveys sent out by the OPTN Contractor to the OPTN members who have participated in this data collection activity. The survey is sent to 9 members per form. The survey includes the form and instructions and asks respondents to estimate the time and effort spent for (A) reviewing instructions, (B) searching and gathering information, (C) preparing required documentation, and (D) completing the necessary fields of the application. The survey results are collected from the respondents, and the Average Burden is calculated. Using annual data from the prior year, each form's Total Burden Hours are calculated as follows; Number of Respondents multiplied by the Number of Responses per Respondent multiplied by the Average Burden per Response (in hours). The total estimated burden hours for this collection increased by 217,366 hours from the previously approved data collection package from March 22, 2022. This increase is for the most part due to the addition of eight collection forms from the OPTN donor management and organ matching system to this data collection package, specifically, the burden increase from the Potential Transplant Recipient form, as mentioned in the 30-day FRN.

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

The OPTN data is used to produce annual, and biannual reports to Congress, and these data are published online in the OPTN/SRTR Annual Data Report: [Current Annual ADR \(hrsa.gov\)](https://www.hrsa.gov/opa/annual-data-report)

The 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.

Routine uses of records maintained in the system include the disclosure to physicians or other health care professionals providing clinical treatment to such individuals for clinical purposes, as outlined in the System of Record Notice (SORN).

HRSA provides selected OPTN data to the public through the HRSA Health Data Warehouse at www.data.hrsa.gov.

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.