**Health Resources and Services Administration**

**Supporting Statement A**

**Data System for Organ Procurement and**

**Transplantation Network**

**OMB Control No. 0915-0157**

**Terms of Clearance:** None.

**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. Seventy forms (Forms 1-70 on the burden table in section 12) were approved on September 13, 2023, and expire on September 30, 2026. These are OPTN Board of Directors (BOD)-approved revisions to existing data collection forms to improve organ matching, allocation, and OPTN policy compliance. Eighty-three forms (Forms 71-153 on the burden table in Section 12) are new additions to the Information Collection. These data collection forms are used by transplant centers to add, update, or remove candidates from the OPTN organ transplant waiting list following completion of a patient’s evaluation. The information provided on these forms is critical for the OPTN electronic organ matching system, which uses it to identify suitable matches between potential recipients and available deceased donor organs.

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 United States (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 programs, organ procurement organizations (OPOs), and histocompatibility laboratories report data to the OPTN data system. The information is used to match donor organs with recipients, monitor member organization compliance with OPTN policies and requirements to guide organ allocation policy development, and report periodically on the clinical and scientific status of organ donation and transplantation in the U.S. 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 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 requirements 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 data uses. 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)). This data is available to OPTN members and the public.

Under the requirements of the Final Rule, the OPTN also must develop organ allocation policies and performance indicators that 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 timely and accurate data and information availability. 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 is 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/>. The OPTN and the SRTR contractors 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 at: [https://www.srtr.org/ww](https://www.srtr.org/). Additionally, HRSA uses data collected by the OPTN to monitor the OPTN contract and carry 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 minimize any intrusion into the immediate organ procurement and transplantation processes. For example, transplant candidates can be registered, and critical data regarding candidates can be 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 decrease. The estimated volume of direct connection varies by application. The majority of DonorNet and Transplant Information Electronic Data Interchange (TIEDI) data is submitted electronically. The majority of waitlist and Kidney Paired Donation (KPD) data is submitted manually. Moving forward, as OPTN members utilize available Application Programming Interfaces (also known as APIs), there should be some reduction in burden hours.

Due to the inclusion of additional forms in this information collection, the overall total burden hours increased; however, HRSA expects to see a reduction in burden hours in future collections due to the direct electronic data submission.

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](http://www.srtr.org/). Program-Specific Graft and Patient Survival data are available on [www.srtr.org](https://nih.sharepoint.com/sites/HRSA-HSB/Team/dot/ODEB%20Doc%20Library/OPERATIONS%20TEAM/Correspondence/OMB%20Packages/2023%200915-0157%20Data%20System%20R+/30-day%20FRN%20R+/www.srtr.org).

Weekly and monthly, the OPTN provides data to the Centers for Medicare and Medicaid Services (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 requires those heart transplant programs that receive OPTN 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 is included in the OPTN data requirements.

OPTN data also contribute to the United States Renal Data System, 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**

Frequency of collection varies by form and data submission requirements as specified in [OPTN Policy 18](https://optn.transplant.hrsa.gov/media/eavh5bf3/optn_policies.pdf). Timeliness in organ transplantation is critical because organ function will begin to deteriorate once cardiac and respiratory functions cease. For example, suppose donor organs are not listed within the OPTN Donor Data and Matching System as soon as they become available. In that case, 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 OPTN data collection has various expectations of timely submission as detailed in OPTN Policy 18, and further specified in OPTN Policy Table 18-1. Each form includes a component titled Section 3 Frequency ofReporting on the form itself. The frequency of reporting is based upon burden. Pertinent OPTN Policy describing member requirements for reporting is available at: URL[.https://optn.transplant.hrsa.gov/media/eavh5bf3/optn\_policies.pdf](https://optn.transplant.hrsa.gov/media/eavh5bf3/optn_policies.pdf)

The current method of collecting race and ethnicity data does not align with SPD-15 guidelines. Efforts to update the OPTN systems to support the revised categories have been limited by time constraints related to the expiration of the OPTN contract at the end of the year, budget, as well as by budgetary and workload challenges. Implementation of these changes is anticipated during the next contract cycle.

**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 Monday, November 1, 2024. 89 Fed. Reg. 87380. HRSA received five comments.

Public comments raised concerns about the financial burden of additional data collection and called for greater collaboration between transplant professionals, HRSA, and SRTR to eliminate redundancies and improve efficiency. Commenters also expressed concern that changes were communicated via the *Federal Register* instead of the OPTN public comment process, limiting input from the transplant community. Additionally, they sought clarification on discrepancies regarding which forms were designated as new and requested access to the data collection plans and draft instruments.

HRSA’s Health Systems Bureau carefully reviewed all public feedback submitted during the 60-day comment period and would like to clarify that the new forms in this package reflect existing data collection within the OPTN system. Over the past five years, HRSA, in coordination with the OPTN, has been executing a plan to receive OMB approval for all existing data collection in the OPTN computer system. The additional Waitlist forms included in this package represent the final set, thus completing the planned roadmap. This package now represents the total amount of the existing OPTN member burden. These forms were unavailable during the initial 60-day public comment period but will be included in the final draft submitted to OMB. The public will have another opportunity to review and provide comments during the 30-day FRN publication period.

1. In addition to these FRN public comment opportunities, OPTN had previously solicited input, through its policy development process, on each of the data collection instruments through four channels: Targeted outreach to relevant stakeholder organizations, including transplant professionals and patient groups.
2. Comments submitted by other OPTN committees.
3. In-person meetings across 11 OPTN regions.
4. An online OPTN public comment forum is open to all on the OPTN website.

HRSA welcomes participation from all interested individuals. HRSA seeks input from transplant candidates directly affected by policy changes and strongly encourages transplant professionals to provide input on the potential financial impacts of proposals. HRSA values all feedback and remains committed to reviewing and refining data collection efforts in collaboration with the OPTN. Additionally, the OPTN contract requires the OPTN Contractor to implement a direct electronic data submission plan and supplement official OPTN data with external sources. This approach aims to reduce the burden of data collection on OPTN members.

HRSA values all feedback and remains committed to reviewing and refining data collection efforts in collaboration with the OPTN.

**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 with other HHS agencies have been with CMS, NIH, CDC, and the Office of the Secretary.

OPTN data collection undergoes an additional public comment period of 55 days outside of the PRA process, during which the general public can submit their comments through a dedicated web page. [The OPTN Public comment](https://optn.transplant.hrsa.gov/policies-bylaws/public-comment/) period is an essential part of the policy development process that occurs twice each year. The OPTN policy development process incorporates public comment feedback on policy and bylaws. 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. Explanation 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 (NISTSP) 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 compliant solution, as well as Information Security Continuous Monitoring in accordance with Federal Information Security Modernization Act 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 they are authorized. The system times out users inactive for more than 30 minutes. Authorized individuals can only access the OPTN Computer System using a user ID and password with a 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, 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, a badge, fingerprint, and optical access are 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 to encrypt data in transit and at rest.

* 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. 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 is performed in accordance with NIST SP 800-88, Guidelines for Media Sanitization.

* Paper Documents

No paper data collection instruments are maintained.

* Confidentiality Agreements

All contractor 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 records system 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) include 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, adversely affecting 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 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.

**12. Estimates of Annualized Hour and Cost Burden**

Estimates are based on the number of OPTN members in each membership category (i.e., transplant center, OPO, histocompatibility laboratory) as of December 31, 2023; form submission volumes from January 1, 2023, to December 31, 2023; and average burden per response estimated by either a survey of OPTN members or consultation with OPTN committees. 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, 2023, there were 248 transplant centers, 56 OPOs, 138 histocompatibility laboratories, 149 transplant centers with heart program, 72 transplant centers with heart-lung program, 74 transplant centers with lung program, 228 transplant centers with kidney program, 142 transplant centers with liver program, 18 transplant centers with intestine program, 123 transplant centers with pancreas program, 16 transplant centers with pancreas islet program, 23 transplant centers with vascularized composite allograft (VCA) program, 207 transplant centers with living donor program, and 156 transplant centers participating in the Kidney Paired Donation Pilot program.

**12A. Estimated Annualized Burden Hours**

| Form # | Form Name | Number of Respondents | Number of Responses per Respondent \*\*\*, \*\*\*\* | Total Responses‡ | Average Burden per Response (in hours) | Total Burden Hours‡ |
| --- | --- | --- | --- | --- | --- | --- |
| 1 | Deceased Donor Registration | 56 | 414.71 | 23,224 | 0.48 | 11,148 |
| 2 | Living Donor Registration | 207 | 33.42 | 6,918 | 2.19 | 15,150 |
| 3 | Living Donor Follow-up | 207 | 94.86 | 19,636 | 1.52 | 29,847 |
| 4 | Donor Histocompatibility | 138 | 173.31 | 23,917 | 0.2 | 4,783 |
| 5 | Recipient Histocompatibility | 138 | 307.09 | 42,378 | 0.4 | 16,951 |
| 6 | Heart Transplant Candidate Registration | 149 | 38.5 | 5,737 | 0.9 | 5,163 |
| 7 | Heart Transplant Recipient Registration | 149 | 30.5 | 4,545 | 1.96 | 8,908 |
| 8 | Heart Transplant Recipient Follow Up (6 Month) | 149 | 27.79 | 4,141 | 0.4 | 1,656 |
| 9 | Heart Transplant Recipient Follow Up (1-5 Year) | 149 | 109.21 | 16,272 | 0.9 | 14,645 |
| 10 | Heart Transplant Recipient Follow Up (Post 5 Year) | 149 | 183.73 | 27,376 | 0.5 | 13,688 |
| 11 | Heart Post-Transplant Malignancy Form | 149 | 12.21 | 1,819 | 0.9 | 1,637 |
| 12 | Lung Transplant Candidate Registration | 74 | 45.36 | 3,357 | 0.95 | 3,189 |
| 13 | Lung Transplant Recipient Registration | 74 | 40.85 | 3,023 | 1.14 | 3,446 |
| 14 | Lung Transplant Recipient Follow Up (6 Month) | 74 | 35.96 | 2,661 | 0.5 | 1,331 |
| 15 | Lung Transplant Recipient Follow Up (1-5 Year) | 74 | 135.61 | 10,035 | 1.1 | 11,039 |
| 16 | Lung Transplant Recipient Follow Up (Post 5 Year) | 74 | 148.09 | 10,959 | 0.6 | 6,575 |
| 17 | Lung Post-Transplant Malignancy Form | 74 | 18.39 | 1,361 | 0.4 | 544 |
| 18 | Heart/Lung Transplant Candidate Registration | 72 | 1.03 | 74 | 1.16 | 86 |
| 19 | Heart/Lung Transplant Recipient Registration | 72 | 0.75 | 54 | 2.09 | 113 |
| 20 | Heart/Lung Transplant Recipient Follow Up (6 Month) | 72 | 0.64 | 46 | 0.8 | 37 |
| 21 | Heart/Lung Transplant Recipient Follow Up (1-5 Year) | 72 | 2.46 | 177 | 1.1 | 195 |
| 22 | Heart/Lung Transplant Recipient Follow Up (Post 5 Year) | 72 | 3.35 | 241 | 0.6 | 145 |
| 23 | Heart/Lung Post-Transplant Malignancy Form | 72 | 0.22 | 16 | 0.4 | 6 |
| 24 | Liver Transplant Candidate Registration | 142 | 103.39 | 14,681 | 0.8 | 11,745 |
| 25 | Liver Transplant Recipient Registration | 142 | 75.08 | 10,661 | 1.2 | 12,793 |
| 26 | Liver Transplant Recipient Follow Up (6 Month - 5 Year) | 142 | 344.55 | 48,926 | 1 | 48,926 |
| 27 | Liver Transplant Recipient Follow Up (Post 5 Year) | 142 | 427.56 | 60,714 | 0.5 | 30,357 |
| 28 | Liver Recipient Explant Pathology Form | 142 | 7.17 | 1,018 | 0.6 | 611 |
| 29 | Liver Post-Transplant Malignancy Form | 142 | 21.21 | 3,012 | 0.8 | 2,410 |
| 30 | Intestine Transplant Candidate Registration | 18 | 7.5 | 135 | 1.3 | 176 |
| 31 | Intestine Transplant Recipient Registration | 18 | 5.28 | 95 | 1.8 | 171 |
| 32 | Intestine Transplant Recipient Follow Up (6 Month - 5 Year) | 18 | 21.5 | 387 | 1.5 | 581 |
| 33 | Intestine Transplant Recipient Follow Up (Post 5 Year) | 18 | 49.61 | 893 | 0.4 | 357 |
| 34 | Intestine Post-Transplant Malignancy Form | 18 | 0.94 | 17 | 1 | 17 |
| 35 | Kidney Transplant Candidate Registration | 228 | 203.12 | 46,311 | 0.8 | 37,049 |
| 36 | Kidney Transplant Recipient Registration | 228 | 119.89 | 27,335 | 1.2 | 32,802 |
| 37 | Kidney Transplant Recipient Follow Up (6 Month - 5 Year) | 228 | 571.22 | 130,238 | 0.9 | 117,214 |
| 38 | Kidney Transplant Recipient Follow Up (Post 5 Year) | 228 | 565.59 | 128,955 | 0.5 | 64,478 |
| 39 | Kidney Post-Transplant Malignancy Form | 228 | 25.6 | 5,837 | 0.8 | 4,670 |
| 40 | Pancreas Transplant Candidate Registration | 123 | 2.63 | 323 | 0.6 | 194 |
| 41 | Pancreas Transplant Recipient Registration | 123 | 0.84 | 103 | 1.2 | 124 |
| 42 | Pancreas Transplant Recipient Follow Up (6 Month - 5 Year) | 123 | 5.05 | 621 | 0.5 | 311 |
| 43 | Pancreas Transplant Recipient Follow Up (Post 5 Year) | 123 | 17.11 | 2,105 | 0.5 | 1,052 |
| 44 | Pancreas Post-Transplant Malignancy Form | 123 | 0.76 | 93 | 0.6 | 56 |
| 45 | Kidney/Pancreas Transplant Candidate Registration | 123 | 12.94 | 1,592 | 0.6 | 955 |
| 46 | Kidney/Pancreas Transplant Recipient Registration | 123 | 6.59 | 811 | 1.2 | 973 |
| 47 | Kidney/Pancreas Transplant Recipient Follow Up (6 Month - 5 Year) | 123 | 38.12 | 4,689 | 0.5 | 2,345 |
| 48 | Kidney/Pancreas Transplant Recipient Follow Up (Post 5 Year) | 123 | 66.63 | 8,195 | 0.6 | 4,917 |
| 49 | Kidney/Pancreas Post-Transplant Malignancy Form | 123 | 2.24 | 276 | 0.4 | 110 |
| 50 | VCA Transplant Candidate Registration | 23 | 1 | 23 | 0.4 | 9 |
| 51 | VCA Transplant Recipient Registration | 23 | 0.39 | 9 | 1.36 | 12 |
| 52 | VCA Transplant Recipient Follow Up | 23 | 2.3 | 53 | 1.31 | 69 |
| 53 | Organ Labeling and Packaging | 56 | 298.27 | 16,703 | 0.18 | 3,007 |
| 54 | Organ Tracking and Validating | 304 | 20.36 | 6,189 | 0.08 | 495 |
| 55 | Kidney Paired Donation Candidate Registration | 156 | 0.34 | 53 | 0.26 | 14 |
| 56 | Kidney Paired Donation Donor Registration | 156 | 0.99 | 154 | 1.08 | 166 |
| 57 | Kidney Paired Donation Match Offer Management | 156 | 0.59 | 92 | 0.67 | 62 |
| 58 | Disease Transmission Event | 304 | 2.33 | 708 | 0.6 | 425 |
| 59 | Living Donor Event | 207 | 0.15 | 31 | 0.56 | 17 |
| 60 | Safety Situation | 442 | 0.93 | 411 | 0.24 | 99 |
| 61 | Potential Disease Transmission Report | 56 | 11.09 | 621 | 1.27 | 789 |
| 62 | Request to Unlock Form | 442 | 174.67 | 77,204 | 0.02 | 1,544 |
| 63 | Initial Donor Registration | 56 | 414.71 | 23,224 | 4.61 | 107,063 |
| 64 | OPO Notification Limit Administration | 56 | 9.52 | 533 | 0.17 | 91 |
| 65 | Potential Transplant Recipient | 304 | 6,017.74 | 1,829,393 | 0.05 | 91,470 |
| 66 | Death Notification Registration \* | 56 | 289.7 | 16,223 | 0.42 | 6,814 |
| 67 | Deceased Donor Death Referral \* | 56 | 58.11 | 3,254 | 0.5 | 1,627 |
| 68 | Donor Hospital Registration | 56 | 0.04 | 2 | 0.08 | 0 |
| 69 | Donor Organ Disposition | 56 | 414.71 | 23,224 | 0.17 | 3,948 |
| 70 | Transplant Center Contact Management | 248 | 808.1 | 200,409 | 0.06 | 12,025 |
| 71 | Adult Kidney Candidate Listing Registration \*\* | 228 | 204.93 | 46,724 | 0.52 | 24,296 |
| 72 | Pediatric Kidney Candidate Listing Registration \*\* | 101 | 11.66 | 1,178 | 0.47 | 554 |
| 73 | Adult Kidney Pancreas Candidate Listing Registration \*\* | 123 | 12.93 | 1,590 | 0.37 | 588 |
| 74 | Pediatric Kidney Pancreas Candidate Listing Registration \*\* | 29 | 0.07 | 2 | 0.3 | 1 |
| 75 | Adult Pancreas Candidate Listing Registration \*\* | 123 | 15.29 | 1,881 | 0.38 | 715 |
| 76 | Pediatric Pancreas Candidate Listing Registration \*\* | 30 | 1.13 | 34 | 0.38 | 13 |
| 77 | Adult Pancreas Islet Listing Registration \*\* | 16 | 2.06 | 33 | 0.38 | 13 |
| 78 | Pediatric Pancreas Islet Listing Registration \*\* | 16 | 0 | 0 | 0.33 | 0 |
| 79 | Adult Liver Candidate Listing Registration \*\* | 142 | 98.43 | 13,977 | 0.32 | 4,473 |
| 80 | Pediatric Liver Candidate Listing Registration \*\* | 57 | 12.37 | 705 | 0.4 | 282 |
| 81 | Adult Intestine Candidate Listing Registration \*\* | 18 | 4.94 | 89 | 0.38 | 34 |
| 82 | Pediatric Intestine Candidate Listing Registration \*\* | 18 | 2.56 | 46 | 0.43 | 20 |
| 83 | Adult Heart Candidate Listing Registration \*\* | 149 | 33.58 | 5,003 | 0.83 | 4,153 |
| 84 | Pediatric Heart Candidate Listing Registration \*\* | 64 | 11.47 | 734 | 0.58 | 426 |
| 85 | Adult HeartLung Candidate Listing Registration \*\* | 72 | 0.97 | 70 | 0.85 | 60 |
| 86 | Pediatric HeartLung Candidate Listing Registration \*\* | 27 | 0.15 | 4 | 0.93 | 4 |
| 87 | Adult Lung Candidate Listing Registration \*\* | 74 | 44.85 | 3,319 | 1 | 3,319 |
| 88 | Pediatric Lung Candidate Listing Registration \*\* | 45 | 0.84 | 38 | 0.83 | 32 |
| 89 | Candidate Registration Listing Removal \*\* | 248 | 289.27 | 71,739 | 0.18 | 12,913 |
| 90 | VCA Abdominal Wall Candidate Listing Registration \*\* | 8 | 0.38 | 3 | 0.33 | 1 |
| 91 | VCA External Male Genitalia Candidate Listing Registration \*\* | 2 | 0 | 0 | 0.33 | 0 |
| 92 | VCA Head and Neck Candidate Listing Registration \*\* | 10 | 0.5 | 5 | 0.33 | 2 |
| 93 | VCA Lower Limb Candidate Listing Registration \*\* | 4 | 0 | 0 | 0.33 | 0 |
| 94 | VCA Musculoskeletal Composite Graft Segment Candidate Listing Registration \*\* | 2 | 0 | 0 | 0.33 | 0 |
| 95 | VCA Other Genitourinary Organ Candidate Listing Registration \*\* | 3 | 0 | 0 | 0.33 | 0 |
| 96 | VCA Spleen Candidate Listing Registration \*\* | 0 | 0 | 0 | 0.33 | 0 |
| 97 | VCA Upper Limb Candidate Listing Registration \*\* | 11 | 0.27 | 3 | 0.33 | 1 |
| 98 | VCA Uterus Candidate Listing Registration \*\* | 6 | 2 | 12 | 0.33 | 4 |
| 99 | VCA Vascularized Gland Candidate Listing Registration \*\* | 8 | 0 | 0 | 0.33 | 0 |
| 100 | Organ Export Verification Form \*\* | 56 | 0.46 | 26 | 0.03 | 1 |
| 101 | OPTN Waiting Time Transfer Form \*\* | 248 | 5.54 | 1,374 | 0.23 | 316 |
| 102 | OPTN Waiting Time Modification Form \*\* | 248 | 59.4 | 14,731 | 0.22 | 3,241 |
| 103 | OPTN Renal Waiting Time Reinstatement Form \*\* | 228 | 1.21 | 276 | 0.27 | 75 |
| 104 | OPTN Pancreas Waiting Time Reinstatement Form \*\* | 123 | 0.03 | 4 | 0.2 | 1 |
| 105 | Intestinal Waiting Time Reinstatement Form \*\* | 18 | 0 | 0 | 0.25 | 0 |
| 106 | Prior Living Donor Priority \*\* | 228 | 0.25 | 57 | 0.27 | 15 |
| 107 | Kidney Minimum Acceptance Criteria \*\* | 228 | 0.47 | 107 | 0.3 | 32 |
| 108 | Adult Liver Status 1A Initial Justification and Extension Form \*\* | 142 | 2.31 | 328 | 0.57 | 187 |
| 109 | Pediatric Liver Status 1A Initial Justification and Extension Form \*\* | 57 | 2.3 | 131 | 0.57 | 75 |
| 110 | Pediatric Liver Status 1B Initial Justification and Extension Form \*\* | 57 | 5.61 | 320 | 0.47 | 150 |
| 111 | Liver Cholangiocarcinoma (CCA) Initial MELD/PELD Score Exception Form \*\* | 142 | 0.42 | 60 | 0.43 | 26 |
| 112 | Liver Cholangiocarcinoma (CCA) MELD/PELD Score Exception Extension Form \*\* | 142 | 0.34 | 48 | 0.32 | 15 |
| 113 | Liver Cystic Fibrosis (CF) Initial MELD/PELD Score Exception and Extension Form \*\* | 142 | 0.1 | 14 | 0.33 | 5 |
| 114 | Liver Familial Amyloid Polyneuropathy (FAP) Initial MELD/PELD Score Exception Form \*\* | 142 | 0.04 | 6 | 0.4 | 2 |
| 115 | Liver Familial Amyloid Polyneuropathy (FAP) MELD/PELD Score Exception Extension Form \*\* | 142 | 0.05 | 7 | 0.3 | 2 |
| 116 | Liver Hepatic Artery Thrombosis (HAT) Initial MELD/PELD Score Exception and Extension Form \*\* | 142 | 0.69 | 98 | 0.35 | 34 |
| 117 | Liver Hepatocellular Carcinoma (HCC) Initial MELD/PELD Score Exception Form \*\* | 142 | 23.3 | 3,309 | 0.47 | 1,555 |
| 118 | Liver Hepatocellular Carcinoma (HCC) MELD/PELD Score Exception Extension Form \*\* | 142 | 33.21 | 4,716 | 0.35 | 1,651 |
| 119 | Liver Hepatopulmonary Syndrome (HPS) Initial MELD/PELD Score Exception Form \*\* | 142 | 1.39 | 197 | 0.32 | 63 |
| 120 | Liver Hepatopulmonary Syndrome (HPS) MELD/PELD Score Exception Extension Form \*\* | 142 | 0.99 | 141 | 0.25 | 35 |
| 121 | Liver Metabolic Disease Initial MELD/PELD Score Exception and Extension Form \*\* | 142 | 0.77 | 109 | 0.28 | 31 |
| 122 | Liver Portopulmonary Hypertension Initial MELD/PELD Score Exception Form \*\* | 142 | 0.51 | 72 | 0.42 | 30 |
| 123 | Liver Portopulmonary Hypertension MELD/PELD Score Exception Extension Form \*\* | 142 | 0.36 | 51 | 0.33 | 17 |
| 124 | Liver Primary Hyperoxaluria Initial MELD/PELD Score Exception and Extension Form \*\* | 142 | 0.13 | 18 | 0.35 | 6 |
| 125 | Liver Other Diagnosis Initial MELD/PELD Score Exception and Extension Form \*\* | 142 | 12.03 | 1,708 | 0.35 | 598 |
| 126 | Pediatric Heart and HeartLung Status 1A Initial Justification Form \*\* | 64 | 16.06 | 1,028 | 0.52 | 535 |
| 127 | Pediatric Heart and HeartLung Status 1A Extension and Appeal Justification Forms \*\* | 64 | 54.61 | 3,495 | 0.47 | 1,643 |
| 128 | Pediatric Heart and HeartLung Status 1B Initial Justification Form \*\* | 64 | 7.31 | 468 | 0.42 | 197 |
| 129 | Adult Heart and HeartLung Status 1-6 Justification Form Demographic Data \*\* | 149 | 135.78 | 20,231 | 0.32 | 6,474 |
| 130 | Adult Heart and HeartLung Status 1-6 Justification Form Risk Stratification Data \*\* | 149 | 135.78 | 20,231 | 0.72 | 14,566 |
| 131 | Adult Heart and HeartLung Status 1 Initial Justification Form Medical Urgency Data \*\* | 149 | 5.69 | 848 | 0.58 | 492 |
| 132 | Adult Heart and HeartLung Status 1 Exception Extension Justification Form Medical Urgency Data \*\* | 149 | 0.46 | 69 | 0.33 | 23 |
| 133 | Adult Heart and HeartLung Status 1 Criteria 1 Extension Justification Form Medical Urgency Data \*\* | 149 | 0.43 | 64 | 0.53 | 34 |
| 134 | Adult Heart and HeartLung Status 2 Initial Justification Form Medical Urgency Data \*\* | 149 | 25.91 | 3,861 | 0.8 | 3,088 |
| 135 | Adult Heart and HeartLung Status 2 Exception Extension Justification Form Medical Urgency Data \*\* | 149 | 9.87 | 1,471 | 0.33 | 485 |
| 136 | Adult Heart and HeartLung Status 2 Criteria 1 Extension Justification Form Medical Urgency Data \*\* | 149 | 0.03 | 4 | 0.42 | 2 |
| 137 | Adult Heart and HeartLung Status 2 Criteria 4 Extension Justification Form Medical Urgency Data \*\* | 149 | 3.05 | 454 | 0.63 | 286 |
| 138 | Adult Heart and HeartLung Status 2 Criteria 5 Extension Justification Form Medical Urgency Data \*\* | 149 | 1.7 | 253 | 0.6 | 152 |
| 139 | Adult Heart and HeartLung Status 3 Initial Justification Form Medical Urgency Data \*\* | 149 | 11.91 | 1,775 | 0.63 | 1,118 |
| 140 | Adult Heart and HeartLung Status 3 Exception Extension Justification Form Medical Urgency Data \*\* | 149 | 6.88 | 1,025 | 0.33 | 338 |
| 141 | Adult Heart and HeartLung Status 3 Criteria 2 Extension Justification Form Medical Urgency Data \*\* | 149 | 0.64 | 95 | 0.32 | 30 |
| 142 | Adult Heart and HeartLung Status 3 Criteria 5 Extension Justification Form Medical Urgency Data \*\* | 149 | 0.11 | 16 | 0.48 | 8 |
| 143 | Adult Heart and HeartLung Status 4 Initial Justification Form Medical Urgency Data \*\* | 149 | 23.51 | 3,503 | 0.5 | 1,752 |
| 144 | Adult Heart and HeartLung Status 4 Exception Extension Justification Form Medical Urgency Data \*\* | 149 | 1.73 | 258 | 0.25 | 65 |
| 145 | Adult Heart and HeartLung Status 4 Criteria 2 Extension Justification Form Medical Urgency Data \*\* | 149 | 0.56 | 83 | 0.4 | 33 |
| 146 | Adult and Pediatric Lung and HeartLung Goal Exception Form \*\* | 149 | 3.72 | 554 | 0.75 | 416 |
| 147 | Pediatric Lung Priority 1 Status Justification Form \*\* | 45 | 1.16 | 52 | 0.33 | 17 |
| 148 | Review Board Voter Form \*\* | 248 | 22.46 | 5,570 | 0.23 | 1,281 |
| 149 | Living Donor Feedback Form \*\* | 207 | 37.73 | 7,810 | 0.13 | 1,015 |
| 150 | Extra Vessels Reporting Form \*\* | 248 | 53.71 | 13,320 | 0.03 | 400 |
| 151 | Non-US Transplants Reporting Form \*\* | 228 | 0 | 0 | 0.03 | 0 |
| 152 | Discrepant HLA Typings Reporting Form \*\* | 138 | 0.78 | 108 | 5.17 | 558 |
| 153 | Interim Event Reporting Form \*\* | 248 | 72.58 | 18,000 | 0.06 | 1,080 |
| Total | | 18,697 |  | 3,184,246 |  | 851,578 |

\* These two forms will not be used once the OPTN Process Data OMB package is approved and implemented. The OPTN Process Data OMB package is new and will be considered separate from this package. We are including these forms in this collection to avoid any lapse in approval of these forms while the OPTN Process Data package is being approved.

\*\* These are new forms.

\*\*\* The numbers of respondents and the numbers of total responses in the burden table were updated with 2023 OPTN data and reflect increases in the number of organ transplants and changes in the number of respondents (Transplant Centers, OPOs and Histocompatibility Labs).

\*\*\*\* If a form has 0.00 under average number of responses, this is an indicator that there were no submissions in calendar year 2023.

‡ Total responses and total burden hours are rounded up to the nearest whole number to ensure the Total Responses match what is sent to OMB for review in ROCIS.

**12B.**

Data collection and reporting is carried out at transplant programs, 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 the United States Department of Labor - Bureau of Labor Statistics [website](https://www.bls.gov/oes/2023/may/oes291141.htm). The median hourly wage as of May 2023, for this position is $ 41.38. Doubling the median hourly wage to account for overhead costs (e.g., benefits) brings the total hourly cost to $82.76. The total estimated burden hours across forms is $70,475,561.57 (see 12B).

**12B. Estimated Annualized Burden Costs**

| Form # | Form Name | Total Burden Hours | Hourly Wage Rate (x2) | Total Cost |
| --- | --- | --- | --- | --- |
| 1 | Deceased Donor Registration | 11,148 | $82.76 | $922,608.48 |
| 2 | Living Donor Registration | 15,150 | $82.76 | $1,253,814.00 |
| 3 | Living Donor Follow-up | 29,847 | $82.76 | $2,470,137.72 |
| 4 | Donor Histocompatibility | 4,783 | $82.76 | $395,841.08 |
| 5 | Recipient Histocompatibility | 16,951 | $82.76 | $1,402,864.76 |
| 6 | Heart Transplant Candidate Registration | 5,163 | $82.76 | $427,289.88 |
| 7 | Heart Transplant Recipient Registration | 8,908 | $82.76 | $737,226.08 |
| 8 | Heart Transplant Recipient Follow Up (6 Month) | 1,656 | $82.76 | $137,050.56 |
| 9 | Heart Transplant Recipient Follow Up (1-5 Year) | 14,645 | $82.76 | $1,212,020.20 |
| 10 | Heart Transplant Recipient Follow Up (Post 5 Year) | 13,688 | $82.76 | $1,132,818.88 |
| 11 | Heart Post-Transplant Malignancy Form | 1,637 | $82.76 | $135,478.12 |
| 12 | Lung Transplant Candidate Registration | 3,189 | $82.76 | $263,921.64 |
| 13 | Lung Transplant Recipient Registration | 3,446 | $82.76 | $285,190.96 |
| 14 | Lung Transplant Recipient Follow Up (6 Month) | 1,331 | $82.76 | $110,153.56 |
| 15 | Lung Transplant Recipient Follow Up (1-5 Year) | 11,039 | $82.76 | $913,587.64 |
| 16 | Lung Transplant Recipient Follow Up (Post 5 Year) | 6,575 | $82.76 | $544,147.00 |
| 17 | Lung Post-Transplant Malignancy Form | 544 | $82.76 | $45,021.44 |
| 18 | Heart/Lung Transplant Candidate Registration | 86 | $82.76 | $7,117.36 |
| 19 | Heart/Lung Transplant Recipient Registration | 113 | $82.76 | $9,351.88 |
| 20 | Heart/Lung Transplant Recipient Follow Up (6 Month) | 37 | $82.76 | $3,062.12 |
| 21 | Heart/Lung Transplant Recipient Follow Up (1-5 Year) | 195 | $82.76 | $16,138.20 |
| 22 | Heart/Lung Transplant Recipient Follow Up (Post 5 Year) | 145 | $82.76 | $12,000.20 |
| 23 | Heart/Lung Post-Transplant Malignancy Form | 6 | $82.76 | $496.56 |
| 24 | Liver Transplant Candidate Registration | 11,745 | $82.76 | $972,016.20 |
| 25 | Liver Transplant Recipient Registration | 12,793 | $82.76 | $1,058,748.68 |
| 26 | Liver Transplant Recipient Follow Up (6 Month - 5 Year) | 48,926 | $82.76 | $4,049,115.76 |
| 27 | Liver Transplant Recipient Follow Up (Post 5 Year) | 30,357 | $82.76 | $2,512,345.32 |
| 28 | Liver Recipient Explant Pathology Form | 611 | $82.76 | $50,566.36 |
| 29 | Liver Post-Transplant Malignancy Form | 2,410 | $82.76 | $199,451.60 |
| 30 | Intestine Transplant Candidate Registration | 176 | $82.76 | $14,565.76 |
| 31 | Intestine Transplant Recipient Registration | 171 | $82.76 | $14,151.96 |
| 32 | Intestine Transplant Recipient Follow Up (6 Month - 5 Year) | 581 | $82.76 | $48,083.56 |
| 33 | Intestine Transplant Recipient Follow Up (Post 5 Year) | 357 | $82.76 | $29,545.32 |
| 34 | Intestine Post-Transplant Malignancy Form | 17 | $82.76 | $1,406.92 |
| 35 | Kidney Transplant Candidate Registration | 37,049 | $82.76 | $3,066,175.24 |
| 36 | Kidney Transplant Recipient Registration | 32,802 | $82.76 | $2,714,693.52 |
| 37 | Kidney Transplant Recipient Follow Up (6 Month - 5 Year) | 117,214 | $82.76 | $9,700,630.64 |
| 38 | Kidney Transplant Recipient Follow Up (Post 5 Year) | 64,478 | $82.76 | $5,336,199.28 |
| 39 | Kidney Post-Transplant Malignancy Form | 4,670 | $82.76 | $386,489.20 |
| 40 | Pancreas Transplant Candidate Registration | 194 | $82.76 | $16,055.44 |
| 41 | Pancreas Transplant Recipient Registration | 124 | $82.76 | $10,262.24 |
| 42 | Pancreas Transplant Recipient Follow Up (6 Month - 5 Year) | 311 | $82.76 | $25,738.36 |
| 43 | Pancreas Transplant Recipient Follow Up (Post 5 Year) | 1,052 | $82.76 | $87,063.52 |
| 44 | Pancreas Post-Transplant Malignancy Form | 56 | $82.76 | $4,634.56 |
| 45 | Kidney/Pancreas Transplant Candidate Registration | 955 | $82.76 | $79,035.80 |
| 46 | Kidney/Pancreas Transplant Recipient Registration | 973 | $82.76 | $80,525.48 |
| 47 | Kidney/Pancreas Transplant Recipient Follow Up (6 Month - 5 Year) | 2,345 | $82.76 | $194,072.20 |
| 48 | Kidney/Pancreas Transplant Recipient Follow Up (Post 5 Year) | 4,917 | $82.76 | $406,930.92 |
| 49 | Kidney/Pancreas Post-Transplant Malignancy Form | 110 | $82.76 | $9,103.60 |
| 50 | VCA Transplant Candidate Registration | 9 | $82.76 | $744.84 |
| 51 | VCA Transplant Recipient Registration | 12 | $82.76 | $993.12 |
| 52 | VCA Transplant Recipient Follow Up | 69 | $82.76 | $5,710.44 |
| 53 | Organ Labeling and Packaging | 3,007 | $82.76 | $248,859.32 |
| 54 | Organ Tracking and Validating | 495 | $82.76 | $40,966.20 |
| 55 | Kidney Paired Donation Candidate Registration | 14 | $82.76 | $1,158.64 |
| 56 | Kidney Paired Donation Donor Registration | 166 | $82.76 | $13,738.16 |
| 57 | Kidney Paired Donation Match Offer Management | 62 | $82.76 | $5,131.12 |
| 58 | Disease Transmission Event | 425 | $82.76 | $35,173.00 |
| 59 | Living Donor Event | 17 | $82.76 | $1,406.92 |
| 60 | Safety Situation | 99 | $82.76 | $8,193.24 |
| 61 | Potential Disease Transmission Report | 789 | $82.76 | $65,297.64 |
| 62 | Request to Unlock Form | 1,544 | $82.76 | $127,781.44 |
| 63 | Initial Donor Registration | 107,063 | $82.76 | $8,860,533.88 |
| 64 | OPO Notification Limit Administration | 91 | $82.76 | $7,531.16 |
| 65 | Potential Transplant Recipient | 91,470 | $82.76 | $7,570,057.20 |
| 66 | Death Notification Registration | 6,814 | $82.76 | $563,926.64 |
| 67 | Deceased Donor Death Referral | 1,627 | $82.76 | $134,650.52 |
| 68 | Donor Hospital Registration | 0 | $82.76 | $0.00 |
| 69 | Donor Organ Disposition | 3,948 | $82.76 | $326,736.48 |
| 70 | Transplant Center Contact Management | 12,025 | $82.76 | $995,189.00 |
| 71 | Adult Kidney Candidate Listing Registration | 24,296 | $82.76 | $2,010,736.96 |
| 72 | Pediatric Kidney Candidate Listing Registration | 554 | $82.76 | $45,849.04 |
| 73 | Adult Kidney Pancreas Candidate Listing Registration | 588 | $82.76 | $48,662.88 |
| 74 | Pediatric Kidney Pancreas Candidate Listing Registration | 1 | $82.76 | $82.76 |
| 75 | Adult Pancreas Candidate Listing Registration | 715 | $82.76 | $59,173.40 |
| 76 | Pediatric Pancreas Candidate Listing Registration | 13 | $82.76 | $1,075.88 |
| 77 | Adult Pancreas Islet Listing Registration | 13 | $82.76 | $1,075.88 |
| 78 | Pediatric Pancreas Islet Listing Registration | 0 | $82.76 | $0.00 |
| 79 | Adult Liver Candidate Listing Registration | 4,473 | $82.76 | $370,185.48 |
| 80 | Pediatric Liver Candidate Listing Registration | 282 | $82.76 | $23,338.32 |
| 81 | Adult Intestine Candidate Listing Registration | 34 | $82.76 | $2,813.84 |
| 82 | Pediatric Intestine Candidate Listing Registration | 20 | $82.76 | $1,655.20 |
| 83 | Adult Heart Candidate Listing Registration | 4,153 | $82.76 | $343,702.28 |
| 84 | Pediatric Heart Candidate Listing Registration | 426 | $82.76 | $35,255.76 |
| 85 | Adult HeartLung Candidate Listing Registration | 60 | $82.76 | $4,965.60 |
| 86 | Pediatric HeartLung Candidate Listing Registration | 4 | $82.76 | $331.04 |
| 87 | Adult Lung Candidate Listing Registration | 3,319 | $82.76 | $274,680.44 |
| 88 | Pediatric Lung Candidate Listing Registration | 32 | $82.76 | $2,648.32 |
| 89 | Candidate Registration Listing Removal | 12,913 | $82.76 | $1,068,679.88 |
| 90 | VCA Abdominal Wall Candidate Listing Registration | 1 | $82.76 | $82.76 |
| 91 | VCA External Male Genitalia Candidate Listing Registration | 0 | $82.76 | $0.00 |
| 92 | VCA Head and Neck Candidate Listing Registration | 2 | $82.76 | $165.52 |
| 93 | VCA Lower Limb Candidate Listing Registration | 0 | $82.76 | $0.00 |
| 94 | VCA Musculoskeletal Composite Graft Segment Candidate Listing Registration | 0 | $82.76 | $0.00 |
| 95 | VCA Other Genitourinary Organ Candidate Listing Registration | 0 | $82.76 | $0.00 |
| 96 | VCA Spleen Candidate Listing Registration | 0 | $82.76 | $0.00 |
| 97 | VCA Upper Limb Candidate Listing Registration | 1 | $82.76 | $82.76 |
| 98 | VCA Uterus Candidate Listing Registration | 4 | $82.76 | $331.04 |
| 99 | VCA Vascularized Gland Candidate Listing Registration | 0 | $82.76 | $0.00 |
| 100 | Organ Export Verification Form | 1 | $82.76 | $82.76 |
| 101 | OPTN Waiting Time Transfer Form | 316 | $82.76 | $26,152.16 |
| 102 | OPTN Waiting Time Modification Form | 3,241 | $82.76 | $268,225.16 |
| 103 | OPTN Renal Waiting Time Reinstatement Form | 75 | $82.76 | $6,207.00 |
| 104 | OPTN Pancreas Waiting Time Reinstatement Form | 1 | $82.76 | $82.76 |
| 105 | Intestinal Waiting Time Reinstatement Form | 0 | $82.76 | $0.00 |
| 106 | Prior Living Donor Priority | 15 | $82.76 | $1,241.40 |
| 107 | Kidney Minimum Acceptance Criteria | 32 | $82.76 | $2,648.32 |
| 108 | Adult Liver Status 1A Initial Justification and Extension Form | 187 | $82.76 | $15,476.12 |
| 109 | Pediatric Liver Status 1A Initial Justification and Extension Form | 75 | $82.76 | $6,207.00 |
| 110 | Pediatric Liver Status 1B Initial Justification and Extension Form | 150 | $82.76 | $12,414.00 |
| 111 | Liver Cholangiocarcinoma (CCA) Initial MELD/PELD Score Exception Form | 26 | $82.76 | $2,151.76 |
| 112 | Liver Cholangiocarcinoma (CCA) MELD/PELD Score Exception Extension Form | 15 | $82.76 | $1,241.40 |
| 113 | Liver Cystic Fibrosis (CF) Initial MELD/PELD Score Exception and Extension Form | 5 | $82.76 | $413.80 |
| 114 | Liver Familial Amyloid Polyneuropathy (FAP) Initial MELD/PELD Score Exception Form | 2 | $82.76 | $165.52 |
| 115 | Liver Familial Amyloid Polyneuropathy (FAP) MELD/PELD Score Exception Extension Form | 2 | $82.76 | $165.52 |
| 116 | Liver Hepatic Artery Thrombosis (HAT) Initial MELD/PELD Score Exception and Extension Form | 34 | $82.76 | $2,813.84 |
| 117 | Liver Hepatocellular Carcinoma (HCC) Initial MELD/PELD Score Exception Form | 1,555 | $82.76 | $128,691.80 |
| 118 | Liver Hepatocellular Carcinoma (HCC) MELD/PELD Score Exception Extension Form | 1,651 | $82.76 | $136,636.76 |
| 119 | Liver Hepatopulmonary Syndrome (HPS) Initial MELD/PELD Score Exception Form | 63 | $82.76 | $5,213.88 |
| 120 | Liver Hepatopulmonary Syndrome (HPS) MELD/PELD Score Exception Extension Form | 35 | $82.76 | $2,896.60 |
| 121 | Liver Metabolic Disease Initial MELD/PELD Score Exception and Extension Form | 31 | $82.76 | $2,565.56 |
| 122 | Liver Portopulmonary Hypertension Initial MELD/PELD Score Exception Form | 30 | $82.76 | $2,482.80 |
| 123 | Liver Portopulmonary Hypertension MELD/PELD Score Exception Extension Form | 17 | $82.76 | $1,406.92 |
| 124 | Liver Primary Hyperoxaluria Initial MELD/PELD Score Exception and Extension Form | 6 | $82.76 | $496.56 |
| 125 | Liver Other Diagnosis Initial MELD/PELD Score Exception and Extension Form | 598 | $82.76 | $49,490.48 |
| 126 | Pediatric Heart and HeartLung Status 1A Initial Justification Form | 535 | $82.76 | $44,276.60 |
| 127 | Pediatric Heart and HeartLung Status 1A Extension and Appeal Justification Forms | 1,643 | $82.76 | $135,974.68 |
| 128 | Pediatric Heart and HeartLung Status 1B Initial Justification Form | 197 | $82.76 | $16,303.72 |
| 129 | Adult Heart and HeartLung Status 1-6 Justification Form Demographic Data | 6,474 | $82.76 | $535,788.24 |
| 130 | Adult Heart and HeartLung Status 1-6 Justification Form Risk Stratification Data | 14,566 | $82.76 | $1,205,482.16 |
| 131 | Adult Heart and HeartLung Status 1 Initial Justification Form Medical Urgency Data | 492 | $82.76 | $40,717.92 |
| 132 | Adult Heart and HeartLung Status 1 Exception Extension Justification Form Medical Urgency Data | 23 | $82.76 | $1,903.48 |
| 133 | Adult Heart and HeartLung Status 1 Criteria 1 Extension Justification Form Medical Urgency Data | 34 | $82.76 | $2,813.84 |
| 134 | Adult Heart and HeartLung Status 2 Initial Justification Form Medical Urgency Data | 3,088 | $82.76 | $255,562.88 |
| 135 | Adult Heart and HeartLung Status 2 Exception Extension Justification Form Medical Urgency Data | 485 | $82.76 | $40,138.60 |
| 136 | Adult Heart and HeartLung Status 2 Criteria 1 Extension Justification Form Medical Urgency Data | 2 | $82.76 | $165.52 |
| 137 | Adult Heart and HeartLung Status 2 Criteria 4 Extension Justification Form Medical Urgency Data | 286 | $82.76 | $23,669.36 |
| 138 | Adult Heart and HeartLung Status 2 Criteria 5 Extension Justification Form Medical Urgency Data | 152 | $82.76 | $12,579.52 |
| 139 | Adult Heart and HeartLung Status 3 Initial Justification Form Medical Urgency Data | 1,118 | $82.76 | $92,525.68 |
| 140 | Adult Heart and HeartLung Status 3 Exception Extension Justification Form Medical Urgency Data | 338 | $82.76 | $27,972.88 |
| 141 | Adult Heart and HeartLung Status 3 Criteria 2 Extension Justification Form Medical Urgency Data | 30 | $82.76 | $2,482.80 |
| 142 | Adult Heart and HeartLung Status 3 Criteria 5 Extension Justification Form Medical Urgency Data | 8 | $82.76 | $662.08 |
| 143 | Adult Heart and HeartLung Status 4 Initial Justification Form Medical Urgency Data | 1,752 | $82.76 | $144,995.52 |
| 144 | Adult Heart and HeartLung Status 4 Exception Extension Justification Form Medical Urgency Data | 65 | $82.76 | $5,379.40 |
| 145 | Adult Heart and HeartLung Status 4 Criteria 2 Extension Justification Form Medical Urgency Data | 33 | $82.76 | $2,731.08 |
| 146 | Adult and Pediatric Lung and HeartLung Goal Exception Form | 416 | $82.76 | $34,428.16 |
| 147 | Pediatric Lung Priority 1 Status Justification Form | 17 | $82.76 | $1,406.92 |
| 148 | Review Board Voter Form | 1,281 | $82.76 | $106,015.56 |
| 149 | Living Donor Feedback Form | 1,015 | $82.76 | $84,001.40 |
| 150 | Extra Vessels Reporting Form | 400 | $82.76 | $33,104.00 |
| 151 | Non-US Transplants Reporting Form | 0 | $82.76 | $0.00 |
| 152 | Discrepant HLA Typings Reporting Form | 558 | $82.76 | $46,180.08 |
| 153 | Interim Event Reporting Form | 1,080 | $82.76 | $89,380.80 |
| Total | | 851,578 |  | $70,476,512.52 |

*Planned frequency of information collection:*

Frequency of information collection varies by form and data submission requirements are specified in [OPTN Policy 18](https://optn.transplant.hrsa.gov/media/eavh5bf3/optn_policies.pdf).

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

Costs

1. 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 personal computers and Internet connections and should incur no costs.

1. 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 proposed data collection modifications and are routinely responsible for most of the data collection volume. Most of the costs 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.

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

Direct Cost

1. Direct Salaries and Wages                                                       $3,886,200

2. Fringe Benefits                                                                           $1,921,300

3. Travel                                                                                                 0

4. Other Direct Costs                                                                      $1,735,100

                Total Direct Costs                                                           $7,542,600

5. Indirect Costs                                                                               $1,018,300

                TOTAL ESTIMATED COST                                          $ 8,560,900\*

\* The OPTN is a cost-share contract with the contractor contributing 92.99 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 2024 is $600,530.

**15. Explanation for Program Changes or Adjustments**

The burden estimates for Form 1 to 70 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.

To improve reliability, consistency, and accuracy of burden estimates, OPTN piloted the consultation method recommended in “A Guide to the Paperwork Reduction Act” ([website](https://pra.digital.gov/burden/)) for the forms added to this information collection in this revision. That is to base OPTN’s burden hour estimates on consultation with a representative sample of potential respondents. Therefore, the burden estimates for Form 71 to 153, reported in Section 12, are derived from consultation with the Transplant Administrator Committee. The committee consists of 19 volunteer members from the transplant community. The committee reviewed the forms and instructions and determined the estimates through consensus among the committee members in meetings. To prepare for the burden consultation meetings, some committee members asked the subject experts in their organization for input.

Unlike the survey method, the PRA guidance for the consultation method does not limit the number of participants.

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 estimated burden hours for this collection increased by 203,945 hours from the currently approved ICR package. This increase included 96,156 hours due to the addition of 83 new data collection forms for the OPTN waiting list and 107,789 hours due to OPTN BOD-approved data collection changes to existing forms and changes in the number of respondents.

**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://srtr.transplant.hrsa.gov/annual_reports/Default.aspx).

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](http://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 (09-15-0055).

HRSA provides selected OPTN data to the public through the HRSA Health Data Warehouse at <https://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.