

SUPPORTING STATEMENT

Data System for Organ Procurement and Transplantation Network

OMB Control No. 0915-0157

Highlighted text is the information changed from the last request.

Terms of Clearance: None

A. Justification

1. Circumstances of Information Collection

This is a request for OMB approval for the revision of the data system for the Organ Procurement and Transplantation Network (OPTN) and the following associated forms: 1) Deceased Donor Registration; 2) Living Donor Registration; 3) Living Donor Follow-Up; 4) Donor Histocompatibility; 5) Recipient Histocompatibility; 6) Heart Candidate Registration; 7) **Heart Recipient Registration**; 8) Heart Follow-Up (6-Months); 9) Heart Follow-Up (1-5 Years); 10) Heart Follow-Up (Post 5 Years); 11) Heart Post Transplant Malignancy; 12) Lung Candidate Registration; **13) Lung Recipient Registration; 14) Lung Follow-Up (6 Months); 15) Lung Follow-Up (1-5 Years)**; 16) Lung Follow-Up (Post 5 Years); 17) Lung Post Transplant Malignancy; 18) Heart/Lung Candidate Registration; **19) Heart/Lung Recipient Registration; 20) Heart/Lung Follow-Up (6 Month); 21) Heart/Lung Follow-Up (1-5 Years)**; 22) Heart/Lung Follow-Up (Post 5 Years) 23) Heart/Lung Post Transplant Malignancy 24) Liver Candidate Registration; **25) Liver Recipient Registration**; 26) Liver Follow-Up (6 Month -5 Years); 27) Liver Follow-Up (Post 5 Years); 28) Liver Recipient Explant Pathology; 29) Liver Post Transplant Malignancy Form 30) Intestine Candidate Registration; **31) Intestine Recipient Registration**; 32) Intestine Follow-Up (6 Month -5 Years); 33) Intestine Follow-Up (Post 5 Years); 34) Intestine Post Transplant Malignancy Form; 35) Kidney Candidate Registration; **36) Kidney Recipient Registration Form**; 37) Kidney Follow-Up (6 Month -5 Years); 38) Kidney Follow-Up (Post 5 Years); 39) Kidney Post Transplant Malignancy; **40) Pancreas Candidate Registration; 41) Pancreas Recipient Registration; 42) Pancreas Follow Up (6 Months -5 Years)**; 43) Pancreas Follow-Up (Post 5 Years); 44) Pancreas Post Transplant Malignancy; **45) Kidney/Pancreas Candidate Registration; 46) Kidney/Pancreas Recipient Registration; 47) Kidney/Pancreas Follow Up (6 Months – 5 Years)**; 48) Kidney/Pancreas (Post 5 Years); 49) Kidney/Pancreas Post Transplant Malignancy; 50) Vascularized Composite Allograft Candidate Registration; 51) Vascularized Composite Allograft Recipient Registration; 52) Vascularized Composite Allograft Recipient Follow-Up. Forms 1-52 are currently approved under OMB No. 0915-0157, which expires on February 28, 2018.

There are revisions to the existing data collection forms. The subset of forms (16) to be amended are denoted in bold. There are multiple additions and modifications to current fields. There is

only one deletion for this submission.

Section 372 of the Public Health Service (PHS) Act (42 USC 274) requires that the Secretary, by contract, provide for the establishment and operation of an Organ Procurement and Transplantation Network (OPTN). The OPTN, among other responsibilities, operates and maintains a national waiting list of individuals requiring organ transplants, maintains a computerized system for matching donor organs with transplant candidates on the waiting list, and operates a 24-hour system to facilitate matching organs with individuals included in the list.

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

2. Purpose and Use of Information

Data for the OPTN data system are collected from transplant hospitals, OPOs, and histocompatibility laboratories. The information is used to facilitate organ placement and match donor organs with recipients, monitor compliance of member organizations with Federal laws and regulations and with OPTN requirements, review and report periodically to the public on the status of organ donation and transplantation in the United States, provide data to researchers and government agencies to study the scientific and clinical status of organ transplantation, and perform transplantation-related public health surveillance including possible transmission of donor disease. OPTN members are assisted in these efforts by the Scientific Registry of Transplant Recipients (SRTR). The SRTR provides statistical and analytic support for the OPTN Board of Directors and committees, Health Resources and Services Administration (HRSA), and the Department of Health and Human Services (HHS) Advisory Committee on Organ Transplantation (ACOT). The SRTR contract currently is held by the Minneapolis Medical Research Foundation (MMRF). Analyses of OPTN data by the OPTN and SRTR are used for the same purposes of the information (described above). 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 Privacy Act System of Records Notice #09-15-0055 (Notification of an altered system of records was published in the Federal Register on November 4, 2009 (74 FR 57184)). The Division of Transplantation (DoT) must report a variety of data to the Secretary of HHS, including data on performance by organ and status category, program-specific data, OPO specific data, data by program size, and data aggregated by organ procurement area, OPTN region, States, the Nation as a whole, and other geographic areas (section 121.8(c)(3) of the final rule). Much of these data are made available to DoT, OPTN members, and the general public via DoT's contracts for the OPTN and SRTR.

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

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

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

3. Use of Improved Information Technology

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

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

Weekly, the OPTN provides a data tape of all newly collected data to CMS to aid in policy development and data analyses for the ESRD Program.

4. Efforts to Identify Duplication

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

- CMS, as a condition of approval for Medicare reimbursement for 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.
- In fulfilling P.L. 95-292 in part, CMS collected kidney transplant data as part of the ESRD Program Management and Medical Information System (PMMIS) data system, encompassing all dialysis and kidney transplant patients covered by the Medicare ESRD program. Some of the transplant data collected by the ESRD Program were the same as that collected for the OPTN data systems. This duplication of effort was recognized as a redundant reporting burden to providers of transplant services. CMS and HRSA agreed to have the OPTN become the sole collector of patient-specific kidney transplant data for these two data systems. In July 1994, the two systems were merged and the OPTN contractor, UNOS, became the sole collector of kidney data. Weekly, the data are transferred to CMS to be incorporated into the ESRD PMMIS.
- The ESRD patient registry is known as the United States Renal Data System and is operated under a contract awarded by NIH, National Institute of Diabetes and Digestive and Kidney Disease (NIDDK). Because the data for this patient registry come from the CMS ESRD PMMIS, the NIH/NIDDK also is considered an end user of this transplant data. Senior personnel of HRSA, CMS, and UNOS meet on an ad hoc basis to review any problems with the data transmission.

5. Involvement of Small Entities

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

6. Consequences if Information Collected Less Frequently

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

will be lower. Timeliness of post-transplant data collection is essential to advancing organ transplantation policy and science.

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

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

8. Consultation Outside the Agency

A 60-day Federal Register Notice was published in the *Federal Register* on March 14, 2016, vol. 81, No. 49, pp. 13378-80. There were no public comments.

The OPTN contractor consulted extensively with representatives of the providers of the data throughout the process of revising the OPTN data system. The contractor consulted with several OPTN Organ Specific Committees as well as the OPTN Policy Oversight Committee (POC). All of these committees are comprised of transplant surgeons, transplant physicians, patients, organ procurement representatives, and computer science specialists. All appropriate OPTN committees provided significant input on the forms. Additionally, each of these changes was included in the OPTN's public comment process associated with the related policy changes that necessitated the additional data collection. During the public comment process, feedback is gathered from relevant stakeholders and community members, including the American Society of Transplantation (AST) and American Society of Transplant Surgeons (ASTS). The changes to data collection in this package reflect input received during this process.

Research and data management staff employed by the OPTN contractor, UNOS, have reviewed these forms extensively and may be contacted at the following address:

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

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

Maureen McBride, PhD, Chief, Contract Operations Officer
Ryan Ehrensberger, PhD, Director Research
Leah Edwards, PhD, Assistant Director Research/Senior Research Scientist
Alexander Garza, Operations Analyst, Research Department

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

and Evaluation, DHHS.

9. Remuneration of Respondents

Respondents will not receive any payments or gifts.

10. Assurances of Confidentiality

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

Captured Accounts

All accounts utilized by organ procurement organizations, transplant centers, or histocompatibility laboratories are captured accounts. This means that, once an authorized individual gains access to the contractor's computer system by an account/password combination, he/she cannot execute any commands except those for which they are authorized. When he/she exits the contractor's software, he/she is automatically logged off the system.

Limited Access

There is extremely limited physical access to the contractor's computer system. The UNOS premises are personally monitored 24 hours a day, 7 days a week. No one can enter the computer area without authorization. There is an electronic pass-card-activated system in place. Card readers have been placed at the main building entrances, elevators, data center and all telecommunication access panels. In addition, for the data center and telecommunications panels, a pin code must be provided in addition to the pass card.

Encrypted Identifiers

Web authentication and authenticated web sessions are encrypted using SSL.

Disaster Recovery

The contractor maintains an up-to-date Continuity of Operations Plan (COOP) which contains emergency operations, backup operations, and recovery plans to ensure continuous operation of the system's facility. Testing of this system occurs every other week. The contractor uses a third party co-location site for its COOP.

Paper Documents

No paper documents 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 an altered system of records was published in the Federal Register on November 4, 2009 (74 FR 57184).

11. Questions of a Sensitive Nature

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

It is essential to ask questions regarding race and ethnicity for comparing the scientific and clinical outcomes among various minority populations, to evaluate access to transplantation, and to understand donation rates among various ethnic and racial populations. Race is not self-identified but is taken from existing donor or candidate records. In some donor cases, the race may be provided by donor families; more than one race category may be indicated. Ethnicity/Race was modified to add subcategories for each of the defined main categories and to provide more specific data concerning ethnicity when communicating with specific groups concerning donation and transplantation.

12. Estimates of Annualized Hour Burden

The following is an estimate of the annual respondent burden.

Form Name	Number of Respondents	Number of Responses per Respondent*	Total Responses	Average Burden per Response (in hours)	Total Burden Hours	Wage Rate	Total Hour Cost
Deceased Donor Registration	58	176.9	10262	1.1	11288.2	34.14	385379.11
Living Donor Registration	304	19.5	5936	1.8	10684.8	34.14	364779.1
Living Donor Follow-Up	304	58.2	17686	1.3	22991.8	34.14	784940.1
Donor Histocompatibility	152	102.7	15611	0.2	3122.2	34.14	106591.9
Recipient Histocompatibility	152	183.0	27810	0.4	11124.0	34.14	379773.4
Heart Candidate Registration	137	32.4	4439	0.9	3995.1	34.14	136392.7
Heart Recipient Registration	137	20.5	2805	1.2	3366.0	34.14	114915.2
Heart Follow-Up (6 Months)	137	16.5	2261	0.4	904.4	34.14	30876.2
Heart Follow-Up (1-5 Years)	137	77.3	10595	0.9	9535.5	34.14	325542.0
Heart Follow-Up (Post 5 Years)	137	117.4	16085	0.5	8042.5	34.14	274571.0
Heart Post-Transplant	137	11.8	1623	0.9	1460.7	34.14	49868.3

Malignancy							
Lung Candidate Registration	70	37.0	2592	0.9	2332.8	34.14	79641.8
Lung Recipient Registration	70	29.4	2058	1.2	2469.6	34.14	84312.1
Lung Follow-Up (6 Months)	70	25.8	1809	0.5	904.5	34.14	30879.6
Lung Follow-Up (1-5 Years)	70	99.1	6939	1.1	7632.9	34.14	260587.2
Lung Follow-Up (Post 5 Years)	70	70.0	4898	0.6	2938.8	34.14	100330.6
Lung Post-Transplant Malignancy	70	15.8	1106	0.4	442.4	34.14	15103.5
Heart/Lung Candidate Registration	68	0.7	46	1.1	50.6	34.14	1727.5
Heart/Lung Recipient Registration	68	0.2	14	1.3	18.2	34.14	621.3
Heart/Lung Follow-Up (6 Months)	68	0.2	13	0.8	10.4	34.14	355.1
Heart/Lung Follow-Up (1-5 Years)	68	1.4	94	1.1	103.4	34.14	3530.1
Heart/Lung Follow-Up (Post 5 Years)	68	2.9	199	0.6	119.4	34.14	4076.3
Heart/Lung Post-Transplant Malignancy	68	0.3	21	0.4	8.4	34.14	286.8
Liver Candidate Registration	140	85.9	12026	0.8	9620.8	34.14	328454.1
Liver Recipient Registration	140	50.9	7125	1.2	8550.0	34.14	291897.0
Liver Follow-Up (6 Months - 5 Years)	140	235.6	32985	1	32985.0	34.14	1126107.9
Liver Follow-Up (Post 5 Years)	140	279.3	39108	0.5	19554.0	34.14	667573.6
Liver Recipient Explant Pathology	140	12.9	1812	0.6	1087.2	34.14	37117.0
Liver Post-Transplant Malignancy	140	14.2	1985	0.8	1588.0	34.14	54214.3
Intestine Candidate Registration	40	5.0	200	1.3	260.0	34.14	8876.4
Intestine Recipient Registration	40	3.5	141	1.8	253.8	34.14	8664.7
Intestine Follow-Up (6 Months - 5 Years)	40	13.3	530	1.5	795.0	34.14	27141.3
Intestine Follow-Up (Post 5 Years)	40	16.4	655	0.4	262.0	34.14	8944.7
Intestine Post-Transplant Malignancy	40	0.6	24	1	24.0	34.14	819.4
Kidney Candidate Registration	238	151.6	36076	0.8	28860.8	34.14	985307.7
Kidney Recipient Registration	238	75.2	17899	1.2	21478.8	34.14	733286.2
Kidney Follow-Up (6 Months - 5 Years)	238	383.3	91234	0.9	82110.6	34.14	2803255.9
Kidney Follow-Up (Post 5 Years)	238	375.9	89453	0.5	44726.5	34.14	1526962.7
Kidney Post-Transplant Malignancy	238	22.4	5327	0.8	4261.6	34.14	145491.0
Pancreas Candidate Registration	133	2.9	389	0.6	233.4	34.14	7968.3
Pancreas Recipient Registration	133	1.8	233	1.2	279.6	34.14	9545.5

Pancreas Follow-Up (6 Months - 5 Years)	133	9.4	1252	0.5	626.0	34.14	21371.6
Pancreas Follow-Up (Post 5 Years)	133	14.7	1953	0.5	976.5	34.14	33337.7
Pancreas Post-Transplant Malignancy	133	0.9	120	0.6	72.0	34.14	2458.1
Kidney/Pancreas Candidate Registration	133	9.5	1265	0.6	759.0	34.14	25912.3
Kidney/Pancreas Recipient Registration	133	5.4	718	1.2	861.6	34.14	29415.0
Kidney/Pancreas Follow-Up (6 Months - 5 Years)	133	32.0	4262	0.5	2131.0	34.14	72752.3
Kidney/Pancreas Follow-Up (Post 5 Years)	133	51.7	6876	0.6	4125.6	34.14	140848.0
Kidney/Pancreas Post-Transplant Malignancy Form	133	2.1	283	0.4	113.2	34.14	3864.6
VCA Candidate Registration	28	1.8	49	0.4	19.6	34.14	669.1
VCA Recipient Registration	28	1.8	49	1.3	63.7	34.14	2174.7
VCA Recipient Follow-Up	28	1.8	49	1	49.0	34.14	1672.9
Total	463**		488,980		370,274.9		\$12,641,185.1

*The Number of Responses per Respondent was calculated by dividing the Total Responses by the Number of Respondents and rounding to the nearest tenth.

** Total number of OPTN member institutions as of April 6, 2017. Number of respondents for transplant candidate or recipient forms based on the organ-specific programs associated with each form.

Basis for Burden Estimates:

The information collected through the burden assessment is based on an estimate of the average time required for selected participants to complete the current subset of forms scheduled to be updated.

These estimates are also based on the current number of OPTN members in each membership category (i.e. transplant center, OPO, histocompatibility laboratory). 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.

There are 152 histocompatibility laboratories that are members of the OPTN and have responsibility for completing the Donor Histocompatibility form and the Transplant Recipient Histocompatibility form.

As of April 6, 2017, there are 137 transplant centers with heart programs, 68 transplant centers with heart-lung programs, 70 transplant centers with lung programs, 238 transplant centers with kidney programs, 140 transplant centers with liver programs, 40 transplant centers with intestine programs, and 133 transplant centers with pancreas programs. They each complete a different Transplant Candidate Registration form, Transplant Recipient Registration form and Transplant Recipient Follow-up form. The Living Donor Registration (LDR) and Follow-up (LDF) forms are completed by the living donor components of the kidney and liver programs at transplant centers. There is a total of 304 components that are responsible for completing the LDRs and LDFs.

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

There are 26 transplant centers with OPTN approved VCA programs. These programs will complete the VCA Candidate Registration, VCA Recipient Registration, and VCA Follow Up forms.

The estimated number of responses is based on the form totals for 2015. The number of responses per respondent is calculated by dividing the number of responses by the number of respondents.

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

Basis for Hour Costs:

Data collection and reporting are 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 May 2015 for this position is \$34.14. The estimated cost to respondents is as follows: 370274.9 total burden hours x \$34.14 = \$12,641,186.79

13. Estimates of Annualized Cost Burden to Respondents

Capital costs and start-up costs:

The OPTN system has been in place for many years; there are no capital or start-up costs for the basic network. The UNetSM 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.

Operation and maintenance costs:

Users have computers for their normal business activities and, therefore, will not need to change maintenance practices for this purpose. Some users do have internal import/export systems that assist in the completion of these forms via their electronic medical record systems. Based on the burden assessment, Transplant Centers only reported an average annual indirect cost of \$46,000. Transplant centers are responsible for all of the proposed data collection modifications and are routinely responsible for a majority of the data collection volume.

14. Estimates of Annualized Cost to the Government

The annual cost to the Federal Government consists of those costs allocated to the data system

under the HRSA contract for the OPTN. There also is the cost to the government to monitor the data system which will be .05 FTE (contracting officer representative) at \$66.09 per hour (\$6,873.36 per year) and .20 FTE (public health analyst/statistician) at \$50.04 per hour (\$20,816.64 per year).

Listed below are costs from the 2015 OPTN budget for OPTN Task #4 “Implement and Maintain a Data Collection System and Website” and OPTN Task #10 “Receive and Transmit Data”. These tasks do not include costs for development and maintenance of OPTN systems and maintaining OPTN security requirements.

A. OPTN contract (HRSA 234-2005-37011C)

Total Direct Cost	
1. Direct Salaries and Wages	\$1,798,860
2. Fringe Benefits	\$768,653
3. Travel	\$0.00
4. Other Direct Costs	\$178,000
Total Direct Costs	\$2,745,513
Indirect Costs	\$408,533
TOTAL ESTIMATED COST	\$3,154,046*

* The OPTN is a cost-share contract with the contractor contributing 93.26 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 2015 is approximately \$212,524 annually.

15. Changes in Burden

Currently, there are a total of 370,274.9 burden hours in the OMB inventory. The total burden hours has decreased from the previous total burden of 373,729 by 3,454.1 hours. The decreased total burden may be attributable to the increase in the use of data import/export capabilities by OPTN members. This has lessened the manual data entry burden on OPTN member staff. Although the contractor submitted the entire form packet for review, the current submission only requires modifications to 16 forms. The changes in burden referenced in above table include all forms.

16. Time Schedule, Publication and Analysis Plans

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

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

17. Exemption for Display of Expiration Date

The expiration date will be displayed.

18. Certifications

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