SUPPORTING STATEMENT

Data System for Organ Procurement and Transplantation Network

OMB Control No. 0915-0157

A. Justification

1. Circumstances of Information Collection

This is a request for OMB approval for the revision of the data system for the Organ Procurement and Transplantation Network (OPTN) and the following associated forms: 1) Deceased Donor Registration; 2) Living Donor Registration; 3) Living Donor Follow-Up; 4) Donor Histocompatibility; 5) Recipient Histocompatibility; 6) Heart Candidate Registration; 7) Heart Recipient Registration; 8) Heart Follow-Up (6-Month); 9) Heart Follow-Up (1-5 Year); 10) Heart Follow-Up (Post 5 Year); 11) Heart Post Transplant Malignancy; 12) Lung Candidate Registration; 13) Lung Recipient Registration; 14) Lung Follow-Up (6 Month); 15) Lung Follow-Up (1-5 Year); 16) Lung Follow-Up (Post 5 Year); 17) Lung Post Transplant Malignancy; 18) Heart/Lung Candidate Registration; 19) Heart/Lung Recipient Registration; 20) Heart/Lung Follow-Up (6 Month); 21) Heart/Lung Follow-Up (1-5 Year); 22) Heart/Lung Follow-Up (Post 5 Year) 23) Heart/Lung Post Transplant Malignancy 24) Liver Candidate Registration; 25) Liver Recipient Registration; 26) Liver Follow-Up (6 Month -5 Year); 27) Liver Follow-Up (Post 5 Year); 28) Liver Post Transplant Malignancy Form 29) Intestine Candidate Registration; 30) Intestine Recipient Registration; 31) Intestine Follow-Up (6 Month - 5 Year); 32) Intestine Follow-Up (Post 5 Year); 33) Intestine Post Transplant Malignancy Form; 34) Kidney Candidate Registration; 35) Kidney Recipient Registration Form; 36) Kidney Follow-Up (6 Month -5 Year); 37) Kidney Follow-Up (Post 5 Year); 38) Kidney Post Transplant Malignancy; 39) Pancreas Candidate Registration; 40) Pancreas Recipient Registration; 41) Pancreas Follow Up (6 Month -5 Year); 42) Pancreas Follow-Up (Post 5 Year); 43) Pancreas Post Transplant Malignancy; 44) Kidney/Pancreas Candidate Registration; 45) Kidney/Pancreas Recipient Registration; 46) Kidney/Pancreas Follow Up (6 Month – 5 Year); 47) Kidney/Pancreas (Post 5 Year); 48) Kidney/Pancreas Post Transplant Malignancy; 49) Vascularized Composite Allograft Candidate Registration; 50) Vascularized Composite Allograft Recipient Registration; 51) Vascularized Composite Allograft Recipient Follow Up. Forms 1-48 form currently approved under OMB No. 0915-0157, which expires on March 31, 2015.

There are revisions to the existing data collection forms. For this submission, most optional fields have been deleted. Though there are some additions, the number of deletions will result in a net reduction of data elements on most of the forms. Some of the fields that remain are “read only” and are included on the forms for information purposes only.

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 match donor organs with recipients, to monitor compliance of member organizations with OPTN policies and requirements to guide organ allocation policy development, and to report periodically on the clinical and scientific status of organ donation and transplantation in this country. OPTN members are assisted in these efforts by the Scientific Registry of Transplant Recipients (SRTR). The SRTR provides statistical and analytic support for the OPTN Board of Directors and committees, HRSA, and the Department of Health and Human Services (HHS) Advisory Committee on Organ Transplantation (ACOT). The SRTR contract currently is held by the Minneapolis Medical Research Foundation (MMRF). 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.

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 September 8, 2003 (68 FR 52950)). The DoT must report a variety of data to the Secretary of HHS, including data on performance by organ and status category, program-specific data, OPO specific data, data by program size, and data aggregated by organ procurement area, OPTN region, States, the Nation as a whole, and other geographic areas (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 to Chronic Disease Research Group of the Minneapolis Medical Research Foundation (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 data are collected by the OPTN contractor and sent 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 systems 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.

On July 3, 2013, HHS modified the definition of an organ as defined in the OPTN Final Rule to now include Vascularized Composite Allografts (VCAs). As a result, HHS tasked UNOS to establish a new OPTN committee – the Vascular Composite Allograft Committee. The committee has developed data collection forms that are included in this submission. The VCA Candidate Registration, VCA Recipient Registration, and the VCA Recipient Follow Up will be implemented outside of the UNet^{SM} system for the time being. Although the forms will not be housed in the UNet^{SM} system, they will remain on the same approval schedule as the forms in this current 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 Web site, http://optn.transplant.hrsa.gov, and the SRTR website, www.srtr.org. Also, Program-Specific Graft and Patient Survival data are available on www.srtr.org.

Weekly, 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). This is the most comprehensive data analysis system for a single mode of therapy anywhere in the world. There are other single organ (e.g., kidney only) data collection efforts and these have been recognized under the contract in the development of the OPTN data systems and addressed as follows:

- CMS, as a condition of approval for Medicare reimbursement for heart transplant, requires those heart transplant programs which receive approval, to submit specified data on all their heart transplant recipients (not just those paid for by Medicare) to CMS. The data required by CMS are included in the OPTN data requirements.

- In fulfilling P.L. 95-292 in part, CMS collected kidney transplant data as part of the End Stage Renal Disease (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 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

The notice required by 5 CFR 1320.8(d) was published in the Federal Register (FRN) on September 8, 2014 (Vol.79 No.173, p.53203). No comments were received.

The contractor consulted extensively with representatives of the providers of the data throughout the process of revising the OPTN data system. The OPTN/UNOS Policy Oversight Committee (POC), comprised of transplant surgeons, transplant physicians, patients, organ procurement representatives, and computer science specialists has provided significant input on the forms. The POC operates under HRSA's OPTN contract as an OPTN committee. Additionally, the American Society of Transplant Surgeons (ASTS) and the American Society of Transplantation (AST) reviewed the proposed modifications and provided feedback. All proposed changes were also approved by the OPTN/UNOS Board of Directors.

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 include the following:

Maureen McBride, PhD, Chief, Contract Operations Officer
Leah Edwards, PhD, Senior Biostatistician, Assistant Director Research
Erick Edwards, PhD, Senior Biostatistician, Assistant Director Research
Wida Cherikh, PhD, Senior Biostatistician/Team Leader
Alexander Garza, Research 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.

A burden assessment was conducted with Transplant Center representatives consisting of an Administrative Director, an Executive Director, and a Vice President, Perioperative Services & Surgical Lines. All respondents were granted anonymity as part of their participation in the burden assessment. All of these individuals received the assessment on May 1, 2014. Responses were received on May 7, 2014; May 20, 2014; and June 3, 2014. For the OPO burden assessment, we contacted three representatives. These representatives consisted of a Chief Operating Officer, an Operations Director, and an Organ Program Director. All of these individuals received the assessment on May 1, 2014 and responses were received on May 2, 2014 and May 16, 2014. The burden assessment was sent to three laboratory representatives at a Histocompatibility Laboratory. These representatives consisted of an Executive Director of an Human Leukocyte Antigen (HLA) Laboratory, a Laboratory Manager, and a Director of a HLA Laboratory. These representatives received the assessment on May 1, 2014 and responses were received on May 1, 2014 and May 16, 2014.

9. Remuneration of Respondents

There is no remuneration to respondents.

10. Assurances of Confidentiality

All data collected will be subject to Privacy Act protection (Privacy Act System of Records #09-15-0055). Data collected under the OPTN and SRTR contracts also are well protected by a number of the contractor's security features. HRSA certifies that 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 systems 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 September 8, 2003 (68 FR 52950).

11. Questions of a Sensitive Nature

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

Social security numbers are requested on a 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 UNet^{SM} 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	Number of respondents	Responses per respondent	Total responses	Hours per response	Total burden hours	Wage Rate	Total Hour Cost
Deceased Donor Registration	58.0	158.2	9,175.6	1.1	10,093.2	33.13	334387.7
Living Donor Registration	296.0	20.2	5,979.2	1.8	10,762.6	33.13	356564.9
Living Donor Follow-up	296.0	59.5	17,612.0	1.3	22,895.6	33.13	758531.2
Donor Histocompatibility	154.0	94.8	14,599.2	0.2	2,919.8	33.13	96732.97
Recipient Histocompatibility	154.0	170.1	26,195.4	0.4	10,478.2	33.13	347142.8
Heart Candidate Registration	131.0	30.5	3,995.5	0.9	3,596.0	33.13	119135.5
Heart Recipient Registration	131.0	19.3	2,528.3	1.4	3,539.6	33.13	117266.9
Heart Follow Up (6 Month)	131.0	17.0	2,227.0	0.4	890.8	33.13	29512.2
Heart Follow Up (1-5 Year)	131.0	73.9	9,680.9	0.9	8,712.8	33.13	288655.1
Heart Follow Up (Post 5 Year)	131.0	115.2	15,091.2	0.5	7,545.6	33.13	249985.7
Heart Post-Transplant Malignancy Form	131.0	11.0	1,441.0	0.9	1,296.9	33.13	42966.3
Lung Candidate Registration	65.0	39.0	2,535.0	0.9	2,281.5	33.13	75586.1
Lung Recipient Registration	65.0	29.6	1,924.0	1.4	2,693.6	33.13	89238.97
Lung Follow Up (6 Month)	65.0	25.8	1,677.0	0.5	838.5	33.13	27779.51
Lung Follow Up (1-5 Year)	65.0	97.9	6,363.5	1.1	6,999.9	33.13	231906.7
Lung Follow Up (Post 5 Year)	65.0	64.6	4,199.0	0.6	2,519.4	33.13	83467.72

Lung Post-Transplant Malignancy Form	65.0	1.5	97.5	0.4	39.0	33.13	1292.07
Heart/Lung Candidate Registration	63.0	0.7	44.1	1.1	48.5	33.13	1606.805
Heart/Lung Recipient Registration	63.0	0.3	18.9	1.4	26.5	33.13	877.945
Heart/Lung Follow Up (6 Month)	63.0	0.3	18.9	0.8	15.1	33.13	500.263
Heart/Lung Follow Up (1-5 Year)	63.0	1.5	94.5	1.1	104.0	33.13	3445.52
Heart/Lung Follow Up (Post 5 Year)	63.0	3.1	195.3	0.6	117.2	33.13	3882.836
Heart/Lung Post-Transplant Malignancy Form	63.0	0.2	12.6	0.4	5.0	33.13	165.65
Liver Candidate Registration	136.0	88.6	12,049.6	0.8	9,639.7	33.13	319363.3
Liver Recipient Registration	136.0	47.5	6,460.0	1.3	8,398.0	33.13	278225.7
Liver Follow-up (6 Month – 5 Year)	136.0	229.4	31,198.4	1.0	31,198.4	33.13	1033603
Liver Follow-up (Post 5 Year)	136.0	254.6	34,625.6	0.5	17,312.8	33.13	573573.1
Liver Recipient Explant Pathology Form	136.0	12.2	1,659.2	0.6	995.5	33.13	32980.92
Liver Post-Transplant Malignancy	136.0	13.1	1,781.6	0.8	1,425.3	33.13	47220.19
Intestine Candidate Registration	41.0	4.4	180.4	1.3	234.5	33.13	7768.985
Intestine Recipient Registration	41.0	2.7	110.7	1.8	199.3	33.13	6602.809
Intestine Follow Up (6 Month – 5 Year)	41.0	13.3	545.3	1.5	818.0	33.13	27100.34
Intestine Follow Up (Post 5 Year)	41.0	13.5	553.5	0.4	221.4	33.13	7334.982
Intestine Post-Transplant Malignancy Form	41.0	0.6	24.6	1.0	24.6	33.13	814.998
Kidney Candidate Registration	235.0	161.2	37,882.0	0.8	30,305.6	33.13	1004025
Kidney Recipient Registration	235.0	71.9	16,896.5	1.3	21,965.5	33.13	727717
Kidney Follow-Up (6 Month – 5 Year)	235.0	376.3	88,430.5	0.9	79,587.5	33.13	2636734
Kidney Follow-up (Post 5 Year)	235.0	343.7	80,769.5	0.5	40,384.8	33.13	1337948
Kidney Post-Transplant Malignancy Form	235.0	17.9	4,206.5	0.8	3,365.2	33.13	111489.1
Pancreas Candidate Registration	135.0	3.5	472.5	0.9	425.3	33.13	14090.19
Pancreas Recipient Registration	135.0	1.9	256.5	1.1	282.2	33.13	9349.286
Pancreas Follow-up (6 Month – 5 Year)	135.0	10.4	1,404.0	1.0	1,404.0	33.13	46514.52
Pancreas Follow-up (Post 5 Year)	135.0	13.4	1,809.0	0.5	904.5	33.13	29966.09

Pancreas Post-Transplant Malignancy Form	135.0	0.8	108.0	0.6	64.8	33.13	2146.824
Kidney/Pancreas Candidate Registration	135.0	98.5	13,297.5	0.9	11,967.8	33.13	396493.2
Kidney/Pancreas Recipient Registration	135.0	5.6	756.0	1.1	831.6	33.13	27550.91
Kidney/Pancreas Follow-up (6 Month – 5 Year)	135.0	33.4	4,509.0	1.0	4,509.0	33.13	149383.2
Kidney/Pancreas Follow-up (Post 5 Year)	135.0	47.9	6,466.5	0.6	3,879.9	33.13	128541.1
Kidney/Pancreas Post-Transplant Malignancy Form	135.0	1.6	216.0	0.4	86.4	33.13	2862.432
Vascular Composite Allograft Candidate Registration	16.0	0.9	14.4	0.4	5.8	33.13	192.154
Vascular Composite Allograft Recipient Registration	16.0	0.9	14.4	1.3	18.7	33.13	619.531
Vascular Composite Allograft Recipient Follow Up	16.0	0.9	14.4	1.0	14.4	33.13	477.072
TOTAL	456*		472,417.7		368,889.8		

*Total number of OPTN member institutions as of 09/9/2014. Number of respondents for transplant candidate or recipient forms based on number of 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 in a pilot test to complete each form.

The Donor Registration forms are to be completed by OPOs certified by CMS. There are 58 OPOs.

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

There are 247 thoracic (131 heart, 63 heart-lung, 65 lung) transplant centers, 235 kidney transplant centers with kidney programs, 136 transplant centers with liver programs, 41 transplant centers with intestine programs, and 135 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 Living Donor Follow-up (LDF) forms are completed by the living donor components of the kidney and liver programs at transplant centers. There are a total of 230 living donor kidney components and 66 liver 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 16 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 2013. 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 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 http://www.bls.gov/OES/current/oes291141.htm. The mean hourly wage as of May 2013 for this position is $33.13. This is comparable to the average hourly wage data collected from nine (three transplant centers, three OPOs, and three Histocompatibility Laboratories) OPTN members who participated in the burden assessment pilot study . The estimated cost to respondents is as follows: 358,092.5 total burden hours x $33.13 = 11,863,604.53.

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 UNet^{SM} 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 pilot study, OPOs reported an average annual direct cost (e.g., software, consultants, etc.) of $2,500.00 and an average annual indirect cost (e.g., administrative staff, equipment rental, utilities, etc.) cost of $5,667.00 incurred by completing the Deceased Donor

Registration form. Histocompatibility Laboratories reported an average annual direct and indirect cost combined of $4,500.00 to complete the Recipient and Donor Histocompatibility forms. Transplant Centers reported a direct cost of $3,333.00 and an average annual indirect cost of $2,1667.00. Transplant centers are responsible for a majority of the data collection volume which could explain the substantial increase in cost compared to OPOs or Histocompatibility laboratories.

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 $53.14 per hour ($6,552.65 per year) and .20 FTE (public health analyst/statistician) at $56.01 per hour ($27,627.20 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
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 91.66 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 $263,047 annually.

15. Changes in Burden

Currently, there are a total of 358,092.5 burden hours in the OMB inventory. The total burden hours has increased since 2011 by 79,326 hours. This increase represents a change in burden estimates based on analysis of the most recent trends in OPTN data form submissions. The current estimates should be a more accurate reflection of total burden since the forms were broken out in a more granular fashion. The pilot study participants provided feedback on each type of form as opposed to grouping them only by organ. For example, a 6 month heart follow up form is much shorter than a 1-5 year heart follow up form and should not require as much effort to complete. There are several factors that must be considered when analyzing the

additional burden hours. OPTN policy mandates that transplant programs follow transplant recipients until graft failure, re-transplant or death. So as patient and graft survival increases the number of recipients still alive with a functioning graft increases, and the transplant centers will be responsible for completing more forms. Although it is a slight increase in the burden hours, the burden assessment took into account the three additional VCA forms. The frame work of the VCA forms is based on the current Liver Candidate Registration, Liver Recipient Registration and the Liver Recipient Follow Up. The burden hours for those forms were used for VCA as well since the forms are not currently active.

Looking forward, the burden time should trend slightly downward after the modifications from this submission.

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 6 months. These reports are published online at www.srtr.org. In addition, the data are used to produce an Annual Report 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.