

# Organ Procurement and Transplantation Network

## SUPPORTING STATEMENT

### 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 worksheets: 1) Kidney Transplant Candidate Registration worksheet; 2) Pancreas Transplant Candidate Registration worksheet; 3) Kidney/Pancreas Transplant Candidate Registration worksheet; 4) Intestine Transplant Candidate Registration worksheet; 5) Liver Transplant Candidate Registration worksheet; 6) Heart Transplant Candidate Registration worksheet; 7) Heart/Lung Transplant Candidate Registration worksheet; 8) Lung Transplant Candidate Registration worksheet; 9) Kidney Transplant Recipient Registration worksheet; 10) Pancreas Transplant Recipient Registration worksheet; 11) Kidney/Pancreas Transplant Recipient Registration worksheet; 12) Intestine Transplant Recipient Registration worksheet; 13) Liver Transplant Recipient Registration worksheet; 14) Thoracic Transplant Recipient Registration worksheet; 15) Kidney Transplant Recipient Followup worksheet; 16) Pancreas Transplant Recipient Followup worksheet; 17) Kidney/Pancreas Transplant Recipient Followup worksheet; 18) Intestine Transplant Recipient Followup worksheet; 19) Liver Transplant Recipient Followup worksheet; 20) Thoracic Transplant Recipient Followup worksheet; 21) Post Transplant Malignancy worksheet; 22) Deceased Donor Registration worksheet; 23) Living Donor Registration worksheet; 24) Living Donor 6-Month/Annual Follow-up worksheet; 25) Recipient Histocompatibility worksheet; 26) Donor Histocompatibility worksheet; and 27) Death Referral Data. The worksheets are currently approved under OMB No. 0915-0157, which expires on August 31, 2007.

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 Acollect, analyze and publish data concerning organ donation and transplants.©

The OPTN worksheets were originally developed by the OPTN Scientific Advisory Committee (SAC). HRSA does not develop or revise the data collection worksheets for the OPTN, but does have oversight responsibility for the contract with the United Network for Organ Sharing

(UNOS), the contractor for the OPTN. The worksheets presented here for approval have been reviewed and modified by the OPTN SAC where needed to reflect changing technology and medical practice. Revisions are intended to implement reduction in data collection for candidates and recipients, to provide additional information specific to pediatric patients and living donors and to clarify existing questions and pick lists. Each worksheet has a set of instructions and a document providing information on all data elements and any changes since the last clearance request.

The Division of Transplantation (DoT) of the Health Resources and Services Administration (HRSA) has reviewed the modified worksheets to assure they address legislative and regulatory data requirements and is submitting this request for approval of the revisions.

## 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 is the entity responsible to provide statistical and analytic support to OPTN members, 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 Arbor Research Collaborative for Health based in Ann Arbor, Michigan. OPTN and SRTR data and analysis are used to develop transplant, donation and allocation policies, to determine if institutional members are complying with policy, to determine member specific performance, to ensure patient safety when no alternative sources of data exist and to fulfill the requirement of the OPTN Final Rule. Data are available for statistical analysis of the End Stage Renal Disease (ESRD) Program as required by Section 1881 of the Social Security Act (42 USC 1395rr(c)(2)).

The practical utility of the data collection is further enhanced by requirements that the OPTN database must be made available, consistent with applicable laws, for use by the OPTN members, the SRTR, HHS, and in many circumstances others, for evaluation, research, patient information, and other important purposes. This disclosure is governed by 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 transmit proposed 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, review procedures, 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 Arbor Research Collaborative for Health (HRSA's SRTR contractor) by UNOS. Annually, the HHS releases an Annual Data Report. 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 Arbor Research, working collaboratively with HRSA, 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.ustransplant.org](http://www.ustransplant.org)).

The 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 needs 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.

Since the last OMB clearance several changes have been made to the existing worksheets.

Changes include:

- Implementation of reduction in data collection for candidates and recipients.
- \$ Clarification of existing fields. Clarifications were made based on feedback from data coordinators and UNOS' experience in conducting quality analysis on data received since the last modifications.
- \$ Collection of information to provide information specific to pediatric patients and living donors.

### 3. Use of Improved Information Technology

The OPTN is using electronic transfer of data 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 telephonic and electronic access by transplant programs and OPOs with the central OPTN/UNOS computer which maintains the national waiting list.

The OPTN utilizes a computer software program allowing centers to enter and edit data on-line. Since January 1, 2003, all data are submitted via the on-line system.

Similarly, the matching of organs with recipients is conducted through direct electronic access to the OPTN/UNOS computer via the internet or through direct telephonic access with the OPTN/UNOS Organ Center. All OPOs have been required to test the match run capability and accuracy of the internet-based system. Whether they add a donor directly into the system themselves or contact the OPTN/UNOS Organ Center to perform this task on their behalf, all donor information and donor-recipient matches will be processed by UNet<sup>SM</sup>. (UNet<sup>SM</sup> is UNOS= internet-based application for data submission by transplant centers and OPOs.)

To handle the increasing organ supply brought about through HRSA's Breakthrough Collaborative initiatives, the OPTN is implementing a strategy that will transform the current practice of notifying individual programs by phone or fax when an organ becomes available to one that will notify multiple programs simultaneously using advanced internet and telecommunications technologies. This system, known as DonorNet<sup>R</sup>, is undergoing a highly successful trial in the Middle Atlantic States and is scheduled to become the national system for organ placement by the end of April 2007.

All major reports issued under the OPTN contract are required to be available in electronic format. The Annual Data Report is available on CD and through the OPTN Web site, [www.optn.org](http://www.optn.org). Also, Specific Graft and Patient Survival data are available on [www.ustransplant.org](http://www.ustransplant.org).

Weekly, the OPTN provides a data tape of all newly collected data to the 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 organ donors, transplant candidates and transplant recipients for all solid organ transplants (i.e., kidney, heart, heart-lung, lung, liver, pancreas, kidney-pancreas, intestines). The final rule to include transplantation of human intestines within the definition of organs covered by the rules governing the operation of the OPTN was published in the Federal Register on March 9, 2007. 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.

§ The 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. CMS and HRSA

have agreed to have the OPTN provide CMS with all of the OPTN data relating to heart transplants, including recipient waiting lists to satisfy this requirement.

\$ 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 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, i.e., 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 March 7, 2007 (72 FR 10226). One letter was received from the National Kidney Foundation. However, the comment was not responsive to the FRN. The letter appears to be addressing an issue unrelated to the revised OPTN data collection instruments. Furthermore, the HRSA

Reports Clearance Officer was never contacted by the commenter requesting a copy of the draft data collection instruments or plans. We believe the commenter may have read the title in the FRN but did not read the notice in its entirety.

The contractor consulted extensively with representatives of the providers of the data throughout the process of revising the OPTN data system. The Policy Oversight Committee (POC), comprised of transplant surgeons, transplant physicians, patients, organ procurement representatives, and computer science specialists, has provided significant input on the worksheets. (The POC operates under HRSA's OPTN contract as an OPTN committee.)

The POC is chaired by:

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Research and data management staff employed by the OPTN contractor reviewed the worksheets, integrated comments from the transplant community and the POC, incorporated elements and specific responses from modifications and hand-written responses, and considered current and proposed analysis plans. The current contractor, UNOS, has reviewed these worksheets extensively and may be contacted at the following address:

United Network for Organ Sharing (UNOS)  
Contact Person: Paula Bryant  
700 North 4<sup>th</sup> Street  
Richmond, Virginia 23218  
Phone: 804/782-4824  
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Specific OPTN staff who provided considerable input on the development of the worksheets include the following:

Paula Bryant, M.B.A., Director, Data Management Services  
Berkeley Keck, BSN, M.P.H., Assistant Executive Director, Information Technology  
Maureen McBride, PhD, Director, Research

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. One result of these collaborations has been to add additional response categories to the existing OPTN data forms to comply with HHS needs.

#### 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' security system meets or exceeds the requirements as prescribed by OMB Circular A-130, Appendix III, A Security of Federal Automated Information Systems, @ and the Department's 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 A captured accounts. @ This means that, once an authorized individual gains access to the contractor's computer system 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. In addition to captured accounts, the user can gain access by an account/password combination.

##### 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

All data are encrypted in motion. All tapes sent offsite are encrypted.

##### 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

The contractor maintains all paper documents in locked cabinets with only certain personnel having access to the cabinets. In addition, the contractor has a shredder and any sensitive material which is no longer needed for maintenance of the records is shredded.

## 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).

The social security number is 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 on all worksheets except the Deceased Donor Registration worksheet.

### 11. Questions of a Sensitive Nature

The Organ Procurement Organizations 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.

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 records; more than one race category may be indicated. The ethnic/racial categories are only used on the Donor Registration worksheet, the Living Donor Registration Worksheet and the Transplant Candidate Registration worksheet are.

No other worksheets include racial or ethnic questions. A@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.

Worksheet	Number of respondents	Responses per respondents	Total responses	Hours per response	Total burden hours	Wage Rate	Total Hour Cost
Deceased Donor Registration	58	215	12,470	0.4200	5,237.4000	\$23.00	\$120,460.20
Death referral data	58	12	696	10.0000	6,960.0000	\$23.00	\$160,080
Living Donor Registration	711	10	7,110	0.4100	2,915.1000	\$23.00	\$67,047.30
Living Donor Follow-up	711	18	12,798	0.3300	4,223.3400	\$23.00	\$97,136.82
Donor Histocompatibility	154	95	14,630	0.0600	877.8000	\$23.00	\$20,189.40
Recipient Histocompatibility	154	172	26,488	0.1100	2,913.6800	\$23.00	\$67,014.64
Heart Candidate Registration	135	23	3,105	0.2800	869.4000	\$23.00	\$19,996.20
Lung Candidate Registration	67	27	1,809	0.2800	506.5200	\$23.00	\$11,649.96
Heart/Lung Candidate Registration	59	1	59	0.2800	16.5200	\$23.00	\$379.96
Thoracic Registration	135	27	3,645	0.4400	1,603.8000	\$23.00	\$36,887.40
Thoracic Follow-up	135	229	30,915	0.4130	12,767.8950	\$23.00	\$293,661.585
Kidney Candidate Registration	250	133	33,250	0.2800	9,310.0000	\$23.00	\$214,130
Kidney Registration	250	69	17,250	0.4400	7,590.0000	\$23.00	\$174,570
Kidney Follow-up	250	544	136,000	0.3332	45,315.2000	\$23.00	\$1,042,249.60
Liver Candidate Registration	125	89	11,125	0.2800	3,115.0000	\$23.00	\$71,645
Liver Registration	125	54	6,750	0.4000	2,700.0000	\$23.00	\$62,100
Liver Follow-up	125	383	47,875	0.3336	15,971.1000	\$23.00	\$367,335.30

Kidney/Pancreas Candidate Registration	146	12	1,752	0.2800	490.5600	\$23.00	\$11,282.88
Kidney/Pancreas Registration	146	7	1,022	0.5300	541.6600	\$23.00	\$12,458.18
Kidney/Pancreas Follow-up	146	65	9,490	0.5027	4,770.6230	\$23.00	\$109,724.329
Pancreas Candidate Registration	146	7	1,022	0.2800	286.1600	\$23.00	\$6,581.68
Pancreas Registration	146	3	438	0.4400	192.7200	\$23.00	\$4,432.56
Pancreas Follow-up	146	23	3,358	0.4133	1,387.8614	\$23.00	\$31,920.8122
Intestine Candidate Registration	45	8	360	0.2400	86.4000	\$23.00	\$1,987.20
Intestine Registration	45	4	180	0.5300	95.4000	\$23.00	\$2,194.20
Intestine Follow-up	45	17	765	0.5059	387.0135	\$23.00	\$8,901.3105
Post Transplant Malignancy	711	6	4,266	0.0800	341.2800	\$23.00	\$7,849.44
Total	923		388,628		131,472.4329		\$3,023,865.956

Basis for Burden Estimates:

The information collection burden is based on an estimate of the average time required for participants in a pre-test to complete each worksheet.

The Donor Registration worksheet and accompanying death referral data are to be completed by OPOs certified by CMS. There are 58 OPOs.

The Living Donor Registration and Follow-up worksheets are completed by the organ specific programs at the transplant centers.

There are 154 histocompatibility laboratories that are members of the OPTN and have responsibility for completing the Donor Histocompatibility worksheet and the Transplant Recipient Histocompatibility worksheet.

There are 135 thoracic (heart, heart-lung, lung) transplant centers, 250 kidney transplant centers, 125 liver transplant centers, 45 intestine transplant centers, and 146 pancreas transplant centers. They each complete a different Transplant Candidate Registration worksheet, Transplant

Recipient Registration worksheet and Transplant Recipient Follow-up worksheet.

Additional information related to Post Transplant Malignancy worksheet is completed by the organ specific programs at the transplant centers.

The estimated number of worksheets expected per year is based on trends of the last three years projected through 2010. The number of responses per respondent is estimated by dividing the number of responses by the number of respondents.

The difference in burden hours among the different worksheets relates both to the number of items on the worksheets 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 worksheets will vary among the respondents. Therefore, for purposes of estimating the cost to the respondents, an average hourly wage for a data coordinator has been used. The estimated cost to respondents is as follows: 131,472.4329 total burden hours x \$23.00 = \$3,023,865.956.

### 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<sup>SM</sup> system is internet-based and, therefore, does not carry capital or start-up costs. Additionally, most 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.

### 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 (project officer) at \$55.63 per hour (\$5,785.65 per year) and .20 FTE (statistician) at \$58.64 per hour (\$24,393.40 per year).

Listed below are costs from the 2007 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		\$761,746
2. Fringe Benefits		
	334,407	
3. Travel		1,000
4. Other Direct Costs		-
	<u>104,012</u>	
TOTAL		\$1,201,165
Indirect Costs		<u>\$200,595</u>
TOTAL ESTIMATED COST		\$1,401,760*

\*The OPTN is a cost-share contract with the contractor contributing 92.4 percent of this cost from patient registration fees. Thus, the estimated net cost to the Federal government for the performance of the contract tasks for data collection and dissemination in 2007 is approximately \$106,955 annually.

15. Changes in Burden

Currently there are a total of 84,057.90 burden hours in the OMB inventory. The Program is requesting 131,472.4329 hours - an increase of 47,414.5329 hours. This adjustment is the result of an increase in several areas; i.e., the number of kidney, liver, intestine, and pancreas transplant centers, which increases the numbers of responses per respondent; the number of living donor registrations and followup. The estimated hours per response for the existing worksheets have been modified. Previously only the time to enter the data was included in the estimated hours per response. The estimated hours per response for this submission include time to gather the information, review instructions if necessary and enter the data.

16. Time Schedule, Publication and Analysis Plans

As required, the 2005 Annual Data Report was submitted by the United Network for Organ Sharing (UNOS) and Arbor Research Collaborative for Health (AR) to HRSA. The form of data presentation is cross-tabulations with some data description. The Annual Data Report includes comparisons with previous years as well as aggregate data for all years for which data have been collected.

Data from the Scientific Registry of Transplant Recipients (SRTR) also are used to complete the Report of Center-Specific Graft and Patient Survival Rates. Center and OPO-Specific Reports

are updated and published to the internet every 6 months ([www.ustransplant.org](http://www.ustransplant.org)). Since 2001, the Center and OPO-Specific Reports have been issued 13 times, the most recent being January 2007. Risk modeling using logistic regression was used to calculate each transplant program's expected graft and survival rates based on their patient mix characteristics. Actual survival rates also were determined for each transplant program.

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.

