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) Deceased Donor Registration; 2) Death Referral Data; 3) Death Notification Referral – Eligible; 4) Death Notification Referral – Imminent; 5) Living Donor Registration; 6) Living Donor Follow-up; 7) Donor Histocompatibility; 8) Recipient Histocompatibility; 9) Heart Candidate Registration; 10) Lung Candidate Registration; 11) Heart/Lung Candidate Registration; 12) Thoracic Registration; 13) Thoracic Follow-up; 14) Kidney Candidate Registration; 15) Kidney Registration; 16) Kidney Follow-up; 17) Liver Candidate Registration; 18) Liver Registration; 19) Liver Explant Pathology; 20)Liver Follow-up; 21) Kidney/Pancreas Candidate Registration; 22) Kidney/Pancreas Registration; 23) Kidney/Pancreas Follow-Up; 24) Pancreas Candidate Registration; 25) Pancreas Registration; 26) Pancreas Follow-up; 27) Intestine Candidate Registration; 28) Intestine Registration; 29) Intestine Follow-up; 30) Post Transplant Malignancy. The worksheets are currently approved under OMB No. 0915-0157, which expires on February 29, 2012.

The OPTN is recommending addition of a new Liver Explant Pathology form to the OPTN data system. This new form was developed by the OPTN Liver and Intestinal Organ Transplantation Committee and will be used to collect pathology data on liver transplant recipients who received waitlist exception points as a result of a diagnosis of hepatocellular carcinoma. Existing OPTN policy requires submission of post-transplant pathology reports by fax transmission, and the proposed form will provide standardized collection of this already-required information.

There are also minor revisions to the existing data collection forms; the added fields were inadvertently left off of the forms at the time of the initial submission. Several of these fields are "read only" and are included on the forms for information purposes only. One field is proposed to be removed as it represented duplicative information.

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.

The OPTN worksheets were originally developed by the OPTN Scientific Advisory Committee (SAC).

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 the Minneapolis Medical Research Foundation (MMRF). 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 MMRF (HRSA=s SRTR

contractor) by UNOS, HRSA's OPTN contractor. 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, 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 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.

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 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 primarily conducted through direct electronic access to the OPTN/UNOS computer via the internet. Although, transplant centers and OPOs also have the ability to communicate with the OPTN Organ Center for this purpose, which can act on the transplant center or OPO's behalf in entering information into the electronic system. 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^{SM}. (UNet^{SM} is UNOS= internet-based application for data submission by transplant centers and OPOs.)

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, 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 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 November 29, 2011 (76 FR 73650-73651). 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 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.)

During this review, the POC was chaired by:

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

United Network for Organ Sharing (UNOS)
Contact Person: Paula Bryant
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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, Architecture, Standards and Quality
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, ASecurity 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 Acaptured 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.

No other worksheets include racial or ethnic questions. 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 respondents	Total responses	Hours per response	Total burden hours	Wage Rate	Total Hour Cost
Deceased Donor Registration	58	228	13,224	0.7500	9918.00	$23.00	$228,114.00
Death referral data	58	12	696	10.0000	6,960.00	$23.00	$160,080.00
Death Notification Referral – Eligible	58	145	8410	0.5000	4205.00	$23.00	$96,715.00
Death Notification Referral – Imminent	58	124	7192	0.5000	3596.00	$23.00	$82,708.00
Living Donor Registration	311	23	7153	0.6500	4649.45	$23.00	$106,937.35
Living Donor Follow-up	311	78	24,258	0.5000	12,129.00	$23.00	$278,967.00
Donor Histocompatibility	158	94	14,852	0.1000	1,485.20	$23.00	$34,159.60
Recipient Histocompatibility	158	171	27,018	0.2000	5,403.60	$23.00	$124,282.80
Heart Candidate Registration	131	27	3,537	0.5000	1,768.50	$23.00	$40,675.50
Lung Candidate Registration	66	41	2706	0.5000	1353.00	$23.00	$31,119.00
Heart/Lung Candidate Registration	50	1	50	0.5000	25.00	$23.00	$575.00
Thoracic Registration	131	34	4454	0.7500	3340.50	$23.00	$76,831.50
Thoracic Follow-up	131	277	36,287	0.6500	23,586.55	$23.00	$542,490.65
Kidney Candidate Registration	239	154	36,806	0.5000	18,403.00	$23.00	$423,269.00
Kidney Registration	239	72	17,208	0.7500	12,906.00	$23.00	$296,838.00
Kidney Follow-up *	239	693	165,627	0.5500	91,094.85	$23.00	$2,095,181.55
Liver Candidate Registration	132	98	12,936	0.5000	6,468.00	$23.00	$148,764.00
Liver Registration	132	48	6,336	0.6500	4,118.40	$23.00	$94,723.20

Liver Explant Pathology	132	11	1,452	0.3400	493.68	$23.00	$11,354.64
Liver Follow-up	132	459	60,588	0.5000	30,294.00	$23.00	$696,762.00
Kidney/Pancreas Candidate Registration	144	11	1,584	0.5000	792.00	$23.00	$18,216.00
Kidney/Pancreas Registration	144	6	864	0.9000	777.60	$23.00	$17,884.80
Kidney/Pancreas Follow-up	144	75	10,800	0.8500	9180.00	$23.00	$211,140.00
Pancreas Candidate Registration	144	4	576	0.5000	288.00	$23.00	$6624.00
Pancreas Islet Candidate Registration	23	5	115	0.5000	57.50	$23.00	$1322.50
Pancreas Registration	144	2	288	0.7500	216.00	$23.00	$4968.00
Pancreas Follow-up	144	23	3312	0.6500	2152.80	$23.00	$49,514.40
Intestine Candidate Registration	43	5	215	0.5000	107.50	$23.00	$2472.50
Intestine Registration	43	3	129	0.9000	116.10	$23.00	$2670.30
Intestine Follow-up	43	25	1075	0.8500	913.75	$23.00	$21,016.25
Post Transplant Malignancy	689	11	7579	0.2000	1515.80	$23.00	$34,863.40
Total *Includes an estimated 2,430 kidney transplant patients transplanted prior to the initiation of the data system.	905		478,270		258,314.78		5,941,239.94

Basis for Burden Estimates:

The information collection burden is based on an estimate of the average time required for participants in a pilot 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.
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 worksheet and the Transplant Recipient Histocompatibility worksheet.

There are 247 thoracic (131 heart, 50 heart-lung, 66 lung) transplant centers, 239 kidney transplant centers, 132 liver transplant centers, 43 intestine transplant centers, and 144 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 proposed liver explants pathology form would be completed by liver transplant centers.

The estimated number of worksheets expected per year is based on trends of the last three years projected through 2014. 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: 258,314.78 total burden hours x $23.00 = 5,941,239.94.

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.

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 $57.13 per hour ($5,941.52 per year) and .20 FTE (public health analyst/statistician) at $48.35 per hour ($20,113.60 per year).

Listed below are costs from the 2010 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	$863,245
2. Fringe Benefits	382,418
3. Travel	0
4. Other Direct Costs	88,908
Total Direct Costs	$1,334,571
Indirect Costs	$200,185
TOTAL ESTIMATED COST	$1,534,756*

*The OPTN is a cost-share contract with the contractor contributing 93.2 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 2010 is approximately $103,289 annually.

15. Changes in Burden

Currently there are a total of 278,765.9500 burden hours in the OMB inventory. The Program is requesting 258,314.78 hours - a decrease of 20,451.17 hours. This change represents a change in burden estimates based on analysis of the most recent trends in OPTN data form submissions.

The estimated number of worksheets expected per year is based on trends of the last three years projected through 2014. In the last submission of this data package in 2010, a significant increase in the burden hours – from 131,472.4329 burden hours to 278,765.9500 burden hours – was approved. This increase in the number of forms submitted was a largely a result of an increase in the number transplant centers and the number of surviving donors and recipients for whom follow-up forms are required. However, it appears that the analysis in 2010 may have overestimated the expected increases in some forms, especially in the numbers of expected kidney and liver candidate registration forms and kidney and liver registration forms. Therefore, based on the number of actual form submissions in the past year, the estimates were adjusted.

16. Time Schedule, Publication and Analysis Plans

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.srtr.org). 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.