

Supporting Statement A

Organ Procurement Transplantation Network (OPTN) Application Form

OMB Control No. 0915-0184 - Revision

Highlighted text is the information changed from the last request.

Terms of Clearance: None

A. Justification

1. Circumstances Making the Collection of Information Necessary

This is a request for OMB approval for a revision to the information collection activities for the application and membership requirements contained in the Final Rule Governing the Operation of the Organ Procurement and Transplantation Network (OPTN), (final rule). HRSA is proposing additions and revisions to selected documents used to collect information from existing or potential members of the OPTN. New membership forms have been created for transplant centers seeking to perform Vascularized Composite Allograft (VCA) transplants, a new and emerging field. This packet contains the membership application documents used to collect information required for membership in and designation of transplant programs by the OPTN. These documents are approved under OMB No. 0915-0184, and currently have an expiration date of May 31, 2017. The OPTN patient level forms associated with the registration, transplantation, and follow-up of transplant recipients are approved as a **separate activity** under OMB No. 0915-0157 and will not be updated at this time in this statement.

The National Organ Transplant Act of 1984, as amended, required the establishment of a unified transplant network to be operated by a private, non-profit organization under federal contract, 42 U.S.C. 273, et seq. Following task force recommendations and extensive public comment, a Final Rule (42 CFR Part 121) was published establishing a regulatory framework for the structure and operation of the OPTN. Policies of the OPTN are developed by professionals in the transplant community in an open environment that includes the public, including transplant patients and donor families. The United Network for Organ Sharing (UNOS), a private corporation, operates the OPTN under contract with the Department of Health and Human Services (HHS).

Membership in the OPTN is determined by submission of application materials to the OPTN (**not** to HRSA) demonstrating that the applicant meets all required criteria for membership

and will agree to comply with all applicable provisions of the National Organ Transplant Act, as amended, 42 U.S.C. 273, et seq. Section 1138 of the Social Security Act, as amended, 42 U.S.C. 1320b-8 (section 1138) requires that hospitals in which transplants are performed be members of, and abide by, the rules and requirements (as approved by the Secretary of the HHS) of the OPTN as a condition of participation in Medicare and Medicaid for the hospital. Section 1138 contains a similar provision for the organ procurement organizations (OPOs) and makes membership in the OPTN and compliance with its operating rules and requirements (that have been approved by the Secretary), including those relating to data collection, mandatory for all transplant hospitals and OPOs. In addition, hospitals wishing to obtain designation for specific (e.g., organ specific) transplant programs must submit applications to the OPTN.

Under Federal law, all U.S. transplant centers and organ procurement organizations must be members of the OPTN to receive any funds through Medicare. Other members of the OPTN include: independent histocompatibility laboratories involved in organ transplantation; relevant medical, scientific, and professional organizations; relevant voluntary health and patient advocacy organizations; and members of the general public with a particular interest in donation and/or transplantation.

The applications associated with this request provide the OPTN with information required to make determinations regarding compliance with membership and designated transplant program requirements established in OPTN policies and bylaws.

Under the regulations and the OPTN Contract, the OPTN has responsibility for developing policies and procedures. The OPTN final rule establishes a mechanism for the Secretary to approve or modify OPTN policies, if needed. The OPTN final rule did not alter the role of the OPTN in using its judgment regarding appropriate medical criteria for organ allocation or in the development of policies recommended for members; however, the final rule creates an enforceable standard that OPTN member transplant programs must meet to qualify to receive organs for transplantation.

2. Purpose and Use of Information Collection

The application materials are needed to ensure that all members and prospective members of the OPTN submit in an organized manner verifiable evidence that they meet the required qualifications, and the OPTN provides written confirmation of their rights and obligations as members. These materials provide the OPTN with information used for the following purposes:

- Application requirements are met and the OPTN demonstrates that all qualified entities are accepted for membership in the OPTN and designation of transplant programs, and that only qualified entities are accepted for membership or designation.
- Evidence of non-qualification can be documented and specific remedial or alternative action can be requested from the member.
- Evidence of non-qualification is collected and documented so a record exists of the application review process and resulting actions for consideration by the Secretary of HHS if an applicant subsequently appeals the rejection.

3. Use of Improved Information Technology and Burden Reduction

The OPTN membership criteria, bylaws, and application materials are available online at <http://optn.transplant.hrsa.gov/>. An executable electronic form of each application is available for completion and printing, but the application submission considered as final and retained in the database as the final product is on paper, as is much of the supporting documentation, letters of commitment, contracts, and required signatures. All final product records are saved and available in electronic format.

An electronic web based application system is in development. These applications are purposely designed to easily adapt for electronic execution and submission.

4. Efforts to Identify Duplication and Use of Similar Information

The information and supporting documentation provided for application for membership (and transplant program designation) in the OPTN does not exist in any current database or system. There is no other source available that could be used to determine whether applicants meet the required membership and designation criteria or compliance with current policies and bylaws.

5. Impact on Small Businesses or Other Small Entities

This activity will not be collecting any data from small businesses. The data collected will not have any significant impact on small business or other small entities.

6. Consequences of Collecting the Information Less Frequently

Organizations and institutions required by the Final Rule to be members of the OPTN and organizations interested in membership (and transplant program designation) in the OPTN must submit the application materials. Without this information, the OPTN cannot determine if the required criteria for membership and designation have been met or if members are compliant with OPTN bylaws and policies.

7. Special Circumstances Relating to the Guidelines of 5 CFR 1320.5

This data collection is consistent with the guidelines under 5 CFR 1320.5(d)(2). It fully complies with this regulation.

8. Comments in Response to the Federal Register Notice/Outside Consultation

- Federal Register, Volume 81 Issue 237 (Friday, December 9, 2016)

Pages 89115-89117

A 60-day Federal Register Notice was published in the *Federal Register* on Friday, December 9, 2016, vol. 81, No. 237; pp.89115-89117 (refer to [hyperlink](#)). There were no public comments.

The OPTN Charter and Bylaws were developed by the Executive and Membership and Professional Standards Committees, with input from other OPTN Committees, OPTN members, and the general public through the contractor's public comment process. The OPTN Charter and Bylaws became effective May 1, 2004 and are amended periodically.

The membership application forms incorporate applicable provisions of the OPTN Bylaws and Charter.

- Currently, every transplant hospital program, organ procurement organization, and histocompatibility laboratory in the United States is an OPTN member. Membership means that their transplant programs are approved by the OPTN, and that they play an active role in forming the policies that govern the transplant community. Individuals from member organizations participate in the decision making process through representation on committees and on the Board of Directors. Designation by transplant programs (e.g., kidney transplant programs) within transplant hospitals means that such programs can receive particular organs for transplantation.
- The following committees, comprised of transplant surgeons, transplant physicians, patients, organ procurement representatives, health policy analysts, and computer science specialists, have provided significant input to this process.

Board of Directors and Executive Committee

President, Stuart C Sweet, MD, PhD
St. Louis Children's Hospital
Email: sweet@kids.wustl.edu

Membership and Professional Standards Committee

Chairman, Jeffrey P. Orlowski, MS, CPTC
LifeShare Transplant Donor Services of Oklahoma
Email: Jorlowski@lifeshareok.org

Additionally, membership staff employed by the OPTN contractor reviewed the forms extensively. They integrated received comments and improvement suggestions along with incorporated revised elements from the current bylaws into these forms.

The current contractor, UNOS, may be contacted at the following address:

United Network for Organ Sharing (UNOS)
Contact Person: Jacqueline O'Keefe
700 North 4th Street
Richmond, Virginia 23218
Phone: 804/782-4800
Fax: 804/782-4896

Specific UNOS staff that provided considerable input on the development of the application forms and/or Charter and Bylaws includes the following:

Jacqueline O'Keefe, Assistant Director, Member Quality
Sally Aungier, Senior Membership Standards Advisor
Ellie Willard, Membership Manager

Chad Waller, Policy Analyst
Emily Kneipp, Senior Membership Analyst
Christi Wong, Senior Membership Analyst

9. Explanation of any Payment/Gift to Respondents

There is no remuneration to respondents.

10. Assurance of Confidentiality Provided to Respondents

The information required by the OPTN to apply for membership can include personally identifiable information on individuals. The application materials collect information on interested individuals seeking membership, organ procurement organizations, transplant hospitals, histocompatibility laboratories, and other organizations and institutions. All application materials received are permanently stored electronically. Processes and protocols to maintain documents confidentiality are imposed and adhered to by the OPTN contractor.

Data collected under the OPTN contract is well protected by a number of the contractor's security features. HRSA certifies that UNOS' security systems meet or exceed the requirements as prescribed by OMB Circular A-130, Appendix III, 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 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.

11. Justification for Sensitive Questions

Questions of a sensitive nature that may exist involving membership application materials are generally related to personnel moving between transplant programs or concern regarding potential competition for transplant business within regions. All membership information is handled with care and attention is given to the need for confidentiality. All staff and reviewing parties exposed to application related information sign confidentiality agreements and will receive training on keeping privileged information confidential.

12. Estimates of Annualized Hour and Cost Burden

12A. Estimated Annualized Burden Hours

Type of Respondent	Form Name	Number of Respondents	Number of Responses per Respondent	Total Responses	Average Burden per Response (in hours)	Total Burden Hours
Transplant administrator or designee	A New Transplant Member/Program Application- General	2	1	2	8	16
Transplant administrator or designee	B Kidney (KI) Designated Program Application	118	2	236	4	944
Transplant administrator or designee	B Liver (LI) Designated Program Application	59	2	118	4	472
Transplant administrator or designee	B Pancreas (PA) Designated Program Application	60	2	120	4	480
Transplant administrator or designee	B Heart (HR) Designated Program Application	92	2	184	4	736
Transplant administrator or designee	B Lung (LU) Designated Program Application	30	2	60	4	240
Transplant administrator or designee	B Islet (PI) Designated Program Application	2	2	4	3	12
Transplant administrator or designee	B Living Donor (LD) Recovery Program Application	42	2	84	3	252
Transplant administrator or designee	B VCA Head and Neck Designated Program Application	14	2	28	3	84
Transplant administrator or designee	B VCA Upper Limb Designated Program Application	17	2	34	3	102
Transplant administrator	B VCA Abdominal Wall* Designated Program	13	2	26	3	78

Type of Respondent	Form Name	Number of Respondents	Number of Responses per Respondent	Total Responses	Average Burden per Response (in hours)	Total Burden Hours
or designee	Application					
Transplant administrator or designee	VCA Abdominal Wall - Kidney					
Transplant administrator or designee	VCA Abdominal Wall - Liver					
Transplant administrator or designee	VCA Abdominal Wall - Pancreas					
Transplant administrator or designee	VCA Abdominal Wall - Intestine					
Transplant administrator or designee	B VCA Other** Designated Program Application	9	2	18	2	36
Transplant administrator or designee	B Intestine Designated Program Application	40	2	80	3	240
OPO Director or designee	C OPO New Application	0	1	0	4	0
Lab Director or designee	D Histocompatibility Lab Application	3	2	6	4	24
Transplant administrator or designee	E Change in Transplant Program Key Personnel	395	2	790	4	3160
Lab Director or designee	F Change in Histocompatibility Lab Director	25	2	50	2	100
OPO Director or designee	G Change in OPO Key Personnel	10	1	10	1	10
Organizational Director or designee	H Medical Scientific Org Application	7	1	7	2	14
Organizational Director or designee	I Public Org Application	4	1	4	2	8
Business Administrator or designee	J Business Member Application	2	1	2	2	4
Individual	K Individual Member Application	4	1	4	1	4
	Total = 25 forms	948		1,867		7,016

*There are 4 types of forms that can be used to apply for designation as a VCA Abdominal Wall Program.

**VCA Other Designated Program Application data based on four categories of "others" including genitourinary and lower limb as defined by the OPTN bylaws.

The estimated burden for the revised collection increased from 6,006 to 7,016. This increase is due to the additions and revisions to selected forms and the addition of new forms around VCA transplants. The burden estimates are derived from prior experience reported by applicants. These revised forms are streamlined and in some instances rearrangements of previously approved OMB application documents. There is no formal pretest performed. There is no requirement for prescreening respondents in order to submit these application materials.

12B. Annualized cost to respondents for the hour burdens for collections of information

Member application information is collected and submitted by a wide range of individuals who represent various medical occupations. The Bureau of Labor Statistics most recent report *May 2015 National Industry-Specific Occupational Employment and Wage Estimates*, http://www.bls.gov/OES/current/naics4_622100.htm#11-0000, contains hourly wage data for hospital staff positions, which are typical organ transplantation occupations designated to collect information. Examples include:

- Program primary administrator mean hourly wage \$54.65
- Medical administrative assistant mean hourly wage \$16.16
- Registered nurse mean hourly wage \$33.41

The \$25.00 hourly rate used for administrative designees seemed defensible and appropriate.

Individual applicants are mainly employed professionals. Individual applicant wages are not easily identifiable. These applicants are in positions covered by the Federal minimum wage. The \$10.00 hourly rate used for individual applicants is slightly above the Federal minimum wage.

	Type of Respondent	Total Burden Hours	Hourly Wage Rate	Total Respondent Costs
13.	Administrative designees	7,012	\$25.00	\$175,300.00
	Individuals	4	\$10.00	\$ 40.00
	Total	7,016		\$175,340.00

Estimates of other Total Annual Cost Burden to Respondents or Record keepers/Capital Costs

There are no capital or start-up costs for application to the network.

14. Annualized Cost to Federal Government

HRSA Division of Transplantation is responsible for coordinating the OPTN contractor’s preparation of OMB 0915-0184, monitoring and reviewing the OPTN membership application

compliance with the National Organ Transplant Act and the OPTN Final Rule, reviewing and responding to public comments, and other activities related to submitting the OPTN membership application for OMB review. Costs associated with Federal staff conducting Pre-OMB approval activities are specified in Table 14-1.

The United Network for Organ Sharing (UNOS) is the contractor selected to operate the Organ OPTN. Since this is a cost-sharing contract it is based on cost-reimbursement with the contractor receiving no fee and being reimbursed only for an agreed-upon portion of its allowable costs. Costs related to membership application are 100% reimbursable. As such the cost given below under “Contractor Costs” represents the estimated cost charged for membership application work. It is an aggregate amount.

Contractor tasks include developing and maintaining membership application forms , providing application forms with instruction as requested, assisting applicants in completing the forms, securing application form completion, packaging and releasing application for peer review, presenting application as required in order to achieve a final decision on the application and always being available as an application subject matter expert for anyone needing assistance.

Table 14-1 Cost to Federal Government

Tasks/Personnel	Annual Salary	% of Time	Cost
Pre-OMB Approval			
Government Personnel Costs:			
Public Health Analyst-GS13, Step 4 ¹	\$104,275	2%	\$2,085.50
Government Non-Personnel Costs:			
	NA	NA	
Contractor Costs:			
Estimated Membership Application Work Effort			\$345,000

15. Explanation for Program Changes or Adjustments

This request is made with revisions to the expiring documents. New membership forms have been created for transplant centers seeking to perform Vascularized Composite Allograft (VCA) transplants, a new and emerging field. VCAs were added to the definition of organs covered by the rules governing the operation of the OPTN, effective July 3, 2014. The

¹ Based on 2017 OPM Pay Schedule for Washington D.C. Metro area, <https://www.opm.gov/policy-data-oversight/pay-leave/salaries-wages/salary-tables/pdf/2017/DCB.pdf>.

OPTN Board approved OPTN membership requirements for VCA programs during late 2015. Because a transplant hospital applying to be an OPTN-approved VCA transplant program must already have current OPTN approval as a designated transplant program for at least one other organ, the VCA membership forms were developed based on existing membership forms.

New forms and revisions to the current OPTN forms include the following:

- Organ-specific program and histocompatibility laboratory applications reflecting key personnel requirement revisions made to the OPTN bylaws (the bylaws revisions will be implemented upon approval of these forms);
- Program applications based on existing organ-specific program application forms, for programs seeking VCA transplantation approval. The OPTN Board of Directors has approved language modifying OPTN Policy 1.2 (definitions) to provide that VCAs, defined generally in OPTN Policy 1.2 include the following:
 - Upper limb (including, but not limited to, any group of body parts from the upper limb or radial forearm flap);
 - Head and neck (including, but not limited to, face including underlying skeleton and muscle, larynx, parathyroid gland, scalp, trachea, or thyroid);
 - Abdominal wall (including, but not limited to, symphysis pubis or other vascularized skeletal elements of the pelvis);
 - Genitourinary organs (including, but not limited to, uterus, internal/external male and female genitalia, or urinary bladder);
 - Glands (including, but not limited to adrenal or thymus);
 - Lower limb (including, but not limited to, pelvic structures that are attached to the lower limb and transplanted intact, gluteal region, vascularized bone transfers from the lower extremity, anterior lateral thigh flaps, or toe transfers);
 - Musculoskeletal composite graft segment (including, but not limited to, latissimus dorsi, spine axis, or any other vascularized muscle, bone, nerve, or skin flap); and
 - Spleen.

Some of the program application forms for programs seeking VCA transplantation approval are specific to these body parts (e.g., VCA Upper Limb Transplant Program Application), and others are classified as VCA Other Program Applications with a checklist to indicate which of the listed body parts the program seeks designation to transplant.

- Program applications based on an existing organ-specific application form for programs seeking designation as an intestine transplant program.
- Cover pages, based on existing cover pages for other organ types, for VCA new transplant program, VCA key personnel change, VCA other new transplant program, and VCA other key personnel change forms.
- Questions and tables reflecting new ordering and numbering for improved flow on various forms.

As these forms are based on OPTN membership applications that organizations have completed in the past, the burden of completing the new and revised forms is minimized.

The application forms were revised to make them more respondent friendly. Specifically, the revised application is rewritten in plain language and asks only for information relevant to current membership requirements. New membership requirements have been approved by the OPTN Board of Directors, resulting in new membership forms and in a few instances, additional data for submission.

It is estimated that the number of respondents will increase significantly. First, there will be more individual forms to fill out. However, each individual form will be shorter and easier to complete.

16. Plans for Tabulation, Publication, and Project Time Schedule

The OPTN accepts applications for membership throughout the year. There are no plans for analysis or publication of the OPTN application materials.

17. Reason(s) Display of OMB Expiration Date is Inappropriate

No exemption is requested. The expiration date will be displayed.

18. Exceptions to Certification for Paperwork Reduction Act Submissions

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