

Supporting Statement A

OPTN Application Form

OMB Control No. 0915-0184 - Revision

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). 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 July 31, 2020. 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.

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 Department of Health and Human Services (HHS) contracted with the United Network for Organ Sharing (UNOS), a private corporation, to be the OPTN.

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 of the OPTN as a condition of participation in Medicare and Medicaid for the hospital. Section 1138 contains a similar provision requiring organ procurement organizations (OPOs) to be members of and abide by

the rules and requirements of the OPTN. 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: 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.

For this revision, changes to the forms are proposed to make application requirements more clear and organized, and thus less cumbersome for applicants to complete (see attachment). Proposed revisions include changes to wording to make questions more consistent with the language of the OPTN Bylaws (Bylaws). In addition, the applications have been revised so that the sequence of questions is parallel to that of the Bylaws. Using the Bylaws as a baseline, the revamped applications have been constructed in parallel order of the Bylaws so that an applicant can have the application and Bylaws side-by-side for easy reference. Additional proposed changes to the application include:

- *A few major changes were made to the application order of documentation and attachments. The embedded transplant logs were revised in the form of a "universal" surgeon and physician log that will be provided as a separate attachment to the application. This new log will provide applicants with all OPTN Bylaws requirements. We hope the added technology utilized in the log will help applicants complete the log with limited errors.*
- *Also, within the applications, "checkboxes"—fillable tables that were not checkboxes at all—were removed, and working checkboxes were inserted. The "narrative" section was replaced by checkbox attestations, which will serve the same purpose—understanding relevant and recent surgeon and physician applicant experience.*
- *The previous membership applications had several places for the applicants to sign. The new application requests only one signature from each member applicant involved (which will be electronically captured if using the new web based application tool).*
- *Additional changes to the application process include streamlining previous application attachments for key personnel and living donor components into one form for the respective organ application.*
- *Pediatric Bylaw Requirements, where applicable, were also given their own sections within the organ applications. Conversely, the Certificate of Assessment (formerly known as Certificate of Investigation) and the Primary Coverage Plan Checklist was*

pulled out of the previous organ-specific applications and given their own, separate attachment. These changes will allow OPTN application reviewers to give these application components to applicants in as few attachments as possible. These changes will also allow the UNOS Membership Team to give these important application components to applicants in as few attachments as possible, but are inclusive of all possible changes within a program.

- *Further changes have been made to the Vascularized Composite Allograft (VCA) Transplant program applications, which were previously submitted as separate applications for OMB approval based on body part transplanted. These forms have been revised into one single application with sections for each VCA organ type.*
- *Changes have been made to the Islet Transplant program application based on updates to OPTN Bylaws, notably the change in requirement for key personnel.*
- *Personnel changes for Organ Procurement Organizations (OPOs) and Histocompatibility Laboratories have also been consolidated into organization applications. OPO and Lab applicants will be able to use one respective application for new program and/or personnel changes.*

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/>. This current cycle of OPTN Membership Application revisions will coincide with the introduction of a web based tool that will assist users in filling out the application and submitting it electronically. Approval signatures required for application submission will also be captured electronically using the web based application tool.

A static version of the OPTN Membership Application will still be available to users to print out and complete if they choose.

The final application, whether submitted via the web-based tool or the printed, as well as supporting documentation, will be retained in the database and available in electronic format.

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 businesses 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

A 60-day Federal Register Notice published in the *Federal Register* on Thursday, February 13, 2020, Vol. 85, No. 30; pp.8300-8302 and available at <https://www.govinfo.gov/content/pkg/FR-2020-02-13/pdf/2020-02870.pdf>. No public comments were received.

The OPTN Charter became effective May 1, 2004. OPTN Policies and Bylaws are approved by the OPTN Board of Directors after being developed by OPTN Committees, OPTN members, and the general public through the OPTN public comment process. The OPTN Policies and Bylaws 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 organizations are approved by the OPTN, that they abide by OPTN Obligations, 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, other transplant professionals, 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, Maryl Johnson, MD
University of Wisconsin Hospital
mrj@medicine.wisc.edu

Membership and Professional Standards Committee

Chairman, Lisa Stocks, RN, MSN, FNP
LifeSharing (San Diego, CA)
lstocks@health.ucsd.edu

Additionally, UNOS membership staff reviewed the forms extensively. They integrated improvement suggestions along with incorporated revised elements from the current bylaws into these forms.

UNOS may be contacted at the following address:

United Network for Organ Sharing (UNOS)
Contact Person: Roger Vacovsky
700 North 4th Street
Richmond, Virginia 23218
Phone: 804-782-4800
Fax: 804-782-4896

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 stored electronically. Processes and protocols to maintain confidentiality is imposed and adhered to by the UNOS.

Data collected under the OPTN contract is well protected by a number of 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 a current Continuity of Operations Plan (COOP), which contains emergency operations, backup operations, and recovery plans to ensure continuous operation of the 'system's facility. The testing of this system occurs every other week. The contractor uses a third-party co-location site for its COOP.

Application materials are also reviewed by OPTN Membership and Professional Standards Committee (MPSC) members, who are volunteer transplant professionals from the transplant community. The MPSC members sign confidentiality agreements, and the applications are reviewed under peer review and are subject to applicable peer review protections and laws.

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 Number of Responses	Average Burden per Response (in hours)	Total Burden Hours
Transplant administrator or designee	OPTN Membership Application for Transplant Hospitals	2	1	2	3	6
Transplant administrator or designee	OPTN Certificate of Assessment and Program Coverage Plan Membership Application	2	1	2	3	6
Transplant administrator or designee	OPTN Membership Application for Kidney Transplant Programs	189	2	378	3	1,134
Transplant administrator or designee	OPTN Membership Application for Liver Transplant Programs	110	2	220	3	660
Transplant administrator or designee	OPTN Membership Application for Pancreas Transplant Programs	120	2	240	3	720
Transplant administrator or designee	OPTN Membership Application for Heart Transplant Programs	142	2	284	3	852
Transplant administrator or designee	OPTN Membership Application for Lung Transplant Programs	60	2	120	3	360
Transplant administrator or designee	OPTN Membership Application for Islet Transplant Programs	4	2	8	2	16
Transplant administrator or designee	OPTN Membership Application for Vascularized Composite Allograft (VCA) Transplant Programs	53	2	106	2	212
Transplant administrator or designee	OPTN Membership Application for Intestine Transplant Programs	90	2	180	3	540
OPO Director or designee	OPTN Membership Application for Organ Procurement Organizations (OPOs)	10	1	10	3	30
Lab Director or designee	OPTN Membership Application for Histocompatibility Laboratories	27	2	54	3	162
Organization Director or Designee	OPTN Representative Form	20	2	40	1	40
Organization Director or Designee	OPTN Medical/Scientific Membership Application	7	1	7	1	7
Organization Director or Designee	OPTN Public Organization Membership Application	4	1	4	1	4

Type of Respondent	Form Name	Number of Respondents	Number of Responses per Respondent	Total Number of Responses	Average Burden per Response (in hours)	Total Burden Hours
Organization Director or Designee	OPTN Business Membership Application	2	1	2	1	2
Organization Director or Designee	OPTN Individual Membership Application	4	1	4	1	4
Transplant administrator or designee	OPTN Membership Application Surgeon or Physician Log*	-	-	-	-	-
	Total = 18 forms	846		1,661		4,755

*The OPTN Membership Application Surgeon or Physician Log accompanies every individual organ application. The burden to complete is built into the organ application data.

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 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 2018 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 \$58.88
- Medical administrative assistant mean hourly wage \$18.11
- Registered nurse mean hourly wage \$37.37

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
Administrative designees	4,751	\$25.00	\$118,775.00
Individuals	4	\$10.00	\$ 40.00
Total	4,755		\$118,815.00

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 UNOS'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.

Since this is a federal cost-sharing contract, it is based on cost-reimbursement with UNOS receiving no fee and being reimbursed only for an agreed-upon portion of its allowable costs. Costs related to membership application are 100 percent 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 to achieve 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	\$98,916	2%	\$1,978.00
Government Non-Personnel Costs:			
	NA	NA	
Contractor Costs:			
Estimated Membership Application Work Effort			\$345,000

15. Explanation for Program Changes or Adjustments

Given the proposed changes in this revision request, the overall estimated burden has decreased from 7,020 total burden hours to 4,755 hours.

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 outlined in 5 CFR 1320.9. The certifications are included in the package.

¹ Based on 2014 OPM Pay Schedule for Washington D.C. Metro area, <https://www.opm.gov/policy-data-oversight/pay-leave/salaries-wages/salary-tables/pdf/2014/DCB.pdf>.