



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

**Agency Information Collection Activities: Submission to OMB for Review and Approval;
Public Comment Request; Information Collection Request Title: Organ Procurement and
Transplantation Network, OMB No. 0915-0184 – Revision**

AGENCY: Health Resources and Services Administration (HRSA), Department of Health and Human Services.

ACTION: Notice

SUMMARY: In compliance with the Paperwork Reduction Act of 1995, HRSA has submitted an Information Collection Request (ICR) to the Office of Management and Budget (OMB) for review and approval. Comments submitted during the first public review of this ICR will be provided to OMB. OMB will accept further comments from the public during the review and approval period.

DATES: Comments on this ICR should be received no later than **[INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER]**.

ADDRESSES: Submit your comments, including the ICR Title, to the desk officer for HRSA, either by email to *OIRA_submission@omb.eop.gov* or by fax to 202-395-5806.

FOR FURTHER INFORMATION CONTACT: To request a copy of the clearance requests submitted to OMB for review, email the HRSA Information Collection Clearance Officer at *paperwork@hrsa.gov* or call (301) 443-1984.

SUPPLEMENTARY INFORMATION: When submitting comments or requesting information, please include the information request collection title for reference, in compliance with Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995.

Information Collection Request Title: Organ Procurement and Transplantation Network
OMB No. 0915-0184 – Revision

Abstract: HRSA is proposing additions and revisions to the following documents used to collect information from existing or potential members of the Organ Procurement and Transplantation Network (OPTN). The documents under revision include: (1) Application forms for individuals or organizations interested in membership in the OPTN; (2) application forms for OPTN members applying to have organ-specific transplant programs designated within their institutions; and (3) forms submitted by OPTN members to report certain personnel changes.

Need and Proposed Use of the Information: 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. (NOTA), OPTN Final Rule, 42 CFR part 121, OPTN bylaws, and OPTN policies. 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 Health and Human Services) of the OPTN, including those related to data collection, 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 (as approved by the Secretary of Health and Human Services), including those relating to data collection, mandatory for all OPOs. The membership application forms listed below enable prospective OPTN members to submit the information necessary for the OPTN to make membership decisions. Likewise, the designated transplant program application forms listed below enable OPTN members to submit the information necessary for the OPTN to make designation decisions.

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 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.

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.

Likely Respondents: Likely respondents to this notice include the following: hospitals performing or seeking to perform organ transplants, organ procurement organizations, and medical laboratories seeking to become OPTN-approved histocompatibility laboratories.

Burden Statement: Burden in this context means the time expended by persons to generate, maintain, retain, disclose, or provide the information requested, including the time needed to: (1) review instructions; (2) develop, acquire, install, and utilize technology and systems for the purpose of collecting, validating, and verifying information, processing and maintaining information, and disclosing and providing information; (3) train personnel to respond to a collection of information; (4) search data sources; (5) complete and review the information collected; and (6) to transmit or otherwise disclose the information. The total annual burden hours estimated for this ICR are summarized in the table below.

Total Estimated Annualized Burden – Hours

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

Form Name	Number of Respondents	Number of Responses per Respondent	Total Responses	Average Burden per Response (in hours)	Total Burden Hours
Application					
B VCA Upper Limb Designated Program Application	17	2	34	3	102
B VCA Abdominal Wall* Designated Program Application					
VCA Abdominal Wall – Kidney					
VCA Abdominal Wall – Liver	13	2	26	3	78
VCA Abdominal Wall – Pancreas					
VCA Abdominal Wall – Intestine					
B VCA Other** Designated Program Application	9	2	18	2	36
B Intestine Designated Program Application	40	2	80	3	240
C OPO New Application	0	1	0	4	0
D Histocompatibility Lab Application	3	2	6	4	24
E Change in Transplant Program Key Personnel	395	2	790	4	3,160
F Change in Histocompatibility Lab Director	25	2	50	2	100
G Change in OPO Key Personnel	10	1	10	1	10
H Medical Scientific Org Application	7	1	7	2	14
I Public Org Application	4	1	4	2	8
J Business Member Application	2	1	2	2	4
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.

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