



**Billing Code 4165-15-P**

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Health Resources and Services Administration**

**Agency Information Collection Activities: Proposed Collection: Public Comment Request**  
**Information Collection Request Title: Data System for Organ Procurement and**  
**Transplantation Network, OMB No. 0915-0157 – Extension**

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

**ACTION:** Notice.

**SUMMARY:** In compliance with the requirement for an opportunity for public comment on proposed data collection projects of the Paperwork Reduction Act of 1995, HRSA announces plans to submit an Information Collection Request (ICR), described below, to the Office of Management and Budget (OMB). Prior to submitting the ICR to OMB, HRSA seeks comments from the public regarding the burden estimate, below, or any other aspect of the ICR.

**DATES:** Comments on this ICR should be received no later than **[INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER]**.

**ADDRESSES:** Submit your comments to [paperwork@hrsa.gov](mailto:paperwork@hrsa.gov) or mail the HRSA Information Collection Clearance Officer, Room 14N136B, 5600 Fishers Lane, Rockville, MD 20857.

**FOR FURTHER INFORMATION CONTACT:** To request more information on the proposed project or to obtain a copy of the data collection plans and draft instruments, email [paperwork@hrsa.gov](mailto:paperwork@hrsa.gov) or call Lisa Wright-Solomon, the HRSA Information Collection Clearance Officer at (301) 443-1984.

**SUPPLEMENTARY INFORMATION:** When submitting comments or requesting information, please include the information request collection title for reference.

*Information Collection Request Title:* Data System for Organ Procurement and Transplantation Network OMB No. 0915- 0157 – Extension

*Abstract:* Section 372 of the Public Health Service (PHS) Act (42 U.S.C. §274) requires that the Secretary, by contract, provide for the establishment and operation of an Organ Procurement and Transplantation Network (OPTN). This is a request for an extension of the current OPTN data collection forms associated with an individual's clinical characteristics at the time of registration, transplant, and follow-up after the transplant. Data are collected from transplant hospitals, organ procurement organizations, and histocompatibility laboratories. The information is used to indicate the disease severity of transplant candidates, to monitor compliance of member organizations with OPTN rules and requirements, and to report

periodically on the clinical and scientific status of organ donation and transplantation in this country.

*Need and Proposed Use of the Information:* Data are used to develop transplant, donation, and allocation policies, to determine whether institutional members are complying with policy, to determine member-specific performance, to ensure patient safety, and to fulfill the requirements of the OPTN Final Rule. The practical utility of the data collection is further enhanced by requirements that the OPTN data must be made available, consistent with applicable laws, for use by OPTN members, the Scientific Registry of Transplant Recipients, the Department of Health and Human Services, and members of the public for evaluation, research, patient information, and other important purposes.

Burden hours have increased since the last reporting period due to an increase in the number of transplant programs for some organs and the overall increase in transplant surgeries at existing programs as well. An increased number of transplants results in an increasing number of forms that require completion while the amount of time it takes to complete the forms remains the same.

*Likely Respondents:* Transplant programs, organ procurement organizations, and histocompatibility laboratories.

*Burden Statement:* Burden, in this context, means the time expended by persons to generate, maintain, retain, disclose or provide the information requested. This includes the time

needed to review instructions; to 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; to train personnel and to be able to respond to a collection of information; to search data sources; to complete and review the collection of information; and 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
Deceased Donor Registration	58	185.0	10,731	1.1	11,804.1
Living Donor Registration	300	22.9	6,855	1.8	12,339.0
Living Donor Follow Up	300	62.2	18,669	1.3	24,269.7
Donor Histocompatibility	147	124.0	18,226	0.2	3,645.2
Recipient Histocompatibility	147	225.1	33,090	0.4	13,236.0
Heart Candidate Registration	140	33.7	4,717	0.9	4,245.3
Heart Recipient Registration	140	24.3	3,406	1.2	4,087.2
Heart Follow Up (6 Month)	140	22.0	3,082	0.4	1,232.8
Heart Follow Up (1-5 Year)	140	90.6	12,686	0.9	11,417.4
Heart Follow Up (Post 5 Year)	140	154.0	21,556	0.5	10,778.0
Heart Post-Transplant Malignancy Form	140	12.8	1,788	0.9	1,609.2
Lung Candidate	71	45.2	3,210	0.9	2,889.0

Registration					
Lung Recipient Registration	71	35.7	2,532	1.2	3,038.4

Lung Follow Up (6 Month)	71	32.4	2,297	0.5	1,148.5
Lung Follow Up (1-5 Year)	71	118.8	8,438	1.1	9,281.8
Lung Follow Up (Post 5 Year)	71	116.5	8,271	0.6	4,962.6
Lung Post-Transplant Malignancy Form	71	19.7	1,400	0.4	560.0
Heart/Lung Candidate Registration	69	1.0	67	1.1	73.7
Heart/Lung Recipient Registration	69	0.5	32	1.3	41.6
Heart/Lung Follow Up (6 Month)	69	0.4	31	0.8	24.8
Heart/Lung Follow Up (1-5 Year)	69	1.1	79	1.1	86.9
Heart/Lung Follow Up (Post 5 Year)	69	3.3	228	0.6	136.8
Heart/Lung Post-Transplant Malignancy Form	69	0.3	21	0.4	8.4
Liver Candidate Registration	146	90.3	13,183	0.8	10,546.4
Liver Recipient Registration	146	56.5	8,256	1.2	9,907.2
Liver Follow-up (6 Month - 5 Year)	146	266.6	38,919	1.0	38,919.0
Liver Follow-up (Post 5 Year)	146	316.6	46,225	0.5	23,112.5
Liver Recipient Explant Pathology Form	146	10.6	1,544	0.6	926.4
Liver Post-Transplant Malignancy	146	16.3	2,387	0.8	1,909.6
Intestine Candidate Registration	20	7.0	139	1.3	180.7
Intestine Recipient Registration	20	5.2	104	1.8	187.2

Intestine Follow Up (6 Month - 5 Year)	20	26.2	524	1.5	786.0
Intestine Follow Up (Post 5 Year)	20	37.2	744	0.4	297.6
Intestine Post-Transplant Malignancy Form	20	2.1	42	1.0	42.0
Kidney Candidate Registration	237	168.8	39,998	0.8	31,998.4
Kidney Recipient Registration	237	89.4	21,195	1.2	25,434.0
Kidney Follow-Up (6 Month - 5 Year)	237	431.9	102,350	0.9	92,115.0
Kidney Follow-up (Post 5 Year)	237	449.4	106,507	0.5	53,253.5
Kidney Post-Transplant Malignancy Form	237	22.6	5,365	0.8	4,292.0
Pancreas Candidate Registration	133	2.8	368	0.6	220.8
Pancreas Recipient Registration	133	1.5	194	1.2	232.8
Pancreas Follow-up (6 Month - 5 Year)	133	7.9	1,047	0.5	523.5
Pancreas Follow-up (Post 5 Year)	133	15.9	2,119	0.5	1,059.5
Pancreas Post-Transplant Malignancy Form	133	0.7	97	0.6	58.2
Kidney/Pancreas Candidate Registration	133	9.8	1,297	0.6	778.2
Kidney/Pancreas Recipient Registration	133	7.7	1,028	1.2	1,233.6
Kidney/Pancreas Follow-up (6 Month - 5 Year)	133	32.8	4,363	0.5	2,181.5
Kidney/Pancreas Follow-up (Post 5	133	57.8	7,688	0.6	4,612.8

Year)					
Kidney/Pancreas Post-Transplant Malignancy Form	133	2.2	292	0.4	116.8
VCA Candidate Registration	27	0.9	24	0.4	9.6
VCA Recipient Registration	27	1.6	43	1.3	55.9
VCA Recipient Follow Up	27	0.7	18	1.0	18.0
Total	6,204	.....	567,472	.....	425,925.1

\*The Number of Responses per Respondent was calculated by dividing the Total Responses by the Number of Respondents and rounding to the nearest tenth.

HRSA specifically requests comments on (1) the necessity and utility of the proposed information collection for the proper performance of the agency's functions; (2) the accuracy of the estimated burden; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

**Maria G. Button,**

*Director, Executive Secretariat.*

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