TABLE 2—ESTIMATED ANNUAL REPORTING BURDEN E-SUBMISSIONS INCLUDING VIA SRP [1]—Continued

FDA Form 3800	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
Total			5,924		3,961

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

The number of respondents for the Voluntary Tobacco Product Health Problem or Product Problem Reports e-submissions has decreased from 204 to 176, according to an updated analysis.

Based on burden estimates associated with the Premarket Tobacco Product applications and Recordkeeping Requirements regulation we have decreased the average burden per response from 1 hour to 36 minutes for 1114.41(a)(2); Mandatory Tobacco Product Health Problem or Product Problem Reports.

CVM reports a decrease in the number of submissions received over the last few years.

CDER/CBER has increased the number of direct safety reports from healthcare providers and consumers. Additionally, CDER mandatory reports, Form FDA 3500A previously included in this information collection, are now reported in the approved information collection, OMB control number 0910–0230. However, increases in receipts of CBER mandatory reports have obscured any decrease in burden. Adverse event reports related 21 CFR 310.305 from outsourcing facilities are also included in 0910–0230 and decreases the total burden of this collection.

Based on updated data, CDRH has revised our estimate for forms FDA 3500 and FDA 3500B. Additionally, we have determined that the estimate previously reported in this information collection for mandatory reporting under 21 CFR part 803, associated with medical device products, using form FDA 3500A, is redundant with our approved burden estimates in OMB control number 0910–0437 *Medical Device Reporting* (under 21 CFR part 803). We have therefore removed CDRH reporting via FDA 3500A from this information collection request and continue to account for its burden in OMB control number 0910–0437.

Based on agency experience HFP's estimated burden for the information collection reflects an overall increase. We attribute this adjustment to an increase in the number of submissions we received over the last few years, due primarily to changes in the infant formula industry.

Therefore, the cumulative changes, both program changes which include form revisions, and adjustments reflecting fluctuations in submissions, as well as removing double-counted burden reflects and overall increase of 116,014 hours to the total burden for this information collection.

Dated: June 18, 2025.

Grace R. Graham,

Deputy Commissioner for Policy, Legislation, and International Affairs.

[FR Doc. 2025–11605 Filed 6–24–25; 8:45 am]

BILLING CODE P

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; Data System for Organ Procurement and Transplantation Network

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

ACTION: Notice.

SUMMARY: In compliance with the Paperwork Reduction Act of 1995, HRSA 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. OMB may act on HRSA's ICR only after the 30-day comment period for this notice has closed.

DATES: Comments on this ICR should be received no later than July 25, 2025.

ADDRESSES: Written comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to *www.reginfo.gov/public/do/PRAMain.* Find this particular information collection by selecting ''Currently under Review—Open for Public Comments'' or by using the search function.

FOR FURTHER INFORMATION CONTACT: To request a copy of the clearance requests submitted to OMB for review, email Samantha Miller, HRSA Information Collection Clearance Officer, at *paperwork@hrsa.gov* or call (301) 443–3983.

SUPPLEMENTARY INFORMATION:

Information Collection Request Title: Data System for Organ Procurement and Transplantation Network, OMB No. 0915–0157—Revision.

Abstract: Section 372 of the Public Health Service Act requires that the Secretary of HHS, by award, provide for the establishment and operation of the Organ Procurement and Transplantation Network (OPTN), which, under oversight of the HRSA, operates the U.S. Organ Procurement and Transplantation system. HRSA, in alignment with the Paperwork Reduction Act of 1995, submits OPTN Board of Directors (BOD)-approved data elements for collection to OMB for approval.

A 60-day notice was published in the **Federal Register** on November 1, 2024, Vol. 89, No. 212, pp. 87380–85. There were six comments, including feedback from OPTN Members and Transplant Centers. Public comments raised concerns about the financial burden of additional data collection. The commenters called for greater collaboration between transplant professionals, HRSA, and the Scientific Registry of Transplant Recipients to eliminate redundancies and improve efficiency. Commenters expressed concern that changes were communicated via the **Federal Register** instead of the OPTN public comment process, limiting input from the transplant community. Additionally, the commenters sought clarification on discrepancies regarding which forms were designated as new, and they requested access to the data collection plans and draft instruments.

HRSA carefully reviewed all public feedback submitted during the 60-day comment period. Through its policy development process, OPTN had previously solicited input on each of the data collection instruments through four channels:

(1) Targeted outreach to relevant stakeholder organizations, including

transplant professionals and patient groups.

(2) Comments submitted by other OPTN committees.

(3) In-person meetings across 11 OPTN regions.

(4) An online OPTN public comment forum open to all on the OPTN website.

HRSA welcomes participation from all interested individuals. HRSA seeks input from transplant candidates directly affected by policy changes and strongly encourages transplant professionals to provide input on the potential financial impacts of proposals. HRSA values all feedback and remains committed to reviewing and refining data collection efforts in collaboration with the OPTN.

Finally, in response to commenter concerns regarding potential burden, the OPTN contract requires the OPTN Contractor to implement a direct electronic data submission plan and supplement official OPTN data with external sources. This approach aims to reduce the burden of data collection on OPTN members.

Need and Proposed Use of the Information: HRSA and the OPTN BOD use data to develop transplant, procurement, 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 regulatory authority in 42 CFR 121.11 (*https://www.ecfr.gov/current/title-42/section-121.11*) of the OPTN Final Rule requires the OPTN data to be made available, consistent with applicable laws, for use by OPTN members, the Scientific Registry of Transplant Recipients, HHS, and members of the public for evaluation, research, patient information, and other important purposes.

This is a request to revise the current OPTN data collection, which includes time-sensitive, life-critical data on transplant candidates and potential organ donors, the organ matching process, histocompatibility results, organ labeling and packaging, and pre- and post-transplantation data on recipients and donors. This revision also includes OPTN BOD-approved changes to the existing OMB data collection forms. OPTN collects these specific data elements from transplant hospitals, organ procurement organizations, and histocompatibility laboratories.

HRSA and the OPTN use this information to (1) facilitate organ placement and match donor organs with recipients; (2) monitor compliance of member organizations with federal laws and regulations and with OPTN requirements; (3) review and report periodically to the public on the status of organ donation, procurement, and transplantation in the United States; (4) provide data to researchers and government agencies to study the scientific and clinical status of organ transplantation; and (5) perform transplantation-related public health surveillance, including the possible transmission of donor disease.

HRSA is requesting to make the following changes to improve the OPTN organ matching and allocation process and improve OPTN member compliance with OPTN requirements:

(1) Adding data collection forms for candidates listed in the OPTN organ transplant waiting list to the existing OMB-approved information collection. These forms allow a transplant center to add, change, or remove candidates from the OPTN waiting list after a transplant center completes the patient evaluation. These forms contain information that the OPTN electronic organ matching system uses to match potential organ recipients with available deceased donor organs. There are 83 new data collection forms: candidate listing registration forms of all organs, candidate status justification forms of all applicable organs, Model for End-Stage Liver Disease or Pediatric End-Stage Liver Disease (MELD/PELD) score exception and extension forms, and other forms.

(2) OPTN BOD-approved revisions to existing data collection forms to improve organ matching, allocation, and OPTN policy compliance.

Likely Respondents: Transplant Centers, Organ Procurement Organizations (OPO), 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.

The estimated burden hours for this collection increased by 203,937.21 hours from the currently approved ICR package. This increase includes 96,148.84 hours due to adding 83 new data collection forms for the OPTN waiting list and 107,788.37 hours due to OPTN BOD-approved data collection changes to existing forms and the number of respondents.

TOTAL ESTIMATED ANNUALIZED BURDEN—HOURS

Form No.	Form name	Number of respondents	Number of responses per respondent * ****	Total responses	Average burden per response (in hours)	Total burden hours
1	Deceased Donor Registration	56	414.71	23,223.76	0.48	11,147.40
2	Living Donor Registration	207	33.42	6,917.94	2.19	15,150.29
3	Living Donor Follow-up	207	94.86	19,636.02	1.52	29,846.75
4	Donor Histocompatibility	138	173.31	23,916.78	0.20	4,783.36
5	Recipient Histocompatibility	138	307.09	42,378.42	0.40	16,951.37
6	Heart Transplant Candidate Registration	149	38.50	5,736.50	0.90	5,162.85
7	Heart Transplant Recipient Registration	149	30.50	4,544.50	1.96	8,907.22
8	Heart Transplant Recipient Follow Up (6-month)	149	27.79	4,140.71	0.40	1,656.28
9	Heart Transplant Recipient Follow Up (1–5 year)	149	109.21	16,272.29	0.90	14,645.06
10	Heart Transplant Recipient Follow Up (Post 5 year).	149	183.73	27,375.77	0.50	13,687.89
11	Heart Post-Transplant Malignancy Form	149	12.21	1,819.29	0.90	1,637.36
12	Lung Transplant Candidate Registration	74	45.36	3,356.64	0.95	3,188.81
13	Lung Transplant Recipient Registration	74	40.85	3,022.90	1.14	3,446.11

TOTAL ESTIMATED ANNUALIZED BURDEN—HOURS—Continued

Form No.	Form name	Number of respondents	Number of responses per respondent*****	Total responses	Average burden per response (in hours)	Total burden hours
14	Lung Transplant Recipient Follow Up (6-month)	74	35.96	2,661.04	0.50	1,330.52
15	Lung Transplant Recipient Follow Up (1–5 year)	74	135.61	10,035.14	1.10	11,038.65
16	Lung Transplant Recipient Follow Up (Post 5 year).	74	148.09	10,958.66	0.60	6,575.20
17	Lung Post-Transplant Malignancy Form	74	18.39	1,360.86	0.40	544.34
18	Heart/Lung Transplant Candidate Registration	72	1.03	74.16	1.16	86.03
19	Heart/Lung Transplant Recipient Registration	72	0.75	54.00	2.09	112.86
20	Heart/Lung Transplant Recipient Follow Up (6-month).	72	0.64	46.08	0.80	36.86
21	Heart/Lung Transplant Recipient Follow Up (1–5 year).	72	2.46	177.12	1.10	194.83
22	Heart/Lung Transplant Recipient Follow Up (Post 5 year).	72	3.35	241.20	0.60	144.72
23	Heart/Lung Post-Transplant Malignancy Form	72	0.22	15.84	0.40	6.34
24	Liver Transplant Candidate Registration	142	103.39	14,681.38	0.80	11,745.10
25	Liver Transplant Recipient Registration	142	75.08	10,661.36	1.20	12,793.63
26	Liver Transplant Recipient Follow Up (6-month–5 year).	142	344.55	48,926.10	1.00	48,926.10
27	Liver Transplant Recipient Follow Up (Post 5 year).	142	427.56	60,713.52	0.50	30,356.76
28	Liver Recipient Explant Pathology Form	142	7.17	1,018.14	0.60	610.88
29	Liver Post-Transplant Malignancy Form	142	21.21	3,011.82	0.80	2,409.46
30	Intestine Transplant Candidate Registration	18	7.50	135.00	1.30	175.50
31	Intestine Transplant Recipient Registration	18	5.28	95.04	1.80	171.07
32	Intestine Transplant Recipient Follow Up (6-month–5 year).	18	21.50	387.00	1.50	580.50
33	Intestine Transplant Recipient Follow Up (Post 5 year).	18	49.61	892.98	0.40	357.19
34	Intestine Post-Transplant Malignancy Form	18	0.94	16.92	1.00	16.92
35	Kidney Transplant Candidate Registration	228	203.12	46,311.36	0.80	37,049.09
36	Kidney Transplant Recipient Registration	228	119.89	27,334.92	1.20	32,801.90
37	Kidney Transplant Recipient Follow Up (6-month–5 year).	228	571.22	130,238.16	0.90	117,214.34
38	Kidney Transplant Recipient Follow Up (Post 5 year).	228	565.59	128,954.52	0.50	64,477.26
39	Kidney Post-Transplant Malignancy Form	228	25.60	5,836.80	0.80	4,669.44
40	Pancreas Transplant Candidate Registration	123	2.63	323.49	0.60	194.09
41	Pancreas Transplant Recipient Registration	123	0.84	103.32	1.20	123.98
42	Pancreas Transplant Recipient Follow Up (6-month–5 year).	123	5.05	621.15	0.50	310.58
43	Pancreas Transplant Recipient Follow Up (Post 5 year).	123	17.11	2,104.53	0.50	1,052.27
44	Pancreas Post-Transplant Malignancy Form	123	0.76	93.48	0.60	56.09
45	Kidney/Pancreas Transplant Candidate Registration.	123	12.94	1,591.62	0.60	954.97
46	Kidney/Pancreas Transplant Recipient Registration.	123	6.59	810.57	1.20	972.68
47	Kidney/Pancreas Transplant Recipient Follow Up (6-month–5 year).	123	38.12	4,688.76	0.50	2,344.38
48	Kidney/Pancreas Transplant Recipient Follow Up (Post 5 year).	123	66.63	8,195.49	0.60	4,917.29
49	Kidney/Pancreas Post-Transplant Malignancy Form.	123	2.24	275.52	0.40	110.21
50	VCA Transplant Candidate Registration	23	1.00	23.00	0.40	9.20
51	VCA Transplant Recipient Registration	23	0.39	8.97	1.36	12.20
52	VCA Transplant Recipient Follow Up	23	2.30	52.90	1.31	69.30
53	Organ Labeling and Packaging	56	298.27	16,703.12	0.18	3,006.56
54	Organ Tracking and Validating	304	20.36	6,189.44	0.08	495.16
55	Kidney Paired Donation Candidate Registration	156	0.34	53.04	0.26	13.79
56	Kidney Paired Donation Donor Registration	156	0.99	154.44	1.08	166.80
57	Kidney Paired Donation Match Offer Management.	156	0.59	92.04	0.67	61.67
58	Disease Transmission Event	304	2.33	708.32	0.60	424.99
59	Living Donor Event	207	0.15	31.05	0.56	17.39
60	Safety Situation	442	0.93	411.06	0.24	98.65
61	Potential Disease Transmission Report	56	11.09	621.04	1.27	788.72
62	Request to Unlock Form	442	174.67	77,204.14	0.02	1,544.08
63	Initial Donor Registration	56	414.71	23,223.76	4.61	107,061.53
64	OPO Notification Limit Administration	56	9.52	533.12	0.17	90.63

TOTAL ESTIMATED ANNUALIZED BURDEN—HOURS—Continued

Form No.	Form name	Number of respondents	Number of responses per respondent*****	Total responses	Average burden per response (in hours)	Total burden hours
65	Potential Transplant Recipient	304	6,017.74	1,829,392.96	0.05	91,469.65
66	Death Notification Registration**	56	289.70	16,223.20	0.42	6,813.74
67	Deceased Donor Death Referral**	56	58.11	3,254.16	0.50	1,627.08
68	Donor Hospital Registration	56	0.04	2.24	0.08	0.18
69	Donor Organ Disposition	56	414.71	23,223.76	0.17	3,948.04
70	Transplant Center Contact Management	248	808.10	200,408.80	0.06	12,024.53
71	Adult Kidney Candidate Listing Registration***	228	204.93	46,724.04	0.52	24,296.50
72	Pediatric Kidney Candidate Listing Registration***.	101	11.66	1,177.66	0.47	553.50
73	Adult Kidney Pancreas Candidate Listing Registration***.	123	12.93	1,590.39	0.37	588.44
74	Pediatric Kidney Pancreas Candidate Listing Registration***.	29	0.07	2.03	0.30	0.61
75	Adult Pancreas Candidate Listing Registration***	123	15.29	1,880.67	0.38	714.65
76	Pediatric Pancreas Candidate Listing Registration***.	30	1.13	33.90	0.38	12.88
77	Adult Pancreas Islet Listing Registration***	16	2.06	32.96	0.38	12.52
78	Pediatric Pancreas Islet Listing Registration***	16	0.00	0.00	0.33	0.00
79	Adult Liver Candidate Listing Registration***	142	98.43	13,977.06	0.32	4,472.66
80	Pediatric Liver Candidate Listing Registration***	57	12.37	705.09	0.40	282.04
81	Adult Intestine Candidate Listing Registration***	18	4.94	88.92	0.38	33.79
82	Pediatric Intestine Candidate Listing Registration***.	18	2.56	46.08	0.43	19.81
83	Adult Heart Candidate Listing Registration***	149	33.58	5,003.42	0.83	4,152.84
84	Pediatric Heart Candidate Listing Registration***	64	11.47	734.08	0.58	425.77
85	Adult HeartLung Candidate Listing Registration***.	72	0.97	69.84	0.85	59.36
86	Pediatric HeartLung Candidate Listing Registration***.	27	0.15	4.05	0.93	3.77
87	Adult Lung Candidate Listing Registration***	74	44.85	3,318.90	1.00	3,318.90
88	Pediatric Lung Candidate Listing Registration***	45	0.84	37.80	0.83	31.37
89	Candidate Registration Listing Removal***	248	289.27	71,738.96	0.18	12,913.01
90	VCA Abdominal Wall Candidate Listing Registration***.	8	0.38	3.04	0.33	1.00
91	VCA External Male Genitalia Candidate Listing Registration***.	2	0.00	0.00	0.33	0.00
92	VCA Head and Neck Candidate Listing Registration***.	10	0.50	5.00	0.33	1.65
93	VCA Lower Limb Candidate Listing Registration***.	4	0.00	0.00	0.33	0.00
94	VCA Musculoskeletal Composite Graft Segment Candidate Listing Registration***.	2	0.00	0.00	0.33	0.00
95	VCA Other Genitourinary Organ Candidate Listing Registration***.	3	0.00	0.00	0.33	0.00
96	VCA Spleen Candidate Listing Registration***	0	0.00	0.00	0.33	0.00
97	VCA Upper Limb Candidate Listing Registration***.	11	0.27	2.97	0.33	0.98
98	VCA Uterus Candidate Listing Registration***	6	2.00	12.00	0.33	3.96
99	VCA Vascularized Gland Candidate Listing Registration***.	8	0.00	0.00	0.33	0.00
100	Organ Export Verification Form***	56	0.46	25.76	0.03	0.77
101	OPTN Waiting Time Transfer Form***	248	5.54	1,373.92	0.23	316.00
102	OPTN Waiting Time Modification Form***	248	59.40	14,731.20	0.22	3,240.86
103	OPTN Renal Waiting Time Reinstatement Form***.	228	1.21	275.88	0.27	74.49
104	OPTN Pancreas Waiting Time Reinstatement Form***.	123	0.03	3.69	0.20	0.74
105	Intestinal Waiting Time Reinstatement Form*** ...	18	0.00	0.00	0.25	0.00
106	Prior Living Donor Priority***	228	0.25	57.00	0.27	15.39
107	Kidney Minimum Acceptance Criteria***	228	0.47	107.16	0.30	32.15
108	Adult Liver Status 1A Initial Justification and Extension Form***.	142	2.31	328.02	0.57	186.97
109	Pediatric Liver Status 1A Initial Justification and Extension Form***.	57	2.30	131.10	0.57	74.73
110	Pediatric Liver Status 1B Initial Justification and Extension Form***.	57	5.61	319.77	0.47	150.29
111	Liver Cholangiocarcinoma (CCA) Initial MELD/PELD Score Exception Form***.	142	0.42	59.64	0.43	25.65

TOTAL ESTIMATED ANNUALIZED BURDEN—HOURS—Continued

Form No.	Form name	Number of respondents	Number of responses per respondent*****	Total responses	Average burden per response (in hours)	Total burden hours
112	Liver Cholangiocarcinoma (CCA) MELD/PELD Score Exception Extension Form***.	142	0.34	48.28	0.32	15.45
113	Liver Cystic Fibrosis (CF) Initial MELD/PELD Score Exception and Extension Form***.	142	0.10	14.20	0.33	4.69
114	Liver Familial Amyloid Polyneuropathy (FAP) Initial MELD/PELD Score Exception Form***.	142	0.04	5.68	0.40	2.27
115	Liver Familial Amyloid Polyneuropathy (FAP) MELD/PELD Score Exception Extension Form***.	142	0.05	7.10	0.30	2.13
116	Liver Hepatic Artery Thrombosis (HAT) Initial MELD/PELD Score Exception and Extension Form***.	142	0.69	97.98	0.35	34.29
117	Liver Hepatocellular Carcinoma (HCC) Initial MELD/PELD Score Exception Form***.	142	23.30	3,308.60	0.47	1,555.04
118	Liver Hepatocellular Carcinoma (HCC) MELD/PELD Score Exception Extension Form***.	142	33.21	4,715.82	0.35	1,650.54
119	Liver Hepatopulmonary Syndrome (HPS) Initial MELD/PELD Score Exception Form***.	142	1.39	197.38	0.32	63.16
120	Liver Hepatopulmonary Syndrome (HPS) MELD/PELD Score Exception Extension Form***.	142	0.99	140.58	0.25	35.15
121	Liver Metabolic Disease Initial MELD/PELD Score Exception and Extension Form***.	142	0.77	109.34	0.28	30.62
122	Liver Portopulmonary Hypertension Initial MELD/PELD Score Exception Form***.	142	0.51	72.42	0.42	30.42
123	Liver Portopulmonary Hypertension MELD/PELD Score Exception Extension Form***.	142	0.36	51.12	0.33	16.87
124	Liver Primary Hyperoxaluria Initial MELD/PELD Score Exception and Extension Form***.	142	0.13	18.46	0.35	6.46
125	Liver Other Diagnosis Initial MELD/PELD Score Exception and Extension Form***.	142	12.03	1,708.26	0.35	597.89
126	Pediatric Heart and HeartLung Status 1A Initial Justification Form***.	64	16.06	1,027.84	0.52	534.48
127	Pediatric Heart and HeartLung Status 1A Extension and Appeal Justification Forms***.	64	54.61	3,495.04	0.47	1,642.67
128	Pediatric Heart and HeartLung Status 1B Initial Justification Form***.	64	7.31	467.84	0.42	196.49
129	Adult Heart and HeartLung Status 1–6 Justification Form Demographic Data***.	149	135.78	20,231.22	0.32	6,473.99
130	Adult Heart and HeartLung Status 1–6 Justification Form Risk Stratification Data***.	149	135.78	20,231.22	0.72	14,566.48
131	Adult Heart and HeartLung Status 1 Initial Justification Form Medical Urgency Data***.	149	5.69	847.81	0.58	491.73
132	Adult Heart and HeartLung Status 1 Exception Extension Justification Form Medical Urgency Data***.	149	0.46	68.54	0.33	22.62
133	Adult Heart and HeartLung Status 1 Criteria 1 Extension Justification Form Medical Urgency Data***.	149	0.43	64.07	0.53	33.96
134	Adult Heart and HeartLung Status 2 Initial Justification Form Medical Urgency Data***.	149	25.91	3,860.59	0.80	3,088.47
135	Adult Heart and HeartLung Status 2 Exception Extension Justification Form Medical Urgency Data***.	149	9.87	1,470.63	0.33	485.31
136	Adult Heart and HeartLung Status 2 Criteria 1 Extension Justification Form Medical Urgency Data***.	149	0.03	4.47	0.42	1.88
137	Adult Heart and HeartLung Status 2 Criteria 4 Extension Justification Form Medical Urgency Data***.	149	3.05	454.45	0.63	286.30
138	Adult Heart and HeartLung Status 2 Criteria 5 Extension Justification Form Medical Urgency Data***.	149	1.70	253.30	0.60	151.98
139	Adult Heart and HeartLung Status 3 Initial Justification Form Medical Urgency Data***.	149	11.91	1,774.59	0.63	1,117.99
140	Adult Heart and HeartLung Status 3 Exception Extension Justification Form Medical Urgency Data***.	149	6.88	1,025.12	0.33	338.29

TOTAL ESTIMATED ANNUALIZED BURDEN—HOURS—Continued

Form No.	Form name	Number of respondents	Number of responses per respondent * ****	Total responses	Average burden per response (in hours)	Total burden hours
141	Adult Heart and HeartLung Status 3 Criteria 2 Extension Justification Form Medical Urgency Data ***.	149	0.64	95.36	0.32	30.52
142	Adult Heart and HeartLung Status 3 Criteria 5 Extension Justification Form Medical Urgency Data ***.	149	0.11	16.39	0.48	7.87
143	Adult Heart and HeartLung Status 4 Initial Justification Form Medical Urgency Data ***.	149	23.51	3,502.99	0.50	1,751.50
144	Adult Heart and HeartLung Status 4 Exception Extension Justification Form Medical Urgency Data ***.	149	1.73	257.77	0.25	64.44
145	Adult Heart and HeartLung Status 4 Criteria 2 Extension Justification Form Medical Urgency Data ***.	149	0.56	83.44	0.40	33.38
146	Adult and Pediatric Lung and HeartLung Goal Exception Form ***.	149	3.72	554.28	0.75	415.71
147	Pediatric Lung Priority 1 Status Justification Form ***.	45	1.16	52.20	0.33	17.23
148	Review Board Voter Form ***	248	22.46	5,570.08	0.23	1,281.12
149	Living Donor Feedback Form ***	207	37.73	7,810.11	0.13	1,015.31
150	Extra Vessels Reporting Form ***	248	53.71	13,320.08	0.03	399.60
151	Non-US Transplants Reporting Form ***	228	0.00	0.00	0.03	0.00
152	Discrepant HLA Typings Reporting Form ***	138	0.78	107.64	5.17	556.50
153	Interim Event Reporting Form ***	248	72.58	17,999.84	0.06	1,079.99
	Total	18,697	.....	3,184,247.26	.....	851,565.51

* The numbers of respondents and total responses in the burden table were updated with 2023 OPTN data and reflect increases in the number of organ transplants and changes in the number of respondents (Transplant Centers, OPOs, and Histocompatibility Labs).

** These two forms will not be used once the OPTN Process Data OMB package is approved and implemented. The OPTN Process Data OMB package is new and will be considered separate from this package. We are including these forms in this collection to avoid any lapse in approval of these forms while the OPTN Process Data package is being approved.

*** These are new forms.

**** If a form has 0.00 under average number of responses, this indicates no submissions in calendar year 2023.

Maria G. Button,

Director, Executive Secretariat.

[FR Doc. 2025–11668 Filed 6–24–25; 8:45 am]

BILLING CODE 4165–15–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Center for Scientific Review; Notice of Closed Meetings

Pursuant to section 1009 of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meetings.

The meetings will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: Center for Scientific Review Special Emphasis Panel; RFA Panel: Supporting the next generation of researchers for ADRD research.

Date: July 23, 2025.

Time: 9:30 a.m. to 8:30 p.m.

Agenda: To review and evaluate grant applications.

Address: National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892.

Meeting Format: Virtual Meeting.

Contact Person: Sue Andersen, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892, (301) 480–5404, *sue.andersen-navalta@nih.gov*.

Name of Committee: Center for Scientific Review Special Emphasis Panel; Special Topics in Biodata Management and Computational Modeling.

Date: July 23–24, 2025.

Time: 9:30 a.m. to 6:30 p.m.

Agenda: To review and evaluate grant applications.

Address: National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892.

Meeting Format: Virtual Meeting.

Contact Person: Christopher Ryan Mahone, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Dr., Room 710F, Bethesda, MD 20892, (443) 224–3992, *mahonecr@csr.nih.gov*.

Name of Committee: Center for Scientific Review Special Emphasis Panel; NIAID Virology Quality Assurance Program.

Date: July 23, 2025.

Time: 10:00 a.m. to 1:00 p.m.

Agenda: To review and evaluate contract proposals.

Address: National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892.

Meeting Format: Virtual Meeting.

Contact Person: Barry Joseph Margulies, Ph.D., Primary is AI, 5601 Fishers Lane, Room 3G11, Rockville, MD 20852, (301) 761–7956, *barry.margulies@nih.gov*.

Name of Committee: Center for Scientific Review Special Emphasis Panel; PAR24–258: Research Resource for Human Organs and Tissues.

Date: July 23, 2025.

Time: 10:00 a.m. to 2:00 p.m.

Agenda: To review and evaluate grant applications.

Address: National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892.

Meeting Format: Virtual Meeting.

Contact Person: David Balasundaram, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5189,