

This leads to administrative burdens and financial inefficiencies for the Agency and can be confusing for manufacturers that participate in other user fee programs. To address this issue, FDA is proposing that Congress shift the facility fee due date to October and change the liability period for annual facility fees to be the 12 months immediately preceding the start of the fiscal year for which the fees are due. The proposal also includes an option for the facility to be paid in two installments in the transition year to ease the burden on fee-paying companies.

To ensure that FDA is adequately resourced with OMUFA fees, FDA is also proposing that Congress authorize a one-time adjustment in calculating annual target revenue if the average number of fee-liable facilities exceeds a particular number in certain years of OMUFA II. This would help accommodate the additional work required to oversee these facilities. If this adjustment is made, FDA is proposing it would be part of the base revenue going forward. Additionally, FDA is proposing that Congress reset the starting base revenue for OMUFA II to include the additional direct cost adjustment from the final year of OMUFA I, which reflects funding to support information technology operations and maintenance activities.

H. Impact of OMUFA II Enhancements on User Fee Revenue

To implement the proposed enhancements for OMUFA II, user fee funding for a cumulative total of 11 full-time equivalent staff is proposed to be phased in by Congress over the course of OMUFA II. The proposed new funding will be phased in as follows, as an additional dollar amount in annual fee setting:

- \$2,373,000 for FY 2026.
- \$1,233,000 for FY 2027.
- \$854,000 for FY 2028.

In addition, to support the other additional direct costs associated with the OMUFA II enhancements, the following amounts are proposed to be added as an additional direct cost adjustment:

- \$135,000 for FY 2026.
- \$300,000 for FY 2027.
- \$55,000 for FY 2028.
- \$30,000 for FY 2030.

IV. Public Meeting Information

A. Purpose and Scope of the Meeting

The public meeting will include a presentation by FDA and a series of invited panels representing different interested parties. For members of the

public who would like to make verbal comments on the proposed enhancements and other recommendations (see instructions below), there will be a public comment period at the end of the meeting. Individuals can also submit written comments to the docket [LINK] before and after the meeting until December 20, 2024.

B. Participating in the Public Meeting

Registration: Persons interested in attending this public meeting must register online by 11:59 p.m. Eastern Time on November 19, 2024, at https://fda.zoomgov.com/webinar/register/WN_aW5YWtFfQiyOSzkABY3G4A#/registration. Provide complete contact information for each attendee, including name, title, affiliation, address, email, and telephone.

Opportunity for Public Comment: Those who register online by November 13, 2024, will have the opportunity to participate in the public comment session of the meeting. If you wish to speak during the public comment session, respond “yes” to that question in the registration form. We will do our best to accommodate requests to make public comments. Individuals and organizations with common interests are urged to consolidate or coordinate their comments and request time jointly. All those who wish to make a public comment during the meeting must be registered by November 13, 2024, at 11:59 p.m. Eastern Time. We will determine the amount of time allotted to each commenter, the approximate time each comment is to begin, and will select and notify participants by November 18, 2024. No commercial or promotional material will be permitted to be presented at the public meeting.

Streaming Webcast of the Public Meeting: This public meeting will also be webcast. You will be asked to indicate in your registration if you plan to attend in person or via the webcast. The webcast for this public meeting is available at https://fda.zoomgov.com/webinar/register/WN_aW5YWtFfQiyOSzkABY3G4A#/registration.

Transcripts: Please be advised that as soon as a transcript of the public meeting is available, it will be accessible at <https://www.regulations.gov>. It may be viewed at the Dockets Management Staff (see **ADDRESSES**). A link to the transcript will also be available on the internet at <https://www.fda.gov/drugs/news-events-human-drugs/public-meeting-recommendations-over-counter-monograph-drug-user-fee-program-omufa-reauthorization>.

Dated: October 28, 2024.

Kimberlee Trzeciak,
Deputy Commissioner for Policy, Legislation,
and International Affairs.

[FR Doc. 2024–25458 Filed 10–31–24; 8:45 am]

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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

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

ACTION: Notice.

SUMMARY: In compliance with the requirement for 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 December 31, 2024.

ADDRESSES: Submit your comments to paperwork@hrsa.gov or mail the HRSA Information Collection Clearance Officer, Room 14NWH04, 5600 Fishers Lane, Rockville, Maryland, 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 or call Joella Roland, the HRSA Information Collection Clearance Officer, at (301) 443–3983.

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

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 Health and Human Services, by awards, provide for the establishment and operation of the Organ Procurement and Transplantation Network (OPTN), which, under HRSA’s

oversight, 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 official Federal approval.

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. In addition, the regulatory authority in 42 CFR 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, the Department of Health and Human Services, 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 includes OPTN BOD-approved changes to the existing OMB data collection forms. The 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 which 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-State 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 (OPOs), 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 included 96,148.84 hours due to the addition of 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 changes in the number of respondents.

TOTAL ESTIMATED ANNUALIZED BURDEN HOURS

Form #	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	23,224	0.48	11,147.40
2	Living Donor Registration	207	33.42	6,918	2.19	15,150.29
3	Living Donor Follow-up	207	94.86	19,636	1.52	29,846.75
4	Donor Histocompatibility	138	173.31	23,917	0.20	4,783.36
5	Recipient Histocompatibility	138	307.09	42,378	0.40	16,951.37
6	Heart Transplant Candidate Registration	149	38.50	5,737	0.90	5,162.85
7	Heart Transplant Recipient Registration	149	30.50	4,545	1.96	8,907.22
8	Heart Transplant Recipient Follow Up (6 Month)	149	27.79	4,141	0.40	1,656.28
9	Heart Transplant Recipient Follow Up (1-5 Year)	149	109.21	16,272	0.90	14,645.06
10	Heart Transplant Recipient Follow Up (Post 5 Year)	149	183.73	27,376	0.50	13,687.89
11	Heart Post-Transplant Malignancy Form	149	12.21	1,819	0.90	1,637.36
12	Lung Transplant Candidate Registration	74	45.36	3,357	0.95	3,188.81
13	Lung Transplant Recipient Registration	74	40.85	3,023	1.14	3,446.11
14	Lung Transplant Recipient Follow Up (6 Month)	74	35.96	2,661	0.50	1,330.52
15	Lung Transplant Recipient Follow Up (1-5 Year)	74	135.61	10,035	1.10	11,038.65
16	Lung Transplant Recipient Follow Up (Post 5 Year)	74	148.09	10,959	0.60	6,575.20
17	Lung Post-Transplant Malignancy Form	74	18.39	1,361	0.40	544.34
18	Heart/Lung Transplant Candidate Registration	72	1.03	74	1.16	86.03
19	Heart/Lung Transplant Recipient Registration	72	0.75	54	2.09	112.86
20	Heart/Lung Transplant Recipient Follow Up (6 Month)	72	0.64	46	0.80	36.86
21	Heart/Lung Transplant Recipient Follow Up (1-5 Year)	72	2.46	177	1.10	194.83
22	Heart/Lung Transplant Recipient Follow Up (Post 5 Year)	72	3.35	241	0.60	144.72
23	Heart/Lung Post-Transplant Malignancy Form	72	0.22	16	0.40	6.34
24	Liver Transplant Candidate Registration	142	103.39	14,681	0.80	11,745.10
25	Liver Transplant Recipient Registration	142	75.08	10,661	1.20	12,793.63

TOTAL ESTIMATED ANNUALIZED BURDEN HOURS—Continued

Form #	Form name	Number of respondents	Number of responses per respondent****	Total responses	Average burden per response (in hours)	Total burden hours
26	Liver Transplant Recipient Follow Up (6 Month–5 Year)	142	344.55	48,926	1.00	48,926.10
27	Liver Transplant Recipient Follow Up (Post 5 Year)	142	427.56	60,714	0.50	30,356.76
28	Liver Recipient Explant Pathology Form	142	7.17	1,018	0.60	610.88
29	Liver Post-Transplant Malignancy Form	142	21.21	3,012	0.80	2,409.46
30	Intestine Transplant Candidate Registration	18	7.50	135	1.30	175.50
31	Intestine Transplant Recipient Registration	18	5.28	95	1.80	171.07
32	Intestine Transplant Recipient Follow Up (6 Month–5 Year)	18	21.50	387	1.50	580.50
33	Intestine Transplant Recipient Follow Up (Post 5 Year)	18	49.61	893	0.40	357.19
34	Intestine Post-Transplant Malignancy Form	18	0.94	17	1.00	16.92
35	Kidney Transplant Candidate Registration	228	203.12	46,311	0.80	37,049.09
36	Kidney Transplant Recipient Registration	228	119.89	27,335	1.20	32,801.90
37	Kidney Transplant Recipient Follow Up (6 Month–5 Year)	228	571.22	130,238	0.90	117,214.34
38	Kidney Transplant Recipient Follow Up (Post 5 Year)	228	565.59	128,955	0.50	64,477.26
39	Kidney Post-Transplant Malignancy Form	228	25.60	5,837	0.80	4,669.44
40	Pancreas Transplant Candidate Registration	123	2.63	323	0.60	194.09
41	Pancreas Transplant Recipient Registration	123	0.84	103	1.20	123.98
42	Pancreas Transplant Recipient Follow Up (6 Month–5 Year)	123	5.05	621	0.50	310.58
43	Pancreas Transplant Recipient Follow Up (Post 5 Year)	123	17.11	2,105	0.50	1,052.27
44	Pancreas Post-Transplant Malignancy Form	123	0.76	93	0.60	56.09
45	Kidney/Pancreas Transplant Candidate Registration	123	12.94	1,592	0.60	954.97
46	Kidney/Pancreas Transplant Recipient Registration	123	6.59	811	1.20	972.68
47	Kidney/Pancreas Transplant Recipient Follow Up (6 Month–5 Year)	123	38.12	4,689	0.50	2,344.38
48	Kidney/Pancreas Transplant Recipient Follow Up (Post 5 Year)	123	66.63	8,195	0.60	4,917.29
49	Kidney/Pancreas Post-Transplant Malignancy Form	123	2.24	276	0.40	110.21
50	VCA Transplant Candidate Registration	23	1.00	23	0.40	9.20
51	VCA Transplant Recipient Registration	23	0.39	9	1.36	12.20
52	VCA Transplant Recipient Follow Up	23	2.30	53	1.31	69.30
53	Organ Labeling and Packaging	56	298.27	16,703	0.18	3,006.56
54	Organ Tracking and Validating	304	20.36	6,189	0.08	495.16
55	Kidney Paired Donation Candidate Registration	156	0.34	53	0.26	13.79
56	Kidney Paired Donation Donor Registration	156	0.99	154	1.08	166.80
57	Kidney Paired Donation Match Offer Management	156	0.59	92	0.67	61.67
58	Disease Transmission Event	304	2.33	708	0.60	424.99
59	Living Donor Event	207	0.15	31	0.56	17.39
60	Safety Situation	442	0.93	411	0.24	98.65
61	Potential Disease Transmission Report	56	11.09	621	1.27	788.72
62	Request to Unlock Form	442	174.67	77,204	0.02	1,544.08
63	Initial Donor Registration	56	414.71	23,224	4.61	107,061.53
64	OPO Notification Limit Administration	56	9.52	533	0.17	90.63
65	Potential Transplant Recipient	304	6,017.74	1,829,393	0.05	91,469.65
66	Death Notification Registration**	56	289.70	16,223	0.42	6,813.74
67	Deceased Donor Death Referral**	56	58.11	3,254	0.50	1,627.08
68	Donor Hospital Registration	56	0.04	2	0.08	0.18
69	Donor Organ Disposition	56	414.71	23,224	0.17	3,948.04
70	Transplant Center Contact Management	248	808.10	200,409	0.06	12,024.53
71	Adult Kidney Candidate Listing Registration***	228	204.93	46,724	0.52	24,296.50
72	Pediatric Kidney Candidate Listing Registration***	101	11.66	1,178	0.47	553.50
73	Adult Kidney Pancreas Candidate Listing Registration***	123	12.93	1,590	0.37	588.44
74	Pediatric Kidney Pancreas Candidate Listing Registration***	29	0.07	2	0.30	0.61
75	Adult Pancreas Candidate Listing Registration***	123	15.29	1,881	0.38	714.65
76	Pediatric Pancreas Candidate Listing Registration***	30	1.13	34	0.38	12.88
77	Adult Pancreas Islet Listing Registration	16	2.06	33	0.38	12.52
78	Pediatric Pancreas Islet Listing Registration***	16	0.00	0	0.33	0.00
79	Adult Liver Candidate Listing Registration***	142	98.43	13,977	0.32	4,472.66
80	Pediatric Liver Candidate Listing Registration***	57	12.37	705	0.40	282.04
81	Adult Intestine Candidate Listing Registration***	18	4.94	89	0.38	33.79
82	Pediatric Intestine Candidate Listing Registration***	18	2.56	46	0.43	19.81
83	Adult Heart Candidate Listing Registration***	149	33.58	5,003	0.83	4,152.84
84	Pediatric Heart Candidate Listing Registration***	64	11.47	734	0.58	425.77
85	Adult HeartLung Candidate Listing Registration***	72	0.97	70	0.85	59.36
86	Pediatric HeartLung Candidate Listing Registration***	27	0.15	4	0.93	3.77
87	Adult Lung Candidate Listing Registration***	74	44.85	3,319	1.00	3,318.90
88	Pediatric Lung Candidate Listing Registration***	45	0.84	38	0.83	31.37
89	Candidate Registration Listing Removal***	248	289.27	71,739	0.18	12,913.01
90	VCA Abdominal Wall Candidate Listing Registration***	8	0.38	3	0.33	1.00
91	VCA External Male Genitalia Candidate Listing Registration***	2	0.00	0	0.33	0.00
92	VCA Head and Neck Candidate Listing Registration***	10	0.50	5	0.33	1.65
93	VCA Lower Limb Candidate Listing Registration***	4	0.00	0	0.33	0.00
94	VCA Musculoskeletal Composite Graft Segment Candidate Listing Registration***	2	0.00	0	0.33	0.00
95	VCA Other Genitourinary Organ Candidate Listing Registration***	3	0.00	0	0.33	0.00
96	VCA Spleen Candidate Listing Registration***	0	0.00	0	0.33	0.00
97	VCA Upper Limb Candidate Listing Registration***	11	0.27	3	0.33	0.98
98	VCA Uterus Candidate Listing Registration***	6	2.00	12	0.33	3.96
99	VCA Vascularized Gland Candidate Listing Registration***	8	0.00	0	0.33	0.00
100	Organ Export Verification Form***	56	0.46	26	0.03	0.77
101	OPTN Waiting Time Transfer Form***	248	5.54	1,374	0.23	316.00

TOTAL ESTIMATED ANNUALIZED BURDEN HOURS—Continued

Form #	Form name	Number of respondents	Number of responses per respondent****	Total responses	Average burden per response (in hours)	Total burden hours
102	OPTN Waiting Time Modification Form***	248	59.40	14,731	0.22	3,240.86
103	OPTN Renal Waiting Time Reinstatement Form***	228	1.21	276	0.27	74.49
104	OPTN Pancreas Waiting Time Reinstatement Form***	123	0.03	4	0.20	0.74
105	Intestinal Waiting Time Reinstatement Form***	18	0.00	0	0.25	0.00
106	Prior Living Donor Priority***	228	0.25	57	0.27	15.39
107	Kidney Minimum Acceptance Criteria***	228	0.47	107	0.30	32.15
108	Adult Liver Status 1A Initial Justification and Extension Form***	142	2.31	328	0.57	186.97
109	Pediatric Liver Status 1A Initial Justification and Extension Form***	57	2.30	131	0.57	74.73
110	Pediatric Liver Status 1B Initial Justification and Extension Form***	57	5.61	320	0.47	150.29
111	Liver Cholangiocarcinoma (CCA) Initial MELD/PELD Score Exception Form***	142	0.42	60	0.43	25.65
112	Liver Cholangiocarcinoma (CCA) MELD/PELD Score Exception Extension Form***	142	0.34	48	0.32	15.45
113	Liver Cystic Fibrosis (CF) Initial MELD/PELD Score Exception and Extension Form***	142	0.10	14	0.33	4.69
114	Liver Familial Amyloid Polyneuropathy (FAP) Initial MELD/PELD Score Exception Form***	142	0.04	6	0.40	2.27
115	Liver Familial Amyloid Polyneuropathy (FAP) MELD/PELD Score Exception Extension Form***	142	0.05	7	0.30	2.13
116	Liver Hepatic Artery Thrombosis (HAT) Initial MELD/PELD Score Exception and Extension Form***	142	0.69	98	0.35	34.29
117	Liver Hepatocellular Carcinoma (HCC) Initial MELD/PELD Score Exception Form***	142	23.30	3,309	0.47	1,555.04
118	Liver Hepatocellular Carcinoma (HCC) MELD/PELD Score Exception Extension Form***	142	33.21	4,716	0.35	1,650.54
119	Liver Hepatopulmonary Syndrome (HPS) Initial MELD/PELD Score Exception Form***	142	1.39	197	0.32	63.16
120	Liver Hepatopulmonary Syndrome (HPS) MELD/PELD Score Exception Extension Form***	142	0.99	141	0.25	35.15
121	Liver Metabolic Disease Initial MELD/PELD Score Exception and Extension Form***	142	0.77	109	0.28	30.62
122	Liver Portopulmonary Hypertension Initial MELD/PELD Score Exception Form***	142	0.51	72	0.42	30.42
123	Liver Portopulmonary Hypertension MELD/PELD Score Exception Extension Form***	142	0.36	51	0.33	16.87
124	Liver Primary Hyperoxaluria Initial MELD/PELD Score Exception and Extension Form***	142	0.13	18	0.35	6.46
125	Liver Other Diagnosis Initial MELD/PELD Score Exception and Extension Form***	142	12.03	1,708	0.35	597.89
126	Pediatric Heart and HeartLung Status 1A Initial Justification Form***	64	16.06	1,028	0.52	534.48
127	Pediatric Heart and HeartLung Status 1A Extension and Appeal Justification Forms***	64	54.61	3,495	0.47	1,642.67
128	Pediatric Heart and HeartLung Status 1B Initial Justification Form***	64	7.31	468	0.42	196.49
129	Adult Heart and HeartLung Status 1–6 Justification Form Demographic Data***	149	135.78	20,231	0.32	6,473.99
130	Adult Heart and HeartLung Status 1–6 Justification Form Risk Stratification Data***	149	135.78	20,231	0.72	14,566.48
131	Adult Heart and HeartLung Status 1 Initial Justification Form Medical Urgency Data***	149	5.69	848	0.58	491.73
132	Adult Heart and HeartLung Status 1 Exception Extension Justification Form Medical Urgency Data***	149	0.46	69	0.33	22.62
133	Adult Heart and HeartLung Status 1 Criteria 1 Extension Justification Form Medical Urgency Data***	149	0.43	64	0.53	33.96
134	Adult Heart and HeartLung Status 2 Initial Justification Form Medical Urgency Data***	149	25.91	3,861	0.80	3,088.47
135	Adult Heart and HeartLung Status 2 Exception Extension Justification Form Medical Urgency Data***	149	9.87	1,471	0.33	485.31
136	Adult Heart and HeartLung Status 2 Criteria 1 Extension Justification Form Medical Urgency Data***	149	0.03	4	0.42	1.88
137	Adult Heart and HeartLung Status 2 Criteria 4 Extension Justification Form Medical Urgency Data***	149	3.05	454	0.63	286.30
138	Adult Heart and HeartLung Status 2 Criteria 5 Extension Justification Form Medical Urgency Data***	149	1.70	253	0.60	151.98
139	Adult Heart and HeartLung Status 3 Initial Justification Form Medical Urgency Data***	149	11.91	1,775	0.63	1,117.99
140	Adult Heart and HeartLung Status 3 Exception Extension Justification Form Medical Urgency Data***	149	6.88	1,025	0.33	338.29
141	Adult Heart and HeartLung Status 3 Criteria 2 Extension Justification Form Medical Urgency Data***	149	0.64	95	0.32	30.52
142	Adult Heart and HeartLung Status 3 Criteria 5 Extension Justification Form Medical Urgency Data***	149	0.11	16	0.48	7.87
143	Adult Heart and HeartLung Status 4 Initial Justification Form Medical Urgency Data***	149	23.51	3,503	0.50	1,751.50

TOTAL ESTIMATED ANNUALIZED BURDEN HOURS—Continued

Form #	Form name	Number of respondents	Number of responses per respondent****	Total responses	Average burden per response (in hours)	Total burden hours
144	Adult Heart and HeartLung Status 4 Exception Extension Justification Form Medical Urgency Data***	149	1.73	258	0.25	64.44
145	Adult Heart and HeartLung Status 4 Criteria 2 Extension Justification Form Medical Urgency Data***	149	0.56	83	0.40	33.38
146	Adult and Pediatric Lung and HeartLung Goal Exception Form***	149	3.72	554	0.75	415.71
147	Pediatric Lung Priority 1 Status Justification Form****	45	1.16	52	0.33	17.23
148	Review Board Voter Form***	248	22.46	5,570	0.23	1,281.12
149	Living Donor Feedback Form***	207	37.73	7,810	0.13	1,015.31
150	Extra Vessels Reporting Form***	248	53.71	13,320	0.03	399.60
151	Non-US Transplants Reporting Form***	228	0.00	0	0.03	0.00
152	Discrepant HLA Typings Reporting Form***	138	0.78	108	5.17	556.50
153	Interim Event Reporting Form***	248	72.58	18,000	0.06	1,079.99
Total		18,697		3,184,246		851,565.51

*The numbers of respondents and the numbers of 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 is an indicator that there were no submissions in calendar year 2023.

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.

Amy P. McNulty,

Deputy Director, Executive Secretariat.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Eunice Kennedy Shriver National Institute of Child Health & Human Development; Notice of Meeting

Pursuant to section 1009 of the Federal Advisory Committee Act, as amended, notice is hereby given of a meeting of the National Advisory Child Health and Human Development Council. The meeting will be held as a virtual meeting and will be open to the public as indicated below. Individuals who plan to view the virtual meeting and need special assistance or other reasonable accommodations to view the meeting, should notify the Contact Person listed below in advance of the meeting. The meeting can be accessed from the NIH Videocast at the following link: <https://videocast.nih.gov/>.

The meeting 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: National Advisory Child Health and Human Development Council.

Date: January 13-14, 2025.

Open: January 13, 2025, 12:00 p.m. to 5:00 p.m.

Agenda: NICHD Director's Report and other Council Business.

Address: Eunice Kennedy Shriver National Institute of Child Health and Human Development, National Institutes of Health, 6710B Rockledge Drive, Bethesda, MD 20892 (Virtual Meeting).

Closed: January 14, 2025, 9:00 a.m. to 12:15 p.m.

Agenda: To review and evaluate grant applications.

Address: Eunice Kennedy Shriver National Institute of Child Health and Human Development, National Institutes of Health, 6710B Rockledge Drive, Bethesda, MD 20892 (Virtual Meeting).

Contact Person: Rebekah S. Rasooly, Ph.D., Director, Division of Extramural Activities, Eunice Kennedy Shriver National Institute of Child Health and Human Development, National Institute of Health, 6710B Rockledge Drive, Room: 2316, Bethesda, MD 20817.

Any interested person may file written comments with the committee by forwarding the statement to the Contact Persons listed on this notice. The statement should include the name, address, telephone number and when

applicable, the business or professional affiliation of the interested person.

Information is also available on the Institute's/Center's home page: <https://www.nichd.nih.gov/about/advisory/council>, where an agenda and any additional information for the meeting will be posted when available.

(Catalogue of Federal Domestic Assistance Program Nos. 93.864, Population Research; 93.865, Research for Mothers and Children; 93.929, Center for Medical Rehabilitation Research; 93.209, Contraception and Infertility Loan Repayment Program, National Institutes of Health, HHS)

Dated: October 28, 2024.

Lauren A. Fleck,

Program Analyst, Office of Federal Advisory Committee Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Diabetes and Digestive and Kidney Diseases; Notice of Meeting

Pursuant to section 1009 of the Federal Advisory Committee Act, as amended, notice is hereby given of a meeting of the Board of Scientific Counselors, NIDDK.

The meeting will be open to the public as indicated below, with attendance limited to space available. Individuals who plan to attend and need special assistance, such as sign language interpretation or other reasonable accommodations, should