

third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on <https://www.regulations.gov>.

- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see "Written/Paper Submissions" and "Instructions").

Written/Paper Submissions

Submit written/paper submissions as follows:

- *Mail/Hand delivery/Courier (for written/paper submissions):* Dockets Management Staff (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in "Instructions."

Instructions: All submissions received must include the Docket No. FDA-2020-D-1518 for "Development of Anti-Infective Drug Products for the Pediatric Population." Received comments will be placed in the docket and, except for those submitted as "Confidential Submissions," publicly viewable at <https://www.regulations.gov> or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday, 240-402-7500.

- **Confidential Submissions**—To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states "THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION." The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on <https://www.regulations.gov>. Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not

in the body of your comments and you must identify this information as "confidential." Any information marked as "confidential" will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: <https://www.govinfo.gov/content/pkg/FR-2015-09-18/pdf/2015-23389.pdf>.

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to <https://www.regulations.gov> and insert the docket number, found in brackets in the heading of this document, into the "Search" box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, 240-402-7500.

You may submit comments on any guidance at any time (see 21 CFR 10.115(g)(5)).

Submit written requests for single copies of the draft guidance to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10001 New Hampshire Ave., Hillandale Building, 4th Floor, Silver Spring, MD 20993-0002; or the Office of Communication, Outreach, and Development, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 3128, Silver Spring, MD 20993-0002. Send one self-addressed adhesive label to assist that office in processing your requests. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

FOR FURTHER INFORMATION CONTACT:

Hiwot Hiruy, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, Rm. 6395, Silver Spring, MD 20993-0002, 240-402-0872; or Stephen Ripley, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 7301, Silver Spring, MD 20993-0002, 240-402-7911.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft guidance for industry entitled "Development of Anti-Infective Drug Products for the Pediatric Population." The purpose of this guidance is to provide general recommendations on the development of anti-infective drug products for pediatric patients. The guidance addresses initiation of

pediatric clinical trials, enrollment strategies, extrapolation of efficacy, and other considerations to help facilitate pediatric anti-infective drug development.

This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the current thinking of FDA on "Development of Anti-Infective Drug Products for the Pediatric Population." It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations.

II. Paperwork Reduction Act of 1995

This draft guidance refers to previously approved FDA collections of information. These collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501-3521). The collections of information in 21 CFR parts 50, 312, and 314, and in 21 CFR 201.56 and 201.57 have been approved under OMB control numbers 0910-0755, 0910-0014, 0910-0001, and 0910-0572, respectively.

III. Electronic Access

Persons with access to the internet may obtain the draft guidance at either <https://www.fda.gov/drugs/guidance-compliance-regulatory-information/guidances-drugs>, <https://www.fda.gov/vaccines-blood-biologics/guidance-compliance-regulatory-information-biologics/biologics-guidances>, or <https://www.regulations.gov>.

Dated: June 25, 2020.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

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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: 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 of 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. 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 30, 2020.

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 Lisa Wright-Solomon, 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.

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 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. This

extension will apply to all forms collecting donor (living and deceased) data at the time of transplant as well. These specific data elements of the OPTN data system 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.

A 60-day notice published in the **Federal Register** on January 3, 2020, vol. 85, No. 2; pp. 324–325. HRSA received one comment. The commenter encouraged HRSA to carefully weigh potential cost implications and work burden against added value when considering future additions or changes to data collection requirements. The commenter suggested that HRSA encourage the use of automated data collection techniques to minimize the information collection burden. The OPTN contract that went into effect in April 2019 includes new tasks to require the OPTN Contractor to: (1) Develop and implement a plan to collect official OPTN data through direct electronic data submission and (2) supplement official OPTN data collected by the Contractor with information from external data sources to reduce the burden on OPTN members. HRSA appreciates all feedback, and we will continue to review and evaluate all data collection efforts going forward in consultation with the OPTN.

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.

On May 31, 2019, OMB approved changes to four forms via the change memo process. The first change added a field to the Deceased Donor Registration form to allow OPOs that perform donor serology testing for Strongyloides to report the results. The second change modified a section of three forms that collect data on the health of lung transplant recipients post-transplant. The change allows for data to be collected on Chronic Lung Allograft Dysfunction, which is a broader, more contemporary definition of post-transplant lung dysfunction. Other fields pertaining to outdated measures of graft function were removed. The modifications were made to these three forms: Heart/Lung Transplant Recipient Follow-up 6 month form; Heart/Lung Transplant Recipient Follow-up 1–5 year form; and Heart/Lung Transplant Recipient Follow-up Post 5 year form.

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

TOTAL ESTIMATED ANNUALIZED BURDEN—HOURS—Continued

Form name	Number of respondents	Number of responses per respondent*	Total responses**	Average burden per response (in hours)	Total burden hours
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 Registration	71	45.2	3,210	0.9	2,889.0
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 Year)	133	57.8	7,688	0.6	4,612.8
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.

** Numbers based on 2018 forms.

Maria G. Button,
 Director, Executive Secretariat.
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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 Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meeting.

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.