

Continuing this collection will enable FDA to deepen our understanding of the outsourcing facility sector and increase our efficacy in developing a Center of Excellence that is responsive to outsourcing facilities' needs. The research results will inform FDA's future activities for the Center of Excellence in the areas of communication, education, training, and other engagement with outsourcing facilities to address challenges and support advancement.

Researchers engage with pharmacists, staff, and management from outsourcing facilities and similar compounding businesses, and related stakeholders and use surveys to obtain information about outsourcing facilities' challenges and opportunities. Within this context, we may pose the following questions or similar, related questions:

1. What financial and operational considerations inform outsourcing facility operational and business model decisions?
2. What factors impact developing a sustainable outsourcing facility business?
3. What financial and operational considerations inform outsourcing facility product decisions?
4. Do outsourcing facilities understand the Federal laws and policies that apply to them? What, if any, knowledge gaps do we need to address?
5. What are outsourcing facilities' challenges when implementing Federal CGMP requirements?
6. How do outsourcing facilities implement quality practices at their facilities?
7. How do outsourcing facilities develop CGMP and quality expertise?

How do they obtain this knowledge, and what training do they need?

8. What are the economic consequences of CGMP noncompliance and product failures for outsourcing facilities?

9. What are outsourcing facility management and staff views on current interactions with FDA? How do they want the interactions to change?

10. What are outsourcing facilities' understanding of how to engage with FDA during and following an inspection?

Respondents to this information collection are employees at outsourcing facilities and related human prescription drug compounding businesses.

FDA estimates the burden of this collection of information as follows:

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN ¹

Activity	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
Survey Invitation	250	1	250	0.0833 (5 mins)	21
Survey Questionnaire	250	1	250	0.75 (45 mins)	188
Total			500		209

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

The universe of registered outsourcing facilities and related human prescription drug compounding businesses known to the Center of Excellence will be sent a survey invitation. We reduced our estimate of the number of respondents from 300 to 250. We estimate that approximately 250 respondents will receive an invitation to participate in the survey and will spend 5 minutes reading the invitation and considering whether to take the survey, for a total of 20.825 burden hours per year, rounded to 21 hours. Based on our historical experience, we anticipate that all those invited to participate in the survey will complete the survey. We anticipate a slight reduction in burden hours to 45 minutes (0.75 hour) per survey response from our previous estimate of 1 hour per response. We estimate that approximately 250 respondents will spend 45 minutes completing the survey, for a total of 187.5 burden hours per year, rounded to 188 hours.

Based on a review of the information collection since our last request for OMB approval, we have made adjustments to our burden estimate. Our estimated burden for the information

collection reflects an overall decrease of 391 hours and a corresponding decrease of 100 responses. We have also reduced our estimated burden per survey response from 1 hour to 45 minutes.

Dated: August 29, 2024.
Lauren K. Roth,
Associate Commissioner for Policy.
 [FR Doc. 2024-19870 Filed 9-4-24; 8:45 am]
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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Allergy and Infectious Diseases; Notice of Closed Meeting

Pursuant to section 1009 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.

Name of Committee: Allergy, Immunology, and Transplantation Research Committee.

Date: October 24–25, 2024.

Time: 10:00 a.m. to 6:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institute of Allergy and Infectious Diseases, National Institutes of Health, 5601 Fishers Lane, Room 3G51, Rockville, MD 20892 (Video Assisted Meeting).

Contact Person: Thomas F. Conway, Ph.D., Scientific Review Officer, Scientific Review Program, Division of Extramural Activities, Room 3G51, National Institute of Allergy and Infectious Diseases, National Institutes of Health, 5601 Fishers Lane, Room 3G51, Rockville, MD 20892, 240-507-9685, thomas.conway@nih.gov.

(Catalogue of Federal Domestic Assistance Program Nos. 93.855, Allergy, Immunology, and Transplantation Research; 93.856, Microbiology and Infectious Diseases Research, National Institutes of Health, HHS)

Dated: August 30, 2024.

Lauren A. Fleck,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2024-19967 Filed 9-4-24; 8:45 am]

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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 Closed Meeting

Pursuant to section 1009 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.

Name of Committee: Eunice Kennedy Shriver National Institute of Child Health and Human Development Special Emphasis Panel; Using Archived Data and Specimen Collections to Advance Maternal and Pediatric HIV/AIDS Research (R21 Clinical Trial Not Allowed).

Date: October 31, 2024.

Time: 10:00 a.m. to 4:00 p.m.

Agenda: To review and evaluate grant applications.

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

Contact Person: Vera A. Cherkasova, Ph.D., Scientific Review Branch (SRB), Eunice Kennedy Shriver National Institute of Child Health and Human Development, National Institutes of Health, 6710B Rockledge Drive, Room 2137B, Bethesda, MD 20817, (240) 478-4580, vera.cherkasova@nih.gov.

(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: August 30, 2024.

Lauren A. Fleck,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2024-19966 Filed 9-4-24; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Heart, Lung, and Blood Institute; Notice of Closed Meeting

Pursuant to section 1009 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.

Name of Committee: National Heart, Lung, and Blood Institute Special Emphasis Panel; Maximizing Opportunities for Scientific and Academic Independent Careers (MOSAIC) Postdoctoral Career Transition Award to Promote Diversity (K99/R00).

Date: October 4, 2024.

Time: 1:00 p.m. to 4:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Rockledge I, 6705 Rockledge Drive, Bethesda, MD 20892, (Virtual Meeting).

Contact Person: Nawazish Ali Naqvi, Scientific Review Officer, Office of Scientific Review/DERA, National Heart, Lung and Blood Institute, National Institutes of Health, 6705 Rockledge Drive, Room 208-Y, Bethesda, MD 20892, Phone: (301) 827-7911, Email: nawazish.naqvi@nih.gov.

(Catalogue of Federal Domestic Assistance Program Nos. 93.233, National Center for Sleep Disorders Research; 93.837, Heart and Vascular Diseases Research; 93.838, Lung Diseases Research; 93.839, Blood Diseases and Resources Research, National Institutes of Health, HHS)

Dated: August 29, 2024.

Bruce A. George,

Program Analyst, Office of Federal Advisory Committee Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Office of the Secretary; Notice of Meeting

Pursuant to section 1009 of the Federal Advisory Committee Act, as amended, notice is hereby given of a meeting of the Interagency Autism

Coordinating Committee (IACC or Committee). The meeting will be virtually held and is open to public viewing. The connection information and how to access the meeting will be available on the IACC website (<https://iacc.hhs.gov>). Advanced registration is recommended. Individuals wishing to participate that need special assistance or other reasonable accommodations should submit a request to the Contact Person listed on this notice at least seven (7) business days prior to the meeting.

The purpose of this IACC meeting is to discuss the draft 2024 IACC Strategic Plan Update, which is focused on co-occurring conditions and their impacts on health outcomes in autistic individuals. This draft report summarizes current knowledge of several physical and mental health conditions and identifies additional research, services, and policy needs to improve health outcomes related to these conditions for autistic people in all communities.

Name of Committee: Interagency Autism Coordinating Committee.

Date: September 23, 2024.

Time: 9:00 a.m. to 11:00 a.m.

Agenda: To discuss the 2024 IACC Strategic Plan Update, which is focused on co-occurring conditions and the impacts on health outcomes for autistic individuals.

Place: National Institutes of Health, Neuroscience Center, 6001 Executive Boulevard, Rockville, MD 20852 (Virtual Meeting).

Cost: The meeting is free and open to the public.

Registration: A registration web link will be posted on the IACC website (www.iacc.hhs.gov) prior to the meeting. Pre-registration is recommended.

Contact Person: Ms. Rebecca Martin, Office of National Autism Coordination, National Institute of Mental Health, NIH.

Phone: 301-435-0886.

Email: IACCPublicInquiries@mail.nih.gov.

Technical issues: If you experience any technical problems, please email IACCPublicInquiries@mail.nih.gov.

Disability Accommodations: Closed Captioning is provided by Zoom. Individuals whose full virtual participation in the meeting will require special accommodations (e.g., sign language or interpreting services, etc.) must submit a request to the Contact Person listed on the notice at least seven (7) business days prior to the meeting. Such requests should include a detailed description of the accommodation needed and a way for the IACC to contact the requester if more information is needed to fill the request. Special requests should be made at least seven (7) business days prior to the meeting; last-minute requests may be