Related to Neurological Disorders; 93.854, Biological Basis Research in the Neurosciences, National Institutes of Health, HHS.)

Dated: November 9, 2022.

Tyeshia M. Roberson-Curtis,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2022–24824 Filed 11–14–22; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Proposed Collection; 60-Day Comment Request Information Program on Clinical Trials: Maintaining a Registry and Results Databank (National Library of Medicine)

AGENCY: National Institutes of Health, HHS.

ACTION: Notice.

SUMMARY: In compliance with the requirement of the Paperwork Reduction Act of 1995 to provide opportunity for public comment on proposed data collection projects, the National Library of Medicine (NLM), National Institutes of Health (NIH), will publish periodic summaries of proposed projects to be submitted to the Office of Management and Budget (OMB) for review and approval.

DATES: Comments regarding this information collection are best assured of having their full effect if received with 60 days of the date of this publication.

FOR FURTHER INFORMATION CONTACT: To obtain a copy of the data collection plans and instruments, submit comments in writing, or request more information on the proposed project, contact: Christeenna Iraheta, Office of Administrative and Management Analysis Services, National Library of Medicine, Building 38A, Room B2N12A, 8600 Rockville Pike, Bethesda, MD 20894, or call non-toll-free number (301) 827–6361, or Email your request, including your address to: *Christeenna.iraheta@nih.gov.* Formal requests for additional plans and instruments must be requested in writing.

SUPPLEMENTARY INFORMATION: Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995 requires written comments and/or suggestions from the public and affected agencies are invited to address one or more of the following points: (1) Whether the proposed collection of information is necessary for the proper performance of the function of the agency, including whether the information will have practical utility; (2) The accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) Ways to enhance the quality, utility, and clarity of the information to be collected; and (4) Ways to minimize the burden of the collection of information on those who are to respond, including the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology.

Proposed Collection Title: Information Program on Clinical Trials: Maintaining a Registry and Results Databank, 0925–0586, Expiration Date: 02/28/2023, EXTENSION, National Library of Medicine (NLM), National Institutes of Health (NIH).

Need and Use of Information Collection: The National Institutes of Health operates *ClinicalTrials.gov,* which was established as a clinical trial registry under section 113 of the Food and Drug Administration Modernization Act of 1997 (Pub. L. 105–115) and was expanded to include a results data bank by Title VIII of the Food and Drug Administration Amendments Act of 2007 (FDAAA) and by the Clinical Trials Registration and Results Information Submission regulations at 42 CFR part 11. *ClinicalTrials.gov* collects registration and results information for clinical trials and other types of clinical studies (*e.g.,* observational studies and patient registries) with the objectives of enhancing patient enrollment and providing a mechanism for tracking subsequent progress of clinical studies to the benefit of public health. It is widely used by patients, physicians, and medical researchers; in particular those involved in clinical research. While many clinical studies are registered and submit results information voluntarily, 42 CFR part 11 requires the registration of certain applicable clinical trials of drug, biological, and device products and the submission of results information for completed applicable clinical trials of drug, biological, and device products whether or not they are approved, licensed, or cleared by the Food and Drug Administration.

OMB approval is requested for 3 years. There are no costs to respondents other than their time. The total estimated annualized burden hours are 1,219,801.

ESTIMATED ANNUALIZED BURDEN HOURS

Submission type	Number of respondents	Number of responses per respondent	Average time per response (in hours)	Total annual burden hours
Registration—attachment 2				
Initial	7,400	1	8	59,200
Updates	7,400	8	2	118,400
Triggered, voluntary	141	1	8	1,128
Initial, non-regulated, NIH Policy	940	1	8	7,520
Updates, non-regulated, NIH Policy	940	8	2	15,040
Initial, voluntary and non-regulated	17,860	1	8	142,880
Updates, voluntary and non-regulated	17,860	8	2	285,760
Results Information Submission—attachment 5				
Initial	7,400	1	40	296,000
Updates	7,400	2	10	148,000
Triggered, voluntary—also attachment 2	47	1	45	2,115
Initial, non-regulated, NIH Policy	940	1	40	37,600
Updates, non-regulated, NIH Policy	940	2	10	18,800
Initial, voluntary and non-regulated	1,400	1	40	56,000

ESTIMATED ANNUALIZED BURDEN HOURS—Continued

Submission type	Number of respondents	Number of responses per respondent	Average time per response (in hours)	Total annual burden hours
Updates, voluntary and non-regulated	1,400	2	10	28,000
Other				
Certification to delay results—attachment 6	5,150	1	30/60	2,575
Extension request and Appeals—attachment 7	125	1	2	250
Initial, expanded access—attachment 3	213	1	2	426
Updates, expanded access—attachment 3	213	2	15/60	107
Total		271,122		1,219,801

Christeenna M. Iraheta,

Project Clearance Liaison, National Library of Medicine, National Institutes of Health.

[FR Doc. 2022–24859 Filed 11–14–22; 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 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.

Name of Committee: National Institute of Allergy and Infectious Diseases Special Emphasis Panel; NIAID Research Education Program (R25 Clinical Trial Not Allowed).

Date: December 9, 2022.

Time: 10:00 a.m. to 5:30 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 3F40A, Rockville, MD 20892 (Virtual Meeting).

Contact Person: Robert C. Unfer, Ph.D., Scientific Review Officer, Scientific Review Program, Division of Extramural Activities, National Institute of Allergy and Infectious Diseases, National Institutes of Health, 5601 Fishers Lane, Room 3F40A, Rockville, MD 20852, (240) 669–5035, *robert.unfer@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: November 8, 2022.

Tyeshia M. Roberson-Curtis,

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 Allergy and Infectious 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.

Name of Committee: National Institute of Allergy and Infectious Diseases Special Emphasis Panel; NIAID Investigator Initiated Program Project Applications (P01 Clinical Trial Not Allowed).

Date: December 7, 2022.

Time: 10:00 a.m. to 5:00 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 3G41, Rockville, MD 20892 (Virtual Meeting).

Contact Person: Kelly L. Hudspeth, Ph.D., Scientific Review Officer, Scientific Review Program, Division of Extramural Activities, National Institute of Allergy and Infectious Diseases, National Institutes of Health, 5601 Fishers Lane, Room 3G41, Rockville, MD 20852, 240–669–5067, *kelly.hudspeth@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: November 8, 2022.

Tyeshia M. Roberson-Curtis,

Program Analyst, Office of Federal Advisory Committee Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute on Drug Abuse; 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 contract proposals and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the contract proposals, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Institute on Drug Abuse Special Emphasis Panel; Using Rodent Behavioral Models to Identify Substance Abuse Pharmacotherapies.

Date: December 6, 2022.

Time: 4:00 p.m. to 5:00 p.m.

Agenda: To review and evaluate contract proposals.

Place: National Institutes of Health, National Institute on Drug Abuse, 301 North