

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 Diabetes and Digestive and Kidney Diseases Special Emphasis Panel; PAR22-069 High Impact, Interdisciplinary Science in NIDDK Research Areas: Adipocyte Heterogeneity (RC2).

*Date:* December 6, 2022.

*Time:* 11:30 a.m. to 1:30 p.m.

*Agenda:* To review and evaluate grant applications.

*Place:* National Institutes of Health, National Institute of Diabetes and Digestive and Kidney Diseases, 2 Democracy, 6707 Democracy Blvd., Bethesda, MD 20892 (Virtual Meeting).

*Contact Person:* Ann A Jerkins, Ph.D., Scientific Review Officer, Review Branch, DEA, NIDDK, National Institutes of Health, Room 7119, 6707 Democracy Boulevard, Bethesda, MD 20892-5452, 301-594-2242, [jerkinsa@nidk.nih.gov](mailto:jerkinsa@nidk.nih.gov).

Information is also available on the Institute's/Center's home page: [www.niddk.nih.gov/](http://www.niddk.nih.gov/), where an agenda and any additional information for the meeting will be posted when available.

(Catalogue of Federal Domestic Assistance Program Nos. 93.847, Diabetes, Endocrinology and Metabolic Research; 93.848, Digestive Diseases and Nutrition Research; 93.849, Kidney Diseases, Urology and Hematology Research, National Institutes of Health, HHS)

Dated: November 8, 2022.

**Miguelina Perez,**

*Program Analyst, Office of Federal Advisory Committee Policy.*

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**BILLING CODE 4140-01-P**

## 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 Clinical Trial Implementation Cooperative Agreement (U01 Clinical Trial Required).

*Date:* December 9, 2022.

*Time:* 9:00 a.m. to 12:00 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 3G54, Rockville, MD 20892 (Virtual Meeting).

*Contact Person:* Hitendra S. Chand, 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 3G54, Rockville, MD 20852, (240) 627-3245, [hiten.chand@nih.gov](mailto:hiten.chand@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

#### Center for Scientific Review; 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:* Center for Scientific Review Special Emphasis Panel; Emerging Imaging Technologies and Applications.

*Date:* December 6, 2022.

*Time:* 9:00 a.m. to 2:00 p.m.

*Agenda:* To review and evaluate grant applications.

*Place:* National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892 (Virtual Meeting).

*Contact Person:* Lawrence Edward Kagemann, Ph.D., Scientific Review Officer, Center for Scientific Review, 6701 Rockledge Drive, Bethesda, MD 20892, (301) 480-6849, [larry.kagemann@nih.gov](mailto:larry.kagemann@nih.gov).

(Catalogue of Federal Domestic Assistance Program Nos. 93.306, Comparative Medicine; 93.333, Clinical Research, 93.306, 93.333, 93.337, 93.393-93.396, 93.837-93.844, 93.846-93.878, 93.892, 93.893, National Institutes of Health, HHS)

Dated: November 8, 2022.

**Miguelina Perez,**

*Program Analyst, Office of Federal Advisory Committee Policy.*

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**BILLING CODE 4140-01-P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### National Institutes of Health

#### National Institute of Neurological Disorders and Stroke; 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 Neurological Disorders and Stroke Special Emphasis Panel; NINDS Special Emphasis Panel.

*Date:* December 5-6, 2022.

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

*Agenda:* To review and evaluate grant applications.

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

*Contact Person:* Marilyn Moore-Hoon, Ph.D., Scientific Review Officer, Scientific Review Branch, Division of Extramural Activities, NINDS/NIH, NSC, 6001 Executive Boulevard, Bethesda, MD 20892, 301-827-9087, [mooremar@mail.nih.gov](mailto:mooremar@mail.nih.gov).

(Catalogue of Federal Domestic Assistance Program Nos. 93.853, Clinical Research

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.*

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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.iraqueta@nih.gov](mailto:Christeenna.iraqueta@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
<b>Registration—attachment 2</b>				
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
<b>Results Information Submission—attachment 5</b>				
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