



December 8, 2021

Ilka Warshawsky, M.D., Ph.D.
 Director, Molecular Diagnostics Laboratory
 Akron Children's Hospital
 One Perkins Square
 Akron, OH 44308
Re: Revocation of EUA202545

Dear Dr. Warshawsky:

This letter is in response to Akron Children's Hospital's request received December 3, 2021, that the U.S. Food and Drug Administration (FDA) revoke the Emergency Use Authorization (EUA202545) for the Akron Children's Hospital SARS-CoV-2 Assay issued on September 29, 2020 and amended on September 23, 2021. Akron Children's Hospital confirmed that it stopped performing the Akron Children's Hospital SARS-CoV-2 Assay, having implemented a number of additional SARS-CoV-2 molecular assays which have received EUA.

The authorization of a device for emergency use under section 564 of the Federal Food, Drug, and Cosmetic Act (the Act) (21 U.S.C. 360bbb-3) may, pursuant to section 564(g)(2) of the Act, be revoked when circumstances make such revocation appropriate to protect the public health or safety (section 564(g)(2)(C) of the Act). Because Akron Children's Hospital has notified FDA that it stopped performing the Akron Children's Hospital SARS-CoV-2 Assay and requests FDA revoke the authorization, FDA has determined that it is appropriate to protect the public health or safety to revoke this authorization. Accordingly, FDA hereby revokes EUA202545 for the Akron Children's Hospital SARS-CoV-2 Assay, pursuant to section 564(g)(2)(C) of the Act. As of the date of this letter, the Akron Children's Hospital SARS-CoV-2 Assay is no longer authorized for emergency use by FDA.

Notice of this revocation will be published in the *Federal Register*, pursuant to section 564(h)(1) of the Act.

Sincerely,

/s/

Jacqueline A. O'Shaughnessy, Ph.D.
 Acting Chief Scientist
 Food and Drug Administration

Dated: January 7, 2022.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2022-00521 Filed 1-12-22; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Center for Scientific Review; Notice of Closed Meetings

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

The meetings 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: Surgical Sciences, Biomedical Imaging and Bioengineering Integrated Review Group; Clinical Translational Imaging Science Study Section.

Date: February 17-18, 2022.

Time: 9:00 a.m. to 8:00 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: Eleni Apostolos Liapi, MD, Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20817, (301) 867-5309, eleni.liapi@nih.gov.

Name of Committee: Digestive, Kidney and Urological Systems Integrated Review Group; Kidney and Urological Systems Function and Dysfunction Study Section.

Date: February 17–18, 2022.

Time: 9:00 a.m. to 6:00 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: Ganesan Ramesh, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 2182, MSC 7818, Bethesda, MD 20892, (301) 827-5467, ganesan.ramesh@nih.gov.

Name of Committee: Cardiovascular and Respiratory Sciences Integrated Review Group; Clinical Integrative Cardiovascular and Hematological Sciences Study Section.

Date: February 17–18, 2022.

Time: 9:00 a.m. to 4:00 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: Margaret Chandler, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4126, MSC 7814, Bethesda, MD 20892, (301) 435-1743, margaret.chandler@nih.gov.

Name of Committee: Biology of Development and Aging Integrated Review Group; Mechanisms of Cancer Therapeutics—1 Study Section.

Date: February 17–18, 2022.

Time: 9:00 a.m. to 7:00 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: Maria Dolores Arjona Mayor, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institute of Health, 6701 Rockledge Drive, Room 806D, Bethesda, MD 20892, (301) 827-8578, dolores.arjonamayor@nih.gov.

Name of Committee: Molecular, Cellular and Developmental Neuroscience Integrated Review Group; Molecular and Cellular Neuropharmacology Study Section.

Date: February 17–18, 2022.

Time: 9:00 a.m. to 6:00 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: Vanessa S. Boyce, Ph.D., Scientific Review Officer, Center for

Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Rm. 4185, MSC 7850, Bethesda, MD 20892, (301) 402-3726, boycevs@csr.nih.gov.

Name of Committee: Integrative, Functional and Cognitive Neuroscience Integrated Review Group; Learning, Memory and Decision Neuroscience Study Section.

Date: February 17–18, 2022.

Time: 9:00 a.m. to 8:00 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: Roger Janz, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892, (301) 402-8515, janrz2@csr.nih.gov.

Name of Committee: Infectious Diseases and Immunology A Integrated Review Group; Cellular and Molecular Immunology—A Study Section.

Date: February 17–18, 2022.

Time: 9:30 a.m. to 6:30 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: Mohammad Samiul Alam, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 809D, Bethesda, MD 20892, (301) 435-1199, alammos@csr.nih.gov.

Name of Committee: Infectious Diseases and Immunology A Integrated Review Group; Bacterial Pathogenesis Study Section.

Date: February 17–18, 2022.

Time: 9:30 a.m. to 7:00 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: Richard G Kostriken, Ph.D., AB, BA Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 3192, MSC 7808, Bethesda, MD 20892, (240) 519-7808, kostrikr@csr.nih.gov.

Name of Committee: Cardiovascular and Respiratory Sciences Integrated Review Group; Cardiovascular Differentiation and Development Study Section.

Date: February 17, 2022.

Time: 9:30 a.m. to 6:30 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: Sara Ahlgren, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, RM 4136, Bethesda, MD 20817-7814, (301) 435-0904, sara.ahlgren@nih.gov.

Name of Committee: Cell Biology Integrated Review Group; Cellular Mechanisms in Aging and Development Study Section.

Date: February 17–18, 2022.

Time: 10:00 a.m. to 8:00 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: Tami Jo Kingsbury, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 710Q, Bethesda, MD 20892, (410) 274-1352, tami.kingsbury@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: January 7, 2022.

Tyeshia M. Roberson-Curtis,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2022-00526 Filed 1-12-22; 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 Meetings

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

The meetings 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 of Allergy and Infectious Diseases Special Emphasis Panel; HHS-NIH-CDC-SBIR PHS 2022-1 Phase I: Adjuvant Discovery for Vaccines and for Autoimmune and Allergic Diseases (Topic 104).

Date: February 7, 2022.

Time: 9:00 a.m. to 6:00 p.m.

Agenda: To review and evaluate contract proposals.

Place: National Institute of Allergy and Infectious Diseases, National Institutes of Health, 5601 Fishers Lane, Room 3G56, Rockville, MD 20892 (Virtual Meeting).

Contact Person: Poonam Tewary, 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 3G56, Rockville, MD