



**FDA U.S. FOOD & DRUG  
ADMINISTRATION**

October 19, 2022

Susan Harrington, Ph.D.  
Medical Director  
The Cleveland Clinic Foundation  
9500 Euclid Avenue  
Cleveland, OH 44195  
**Re: Revocation of EUA210363**

Dear Dr. Harrington:

This letter is in response to the request from Cleveland Clinic Robert J. Tomsich Pathology and Laboratory Medicine Institute ("Cleveland Clinic"), received via email on October 7, 2022, that the U.S. Food and Drug Administration (FDA) revoke the EUA for the SelfCheck COVID-19 TaqPath Multiplex PCR assay issued on August 9, 2021. Cleveland Clinic indicated that it is no longer using the SelfCheck COVID-19 TaqPath Multiplex PCR assay and does not plan to use it in the future.

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 Cleveland Clinic has notified FDA that it is no longer using the SelfCheck COVID-19 TaqPath Multiplex PCR assay and does not plan to use it in the future and requested FDA revoke the EUA for the SelfCheck COVID-19 TaqPath Multiplex PCR assay, FDA has determined that it is appropriate to protect the public health or safety to revoke this authorization. Accordingly, FDA hereby revokes EUA210363 for the SelfCheck COVID-19 TaqPath Multiplex PCR assay, pursuant to section 564(g)(2)(C) of the Act. As of the date of this letter, the SelfCheck COVID-19 TaqPath Multiplex PCR 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/

Namandjé N. Bumpus, Ph.D.  
Chief Scientist  
Food and Drug Administration

Dated: October 31, 2022.

**Lauren K. Roth,**

*Associate Commissioner for Policy.*

[FR Doc. 2022-24072 Filed 11-3-22; 8:45 am]

**BILLING CODE 4164-01-C**

## **DEPARTMENT OF HEALTH AND HUMAN SERVICES**

### **Meeting of the Tick-Borne Disease Working Group**

**AGENCY:** Office of the Assistant  
Secretary for Health, Office of the

Secretary, Department of Health and  
Human Services.

**ACTION:** Notice; revision to meeting date.

**SUMMARY:** The Office of the Assistant Secretary for Health published a notice in the **Federal Register** on September 16, 2022, concerning a meeting of the Tick-Borne Disease Working Group (TBDWG) that was scheduled to occur on December 7, 2022. This notice is being amended to announce that the meeting has been rescheduled to November 21, 2022. This will be the final TBDWG meeting.

**DATES:** The meeting date announced in the **Federal Register** at 87 FR 5693 on September 16, 2022 is amended. The public can view the meeting online via webcast on November 21, 2022 from approximately 10 a.m. to 12 p.m. ET (times are tentative and subject to change). The confirmed times and agenda items for the meeting will be posted on the TBDWG web page at <https://www.hhs.gov/ash/advisory-committees/tickbornedisease/meetings/index.html> when this information becomes available.

**FOR FURTHER INFORMATION CONTACT:**

James Berger, Designated Federal Officer for the TBDWG; Office of Infectious Disease and HIV/AIDS Policy, Office of the Assistant Secretary for Health, Department of Health and Human Services, Tower Building, 1101 Wootton Parkway, Rockville, MD 20852. Email: [tickbornedisease@hhs.gov](mailto:tickbornedisease@hhs.gov). Phone: 202-795-7608.

**SUPPLEMENTARY INFORMATION:** A link to view the webcast can be found on the meeting website at <https://www.hhs.gov/ash/advisory-committees/tickbornedisease/meetings/index.html> when it becomes available. The public will have an opportunity to present their views to the TBDWG orally during the meeting's public comment session or by submitting a written public comment. Comments should be pertinent to the meeting discussion. Persons who wish to provide verbal or written public comment should review instructions at <https://www.hhs.gov/ash/advisory-committees/tickbornedisease/meetings/index.html> and respond by midnight November 13, 2022 ET. Verbal comments will be limited to three minutes each to accommodate as many speakers as possible during the 30-minute session. Written public comments will be accessible to the public on the TBDWG web page prior to the meeting.

Dated: October 25, 2022.

**James J. Berger,**

*Designated Federal Officer, Tick-Borne Disease Working Group, Office of Infectious Disease and HIV/AIDS Policy.*

[FR Doc. 2022-23989 Filed 11-3-22; 8:45 am]

**BILLING CODE 4150-28-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; NIH Support for Conferences and Scientific Meetings (Parent R13 Clinical Trial Not Allowed) Re-Issue PA-20-207.

*Date:* December 5-7, 2022.

*Time:* 9:00 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 3G13B, Rockville, MD 20892 (Virtual Meeting).

*Contact Person:* Yong Gao, 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 3G13B, Rockville, MD 20852, (240) 669-5048, [yong.gao@nih.gov](mailto:yong.gao@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 1, 2022.

**Tyeshia M. Roberson-Curtis,**

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

[FR Doc. 2022-24064 Filed 11-3-22; 8:45 am]

**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; Enhancing HIV Reservoir Susceptibility to Elimination (R01 Clinical Trial Not Allowed).

*Date:* November 30-December 1, 2022.

*Time:* 10:00 a.m. to 2:00 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 3G22B, Rockville, MD 20892 (Virtual Meeting).

*Contact Person:* Kristina S. Wickham, 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 3G22B, Rockville, MD 20852, 301-761-5390, [kristina.wickham@nih.gov](mailto:kristina.wickham@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 1, 2022.

**Tyeshia M. Roberson-Curtis,**

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

[FR Doc. 2022-24063 Filed 11-3-22; 8:45 am]

**BILLING CODE 4140-01-P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### National Institutes of Health

#### National Toxicology Program Board of Scientific Counselors; Announcement of Meeting; Request for Comments

**AGENCY:** National Institutes of Health, HHS.

**ACTION:** Notice.

**SUMMARY:** This notice announces the next meeting of the National Toxicology Program (NTP) Board of Scientific Counselors (BSC). The BSC, a federally chartered, external advisory group composed of scientists from the public and private sectors, will review and provide advice on programmatic activities. This meeting is a virtual meeting and is open to the public. Written comments will be accepted, and registration is required to present oral comments.

**DATES:** Meeting: Scheduled for December 15, 2022, 1:30 p.m.-5:00 p.m. Eastern Standard Time (EST). Ending times are approximate; meeting may end earlier or run later. Written Public Comment Submissions: Deadline is December 08, 2022. Registration for Oral Comments: Deadline is December 08, 2022.

**ADDRESSES:** Meeting web page: The preliminary agenda, registration, and other meeting materials will be available at <https://ntp.niehs.nih.gov/go/165> by November 10, 2022. Virtual Meeting: The URL for viewing the virtual meeting will be provided on the meeting web page the day before the meeting.

**FOR FURTHER INFORMATION CONTACT:** Dr. Milene Brownlow, Designated Federal