



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

February 14, 2022

Mohammad Kamal, MD
Omnipathology Solutions Medical Corporation
11 West Del Mar Blvd. Suite 203
Pasadena, CA 91105
Re: Revocation of EUA200170

Dear Dr. Kamal:

This letter is in response to requests from Omnipathology Solutions Medical Corporation received via email on February 7, 2022 and February 9, 2022, that the U.S. Food and Drug Administration (FDA) revoke the EUA for the COVID-19 Assay by RT-PCR issued on June 17, 2020 and amended on December 28, 2020 and September 23, 2021. Omnipathology Solutions Medical Corporation confirmed that due to discontinuation of the commercial primer and probe products used in the Omni COVID-19 Assay by RT-PCR it has decided to discontinue use of this test but continue to offer COVID-19 testing using another FDA EUA-authorized test.

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 Omnipathology Solutions Medical Corporation has notified FDA that it is no longer using the Omni COVID-19 Assay by RT-PCR and requested FDA revoke the EUA for the Omni COVID-19 Assay by RT-PCR, FDA has determined that it is appropriate to protect the public health or safety to revoke this authorization. Accordingly, FDA hereby revokes EUA200170 for the Omni COVID-19 Assay by RT-PCR, pursuant to section 564(g)(2)(C) of the Act. As of the date of this letter, the Omni COVID-19 Assay by RT-PCR 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: March 3, 2022.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2022-05310 Filed 3-11-22; 8:45 am]

BILLING CODE 4164-01-C

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Committee on Vital and Health Statistics

AGENCY: Centers for Disease Control and
Prevention.

ACTION: Notice of meeting.

SUMMARY: Pursuant to the Federal Advisory Committee Act, the Department of Health and Human Services (HHS) announces the following advisory committee meeting. This meeting is open to the public. The public is welcome to obtain the link to attend this meeting by following the instructions posted on the Committee website: <https://ncvhs.hhs.gov/meetings/full-committee-meeting-10/>.

Name: National Committee on Vital and Health Statistics (NCVHS), Meeting of the full Committee.

DATES: The meeting will be held Wednesday, March 30, 2022: 11:00 a.m.–3:00 p.m. EST.

ADDRESSES: Virtual open meeting.

FOR FURTHER INFORMATION CONTACT: Substantive program information may be obtained from Rebecca Hines, MHS, Executive Secretary, NCVHS, National Center for Health Statistics, Centers for Disease Control and Prevention, 3311 Toledo Road, Hyattsville, Maryland 20782, or via electronic mail to vgh4@cdc.gov; or by telephone (301) 458-4715. Summaries of meetings and a roster of Committee members are available on the home page of the

NCVHS website, <https://ncvhs.hhs.gov/>, where further information including an agenda and instructions to access the broadcast of the meeting will be posted.

Should you require reasonable accommodation, please contact the CDC Office of Equal Employment Opportunity on (770) 488–3210 as soon as possible.

SUPPLEMENTARY INFORMATION:

Purpose: As outlined in its Charter, the National Committee on Vital and Health Statistics assists and advises the Secretary of HHS on health data, data standards, statistics, privacy, national health information policy, and the Department's strategy to best address those issues. This includes the adoption and implementation of transaction standards, unique identifiers, operating rules and code sets adopted under the Health Insurance and Portability Act of 1996 (HIPAA).¹

At this meeting, the Committee will discuss two letters for approval, each containing a set of recommendations for HHS action. The first set conveys recommendations regarding privacy, confidentiality, and security considerations for data collection and use during a public health emergency. The second set conveys recommendations regarding standards for prior authorization, attachments, and HIPAA-designated transactions in general to support the goal to improve data sharing among patients, providers, payers, public health systems, and other actors in health care.

The Committee will reserve time for public comment toward the end of the agenda. Meeting times and topics are subject to change. Please refer to the agenda posted at the NCVHS website for this meeting at: <https://ncvhs.hhs.gov/meetings/full-committee-meeting-10/> for updates.

Sharon Arnold,

Associate Deputy Assistant Secretary, Science and Data Policy, Office of the Assistant Secretary for Planning and Evaluation.

[FR Doc. 2022–05289 Filed 3–11–22; 8:45 am]

BILLING CODE 4150–05–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Eunice Kennedy Shriver National Institute of Child Health and Human Development; 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 Child Health and Human Development Special Emphasis Panel; Contraception Development Research Center Program (P50 Clinical Trial Optional).

Date: March 23, 2022.

Time: 9:00 a.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: Eunice Kennedy Shriver National Institute of Child Health and Human Development, National Institutes of Health, 6710B Rockledge Drive, Room 2125B, Bethesda, MD 20892–7002 (Video Assisted Meeting).

Contact Person: Derek J. McLean, Ph.D., Scientific Review Officer, Scientific Review Branch, Eunice Kennedy Shriver National Institute of Child Health and Human Development, National Institute Health, 6710B Rockledge Drive, Room 2125B, Bethesda, MD 20892–7002, Derek.McLean@nih.gov.

This notice is being published less than 15 days prior to the meeting due to scheduling conflicts.

(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; National Institutes of Health, HHS)

Dated: March 9, 2022.

Melanie J. Pantoja,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2022–05330 Filed 3–11–22; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Diabetes and Digestive and Kidney 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 Diabetes and Digestive and Kidney Diseases Special Emphasis Panel; PAR19–202 High Impact, Interdisciplinary Science in NIDDK Research Areas: Hematology (RC2).

Date: April 5, 2022.

Time: 11:00 a.m. to 1:00 p.m.

Agenda: To review and evaluate grant applications.

Place: NIDDK, NIH, 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@nidddk.nih.gov.

(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: March 8, 2022.

Miguelina Perez,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2022–05284 Filed 3–11–22; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute on Aging; 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

¹ Public Law 104–191, 110 Stat. 1936 (Aug 21, 1996), available at <https://www.congress.gov/104/plaws/publ191/PLAW-104publ191.pdf>.