an opportunity for FDA to provide advice regarding how particular MIDD approaches can be used in a specific drug development program. Other deliverables as part of PDUFA VI included increasing regulatory science and review capacity in MIDD approaches and convening multiple workshops to identify best practices for MIDD (topics including E–R, PBPK, disease progression modeling, and immunogenicity assessments). In addition, FDA published or revised multiple guidances on MIDD. As part of PDUFA VII, the MIDD Paired Meeting Program has been continued and this RFI is to elicit public input on future focus areas for advancing MIDD. More information on the MIDD Paired Meeting program can be found at *https://www.fda.gov/drugs/development-resources/model-informed-drug-development-paired-meeting-program.*

II. Request for Information

FDA is interested in detailed comments on the topics listed in this section below to identify and inform future priorities for MIDD-related policy, including guidance development and engagement with interested parties. The topics identified in this section are not meant to be exhaustive. FDA is also interested in any other pertinent information that interested parties would like to share related to guidance and enhancing MIDD-related interactions with FDA. FDA encourages interested parties to provide the specific rationale and basis for their comments, including any available supporting data and information.

A. Methods and Best Practices

Several quantitative approaches, such as popPK, E–R, and PBPK, are routinely employed in drug development and regulatory assessment. The Agency aims to identify areas within these approaches that would benefit from the development of additional policies or guidance on methodology and best practices. In addition, with this RFI, the Agency is seeking input to explore potential guidance needs and appropriately identify and prioritize potential topics for guidance development in all emerging MIDD approaches for drug and biological products, including but not limited to, AI/ML used in both drug design and evaluation and digital-twin technology.

B. Context-Specific Considerations

MIDD approaches that leverage comprehensive information—including disease and patient population characteristics (*e.g.,* intrinsic and extrinsic factors), drug properties, placebo effects, nonclinical and clinical E–R relationships—are potent tools and can be utilized across all stages of the drug development life cycle to support decision making. This is particularly important for rare diseases and emerging therapeutic and prophylactic/preventative modalities where there may be practical and ethical challenges in conducting traditional drug development programs or where there is limited drug development experience. We seek input on the need to develop guidances that discuss considerations to facilitate MIDD methods development, application, uptake, and acceptance in specific therapeutic areas. Related topics include identification of opportunities for incorporation of real-world data, specific therapeutic modality considerations, and preclinical to clinical translations and to appropriately identify and prioritize potential topics in this area.

C. Regulatory Engagement

Building on the success of the MIDD Paired Meeting Program, FDA is interested in better understanding ways to facilitate discussion around MIDD approaches outside the MIDD Paired Meeting Program as part of regulatory meetings and regulatory submissions. This includes identifying what is currently working well and what are the barriers (*e.g.,* technical, regulatory) encountered while trying to interact with FDA on MIDD-related activities.

D. Communication of Policies and Interested Parties' Engagement

FDA continues to engage on MIDD approaches as part of external workshops with interested parties, including workshops described and completed under PDUFA VI. FDA seeks to identify and prioritize potential topics and better ways for communication and engagement with interested parties.

Dated: August 28, 2024.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2024–19712 Filed 8–30–24; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Charter Renewal for the Advisory Committee on Organ Transplantation

AGENCY: Health Resources and Services Administration (HRSA), Department of Health and Human Services.

ACTION: Notice.

SUMMARY: In accordance with the Federal Advisory Committee Act, the Department of Health and Human Services is hereby giving notice that the charter for the Advisory Committee on Organ Transplantation (ACOT or Committee) is renewed. The effective date of the renewed charter is August 31, 2024.

FOR FURTHER INFORMATION CONTACT: Shelley Tims Grant, Division of Transplantation, HRSA, 5600 Fishers Lane, 08W67, Rockville, Maryland 20857; 301–443–8036; or *sgrant@hrsa.gov.*

SUPPLEMENTARY INFORMATION: ACOT provides advice and recommendations to the Secretary of Health and Human Services on policy, program development, and other matters of significance concerning the activities under 42 U.S.C. 217a; Section 222 of the Public Health Service Act, as amended. ACOT provides advice and recommendations on proposed or implemented Organ Procurement and Transplantation Network policies (including those related to organ donation, procurement, allocation, transplantation, patient safety, and data collection, among other policy topics), and on such other matters that the Secretary of Health and Human Services determines. ACOT ensures checks and balances, transparency, and a focus on patient-centered practices. The topics covered by ACOT may be broad and cross-sectional.

The renewed charter for ACOT was approved on August 9, 2024. The filing date is August 31, 2024. Renewal of the ACOT charter gives authorization for the Committee to operate until August 31, 2026.

A copy of the ACOT charter is available on the ACOT website at *https://www.hrsa.gov/advisory-committees/organ-transplantation.* A copy of the charter also can be obtained by accessing the FACA database that is maintained by the Committee Management Secretariat under the General Services Administration. The

website address for the FACA database is *http://www.facadatabase.gov/.*

Maria G. Button,

Director, Executive Secretariat.

[FR Doc. 2024–19618 Filed 8–30–24; 8:45 am]

BILLING CODE 4165–15–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Eunice Kennedy Shriver National Institute of Child Health & Human Development; Notice of Closed Meeting

Pursuant to section 1009 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: Eunice Kennedy Shriver National Institute of Child Health and Human Development Special Emphasis Panel; Obstetrics and Maternal-Fetal Biology & Reproduction/Member Conflict.

Date: November 6, 2024.

Time: 12:00 p.m. to 4:00 p.m.

Agenda: To review and evaluate grant applications.

Place: Eunice Kennedy Shriver National Institute of Child Health and Human Development, 6710 Rockledge Drive, Bethesda, MD 20892 (Virtual Meeting).

Contact Person: Anita Szajek, Ph.D., Scientific Review Branch, *Eunice Kennedy Shriver* National Institute of Child Health and Human Development, NIH, 6701 Rockledge Drive, Room 2131D, Bethesda, MD 20892, (301) 496–5966, *anita.szajek@nih.gov*

(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; 93.209, Contraception and Infertility Loan Repayment Program, National Institutes of Health, HHS)

Dated: August 27, 2024.

Lauren A. Fleck,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2024–19651 Filed 8–30–24; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Cancer Institute; Amended Notice of Meeting

Notice is hereby given of a change in the meeting of the National Cancer Advisory Board, September 03, 2024, 06:00 p.m. to September 05, 2024, 12:00 p.m., National Cancer Institute, Shady Grove, 9609 Medical Center Drive, Room TE406 & 408, Bethesda, MD 20892, (In Person and Virtual Meeting), which was published in the **Federal Register** on July 31, 2024, FR Doc 2024–16816, 89 FR 61490.

This meeting notice is being amended to change the meeting time of the National Cancer Advisory Board (NCAB) Subcommittee Meetings; the date and time of the open session of the NCAB Meeting; and the time of the closed session of the NCAB. The NCAB Subcommittee Meetings on September 3, 2024, will now be held from 6:00 p.m. to 8:15 p.m. instead of from 6:00 p.m. to 9:00 p.m. The open session of the NCAB will now be held on September 4, 2024, from 9:00 a.m. to 3:15 p.m. instead of on September 4–5, 2024, from 9:00 a.m. to 12:00 p.m. The closed session of the NCAB on September 3, 2024, will now be held from 3:30 p.m. to 4:30 p.m. instead of from 3:50 p.m. to 5:00 p.m. The open session of the NCAB can be accessed from the NIH Videocast at the following link: *https://videocast.nih.gov/.* The meeting is partially closed to the public.

Dated: August 27, 2024.

David W. Freeman,

Supervisory Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2024–19701 Filed 8–30–24; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Eunice Kennedy Shriver National Institute of Child Health & Human Development; Notice of Closed Meeting

Pursuant to section 1009 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: Eunice Kennedy Shriver National Institute of Child Health and Human Development Special Emphasis Panel; Member Conflict: Biobehavioral and Behavioral Sciences.

Date: November 8, 2024.

Time: 11:30 a.m. to 12:30 p.m.

Agenda: To review and evaluate grant applications.

Place: Eunice Kennedy Shriver National Institute of Child Health and Human Development, 6710 Rockledge Drive, Bethesda, MD 20892 (Virtual Meeting).

Contact Person: Luis E. Dettin, Ph.D., MA, MS, Scientific Review Branch (SRB), *Eunice Kennedy Shriver* National Institute of Child Health and Human Development, National Institutes of Health, 6710B Rockledge Drive, Room 2131D, Bethesda, MD 20817, (301) 827–8231, *luis.dettin@nih.gov.*

(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; 93.209, Contraception and Infertility Loan Repayment Program, National Institutes of Health, HHS)

Dated: August 27, 2024.

Lauren A. Fleck,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2024–19647 Filed 8–30–24; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Substance Abuse and Mental Health Services Administration

Current List of HHS-Certified Laboratories and Instrumented Initial Testing Facilities Which Meet Minimum Standards To Engage in Urine and Oral Fluid Drug Testing for Federal Agencies

AGENCY: Substance Abuse and Mental Health Services Administration, HHS.

ACTION: Notice.

SUMMARY: The Department of Health and Human Services (HHS) notifies Federal agencies of the laboratories and Instrumented Initial Testing Facilities (IITFs) currently certified to meet the standards of the Mandatory Guidelines for Federal Workplace Drug Testing Programs (Mandatory Guidelines) using Urine and the laboratories currently certified to meet the standards of the Mandatory Guidelines using Oral Fluid.