II. Project Participation

CDER is seeking a maximum of five participants in this pilot. The Center will use its discretion in choosing participants based on the completeness of the submission per the guidelines below. CDER requests participants to submit a nonclinical study package containing the materials:

- SEND–DART v1.1 datasets;
- final related study report containing individual animal data and summary tables [6] (PDF Format);
- nonclinical Study Data Reviewers Guide; [7]
- define.xml (v2.0); [8] and
- sample standardization study protocol.

CDER will prioritize nonclinical packages that contain Embryo-Fetal Development (EFD) Toxicity studies (using pre-bred females only) that contain data that is consistent with SEND–DART v1.1. Therefore, the studies that meet as many of the following use cases as possible will be the most sought out as participants in this pilot:

- Small animals (rodents, rabbits), pre-bred females, treatment period during implanted embryo's major organogenesis period;
- material toxicity endpoints (minimum CL, BW, FW, DS);
- caesarean section endpoints in PY, IC, FM, FX (pregnancy, Corpora Lutea, implantations, resorptions, fetal viability, fetal sex and body weights, fetal morphology);
- toxicokinetic females to illustrate in Trial Design and pregnancy results (PC, PP domains optional);
- LB domain optional since not routine in EFD Toxicity study;
- MA optional (if gross observations scheduled, may not be in preliminary EFD study);
- gravid uterine weights (OM domain) for deriving gravid uterus adjusted body weight; and
- pregnant, non-pregnant, toxicokinetic females to illustrate in Trial Design and pregnancy results (PC, PP domains optional).

Please indicate in your request for participation the extent to which your submission will meet the above listed criteria. Please also indicate whether you are willing to share anonymized data with the CDISC FFU team.

This pilot is intended to inform of the readiness of the SEND–DART standard and support improvements to the SEND–DART that will benefit FDA and submitters. Pilot participants commit to publicly share lessons learned with the CDISC SEND team to ensure that the CDISC SEND standard is improved for the community. Participants may redact any sensitive information as needed to enable sharing FDA feedback with the CDISC SEND team.

III. Requests for Participation

Requests to participate in the SEND–DART FFU pilot are to be identified with the Docket No. FDA–2020–N–1806. Interested persons should include the following information in the request: Contact name, contact phone number, email address, name of the sponsor, and address, as well as the description of the criteria met, addressing each of the items in the Project participation section.

Once requests for participation are received CDER will contact interested sponsors to discuss the pilot project and clarify requirements and expectations. The elapsed time duration of the pilot is expected to be approximately 9 months but may be extended as needed.

Dated: October 16, 2020.

Lauren K. Roth,

Acting Principal Associate Commissioner for Policy.

[FR Doc. 2020–23393 Filed 10–21–20; 8:45 am]

BILLING CODE 4164–01–P

[6] See the FDA Study Data Resources web page, available at *https://www.fda.gov/ForIndustry/DataStandards/StudyDataStandards/default.htm.*

[7] See the PhUSE Wiki web page, available at *https://www.phusewiki.org/wiki/index.php?title=Nonclinical_Study_Data_Reviewers_Guide.*

[8] See Footnote 6.

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Proposed Establishment of the Advisory Committee on Heritable Disorders in Newborns and Children

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

ACTION: Proposed Establishment of the Advisory Committee on Heritable Disorders in Newborns and Children (ACHDNC or Committee).

SUMMARY: In accordance with the Federal Advisory Committee Act (FACA) and section 1111 of the Public Health Service (PHS) Act, HHS announces the establishment of the ACHDNC as a discretionary advisory committee.

FOR FURTHER INFORMATION CONTACT: Mia Morrison (DFO), Maternal and Child Health Bureau, HRSA, 5600 Fishers Lane, Rockville, Maryland 20857; 301–443–2521; or *mmorrison@hrsa.gov.*

SUPPLEMENTARY INFORMATION: The ACHDNC provides advice and recommendations to the Secretary of HHS on policy, program development, and other matters of significance concerning certain activities described in section 1111 of the PHS Act (42 U.S.C. 300b–10), as further described below. The ACHDNC is also governed by the provisions of the FACA, as amended (5 U.S.C. App.), which sets forth standards for the formation and use of advisory committees. The ACHDNC advises the Secretary of HHS about aspects of newborn and childhood screening and technical information for the development of policies and priorities that will enhance the ability of the state and local health agencies to provide for newborn and child screening, counseling, and health care services for newborns and children having, or at risk for, heritable disorders. The ACHDNC will review and report regularly on newborn and childhood screening practices, recommend improvements in the national newborn and childhood screening programs, and fulfill responsibilities described in section 1111 of the PHS Act. In addition, the ACHDNC's recommendations regarding inclusion of additional conditions for screening, following adoption by the Secretary of HHS, are considered evidence-informed preventive health services provided for in the comprehensive guidelines supported by HRSA through the Recommended Uniform Screening Panel (RUSP) pursuant to section 2713 of the PHS Act (42 U.S.C. 300gg–13). Under this provision, non-grandfathered group health plans and health insurance issuers offering group or individual health insurance are required to provide insurance coverage without cost-sharing (a co-payment, co-insurance, or deductible) for preventive services for plan years (*i.e.,* policy years) beginning on or after the date that is one year from the Secretary's adoption of the condition for screening.

Notice of Establishment: In accordance with the FACA and section 1111 of the PHS Act, (42 U.S.C. 300b–10) the Secretary of HHS announces the proposed establishment of the ACHDNC.

It has been determined that the formation of the ACHDNC is in the public interest in connection with the performance of duties imposed on the Department of Health and Human Services by law. A copy of the ACHDNC charter can be accessed on the ACHDNC website once available. A copy of the charter also can be obtained, once available, by accessing the FACA

database that is maintained by the Committee Management Secretariat of the General Services Administration. The website address for this database is *http://www.facadatabase.gov/.*

Maria G. Button,

Director, Executive Secretariat.

[FR Doc. 2020–23363 Filed 10–21–20; 8:45 am]

BILLING CODE 4165–15–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Meeting of the Presidential Advisory Council on HIV/AIDS

AGENCY: Department of Health and Human Services, Office of the Secretary, Office of the Assistant Secretary for Health.

ACTION: Notice of a virtual meeting.

SUMMARY: As stipulated by the Federal Advisory Committee Act, the U.S. Department of Health and Human Service is hereby giving notice that the Presidential Advisory Council on HIV/AIDS (PACHA or the Council) will be holding the 69th full Council meeting utilizing virtual technology. PACHA members will be discussing HIV, the *Ending the HIV Epidemic: A Plan for America* (EHE) initiative, and the novel coronavirus (COVID–19). The meeting will be open to the public; a public comment session will be held during the meeting. Pre-registration is required to provide public comment. To pre-register to attend or to provide public comment, please send an email to *PACHA@hhs.gov* and include your name, organization, and title by close of business Friday November 20, 2020. If you decide you would like to provide public comment but do not pre-register, you may submit your written statement by emailing *PACHA@hhs.gov* by close of business Thursday, December 10, 2020. The meeting agenda will be posted on the PACHA page on *HIV.gov* at *https://www.hiv.gov/ federal-response/pacha/about-pacha* prior to the meeting.

DATES: The meeting will be held on Wednesday, December 2 and Thursday, December 3, 2020, from approximately 1:00 p.m. to 5:00 p.m. (ET) on both days. This meeting will be conducted utilizing virtual technology.

ADDRESSES: Instructions on attending this meeting virtually will be posted one week prior to the meeting at: *https://www.hiv.gov/federal-response/pacha/about-pacha.*

FOR FURTHER INFORMATION CONTACT: Ms. Caroline Talev, MPA, Public Health Analyst, Presidential Advisory Council on HIV/AIDS, 330 C Street SW, Room L609A, Washington, DC 20024; (202) 795–7622 or *PACHA@hhs.gov.* Additional information can be obtained by accessing the Council's page on the *HIV.gov* site at *www.hiv.gov/pacha.*

SUPPLEMENTARY INFORMATION: PACHA was established by Executive Order 12963, dated June 14, 1995, as amended by Executive Order 13009, dated June 14, 1996 and is currently operating under the authority given in Executive Order 13889, dated September 27, 2019. The Council was established to provide advice, information, and recommendations to the Secretary regarding programs and policies intended to promote effective prevention and care of HIV infection and AIDS. The functions of the Council are solely advisory in nature.

The Council consists of not more than 25 members. Council members are selected from prominent community leaders with particular expertise in, or knowledge of, matters concerning HIV and AIDS, public health, global health, philanthropy, marketing or business, as well as other national leaders held in high esteem from other sectors of society. Council members are appointed by the Secretary or designee, in consultation with the White House.

Dated: October 15, 2020.

B. Kaye Hayes,

Principal Deputy Director, Office of Infectious Disease and HIV/AIDS Policy, Executive Director, Presidential Advisory Council on HIV/AIDS, Office of the Assistant Secretary for Health, Department of Health and Human Services.

[FR Doc. 2020–23397 Filed 10–21–20; 8:45 am]

BILLING CODE 4150–43–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; Engineering Immunity to HIV–1 Through Next Generation Vaccines (R61/R33 Clinical Trial Not Allowed).

Date: November 20, 2020.

Time: 11:00 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, 6701 Rockledge Drive, Room 1206, Bethesda, MD 20892 (Virtual Meeting).

Contact Person: John C. Pugh, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institute of Allergy and Infectious Diseases, National Institutes of Health, 6701 Rockledge Drive, Room 1206, Bethesda, MD 20892, (301) 435–2398, *pughjohn@csr.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: October 16, 2020.

Tyeshia M. Roberson,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2020–23369 Filed 10–21–20; 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; Rational Design of Vaccines Against Hepatitis C Virus (U19 Clinical Trial Not Allowed).

Date: November 18–19, 2020.

Time: 10:00 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