

“confidential.” Any information marked as “confidential” will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA’s posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: <https://www.gpo.gov/fdsys/pkg/FR-2015-09-18/pdf/2015-23389.pdf>.

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to <https://www.regulations.gov> and insert the docket number, found in brackets in the heading of this document, into the “Search” box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Susan Storey, Center for Veterinary Medicine, Food and Drug Administration, 7500 Standish Pl. (HFV–131), Rockville, MD, 20855, 240–402–0578, susan.storey@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of July 9, 2019 (84 FR 32749), FDA published a notice of public meeting and request for comment with a 30-day comment period to request comments on the use of complex adaptive and other novel investigation designs, data from foreign countries, real world evidence, and biomarkers and surrogate endpoints in animal drug development and regulatory decision making. Comments are intended to support FDA guidance development as required under section 305 of the Animal Drug and Animal Generic Drug User Fee Amendments of 2018 (Pub. L. 115–234). Section 305 directs FDA to develop guidance to address several alternative approaches in clinical investigations for new animal drugs.

The Agency has received a request for a 30-day extension of the comment period for the notice of meeting. The request conveyed concern that the current 30-day comment period does not allow sufficient time to develop a meaningful or thoughtful response to alternative approaches in clinical investigations for new animal drugs.

FDA has considered the request and is extending the comment period for the notice of public meeting for 30 days, until September 16, 2019. The Agency believes that a 30-day extension allows adequate time for interested persons to submit comments without significantly delaying the development of guidance on these important issues.

Dated: August 7, 2019.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

[FR Doc. 2019–17258 Filed 8–12–19; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Office of the Director; Notice of Charter Renewal

In accordance with Title 41 of the U.S. Code of Federal Regulations, Section 102–3.65(a), notice is hereby given that the Charter for the Novel and Exceptional Technology and Research Advisory Committee was renewed for an additional two-year period on June 30, 2019. Prior to this renewal, the Charter was amended to reflect the Committee’s name change from the Recombinant DNA Advisory Committee to the Novel and Exceptional Technology and Research Advisory Committee.

It is determined that the Novel and Exceptional Technology and Research Advisory Committee is in the public interest in connection with the performance of duties imposed on the National Institutes of Health by law, and that these duties can best be performed through the advice and counsel of this group.

Inquiries may be directed to Claire Harris, Director, Office of Federal Advisory Committee Policy, Office of the Director, National Institutes of Health, 6701 Democracy Boulevard, Suite 1000, Bethesda, Maryland 20892 (Mail code 4875), Telephone (301) 496–2123, or harriscl@mail.nih.gov.

Dated: August 7, 2019.

Ronald J. Livingston, Jr.,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2019–17244 Filed 8–12–19; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Center for Scientific Review; 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: Center for Scientific Review Special Emphasis Panel; PAR17–097: Planning for Non-Communicable Diseases and Disorders Research Training Programs.

Date: August 20, 2019.

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

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892 (Telephone Conference Call).

Contact Person: Brian H. Scott, Ph.D., Scientific Review Officer, National Institutes of Health, Center for Scientific Review, 6701 Rockledge Drive, Bethesda, MD 20892, 301–827–7490, brianscott@mail.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: August 7, 2019.

Sylvia L. Neal,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2019–17246 Filed 8–12–19; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Scientific Advisory Committee on Alternative Toxicological Methods; Announcement of Meeting; Request for Comments

AGENCY: National Institutes of Health, HHS.

ACTION: Notice.

SUMMARY: This notice announces the next meeting of the Scientific Advisory Committee on Alternative Toxicological Methods (SACATM). SACATM, a federally chartered external advisory group of scientists from the public and private sectors, including representatives of regulated industry and national animal protection organizations, advises the Interagency Coordinating Committee on the Validation of Alternative Methods (ICCVAM), the National Toxicology Program (NTP) Interagency Center for the Evaluation of Alternative Toxicological Methods (NICEATM), and the Director of the National Institute of

Environmental Sciences (NIEHS) and NTP regarding statutorily mandated duties of ICCVAM and activities of NICEATM. The meeting is open to the public and registration is requested for both attendance and oral comments and required to access the webcast. Information about the meeting and registration are available at <https://ntp.niehs.nih.gov/go/32822>.

DATES:

Meeting: September 19–20, 2019; begins at 9:00 a.m. (EDT) each day and continues until adjournment.

Written Public Comment

Submissions: Deadline is September 12, 2019.

Register to Present Oral Comments: Deadline is September 12, 2019.

Registration for Meeting: Deadline is September 12, 2019 to attend in person and September 20, 2019 to view the webcast.

Registration to view the meeting via the webcast is required.

ADDRESSES:

Meeting Location: Crowne Plaza Crystal City—Washington, DC, 1480 Crystal Drive, Arlington, Virginia 22202.

Meeting Web Page: The preliminary agenda, registration, and other meeting materials are at <https://ntp.niehs.nih.gov/go/32822>.

Webcast: The meeting will be webcast; the URL will be provided to those who register for viewing.

FOR FURTHER INFORMATION CONTACT: Dr. Elizabeth Maull, Designated Federal Official for SACATM, Office of Liaison, Policy and Review, Division of NTP, NIEHS, P.O. Box 12233, K2–17, Research Triangle Park, NC 27709. Phone: 984–287–3157, Fax: 301–480–3008, Email: maull@niehs.nih.gov. Hand Deliver/Courier address: 530 Davis Drive, Room K2021, Morrisville, NC 27560.

SUPPLEMENTARY INFORMATION:

Meeting and Registration: The meeting is open to the public with time scheduled for oral public comments; attendance at the meeting is limited only by the space available.

SACATM will provide input to ICCVAM, NICEATM, and NIEHS on programmatic activities and issues. Preliminary agenda items for the upcoming meeting include: (1) New approaches to the principles and practice of validation, (2) developing a next generation data infrastructure to support the development and implementation of new approach methodologies (NAMs) for complex endpoints, and (3) translational impact and human relevance of NAMs. Please see the preliminary agenda for

information about the specific presentations.

The preliminary agenda, roster of SACATM members, background materials, public comments, and any additional information will be posted when available on the SACATM meeting website (<https://ntp.niehs.nih.gov/go/32822>) or may be requested in hardcopy from the Designated Federal Official for SACATM. Following the meeting, summary minutes will be prepared and made available on the SACATM meeting website.

Interested persons may attend the meeting in person or view the webcast. Registration is required to view the webcast; the URL for the webcast will be provided in the email confirming registration. Individuals who plan to provide oral comments (see below) are encouraged to register online at the SACATM meeting website (<https://ntp.niehs.nih.gov/go/32822>) by September 12, 2019, to facilitate planning for the meeting. Individuals are encouraged to visit the website often to stay abreast of the most current information regarding the meeting. Individuals with disabilities who need accommodation to participate in this event should contact Ms. Robbin Guy at phone: (984) 287–3136 or email: guyr2@niehs.nih.gov. TTY users should contact the Federal TTY Relay Service at 800–877–8339. Requests should be made at least five business days in advance of the event.

Written Public Comments: Written and oral public comments are invited for the agenda topics. Guidelines for public comments are available at https://ntp.niehs.nih.gov/ntp/about_ntp/guidelines_public_comments_508.pdf. The deadline for submission of written comments is September 12, 2019. Written public comments should be submitted through the meeting website. Persons submitting written comments should include name, affiliation, mailing address, phone, email, and sponsoring organization (if any). Written comments received in response to this notice will be posted on the NTP website, and the submitter will be identified by name, affiliation, and sponsoring organization (if any).

Oral Public Comment Registration: The preliminary agenda allows for several public comment periods, each allowing up to four commenters a maximum of five minutes per speaker. Oral comments may be presented in person at Crowne Plaza Crystal City—Washington, DC, 1480 Crystal Drive, Arlington, Virginia 22202 or by teleconference line. Registration for oral comments is on or before September 12,

2019, at <https://ntp.niehs.nih.gov/go/32822>. Registration is on a first-come, first-served basis, and each registrant will be assigned a number in their confirmation email. Each organization is allowed one time slot per comment period. After the maximum number of speakers per comment period is exceeded, individuals registering to submit an oral comment for the topic will be placed on a wait list and notified should an opening become available. Commenters will be notified after September 12, 2019, about the actual time allotted per speaker, and the teleconference number will be sent to those registered to give oral comments by teleconference line. If possible, oral public commenters should send a copy of their slides and/or statement or talking points to Robbin Guy by email: guyr2@niehs.nih.gov by September 12, 2019.

Meeting Materials: The preliminary meeting agenda will be posted when available on the meeting web page <https://ntp.niehs.nih.gov/go/32822> and will be updated one week before the meeting. Individuals are encouraged to visit this web page often to stay abreast of the most current information regarding the meeting.

Background Information on ICCVAM, NICEATM, and SACATM: ICCVAM is an interagency committee composed of representatives from 16 federal regulatory and research agencies that require, use, generate, or disseminate toxicological and safety testing information. ICCVAM conducts technical evaluations of new, revised, and alternative safety testing methods and integrated testing strategies with regulatory applicability and promotes the scientific validation and regulatory acceptance of testing methods that more accurately assess the safety and hazards of chemicals and products and replace, reduce, or refine (enhance animal well-being and lessen or avoid pain and distress) animal use.

The ICCVAM Authorization Act of 2000 (42 U.S.C. 285l–3) establishes ICCVAM as a permanent interagency committee of NIEHS and provides the authority for ICCVAM involvement in activities relevant to the development of alternative test methods. Additional information about ICCVAM can be found at <http://ntp.niehs.nih.gov/go/iccvam>.

NICEATM administers ICCVAM, provides scientific and operational support for ICCVAM-related activities, and conducts and publishes analyses and evaluations of data from new, revised, and alternative testing approaches. NICEATM and ICCVAM work collaboratively to evaluate new

and improved testing approaches applicable to the needs of U.S. federal agencies. NICEATM and ICCVAM welcome the public nomination of new, revised, and alternative test methods and strategies for validation studies and technical evaluations. Additional information about NICEATM can be found at <http://ntp.niehs.nih.gov/go/niceatm>.

SACATM, established by the ICCVAM Authorization Act [Section 285]–3(d)], provides advice on priorities and activities related to the development, validation, scientific review, regulatory acceptance, implementation, and national and international harmonization of new, revised, and alternative toxicological test methods to ICCVAM, NICEATM, and Director of NIEHS and NTP. Additional information about SACATM, including the charter, roster, and records of past meetings, can be found at <http://ntp.niehs.nih.gov/go/167>.

Brian R. Berridge,

Associate Director, National Toxicology Program.

[FR Doc. 2019–17269 Filed 8–12–19; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Center for Advancing Translational Sciences; Amended Notice of Meeting

Notice is hereby given of a change in the meeting of the National Center for Advancing Translational Sciences Advisory Council, which was published in the **Federal Register** on June 27, 2019, 84 FR 30740, Pg. 30744.

Amendment to change start time of the closed session from 9 a.m. to 8:30 a.m. and to change the start time of the open session from 11 a.m. to 10 a.m. The meeting is partially Closed to the public.

Dated: August 7, 2019.

Melanie J. Pantoja,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2019–17245 Filed 8–12–19; 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; NIH Support for Conferences and Scientific Meetings (Parent R13 Clinical Trial Not Allowed).

Date: August 28, 2019.

Time: 1:00 p.m. to 3:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 5601 Fishers Lane, Rockville, MD 20892 (Telephone Conference Call).

Contact Person: Steven F. Santos, Ph.D., Scientific Review Officer, SRP, DEA, NIAID–NIH, DHHS, 5601 Fishers Lane, 3G33, Rockville, MD 20852, Phone: 301–761–7049, Cell: 202–306–4207, steven.santos@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: August 7, 2019.

Sylvia L. Neal,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2019–17247 Filed 8–12–19; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Substance Abuse and Mental Health Services Administration

Agency Information Collection Activities: Submission for OMB Review; Comment Request

Periodically, the Substance Abuse and Mental Health Services Administration (SAMHSA) will publish a summary of information collection requests under OMB review, in compliance with the

Paperwork Reduction Act (44 U.S.C. Chapter 35). To request a copy of these documents, call the SAMHSA Reports Clearance Officer on (240) 276–1243.

Project: Protection and Advocacy for Individuals With Mental Illness (PAIMI) Final Rule, 42 CFR Part 51 (OMB No. 0930–0172)—Extension

These regulations meet the directive under 42 U.S.C. 10826(b) requiring the Secretary to promulgate final regulations to carry out the PAIMI Act (42 U.S.C. 10801 *et seq.*). The regulations contain information collection requirements associated with the rule. The Act authorizes funds to support activities on behalf of individuals with significant (severe) mental illness (adults) or significant (severe) emotional impairment (children/youth) as defined by the Act at 42 U.S.C. 10802(4) and 10804(d). Only entities designated by the governor of each state, including the American Samoa, Guam, Commonwealth of the Northern Mariana Islands, Commonwealth of Puerto Rico, U.S. Virgin Islands, District of Columbia (Mayor), and the tribal councils of the American Indian Consortium (the Hopi Tribe and the Navajo Nation located in the Four Corners region of the Southwest), to protect and advocate the rights of persons with developmental disabilities are eligible to receive PAIMI Program grants [*ibid* at 42 U.S.C. at 10802(2)]. These grants are based on a formula prescribed by the Secretary [*ibid* at 42 U.S.C. at 10822(a)(1)(A)].

On January 1, each eligible state protection and advocacy (P&A) system is required to prepare an annual PAIMI Program Performance Report (PPR). Each annual PPR describes a P&A system's activities, accomplishments and expenditures to protect the rights of individuals with mental illness supported with payments from PAIMI program allotments during the most recently completed fiscal year. Each P&A system transmit a copy of its annual report to the Secretary (via SAMHSA) and to the State Mental Health Agency where the system is located per the PAIMI Act at 42 U.S.C. 10824(a). Each annual PPR must provide the Secretary with the following information:

- The number of (PAIMI-eligible) individuals with mental illness served;
- A description of the types of activities undertaken;
- A description of the types of facilities providing care or treatment to which such activities are undertaken;
- A description of the manner in which the activities are initiated;