

2016; PCT Application No. PCT/US2017/039595 filed 06/27/2017 (pending).

Related Intellectual Property: HHS Reference Number E-531-2013, E-293-2011, E-060-2015.

Licensing Contact: Barry Buchbinder, Ph.D., 240-627-3678; barry.buchbinder@nih.gov.

Dated: July 20, 2018.

Suzanne M. Frisbie,

Deputy Director, Technology Transfer and Intellectual Property Office, National Institute of Allergy and Infectious Diseases.

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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 composed of scientists from the public and private sectors, including representatives of regulated industry and national animal protection organization, will review and provide advice on programmatic activities. SACATM 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 comment 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 5-6, 2018; Begins at 9:00 a.m. (EDT) each day and continues until adjournment.

Written Public Comment Submissions: Deadline is August 29, 2018.

Oral Comments: Deadline is August 29, 2018.

Registration for Meeting: Deadline September 6, 2018.

Registration to view the meeting via the webcast is required.

ADDRESSES:

Meeting Location: Rodbell Auditorium, Rall Building, National Institute of Environmental Health Sciences (NIEHS), 111 T.W. Alexander Drive, Research Triangle Park, NC 27709.

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. Mary Wolfe, Designated Federal Official for the SACATM, Office of Liaison, Policy and Review, Division of NTP, NIEHS, P.O. Box 12233, K2-03, Research Triangle Park, NC 27709. Phone: 984-287-3209, Fax: 301-451-5759, Email: wolfe@niehs.nih.gov. Hand Deliver/Courier address: 530 Davis Drive, Room K2130, 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 includes the US Strategic Roadmap including challenges to and opportunities for implementing non-animal approaches to evaluate chemicals and medical products and the importance of international harmonization through the Organisation for Economic Co-operation and Development activities. 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, when available, will be posted 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 BSC meeting website.

The public 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 August 29, 2018, to facilitate planning for the meeting. Individuals are encouraged to access the website to stay abreast of the most current information regarding the meeting. Visitor and security information for those attending in-person is available at niehs.nih.gov/about/visiting/index.cfm. 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 comment 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 August 29, 2018. 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 with each allowing for up to 4 commenters for up to 5 minutes per speaker. Oral comments may be presented in person at NIEHS or by teleconference line. Registration for oral comments is on or before August 29, 2018, at <https://ntp.niehs.nih.gov/go/32822>. Registration is on a first-come, first-served basis, and registrants 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 registered to provide oral comment will be placed on a wait list and notified should an opening become available. Commenters will be notified after August 29, 2018, 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 August 29, 2018.

Meeting Materials: The preliminary meeting agenda is 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 access the meeting web page 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 with regulatory applicability and promotes the scientific validation and regulatory acceptance of toxicological and safety-testing methods that more accurately assess the safety and hazards of chemicals and products and that reduce, refine (decrease or eliminate pain and distress), or replace animal use. The ICCVAM Authorization Act of 2000 (42 U.S.C. 285l-3) established ICCVAM as a permanent interagency committee of the NIEHS under NICEATM.

NICEATM administers ICCVAM, provides scientific and operational support for ICCVAM-related activities, and conducts independent validation studies to assess the usefulness and limitations of new, revised, and alternative test methods and strategies. NICEATM and ICCVAM work collaboratively to evaluate new and improved test methods and strategies 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 ICCVAM and NICEATM can be found at <http://ntp.niehs.nih.gov/go/iccvam> and <http://ntp.niehs.nih.gov/go/niceatm>.

SACATM was established in response to the ICCVAM Authorization Act [Section 285l-3(d)] and is composed of scientists from the public and private sectors. SACATM advises ICCVAM, NICEATM, and the Director of the NIEHS and NTP regarding statutorily mandated duties of ICCVAM and activities of NICEATM. SACATM 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.

Additional information about SACATM, including the charter, roster, and records of past meetings, can be found at <http://ntp.niehs.nih.gov/go/167>.

Dated: July 24, 2018.

Brian R. Berridge,

Associate Director, National Toxicology Program.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Mental Health; Notice of Meeting

Pursuant to section 10(a) of the Federal Advisory Committee Act, as amended, notice is hereby given of a meeting of the Interagency Autism Coordinating Committee.

The meeting will be open to the public, with attendance limited to space available. Individuals who plan to attend and need special assistance, such as sign language interpretation or other reasonable accommodations, should notify the Contact Person listed below in advance of the meeting.

Name of Committee: Interagency Autism Coordinating Committee (IACC).

Type of Meeting: Open Meeting.

Date: Wednesday, October 17, 2018.

Time: 9:00 a.m. to 5:00 p.m. *Eastern Time* Approximate end time.

Agenda: To discuss business, updates, and issues related to ASD research and services activities.

Place: National Institutes of Health, Neuroscience Center, 6001 Executive Boulevard, Conference Room C and D, Rockville, MD 20852.

Webcast Live: <https://videocast.nih.gov>.

Conference Call Access: Dial: 800-369-3190.

Access Code: 1724926.

Cost: The meeting is free and open to the public.

Registration: A registration web link will be posted on the IACC website (www.iacc.hhs.gov) prior to the meeting. Pre-registration is recommended to expedite check-in. Seating in the meeting room is limited to room capacity and on a first come, first served basis. Onsite registration will also be available.

Deadlines: Notification of interest to present oral comments: Friday, October 5, 2018 by 5:00 p.m. ET

Submission of written/electronic statement for oral comments: Tuesday, October 9, 2018 by 5:00 p.m. ET

Submission of written comments: Tuesday, October 9, 2018 by 5:00 p.m. ET

For IACC Public Comment guidelines please see: <https://iacc.hhs.gov/meetings/public-comments/guidelines/>

Access: White Flint Metro Station (Red Line) in combination with a brief walk.

Contact Person: Ms. Angelice Mitrasak, Office of Autism Research Coordination, National Institute of Mental Health, NIH, 6001 Executive Boulevard, Room 6182A, Bethesda, MD 20892-9669, Phone: 301-435-9269, Email: IACCPublicInquiries@mail.nih.gov.

Public Comments: Any member of the public interested in presenting oral comments to the IACC must notify the Contact Person listed on this notice by 5:00 p.m. ET on Friday, October 5, 2018 with their request to present oral comments at the meeting, and a written/electronic copy of the oral presentation/statement must be submitted by 5:00 p.m. ET on Tuesday, October 9, 2018. A limited number of slots for oral comment are available, and in order to ensure that as many different individuals are able to present throughout the year as possible, any given individual only will be permitted to present oral comments once per calendar year (2018). Only one representative of an organization will be allowed to present oral comments in any given meeting; other representatives of the same group may provide written comments. If the oral comment session is full, individuals who could not be accommodated are welcome to provide written comments instead. Comments to be read or presented in the meeting will be assigned a 3-5 minute time slot depending on the number of comments, but a longer version may be submitted in writing for the record. Commenters going beyond their allotted time in the meeting may be asked to conclude immediately in order to allow other comments and presentations to proceed on schedule.

Any interested person may submit written public comments to the IACC prior to the meeting by emailing the comments to IACCPublicInquiries@mail.nih.gov or by submitting comments at the web link: <https://iacc.hhs.gov/meetings/public-comments/submit/index.jsp> by 5:00 p.m. ET on Tuesday, October 9, 2018. The comments should include the name, address, telephone number, and when applicable, the business or professional affiliation of the interested person. National Institute on Mental Health (NIMH) anticipates written public comments received by 5:00 p.m. ET on Tuesday, October 9, 2018 will be presented to the IACC prior to the meeting for the IACC's consideration. Any written comments received after the 5:00 p.m. ET, October 9, 2018 deadline through October 15,