

“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