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- **Confidential Submissions**—To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states “THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.” The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on <https://www.regulations.gov>. Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as “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.

You may submit comments on any guidance at any time (see 21 CFR 10.115(g)(5)).

Submit written requests for single copies of the guidance to the Policy and Regulations Staff (HFV-6), Center for Veterinary Medicine, Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855. Send one self-addressed adhesive label to assist that office in processing your request. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance document.

**FOR FURTHER INFORMATION CONTACT:** Julia Oriani, Center for Veterinary Medicine (HFV-151), Food and Drug

Administration, 7500 Standish Pl., Rockville, MD 20855, 240-402-0788, [julia.oriani@fda.hhs.gov](mailto:julia.oriani@fda.hhs.gov).

#### **SUPPLEMENTARY INFORMATION:**

##### **I. Background**

In the **Federal Register** of July 21, 2016 (81 FR 47397), FDA published the notice of availability for a draft revised GFI #3 entitled “General Principles for Evaluating the Human Food Safety of New Animal Drugs Used in Food-Producing Animals” giving interested persons until September 19, 2016, to comment on the draft revised GFI. FDA received several comments on the draft revised GFI, and those comments were considered as the guidance was finalized. Revisions to the document were made for accuracy and clarification based on comments received from the public, including reinsertion of information specific to endogenous sex steroids, and minor editorial edits. The guidance announced in this notice finalizes the draft revised GFI dated July 2016.

##### **II. Significance of Guidance**

This level 1 guidance is being issued consistent with FDA’s good guidance practices regulation (21 CFR 10.115). The guidance represents the current thinking of FDA on “General Principles for Evaluating the Human Food Safety of New Animal Drugs Used in Food-Producing Animals.” It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations. This guidance is not subject to Executive Order 12866.

##### **III. Paperwork Reduction Act of 1995**

This guidance refers to previously approved collections of information found in FDA regulations. These collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). The collections of information in 21 CFR part 514 have been approved under OMB control number 0910-0032.

##### **IV. Electronic Access**

Persons with access to the internet may obtain the guidance at either <https://www.fda.gov/AnimalVeterinary/GuidanceComplianceEnforcement/GuidanceforIndustry/default.htm> or <https://www.regulations.gov>.

Dated: June 7, 2018.

**Leslie Kux,**

*Associate Commissioner for Policy.*

[FR Doc. 2018-12607 Filed 6-11-18; 8:45 am]

**BILLING CODE 4164-01-P**

## **DEPARTMENT OF HEALTH AND HUMAN SERVICES**

### **National Institutes of Health**

#### **National Library of Medicine: Notice of Meetings**

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended, notice is hereby given of a meeting of the Board of Scientific Counselors, Lister Hill National Center for Biomedical Communications.

The meeting will be open to the public as indicated below, 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.

The meeting will be closed to the public as indicated below in accordance with the provisions set forth in section 552b(c)(6), Title 5 U.S.C., as amended for review, discussion, and evaluation of individual intramural programs and projects conducted by the National Library of Medicine, including consideration of personnel qualifications and performance, and the competence of individual investigators, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

*Name of Committee:* Board of Scientific Counselors, Lister Hill National Center for Biomedical Communications.

*Date:* September 6–7, 2018.

*Open:* September 6, 2018, 9:00 a.m. to 12:00 p.m.

*Agenda:* Review of research and development programs and preparation of reports of the Lister Hill National Center for Biomedical Communications.

*Place:* National Library of Medicine, Building 38, 2nd Floor, The Lindberg Room, 8600 Rockville Pike, Bethesda, MD 20892.

*Closed:* September 6, 2018, 12:00 p.m. to 4:30 p.m.

*Agenda:* To review and evaluate personal qualifications, performance, and competence of individual investigators.

*Place:* National Library of Medicine, Building 38, 2nd Floor, The Lindberg Room, 8600 Rockville Pike, Bethesda, MD 20892.

*Closed:* September 7, 2018, 9:00 a.m. to 10:00 a.m.

*Agenda:* To review and evaluate personal qualifications, performance, and competence of individual investigators.

*Place:* National Library of Medicine, Building 38, 2nd Floor, The Lindberg Room, 8600 Rockville Pike, Bethesda, MD 20892.

*Contact Person:* Karen Steely, Program Assistant, Lister Hill National Center for Biomedical Communications, National Library of Medicine, Building 38A, Room 7S707, Bethesda, MD 20892, 301-827-4385, [ksteely@mail.nih.gov](mailto:ksteely@mail.nih.gov).

*Open:* September 7, 2018, 10:00 a.m. to 11:30 a.m.

*Agenda:* Review of research and development programs and preparation of reports of the Lister Hill National Center for Biomedical Communications.

*Place:* National Library of Medicine, Building 38, 2nd Floor, The Lindberg Room, 8600 Rockville Pike, Bethesda, MD 20892.

*Contact Person:* Karen Steely, Program Assistant, Lister Hill National Center for Biomedical Communications, National Library of Medicine, Building 38A, Room 7S707, Bethesda, MD 20892, 301-827-4385, [ksteely@mail.nih.gov](mailto:ksteely@mail.nih.gov).

Any interested person may file written comments with the committee by forwarding the statement to the Contact Person listed on this notice. The statement should include the name, address, telephone number and when applicable, the business or professional affiliation of the interested person.

In the interest of security, NIH has instituted stringent procedures for entrance onto the NIH campus. All visitor vehicles, including taxicabs, hotel, and airport shuttles will be inspected before being allowed on campus. Visitors will be asked to show one form of identification (for example, a government-issued photo ID, driver's license, or passport) and to state the purpose of their visit.

(Catalogue of Federal Domestic Assistance Program No. 93.879, Medical Library Assistance, National Institutes of Health, HHS)

Dated: June 6, 2018.

**Michelle D. Trout,**

*Program Analyst, Office of Federal Advisory Committee Policy.*

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**BILLING CODE 4140-01-P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### National Institutes of Health

#### National Library of Medicine; Notice of Closed Meetings

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended, notice is hereby given of the meetings.

The meetings 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 materials,

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:* Biomedical Informatics, Library and Data Sciences Review Committee.

*Date:* November 15-16, 2018.

*Time:* November 15, 2018, 8:00 a.m. to 5:00 p.m.

*Agenda:* To review and evaluate grant applications.

*Place:* Bethesda Hyatt, 1 Bethesda Metro Center, Bethesda, MD 20814.

*Time:* November 16, 2018, 8:00 a.m. to 5:00 p.m.

*Agenda:* To review and evaluate grant applications.

*Contact Person:* Zoe E. Huang, MD, Acting Chief Scientific Review Officer, Scientific Review Office, Extramural Programs, National Library of Medicine, NIH, 6705 Rockledge Drive, Suite 301, Bethesda, MD 20892-7968, 301-594-4937, [huangz@mail.nih.gov](mailto:huangz@mail.nih.gov).

(Catalogue of Federal Domestic Assistance Program No. 93.879, Medical Library Assistance, National Institutes of Health, HHS)

Dated: June 6, 2018.

**Michelle D. Trout,**

*Program Analyst, Office of Federal Advisory Committee Policy.*

[FR Doc. 2018-12536 Filed 6-11-18; 8:45 am]

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### National Institutes of Health

#### Center for Scientific Review; Notice of Closed Meetings

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meetings.

The meetings 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; Planning for Non-Communicable Diseases and Disorders Research Training Programs in Low and Middle Income Countries (D71).

*Date:* June 21, 2018.

*Time:* 1:00 p.m. to 4:00 p.m.

*Agenda:* To review and evaluate grant applications.

*Place:* National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892 (Virtual Meeting).

*Contact Person:* Fungai Chanetsa, MPH, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 3135, MSC 7770, Bethesda, MD 20892, 301-408-9436, [fungai.chanetsa@nih.hhs.gov](mailto:fungai.chanetsa@nih.hhs.gov).

This notice is being published less than 15 days prior to the meeting due to the timing limitations imposed by the review and funding cycle.

*Name of Committee:* Center for Scientific Review Special Emphasis Panel; Research on Current Topics in Alzheimer's Disease and Its Related Dementias.

*Date:* July 2-3, 2018.

*Time:* 8:00 a.m. to 5:00 p.m.

*Agenda:* To review and evaluate grant applications.

*Place:* National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892 (Virtual Meeting).

*Contact Person:* Michael Selmanoff, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5164, MSC 7844, Bethesda, MD 20892, 301-435-1119, [selmanom@csr.nih.gov](mailto:selmanom@csr.nih.gov).

*Name of Committee:* Center for Scientific Review Special Emphasis Panel; Member Conflict: Computational Structural Biology.

*Date:* July 9, 2018.

*Time:* 1:00 p.m. to 4:00 p.m.

*Agenda:* To review and evaluate grant applications.

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

*Contact Person:* Sergei Ruvinov, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4158, MSC 7806, Bethesda, MD 20892, 301-435-1180, [ruvinser@csr.nih.gov](mailto:ruvinser@csr.nih.gov).

*Name of Committee:* Center for Scientific Review Special Emphasis Panel; Fellowships: Cell Biology, Developmental Biology, and Bioengineering.

*Date:* July 10-11, 2018.

*Time:* 8:00 a.m. to 6:00 p.m.

*Agenda:* To review and evaluate grant applications.

*Place:* Doubletree Hotel Bethesda (Formerly Holiday Inn Select), 8120 Wisconsin Avenue, Bethesda, MD 20814.

*Contact Person:* Alexander Gubin, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4196, MSC 7812, Bethesda, MD 20892, 301-435-2902, [gubina@csr.nih.gov](mailto:gubina@csr.nih.gov).

*Name of Committee:* AIDS and Related Research Integrated Review Group, AIDS-associated Opportunistic Infections and Cancer Study Section.

*Date:* July 10, 2018.

*Time:* 8:00 a.m. to 6:00 p.m.

*Agenda:* To review and evaluate grant applications.

*Place:* Embassy Suites at the Chevy Chase Pavilion, 4300 Military Road NW, Washington, DC 20015.

*Contact Person:* Eduardo A. Montalvo, Ph.D., Scientific Review Officer, Center for