

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Submit written requests for single copies of the draft guidance to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10001 New Hampshire Ave., Hillandale Building, 4th Floor, Silver Spring, MD 20993-0002, or the Office of Communication, Outreach and Development, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 3128, Silver Spring, MD 20993-0002. Send one self-addressed adhesive label to assist that office in processing your requests. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

FOR FURTHER INFORMATION CONTACT: Patrick McNeilly, Office of Good Clinical Practice, Food and Drug Administration, 10903 New Hampshire

Avenue, Bldg. 32, Rm. 5172, Silver Spring, MD 20993-0002, 301-796-2941.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft guidance for industry entitled "Civil Money Penalties Relating to the ClinicalTrials.gov Data Bank; Draft Guidance for FDA Staff, Responsible Parties, and Submitters of Certain Applications and Submissions to FDA." The draft guidance provides the current thinking of FDA's CDER, CBER, and CDRH (Center, or collectively Centers), regarding civil money penalties for responsible parties and/or submitters of certain applications and submissions to FDA regarding drug products, biological products, or device products (submitters) who violate applicable FD&C Act (21 U.S.C. 301 *et seq.*) prohibitions relating to requirements under section 402(j) of the Public Health Service Act (PHS Act) (42 U.S.C. 282(j)), including its implementing regulations in 42 CFR part 11, to submit registration and/or results information to the *ClinicalTrials.gov* data bank and/or certain certifications to FDA. The draft guidance is intended to address several questions. First, how the Centers identify whether responsible parties have failed to submit required clinical trial registration and/or results information to the *ClinicalTrials.gov* data bank or submitted false or misleading information to the data bank, and whether submitters have failed to submit the certification required by section 402(j)(5)(B) of the PHS Act (42 U.S.C. 282(j)(5)(B)) to FDA or knowingly submitted a false certification to FDA. Second, under what circumstances a Center may decide to seek civil money penalties against a responsible party or submitter. Third, what procedures apply when a Center seeks civil money penalties; and finally, what civil money penalty amounts may be assessed for: (1) Failing to submit required clinical trial registration and/or results information to the *ClinicalTrials.gov* data bank, (2) knowingly submitting false or misleading clinical trial information to the data bank, (3) failing to submit the required certification to FDA, or (4) knowingly submitting a false certification to FDA.

This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the current thinking of FDA on civil money penalties relating to the *ClinicalTrials.gov* data bank. 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.

II. Electronic Access

Persons with access to the internet may obtain the draft guidance at either <https://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm> or <https://www.regulations.gov>.

Dated: September 17, 2018.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2018-20560 Filed 9-20-18; 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; Evaluation and Implementation of Patient Care.

Date: October 11, 2018.

Time: 10:00 a.m. to 12:00 p.m.

Agenda: To review and evaluate grant applications.

Place: Capital Skyline Hotel, 10 I Street SW, Washington, DC 20024.

Contact Person: Gabriel B. Fosu, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 3108, MSC 7808, Bethesda, MD 20892, (301) 435-3562, fosug@csr.nih.gov.

Name of Committee: Center for Scientific Review Special Emphasis Panel; PAR Panel: Academic-Industrial Partnerships Research for Cancer Diagnosis and Treatment.

Date: October 15-16, 2018.

Time: 8:00 a.m. to 5:30 p.m.

Agenda: To review and evaluate grant applications.

Place: Hyatt Regency Bethesda, One Bethesda Metro Center, 7400 Wisconsin Avenue, Bethesda, MD 20814.

Contact Person: Guo Feng Xu, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5122, MSC 7854, Bethesda, MD 20892, 301-237-9870, xuguofen@csr.nih.gov.

Name of Committee: Genes, Genomes, and Genetics Integrated Review Group; Genetic Variation and Evolution Study Section.

Date: October 15–16, 2018.

Time: 8:30 a.m. to 3:00 p.m.

Agenda: To review and evaluate grant applications.

Place: Residence Inn San Diego Downtown Bayfront, 900 Bayfront Court, San Diego, CA 92104.

Contact Person: Cheryl M. Corsaro, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 2204, MSC 7890, Bethesda, MD 20892, (301) 435-1045, corsaroc@csr.nih.gov.

Name of Committee: Biobehavioral and Behavioral Processes Integrated Review Group; Child Psychopathology and Developmental Disabilities Study Section.

Date: October 18–19, 2018.

Time: 8:00 a.m. to 3:00 p.m.

Agenda: To review and evaluate grant applications.

Place: Ritz-Carlton Hotel, 1700 Tysons Boulevard, McLean, VA 22102.

Contact Person: Katherine Colona Morasch, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 3170, Bethesda, MD 20892, moraschkc@csr.nih.gov.

Name of Committee: Endocrinology, Metabolism, Nutrition and Reproductive Sciences Integrated Review Group; Integrative and Clinical Endocrinology and Reproduction Study Section.

Date: October 18, 2018.

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

Agenda: To review and evaluate grant applications.

Place: Courtyard by Marriott Silver Spring, 8506 Fenton Street, Silver Spring, MD 20910.

Contact Person: Dianne Hardy, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 6175, MSC 7892, Bethesda, MD 20892, 301-435-1154, dianne.hardy@nih.gov.

Name of Committee: Center for Scientific Review Special Emphasis Panel; PAR Panel: Surgical Disparities Research.

Date: October 19, 2018.

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

Agenda: To review and evaluate grant applications.

Place: Hotel Palomar, 2121 P Street NW, Washington, DC 20037.

Contact Person: Yvonne Owens Ferguson, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 3139, Bethesda, MD 20892, 301-827-3689, fergusonyo@csr.nih.gov.

Name of Committee: Center for Scientific Review Special Emphasis Panel; PAR18-721: Counter Act Exploratory Grants.

Date: October 19, 2018.

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

Agenda: To review and evaluate grant applications.

Place: Lord Baltimore Hotel, 20 West Baltimore Street, Baltimore, MD 21201.

Contact Person: Geoffrey G. Schofield, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4040-A, MSC 7850, Bethesda, MD 20892, 301-435-1235, geoffreys@csr.nih.gov.

Name of Committee: Center for Scientific Review Special Emphasis Panel; Member Conflict: Medical Imaging Investigations.

Date: October 19, 2018.

Time: 10:00 a.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: Guo Feng Xu, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5122, MSC 7854, Bethesda, MD 20892, 301-237-9870, xuguofen@csr.nih.gov.

Name of Committee: Center for Scientific Review Special Emphasis Panel; PAR 18-039: Intellectual and Developmental Disabilities Outcomes.

Date: October 19, 2018.

Time: 3:00 p.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: Ritz-Carlton Hotel, 1700 Tysons Boulevard, McLean, VA 22102.

Contact Person: Katherine Colona Morasch, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 3170, Bethesda, MD 20892, moraschkc@csr.nih.gov.

Name of Committee: Center for Scientific Review Special Emphasis Panel; Ocular Surface, Cornea, Anterior Segment Glaucoma and Refractive Error.

Date: October 22–23, 2018.

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

Agenda: To review and evaluate grant applications.

Place: Beacon Hotel and Corporate Quarters, 1615 Rhode Island Avenue NW, Washington, DC 20036.

Contact Person: Kristin Kramer, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5205, MSC 7846, Bethesda, MD 20892, (301) 437-0911, kramerkm@csr.nih.gov.

Name of Committee: Infectious Diseases and Microbiology Integrated Review Group; Virology—A Study Section.

Date: October 22–23, 2018.

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

Agenda: To review and evaluate grant applications.

Place: Westin Crystal City, 1800 Jefferson Davis Highway, Arlington, VA 22202.

Contact Person: Kenneth M Izumi, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 3204, MSC 7808, Bethesda, MD 20892, 301-496-6980, izumikm@csr.nih.gov.

Name of Committee: Oncology 1—Basic Translational Integrated Review Group; Tumor Microenvironment Study Section.

Date: October 22–23, 2018.

Time: 8:00 a.m. to 5:30 p.m.

Agenda: To review and evaluate grant applications.

Place: Ritz-Carlton Hotel, 1700 Tysons Boulevard, McLean, VA 22102.

Contact Person: Angela Y. Ng, Ph.D., MBA, Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 6200, MSC 7804, Bethesda, MD 20892, 301-435-1715, ngan@mail.nih.gov.

Name of Committee: Cell Biology Integrated Review Group; Membrane Biology and Protein Processing Study Section.

Date: October 22–23, 2018.

Time: 8:00 a.m. to 1:00 p.m.

Agenda: To review and evaluate grant applications.

Place: Residence Inn Bethesda, 7335 Wisconsin Avenue, Bethesda, MD 20814.

Contact Person: Janet M. Larkin, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5142, MSC 7840, Bethesda, MD 20892, 301-806-2765, larkinja@csr.nih.gov.

Name of Committee: Brain Disorders and Clinical Neuroscience Integrated Review Group; Aging Systems and Geriatrics Study Section.

Date: October 22–23, 2018.

Time: 8:00 a.m. to 5:00 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: Inese Z. Beitins, MD, Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 6152, MSC 7892, Bethesda, MD 20892, 301-435-1034, beitinsi@csr.nih.gov.

Name of Committee: Oncology 1—Basic Translational Integrated Review Group; Cancer Genetics Study Section.

Date: October 22–23, 2018.

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

Agenda: To review and evaluate grant applications.

Place: Bahia Resort Hotel, 998 West Mission Bay Drive, San Diego, CA 92109.

Contact Person: Juraj Bies, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4158, MSC 7806, Bethesda, MD 20892, 301-435-1256, biesj@mail.nih.gov.

Name of Committee: Infectious Diseases and Microbiology Integrated Review Group; Virology—B Study Section.

Date: October 22–23, 2018.

Time: 8:30 a.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: The Alexandrian, 480 King Street, Alexandria, VA 22314.

Contact Person: John C. Pugh, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 1206, MSC 7808, Bethesda, MD 20892, (301) 435-2398, pughjohn@csr.nih.gov.

Name of Committee: Vascular and Hematology Integrated Review Group;

Vascular Cell and Molecular Biology Study Section.

Date: October 22–23, 2018.

Time: 8:30 a.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: Hyatt Regency Bethesda, One Bethesda Metro Center, 7400 Wisconsin Avenue, Bethesda, MD 20814.

Contact Person: Larry Pinkus, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4132, MSC 7802, Bethesda, MD 20892, (301) 435–1214, lpinkusl@csr.nih.gov.

Name of Committee: Biobehavioral and Behavioral Processes Integrated Review Group; Adult Psychopathology and Disorders of Aging Study Section.

Date: October 22–23, 2018.

Time: 8:30 a.m. to 3:00 p.m.

Agenda: To review and evaluate grant applications.

Place: Ritz-Carlton Hotel at Pentagon City, 1250 South Hayes Street, Arlington, VA 22202.

Contact Person: Serena Chu, Ph.D., Scientific Review Officer, BBBP IRG, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 3178, MSC 7848, Bethesda, MD 20892, (301) 500–5829, sechu@csr.nih.gov.

Name of Committee: Center for Scientific Review Special Emphasis Panel; Risk Prevention and Health Behavior AREA Review.

Date: October 22, 2018.

Time: 11:00 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: John H. Newman, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 3222, MSC 7808, Bethesda, MD 20892, (301) 435–0628, newmanjh@csr.nih.gov.

Name of Committee: Center for Scientific Review Special Emphasis Panel; Member Conflict: Psychosocial Risks and Disease Prevention.

Date: October 22, 2018.

Time: 12:00 p.m. to 3:00 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: Weijia Ni, Ph.D., Chief/Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 3100, MSC 7808, Bethesda, MD 20892, 301–594–3292, niw@csr.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: September 17, 2018.

Sylvia L. Neal,

Program Analyst, Office of Federal Advisory Committee Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Center for Scientific Review; Notice of Closed Meetings

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Name of Committee: Bioengineering Sciences & Technologies Integrated Review Group; Modeling and Analysis of Biological Systems Study Section.

Date: October 18–19, 2018.

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

Agenda: To review and evaluate grant applications.

Place: The William F. Bolger Center, 9600 Newbridge Drive, Potomac, MD 20854.

Contact Person: Craig Giroux, Ph.D., Scientific Review Officer, BST IRG, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5150, Bethesda, MD 20892, 301–435–2204, girouxcn@csr.nih.gov.

Name of Committee: Vascular and Hematology Integrated Review Group; Hemostasis and Thrombosis Study Section.

Date: October 18, 2018.

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

Agenda: To review and evaluate grant applications.

Place: Hyatt Regency Bethesda, One Bethesda Metro Center, 7400 Wisconsin Avenue, Bethesda, MD 20814.

Contact Person: Bukhtiar H. Shah, DVM, Ph.D., Scientific Review Officer, Vascular and Hematology IRG, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4120, MSC 7802, Bethesda, MD 20892, (301) 806–7314, shahbh@csr.nih.gov.

Name of Committee: Infectious Diseases and Microbiology Integrated Review Group; Host Interactions with Bacterial Pathogens Study Section.

Date: October 18–19, 2018.

Time: 8:00 a.m. to 3:00 p.m.

Agenda: To review and evaluate grant applications.

Place: Warwick Denver, 1776 Grant Street, Denver, CO 80203.

Contact Person: Fouad A. El-Zaatari, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 3186, MSC 7808, Bethesda, MD 20892, (301) 435–1149, elzaataf@csr.nih.gov.

Name of Committee: Musculoskeletal, Oral and Skin Sciences Integrated Review Group; Oral, Dental and Craniofacial Sciences Study Section.

Date: October 18–19, 2018.

Time: 8:00 a.m. to 12:00 p.m.

Agenda: To review and evaluate grant applications.

Place: Residence Inn Capital View, 2850 South Potomac Avenue, Arlington, VA 22202.

Contact Person: Yi-Hsin Liu, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4214, MSC 7814, Bethesda, MD 20892, 301–435–1781, liuyh@csr.nih.gov.

Name of Committee: Center for Scientific Review Special Emphasis Panel; Fellowships: Neurodevelopment, Synaptic Plasticity and Neurodegeneration.

Date: October 18–19, 2018.

Time: 8:00 a.m. to 5:00 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: Mary Schueler, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5214, MSC 7846, Bethesda, MD 20892, 301–451–0996, marygs@csr.nih.gov.

Name of Committee: Center for Scientific Review Special Emphasis Panel; Fellowship: Behavioral Neuroscience.

Date: October 18–19, 2018.

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

Agenda: To review and evaluate grant applications.

Place: Embassy Suites DC Convention Center, 900 10th Street NW, Washington, DC 20001.

Contact Person: Mei Qin, MD, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5213, Bethesda, MD 20892, 301–875–2215, qinmei@csr.nih.gov.

Name of Committee: Center for Scientific Review Special Emphasis Panel; Fellowships: Biophysical, Physiological, Pharmacological and Bioengineering Neuroscience.

Date: October 18–19, 2018.

Time: 8:00 a.m. to 5:00 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: Sussan Paydar, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of