

guidance as appropriate in response to the comments. This guidance supersedes "Implementation of Third Party Programs Under the FDA Modernization Act of 1997; Final Guidance for Staff, Industry, and Third Parties" issued on February 2, 2001, and "Guidance for Third Parties and FDA Staff; Third Party Review of Premarket Notifications" issued on September 28, 2004.

## II. Significance of Guidance

This 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 the 510(k) Third Party Review Program. 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.

## III. Electronic Access

Persons interested in obtaining a copy of the guidance may do so by downloading an electronic copy from the internet. A search capability for all Center for Devices and Radiological Health guidance documents is available at <https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/default.htm>. This guidance document is also available at <https://www.regulations.gov>. Persons unable to download an electronic copy of "510(k) Third Party Review Program" may send an email request to *CDRH-*

*Guidance@fda.hhs.gov* to receive an electronic copy of the document. Please use the document number 17-028 to identify the guidance you are requesting.

## IV. Paperwork Reduction Act of 1995

This guidance refers to previously approved collections of information. 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. 3501-3521). The collections of information in the following FDA regulations and guidance have been approved by OMB as listed in the following table:

21 CFR part or guidance	Topic	OMB control No.
807 .....	Medical Devices: Third-Party Review under FDAMA.	0910-0375
807, subpart E .....	Premarket notification .....	0910-0120
"Center for Devices and Radiological Health (CDRH) Appeals Processes" .....	CDRH Appeals Process .....	0910-0738
"Requests for Feedback on Medical Device Submissions: The Pre-Submission Program and Meetings with Food and Drug Administration Staff".	Q-submissions .....	0910-0756

Dated: March 9, 2020.

**Lowell J. Schiller,**

*Principal Associate Commissioner for Policy.*

[FR Doc. 2020-05080 Filed 3-11-20; 8:45 am]

**BILLING CODE 4164-01-P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

[Document Identifier: OS-0990-0419]

### Agency Information Collection Request; 60-Day Public Comment Request

**AGENCY:** Office of the Secretary, HHS.

**ACTION:** Notice.

**SUMMARY:** In compliance with the requirement of the Paperwork Reduction Act of 1995, the Office of the Secretary (OS), Department of Health and Human Services, is publishing the following summary of a proposed collection for public comment.

**DATES:** Comments on the ICR must be received on or before May 11, 2020.

**ADDRESSES:** Submit your comments to *Sherrette.Funn@hhs.gov* or by calling (202) 795-7714.

**FOR FURTHER INFORMATION CONTACT:** When submitting comments or requesting information, please include the document identifier 0990-0419 60D, and project title for reference, to

Sherrette Funn, the Reports Clearance Officer, *Sherrette.funn@hhs.gov*, or call 202-795-7714.

**SUPPLEMENTARY INFORMATION:** Interested persons are invited to send comments regarding this burden estimate or any other aspect of this collection of information, including any of the following subjects: (1) The necessity and utility of the proposed information collection for the proper performance of the agency's functions; (2) the accuracy of the estimated burden; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

*Title of the Collection:* Acquisition Regulation Clause Patent Rights and Rights and Data.

*Type of Collection:* Extension.

*OMB No.* 0990-0419.

*Abstract:* The Department of Health and Human Services; Office of the Assistant Secretary for Financial Resources and Office of Grants and Acquisition Policy and Accountability, Division of Acquisition is requesting an approval by OMB for an extension of a previously approved information collection request, Acquisition Regulation Clause Patent rights and Rights in Data. HHS found that systematically, over a period of several

years, when Determination of Exceptional Circumstances (DEC) were executed, additional legal protection for the patent and data rights of third parties beyond those covered by FAR 27.306 were necessary. A DEC is executed consistent with the policy and objectives of the Bayh-Dole Act, 35 U.S.C. 200, *et seq.*, to ensure that subject inventions made under contracts and subcontracts (at all tiers) are used in a manner to promote free competition and enterprise without unduly encumbering future research and discovery; to encourage maximum participation of small business firms in federally supported research and development efforts; to promote collaboration between commercial concerns and nonprofit organizations including universities; to ensure that the Government obtains sufficient rights in federally supported inventions to meet its needs; to protect the public against nonuse or unreasonable use of inventions; and in the case of fulfilling the mission of the U.S. Department of Health and Human Services, to ultimately to benefit the public health.

*Likely Respondents:* Administrative, technical, legal and management personnel.

## ANNUALIZED BURDEN HOUR TABLE

Type of respondent and hours for each	Number of respondents	Number of responses per respondent	Average burden per response (hours)	Total burden hours
Technical (4), Legal (2), Management (2) .....	63	1	8	504
Technical (8), Legal (2), Management (2) .....	63	1	12	756
Technical (8), Legal (3), Management (1) .....	63	3	12	2,268
Technical (8), Legal (4), Management (2) .....	63	3	14	2,646
Technical (6), Legal (2), Management (2) .....	63	1	10	630
Technical (4), Legal (2), Management (2) .....	63	1	8	504
Administrative (8) .....	63	3	8	1,512
Administrative (2), Management (1) .....	63	3	3	567
Technical (4), Legal (2), Management (2) .....	63	3	8	1,512
.....	.....	.....	.....	10,899

Dated: March 6, 2020.

**Sherrette A. Funn,**

*Paperwork Reduction Act Reports Clearance Officer, Office of the Secretary.*

[FR Doc. 2020-05023 Filed 3-11-20; 8:45 am]

**BILLING CODE 4150-04-P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### National Institutes of Health

#### National Institute on Aging; Amended Notice of Meeting

Notice is hereby given of a change in the meeting of the National Institute on Aging Special Emphasis Panel, March 20, 2020, 8:00 a.m. to 6:00 p.m., Hyatt Regency, Bethesda, Conference Room Cabinet Suite, One Bethesda Metro Center, 7400 Wisconsin Avenue, Bethesda, MD 20814 which was published in the **Federal Register** on January 15, 2020, 85 FR 2431.

The meeting notice is amended to change the Meeting Format from Regular Meeting on March 20, 2020 to a Teleconference Meeting on March 20, 2020. The meeting is closed to the public.

Dated: March 6, 2020.

**Miguelina Perez,**

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

[FR Doc. 2020-05039 Filed 3-11-20; 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 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; Member Conflict: Neuropharmacology.

*Date:* April 2, 2020.

*Time:* 12:00 p.m. to 2:30 p.m.

*Agenda:* To review and evaluate grant applications.

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

*Contact Person:* Richard D. Crosland, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4190, MSC 7850, Bethesda, MD 20892, 301-694-7084, [crosland@nih.gov](mailto:crosland@nih.gov).

*Name of Committee:* Center for Scientific Review Special Emphasis Panel; Member Conflict: AIDS and Related Research.

*Date:* April 3, 2020.

*Time:* 10:00 a.m. to 5:00 p.m.

*Agenda:* To review and evaluate grant applications.

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

*Contact Person:* Barna Dey, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 3184, Bethesda, MD 20892, 301-451-2796 [bdey@mail.nih.gov](mailto:bdey@mail.nih.gov).

*Name of Committee:* Center for Scientific Review Special Emphasis Panel; Fellowships: Endocrinology, Metabolism, Nutrition and Reproductive Science.

*Date:* April 3, 2020.

*Time:* 10:30 a.m. to 5:00 p.m.

*Agenda:* To review and evaluate grant applications.

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

*Contact Person:* Antonello Pileggi, MD, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 6166, Bethesda, MD 20892, (301) 402-6297, [pileggia@csr.nih.gov](mailto:pileggia@csr.nih.gov).

*Name of Committee:* Center for Scientific Review Special Emphasis Panel; Member Conflicts: Biobehavioral Applications in Substance Abuse and Pain Management.

*Date:* April 3, 2020.

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

*Agenda:* To review and evaluate grant applications.

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

*Contact Person:* Andrea B. Kelly, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 3182, MSC 7770, Bethesda, MD 20892, (301) 455-1761, [kellya2@csr.nih.gov](mailto:kellya2@csr.nih.gov).

*Name of Committee:* Center for Scientific Review Special Emphasis Panel; PAR-18-669: SPF Macaque Colonies.

*Date:* April 3, 2020.

*Time:* 3:00 p.m. to 4:30 p.m.

*Agenda:* To review and evaluate grant applications.

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

*Contact Person:* Shiv A. Prasad, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5220, MSC 7852, Bethesda, MD 20892, 301-443-5779, [prasads@csr.nih.gov](mailto:prasads@csr.nih.gov).

*Name of Committee:* Center for Scientific Review Special Emphasis Panel; Epilepsy and Neuroprotective Drug Development.

*Date:* April 6, 2020.

*Time:* 10:30 a.m. to 3:00 p.m.

*Agenda:* To review and evaluate grant applications.

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

*Contact Person:* Seetha Bhagavan, Ph.D., Scientific Review Officer, Center for