

3. *The date the application was approved:* November 16, 2016. FDA has verified the applicant's claim that NDA 208470 was approved on November 16, 2016.

This determination of the regulatory review period establishes the maximum potential length of a patent extension. However, the USPTO applies several statutory limitations in its calculations of the actual period for patent extension. In its applications for patent extension, this applicant seeks 717 days or 518 days of patent term extension.

III. Petitions

Anyone with knowledge that any of the dates as published are incorrect may submit either electronic or written comments and, under 21 CFR 60.24, ask for a redetermination (see **DATES**). Furthermore, as specified in § 60.30 (21 CFR 60.30), any interested person may petition FDA for a determination regarding whether the applicant for extension acted with due diligence during the regulatory review period. To meet its burden, the petition must comply with all the requirements of § 60.30, including but not limited to: Must be timely (see **DATES**), must be filed in accordance with § 10.20, must contain sufficient facts to merit an FDA investigation, and must certify that a true and complete copy of the petition has been served upon the patent applicant. (See H. Rept. 857, part 1, 98th Cong., 2d sess., pp. 41–42, 1984.) Petitions should be in the format specified in 21 CFR 10.30.

Submit petitions electronically to <https://www.regulations.gov> at Docket No. FDA–2013–S–0610. Submit written petitions (two copies are required) to the Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

Dated: February 12, 2020.
Lowell J. Schiller,
Principal Associate Commissioner for Policy.
 [FR Doc. 2020–03115 Filed 2–14–20; 8:45 am]
BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

[Document Identifier: OS–4040–0019]

Agency Information Collection Request; 30-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 March 19, 2020.

ADDRESSES: Submit your comments to OIRA_submission@omb.eop.gov or via facsimile to (202) 395–5806.

FOR FURTHER INFORMATION CONTACT: Ed Calimag, ed.calimag@hhs.gov or (202)

690–7569. When submitting comments or requesting information, please include the document identifier 4040–0019–30D and project title for reference.

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 Collections: Project Abstract Summary.

Type of Collection: Revision.

OMB No.: 4040–0019.

Abstract: Project Abstract Summary form provides the Federal grant-making agencies an alternative to the Standard Form 424 data set and form. Project Abstract Summary programs are not required to collect all the data that is required on the SF–424 core data set and form. *Grants.gov* seeks revision without renewal and designation as a Common Form due to updates to the IC. The IC was modified to remove data elements. The IC was renewed with an expiration date of 02/28/2022 and does not require an extension.

ESTIMATED ANNUALIZED BURDEN TABLE

Forms	Number of respondents	Number of responses per respondent	Average burden hours per response	Total burden hours
Project Abstract Summary	3,467	1	1	3,467
Total	3,467			3,467

Sherrette A. Funn,
Paperwork Reduction Act Reports Clearance Officer, Office of the Secretary.
 [FR Doc. 2020–03128 Filed 2–14–20; 8:45 am]
BILLING CODE 4151–AE–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Heart, Lung, and Blood Institute; 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: National Heart, Lung, and Blood Institute Special Emphasis Panel; Blood Brain Barrier.

Date: March 19, 2020.

Time: 8:00 a.m. to 4:30 p.m.

Agenda: To review and evaluate grant applications.

Place: Bethesda North Marriott Hotel & Conference Center, Montgomery County Conference Center Facility, 5701 Marinelli Road, North Bethesda, MD 20852.

Contact Person: Michael P. Reilly, Ph.D., Scientific Review Officer, Office of Scientific Review, National Heart, Lung, and Blood Institute, National Institutes of Health, 6701 Rockledge Drive, Room 7200, Bethesda, MD 20892, 301–827–7975, reillymp@nhlbi.nih.gov.

(Catalogue of Federal Domestic Assistance Program Nos. 93.233, National Center for Sleep Disorders Research; 93.837, Heart and Vascular Diseases Research; 93.838, Lung Diseases Research; 93.839, Blood Diseases

and Resources Research, National Institutes of Health, HHS)

Dated: February 11, 2020.

Ronald J. Livingston, Jr.,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2020-03077 Filed 2-14-20; 8:45 am]

BILLING CODE 4140-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Mental Health; 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: National Institute of Mental Health Special Emphasis Panel; BRAIN Initiative; Novel Tools to Probe Cells and Circuits in the Brain (R01) & Human and NHP Brain (UG3/UH3).

Date: March 11, 2020.

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

Agenda: To review and evaluate grant applications.

Place: St. Gregory Hotel, 2033 M Street NW, Washington, DC 20036.

Contact Person: Erin E. Gray, Ph.D., Scientific Review Officer, Division of Extramural Activities, National Institute of Mental Health, National Institutes of Health, 6001 Executive Boulevard, NSC 6152B, Bethesda, MD 20892, 301-402-8152, erin.gray@nih.gov.

Name of Committee: National Institute of Mental Health Special Emphasis Panel; BRAIN Initiative; Advanced Human Cell-Based Assays to Model Brain Structure and Function (R01).

Date: March 13, 2020.

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

Agenda: To review and evaluate grant applications.

Place: The Westin Georgetown, 2350 M Street NW, Washington, DC 20037.

Contact Person: David W. Miller, Ph.D., Scientific Review Officer, Division of Extramural Activities, National Institute of Mental Health, NIH, Neuroscience Center, 6001 Executive Blvd., Room 6140, MSC 9608, Bethesda, MD 20892-9608, 301-443-9734, millerda@mail.nih.gov.

Name of Committee: National Institute of Mental Health Special Emphasis Panel;

NIMH Clinical Trials Effectiveness Studies (R34/R01/R01 Collaborative).

Date: March 30, 2020.

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

Agenda: To review and evaluate grant applications.

Place: The Fairmont Washington, DC, 2401 M Street NW, Washington, DC 20037.

Contact Person: Karen Gavin-Evans, Ph.D., Scientific Review Officer, Division of Extramural Activities, National Institute of Mental Health, NIH, Neuroscience Center, 6001 Executive Boulevard, Room 6153, MSC 9606, Bethesda, MD 20892, 301-451-2356, gavinevanskm@mail.nih.gov.

(Catalogue of Federal Domestic Assistance Program No. 93.242, Mental Health Research Grants, National Institutes of Health, HHS)

Dated: February 11, 2020.

Melanie J. Pantoja,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2020-03078 Filed 2-14-20; 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; Small Business: Cell and Molecular Biology.

Date: March 10-11, 2020.

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

Agenda: To review and evaluate grant applications.

Place: Melrose Hotel, 2430 Pennsylvania Ave. NW, Washington, DC 20037.

Contact Person: Amy Kathleen Wernimont, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 6198, Bethesda, MD 20892, (301) 827-6427, amy.wernimont@nih.gov.

Name of Committee: Center for Scientific Review Special Emphasis Panel; Infectious Diseases, Reproductive Health, Asthma and Pulmonary Conditions; Infectious Disease Epidemiology.

Date: March 13, 2020.

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

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892.

Contact Person: Lisa Steele, Ph.D., Scientific Review Officer, PSE IRG, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 3139, MSC 7770, Bethesda, MD 20892, (301) 594-6594, steeleln@csr.nih.gov.

Name of Committee: Center for Scientific Review Special Emphasis Panel; PAR-19-326: Reducing Stigma to Improve HIV/AIDS Prevention, Treatment and Care in Low- and Middle-Income Countries.

Date: March 13, 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: Shalanda A. Bynum, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 3206, Bethesda, MD 20892, (301) 755-4355, bynumsa@csr.nih.gov.

Name of Committee: Center for Scientific Review Special Emphasis Panel; Dissemination and Implementation Research in Health Review-Overflow.

Date: March 16, 2020.

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: 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; PAR 17-190: Maximizing Investigators' Research Award for Early Stage Investigators (R35).

Date: March 16-17, 2020.

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

Agenda: To review and evaluate grant applications.

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

Contact Person: Thomas Beres, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Rm. 5201, MSC 7840, Bethesda, MD 20892, (301) 435-1175, berestm@mail.nih.gov.

Name of Committee: Center for Scientific Review Special Emphasis Panel; Fellowships: Oncology.

Date: March 16-17, 2020.

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

Agenda: To review and evaluate grant applications.

Place: Bethesda North Marriott Hotel & Conference Center, Montgomery County Conference Center Facility, 5701 Marinelli Road, North Bethesda, MD 20852.

Contact Person: Reigh-Yi Lin, Ph.D., Scientific Review Officer, Center for