DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2018–N–1896]

Quality Metrics Site Visit Program for Center for Drug Evaluation and Research and Center for Biologics Evaluation and Research Staff; Information Available to Industry; Extension of the Proposal Period

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; extension of the proposal period.

SUMMARY: The Food and Drug Administration (FDA, Agency, or we) is extending the proposal period for the ''Quality Metrics Site Visit Program for Center for Drug Evaluation and Research and Center for Biologics Evaluation and Research Staff,'' published in the **Federal Register** of June 29, 2018. FDA is extending the proposal period to allow interested persons additional time to submit an electronic or written proposal.

DATES: FDA is extending the proposal period on the notice published June 29, 2018 (83 FR 30751). Submit either an electronic or written proposal by December 17, 2018 directly to Tara Gooen Bizjak or Stephen Ripley (see **FOR FURTHER INFORMATION CONTACT**).

FOR FURTHER INFORMATION CONTACT: Tara Gooen Bizjak, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 2109, Silver Spring, MD 20993–0002, 301–796–3257, email: *Tara.Gooen@fda.hhs.gov,* or Stephen Ripley, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 7301, Silver Spring, MD 20993–0002, 240–402–7911.

SUPPLEMENTARY INFORMATION:

I. Background

In the **Federal Register** of June 29, 2018 (83 FR 30751), FDA announced the availability of a notice for industry entitled ''Quality Metrics Site Visit Program for Center for Drug Evaluation and Research and Center for Biologics Evaluation and Research Staff.'' Interested persons were originally given until August 28, 2018, to submit a proposal to the Quality Metrics Site Visit Program per the notice. The Agency believes that extending the proposal period for an additional 120 days from the date of publication of this notice will allow adequate time for interested persons to submit proposals for FDA's consideration. The Site Visit Program is to provide experiential and firsthand learning opportunities to FDA staff involved in the development of the FDA Quality Metrics Program and to provide stakeholders with an opportunity to explain the advantages and challenges associated with implementing and managing a robust Quality Metrics Program. The program and information to be included in the proposal are explained more fully in the original notice.

II. Electronic Access

Persons with access to the internet may obtain the information about the FDA Quality Metrics for Drug Manufacturing Program, including this Quality Metric Site Visit Program, at *https://www.fda.gov/drugs/developmentapprovalprocess/manufacturing/ucm526869.htm.*

Dated: August 10, 2018.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2018–17783 Filed 8–16–18; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

[Document Identifier: OS–0990–0279]

Agency Information Collection Activities; Proposed Collection; 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 October 16, 2018.

ADDRESSES: Submit your comments to *Sherette.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–New–60D and project title for reference, to *Sherrette.funn@hhs.gov,* or call the Reports Clearance Officer.

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.

Information Collection Request Title: 0990–0279—Extension Institutional Review Board Registration Form

Abstract: Assistant Secretary for Health, Office for Human Research Protections is requesting an extension on a currently approved information collection by the Office of Management and Budget, on the Protection of Human Subjects, on the Institutional Review Board (IRB) Form. The purpose of the IRB Registration Form is to provide a simplified procedure for institutions engaged in research conducted or supported by HHS to satisfy the (1) HHS regulations for the protection of human subjects at 45 CFR 46.103((b), 45 CFR 46.107, and 45 CFR 46, subpart E, Registration of Institutional Review Boards; and, the Food and Drug Administration (FDA) regulations for institutional review boards at 21 CFR 56.106.

Likely Respondents: Institutions or organizations operating IRBs that review human subjects research conducted or supported by HHS, or, in the case of FDA's requirements, each IRB in the United States that reviews clinical investigations regulated by FDA under sections 505(i) or 520(g) of the Federal Food, Drug and Cosmetic Act; and each IRB in the United States that reviews clinical investigations that are intended to support applications for research or marketing permits for FDA-regulated products.

ESTIMATE ANNUALIZED BURDEN IN HOURS TABLE

Form name	Number of respondents	Number of responses per respondent	Average burden per response (in hours)	Total burden hours
IRB Registration 0990–0279	5,650	2	1	11,300
	350	2	1.5	525
Total				11,825

Terry Clark,

Asst. Information Collection Clearance Officer.

[FR Doc. 2018–17748 Filed 8–16–18; 8:45 am]

BILLING CODE 4150–36–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Neurological Disorders and Stroke; 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: Neurological Sciences Training Initial Review Group; NST–1 Subcommittee.

Date: September 17–18, 2018.

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

Agenda: To review and evaluate grant applications.

Place: Kinzie Hotel, 20 West Kinzie Street, Chicago, IL 60654.

Contact Person: William C. Benzing, Ph.D., Scientific Review Officer, Scientific Review Branch, NINDS/NIH/DHHS, Neuroscience Center, 6001 Executive Blvd., SUITE 3204, MSC 9529, Bethesda, MD 20892–9529, (301) 496–0660, *benzingw@mail.nih.gov*.

Name of Committee: National Institute of Neurological Disorders and Stroke Special Emphasis Panel; Ruth L. Kirschstein National Research Service Award (NRSA) Institutional Research Training Grant (T32) Program.

Date: November 14–15, 2018.

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

Agenda: To review and evaluate grant applications.

Place: Hilton Crystal City, 2399 Jefferson Davis Hwy., Arlington, VA 22202.

Contact Person: Elizabeth A. Webber, Ph.D., Scientific Review Officer, Scientific Review Branch, NINDS/NIH/DHHS, Neuroscience Center, 6001 Executive Blvd., Suite 3208, MSC 9529, Bethesda, MD 20892–9529, (301) 496–1917, *webbere@mail.nih.gov*.

(Catalogue of Federal Domestic Assistance Program Nos. 93.853, Clinical Research Related to Neurological Disorders; 93.854, Biological Basis Research in the Neurosciences, National Institutes of Health, HHS)

Dated: August 13, 2018.

Sylvia L. Neal,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2018–17780 Filed 8–16–18; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Request for Information To Solicit Feedback on the Brain Research Through Advancing Innovative Neurotechnologies (BRAIN) Initiative

AGENCY: National Institutes for Health, HHS.

ACTION: Notice.

SUMMARY: The purpose of this Request for Information (RFI) is to solicit input on how best to accomplish the ambitious vision for the Brain Research through Advancing Innovative Neurotechnologies (BRAIN) Initiative® set forth in BRAIN 2025: A Scientific Vision. NIH is soliciting input from all interested stakeholders, including members of the scientific community, trainees, academic institutions, the private sector, health professionals, professional societies, advocacy groups, and patient communities, as well as other interested members of the public.

DATES: The Request for Information is open for public comment. To assure consideration, your responded must be received by November 15, 2018, 11:59 p.m.

ADDRESSES: Responses to this RFI must be submitted electronically using the web-based form at *https://www.braininitiative.nih.gov/rfi.aspx.*

FOR FURTHER INFORMATION CONTACT: Please direct all inquiries to Samantha White, Ph.D., National Institute of Neurological Disorders and Stroke, 301–496–1675; *BRAINFeedback@nih.gov* with ''BRAIN RFI'' in the subject line.

SUPPLEMENTARY INFORMATION:

Background

The BRAIN Initiative aims to develop new tools and technologies to understand and manipulate networks of cells in the brain. BRAIN 2025: A Scientific Vision serves as the strategic plan for the BRAIN Initiative at NIH and outlines an overarching vision, seven high level scientific priorities, and many specific goals. Designed to be achieved over at least a decade, the first five years of BRAIN 2025 emphasizes development of tools and technology, and the next five years shifts emphasis to using these tools to make fundamental discoveries about how brain circuits work and what goes wrong in disease.

The BRAIN Initiative is well underway (see *http://www.braininitiative.nih.gov*), and we are now approaching the midpoint. At this time, NIH is seeking feedback on the BRAIN Initiative's progress and on opportunities moving forward given the current state of the science. NIH has established a new BRAIN Initiative Advisory Committee of the NIH Director (ACD) Working Group that will provide scientific guidance to the ACD on how best to continue to accelerate the ambitious vision for the BRAIN Initiative.

The ACD–WG will use the responses to this RFI, along with information gathered through a series of public workshops, to help inform their discussions of the BRAIN Initiative's progress and potential updates to the plan moving forward.

Information Requested

Anyone wishing to submit a response is asked to include:

- Ideas for new tools and technologies that have the potential to transform brain circuit research.
- Suggestions for fundamental questions about brain circuit function in