contain any recommendations that exceed the requirements in those regulations. FDA has estimated the information collection requirements resulting from the preparation and submission of an IND under part 312, and OMB has approved the reporting and recordkeeping burden under OMB control number 0910–0014.

III. Electronic Access

Persons with access to the Internet may obtain the guidance at either *http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm* or *https://www.regulations.gov.*

Dated: December 23, 2016.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2016–31627 Filed 12–28–16; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Proposed Collection; 60-Day Comment Request; Continuation of Use of the Early Career Reviewer Program Online Application and Vetting System—Center for Scientific Review (CSR)

AGENCY: National Institutes of Health, HHS.

ACTION: Notice.

SUMMARY: In compliance with the requirement of the Paperwork Reduction Act of 1995 to provide opportunity for public comment on proposed data collection projects, Center for Scientific Review, the National Institutes of Health (NIH) will publish periodic summaries of proposed projects to be submitted to the Office of Management and Budget (OMB) for review and approval.

DATES: Comments regarding this information collection are best assured of having their full effect if received within 60 days of the date of this publication.

FOR FURTHER INFORMATION CONTACT: To obtain a copy of the data collection plans and instruments, submit comments in writing, or request more information on the proposed project, contact: Dr. Monica Basco, Early Career Reviewer Program Coordinator, Center for Scientific Review, 6701 Rockledge Drive, Room 3030, Bethesda, Maryland 20892 or call non-toll-free number (301)–300–3839 or Email your request, including your address to: *CSRearlyCareerReviewer@mail.nih.gov.* Formal requests for additional plans and instruments must be requested in writing.

SUPPLEMENTARY INFORMATION: Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995 requires: Written comments and/or suggestions from the public and affected agencies are invited to address one or more of the following points: (1) Whether the proposed collection of information is necessary for the proper performance of the function of the agency, including whether the information will have practical utility; (2) The accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) Ways to enhance the quality, utility, and clarity of the information to be collected; and (4) Ways to minimize the burden of the collection of information on those who are to respond, including the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology.

Proposed Collection Title: Early Career Reviewer Program Online Application and Vetting System—Center for Scientific Review (CSR), 0925—Extension of Information Collection Request, Center for Scientific Review (CSR), National Institutes of Health (NIH) (OMB Control Number: 0925–0695; Expiration: 04/30/2017).

Need and Use of Information Collection: The Center for Scientific Review (CSR) is the portal for NIH grant applications and their review for scientific merit. Our mission is to see that NIH grant applications receive fair, independent, expert, and timely reviews—free from inappropriate influences—so NIH can fund the most promising research. To accomplish this goal, Scientific Review Officers (SRO) form study sections consisting of scientists who have the technical and scientific expertise to evaluate the merit of grant applications. Study section members are generally scientists who have established independent programs of research as demonstrated by their publications and their grant award experiences.

The CSR Early Career Reviewer program was developed to identify and train qualified scientists who are early in their scientific careers and who have not had prior CSR review experience. The goals of the program are to expose these early career scientists to the peer review experience so that they become more competitive as applicants as well as to enrich the existing pool of NIH reviewers. Currently, online application software, the Early Career Reviewer Application and Vetting System, is accessed online by applicants to the Early Career Reviewer Program who provide their names, contact information, a description of their areas of expertise, their study section preferences, professional Curriculum Vitae and links to their professional Web site. This Information Collection Request (ICR) is to continue to use the Early Career Reviewer Application and Vetting System to process applications for the Early Career Reviewer program.

OMB approval is requested for 3 years. There are no costs to respondents other than their time. The total estimated annualized burden hours are 450.

ESTIMATED ANNUALIZED BURDEN HOURS

Type of respondent	Number of respondents	Number of responses per respondent	Average time per response (in hours)	Total annual burden hour
Applicants	1,080	1	25/60	450
Total	1,080	1,080		450

Dated: December 21, 2016.

Joanna Bare,

Executive Officer, Division of Management Services, Center for Scientific Review, NIH.

[FR Doc. 2016–31543 Filed 12–28–16; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Meeting of the National Vaccine Advisory Committee

AGENCY: National Vaccine Program Office, Office of the Assistant Secretary for Health, Office of the Secretary, Department of Health and Human Services.

ACTION: Notice.

SUMMARY: As stipulated by the Federal Advisory Committee Act, the Department of Health and Human Services (HHS) is hereby giving notice that a meeting is scheduled to be held for the National Vaccine Advisory Committee (NVAC). The meeting will be open to the public; public comment sessions will be held during the meeting.

DATES: The meeting will be held on February 7 and 8, 2017. The meeting times and agenda will be posted on the NVAC Web site at *http://www.hhs.gov/nvpo/nvac/meetings/index.html* as soon as they become available.

ADDRESSES: Pre-registration is required for members of the public who wish to attend the meeting and who wish to participate in the public comment session. Individuals who wish to attend the meeting and/or participate in the public comment session should register at *http://www.hhs.gov/nvpo/nvac/meetings/index.html.* Participants may also register by emailing *nvpo@hhs.gov* or by calling (202) 690–5566 and providing their name, organization, and email address.

U.S. Department of Health and Human Services, Hubert H. Humphrey Building, Great Hall, 200 Independence Avenue SW., Washington, DC 20201.

The meeting can also be accessed through a live webcast on both days of the meeting. For more information, visit *http://www.hhs.gov/nvpo/nvac/meetings/index.html.*

FOR FURTHER INFORMATION CONTACT: National Vaccine Program Office, U.S. Department of Health and Human Services, Room 715H, Hubert H. Humphrey Building, 200 Independence Avenue SW., Washington, DC 20201. Phone: (202) 690–5566; email: *nvpo@hhs.gov.*

SUPPLEMENTARY INFORMATION: Pursuant to Section 2101 of the Public Health Service Act (42 U.S.C. 300aa–1), the Secretary of Health and Human Services was mandated to establish the National Vaccine Program to achieve optimal prevention of human infectious diseases through immunization and to achieve optimal prevention against adverse reactions to vaccines. The NVAC was established to provide advice and make recommendations to the Director of the National Vaccine Program on matters related to the Program's responsibilities. The Assistant Secretary for Health serves as Director of the National Vaccine Program.

During the February 2017 NVAC meeting, there will be a discussion of the 21st Century Cures Act and vaccines; an update on the recent mumps outbreaks in the US; presentations on Zika virus disease and the status of Zika vaccine development; presentations on vaccine adverse events and insights from personalized medicine; and the NVAC's Mid-course Review Working Group will present its findings and draft recommendations for deliberation and vote by the Committee. Please note that agenda items are subject to change as priorities dictate. Information on the final meeting agenda will be posted prior to the meeting on the NVAC Web site: *http://www.hhs.gov/nvpo/nvac/index.html.*

Public attendance at the meeting is limited to the available space. Individuals who plan to attend in person and need special assistance, such as sign language interpretation or other reasonable accommodations, should notify the National Vaccine Program Office at the address/phone listed above at least one week prior to the meeting. For those unable to attend in person, a live webcast will be available. More information on registration and accessing the webcast can be found at *http://www.hhs.gov/nvpo/nvac/meetings/index.html.*

Members of the public will have the opportunity to provide comments at the NVAC meeting during the public comment periods designated on the agenda. Public comments made during the meeting will be limited to three minutes per person to ensure time is allotted for all those wishing to speak. Individuals are also welcome to submit their written comments. Written comments should not exceed three pages in length. Individuals submitting written comments should email their comments to the National Vaccine Program Office (*nvpo@hhs.gov*) at least five business days prior to the meeting.

Dated: December 21, 2016.

Bruce Gellin,

Designated Federal Officer, National Vaccine Advisory Committee, Deputy Assistant Secretary for Health.

[FR Doc. 2016–31530 Filed 12–28–16; 8:45 am]

BILLING CODE 4150–44–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Office of the Director; Notice of Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App), notice is hereby given of a meeting of the NIH Clinical Center Research Hospital Board.

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 portions of the meeting devoted to the Anonymous Safety Hotline and the laboratories or units and staff involved in the individual reports to the Hotline, staff, as well as discussions regarding non-executive employees holding specific positions in the Clinical Center will be closed to the public in accordance with the provisions set forth in section 552b(c)(9)(B) and 552b(c)(6), Title 5 U.S.C., as amended. Premature disclosure of the laboratories or units and staff involved in the individual reports could significantly limit the Hotline's purpose by compromising anonymity. Discussion of specific non-executive employees would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: NIH Clinical Center Research Hospital Board.

Date: January 13, 2017.

Open: 8:30 a.m. to 12:30 p.m.

Agenda: Board Chair's Overview, Remarks from the NIH Director and the New CEO, Clinical Center Focus Groups, Improving the Clinical Center's Census, Clinical Center Patient and Worker Safety Metrics.

Open: 1:30 p.m. to 3:30 p.m.

Agenda: IT Infrastructure and Security, Audits of Delayed Reporting—Self-Audit Results and Formal Audit Planning, Facilities Update.

Closed: 3:45 p.m. to Adjournment.

Agenda: Anonymous Safety Hotline, Clinical Center Employees.