7200, Bethesda, MD 20892, 301–496–9659, *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: August 16, 2016.

Michelle Trout,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2016–19882 Filed 8–19–16; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Proposed Collection; 60-Day Comment Request; Materials To Support NIH Serving as an Institutional Review Board (IRB) of Record or a Single IRB for Outside Institutions

SUMMARY: To provide the opportunity for public comment on proposed data collection projects, the Office of Human Subjects Research Protections (OHSRP), Office of the Director, 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 with 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. Julia Slutsman, Health Science Policy Analyst, Office of Human Subjects Research Protections (OHSRP), IRP, OD, NIH, Building 10, Room 1C154, 10 Center Drive, Bethesda, MD 20892, or call non-toll-free number (301) 402–3444 or Email your request, including your address to: *PHERRB@mail.nih.gov*. Formal requests for additional plans and instruments must be requested in writing.

SUPPLEMENTARY INFORMATION: In compliance with the requirement of Section 350(c)(2)(A) of the Paperwork Reduction Act of 1995, written comments and/or suggestions from the public and affected agencies are invited on 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: Materials to support the NIH Serving As an Institutional Review Board (IRB) of Record or a Single IRB for Outside Institutions, 0925—New, Office of Human Subjects Research Protections (OHSRP), Office of the Director, National Institutes of Health (NIH).

Need and Use of Information Collection: The NIH Human Research Protections Program (HRPP) is preparing to implement the recent ''NIH Policy on the Use of a Single Institutional Review Board (sIRB) of Record for Multi-Site Research,'' which requires the use of a single IRB of record for human subject protections review of certain multisite studies. Additionally, the NIH and HHS have recently established the Public Health Emergency Research Review Board (PHERRB) mechanism, for human subject protections review of certain—typically multi-site—public health emergency research studies. Any of the 12 NIH intramural IRBs can be designated to serve as the PHERRB for review of a public health emergency research protocol. Finally, proposed changes to federal human subject protections regulations, if finalized, will require the use of single IRB review for the majority of HHS funded, multi-site studies.

To meet all of these needs, and support efficient single IRB review, researchers at outside institutions will need to provide information to the NIH HRPP, which includes the NIH intramural IRBs, using materials developed by the NIH Office of Human Subject Protections. The required materials which include: The Application for PHERRB Review (APR); the Initial Review Local Context Worksheet (IRLCW); and the Continuing Review Local Context Worksheet (CRLCW). This information collection is intended to provide the NIH HRPP and the NIH IRBs with information necessary for the NIH to maintain regulatory compliance in its conduct of human subject protections review when an NIH IRB serves an IRB of record for multi-site research and to provide high quality and timely human subject protections reviews.

When an NIH IRB serves as the PHERRB, investigators seeking PHERRB human subject protections review will need to submit their request using the ''Application for PHERRB Review (APR).'' This application will be used to collect information to allow the NIH to evaluate public health emergency research protocol submissions' suitability for review by the PHERRB. The form will collect the investigator's name, work address, phone, fax and email, the curriculum vitae of the principal investigator and all co-investigators on the research study, and a detailed description of the proposed research study including the funding source for the study. The APR will facilitate the timely review of public health emergency protocols for human subjects protections review by the PHERRB for protocols meeting PHERRB review eligibility criteria.

As part of meeting regulatory requirements for IRB review of protocols and ensuring the welfare and safety of human subjects, IRBs need to consider local context considerations, that is the sum of state and local laws related to the conduct of human subjects research, relevant institutional policies and resources, research team qualifications and contextual considerations particular to the site where research is taking place. When an NIH IRB serves as the IRB of record for institutions participating in a multisite study, it is necessary for IRBS to have a systematic way of collecting information about local context.

To facilitate local context information collection, the NIH has developed two forms: The Initial Review Local Context Worksheet (IRLCW) and the Continuing Review Local Context Worksheet (CRLCW). The IRLCW will be submitted by investigators at each institution participating in a multi-site study for which an NIH IRB is the IRB of record at the time of submission of the research protocol. The CRLCW will be submitted at the time of continuing review of the protocol. These forms asks principal investigators to PIs to provide their name and the name of the institution with which they are affiliated, as well as names of regulatory points of contact and information about institutional policies and state and local laws on issues related to informed consent, legally authorized representative designation procedures and other relevant laws. This data collection is authorized pursuant to sections 301, 307, 465, and 478A of the Public Health Service Act [42 U.S.C. 241, 242l, 286

and 286d]. OHSRP has as part of its mission a commitment to provide high quality human subject protections review to all research reviewed by NIH IRBs.

OMB approval is requested for 3 years. There are no costs to respondents other than their time. The total estimated annual burden hours are 790.

ESTIMATED ANNUALIZED BURDEN HOURS

Data collection activity	Type of respondents	Estimated number of respondents	Estimated number of responses per respondent	Average time per response (in hours)	Estimated total annual burden hours
APR	Principal Investigator (M.D. or Ph.D.)	20	1	2	40
IRLCW	Principal Investigator (M.D. or Ph.D. degree) or Research Coordinator (RN, BA, MA degree) or Regulatory Staff (BA degree).	250	1	2	500
CRLCW	Principal Investigator (M.D. or Ph.D. degree) or Research Coordinator (RN, BA, MA degree) or Regulatory Staff (BA degree).	250	1	1	250
Total		520	520		790

Dated: August 13, 2016.

Lawrence A. Tabak,

Deputy Director, National Institutes of Health.

[FR Doc. 2016–19829 Filed 8–19–16; 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 (5 U.S.C. App.), 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; PAR–15–276: Turkey-US Collaborative Program for Affordable Medical Technologies (R01).

Date: September 16, 2016.

Time: 11:00 a.m. to 12:30 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: Careen K. Tang-Toth, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 6214, MSC 7804, Bethesda, MD 20892, (301) 435–3504, *tothct@csr.nih.gov*.

Name of Committee: Cardiovascular and Respiratory Sciences Integrated Review Group; Lung Injury, Repair, and Remodeling Study Section.

Date: September 19–20, 2016.

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: Ghenima Dirami, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4122, MSC 7814, Bethesda, MD 20892, 240–498–7546, *diramig@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: August 16, 2016.

Natasha M. Copeland,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2016–19885 Filed 8–19–16; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Proposed Collection; 60-Day Comment Request; A National Survey of Nurse Coaches (CC)

SUMMARY: To provide opportunity for public comment on proposed data collection projects, the National Institutes of Health Clinical Center (CC) 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. Alyson Ross, Nurse Researcher, Department of Nursing Research and Translational Science, NIH Clinical Center, Building 10, Room 2B07, MSC–1151, Bethesda, Maryland, 20892 or call non-toll-free number (301) 451–8338 or Email your request, including your address to: *Alyson.ross@nih.gov.* Formal requests for additional plans and instruments must be requested in writing.

SUPPLEMENTARY INFORMATION: In compliance with the requirement of Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, 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