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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Submission for OMB review; 30-day comment request

Materials to Support NIH Serving as An IRB of Record Or A Single IRB for Outside Institutions (Office of the Director)

AGENCY: National Institutes of Health.

ACTION: Notice.

SUMMARY: In compliance with the Paperwork Reduction Act of 1995, the National Institutes of Health (NIH) has submitted to the Office of Management and Budget (OMB) a request for review and approval of the information collection listed below. This proposed information collection was previously published in the Federal Register on August 22, 2016, page 56667 (81 FR 56667) and allowed 60 days for public comment. No public comments were received. The purpose of this notice is to allow an additional 30 days for public comment.

DATES: Comments regarding this information collection are best assured of having their full effect if received within 30 days of the date of this publication.

ADDRESS: Written comments and/or suggestions regarding the items(s) contained in this notice, especially regarding the estimated public burden and associated response time, should be directed to the: Office of Management and Budget, Office of Regulatory Affairs, OIRA_submission@omb.eop.gov or by fax to 202-395-6974, Attention: Desk Officer for NIH.

FOR FURTHER INFORMATION CONTACT: To request more information on the proposed project or to obtain a copy of the data collection plans and instruments, contact: 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 e-mail your request, including your address to: PHERRB@mail.nih.gov. Formal requests for additional materials must be requested in writing.

SUPPLEMENTARY INFORMATION: The Office of Human Subjects Research Protections (OHSRP), Office of the Director (OD), National Institutes of Health, may not conduct or sponsor, and the respondent is not required to respond to, an information collection that has been extended, revised, or implemented on or after October 1, 1995, unless it displays a currently valid OMB control number.

In compliance with Section 3507(a)(1)(D) of the Paperwork Reduction Act of 1995, the National Institutes of Health has submitted to the Office of Management and Budget (OMB) a request for review and approval of the information collection listed below.

Proposed Collection: Materials to Support NIH Serving As an 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 multisite – 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 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 NIH to maintain regulatory compliance in its conduct of human subject protections review when

an NIH IRB serves an IRB of record for multisite research and to provide high quality and timely human subject protections reviews.

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 (MD or PhD)	20	1	2	40
IRLCW	Principal Investigator (MD or PhD degree) or Research Coordinator (RN, BA, MA degree) or Regulatory Staff (BA degree)	250	1	2	500
CRLCW	Principal Investigator (MD or PhD degree) or Research Coordinator (RN, BA, MA degree) or Regulatory Staff (BA degree)	250	1	1	250
Total		520	520		790

Dated: November 16, 2016

Lawrence A. Tabak,

Deputy Director

National Institutes of Health

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