SUPPORTING STATEMENT A

Materials to Support NIH Serving As an Institutional Review Board (IRB) of Record Or A Single IRB for Outside Institutions

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Table of Contents

LIST OF ATTACHMENTS

1. Attachment 1 PHERRB Terms of Reference, October 2012
2. Attachment 2 Application for PHERRB Review (APR)
3. Attachment 3 Initial Review Local Context Worksheet (IRLCW)
4. Attachment 4 Continuing Review Local Context Worksheet (CRLCW)
5. Attachment 5 Privacy Impact Assessment Documentation for NIH IRB Submission Systems
6. Attachment 6 Privacy Act Memorandum

A. Justification

ABSTRACT: 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. Additionally, 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,

To meet all of these needs, researchers at outside institutions will need to provide information to the NIH HRPP, which includes the NIH intramural IRBs. To facilitate and systematize collection of the necessary information, NIH has developed a set of required materials. These include the Application for PHERRB Review (APR); the Initial Review Local Context Worksheet (IRLCW); and the Continuing Review Local Context Worksheet (CRLCW). These materials are 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.

A.1 Circumstances Making the Collection of Information Necessary

NIH and HHS have established a 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. The "Terms of the PHERRB," document describes the purpose and scope of the PHERRB as agreed upon by HHS and NIH and is included for reference as Attachment 1.

Additionally, 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. The policy can be found at: https://grants.nih.gov/grants/guide/notice-files/NOT-OD-16-094.html. Proposed changes to federal human subject protections regulations, if promulgated, will also require the use of single IRBs for certain multi-site studies (see https://www.gpo.gov/fdsys/pkg/FR-2015-09-08/pdf/2015-21756.pdf for Notice of Proposed Rule Making published on September 8, 2015.) Lastly, proposed changes to federal human subject protections regulations, if finalized, will require the use if single IRB review for the majority of HHS funded, multi-site studies.

To meet all of these needs, 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. The required materials include the Application for PHERRB Review (APR) attached as Attachment 2; the Initial Review Local Context Worksheet (IRLCW) attached as Attachment 2; and the Continuing Review Local Context Worksheet (CRLCW) attached as Attachment 4. These materials are 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.

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.]

A.2 Purpose and Use of the Information Collection

We are submitting materials that will need to be completed by any institution participating in multisite research that will be reviewed by an NIH intramural IRB serving as the IRB of record. This is a New Information Collection Request seeking approval for 3 years.

1. Application for PHERRB Review

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 NIH to efficiently 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 e-mail, 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. In addition, the PHEP-PSA will collect the name, title and work contact information for the Institutional Official who is the signatory for the Federal-wide Assurance (FWA) for the investigator's Institution.

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. Because of the time-sensitive nature of research during public health emergencies, the APR allows non-NIH investigators to submit a short pre-application that can then be reviewed by NIH HRPP staff and the NIH Deputy Director of Intramural Research (DDIR) staff for its suitability for PHERRB review. The NIH Deputy Director of Intramural Research has authority to determine which protocols are eligible for PHERRB review. The APR can be downloaded from the PHSRP website: (http://ohsr.od.nih.gov/OHSR/index.php).

2. Initial Local Context Review Worksheet and Continuing Review Local Context Worksheet

As part of meeting HHS regulatory requirements for IRB review of protocols and ensuring the welfare and safety of human subjects, IRBs need to consider local context considerations. Such

considerations are 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: (1) the Initial Review Local Context Worksheet (IRLCW) and the (2) Continuing Review Local Context Worksheet (CRLCW). The IRLCW will be submitted by investigators at each institution participating in a multisite 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. By regulation, IRBs are required to set a continuing review date for each protocol. Continuing review is required by regulation to take place no longer than a year from the initial review date. 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, etc. These forms can be downloaded from the NIH OHSRP website (http://ohsr.od.nih.gov/OHSR/index.php).

A.3 Use of Information Technology and Burden Reduction

All of the forms in this package will be available for downloading by potential respondents as Word and/or PDF documents from the OHSRP website (http://ohsr.od.nih.gov/OHSR/index.php).

The respondent will download the Application for PHERRB Review (APR), complete it and e-mail it to the following NIH mailbox which was set up to support PHERRB communications: PHERRB@mail.NIH.gov.

1. The IRLCW and CRLCW forms will be downloaded from the OHSRP website by investigators at outside institutions participating in multisite studies and submitted to the NIH principal investigator (PI). The NIH PI is a federal employee. In the case of studies for which there is no NIH PI (for example, we anticipate that for many PHERRB studies, there may not be an NIH PI), outside investigators can either submit the forms to the NIH IRB directly when granted access to an NIH IRB electronic submission system (NIH currently has three electronic submission systems in place); or can submit these forms via email to the NIH PHERRB point of contact within the NIH Office of Human Subject Protections (OHSRP) who can then submit internally to the NIH IRB. One of the three NIH electronic IRB submission systems has already had a Privacy Impact Assessment and the NIH is in the process of obtaining NIH Privacy Impact Assessment for the other two systems. We will provide the documentation of the Privacy Impact Assessments for the 3 NIH IRB submission systems (Attachment 5) once available.

A.4 Efforts to Identify Duplication and Use of Similar Information

The research protocols that the forms will be associated with are unique research projects. There is no similar information available and therefore no duplication in the information collection.

A.5 Impact on Small Businesses or Other Small Entities

No small businesses will be involved in the information collection.

A.6 Consequences of Collecting the Information Less Frequently

The APR and IRLCW forms are single information collections. Respondents will only be re-contacted if either of the forms were incomplete upon submission. The respondent will be given the opportunity to complete the form and re-submit it for review. The CRLCW will be submitted annually, however if there is information provided the previous year that has not changed, the respondent can indicate this and is not required to provide the same information in the form each year, only information that has changed.

A.7 Special Circumstances Relating to the Guidelines of 5 CFR 1320.5

This information collection meets the guidelines in 5 CFR 1320.5.

A.8.1 Comments in Response to the Federal Register Notice

The 60-day notice was published in Volume 81, no. 162 Federal Register on August 22, 2016, and starts on page 56668. No comments were received.

A.8.2. Efforts to Consult Outside Agencies

OHSRP has as part of its mission a commitment to provide high quality human subject protections review to all research reviewed by NIH IRBs. No outside agencies were consulted with regard to the development of these forms, as these forms are intended to meet processes and requirements established for the NIH intramural HRPP and IRBs.
The PHEP-PSA has been reviewed by the Director of OHSRP, Deputy Director of OHSRP and the PHERRB point of contact in OHSRP.

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A.9 Explanation of Any Payment or Gift to Respondents

No payment or gift will be made to respondents.

A.10 Assurance of Privacy Provided to Respondents

The basis for the protection of the information collected by the forms in this application is the Privacy Act. The information collected will be held private to the extent permitted by law.

PII collected will include principal investigators' (who will be the respondents for these materials) names, work address, work phone and work email and a CV to be included with the APR form. The IRLCW and CRLCW will include investigator's name and institutional affiliation. The Privacy Act Memorandum (Attachment 6) will be provided upon receipt.

A.11 Justification for Sensitive Questions

There are no sensitive questions in any of the forms included in this application. The APR will collect Personally Identifiable Information (PII) from respondents. The PII requested will include name, work address, and the curriculum vitae of the principal investigator and all co-investigators. This information is necessary to determine the qualification of the proposed public health emergency research protocol for PHERRB review. The IRCRW and CRLCW forms collect the principal investigator's name and his or her institutional affiliation

A.12 Estimates of Annualized Hourly Burden and Cost

A.12.1 ESTIMATED ANNUALIZED BURDEN HOURS

Data Collection Activity	**Type of Respondents**	**Number of Respondents**	**Number of Responses per Respondent**	**Average Burden 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)	250	1	2	500
CRLCW	Principal Investigator (MD or PhD	250	1	1	250

	degree)				
Total		520	520		790

A.12.2 ANNUALIZED COST TO RESPONDENTS

Data Collection Activity	**Type of Respondents**	**Total Annual Burden Hours**	**Hourly Respondent Wage Rate***	**Respondent Cost**
APR	Principal Investigator (MD or PhD degree)	40	$95.05	$3,802
IRLCW	Principal Investigator (MD or PhD degree)	250	$95.05	$23,762.50
CRLCW	Principal Investigator (MD or PhD degree)	250	$95.05	$23,762.50
Total		790		$51,327

*Source: U.S. Department of Labor, Bureau of Labor Statistics, last accessed on 7/12/2016: http://www.bls.gov/oes/current/oes_nat.htm

A.13 Estimate of Other Total Annual Cost Burden to Respondents or Record Keepers

There are no other costs to the respondents or record keepers.

A.14 Annualized Cost to the Federal Government

The annualized cost to the Federal Government is $23,450.

Cost Description	**Grade/Step**	**Salary**	**% of Effort**	**Fringe Benefits (40%)**	**Annual Cost to federal government**
Federal Oversight					
Review of APR Federal Staff,	GS 14, Step 5	123,406*	.01	$49,362	$1728
Review of IRLCW by IRB Administrator	GS 11, Step 1	$64,650	.12	$25,860	$10,861
Review of CRLCW by IRB Administrator	GS 11, Step 1	$64,650	.12	$25,860	$10,861
TOTAL					$23,450

*From OPM GS Pay Tables FY 2016, last accessed on 9/21/16: https://www.opm.gov/policy-data-oversight/pay-leave/salaries-wages/salary-tables/pdf/2016/DCB.pdf

A.15 Explanation for Program Changes or Adjustments

This is a new information collection request.

A.16 Plans for Tabulation and Publication and Project Time Schedule

There are no plans for the results of statistical analyses to be included in publications. The only planned statistical analysis will be conducted for an Annual Report to the Director of the National Institutes of Health.

The submitted materials (APR, IRLCW, CRLCW) will be put in use once OMB approval is obtained as NIH occasionally serves an IRB of record for multisite studies and expects that the frequency of such studies will increase steadily with time both because of requests for PHERRB as well as increasing acceptance of sIRB review generally.

A.16 - 1 Project Time Schedule

Activity	Time Schedule
NIH will post forms to OHSRP public website and review and process APR forms when received	1 - 2 months after OMB approval
NIH will post forms to OHSRP public website and review and process IRLCW and CRLCW forms when recieved	1 - 2 months after OMB approval

A.17 Reason(s) Display of OMB Expiration Date is Inappropriate

There is no request for an exception.

A.18 Exceptions to Certification for Paperwork Reduction Act Submissions

There is no request for an exception.