Public Health Emergency Research Review Board (PHERRB) Frequently Asked Questions (FAQs)

1. What is the Public Health Emergency Research Review Board (PHERRB)?

The Public Health Emergency Research Review Board (PHERRB) was established by the U.S. Department of Health and Human Services (DHHS) in October 2012 as a central Institutional Review Board. The purpose of the PHERRB is to provide Institutional Review Board (IRB) review of multi-site public health emergency research (PHER) protocols that are conducted, supported, or regulated by the DHHS and on a case by case basis by other agencies or sponsors and subject to 45 CFR 46, and 21 CFR parts 50 and 56, as applicable.

The National Institutes of Health (NIH) provides staff and infrastructure to support the operations of the PHERRB. Any of the NIH intramural IRBs may serve as the PHERRB based on the subject matter of the study.

The mandate of the PHERRB is to provide investigators with expert, expeditious IRB review of human subjects protections provided within PHER protocols. Additional information and materials about the PHERRB can be found at http://ohsr.od.nih.gov/OHSR/index.php

2. Why do we need the PHERRB?

The PHERRB provides a critical efficiency by assuring that studies carried out in the United States during a public health emergency or threat are rigorously and expeditiously reviewed and to avoid delays that may be experienced by relying on individual-site IRBs for large scale, multi-site studies.

3. What types of public health emergency research will the PHERRB review?

The PHERRB's jurisdiction includes, but is not limited to, review of PHER protocols that relate to public health emergencies caused by:

a. Disasters that are naturally occurring, accidental or deliberate;

b. Biological, chemical, or radiological agents (e.g. infectious disease outbreaks, natural disasters, or bioterrorist events);
c. Socioeconomic crises

For additional resources about public health emergencies see www.phe.gov/emergency/pages/default.aspxee and http://emergency.cdc.gov/?s_cid=cdc_homepage_topmenu_004

4. How is the PHERRB constituted?

Any NIH intramural program IRB may serve as the IRB of record for the PHERRB. If a public health emergency research protocol is accepted for PHERRB review, the NIH will assign the protocol to an appropriate IRB to serve as the PHERRB. The PHERRB will utilize expert consultants on an *ad hoc* basis if the review of a particular protocol requires additional expertise. For example, potential consultants may have knowledge in the following areas:

a. expected causes of the public health emergency (e.g. a specific infectious agent, disease, or class of diseases; chemical or radiation-emitting agent; socioeconomic crisis) and its effects on human health;
b. populations, communities or regions under study in the proposed research.

5. What criteria must be met to initiate PHERRB review?

A PHER study must meet the following criteria:

a. Generally, it must be conducted, supported, or regulated by DHHS; however protocols also conducted, supported or regulated by other, non-DHHS agencies or sponsors may be approved for PHERRB review on a case by case basis;
b. It must be PHER;
c. Generally, it must be a multi-site study or otherwise require multiple IRB review. However, single site studies may be approved for PHERRB review on a case-by-case basis;
d. It must be subject to IRB review pursuant to 45 CFR 46 and, if applicable, 21 CFR 56. The PHERRB will not review "exempt" research as defined in those regulations.

e. Regulations of other, non-DHHS agencies may apply on a case by case basis if a protocol that is conducted, supported, or regulated by a non-DHHS agency is approved.

6. Will the PHERRB review process differ from the review process of other IRBs?

No, the PHERRB review process and oversight complies with applicable federal regulations, namely 45 CFR 46, and, as applicable, 21 CFR parts 50 and 56.

7. How does the Principal Investigator (PI) initiate a request for PHERRB review of a PHER protocol?

Any PI whose protocol meets the criteria stated in response to FAQ #5 may apply for PHERRB review. The PI should obtain concurrence from his or her local site's Institutional Official for conduct of the proposed research prior to submitting an Application for PHERRB Review. To request PHERRB review of a PHER protocol, the PI should review the Application for PHERRB Review on the NIH Office of Human Subjects Research Protections (OHSRP) website at http://ohsr.od.nih.gov/OHSR/index.php. To initiate an IRB authorization agreement (IAA) to rely upon the PHERRB, see FAQ#11 below.

8. Does one of the research sites need to be an intramural NIH site?

No. There is no requirement that research sites must include an intramural NIH site or be affiliated with the NIH.

9. What documents are required for protocol submission to the PHERRB?
The NIH has a standard operating procedure that describes the operations and requirements of the PHERRB. As described in greater detail in the NIH Human Research Protections Program (HRPP) Standard Operating Procedure (SOP) 28, "NIH PUBLIC HEALTH EMERGENCY RESEARCH REVIEW BOARD (PHERRB)," once a

protocol is accepted for PHERRB review, the following documents must be submitted to the PHERRB for initial review:

- Report of scientific review
- Initial protocol application
- Protocol document
- Proposed consent and/or assent form(s)
- Initial Review Local Context Worksheet
- A statement of whether the research requires an IND or IDE and supporting FDA IND/IDE documentation, as applicable
- Ancillary required reviews, as applicable
- COI certifications, as applicable

10. To rely upon the PHERRB, will the relying institution(s) need an IRB authorization agreement (IAA) (also called a reliance agreement) with the NIH?

Yes. PHERRB review cannot take place prior to the execution of a reliance agreement between the NIH and the relying institution. The NIH will provide the NIH Central IRB reliance agreement template to the Institutional Official listed on the "Initial Application for a Reliance Agreement." The reliance agreement is available on the NIH Office of Human Subjects Research Protections (OHSRP) website at http://ohsr.od.nih.gov/OHSR/index.php. Review of the PHER protocol by the PHERRB will occur as soon as possible after the Application for PHERRB Review is submitted and a reliance agreement is executed.

11. Will the PHERRB serve as the IRB of Record for the protocol?

Yes. Once a reliance agreement has been signed by the NIH and the engaged institution(s), the PHERRB will be the IRB of Record and will conduct IRB review of the protocol, including the initial review, continuing review, review of amendments, unanticipated problems etc.

12. What policies must be followed if the PHER is accepted for PHERRB review?

Non-NIH PIs, investigators and non-investigator study staff must follow their local institutional policies consistent with the Common Rule and FDA requirements as well as NIH HRPP SOP 28, "NIH PUBLIC HEALTH EMERGENCY RESEARCH REVIEW BOARD (PHERRB)," and the other NIH HRPP SOPs indicated to be applicable within SOP 28. If the PI is an NIH employee, or study staff includes NIH investigators and/or NIH non-investigators, they must follow the NIH HRPP SOPs.

13. What role will the relying institution(s) play in the protocol approval process and the on-going human subjects protections oversight?

The relying institution(s) must maintain a valid FWA and will have other institutional responsibilities as enumerated in the PHERRB reliance agreement and NIH HRPP SOP 28. In addition, the relying institution has responsibilities to protect human subjects under its own policies and/or applicable local law.

14. Will the relying institution(s) need any ancillary reviews (for example, radiation safety review, RAC review, etc.) besides the PHERRB before submitting a protocol?

This depends on the nature of the protocol and will be determined by each relying institution's policy on a case-by-case basis. If there are responsibilities other than those under 45 CFR 46, and 21 CFR 50 and 56, as applicable, PHERRB review will not preempt or fulfill those responsibilities.

15. Will the PHERRB accept the scientific review conducted prior to PHERRB review by a federal funder or by the relying institution(s)?

Scientific review approval must be obtained before PHERRB review. For example, scientific review by a federal funder or the relying institution(s) will be sufficient. If additional questions regarding scientific review of the protocol arise during the PHERRB review, they will be addressed on a case-by-case basis.

16. How does the PHERRB address regulatory requirements for review of the local research context(s)? Will the relying institution(s) need to provide information about the local research context(s)?

The PHERRB addresses regulatory requirements related to local research context(s) by requesting such information from the relying institution(s). The relying institution(s) must provide information about local research context(s) as part of the PHERRB protocol submission. For a more detailed description of what the NIH requires regarding local research context please see NIH HRPP SOP 20B at the following url: http://ohsr.od.nih.gov/OHSR/index.php

17. Who do I contact for additional information regarding the PHERRB?

Please send any questions to PHERRB@mail.nih.gov or call the NIH Office of Human Subjects Research Protections on 301-402-3444.