NIH Policy Manual

3014-207 - Public Health Emergency Research Review Board

Issuing Office: OD/OIR/OHSRP **Phone:** (301) 402-3713

Release Date: 6/10/2020 ? **Technical Revision Date:** 7/17/2023 ?

Transmittal Notice

1. **Explanation of Material Transmitted:** NIH Human Research Protection Program (HRPP) policies have been revised to comport with the revised DHHS Common Rule (45 CFR 46) and to reflect the newly consolidated Institutional Review Board (IRB) structure within the NIH Intramural Research Program (IRP). This policy describes the requirements and responsibilities of non-NIH investigators conducting Public Health Emergency Research (PHER) when the NIH IRB is the Reviewing IRB and serving as the Public Health Emergency Research Review Board (PHERRB), or when a non-NIH investigator seeks permission from the NIH Deputy Director for Intramural Research (DDIR) for the NIH IRB to serve as the PHERRB; and the responsibilities of the NIH IRB, Office of Human Subjects Research Protection (OHSRP) and the NIH DDIR when the NIH IRB is serving as the PHERRB, or is requested to serve as the PHERRB. Upon implementation, this policy fully supersedes the *SOP 28 NIH Public Health Emergency Research Review Board (PHERRB)*.
2. **Filing Instructions:**

    - **Insert:** NIH Manual Chapter 3014-207, dated 6/10/2020
    - **Implementation Date:** 11/09/2020

3. **PLEASE NOTE:** For information on:

    - The current policies can also be found at: https://irbo.nih.gov/confluence/display/ohsrp/Policy.
    - Content of this chapter, contact the issuing office listed above.
    - NIH Policy Manual, contact the Division of Compliance Management, OMA, on (301) 496-4606, or enter this URL: https://oma.od.nih.gov/DMS/Pages/Manual-Chapters.aspx

A. Purpose

1. The PHERRB was established by the U.S. Department of Health and Human Services (HHS), under the auspices of NIH, as a specialized central IRB to provide review of Public Health Emergency Research (PHER) conducted or

supported by any U.S. Executive Branch Agency or Department.
2. This policy describes the requirements and responsibilities of non-NIH investigators conducting PHER when the NIH IRB is the Reviewing IRB and serving as the PHERRB, or when a non-NIH investigator seeks permission from the NIH DDIR for the NIH IRB to serve as the PHERRB.
3. This policy describes the requirements and responsibilities of the NIH IRB, Office of Human Subjects Research Protection (OHSRP) and the NIH Deputy Director for Intramural Research (DDIR) when the NIH IRB is serving as the PHERRB, or is requested to serve as the PHERRB.

B. Scope

1. This policy applies to non-NIH investigators when requesting PHERRB review of a PHER protocol that is conducted or supported by any U.S. Executive Branch Agency or Department, and when the PHERRB is the Reviewing IRB.
2. This policy applies to the NIH IRB when serving as the PHERRB.
3. This policy applies to the OHSRP, its offices, and OHSRP staff serving as the PHERRB Coordinator.
4. This policy applies to the NIH DDIR (who is also the NIH Institutional Official (IO)) when determining eligibility for PHER protocols to be reviewed by the PHERRB.

NOTE: NIH investigators are subject to NIH Human Research Protection Program (HRPP) policies and NIH IRB oversight. NIH investigators who wish to conduct PHER research must follow NIH HRPP policies and NIH IRB procedures. NIH investigators who wish to rely on an external IRB for review of PHER research should refer to *Policy 3014-105 IRB Reliance* for information about NIH requirements.

C. Policy

1. The DDIR determines the eligibility of PHER protocols for PHERRB review, in accordance with this policy.
2. The NIH DDIR has the authority to waive or modify NIH HRPP policy requirements in response to a public health emergency.
3. For research to be eligible for submission to the PHERRB, it must be:

    a. PHER that is conducted or supported by any U.S. Executive Branch Agency or Department. Such protocols may include, but are not limited to, emergencies that are:

        I. Naturally occurring, accidental or deliberate; or
        II. Caused by biological, chemical, or radiological agents; or
        III. The result of socioeconomic crises.

    b. Subject to the HHS Common Rule (45 CFR 46) and/or, as applicable, the Food and Drug Administration (FDA) regulations at 21 CFR parts 50, 56, 312 and 812;

c. Conducted in the United States of America.

I. At the discretion of the DDIR, with input from Director OHSRP, the PHERRB may agree to oversee PHER conducted by personnel of US-based institutions at international sites.

4. Institutions seeking to rely upon the PHERRB must execute a reliance agreement with the NIH. (See *Policy 3014-105 IRB Reliance* for more information.)

   a. In order to rely upon the PHERRB, the relying institution must have on file with the Office of Human Research Protections (OHRP), an approved written assurance (Federalwide Assurance (FWA)) that it will follow the requirements of Policy for the Protection of Human Research Subjects (45 CFR 46), as described in 45 CFR 46.103.

5. Non-NIH investigators will comply with the requirements of this policy, NIH IRB requirements, and the terms of executed reliance agreements. (See, *Policy 3014-801 Reporting Research Events* and *Policy 3014-205 Types of IRB Submissions* for more information.)
6. The NIH IRB, when serving as the PHERRB, has all of the same authorities and responsibilities as a duly constituted IRB under 45 CFR part 46 and 21 CFR part 56, as applicable. (See *Policy 3014-200 IRB Scope and Authority*.)
7. The OHSRP, through its appropriate offices, will oversee the management and operations of the PHERRB, and oversee its structure and procedures.
8. The OHSRP Director will designate a PHERRB Coordinator to coordinate the day to day operations of the PHERRB.

D. Definitions

OHSRP has developed a comprehensive glossary of definitions that describe the terms listed below.The glossary can be found at the following link:NIH IRP HRPP Policy Glossary

Note: There may be more than one definition per term, so please review terms carefully to make sure they match the terms listed below. Qualified terms are indicated with a parenthetical qualification. When reviewing a definition, be sure that you are reviewing the appropriate definition that links to this policy. To further assist the reader, each term in the glossary cites the relevant policy number(s) indicating where the term is utilized.

1. Federalwide Assurance (FWA)
2. Individual or Institutional Investigator Agreement (IIA)
3. Institutional Official
4. NIH Investigator
5. Reliance (Authorization) Agreement

E. Responsibilities and Requirements

1. **Non-NIH Principal Investigator (PI) Responsibilities**

   a. Before submitting a PHER protocol to the PHERRB, the non-NIH PI must:

      I. Ensure the research meets the requirements of a PHER protocol (see C.3. above);
      II. Ensure that their home institution holds an active FWA (see C.4. above).
      III. Secure a written concurrence from their home institution's Institutional Official (IO) indicating willingness to rely upon the PHERRB; and
      IV. Complete the Application for PHERRB Review.

   b. Upon completing the requirements in *E.1.a.* above, the non-NIH PI must submit the following items to the OHSRP PHERRB Coordinator (irb@od.nih.gov) for submission to the NIH DDIR for review:

      I. A PHER protocol;
      II. The written concurrence from the home institution's IO; and
      III. The completed Application for PHERRB Review.

   c. Upon receipt of DDIR permission for the PHER protocol to be reviewed by the PHERRB, the non-NIH PI must:

      I. Ensure execution of a reliance agreement between NIH and their home institution to rely upon the PHERRB for IRB oversight, consistent with *Policy 3014-105 IRB Reliance and Collaborative Research* (see *C.4.* above).
      II. Upon execution of the reliance agreement, work with the PHERRB Coordinator, as necessary, to submit all required materials to the PHERRB for review, including, but not limited to:

         i. Proof of scientific review, human subjects protection training, and conflict of interest review by the home institution;
         ii. The PHER protocol, any consents/assents, and any applicable supporting documentation; and
         iii. The local context information for each site where the research is to take place. (See *Policy 3014-105 IRB Reliance and Collaborative Research* and *Policy 3014-205Requirements for IRB Submissions*.)

   d. Following approval from the PHERRB, the non-NIH PI must continue to follow normal submission requirements of the NIH IRB (using the assistance of the PHERRB Coordinator, as needed), and comply with the terms of the reliance agreement. (See *Policy 3014-105 IRB Reliance* and *Policy 3014-205 Types of IRB Submissions*.)

2. **Responsibilities of the Office of Human Subjects Research Protections (OHSRP) and its offices**

    a. The OHSRP Director must:

        I. Provide the proper staffing and resources, sufficient to support the operations of the NIH IRB, when serving as the PHERRB.
        II. Appoint dedicated staff to serve as the PHERRB Coordinator (see *E.2.e.* below).

    b. The OHSRP Office of Policy must maintain the PHERRB policy.
    c. The Office of IRB Operations (IRBO) Director must ensure procedures are in place to support the expeditious review of PHER protocols by the NIH IRB, when it is serving as the PHERRB.
    d. The Office of IRB Operations (IRBO) must ensure that PHERRB meetings are scheduled promptly, as needed, or as directed by the DDIR.
    e. The The PHERRB Coordinator must:

        I. Serve as the point of contact for the PHERRB, (e.g., monitor and respond to inquiries and communications about the PHERRB, including communications with non-NIH investigators and institutions; and assist non-NIH investigators with submissions to the PHERRB as necessary);
        II. When received from the non-NIH PI, review the *Application for PHERRB Review,* and the required supporting documentation (see *E.1.b.* above) for completeness and compliance with this policy, and submit these to the DDIR; and
        III. When the DDIR has granted permission for a PHER protocol to be reviewed by the PHERRB, notify:

            i. The IRBO reliance staff to ensure execution of any needed reliance agreements between the NIH and other institutions;
            ii. The non-NIH PI of the DDIR's determination.

3. **NIH DDIR Responsibilities**

    a. The NIH DDIR must:

        I. Review and determine the eligibility of PHER protocols for PHERRB review, in accordance with this policy.
        II. Determine whether it is necessary to waive or modify NIH HRPP policy requirements in response to a public health emergency consistent with his/her authority and the HHS Federalwide Assurance.

4. **Responsibilities of the NIH IRB, when serving as the PHERRB**

a. The NIH IRB, when serving as the PHERRB, must comply with its responsibilities as a duly constituted IRB under 45 CFR part 46 and 21 CFR part 56, as applicable. (See Policy 3014-200 IRB Scope and Authority and Policy 3014-204 Levels of IRB Review and Criteria for IRB Approval of Research.)

F. References

1. Federal Regulations:

   HHS: 45 CFR 46
   FDA: 21 CFR 50, 56, 312 and 812

2. NIH policy:

   Policy 3014-105 IRB Reliance and Collaborative Research
   Policy 3014-200 IRB Scope and Authority
   Policy 3014-204 Levels of IRB Review and Criteria for IRB Approval of Research
   Policy 3014-205Requirements for IRB Submissions
   Policy 3014-801 Reporting Research Events

3. Guidance: NA