HRPP POLICY APPROVAL & IMPLEMENTATION
OFFICE OF HUMAN SUBJECTS RESEARCH PROTECTIONS

Policy Number: 207

SOP Title: Public Health Emergency Research Review Board

Distribution: Scientific Directors; Clinical Directors; Clinical Investigators, IRB Chairs, IRB Administrators, Protocol Navigators

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POLICY

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 (PER) 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 PER 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 PER 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 PER 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 PER research must follow NIH HRPP policies and NIH IRB procedures. NIH investigators who wish to rely on an external IRB for review of PER research should refer to Policy 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 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 105 IRB Reliance, Policy 801 Reporting Research Events and Policy 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 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

1. Federalwide Assurance (FWA) – A written commitment that human subjects research conducted on behalf of an institution will comply with the protections for human subjects specified in the Common Rule regulation (e.g., 45 CFR 46). The FWA is filed with the US Department of Health and Human Services (HHS) Office for Human Research Protections (OHRP).

2. Individual or Institutional Investigator Agreement (IIA) – An agreement between the NIH and a non-NIH investigator that extends the NIH Federalwide Assurance (FWA) to either an individual investigator or to institutional investigators who are not covered by an FWA (e.g., physicians in private practice or individuals who work at an institution that does not have an FWA).

3. Institutional Official – The individual who is legally authorized to act for the institution and can obligate the institution to the terms of the Federalwide Assurance (FWA). The Institutional Official (IO) is the signatory on the FWA which is on file with the HHS Office for Human Research Protections (OHRP).

4. NIH Investigator – An NIH federal employee (intramural or extramural), Special Volunteer, Intramural Research Training Awardee (IRTA) or Cancer Research Training Awardee (CRTA) who is conducting NIH human subjects research on behalf of the NIH. This may include a contractor in accordance with policy.

5. Reliance (Authorization) Agreement – An agreement between institutions involved in the same multi-site research that provides a mechanism to delegate IRB review, and that sets forth the authorities, roles, and responsibilities of the IRB and participating institutions. The agreement may apply to a single study or to certain categories of studies.

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 \textit{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 \textit{Policy 105 IRB Reliance} (see \textit{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 \textit{Initial Review Local Context Worksheet} for each site where the research is to take place. (See \textit{Policies 105 IRB Reliance} and \textit{205 Types of 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 \textit{Policies 105 IRB Reliance} and \textit{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 \textit{E.2.e}, below).
   b. The OHSRP Office of Policy must maintain the PHERRB policy.
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 200 IRB Scope and Authority and 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 Policies:
   Policy 105 IRB Reliance
   Policy 200 IRB Scope and Authority
   Policy 204 Levels of IRB Review and Criteria for IRB Approval of Research
   Policy 205 Types of IRB Submissions
   Policy 801 Reporting Research Events

3. Guidance and other documents: NA

G. APPENDICES: NA

H. REVISION HISTORY: NA

I. SUPERSEDES DATE: 11/09/2020
   SOP 28 – NIH Public Health Emergency Research Review Board (PHERRB)