Attachment1. PUBLIC HEALTH EMERGENCY RESEARCH REVIEW BOARD (PHERRB)

Terms of Reference, October 2012

Purpose and Scope

The Public Health Emergency Research Review Board (PHERRB) is established under the auspices of the National Institutes of Health (NIH) as a network of NIH Institute and Center (IC) Institutional Review Boards (IRBs) to carry out ethical review of research protocols that are designed to address public health emergencies and that are conducted, supported, or regulated by the U.S. Department of Health and Human Services (HHS) and subject to 45 CFR 46 and/or 21 CFR 50 and 56. Through a dedicated review of human subjects protections for research protocols that address public health emergencies, the PHERRB network will provide a critical national service by helping to assure that studies carried out across the country are rigorously and expeditiously reviewed to enable the ethical conduct of essential research in the context of these emergencies. The specific IRB within the network that will carry out the review for a particular protocol(s), which will depend on the nature of the study, will be designated as the IRB of Record under NIH's assurance from the Office for Human Research Protections (OHRP).

In serving to review human subjects research protocols that arise in connection with public health emergencies the PHERRB's jurisdiction includes, but is not limited to, protocols to prepare for, mitigate, or otherwise respond to emergencies that are naturally occurring, accidental or deliberate; are caused by biological, chemical, or radiological agents (e.g., infectious disease outbreaks, natural disasters, or bioterrorist events); or are the results of socioeconomic crises. Such research might include, for example, studies aimed at mitigating or otherwise responding to a public health emergency, exploring causes of a public health emergency, or addressing another public health need. Any type of research protocol involving human subjects, e.g., biomedical and behavioral research, health services research, and public health research, may be reviewed by the PHERRB. Such research includes research conducted under an investigational new drug application (IND) or an investigational device exemption application (IDE), including emergency and treatment INDs and IDEs, and IND or IDE research that is carried out concurrent with or in concert with Emergency Use Authorizations.

Functions

In compliance with 45 CFR 46 and/or 21 CFR 50 and 56, institutions and sponsors engaged in research involving human subjects that is conducted, supported, or regulated by HHS may rely on the NIH IC IRB serving as the PHERRB as the IRB of Record for its public health emergency research.

The NIH Director or designee will provide guidance on specific public health emergency research that is eligible for PHERRB review. In identifying protocols that are eligible for review by the PHERRB, the NIH Director, Assistant Secretary for Preparedness and Response (ASPR), Commissioner of Food and Drugs, and/or the Director of the Centers for Disease Control and Prevention (CDC) or their designees may be consulted.

Based on the criteria at 45 CFR 46.111 and 21 CFR 56.111, comparable regulations for research funded by other Federal agencies, if applicable, and all applicable subparts of these regulations, the NIH IC IRB seving as the PHERRB will either approve or disapprove a research proposal or it may require modification of the proposed research in order to grant approval.

The NIH IC IRB serving as the PHERRB will notify the principal investigator of the protocol, institution, and funding Agency (if any) of its decision to approve or disapprove any proposed research protocol or of modifications required to secure IRB approval of the research activity.

Structure and Membership

The PHERRB is a network of the 12 active IRBs of the NIH IRB system. These IRBs have discrete missions and research portfolios, and they regularly review research proposals submitted by intramural investigators working at the NIH. Each also has the role and responsibility of serving as the PHERRB when a public health emergency research protocol is submitted for PHERRB review. The selection of the individual IC IRB to perform the ethical review a particular protocol will depend on the focus of the research being proposed.

The membership of the PHERRB will be consistent with the requirements at 45 CFR 46.107 and 21 CFR 56.107. Non-voting ad hoc consultants will be added to the PHERRB as needed depending upon the subject matter being reviewed. Examples of additional expertise that may be needed on an ad hoc basis include the following:

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

Procedures

PHERRB procedures, which are outlined in the Standard Operating Procedures of the NIH IRB System, comport with the requirements in 45 CFR 46 and 21 CFR 50 and 56 and will comply with institutional requirements as applicable.

Meetings

Meetings will be convened, as needed, at the request of the NIH Director or designee. All meetings will be conducted in compliance with procedures outlined at 45 CFR 46 and 21 CFR 56 and institutional requirements as applicable.

Support

The NIH will provide the organizational locus and management and support services for PHERRB.

Reports

The Executive Secretary will prepare an Annual Report for approval by the Chair of each NIH IC IRB that served as the PHERRB during the previous year each October 1 that will contain a summary of the proposals reviewed, actions taken, and any lessons learned. The consolidated Report will be submitted to the NIH Director as well as other HHS components.

Termination

The functions of the PHERRB can be dissolved at any time by the decision of the NIH Director after consultation with the Assistant Secretary for Health.