NATIONAL RESEARCH ETHICS BOARD (NREB) EMERGENCY GUIDELINES 2024

GUIDELINES FOR RAPID CLINICAL TRIALS REVIEW AND PROCESSES DURING PUBLIC HEALTH EMERGENCIES IN LIBERIA

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I. Background

The sporadic outbreaks of epidemics and pandemics worldwide in under-prepared health systems emphasize the urgent need for immediate and responsible action from key stakeholders. This response must be carried out both ethically and responsibly. There is increasing recognition of the moral obligation to conduct ethically and scientifically rigorous clinical research during infectious disease outbreaks such as Ebola, COVID-19, and other infectious diseases. However, this type of research often presents complex ethical challenges and issues for research ethics oversight. Existing national or institutional research ethics systems have limitations in addressing the practical ethical dilemmas that may arise when conducting research during epidemics or pandemics.

For example, despite the rapid development of multiple vaccines during the COVID-19 pandemic, it underscored the need for a careful balance between equity, quality, and timely review processes. Numerous articles and reports published after the 2014 Ebola outbreak also addressed ethical challenges in research during outbreaks and research ethics governance. These discussions highlighted the time-sensitive nature of review processes and the need to protect participants in clinical trials, many of whom may be in desperate need of potentially life-saving interventions.

Health epidemics have shown that countries vary in their readiness and preparedness to provide research ethics reviews. Despite these disparities, ethics committees often attempt to expedite research processes to meet the demands of rapid response during health emergencies. However, it remains essential to strike a balance between the urgency of conducting research and the need for a thorough ethical review process to maintain high standards of research ethics, even in times of crisis.

Notably, if Liberia had more than one research ethics committee (REC), the creation of an ad hoc committee focused specifically on addressing research during emergencies and epidemics would not only be recommended but essential. This committee should include representatives from relevant RECs, the Ministry of Health, and affected communities, with legislative backing and additional support from the Ministry of Health. A comprehensive approach is required to address the magnitude of these situations.

This document aims to highlight the ethical considerations relevant to conducting research involving human participants during epidemics in Liberia.

II. Specific Guidance

The following guidance becomes applicable once an outbreak is declared an emergency in Liberia or a neighboring country. Such a declaration will come from the World Health Organization (WHO), the Ministry of Health, or the National Public Health Institute of Liberia (NPHIL). To expedite the initiation of research, many processes (such as drafting documents, translations, and obtaining approvals) will occur in parallel, rather than sequentially, as is typical in non-emergency situations.

The time and effort contributed by research ethics committee members are highly appreciated, especially since they may have additional responsibilities or face illness among family members or colleagues during a public health emergency. Face-to-face meetings during epidemics or pandemics could pose additional risks, so it is essential to consider virtual meetings and review processes whenever feasible. When submitting a protocol for consideration, it must be written in English and include the proposed

study, corresponding ethics approval, consent or assent forms, and data collection tools and forms, at a minimum.

III. Emergency Requirements

The National Research Ethics Board (NREB) will ensure adherence to the following guidelines during health emergencies:

1. **Checklist for Expedited Review**
   In addition to the NREB review form (if applicable), the following checklist will be included to streamline fast-tracking of epidemic-related research:

   a) Identify the research as epidemic or outbreak-related to facilitate fast-tracking.
   b) Specify whether prior research data on the disease exist, referencing relevant local and international studies.
   c) Ensure the inclusion of at least one (preferably two) principal investigators or co-principal investigators from the country where the research and review take place.
   d) Provide qualifications of key investigators, including details of their previous experience with outbreak-relevant research.
   e) Indicate if the protocol is part of a multi-center trial. If so, describe the status of ethics approval for the master protocol or the ethics approval from the sponsoring country.
2. **Additional Submission Documents**
   Along with the usual documents for review (protocols, CVs, Human Subject Certificates, GCP, etc.), the following must be submitted:

   a) A collaboration letter (in the form of a memorandum of understanding) with sponsor institutions and research funders, including declarations of interest when possible.
   b) A monitoring and safety management plan for the project, provided by the principal investigator and study sponsor.
   c) Data-sharing and Material Transfer Agreements for data and biological materials, especially if samples will be exported out of the country, ensuring compliance with the Laws of Liberia (a draft version may be submitted initially).
   d) Clear procedures for dissemination, publication, co-authorship, co-presentation, and intellectual property rights.
   e) Plans to disseminate findings to the affected community, ensuring continued engagement and trust, especially among research participants.
   f) Depending on the type of research, a local insurance policy for trials and interventions may be required.
   g) The NREB will establish a rapid review process for emergency research, reviewing protocols as they are submitted rather than waiting for scheduled meetings. This process will be communicated to researchers, including potential delays for non-emergency projects.

3. **Practical Considerations**

    a) Establish surge capacity for reviews and systems for virtual discussions (via platforms like Zoom).
    b) Identify core members who will handle the majority of the review burden, providing specialized training in outbreak-related research review to ensure high standards without compromising ethical considerations. Additional members can be called upon as demand increases.

4. **Notification and Availability**
   Once an outbreak is imminent or in progress, the Director will alert members and determine whether they are available for emergency review.

5. **Ad Hoc and Co-Opted Members**
   Identify subject experts (technical and ethical) within the country and abroad who are willing to serve as ad hoc or co-opted members during outbreaks, anticipating the need to review multiple studies in a short time.

6. **Quorum Requirements**
   A quorum will consist of one-third of NREB members, including pre-identified subject matter experts.

    a) If a pre-identified member submits their review but cannot attend the meeting, they will still count towards the quorum.

IV. Standard Operating Procedures (SOPs)

Revised SOPs will be circulated to all review committee members. To reduce health risks, meetings may be virtual or electronic, especially in highly infectious outbreaks (e.g., COVID-19, Ebola).

7. **Protocol Submission Process**
   Protocols should be submitted electronically for efficiency, with hard copies to follow if mandatory. Principal investigators must inform NREB as early as possible about their intent to submit a high-level overview of their research (e.g., trial of a new medicine or vaccine, observational study, or survey) to prepare the committee for forthcoming protocols.

8. **Meetings with Investigators**
   Face-to-face meetings with principal investigators are not mandatory and may be conducted electronically or virtually if necessary.

9. **Protocol Review Timelines**

a) Protocols will be sent to reviewers within 48 hours of submission.
b) Reviewers should complete their reviews within five (5) days during an outbreak.
c) The principal investigator should receive Consolidated reviews with suggestions or approval within ten (10) working days.

d) Principal investigators should respond to the review within 48 hours.

10. **Communication and Documentation**

a) The Director of the NREB secretariat will be the primary contact for communication with principal investigators.
b) All communications will be documented and archived for future reference.

V. Conclusion

Research during emergencies presents unique ethical challenges that differ from those encountered in normal situations. Currently, there are no comprehensive guidelines or publications advising Research Ethics Committees (RECs) or Institutional Review Boards (IRBs) on how to communicate and collaborate efficiently in reviewing proposed research during disasters, epidemics, or other emergency conditions. However, during the COVID-19 pandemic, the World Health Organization (WHO) developed emergency guidelines, which have been adapted to fit Liberia's context in this guideline document.

While the urgency of conducting research in health emergencies is paramount, it must not compromise the integrity of the ethical review process. A rigorous and thorough ethical review remains essential, even under time constraints.

In addition to the National Research Ethics Board (NREB), if multiple RECs exist in Liberia, it is recommended that an ad hoc committee be established specifically to address research in emergency and epidemic conditions. This committee should include representatives from relevant RECs, the Ministry of Health, and affected communities. The Ministry of Health should provide legislative authority and the necessary support for the committee to function effectively.

The NREB remains committed to upholding best practices in ethical review, adapting to evolving ethical issues in health emergencies, and contributing to solutions that improve the research review process.

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