

**Guidance for research ethics committees
for rapid review of research during public health emergencies**

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1. Background

Disasters in general and epidemics or outbreaks in particular raise and magnify many ethical issues related to the provision and standard of health care delivery, privacy and confidentiality, informed consent, community engagement, benefit sharing, and resource allocation. To date, there are no approved treatments or prophylactic products known to be safe and effective for COVID-19, which is similar to such previous outbreaks as Ebola virus disease, Zika virus disease and Lassa fever. Consequently, conducting research on new medications or vaccines during a pandemic is essential, and research ethics committees need to be prepared to rapidly review related research projects.

Different countries will be in different stages of readiness to provide an ethics review of epidemic-relevant research. Regardless of preparatory work that has been done so far, there are actions that ethics committees can and should undertake to prepare for rapid review of emergency research protocols, such as for COVID-19.

Many articles and reports published after the 2014 Ebola outbreak addressed ethical issues in research during outbreaks and research ethics governance (1–5). Of note, issues were raised about time sensitivity and the balance between, on the one hand, quality and time to review, and, on the other hand, ensuring the protection of participants in clinical trials, many of whom are in desperate need of the lifesaving benefits of management protocols.

Two workshops held in 2018 addressed important issues in this context:

- “Ethics preparedness: facilitating ethics review during outbreaks”, organized by ALERRT (African Coalition for Epidemic Research, Response and Training) and the World Health Organization (WHO) in Dakar, Senegal, March 2018 (6);
- “Ethics review of research on Lassa and other infectious disease outbreaks”, organized by WHO in Abuja, Nigeria, October 2018.

These workshops provided recommendations for addressing how national and institutional (research) ethics committees and other research review committees should prepare for changes that may be necessary to their standard operating procedures in order to respond efficiently during a pandemic.

2. Specific guidance

The following guidance should come into action once an outbreak is declared an emergency. This declaration will come from the public health authority of the country. To expedite commencement of the research, many processes (drafting documents, translations, approvals) will be happening in parallel rather than sequentially, as is the case in non-emergencies.

The time and effort invested by research ethics committee members is much appreciated, particularly since they also have other duties and may be dealing with illnesses among family members or colleagues during a public health emergency. During epidemics or pandemics there are increased potential risks to members during face-to-face meetings, and it is thus imperative to consider virtual meetings and review processes where and when possible.

When a protocol is being considered for submission in a language other than that in which the review is conducted, the synopsis, plan, documents of consent or assent, and data collection tools and forms at a minimum should be submitted in the official language of the country where the review will take place. Other documents in the reviewing country's language should be submitted as soon as possible.

In order to facilitate rapid, time-sensitive reviews, research ethics committees need to consider the following recommendations for additions or changes to existing standard operating procedures:

1. A checklist including the following items should be included in addition to the ethics review form (if used by the review committee):
 - a. identification of the research as epidemic or outbreak related in order to facilitate fast-tracking;
 - b. description of whether prior research data about the disease exist (include references of recent local and international studies);
 - c. inclusion of at least one (preferably two) principal investigators or co-principal investigators of the country where research and review is taking place;
 - d. qualifications of key investigators, including a description of previous track record with outbreak-relevant research among the research group;
 - e. an indication as to whether the protocol is part of a multi-centred trial (if yes, an opportunity should be provided to describe the status of ethics approval of the master protocol or the ethics approval of the sponsoring country).
2. Apart from the usual documents submitted for review (such as protocols or CVs), the following should also be submitted:
 - a. a letter of collaboration (in the form of a memorandum of understanding) with sponsor institutions and the funders of the research, along with declarations of interest when possible;
 - b. a monitoring and safety management plan for the project by the principal investigator and the study sponsor;
 - c. both data-sharing and material transfer agreements for data and human biological material, especially if samples are being exported out of the country, while honouring the laws of the land (a draft may be submitted initially);
 - d. clear processes and procedures for follow-up dissemination and publication, co-authorship, co-presentation, and intellectual property rights;
 - e. procedures for dissemination of findings to the affected community (important to ensure maintaining contact with and upholding the trust of the affected populations, especially research participants);
 - f. local requirements on insurance policies, particularly with regard to trials and interventions, may also be included.

3. To prepare for the review of emergency research, research ethics committees should agree on a process for rapid review (this would mean reviewing protocols as and when they are submitted rather than waiting for a scheduled meeting). This process should be communicated to the researchers. Any anticipated delays for non-emergency research should also be communicated to all principal investigators who had previously submitted such research projects.
4. Other practical considerations include identification of the surge capacity for review, setting up systems for remote discussions (for example, which software platform, does everybody who needs it have access to it and know how to use it, what will be the back-up plan if the Internet is not functioning).
5. It is essential to pre-identify a certain number of members who will share the major burden of review. These members would require specialized training (or equivalent experience) in reviewing research in outbreaks so that they are able to rapidly review research proposals without compromising ethical considerations. Additional members should be identified and called for review at times when demand increases.
6. Once an outbreak is imminent or in progress, the chair or the secretary of the review committee should alert members and ascertain which members would be available for the rapid review.
7. Subject experts (technical) and people with strong knowledge of ethics (both in country and abroad) willing to serve as ad hoc or co-opted members during outbreaks should be identified and contacted in advance, as there is a likelihood of receiving multiple projects that need to be reviewed in a short time.
8. A quorum shall consist of one third of all members of the research ethics committee (pre-identified to include relevant people).
9. If a pre-identified member of the committee submits their review but is unable to join the meeting, they should be considered as part of the quorum requirement.
10. Once revised, the new standard operating procedures should be circulated to all members of the review committee.
11. The review meetings could be virtual or electronic, especially if a face-to-face meeting in a highly infectious outbreak such as COVID-19 represents a health risk to committee members.
12. Protocol submission should be done electronically to save time; a hard copy, if mandatory, can follow. Principal investigators should contact the research ethics committee as soon as possible to communicate their intention to submit a high-level overview of research (for example, is it a trial of a new medicine or vaccine, an observational study, or a survey), so that the committee is aware of protocols that may be forthcoming.
13. Face-to-face meetings with the principal investigators should not be mandatory, and if necessary electronic or virtual venues may be adopted.

14. Protocols should be sent to reviewers within 24 hours of submission.
15. Reviewers should complete their reviews within a specified period of time (usually three days is sufficient and appropriate during an outbreak).
16. The consolidated review and suggestions (or approval) should be communicated to the principal investigator within a specified period of time (usually five days).
17. Electronic or telephonic communication with principal investigators should be initiated to seek clarifications, thus saving time.
18. The principal investigator should respond to the review as soon as possible, but not later than 48 hours.
19. Focal points or persons for communication in respective national and institutional (research) ethics committees should be identified as early in the process as possible.
20. All communications should be documented and archived.

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