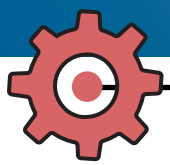
PAHO Pan American Health Organization World Health Organization Americas

CATALYZING ETHICAL RESEARCH IN EMERGENCIES

Recommendations for research ethics committees



This technical note includes the specific recommendations for research ethics committees (RECs) contained in the report Catalyzing ethical research in emergencies. Ethics guidance, lessons learned from the COVID-19 pandemic, and pending agenda, published by the Pan American Health Organization in 2022.

The recommendations are divided into recommendations for action, and recommendations for conceptualization. In both cases, the recommendations may be relevant only to health emergencies or may apply to both emergency and non-emergency situations. Their aim is to improve ethical preparedness for future emergencies and to strengthen research ethics in the Region of the Americas in general.

RECOMMENDATIONS FOR ACTION

RECs should implement these recommendations immediately. For this purpose, it will be necessary in most cases to adapt their internal regulations and work in coordination with the other relevant research stakeholders.

I. RECOMMENDATIONS FOR HEALTH EMERGENCIES

Recommendations for emergency situations involve actions that must be implemented before a health emergency occurs, as part of emergency preparedness.

In consideration of the strategy for ethics oversight of research in emergencies adopted by health authorities, RECs should establish:

1. Rapid and rigorous standard operating procedures (SOPs) to review and adequately monitor emergency research, which entails taking into account the rapid production of evidence that occurs in emergency situations.
2. Procedures to review and monitor the emergency use of an unproven intervention outside of research in accordance with the MEURI (*monitored emergency use of unregistered and experimental interventions*) ethical framework.
3. Rapid and agile mechanisms for communication and coordination with health authorities and other research stakeholders.

II. RECOMMENDATIONS FOR ORDINARY SITUATIONS, INCLUDING HEALTH EMERGENCIES

1. Review their procedures to incorporate virtual. To this effect, the documents or regulations that govern the operation of RECs should be modified and their capacities and resources strengthened, as necessary.
2. Allow different ways of carrying out informed consent processes, so that they are not limited to face-to-face processes in which willingness to participate in a study is expressed in writing and on paper. To this effect, the documents or regulations that govern these processes should be modified, as needed.

3. Establish clear and agile procedures to determine which activities constitute research with human subjects and thus require REC review. This will make it easier for epidemiological surveillance and other public health activities to avoid being erroneously treated as research and to promote their adherence to the appropriate ethical framework.
4. Require that researchers submitting a proposal for review report prior reviews conducted by other (local or international) RECs and, if so, include a copy of their decisions.
5. Create communications mechanisms (e.g. through social media) when necessary to inform the public about studies they are supervising. In addition, RECs should inform the public about their purpose and role during health emergencies, and the ethical aspects of research with human participants that could be challenging in emergencies or perceived as problematic.
6. Strengthen capacities in research ethics, particularly in the following topics:
    - the distinction between research with human subjects and public health activities,
    - emergency use of unproven interventions outside of research (MEURI framework),
    - ethical use of samples and data in futureresearch (including the importance of avoiding the destruction of samples and using material and data sharing agreements),
    - adaptive designs,
    - human challenge studies,
    - online studies,
    - scientific integrity, and
    - REC's obligations regarding what must be kept confidential and what must be made public.

RECOMMENDATIONS FOR CONCEPTUALIZATION

Because RECs play a central role within research ethics systems, RECs should further conceptualize specific actions needed to put these recommendations into practice, in coordination with other relevant stakeholders.

I. RECOMMENDATIONS FOR HEALTH EMERGENCIES

1. Design and implement mechanisms for effective coordination of research efforts initiated in emergencies, in order to know which initiatives are underway and who is responsible for them before studies are registered. This, in turn, will prevent the duplication of research and make collaboration possible (e.g. by conducting network trials or multicenter studies).
2. Plan a strategy to generate collaborations within the Region to conduct research in emergencies that addresses the logistical challenges posed by conducting regional multicenter clinical trials during health emergencies, and the legal instruments that may be needed to implement those trials.
3. Develop mechanisms for the ethics oversight of research at the (sub)regional level (e.g., using the strategy of extraterritorial ethics oversight during health emergencies).

II. RECOMMENDATIONS FOR ORDINARY SITUATIONS, INCLUDING HEALTH EMERGENCIES

1. Design and implement strategies that streamline the review and monitoring of research carried out by multiple RECs, either through coordination mechanisms (which may involve the review of different RECs in a simultaneous deliberation) or by establishing mechanisms that allow a REC to adopt the review carried out by another, without the need to repeat the review process (e.g., through previous reliance agreements).

Access the website of the publication *Catalyzing ethical research in emergencies.*

Access PAHO's communication resources on research ethics: https://www.paho.org/en/bioethics/videos-research-ethics

PAHO's Regional Program on Bioethics: www.paho.org/bioethics

Department of Evidence and Intelligence for Action in Health: https://www.paho.org/en/evidence-and-intelligence-action-health

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