PAHO Pan American Health Organization World Health Organization Americas

CATALYZING ETHICAL RESEARCH IN EMERGENCIES

Recommendations for health authorities

This technical note includes the specific recommendations for health authorities 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

Health authorities should implement these recommendations immediately. For this purpose, it will be necessary in most cases to adapt the corresponding legal instruments 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.

1. Establish strategies for the oversight of research ethics in future health emergencies, which include procedures for prompt and rigorous ethics review and monitoring. For this purpose, health authorities should:
   a. Consider the relevance of combining strategies as appropriate to the duration and severity of the emergency. For example, a strategy for short-term emergencies may be envisaged, with provisions for migrating to a different strategy with different procedures if the emergency is prolonged or worsens.
   b. Formalize the chosen strategies through the appropriate legal instruments.
   c. Allocate the necessary resources to implement the chosen strategy efficiently and sustainably for the duration of the health emergency.
   d. Establish rapid communication mechanisms between the research ethics committees and the national authorities to be activated as part of the strategy.
2. Develop, in coordination with other relevant research stakeholders, generic research protocols for potential health emergencies (also called master protocols) which harmonize key methodological aspects. It is important to include an ethicist when designing these protocols and submit them to a research ethics committee for preliminary ethics approval. As soon as an emergency occurs, these protocols should be adapted as necessary, and the final versions must be reviewed and approved rapidly by the research ethics committee.
3. Entrust the relevant research authorities (e.g., the National Institute of Health or the Research Office within the Ministry of Health) with responsibility for coordinating research efforts in emergencies. This includes establishing research priorities and networks of experts.
4. Designate a person who serves as a contact point for research as part of the national incident response team that is established during every health emergency.
5. Establish processes for involvement in the research conducted in response to health emergencies from the beginning in order to ensure that countries and their populations benefit from their potential results.

Recommendations for the monitored emergency use of unregistered and experimental interventions (MEURI)

1. Establish mechanisms and procedures to find out which interventions are being offered in the country under the MEURI framework, as well as to evaluate and authorize them prior to their initiation. Health authorities are recommended to collaborate in developing the protocol for the intervention offered under the MEURI framework, in order to ensure the quality and usefulness of the data that will be collected. Additionally, health authorities should establish and advance coordination with the relevant stakeholders to ensure an adequate oversight in timeframes that are responsive to the health emergency.

2. Require the registration of the interventions offered under the MEURI framework in a differentiated registry that allows them to be distinguished from the interventions that are offered as part of research. This information should be publicly available, e.g, through the website of the corresponding health authority.

3. Establish mechanisms to communicate to the population the importance of using interventions that are supported by scientific evidence, the need to evaluate interventions as part of research studies with adequate safeguards, and the risks of interventions that have not yet been scientifically proven. In the exceptional cases in which interventions under the MEURI framework are used, health authorities should clearly communicate that the interventions have not been proven, encouraging an open dialogue about their risks and potential benefits and providing information about the ongoing oversight.

II. RECOMMENDATIONS FOR ORDINARY SITUATIONS, INCLUDING HEALTH EMERGENCIES

1. Review their procedures to incorporate virtual tools as well as agile communication and coordination mechanisms with other RECs and regulatory authorities. 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. Establish information and coordination mechanisms to gather information about studies that were submitted for REC review and not approved, and, if necessary, share this information (with the corresponding decisions) with other RECs that are asked to review the same protocols.
5. Establish in each jurisdiction a publicly accessible website that lists the studies with human participants that have been approved. For clinical trials, reference to the registration in an ICTRP registry should be included.
6. Formally require all clinical trials to be registered in registries that feed ICTRP before they begin. This requirement could be formalized through a legally binding instrument (such as a Ministerial Resolution) and should apply to all clinical trials, not just those on drugs and devices.
7. Advocate for expanding the scope of ICTRP so that it includes all research with human participants and not only clinical trials, which will allow for the global implementation of the stipulations from the 2013 Declaration of Helsinki.
8. Formally assume responsibility for continually informing the public about the research conducted, e.g., through social media or other strategies identified by their communications offices, in order to facilitate public engagement and promote trust in research and in the knowledge that results from it. It is also important to create communication channels for the population to seek and obtain clarification about research and its ethical governance.
9. Encourage scientific journalism and spaces to disseminate scientific research in the media in order to promote a better understanding of research and the ways to ensure it is conducted ethically.
10. 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 future research (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

In coordination with the other relevant stakeholders, health authorities should further conceptualize the specific actions needed to put these recommendations into practice.

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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