

Guidance and strategies to streamline ethics review and oversight of **COVID-19-** related research

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SUMMARY

Faced with the COVID-19 pandemic, we have the moral duty to conduct research that generates evidence to maintain, promote and improve health care delivery and decision-making, and to define policies for managing and mitigating the pandemic. In order to efficiently respond to this health emergency, it is necessary to adapt existing ethics review procedures and search for alternatives to reduce as much as possible the practical obstacles to conducting research. This document offers health authorities and ethics review committees guidance and strategies with which to implement rapid and rigorous ethics review and oversight processes for COVID-19-related research with human subjects.

How can we ensure that COVID-19-related human subjects research is conducted rapidly, rigorously and ethically during the pandemic?

The moral imperative to catalyze COVID-19-related ethical research requires that ethics review and oversight processes be rapid, rigorous, and adapted to the emergency context. To achieve this, we should:

- Create alternative and flexible mechanisms and procedures for ethics review and oversight best suited to the characteristics of the country.
- Maintain procedures that enable efficient communication, harmonization of criteria, and cooperation between committees at different institutions and at different levels (where applicable), and relevant health authorities.
- Maintain coordinated procedures for the review of multicenter studies that enable streamlined evaluations and avoid duplication of efforts within or among countries.
- Support mechanisms to ensure coordination between the reviews of the ethics review committee and the activities of regulatory authorities, such as the health authority responsible for regulating clinical trials. Ideally, the actions of ethics review committees and regulatory authorities should occur simultaneously.

What alternatives can be considered for ethics review and oversight during the COVID-19 pandemic?

Although a single formula does not exist, the following organizational alternatives have been identified as possible strategies for streamlining ethics review and oversight processes during the

COVID-19¹ pandemic. These strategies seek to avoid duplications and delays, as well as overwhelming the capacity of committees. The order of the strategies below does not indicate preference. The relevant authorities should evaluate which strategy is most suitable for their context.

Ad hoc committee	The corresponding authority creates an ethics review committee that assumes responsibility for the ethics review and oversight of COVID-19-related research with human subjects for the duration of the emergency. This ad hoc committee could review all COVID-19-related research with human subjects or a previously identified subset, such as clinical or multicenter studies.
National-level committee	The corresponding authority designates a research ethics review committee of a national government entity to be responsible for the ethics review and oversight of COVID-19-related research with human subjects for the duration of the emergency. This designated committee could review all COVID-19-related research with human subjects or a previously identified subset, such as clinical or multicenter studies.
(Sub) Regional extra-territorial committee	The corresponding authorities of several states within the same geographic region establish an ethics review committee to assume responsibility for ethics review and oversight of COVID-19-related research with human subjects conducted in the involved countries or territories for the duration of the emergency. They may also delegate this responsibility to an existing committee. This (sub)-regional committee could review all COVID-19-related research with human subjects or a previously identified subset, such as clinical or multicenter studies.
Provincial or sub-national committee	The corresponding health authorities establish an ethics review committee for a subnational jurisdiction or delegate an existing committee, based on the governmental organization of the country, to assume responsibility of ethics review and oversight of COVID-19-related research with human subjects carried out within said jurisdiction for the duration of the emergency. This subnational

¹ If you have identified another alternative for the organization of ethics review and oversight processes during the COVID-19 pandemic in your country, you may contact the PAHO's Regional Bioethics Program (bioethics@paho.org) for additional guidance.

committee could review all COVID-19-related research with human subjects or a previously identified subset, such as clinical or multicenter studies.

**Institutional-
level
committees**

The corresponding authority designates one or several institutional ethics review committees to assume responsibility for ethics review and oversight of COVID-19-related research with human subjects conducted in the country for the duration of the emergency. The selection of one committee or another may be based on varying criteria, including, for instance: its experience as a research ethics committee in the country; its functional capacity; its association with a health institution with a high incidence of COVID-19 patients; the research topic, or by the risks involved in the research, among other criteria.

The health authority might also decide that ethics review and oversight of COVID-19-related research with human subjects will be handled by existing institutional ethics review committees exactly as would occur under normal circumstances in the country. Regardless of the chosen option, ethics review committees should have in place adequate operational procedures with which to carry out rapid and rigorous ethics review during emergencies and avoid duplications and delays.

It is important to note that more than one committee reviewing protocols on COVID-19 during the emergency may result in practical difficulties, particularly in the case of multicenter studies. Therefore, it is crucial that all COVID-19 ethics review committees, regardless of structure, have mechanisms in place to effectively coordinate and communicate between themselves and with health authorities in order to avoid duplication of efforts or the loss of valuable time. In these situations, it is recommended that committees agree on a single committee whose review and decision on each research protocol will be binding for the rest involved in the ethics review process along with establishing responsibilities related to the protocol such as the oversight and communication, among others.

What should be taken into account to streamline the review of COVID-19-related protocols?

Regardless which organizational alternative to the typical ethics review and oversight is chosen, the following aspects should be taken into account during the health emergency in order to streamline ethics review and oversight processes:

Ethics review committee composition during an emergency: The committee should be diverse in terms of gender and include health professionals with knowledge about COVID-19, methodologists, ethicists and community representatives. If this is not the case, committees can convene independent national or international consultants to review protocols. The committee should include diverse perspectives with the adequate expertise to rapidly evaluate COVID-19-related research with human subjects.

Members must be available to conduct a rapid review of protocols. To achieve this, committee members who can meet the time and expertise requirements should be preidentified before they are assigned protocols.

Member training: Members should be knowledgeable about ethics of research with human subjects, including on ethical aspects of research during emergencies. The following documents can serve as guidance:

- CIOMS. **International ethical guidelines for health-related research involving humans.** (Guideline 20: Research in disasters and disease outbreaks). Available at: <https://cioms.ch/publications/product/international-ethical-guidelines-for-health-related-research-involving-humans/>
- PAHO. **Ethics guidance on issues raised by the novel coronavirus disease (COVID-19) pandemic.** Available at: <https://www.paho.org/en/documents/ethics-guidance-issues-raised-novel-coronavirus-disease-covid-19-pandemic>
- Nuffield Council on Bioethics, **Research in global health emergencies: ethical issues.** Available at: <https://www.nuffieldbioethics.org/publications/research-in-global-health-emergencies>
- WHO. **Guidance for managing ethical issues in infectious disease outbreaks.** Available at: <https://apps.who.int/iris/bitstream/handle/10665/250580/9789241549837-eng.pdf?sequence=1>

Selecting independent consultants: Identifying experts (researchers, health professionals, social scientists, methodologists, ethicists, etc.) and establishing their availability in advance to consult on issues related to the response to the COVID-19 pandemic allows the committee to rely on their

support when required for the review of specific studies. It is important for the committee to identify and properly manage any potential conflicts of interest consultants may have.

It is possible that committee members will not be available to conduct rapid reviews because of their duties related to pandemic response. In such cases, consultants may be called upon to serve as ad hoc committee members, with voice and vote.

What strategies should be considered to streamline ethics review processes?

Digital communications and document submission: Electronic systems like email and instant messaging facilitate and streamline communication between members of the committee, as well as with investigators, authorities and others involved in the research; they are also adaptable to the restrictions placed on physical movement that help prevent the propagation of the new coronavirus cases among the population. Therefore, their use should be encouraged as long as confidentiality of information is guaranteed.

Maintaining online systems for the review of research protocols (such as ProEthos) facilitates the work of the committee and decreases considerably the amount of time required for the submission of documentation and information. If the committee does not have an online system in place, it should request that all documents be submitted through other electronic means.

Committee members and researchers should designate an email address and cell phone number as communication channels with the committee and commit to checking these regularly during the emergency. Likewise, the committee should have a unique email address with which to receive, handle and register documents and information.

Flexibility in the requirements for document submission: It is important to not reject studies due to concerns about their presentation (for example, missing complementary documents or signatures on documents). If there are substantive gaps to be filled, committees can require researchers to respond within a reasonable time frame without impeding the start of the review of the study.

Virtual meetings: Virtual meetings should be conducted through video or telephone calls to facilitate meetings during the pandemic without causing unnecessary risk to members. Researchers can also be called or included virtually if it becomes necessary to consult them during the meeting. It is advisable to ensure researchers will be available by informing them of the date and time of the meeting in advance.

Staggered review and decision-making: It is possible that a majority of committee members will be overwhelmed with duties related to the pandemic response, which could complicate their participation in virtual meetings. In this case, and in order to not affect quorum, committees can make use of staggered deliberations and decision-making.

Reduced quorum: Given the exceptional nature of the emergency, a lower than normal quorum of members may be allowed, while taking into account the number of committee members and their experience and knowledge relevant to the review of the research. If certain members cannot participate in a virtual meeting they may send in their comments, questions, and reviews electronically to be counted for quorum.

Minutes: It is important that any actions taken by the committee are recorded in minutes. These minutes can be digitalized, shared and ratified through electronic signatures. Once the pandemic is over, minutes can be aggregated into the official records and endorsed by members who participated in the deliberations.

Tight deadlines: Responding in a timely manner is the objective of streamlined review. Because of this, it is necessary to set tight deadlines for the review of protocols, meetings, communications with researchers, time to receive responses from researchers, and the committee's final decisions. Although the time that elapses from review until the committee's decision is issued will depend on various factors (complexity, level of development and technical rigor of the study, number of observations, response times of the researchers, duration of the sessions, etc.), deadlines similar to the following should be met:

- The research protocol must be sent to members for review within 24 hours of receipt.
- The reviewing committee members should review the research protocol within 72 hours.
- The meeting should be conducted as soon as members complete their review.
- Communication to the researchers following committee review should occur as soon as possible after the meeting.
- Researchers should respond to the committee within 48 hours.

Digital archive of committee documentation: All documentation stemming from streamlined reviews during the emergency should be digitally archived. It is important that the platforms or programs used guarantee the confidentiality of archived information.

What should be taken into account for decision-making?

Although conducting research during COVID-19 pandemic is an ethical duty toward understand the disease and improving prevention and health care delivery, it is important to consider that this should not interfere inappropriately with attention given to patients, the work of healthcare professionals or the functioning of health care delivery centers where research will occur.

The research carried out during an emergency should be rigorous and adhere to national and international ethical standards. Nevertheless, careful analysis needs to be given to what ethical considerations imply in the exceptional context of this emergency. It is therefore essential to keep context in mind.

For example, in the current pandemic, the potential vulnerability of participants and healthcare professionals, isolation of participants preventing familial support and existing health care delivery protocols may impede the use of habitual processes when obtaining informed consent. Faced with this reality, committees should consider appropriate alternative mechanisms to guarantee the process is carried out in a way that avoids risks of contagion while allowing the will of the participant to be registered. Contact with participants in COVID-19-related research might thus be made through video or phone calls, with the registry of consent carried out through audiovisual means. In the event that the participant is unable to provide consent, phone or instant messaging can be used to request relatives' support or consent.

What should be taken into account for ethics oversight and monitoring?

To avoid putting committee members at risk or affecting patient care and the operation of health care delivery centers, ethics monitoring can be carried out through reports submitted by researchers at established deadlines, submitted remotely, and/or deferred. For example, participants could be contacted by phone or electronically once they have recovered, provided their privacy and confidentiality of information are protected.

It is important that ethics review committees keep in mind that, in an emergency situation such as the one we are currently experiencing, a large volume of knowledge about COVID-19 is being produced rapidly. Because of this, there is a high probability that research will need to be modified, or even suspended, based on the results that are obtained locally or globally.

How will research be followed-up on when the COVID-19 pandemic ends?

Regardless of the organization of ethics review and oversight process adopted, once the COVID-19 pandemic has ended the ethics review committees that have approved COVID-19-related

research with human subjects should continue their monitoring responsibilities until the conclusion of the studies.

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