



Pan American Health Organization Ethics Review Committee

2020 Annual Report

Abridged version, June 2021

PAHO



Pan American
Health
Organization



World Health
Organization
Americas

1. Overview

PAHOERC was challenged in 2020 by the COVID pandemic, which brought global attention to the urgent need to conduct research and the importance of ethics review to ensure that the research with human participants is ethical. The pandemic led to an increased demand for research ethics guidance and support for streamlining ethics review processes, including adapting them to teleworking scenarios. Furthermore, it prompted PAHOERC to operate under its emergency operating procedures —as defined in its [Standard Operating Procedures \(SOPs\)](#)— to meet the increased needs for timely ethics review.

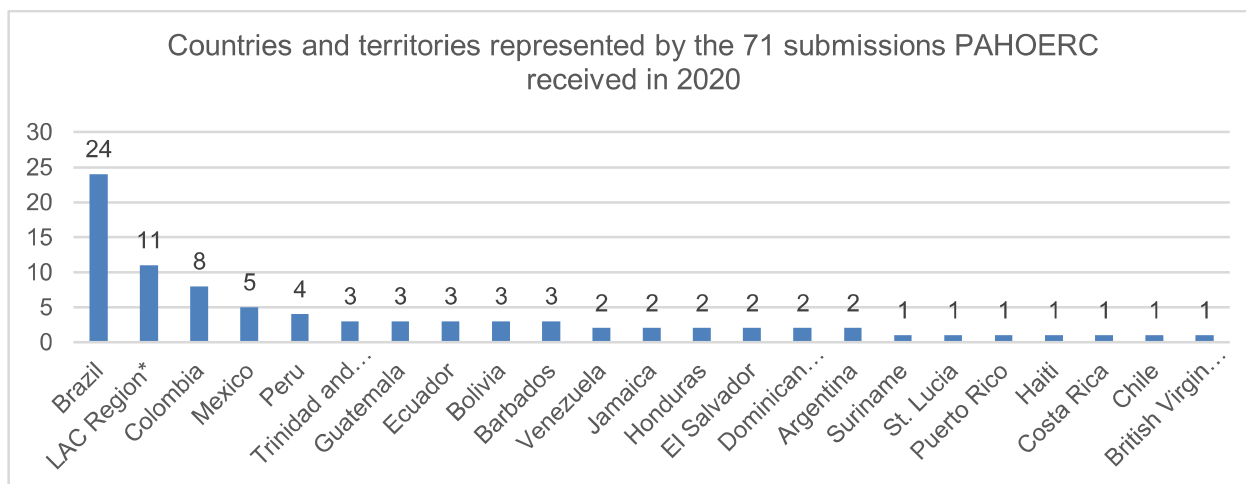
PAHOERC met those challenges because of (1) the sustained commitment of its members and observers; (2) support for the Secretariat; (3) the 2019 revision of its SOPs, which delineate the process to be followed in emergencies; and (4) the use of an online platform (ProEthos), which allowed PAHOERC to remotely manage the ethics review process and retain institutional memory.

The total number of submissions to PAHOERC in 2020 (71) was similar to the number submitted in previous years, although slightly lower due to a reduction in the expected clusters of annual projects being carried out at PAHO. We believe that even omitting the number of research projects PAHOERC typically receives, this number of submissions is notable, reflecting efforts among technical teams to engage in COVID-19 related research along with the continued institutionalization of the ethics review requirement in the Organization.

2. Summary of PAHOERC activities

Ensuring all human subjects research in which PAHO is involved meets ethical standards

In 2020, PAHOERC received 71 unique submissions representing research set to take place in 24 countries or territories, or the Latin American and the Caribbean (LAC) Region as a whole. Some proposals sought to conduct research in multiple countries (each country is accounted for in the figure below); most proposals targeting the LAC Region as a whole involved online surveys or regional databases.



Some proposal submissions represent research that will take place in more than one country; all countries are represented here.

*Including one sub-regional submission from the English-speaking Caribbean.

Of these 71 unique proposals submitted to PAHOERC in 2020:

- 27 received exemptions from full PAHOERC review, in accordance with the criteria established by its SOPs.
- 43 (61%) required full review by the committee or further action by the Secretariat (an increase from previous years).
- 30 proposals were reviewed by PAHOERC during 10 regular meetings and 8 auxiliary meetings scheduled to address COVID-19-related research.
- 1 non-approval decision was issued for a study that had already been initiated.
- 26 proposals were ultimately approved for implementation in countries of the LAC Region in 2020.

The 71 proposals received reflect the context of the pandemic: a surge (21 submissions) of COVID-19-related projects and fewer proposals on regular annual cluster projects (grant-sponsored proposals on a set topic). Eighteen projects were related to a new World Health Organization (TDR & HRP) grant-sponsored cluster of projects that are related to the needs of migrant women and children, reproductive health, and infectious diseases, managed by CLAP. Other repeated topics of proposals PAHOERC received in 2020 included institutional surveys, alcohol / tobacco use, and HIV/AIDS prevention.

PAHOERC members and observers continue to exhibit remarkable commitment to their duties ensuring all research in which the Organization is involved is ethical. A significant number of COVID-19-related research proposals created a greater than usual workload in 2020 by prompting eight additional PAHOERC meetings (held only once per month in a typical year). COVID-19-related research proposals necessarily required more attention due the newly emergent evidence base on any project related to SARS-CoV-2 (COVID-19 pandemic). Members volunteered additional time and efforts to support researchers working with the Organization on projects or challenges related to their areas of expertise (via ad-hoc meetings with research teams, analyses of proposal components, written comments). Members and observers also participated at a meeting with colleagues from the Department of Communicable Diseases and Environmental Determinants of Health (CDE) to discuss the process of distinguishing research projects requiring ethics review from other types of activities, and training sessions for PAHO personnel on the importance of obtaining PAHOERC review during the pandemic.

Building capacity in research ethics

PAHOERC continues to build capacity in research ethics within the Organization and throughout the LAC Region in tandem with PAHO's Regional Program on Bioethics. The volume of capacity building activities within the Organization was higher than usual in 2020, in part because many teams that do not regularly conduct research sought to participate in COVID-19-related research activities in 2020. Internal capacity-building activities included:

- Individual consultations on proposals and ethics challenges via phone and email.
- Targeted trainings to certain grant project teams (CLAP-managed research grants).
- Organization-wide trainings on the PAHOERC ethics review requirement for staff.

Capacity-building efforts for the LAC Region in 2020 mainly focused on the challenges posed by COVID-19 research¹ and included:

- Numerous regional training sessions in both languages on pandemic-related topics, supplemented by presentations at the request of national authorities or key institutions of

¹ Carracedo S, Palmero A, Neil M, Hasan-Granier A, Saenz C, Reveiz L. The landscape of COVID-19 clinical trials in Latin America and the Caribbean: assessment and challenges. *Rev Panam Salud Publica.* 2020;44:e177 <https://doi.org/10.26633/RPSP.2020.177>

many LAC countries (including Argentina, Belize, Brazil, Chile, Colombia, Costa Rica, Dominican Republic, Ecuador, Honduras, Mexico, Panama and Peru).

- A regional bilingual COVID-19 vaccine research ethics workshop, (October) which was widely attended and continues to be viewed on YouTube and incorporated in capacity-building efforts.
- A series of six bilingual COVID-19 regional research ethics dialogues featuring ethics review committees, health authorities and researchers from different LAC countries (October–December), attended by over 1,000 participants.

Advancing ethical standards in research

The proliferation of COVID-19 research in the LAC Region has highlighted the need for ethical standards for human subjects research and strong research ethics systems. In conjunction with the Regional Program on Bioethics, ethical standards in research were advanced in 2020 with a systemic approach using indicators and supporting countries to develop national research ethics policies that meet them.² Support was provided to countries developing and implementing national research ethics policies (including [Peru](#), Trinidad and Tobago, Guatemala, Honduras, Bolivia) or that were addressing issues raised by the pandemic (Argentina, Brazil, Costa Rica, Ecuador, Panama, Peru, etc.).

² As featured in *The Lancet Global Health*, this is a strategy other LMICs can follow:
Neil M, Saenz C. Advancing research ethics systems in Latin America and the Caribbean: a path for other LMICs? *Lancet Glob Health*. 2020 Jan 1;8(1):e23-4.

Ethical standards were advanced during the pandemic through the development of key guidance documents (listed in the table below) in close coordination with PAHO's Incident Management System (IMS). The documents are also available in Spanish and have been presented regionally and discussed with numerous health authorities and research institutions.

- [Ethics guidance on issues raised by the novel coronavirus disease \(COVID-19\) pandemic](#)
- [Guidance and strategies to streamline ethics review and oversight of COVID-19-related research](#)
- [Template and operational guidance for the ethics review and oversight of COVID-19-related research](#)
- [Key criteria for the ethical acceptability of COVID-19 human challenge studies](#)
- [Emergency use of unproven interventions outside of research. Ethics guidance for the COVID-19 pandemic](#)
- [How can research transparency be promoted?](#)
- [Guidance for ethics oversight of COVID-19 research in response to emerging evidence](#)
- [How can research transparency be promoted? Actions for national health authorities during the COVID-19 pandemic](#)

The PAHOERC Secretariat continued advancing ethical standards for the inclusion of pregnant women in research, including for COVID-19 and vaccine research³. Further support advancing specific ethical standards was provided to (1) Argentina's Ministry of Health on the regulation for biobanking research (approved in early 2021), (2) Trinidad and Tobago's North West Regional Health Authority on the ethics review of a genetic research protocol (with the involvement of NIH), (3) Panama's National Committee on Bioethics in Research on stem cell research, (4) Peru's National Institute of Health, on the distinction between surveillance and research, and (5) various teams across the LAC region working on COVID-19 research (e.g. convalescent plasma, other potentially therapeutic interventions and vaccines), including WHO's Solidarity trial.

The Secretariat continues to promote and support the implementation of ProEthos, a PAHO-developed online platform, as a tool to advance ethical standards while streamlining review processes. Activities supporting the implementation of ProEthos in 2020 included training sessions to institutions in Panama and Argentina, and numerous online consultations. Following a training

³ Following the PREVENT guidance (Krubiner CB, Faden RR, Karron RA, Little MO, Lysterly AD, Abramson JS, et al. Pregnant women & vaccines against emerging epidemic threats: ethics guidance for preparedness, research, and response. Vaccine. 2019 May 3. doi.org/10.1016/j.vaccine.2019.01.011), which was launched [in Spanish in 2020](#).)

session by the Secretariat with the health authorities of the City of Buenos Aires, they developed an adaptation of ProEthos whose use is now mandatory by all the committees under its jurisdiction. The Secretariat also supported institutions outside the LAC region, including the AFRO Regional Office, WHO-ERC and WHO's ad hoc COVID-19 Ethics Review Committee (ERC). 2020 was PAHOERC's first full year utilizing ProEthos as the sole platform for process facilitation and institutional recordkeeping, which eliminated subscription and maintenance costs for PAHOERC to conduct its work effectively.

In 2020, the PAHOERC Secretariat worked closely with WHO's Ethical Review Committees (ERCs) to advance Organization-wide rigorous and efficient review processes, avoid duplication and ensure observations provided to master protocols reviewed by WHO-ERC are addressed when reviewing corresponding specific protocols for implementation in the LAC Region. The PAHOERC Secretariat supported WHO-EURO's handling of a case of non-compliance with the Organization's ethics review requirement, as well as assisted WHO's ERCs on procedural improvements and best practices. The Secretariat supported WHO's COVID-19 ad hoc ERC on the implementation of ProEthos and devised a plan to collaborate with WHO ERCs to effectively advance research standards.

Maintaining institutional memory

2020 was PAHOERC's first full year utilizing ProEthos as the sole platform for process facilitation and institutional recordkeeping. This means that there are now no subscription or maintenance costs incurred by the Organization for the platform employed by PAHOERC to conduct its work effectively. The Secretariat conducted additional testing and worked with BIREME on adjustments to optimize the platform, which have included substantive modifications to adhere to WHO's new cybersecurity standards.

As proposed by the Office of the Director in 2019, PAHOERC worked with the communications department in 2020 to develop a strategy and materials to disseminate the work done by the Committee and stress the importance of ethics review and research ethics. In response to the pandemic, the focus of the collaboration shifted to the development of communication materials (including [infographics](#) and [social media cards](#)) on the importance of conducting ethical research

on COVID-19, which have been well-received and are being used by the Organization and health authorities including some beyond the Region of the Americas.

3. Recommendations

Upon evaluation of PAHOERC's needs and challenges, we recommend the following:

1. Continue with in-house training on research ethics and the Organization's ethics review requirement, focusing on challenges posed by the COVID-19 pandemic as appropriate.
2. Conduct an assessment, based on an analysis of the experience in 2020, of the need to adjust the emergency procedures included in the PAHOERC SOPs to improve the Committee's response to emergency scenarios.
3. Develop and implement a coordinated work plan with WHO to advance closer collaboration between the ERCs, and mutual support of research ethics training for ERC members and the Organization's personnel.
4. Disseminate PAHOERC's 2020 Annual Report throughout the Organization.

PAHOERC Members

Ana Boischio (departed 2020), Ana Luciañez, Andrea Vicari, Bernardo Nuche Berenguer, Carolina Chávez Cortes, Carla Saenz (Secretary), Fernanda Alonso (External member), Hannah Kurtis, Jonás Gonseth-García, Lúcia Helena de Oliveira, Ludovic Reveiz (Vice President), Maria Paz Ade (President), Maristela Monteiro, Pedro Ordúñez, Vilma Gawryszewski.

PAHOERC Observers

Christina Marsigli (Department of External Relations, Partnerships and Resource Mobilization), Gabriela Gergely (Ethics Office), Pamela Zúñiga (Office of the Legal Counsel), Roberto Samayoa (Department of Procurement and Supply Management).

Report compiled by: Marcie Neil and Carla Saenz, PAHOERC Secretariat.

Reviewed and approved by: Ludovic Reveiz (Vice President) and Maria Paz Ade (President).