

# Regional assessment of national research ethics systems

Regional Program on Bioethics

Unit of Science and Knowledge for Impact (SK)

Department of Evidence and Intelligence for Action in Health (EIH)



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# Indicators of national research ethics systems

## Advancing research ethics systems in Latin America and the Caribbean: a path for other LMICs?



Low-income and middle-income countries (LMICs) need to do research to achieve improvements in public health, which comes with the imperative to do research ethically. Countries in Latin America and the Caribbean have continuously strengthened their capacities to advance ethical research over the past few decades, though challenges remain in ensuring that all research is ethical. During the 56th Pan American Health Organization (PAHO) Directing Council in September, 2018, countries in Latin America and the Caribbean assessed the outcomes of the 2012 regional mandate to incorporate bioethics in health.<sup>14</sup> They agreed on the need to escalate their efforts in bioethics. Regarding research ethics, countries acknowledged progress but noted that interventions mostly focused on one specific element of research ethics systems, thus not advancing research ethics comprehensively and ensuring research is always ethical. A systemic approach for research ethics was therefore deemed a regional priority. Improving ethics preparedness for emergencies that would incorporate the lessons learned from Ebola and Zika virus outbreaks was also prioritised.<sup>15</sup>

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**Indicators for Strengthening National Research Ethics Systems**

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## Strengthening research ethics systems

OBJECTIVE	INDICATOR
<b>Adopt ethical standards for research with human participants in accordance with international guidelines.</b>	Number of countries with legislation or other legally binding instrument governing health-related research with human participants that is consistent with international ethical standards, including requirements for ethics review by an independent committee.
<b>Establish effective mechanisms for the ethics oversight of research.</b>	Number of countries with a national body tasked with the oversight of ethics review committees, including establishing mechanisms for registration, training, and compliance.
<b>Enhance ethics capacity among researchers and ethics review committees.</b>	Number of countries with policies that support research ethics training for investigators and ethics review committees.
<b>Advance transparency and integrity in research.</b>	Number of countries requiring the prospective registration of clinical trials in accordance with World Health Organization standards. Number of countries with policies on responsible conduct of research.

## Strengthening ethics preparedness for emergencies

OBJECTIVE	INDICATOR
<b>Strengthen the capacity to do research ethically during emergencies.</b>	Number of countries with established procedures to do thorough accelerated ethics review of research during emergencies.

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# Research ethics indicators

Ethical standards for research	1. Law or other legally binding instrument governing health-related research involving human participants, including the requirement of ethics review of research.
Mechanisms for ethics oversight	2. National body tasked with the oversight of research ethics committees (RECs).
Ethics capacity	3. Policies on ethics training for researchers and RECs.
Transparency	4. Requirement of clinical trial registration in accordance with WHO standards.
Integrity	5. National policy on responsible conduct of research.
Research in emergencies	6. Procedures for rapid ethics review in emergencies.

# Baseline: 2020-2021 assessment (published in 2022)

Indicator	Achieved	In progress	Not initiated
1 Legal instruments for research involving humans in accordance with international standards.	Argentina, Brazil, Chile, Colombia, Costa Rica, Cuba, Dominican Republic, Ecuador, Mexico, Panama, Peru, Uruguay	Bolivia, El Salvador, Guatemala, Haiti, Honduras, Jamaica, Nicaragua, Paraguay, Venezuela	Trinidad and Tobago
2 National body that oversees RECs	Argentina, Brazil, Chile, Costa Rica, Cuba, Ecuador, El Salvador, Mexico, Panama, Paraguay, Peru, Uruguay	Bolivia, Colombia, Dominican Republic, Guatemala, Haiti, Honduras, Venezuela	Jamaica, Nicaragua, Trinidad and Tobago
3 Policies on training for researchers and RECs	Argentina, Colombia, Costa Rica, Panama, Peru, Venezuela	Bolivia, Brazil, Chile, Cuba, Ecuador, Dominican Republic, El Salvador, Guatemala, Mexico, Uruguay	Haiti, Honduras, Jamaica, Nicaragua, Trinidad and Tobago
4 Prospective registration of clinical trials	Cuba	Argentina, Brazil, Chile, Colombia, Costa Rica, Ecuador, Guatemala, Haiti, Mexico, Panama, Peru, Uruguay	Bolivia, Dominican Republic, El Salvador, Honduras, Jamaica, Nicaragua, Paraguay, Trinidad and Tobago, Venezuela
5 Policy on responsible conduct of research	Peru	Colombia, Panama	Argentina, Bolivia, Brazil, Chile, Costa Rica, Cuba, Dominican Republic, Ecuador, El Salvador, Guatemala, Haiti, Honduras, Jamaica, Mexico, Nicaragua, Paraguay, Trinidad and Tobago, Uruguay, Venezuela
6 Procedures for emergencies	Panama	Brazil, Peru	Argentina, Bolivia, Chile, Colombia, Costa Rica, Cuba, Dominican Republic, Ecuador, El Salvador, Guatemala, Haiti, Honduras, Jamaica, Mexico, Nicaragua, Paraguay, Trinidad and Tobago, Uruguay, Venezuela



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## Research ethics systems in Latin America and the Caribbean: a systemic assessment using indicators



Bernardo Aguilera, Sarah Carracedo, Carla Saenz

To strengthen research ethics systemically, the Pan American Health Organization (PAHO) devised a strategy that includes objectives and indicators to address core components of research ethics systems. We assessed 22 countries in Latin America and the Caribbean using these indicators. Most countries have adopted legal instruments to govern research with human participants and have implemented national bodies tasked with the oversight of research ethics committees. However, performance with regard to ethics training policies and clinical trial registration was less advanced, and efforts to adopt policies on responsible conduct of research and accelerated ethics review of emergency research did not meet the PAHO objectives in most countries. We discuss the pending challenges and provide recommendations aimed at helping countries from Latin America and the Caribbean to achieve the indicators, and, more generally, to strengthen research ethics with a systemic approach.

### Background

Countries in Latin America and the Caribbean have seen substantial improvements in the last decade in their governance frameworks for the ethical oversight of research. Such progress, however, has targeted specific areas of research ethics. It is a challenge to approach research ethics as a system—ie, with a comprehensive scope that pertains to all areas of research and the coordination with all relevant stakeholders.<sup>1,2</sup> To realise this goal, member states of the Pan American Health Organization (PAHO), which is the Regional Office for the Americas of the World Health Organization (WHO), agreed to promote a systemic

for progress on tangible goals for countries, striking a balance between being too easy to reach and overly ambitious to motivate action. PAHO is committed to periodically reviewing and updating the indicators, to foster progress in the region.

We present the current situation of Latin America and the Caribbean countries based on the indicators, reflect on pending challenges, and provide recommendations to strengthen research ethics systems. 22 Latin America and the Caribbean countries were selected on the basis of population size (more than 1 million inhabitants), which in where more than 90% of research in the region is being



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# 2024 Assessment

Ecuador, Guatemala, Nicaragua and Paraguay approved or modified laws or policies that imply progress towards achieving the indicators.

Indicator	Achieved	In progress	Not initiated
1 Legal instruments for research involving humans in accordance with international standards.	Argentina, Brazil, Chile, Colombia, Costa Rica, Cuba, Dominican Republic, Ecuador, Mexico, Panama, <b><u>Paraguay</u></b> , Peru, Uruguay	Bolivia, El Salvador, Guatemala, Haiti, Honduras, Jamaica, Nicaragua, Venezuela	Trinidad and Tobago
2 National body that oversees RECs	Argentina, Brazil, Chile, Costa Rica, Cuba, Ecuador, El Salvador, Mexico, Panama, <b><u>Paraguay</u></b> , Peru, Uruguay	Bolivia, Colombia, Dominican Republic, Guatemala, Haiti, Honduras, <b><u>Nicaragua</u></b> , Venezuela	Jamaica, Trinidad and Tobago
3 Policies on training for researchers and RECs	Argentina, Colombia, Costa Rica, <b><u>Ecuador</u></b> , Panama, <b><u>Paraguay</u></b> , Peru, Venezuela	Bolivia, Brazil, Chile, Cuba, Dominican Republic, El Salvador, Guatemala, Mexico, <b><u>Nicaragua</u></b> , Uruguay	Haiti, Honduras, Jamaica, Trinidad and Tobago
4 Prospective registration of clinical trials	Cuba, <b><u>Ecuador</u></b> , <b><u>Paraguay</u></b>	Argentina, Brazil, Chile, Colombia, Costa Rica, Guatemala, Haiti, Mexico, Panama, Peru, Uruguay	Bolivia, Dominican Republic, El Salvador, Honduras, Jamaica, Nicaragua, Paraguay, Trinidad and Tobago, Venezuela
5 Policy on responsible conduct of research	<b><u>Paraguay</u></b> , Peru	Colombia, <b><u>Ecuador</u></b> , <b><u>Guatemala</u></b> , Panama	Argentina, Bolivia, Brazil, Chile, Costa Rica, Cuba, Dominican Republic, El Salvador, Haiti, Honduras, Jamaica, Mexico, Nicaragua, Trinidad and Tobago, Uruguay, Venezuela
6 Procedures for emergencies	Panama	Brazil, <b><u>Ecuador</u></b> , <b><u>Paraguay</u></b> , Peru	Argentina, Bolivia, Chile, Colombia, Costa Rica, Cuba, Dominican Republic, El Salvador, Guatemala, Haiti, Honduras, Jamaica, Mexico, Nicaragua, Trinidad and Tobago, Uruguay, Venezuela



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- **Ecuador**: An amendment to the Regulation for the Approval and Monitoring of Ethics Committees for Research involving Human Beings and Ethics Committees for Health Care ([Ministerial Agreement 0005-2022](#)) was approved. The agreement establishes that research institutions should facilitate research ethics training to REC members and researchers, and that ethics review of research should be conducted rapidly in health emergencies. In addition, the Regulation for Clinical Trials was also approved (Ministerial Agreement 00069-2024). It requires the registration of clinical trials in a registry that feeds ICTRP and includes references to the responsible conduct of research.
- **Guatemala**: Regulation for clinical trials involving humans ([Ministerial Agreement 206-2021](#)) was approved. It establishes that the falsification of information is research misconduct.



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# 2024 Assessment

- **Nicaragua**: Regulation for the National Committee for Health Research – CONIS was approved ([Ministerial Agreement 491-2020](#)). It establishes that CONIS is responsible for the accreditation of RECs and the promotion of bioethics training.
- **Paraguay**: The National Policy on Health Research Ethics ([Resolution S.G. N° 355](#)) was approved. It establishes adherence to international ethical standards, tasks relevant entities with the oversight of RECs and ethics training, addresses research integrity requires clinical trial registration, and calls for rapid review of research in emergencies.



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# Work in progress

PAHO is supporting many countries in the development of laws or policies that are undergoing approval. If approved, the regional landscape would be as described.

Indicator	Achieved	In progress	Not initiated
1 Legal instruments for research involving humans in accordance with international standards.	Argentina, <b>Bolivia</b> , Brazil, Chile, Colombia, Costa Rica, Cuba, Dominican Republic, Ecuador, <b>El Salvador</b> , <b>Guatemala</b> , Mexico, <b>Nicaragua</b> , Panama, Paraguay, Peru, <b>Trinidad and Tobago</b> , Uruguay	Haiti, Honduras, Jamaica, Venezuela	
2 National body that oversees RECs	Argentina, <b>Bolivia</b> , Brazil, Chile, Costa Rica, Cuba, Ecuador, <b>El Salvador</b> , <b>Guatemala</b> , Mexico, <b>Nicaragua</b> , Panama, Paraguay, Peru, <b>Trinidad and Tobago</b> , Uruguay	Colombia, Dominican Republic, Haiti, Honduras, Venezuela	Jamaica
3 Policies on training for researchers and RECs	Argentina, <b>Bolivia</b> , Colombia, Costa Rica, <b>Cuba</b> , Ecuador, <b>El Salvador</b> , <b>Guatemala</b> , <b>Nicaragua</b> , Panama, Paraguay, Peru, <b>Trinidad and Tobago</b> , Venezuela	Brazil, Chile, Dominican Republic, Mexico, Uruguay	Haiti, Honduras, Jamaica
4 Prospective registration of clinical trials	<b>Bolivia</b> , <b>Costa Rica</b> , Cuba, Ecuador, <b>El Salvador</b> , <b>Guatemala</b> , <b>Nicaragua</b> , Paraguay, <b>Trinidad and Tobago</b> ,	Argentina, Brazil, Chile, Colombia, Haiti, Mexico, Panama, Peru, Uruguay	Dominic Republic, Honduras, Jamaica, Venezuela
5 Policy on responsible conduct of research	<b>Bolivia</b> , <b>Costa Rica</b> , <b>Cuba</b> , <b>El Salvador</b> , <b>Guatemala</b> , <b>Nicaragua</b> , Paraguay, Peru, <b>Trinidad and Tobago</b> ,	Colombia, Ecuador, Panama	Argentina, Brazil, Chile, Dominican Republic, Haiti, Honduras, Jamaica, Mexico, Uruguay, Venezuela
6 Procedures for emergencies	Panama	<b>Bolivia</b> , Brazil, <b>Costa Rica</b> , <b>Cuba</b> , Ecuador, <b>El Salvador</b> , <b>Nicaragua</b> , Paraguay, Peru, <b>Trinidad and Tobago</b>	Argentina, Chile, Colombia, Dominican Republic, Haiti, Honduras, Jamaica, Mexico, Uruguay, Venezuela



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# Work in progress

- **Bolivia**: The Ministry of Health and Sports, through the National Program of Research and Development, drafted the *National Norm on the Ethical Governance of Research*. After public consultations and additional revisions, the proposal is in the process of being approved.
- **Costa Rica**: At the request of the Ministry of Health, a proposal to amend Law No. 9234, for the regulation of biomedical research, that would govern all health-related research involving persons (and not only biomedical research) was developed and submitted to the relevant authorities. It is currently under review by the Ministry of Health.
- **Cuba**: A regulation for the health research section of the new General Health Law has been drafted. The proposal is currently under review process led by the National Research Ethics Commission.



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# Work in progress

- **El Salvador**: A proposal of a Law on Health Research has been drafted. After several revisions, the law is in the final stages of the approval process.
- **Guatemala**: A National Health Research Ethics Policy was developed. After several revisions by the Ministry of Health and the National Committee on Health Ethics, the policy is in the process of being approved.
- **Nicaragua**: A proposal for a new Regulation of the National Committee for Health Research (CONIS) has been developed. After several revisions, the proposal is in the process of being approved.
- **Trinidad and Tobago**: A National Policy on Health Research Ethics that adopts international standards was drafted. The policy has already been approved at the ministerial level and continues in the approval process.



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# Final considerations and pending challenges

- As a result of the COVID-19 pandemic, there is a renewed focus on the importance of health research. Latin American and Caribbean countries have renewed efforts to strengthen national research ethics systems and prioritized work on research ethics.
- As national research systems become more robust and countries produce more research, it is imperative to improve the efficiency and impact of clinical trials. As part of the implementation of [resolution WHA75.8](#), the [2023 Brasilia regional workshop](#) has led to dialogue and reflection to strengthen the conduct of scientifically and ethically sound clinical trials in the Region of the Americas.

FINAL REPORT  
Regional workshop  
Strengthening clinical trials to provide high-quality evidence on health interventions, and to improve research quality and coordination



Brasilia, October 4 and 5, 2023



# Final considerations and pending challenges

- Confusion persists in the region between the ethics oversight of research (led by research ethics committees) and the regulatory oversight of clinical trials that seek the authorization of a new drug or device (led by the national regulatory authority).

Collaborative work between the relevant authorities and research ethics committees, as well as coordinated technical cooperation for regulatory and ethics topics provided by PAHO, are essential to ensure that research in the region adheres to the corresponding international regulatory and ethical standards.

[Infographic: Oversight of research](#)



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# Final considerations and pending challenges

- Despite recent progress and specific actions taken by countries to ensure ethical research during the COVID-19 pandemic, there still is a regional pending agenda to improve ethical preparedness for future emergencies which in some cases, only requires formalizing for any future emergency what was implemented for COVID-19. Part of this pending agenda is also relevant for ordinary (non-emergency) situations in order to strengthen research ethics in general.



Webpage: [Catalyzing Ethical Research in Emergencies](#)



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