



# Indicators for Strengthening National Research Ethics Systems

**PAHO**



Pan American  
Health  
Organization



World Health  
Organization  
REGIONAL OFFICE FOR THE  
Americas

In 2018, the Member States of the Pan American Health Organization (PAHO) evaluated their progress on integrating ethics in distinct areas of health, and highlighted the importance of escalating their efforts to continue strengthening bioethics in the Region of the Americas. Regarding research ethics, they deemed it essential that a systemic approach be promoted so that research is **always** conducted ethically. They also emphasized the importance of strengthening ethics preparedness for emergencies in the Region, which includes the capacity to conduct ethical research during health emergencies.



### **Why a systemic approach to research ethics is necessary**

Although advances in the Region have been notable, they have primarily focused on specific elements of research ethics systems and are insufficient to ensure research is always conducted ethically. It is necessary to adopt a systemic approach that encompass all relevant aspects and foster a commitment from all involved to ensure nothing falls through the cracks. Such a comprehensive view allows for the establishment and strengthening of national research ethics systems, which are key to promoting ethical research in the Region, and ultimately to improving the health of populations.



## How research ethics systems can be promoted

To strengthen research ethics systemically, PAHO has developed research ethics indicators that address the core components of a national research ethics system. The indicators allow to: 1) identify advances on each component; 2) evaluate progress toward strengthening systems; and 3) develop a plan of action for each country based on the indicators not yet reached.

As a starting point for developing the indicators, two strategic lines of action were identified from the general mandate of Member States:

**1**

Strengthen research ethics systems so they are capable of ensuring all research is ethical.

**2**

Strengthen ethics preparedness for emergencies.

For each strategic line of action, specific objectives were identified along with their respective indicators, which allow for an evaluation of the research ethics systems of the different countries of the Region.

# Objectives and indicators for evaluating research ethics systems

## Strengthening research ethics systems

**OBJECTIVE**

**INDICATOR**

**Adopt ethical standards for research with human participants in accordance with international guidelines.**

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.

**Establish effective mechanisms for the ethics oversight of research.**

Number of countries with a national body tasked with the oversight of ethics review committees, including establishing mechanisms for registration, training, and compliance.

**Enhance ethics capacity among researchers and ethics review committees.**

Number of countries with policies that support research ethics training for investigators and ethics review committees.

**Advance transparency and integrity in research.**

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**

**Strengthen the capacity to do research ethically during emergencies.**

Number of countries with established procedures to do thorough accelerated ethics review of research during emergencies.

These indicators imply challenges for the Region. For example, many countries have focused their efforts in research ethics on only a subset of research: clinical trials with drugs and devices. In others, progress toward the compliance with various indicators may have been made yet not formalized; as a result, achievements are fragile or subject to the goodwill of relevant actors that may themselves be temporary. In other cases, indicators may have only been achieved within countries at the level of certain institutions. Despite this, achieving compliance with the indicators is a tangible goal for any country in the Region. Thus, these indicators are also a motivation to work to strengthen national research ethics systems.



## **How the Regional Program on Bioethics works to strengthen research ethics systems**

The first step is to know a country's situation using a tool based on the indicators. This tool will allow each country to evaluate its progress with the indicators, and from there develop technical cooperation oriented toward the fulfillment of the indicators it has not yet reached.

In many cases, it is possible to achieve these through a national research ethics policy. PAHO's Regional Program on Bioethics supports countries throughout this process by 1) developing drafts of national research ethics policies in line with the needs of each country; 2) coordinating successive reviews with key actors; 3) facilitating national consultations; and 4) advocating for their approval. Support also includes advocating for the establishment of governance structures for such policies to be implemented and put into practice.

# Country assessment tool for indicators for research ethics systems

Country:

## Strengthening research ethics systems

<p><b>Ethical standards for research with human subjects.</b></p>	<p>Existence of legally binding instruments for health-related research with human subjects in alignment with international guidelines.</p>	
<p><b>Effective mechanisms for the ethics oversight of research.</b></p>	<p>Existence of a national body responsible for the oversight of research ethics committees.</p>	
<p><b>Research ethics capacity among investigators and ethics review committees.</b></p>	<p>Existence of policies that support research ethics training for investigators and ethics review committees.</p>	
<p><b>Research transparency and integrity.</b></p>	<p>Existence of the requirement of the prospective registration of clinical trials in accordance with WHO standards.</p>	
	<p>Existence of policies on the responsible conduct of research.</p>	

## Strengthening ethics preparedness for emergencies

<p><b>Capacity to do research ethically during emergencies.</b></p>	<p>Existence of established procedures to do thorough accelerated ethics review of research during emergencies.</p>	
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This indicator-based strategy could be useful beyond the Region and be a model for other countries and regions to strengthen their national research ethics systems and catalyze research ethics.

### Further information

Consultations can be directed to the  
**Regional Program on Bioethics**

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For more information about the  
**Regional Program on Bioethics**

[www.paho.org/en/bioethics](http://www.paho.org/en/bioethics)



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## Additional Resources

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