



# Pan American Health Organization Ethics Review Committee

## 2024 Annual Report

Abridged version, June 2025

**PAHO**



Pan American  
Health  
Organization



World Health  
Organization  
Americas

## I. Overview

In 2024, PAHOERC continued to meet the demand for timely reviews of research proposals with human participants that receive funding or technical support from the Organization. PAHOERC received 68 submissions in 2024, many of which constitute studies conducted at the regional or subregional level. The Committee operated under its emergency procedures to conduct a rapid review of two Oropouche virus (OROV) disease protocols.

The increasing impact of science on health continues to lead to greater interest in research across the Organization, which often leads to submissions by teams with little or no expertise in research. Therefore, PAHOERC had to provide extensive support to teams throughout 2024 to produce research proposals with sufficient social and scientific value to be considered ethical. The Secretariat of PAHOERC has skilled and stable support to fulfill its corporate function efficiently, which further reflects PAHO's commitment to advancing ethical research within the Organization and across the Region.

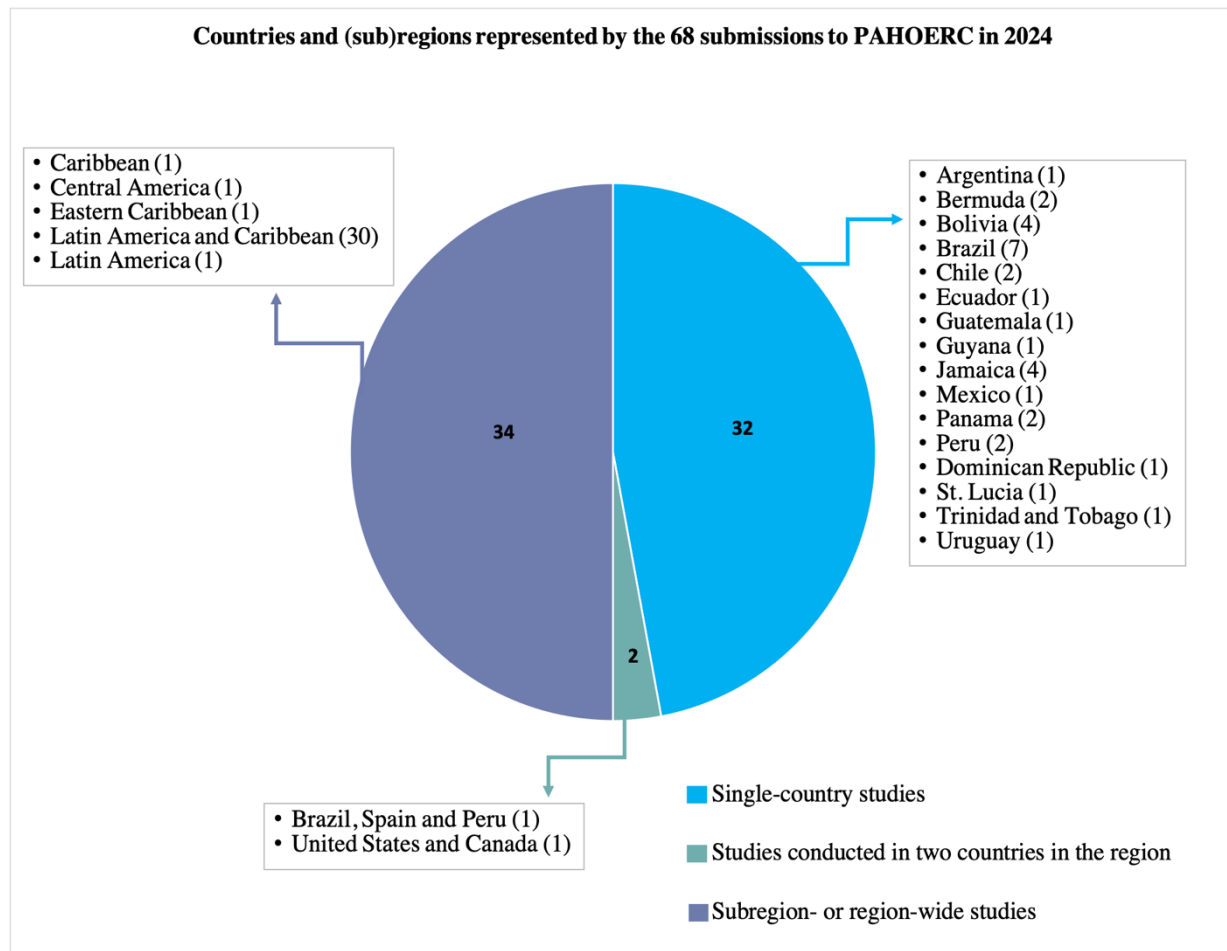
## II. Summary of activities

### A. Ensuring that research with human participants conducted with PAHO's involvement meets ethical standards

PAHOERC's activities in 2024 can be summarized by the following numbers:

- **68** submissions (in English, Spanish, Portuguese, and French), representing research proposed for **24** countries or territories.
- **54** submissions screened through a three-member process to determine whether they were research with human participants, thus requiring full PAHOERC review.
- **46** proposals granted an exemption from full PAHOERC review, in accordance with the criteria established by [PAHOERC's SOPs](#).
- **19** proposals determined to be research with human participants, thus requiring full review by the Committee or further action by the Secretariat.
- **21** reviews during **8** meetings: **6** ordinary meetings and **2** emergency meetings.

- 3 proposals still undergoing the review process.
- 11 proposals approved for implementation in the Region (including two proposals whose review had been initiated in 2023).



In 2024, PAHOERC members reviewed two standardized protocols on OROV infection that were developed by the Organization in response to the PAHO-declared OROV emergency. In accordance with the emergency procedures established by [PAHOERC's SOPs](#), PAHOERC Members were convened immediately upon submission of the first OROV protocol, and the Secretariat shared the Committee's observations with the principal investigator without delay. Subsequent additional meetings were held with PAHOERC Members and the OROV research team to clarify PAHOERC's concerns and discuss possible ways of addressing them promptly.

Similar additional meetings involving research teams and PAHOERC Members and Secretariat were held

for at least three other studies. These meetings supplement the numerous exchanges between research teams and the Secretariat, and are key to elucidating research ethics standards, explain PAHOERC's concerns to research teams, and thus expedite review processes. They foster a collaborative approach to research ethics and are particularly useful for studies that have received multiple substantive observations from PAHOERC or are led by teams with limited research experience.

As in prior years, many submissions to PAHOERC in 2024 could be described as “premature” – lacking adequate methodology or other essential information for members to effectively conduct their review. They are often submitted by teams with limited experience conducting research. These submissions are time-consuming for the Secretariat, because they need to undergo numerous revisions to be ready for an assessment at a PAHOERC meeting. In 2024, three submissions needed substantive revisions and resubmission of the entire proposal. In addition, several proposals were abandoned by teams after receiving PAHOERC review and observations. Research teams have explained that the PAHOERC review allowed them to understand the work that was needed to conduct the research rigorously and that this work exceeded what they had initially anticipated.

PAHOERC also observed that the tendency of recent years to outsource the development of research protocols does not guarantee that these protocols have basic scientific rigor. It is still necessary for PAHO personnel to supervise the professionals or the companies that are hired for this purpose to assess the quality of the products they deliver, e.g., that protocols fulfill the minimum requirements to be submitted to PAHOERC. Therefore, strengthening research capacities within the Organization is imperative. It is also strategic, considering the increasing impact of health research –an essential public health function that countries in the Region prioritize since the pandemic— and the increasing availability of technologies that facilitate the conduct of high-impact research (e.g., data mining). Moreover, PAHOERC reviews only a subset of research, namely research with human participants, and stronger research capacities are necessary for the Organization to ensure that studies that do not involve human participants are also conducted rigorously.

In 2024, the number of studies conducted at subregional or regional levels almost tripled compared to the previous year. This increase reflects global trends for the conduct of health research. Larger studies allow maximizing the impact of research efforts and fostering regional collaboration, but their review often entails additional complexities.

PAHOERC's timely and efficient management of the review processes and its responsiveness to emergencies and the Organization's needs depend on the support of the Secretariat, which is tasked with screening proposals to determine their readiness for the Committee's review, reviewing revised protocols and responses to observations, and meeting with research teams to explain review processes and discuss the Committee's observations. The Secretariat is adequately supported. Two new Members joined the committee in 2024 to replace two departing members. The Committee also increased its number of external Members, consistently with international trends for enhanced transparency of ethics review processes, and promoted another member to the Vice President role, after the Vice President stepped down following his promotion to Unit Chief, as required by the SOPs. As in previous years, the remarkable commitment of PAHOERC members and observers to ensuring all research in which the Organization is involved is ethical was observed in 2024.

#### B. 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. In 2024, regional capacity building efforts focused on topics related to clinical trials were prioritized, in line with the implementation of the recommendations in PAHO's [Catalyzing Ethical Research in Emergencies. Ethics Guidance, Lessons Learned from the COVID-19 Pandemic, and Pending Agenda](#) and the [regional workshop](#) focused on World Health Assembly's resolution [WHA75.8](#) to strengthen clinical trials. Seven [regional bilingual webinars](#) were organized in coordination with the Unit of Quality and Regulation of Medicines and Health Technologies of the Department of Innovation, Medicine and Health Technologies (IMT/QR) on the following topics: [committees for the care and use of animals in laboratory research](#) (June), [Data Monitoring Committees](#) (July), [the U.S. policy of single research ethics committee review](#) (August), [adaptive trials](#) (September), [clinical trial registration](#) (October), [research integrity](#) (November), and [research contracts and insurance policies for clinical trials](#) (December). These webinars had more than 1,650 attendees and the recordings had almost 3,600 views by the end of 2024 –a number that is expected to increase because the videos are being used as part of ethics training throughout the region.

At country level, capacity building efforts co-organized with national health authorities were prioritized. Monthly training sessions open to all research ethics committees in the country were delivered to Bolivia, Costa Rica, and Paraguay. Similar in-person one-day research ethics workshops were delivered in

Nicaragua (June) and Paraguay (October). Additional virtual research ethics training was delivered at the request of health authorities from Cuba, Mexico, and Nicaragua, and Peru.

Research ethics capacity building efforts within the Organization included responding to consultations by internal and external teams for proposals in various stages of development. Moreover, meetings held between PAHOERC and research teams to discuss observations raised by the Committee were often de facto training sessions. In March 2024, PAHOERC was featured in PAHO's Intranet. In an interview entitled [How does PAHOERC address an increased interest in conducting research?](#), PAHOERC President and Vice President discussed the importance of ethics review and the challenges that result from the increase in studies that the Region has seen since the COVID-19 pandemic.

Lastly, public health ethics capacity building activities contributed to clarifying which proposals must be submitted for review by a research ethics committee. These activities included a [regional bilingual webinar](#) on the ethics guidelines for surveillance held in September with the involvement of different Departments, and the development of a [public health ethics course](#) that is available in the Virtual Campus (Puerto Rico node). This is the only online public health ethics course available in Spanish. Over 14,000 people have enrolled since its launch in April and its regional presentation at a [webinar](#) in May.

### C. Advancing ethical standards in research

In conjunction with the Regional Program on Bioethics, ethical standards in research were advanced in 2024 by providing direct support to countries strengthening their research ethics systems. Bolivia, Costa Rica, Cuba, Ecuador, El Salvador, Guatemala, Guyana, Jamaica, Nicaragua, Paraguay, and Peru were supported on the development or revision of laws, regulations, and national policies aimed at ensuring research adheres to international ethical standards, which include establishing or strengthening of national bodies tasked with the oversight of research ethics committees. A regional assessment of national research ethics systems, inclusive of work in progress, is available from PAHO's [Portal of clinical trials of the Americas](#), which was launched by EIH/SK in December 2024.

Ethical standards in research were also advanced in 2024 through the publication in PAHO's [Tool for the accreditation of research ethics committees](#) in the Organization's four languages. Launched in a [regional bilingual webinar](#), the tool aims at ensuring that health authorities accredit committees in accordance with international standards and in a way that is responsive to the type of research they review, which further

advances efficiency in research ethics systems. Moreover, the tool incorporates recommendations of the [Catalyzing Ethical Research in Emergencies](#) guidance to improve ethics preparedness for future emergencies.

International ethical standards for research with human participants and international regulatory standards for clinical trials that seek the authorization of new drugs and devices were also advanced as part of the implementation of resolution [WHA75.8](#) on clinical trials and the specific recommendations of the [regional workshop](#) on the resolution. Accordingly, initiatives aimed at advancing efficiency in the conduct of clinical trials and clarifying the distinction between ethical oversight and regulatory oversight of research were prioritized in 2024. Close collaboration with IMT/QR has been key to support countries on these matters, develop [tools](#) to promote clarity about research oversight, and discuss pervasive confusions with key stakeholders, e.g. as part of a [panel on clinical trials](#) at the XI Conference of the Pan American Network on Drug Regulatory Harmonization (CPANDRH).

The revision of the Declaration of Helsinki of the World Medical Association (WMA) on ethical principles for medical research involving human participants provided a valuable opportunity to advance evolving ethical standards. Contribution to the 2024 revision included proposing revisions of prior drafts, engaging the Region to provide comments to public consultations led by WMA (which entailed collecting and translating comments), disseminating the Declaration, and revising the Spanish translation of the Declaration. An [article](#) analyzing its relevance for the Region of the Americas was published in JAMA by the Regional Program on Bioethics.

Ethical standards for research were also advanced with a focus on specific topics, such as the ethical inclusion of groups that have been historically excluded from research and thus unfairly deprived of the knowledge that research yields. In addition to PAHOERC's deliberate efforts to address categorical exclusions from research when reviewing each protocol, countries were supported to advance the ethical inclusion of pregnant persons. Other specific topics on which countries were supported to adhere to international ethical standards include cellular and genetic therapies, and clinical trial registration, for which an [infographic](#) was developed to clarify recurring confusions. Lastly, an [ethical framework for collaborative health research](#) was developed in response to prominent regional challenges identified during the pandemic and discussed in the [Catalyzing Ethical Research in Emergencies](#) guidance.



#### D. Maintaining PAHOERC's institutional memory

PAHOERC continues to use ProEthos as the sole platform for recordkeeping, and efficient management of ethics review processes and monitoring of ongoing research. In 2024, the Secretariat received additional feedback from countries and worked with BIREME to optimize ProEthos, e.g., to ensure the platform continues to meet evolving needs, and to improve the user experience.

The [searchable research repository](#) that PAHOERC launched in 2023 to increase transparency within the Organization, in line with the PAHO Forward initiative, was continuously updated in 2024. PAHO personnel have access to information about the more than 1,000 proposals that PAHOERC has reviewed since 2009. The repository helps technical teams build on prior research initiatives and avoid repetitive studies.

PAHOERC's 2023 annual report was disseminated in the Organization upon approval from the Director, and an abridged version was developed and disseminated to a broader audience.

### **III. Recommendations**

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

1. Continue with in-house training on research ethics, primarily to clarify the ethical standards for research with human participants (e.g., as opposed to surveillance, for which a public health ethics framework applies) and the measures that can facilitate future research with human participants in adherence with ethical standards.
2. Promote an organization-wide discussion on strategies to strengthen personnel's capacities in research.
3. Based on WHO's Code of Conduct for Responsible Research and WHO's Policy on Misconduct in Research, develop appropriate documents to be adopted by PAHO and incorporated in the E-manual with the aim of improving adherence to ethical standards in research among PAHO personnel.
4. Continue supporting the implementation of ProEthos and its continued improvement, with the collaboration of BIREME.
5. Disseminate PAHOERC's 2024 Annual Report throughout the Organization and develop an abridged version for dissemination outside the Organization.



## **PAHOERC Members (2024)**

Aleida Domingo Gisbert  
Bernardo Nuche Berenguer  
Carolina Chávez Cortes (External)  
Carla Saenz (Secretary)  
Hannah Kurtis <sup>(1)</sup>  
Hernán Rodríguez González  
Jonás Gonseth-García <sup>(2)</sup>  
Lionel Gresh (Vice President) <sup>(3)</sup>  
Ludovic Reveiz (Vice President) <sup>(4)</sup>  
Margherita E. Ghiselli <sup>(5)</sup>  
María Paz Ade (President)  
Maristela G. Monteiro (External)  
Mauricio Beltrán Durán <sup>(6)</sup>  
Omar Sued  
Pedro Ordúñez  
Regina Campa Sole  
Sergio Surugi de Siqueira (External)

1. until September 2024
2. until May 2024
3. Vice President since October 2024
4. until October 2024
5. started in August 2024
6. started in May 2024

## **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

### Annex: Proposals submitted to PAHOERC in 2024

PAHOERC ID	Title	Countries	Department
811.01	Vaccine effectiveness evaluation of maternal RSV PreF vaccine using the SARI surveillance, Argentina 2024	Argentina	CIM
810.01	Management of pain during abortion service provision in Latin America: An analysis of sentinel sites in nineteen countries, 2015-2024	Latin America and the Caribbean	HSS
809.01	Understanding the barriers and facilitators for developing and implementing evidence-based practice guidelines during a pandemic: A protocol of an exploratory sequential mixed-methods study	United States and Canada	EIH
807.01	Estudo comparado sobre o papel dos profissionais da Atenção Primária à Saúde no Brasil, Espanha e Peru à prevenção da Desinformação em Saúde.	Brazil, Spain and Peru	IMT
806.01	Formative Assessment of the HEARTS initiative in Guyana	Guyana	NMH
805.01	Determining the prevalence of elevated blood alcohol levels amongst motorists stopped by the police for speeding infraction	Jamaica	NMH
803.01	3ra ENFRENT	Uruguay	NMH
801.01	Experiencia regional en gestión de la calidad a través del uso de la Metodología VCem	Latin America and the Caribbean	CDE
800.01	Mapeo comunitario para la Eliminación del VIH, ITS, hepatitis virales y Tuberculosis	Latin America and the Caribbean	CDE
799.01	Estudio de seguimiento de la transición hacia el uso de Dolutegravir pediátrico en la población menor de 6 años viviendo con VIH en Centroamérica	Central America	CDE
798.01	Enhancing mental health services in Barbados and the Eastern Caribbean Countries	Eastern Caribbean	NMH
797.02	Estudio de línea de base para determinar el acceso efectivo a los servicios de salud y el nivel de percepción de xenofobia, estigma y discriminación en la población migrante y refugiada en el Perú	Peru	HSS
796.01	Pesquisa Nacional sobre Custo do Paciente com Tuberculose para avaliar os custos catastróficos pelos domicílios afetados pela TB no Brasil, 2024 - 2026	Brazil	CDE

795.01	A Trial of Same-Day Testing and Treatment to Improve Outcomes among Symptomatic Patients Newly Diagnosed with HIV	Latin America and the Caribbean	CDE
793.01	Caracterización de la salud neonatal en América Latina en países seleccionados	Latin America and the Caribbean	HSS
792.01	CanGIVE (452033) - Output 1: Adult Vaccination Policy in Jamaica - Concept Note. Interviews to key informants.	Jamaica	NMH
791.01	Characterizing the timing and attendance of antenatal care visits to inform the delivery of new maternal vaccines in low- and middle-income countries	Latin America and the Caribbean	HSS
790.01	Factores asociados al diagnóstico y la vinculación tardía con la presencia de enfermedad avanzada y mortalidad asociada a VIH en Panamá. Enero 2021 a marzo 2022	Panama	CDE
788.01	Eventos adversos neonatales posteriores a la inmunización con la vacuna bivalente contra el virus respiratorio sincitial (VRS) en mujeres embarazadas en la Red CLAP. Análisis caso-control anidado en una cohorte	Latin America and the Caribbean	HSS
785.01	Encuesta Mundial de Salud a escolares (GSHS) y Encuesta Mundial sobre Tabaco en Jóvenes (GYTS) Guatemala 2024	Guatemala	NMH
784.01	Medición del nivel de estigma y discriminación, percibido por la población haitiana que recibe atención VIH en los servicios de atención en las provincias priorizadas en República Dominicana, 2024	Dominican Republic	CDE
783.01	Priorización de temas para una agenda de investigación para América Latina y el Caribe sobre enfermedad por VIH avanzada	Latin America and the Caribbean	CDE
782.01	Ecossistema de evidências para saúde do Brasil: adaptação transcultural e validação de ferramentas de diagnóstico situacional para mapeamento do uso de evidências no Brasil – Ecoevi	Brazil	CDE
781.01	Mapeio dos trabalhadores técnicos da APS na América Latina	Brazil	HSS
780.01	GSHS survey - Ecuador	Ecuador	DHE
778.02	Protocol for a follow-up national schistosomiasis prevalence survey in school age children in St. Lucia	St. Lucia	CDE
777.01	Determining the prevalence of speeding in Jamaica and its association with other risk factors, including drink driving	Jamaica	NMH

776.01	Modelo de encuestas para identificar necesidades de capacitación	Latin America and the Caribbean	HSS
775.03	Protocolo estandarizado: Estudio longitudinal prospectivo en una cohorte de mujeres y recién nacidos expuestos al OROV durante el embarazo	Latin America and the Caribbean	PHE
774.02	Impulsores sociales y comportamentales (BeSD) sobre las vacunas contra influenza, COVID-19 y virus sincial respiratorio (VSR) en personas embarazadas en Argentina	Latin America and the Caribbean	CIM
773.03	Protocolo estandarizado: Estudio longitudinal prospectivo de cohorte de recién nacidos de madres con y sin infección por el virus de Oropouche para evaluar el riesgo de resultados adversos del embarazo	Latin America and the Caribbean	PHE
772.01	Protocol for Development of a Policy Framework on PHC and Resilience in Latin America and the Caribbean (PHC) for the Lancet Americas Commission on PHC Resilience	Latin America and the Caribbean	HSS
766.01	Oportunidades para integrar el currículum de la OMS sobre la violencia contra mujeres y niñas en la formación universitaria previa al servicio del personal de salud en América Latina	Latin America and the Caribbean	NMH
765.01	Avaliação da eficácia da utilização de produtos químicos (pesticidas) no controle de escorpiões no meio urbano	Brazil	CDE
764.01	Encuestas de resistencia del VIH, métodos basados en laboratorio y centinela	Latin America and the Caribbean	CDE
763.01	Protocolo Genérico para la Encuesta transversal de resistencia adquirida del VIH a los ARVs en niños, adolescentes y adultos recibiendo tratamiento antirretroviral con el método nacionalmente representativo basado en clínicas TAR	Latin America and the Caribbean	CDE
762.01	CCASAnet Study	Latin America and the Caribbean	CDE
761.01	Evaluación Chaco Bolivia	Bolivia	CIM
760.01	YouthSpeak360	Latin America and the Caribbean	NMH
759.01	Regional Campaign: Time To Act on Dementia	Latin America and the Caribbean	NMH & HSS
758.01	Implementação de um novo teste rápido sorológico para vigilância de peste em cães nos estados focais do Brasil	Brazil	CDE

757.01	Integración del currículum de la OMS sobre la violencia contra mujeres y niñas (VCMN) en la formación universitaria previa al servicio de los profesionales de salud en América Latina: Un estudio de factibilidad	Latin America and the Caribbean	NMH
753.03	Technical briefs on Long Term Care	Latin America and the Caribbean	HSS
750.01	Evaluación Programática de Línea de Base y Situación de Salud de la Iniciativa Chaco Bolivia	Bolivia	CIM
749.01	2024 STEPS survey, Bermuda	Bermuda	NMH
746.01	Encuesta Mundial Sobre Tabaco en Jóvenes GYTS - Chile	Chile	NMH
745.01	HEARTS in Bermuda: A year of transformation on the path to Universal Health Coverage	Bermuda	NMH
742.01	Situation of Family Medicine and Family & Community Medicine Professionals in the Region of the Americas	Latin America and the Caribbean	HSS
741.01	Priorización de guías de práctica clínica en la región de las Américas	Latin America and the Caribbean	EIH
740.01	Plan de Implementación del software DHIS2 en la Vigilancia de ESAVI/EVADIE en Honduras	Latin America and the Caribbean	CIM
739.02	Applying the Human Security Approach to Advance an Integrated Response to Health and Migration in the Northern Triangle of Central America and Mexico	Latin America and the Caribbean	HSS
738.01	Evaluation of the integration of gender equality in PAHO's technical cooperation in health in the Americas (EGEH) 2005-2023	Latin America and the Caribbean	PBE
736.01	Exploración de la ocurrencia de oportunidades perdidas de vacunación simultánea y análisis de la magnitud de las discordancias entre el lugar de ocurrencia de vacunación versus residencia de la población	Chile	CIM
735.01	WHO STEPwise Survey Trinidad and Tobago 2024	Trinidad and Tobago	NMH
734.05	Estudio para comparar oxfendazol versus triclabendazol para tratar fascioliasis crónica	Peru	CDE
733.01	Nursing and midwifery scoping initiative on primary health care, education, and advanced practice in the Caribbean region	Latin America and the Caribbean	HSS

732.01	Diagnóstico integral del funcionamiento de 44 redes de salud priorizadas a nivel nacional con énfasis en el servicio de vacunación y elaboración de planes de fortalecimiento del PAI en estas redes	Bolivia	CIM
731.02	Implementación de un sistema de tamizaje y clasificación del riesgo en la salud mental de jóvenes mexicanos, a través de herramientas digitales	Mexico	FPL
728.01	Aplicación de la herramienta de monitoreo del programa ampliado de inmunización nacional	Latin America and the Caribbean	CIM
727.01	Unlocking access: Bridging access for Non-Communicable Diseases' medicines through lessons from Communicable Diseases.	Brazil	RRF
726.01	Gender and intersectionality situational analysis - Jamaica - Sponsored by the Government of Canada & PAHO/WHO Project: "Improving Equitable Access and Vaccination Coverage against COVID-19, 2023-2024"	Jamaica	DHE
725.02	Estudio de identificación de las principales causas de no vacunación y oportunidades perdidas de vacunación en menores de 5 años, enfatizando en niños 0 dosis, en 44 redes de salud	Bolivia	CIM
724.01	Progress report on the implementation of Resolution CD52.R6 - Addressing the Causes of Disparities in Health Services Access and Utilization for Lesbian, Gay, Bisexual and Trans (LGBT) Persons	Latin America and the Caribbean	DHE
722.01	Self-analysis survey regarding faculty development/assessment	Latin America and the Caribbean	HSS
721.02	ProtecTB - Proteção Social para adesão ao tratamento de pessoas com Tuberculose	Brazil	CDE
713.02	Health workers and vaccination: effect of the pandemic in the Caribbean 2024	Caribbean	CIM & HSS
707.03	Interrupção do tratamento da tuberculose como analisador para a intervenção na rede de atenção à saúde do estado do Rio de Janeiro: uma estratégia de inovação tecnológica no cuidado de si e do outro	Brazil	CDE
690.01	Estudio nacional de costos catastróficos que experimentan las personas con tuberculosis en Chile	Chile	CDE