



Pan American Health Organization Ethics Review Committee 2023 Annual Report

Abridged version, March 2024

PAHO



Pan American
Health
Organization



World Health
Organization
REGIONAL OFFICE FOR THE
Americas

I. Overview

In 2023, 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 82 submissions in 2023, representing projects for 23 countries and territories. Proposals aiming to analyze the ongoing effects of the COVID-19 pandemic and using easily accessible digital tools (e.g., online surveys and digital interviews) remain popular despite the end of WHO-declared emergencies (COVID-19 and mpox).

In 2023, PAHOERC revised its [standard operating procedures \(SOPs\)](#) to incorporate lessons learned from the COVID-19 experience and recent research ethics guidance. In line with the PAHO Forward initiative to increase transparency within the Organization, PAHOERC published a searchable research repository for PAHO personnel containing information about the more than 900 proposals PAHOERC has reviewed since 2009.

PAHOERC continues to be challenged by proposals submitted by teams with little or no experience conducting research. PAHOERC provided extensive support to teams throughout 2023 to produce research proposals with sufficient social and scientific value to be considered ethical. Strengthening research capacities across the Organization and throughout the Region remains a high priority.

Since April 2023, PAHOERC has been housed in the Unit of Science and Knowledge for Impact of the Department of Evidence and Intelligence for Action in Health (EIH/SK).

II. Summary of activities

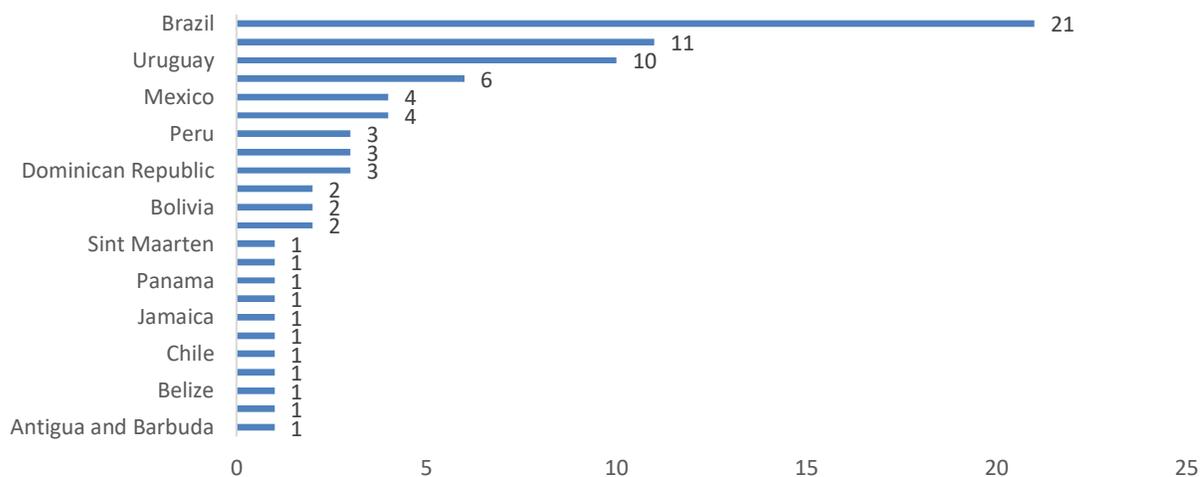
A. Ensuring research with human participants conducted with PAHO's involvement meets ethical standards

PAHOERC's activities in 2023 can be summarized by the following numbers:

- **82** submissions (in English, Spanish, Portuguese, and French), representing research proposed for **23** countries or territories.
- **67** submissions screened through a three-member process to determine whether they were research with human participants that require full PAHOERC review.

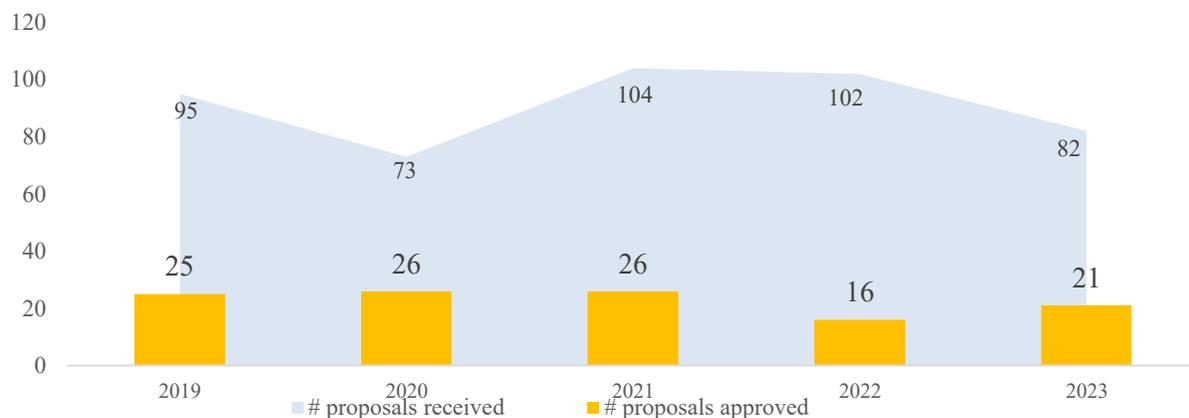
- **36** proposals granted an exemption from full PAHOERC review, in accordance with the criteria established by PAHOERC’s [SOPs](#).
- **31** proposals determined to be research with human participants, thus requiring full review by the Committee or further action by the Secretariat.
- **19** proposals reviewed during **8** meetings (one proposal was reviewed 3 times).
- **12** proposals still undergoing the review process in 2023 but have not yet been reviewed during a meeting (e.g. because they are missing requirements such as local approval).
- **21** proposals approved for implementation in the Region (includes approvals of proposals whose review had been initiated in 2022).
- **2** proposals received non-approval decisions; **2** were discontinued because the research team did not clarify whether the study had already started before the submission.
- **2** new members were added to the committee in 2023 to replace departing members.
- **2** members who left the Organization in 2023 will continue to serve PAHOERC as external members, which maintains needed expertise in the Committee.

Countries represented by the 82 submissions to PAHOERC in 2023



**Some proposals aimed to conduct research in multiple countries or across the Latin America or Caribbean Subregions (each country/subregion is accounted for in the figure).*

Number of proposals received, and number approved by PAHOERC, 2019-2023



Many submissions to PAHOERC in 2023 could be described as “premature” – lacking adequate methodology or other essential information for members to effectively conduct their review. Several needed to undergo revisions by the Secretariat to be ready for an assessment during a PAHOERC meeting; 4 needed substantive revisions and resubmission of the entire proposal, 3 were abandoned by teams after receiving PAHOERC review and observations. Ten projects were related to COVID-19, of which the most popular subtopic was “perceptions of the COVID-19 vaccine,” particularly among health care workers or specific populations. Other repeated topics were vaccination, antibiotic resistance, alternative methods of STI contact tracing, and care for tuberculosis patients.

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 and Members.

- **Secretariat** screens proposals to determine their readiness for the Committee’s review, reviews revised protocols and responses to observations, and meets with research teams to explain review processes and discuss the Committee’s observations.
- **Members** provide (written and verbal) reviews of proposals in their areas of expertise and support the Secretariat and research teams. As many proposals required additional scrutiny from PAHOERC members in 2023, members provided key support such as detailed reviews of protocol components, meeting with research teams to clarify the observations, and discussing problems and their potential solutions.

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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 2023, capacity building efforts included:

- Monthly training sessions delivered to Bolivia and Paraguay, which were co-organized with the national health authority and open to all research ethics committees in these countries.
- Additional research ethics training delivered to Costa Rica, El Salvador and Panama, at the request of the health authorities.
- Trainings focused on the implementation of ProEthos, a PAHO-developed platform for ethics review processes (Guatemala, Bolivia); in-person trainings on ProEthos were provided to Panama as its National Committee for Bioethics in Research began using ProEthos and requiring the use of ProEthos by accredited research ethics committees in the country.

Capacity building efforts aimed at implementing the recommendations in PAHO's [*Catalyzing Ethical Research in Emergencies. Ethics Guidance, Lessons Learned from the COVID-19 Pandemic, and Pending Agenda*](#) guidance (which is still the only comprehensive research ethics guidance assessing the COVID-19 experience available worldwide) included:

- In-person presentations for a Ministry of Health-organized national symposium with research ethics committees in Chile (July).
- A virtual regional bilingual session, with participants including health authorities, members of research ethics committees, ethicists and researchers, titled What actions should we take now to improve our ethics preparedness for future emergencies and strengthen research ethics? (August).

- In-person presentations organized by Panama’s National Committee of Bioethics in Research at the national conference for the advancement of science, and the annual meeting of research ethics committees (September).
- A virtual regional bilingual workshop on [Material Transfer Agreements and Data Transfer Agreements](#), with over 1,000 attendees registered throughout four sessions, including national health authorities, members of research ethics committees, ethicists, researchers and representatives of research institutions (October).

Additional research ethics training was delivered at the request of academic institutions in Ecuador and Brazil (November) with the goal of clarifying the [distinction between the ethical and regulatory tasks in the oversight of clinical trials](#), in collaboration with the Unit of Quality and Regulation of Medicines and Health Technologies within the Department of Innovation, Medicine and Health Technologies (IMT/QR).

Capacity building efforts within the Organization included:

- Responding to consultations by internal/external teams for proposals in various stages of development.
- Training PAHO personnel (in English and Spanish, April) on the PAHO ethics review requirement, with a focus on the most common protocol issues encountered by PAHOERC.
- Introductory research ethics training for personnel in English and Spanish (September).
- Compiling and disseminating resources to support researchers (quality free courses, reference books).

C. Advancing ethical standards in research

In conjunction with the Regional Program on Bioethics, ethical standards in research were advanced in 2023 by providing direct support to countries strengthening their research ethics system. Bahamas, Bolivia, Costa Rica, Guatemala, Paraguay, Peru, and Trinidad and Tobago 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. Such

support was provided jointly with IMT/QR to ensure appropriate ethical and regulatory oversight of clinical trials with drugs and devices.

Ethical standards in research were also advanced in 2023 through the publication of the [Tool for the accreditation of research ethics committees](#). The tool aims to ensure health authorities accredit committees in accordance with international ethical standards and in a way that is responsive to the type of research they review, which further advances efficiency in research ethics systems. Many health authorities immediately informed PAHO of their commitment to implement the tool following its launch and [webinar](#) in December.

The implementation of the recommendations of the [Catalyzing Ethical Research in Emergencies guidance](#), which aims at improving ethics preparedness for future emergencies and strengthening ethics in non-emergency research, was advanced in 2023 through the publication of specific recommendations for [health authorities](#) and for [research ethics committees](#), and the launch of a [website](#) focused on the guidance that includes slide decks to facilitate the presentation of its content. The guidance was presented for global audiences at the annual meeting for research ethics training programs funded by the Fogarty International Center meeting (May) and in a [publication](#) that resulted from the 13th Global Summit of National Ethics Committees.

The Organization continued implementing the [Catalyzing Ethical Research in Emergencies guidance](#) as part of the mpox response to ensure the ethical use of unproven interventions outside of research (i.e. “monitored emergency use of unregistered and experimental interventions” or MEURI framework), for which support was continuously provided to Member States and the Incident Management Support Teams (IMST). PAHOERC also published [a revised version of its SOPs](#) to incorporate lessons learned from the COVID-19 experience and address issues covered by the Catalyzing Ethical Research in Emergencies guidance, such as MEURI protocols.

Further contribution to updating international ethical standards for research was achieved through participation at the meeting to revise the World Medical Association’s Declaration of Helsinki on ethical principles for medical research involving human subjects. The meeting took place in Brazil (February) and focused on the use of placebo. Participation included presenting the regional

understanding and consensus on the use of placebo in different types of trials. A regional reflection on the ethical inclusion of persons with disabilities in mental health research was advanced as part of a partnership with the Global Forum on Bioethics in Research (GFBR), for which two webinars were hosted in July and September. In order to advance the ethical inclusion of groups that have been historically excluded from research and thus unfairly deprived of the knowledge that research yields, [communication materials to promote the responsible inclusion of pregnant women](#) were developed and disseminated. [Communication materials to advance research with children](#) and ethical research in general, that were developed during the pandemic, were adapted to a non-emergency situation.

Lastly, as part of broader efforts of EIH/SK to advance the implementation of the [World Health Assembly's resolution 75.8](#) aimed at improving the quality and coordination of clinical trials, a workshop (Brazil, October) brought together experts from the region to discuss and propose concrete actions to strengthen the conduct of scientifically and ethically sound clinical trials in the Americas. Regarding ethical standards for research, the discussion focused on strategies to avoid repetitive ethics review processes, as summarized in the [report from the workshop](#).

D. Maintaining PAHOERC's institutional memory

- PAHOERC continues to use ProEthos as the platform for process facilitation and institutional recordkeeping and to conduct its work effectively.
- PAHOERC Secretariat continued gathering feedback from countries on the ProEthos platform and working with BIREME to optimize it for all users.
- PAHOERC Secretariat published a searchable research repository on the intranet for personnel to access key information about all the proposals with human participants that PAHOERC has reviewed since 2009, in alignment with the PAHO Forward initiative to strengthen efficiency, transparency, and accountability within the Organization.
- PAHOERC continues to maintain an update list of COVID-19 submissions available at www.paho.org/pahoerc

III. Recommendations

Recommendations proposed by PAHOERC include:

1. Develop an organization-wide strategy to strengthen personnel's capacities in research.
2. Continue with in-house training on research ethics.
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.

PAHOERC Members 2023

Aleida Domingo Gisbert*
Ana Luciañez**
Bernardo Nuche Berenguer
Carolina Chávez Cortes
Carla Saenz (Secretary)
Hannah Kurtis
Hernán Rodríguez González
Jonás Gonseth-García
Lionel Gresh
Lúcia Helena de Oliveira***
Ludovic Reveiz (Vice President)

María Paz Ade (President)
Marcia Erazo Bahamondes****
Maristela G. Monteiro
Omar Sued
Pedro Ordúñez
Regina Campa Sole*****
Sergio Surugi de Siqueira (External)
* started in September 2023
** until September 2023
*** until January 2023
**** until November 2023
***** started in February 2023

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 2023

PAHOERC ID	TITLE	COUNTRIES	DEPARTMENT
721.01	ProtecTB – Proteção Social para adesão ao tratamento de pessoas com Tuberculose	Brazil	CDE
720.01	Proyecto piloto para mejorar las estimaciones demográficas en Panamá, para apoyar el programa ampliado de inmunización (PAI) y otros programas de salud en el país	Panamá	CIM
719.02	Evaluación basada en género de los sistemas regulatorios y las organizaciones productoras de vacunas de la región	Region	IMT & DHE
718.02	The Haiti cardiovascular disease cohort: study protocol for a population-based longitudinal cohort	Haiti	HSS
716.01	Anthropometric measurements in national health surveys	Brazil	CDE
715.01	Proyecto piloto para mejorar las estimaciones demográficas en Uruguay, para apoyar el programa ampliado de inmunización (PAI) y otros programas de salud en el país	Uruguay	CIM
713.01	Health workers and vaccination: effect of the pandemic in the Caribbean 2023	Caribbean	CIM & HSS
712.01	Proyecto piloto para mejorar las estimaciones demográficas en Perú, para apoyar el programa ampliado de inmunización (PAI) y otros programas de salud en el país	Peru	CIM
711.01	Republic of Suriname Antimicrobial Resistance (AMR) prevalence survey in human bloodstream bacterial and fungal infections	Suriname	CDE
710.01	Navegação ampliada para vigilância intensiva e otimizada	Brazil	CDE
709.01	Implementación del Sistema de tamizaje y clasificación del riesgo en la salud mental de jóvenes mexicanos a través de una aplicación móvil	Mexico	NMH
707.01	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

706.01	Implementación de la plataforma múltiplex para la vigilancia serológica integrada de enfermedades infecciosas en México	Mexico	CDE
705.01	ProtecTB - Proteção Social para adesão ao tratamento de pessoas com Tuberculose	Brazil	CDE
704.01	Exploring WHO Member States' Surveillance Response to the COVID-19 Pandemic	LAC Region	PHE (WHO-ERC approval)
703.01	Evaluación basada en género de las agencias de regulación y las industrias productoras de vacunas	LAC Region	IMT & DHE
702.01	Caracterização de episódios de recorrência de malária vivax e identificação de biomarcadores preditivos de recaídas da doença	Brazil	N/A unconfirmed PAHO involvement
701.01	Implementação da plataforma multiplex no Brasil para subsidiar ações de vigilância de doenças tropicais negligenciadas e outras doenças infecciosas e parasitárias	Brazil	CDE
700.01	Lecciones Aprendidas sobre el uso de la PCM en Colombia: Facilitadores y barreras del uso de macrodatos para la toma de decisiones clínicas	Colombia	EIH
699.01	National antimicrobial resistance (AMR) prevalence survey in Suriname	Suriname	CDE
697.01	Consumo de sustancias psicoactivas en conductores implicados en accidentes de tránsito en la República Dominicana	Dominican Republic	NMH
696.01	Consenso de Expertos para el perfeccionamiento y validación del marco metodológico para la síntesis de evidencia para el análisis de causalidad de eventos supuestamente atribuibles a la vacunación e inmunización (ESAVI)	Region	CIM
695.01	Mapa conceptual y cognitivo sobre percepciones y actitudes sobre los determinantes sociales y la equidad en salud	Region	DHE
694.02	Diagnóstico para determinar las barreras de acceso a los servicios de salud y percepciones sobre la vacunación en población en condiciones de vulnerabilidad en zonas fronterizas de Puno y Tacna	Peru	HSS
693.01	Estudio de impacto de la prevalencia e intensidad de infección por geohelminths en niños escolares de 5 a 14 años de Nicaragua	Nicaragua	CDE

692.01	Proyecto piloto para mejorar las estimaciones demográficas en Bolivia, para apoyar el programa ampliado de inmunización (PAI) y otros programas de salud en el país	Peru	CIM
690.01	Estudio nacional de costos catastróficos que experimentan las personas con tuberculosis en Chile	Chile	CDE
688.02	Perfil formativo e modelagem das trilhas formativas dos médicos do Projeto Mais Médicos pelo Brasil	Brazil	HSS
687.01	Seroprevalencia de <i>Treponema pallidum</i> subespecie pertenue en los focos históricos (cantones Eloy Alfaro y San Lorenzo) y el cantón aledaño (cantón Río Verde) en la provincia de Esmeraldas – Ecuador	Ecuador	CDE
685.01	Demografia e mercado de trabalho em enfermagem	Brazil	HSS
684.01	Mapeo de políticas y prácticas para abordar la salud mental durante el embarazo y puerperio en países seleccionados	Uruguay	CLAP-SMR
683.01	Evaluation of the effectiveness of labeling models aimed to identify the presence of sweeteners in packaged foods and beverages in Brazil	Brazil	NMH
682.01	Proyecto PILARES Fase II: Perfil sobre calidad de vida y actividad física en escolares	Region	NMH
681.01	Vigilancia de la seguridad de nirmatrelvir/ritonavir para el tratamiento de la infección por COVID-19 mediante el monitoreo de eventos aplicado en una cohorte	Uruguay	IMT
680.01	WHO Hospital Antimicrobial Use Point Prevalence Survey	Belize	CDE
679.02	Demografia médica no Brasil 2025	Brazil	CDE
676.01	Aplicación de Tecnologías de Secuenciación de Nueva Generación (NGS) en el Análisis de Contaminación Microbiana en Cuerpos Hídricos y en la Evaluación de Patógenos de Alta Prioridad	Ecuador	N/A (no PAHO involvement)
675.01	La normalización de elementos propios del acoso escolar por parte de los docentes y su afectación a la detección y atención oportuna de los casos en población escolar de básica secundaria en Colombia y en España	Colombia, Spain	N/A (no PAHO involvement)

673.02	Unpacking PHC reform in the Commonwealth of Dominica from post-Hurricane David (1979) to post-Hurricane Maria (2017) through political economy lenses: Lessons learned from assimilating local innovations and creative solutions.	Barbados	HSS
670.01	A behavioral insights approach to Improve nutrition-related behaviors among school-going children in Jamaica	Jamaica	NMH
667.01	Evaluation of the Implementation of RBM in PAHO	Region	NMH
666.01	Diagnóstico situacional del estado de los planes nacionales para reducir la mortalidad materna	Uruguay	CLAP
665.03	Costos catastróficos para personas afectadas por Tuberculosis en Guatemala	Dominican Republic	CDE
664.01	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
661.01	Caracterização epidemiológica, clínica e laboratorial de casos de monkeypox: um estudo de coorte retrospectivo	Brazil	EIH (WHO-ERC review)
660.01	Proyecto para la incorporación de componentes de telemedicina en la atención prenatal en sitios seleccionados de Perú	Peru	CLAP-SMR
659.01	Estudo sobre modelos de regulação em saúde no contexto nacional e internacional para apoiar a revisão das diretrizes da política nacional de regulação do SUS	Brazil	HSS
658.01	WHO Stepwise Survey – Sint Maarten	Sint Maarten	NMH
657.01	Primary Health Care and the COVID-19 Pandemic Case Studies: Uruguay (Amendment: The political economy dynamics of PHC reform)	Uruguay	HSS
656.02	Conocimientos, actitudes y prácticas de la vacunación en profesionales de salud con énfasis en vacunas contra la COVID-19 en Paraguay	Paraguay	CIM
654.01	Healthcare-associated infections case definitions for low-resource settings – a testing protocol	Region	DHE
652.01	Encuesta Mundial sobre Tabaco en Jóvenes – GYTS Panamá	Region	NMH

651.04	Parents d'enfants de 0-23 mois, leaders communautaires et prestataires de la vaccination	Haiti	CIM
650.01	Georreferenciar para vacunar: uso del registro nominal de vacunación para identificar a los no vacunados Bogotá Colombia	Colombia	CIM
649.04	Estudio de la percepción de la vacunación contra covid-19 en comunidades indígenas de cinco departamentos de Colombia 2023	Colombia	IMT
645.01	Telerehabilitation in the Americas Response to COVID-19 and Current Practice	Region	NMH
643.02	Point of Care Tests to Identify Opportunistic Infections in Advanced HIV Patients in Mexico City	Mexico	CDE
642.02	Electronic Partner Notification & Pharmacy-based Expedited Partner Therapy to Improve STI Management	Peru	CDE
641.01	Parents d'enfants de 0-23 mois	Haiti	CIM
640.01	Identificación de procesos críticos en el manejo de la resistencia a los antibióticos y su evolución en las Unidades de Cuidados Intensivos de tres Hospitales de la Red Pública Integral de Salud de Ecuador en el periodo 2019-2021	Ecuador	N/A (unconfirmed PAHO involvement)
638.01	Tele-rehabilitation in the Americas: Response to COVID-19 and Current Practice	Region	NMH
635.01	Global Adult Tobacco Survey (GATS), Mexico 2023	Mexico	NMH
634.01	2023 STEPS survey, Cayman Islands	Barbados	NMH
633.04	Exploring knowledge, attitudes, and practices related to COVID-19 vaccine decision-making among pregnant people in Brazil	Brazil	CLAP
632.02	HTLV vertical transmission: validation of the protective effect of integrase inhibitors in the transmissibility of the lacteous infectious inoculum and the importance of oral fluid as a tool for diagnostics	Brazil	CDE
631.01	ProtecTB – Proteção social para adesão ao tratamento de pessoas com Tuberculose	Brazil	CDE
630.02	Piloting a rapid service assessment tool to review and improve post-rape care for women survivors of sexual violence	Region	NMH

629.01	El Rol de las enfermeras y los enfermeros en la mejora de la salud de las/los adolescentes en situación de vulnerabilidad en Bolivia y Honduras	Bolivia, Honduras, Colombia	HSS
628.01	Pan American STEPS Survey - Antigua and Barbuda	Antigua and Barbuda	NMH
627.01	Estudio de la coinfección COVID-19 y la tos ferina en América Latina	Argentina	HSS
625.01	Diagnostico laboratorial de micosis e tuberculose em pacientes com HIV/aids	Brazil	CDE
624.01	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
623.01	Encuesta STEPS Cienfuegos, Cuba 2023	Cuba	HSS
622.01	Profesionales de enfermería y sistemas de salud en países de América Latina: posibilidades para la ampliación del ámbito de prácticas	Brazil	HSS
621.01	Monitoreo de la eficacia de las campañas anuales de quimioterapia preventiva contra la fascioliasis humana y de la eficacia del triclabendazol para el tratamiento de la fascioliasis humana en el altiplano norte de Bolivia – amendment of PAHOERC-2018-0007)	Bolivia	CDE
620.01	Global Study on Male Contraception	Uruguay	(WHO-ERC review)
618.01	Projeto Apoio e Difusão ao Manejo Integrado do vetor Aedes aegypti com foco na Técnica de Inseto Estéril-TIE	Brazil	CDE
617.01	Understanding factors affecting implementation of perinatal death reviews in Latin America and the Caribbean: an explanatory sequential mixed methods study	Uruguay	CLAP
616.02	Motivos para no vacunarse contra la COVID-19 entre las mujeres previo y durante el embarazo. Estudio Descriptivo	Uruguay	CLAP
615.01	Protocolo para estimación de los costos catastróficos del tratamiento de tuberculosis en la República Dominicana.	Dominican Republic	CDE
613.02	Evaluating the Feasibility of Using Community Health Workers (CHW) to Conduct Contact Tracing via at home STI Testing	Haiti	CDE

