

Management Response

Evaluation Title	Evaluation of the WHO Ethics Review Committee (ERC)	
Commissioning Unit	HQ/SCI/RFH	
Link to the evaluation	URL link to report, annexes, Evaluation Brief	
WHO Evaluation Workplan	WHO Organization-wide Evaluation Workplan 2024-2025	
Unit Responsible for providing the management response	HQ/SCI/RFH	
Overall Management Response: Accepted. The WHO HQ Ethics Review Committee (ERC) underwent an independent external evaluation to assess its relevance, effectiveness, and efficiency in safeguarding research ethics within the organization. The evaluation also assessed how ERC’s role has evolved over time to respond to new demands and ethical challenges shaping the context of WHO’s research work, as well as policy coherence of ethics oversight across different WHO Offices. The evaluation resulted in a number of important findings and recommendations to ensure continued relevance and adequate positioning of the ERC to support WHO research. In response, WHO management has accepted all recommendations and outlined a comprehensive action plan to enhance the ERC’s recognition, coordination, and processes. The response acknowledges the ERC’s critical function in maintaining the integrity of WHO research and commits to strengthening its role through increased resources, clearer responsibilities, and improved procedures. A key focus is on ensuring that ERC is independent, adequately funded and staffed, with a separate budget allocation and strategic planning efforts. Additionally, WHO aims to formally recognize the contributions of ERC members by introducing certificates, compensatory days, and other forms of acknowledgment. Ensuring high-quality scientific review before ethical evaluations is also a priority, with plans to establish a more systematic and consistent review process. To improve coordination, WHO is working on clarifying the roles of ERCs at the HQ and regional levels. A mapping exercise will define responsibilities and assess human resource needs. Enhancing the accessibility of ERC’s guidance documents, templates, and training materials is another crucial step in strengthening its capacity. WHO is also promoting mutual recognition processes, reducing the burden on HQ ERC and regional ERCs. Additionally, WHO will regularly benchmark its own ERC against international standards to ensure continuous improvement and alignment with best practices. Another major focus is on fostering a stronger culture of research ethics within WHO. Efforts are being made to expand training initiatives at both headquarters and regional offices, ensuring that responsible officers are well-informed about ethical review processes and risk-based decision-making. To modernize and streamline its ethical review processes, WHO is reviewing the ERC’s Rules of Procedure to align them with the latest guidance, particularly for emergency responses post-COVID-19. Efforts are underway to improve document management, including version control and archiving, and to upgrade the ERC’s management software to a more user-friendly platform. WHO is also integrating its Open Data Policy into ERC processes to enhance data transparency. As part of its long-term commitment, WHO has pledged to conduct an external evaluation of the ERC every five years, ensuring accountability and ongoing improvements in research ethics governance.		
Management Response Status	In Progress	
Date	February 2025	

Evaluation Recommendations and Action Plan

Recommendation 1: Strengthen buy-in and recognition of the role of the ERC commensurate with its critical function in safeguarding the integrity and reputation of the WHO.				
1. If conducting research ethically, including ensuring human protection in research, is a WHO priority, this function needs to be recognized and adequately resourced within WHO. WHO may consider a core administrative function and budget the ERC Secretariat separately from the divisional science business. 2. This includes ensuring adequate human resources, including administrative staff and strong support to foster a culture within WHO that promotes research ethics. 3. Provide formal recognition of the time and effort both by internal ERC members (beyond tracking in the WHO Performance Management Development System (PMDS)), and of external members. 4. Consider a formal mechanism across WHO to enable the WHO ERC to focus on its core task to review the ethical implications of a study involving human participants that ensures consistent, systematic, and high-quality scientific review prior to submission for ethical review (where this is not currently adequate).				
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Develop a strategic plan for the ERC function, informed by a coordinated mapping of linkages and critical needs across the 3 levels of the Organization.	SCI/RFH, SCI, DGO; in consultation with ROs	Q3 2025	Not initiated	WHO HQ is organizing the mapping of existing linkages and related functions across the Organization. The mapping exercise will be done in coordination with Regional/Country Offices to define critical needs at global, regional, and country level, which will inform a strategic plan to improve the coordinated efforts towards independent ethics governance throughout the Organization.
Identify financial and HR requirements as part of PB2026-2027 development and operational planning.	SCI & DGO with PRP	Q3 2025	Not initiated	<p>WHO is seeking solutions to ensure that the ERC Secretariat is adequately resourced based on identified needs.</p> <p>As a first step, the financial and HR requirements to carry out ERC as a core function will be addressed through discussions with appropriate departments (SCI, DGO, PRP) and Regional Offices, to secure essential resources amidst current constraints.</p> <p>In order to execute these reforms optimally, the ERC will require these additional resources:</p> <ul style="list-style-type: none"> - One P4 post in addition to the existing P3 - Dedicated administrative staff (i.e. G5)

Develop internal formal recognition mechanisms for valuing ERC members' dedication and efforts.	SCI/RFH, HRT	Q3 2025	Not initiated	WHO is seeking alternatives to formally recognize ERC members, such as an annual certificate from the DG, or compensatory days. As a first step, discussions with ERC members are underway to understand the type of recognition they find desirable and appropriate. As a second step, discussions will take place with HRT to inform the implementation of possible measures.
Conduct an assessment and implement a system to ensure consistent, systematic, and high-quality scientific review prior to submission for ethical review.	SCI/RFH, EPS BOS/IMT	Q1 2026	In progress	In collaboration with colleagues across the Organization, the Emerging Technologies, Research Prioritisation & Support unit (EPS) within the Research for Health Department, is currently working on a phased approach to establish the WHO scientific review process. The ERC Secretariat is providing support to this development.

Recommendation 2: Clarify roles and responsibilities for stronger internal coordination with regional ethics review committees and enhance coherence of engagement with external ethics review mechanisms.

1. Clarify roles and responsibilities with regional ethics review mechanisms, identifying when a review goes to WHO Headquarters or the Regional Offices, and prioritize reviews based on the level of risk to patient safety and WHO's integrity and reputation, e.g., where reviews are needed for multi-country work, emergency work, and other high-priority and high-risk reviews. Given the lack of capacity and resources across all levels, explore the option of centralizing ethical review for all WHO-related work at Headquarters.
2. Ensure that WHO ERC processes, procedures, guidance, templates, trainings and forms are all accessible and visible so others, including at regional, national and local levels, can increase their capacity to conduct ethical reviews.
3. Based on the ongoing WHO benchmarking of other ethics review committees, put in place a process to accredit national, university and other ethics committees to establish a mutual recognition process, which could potentially decrease the burden of reviews that need to be completed by WHO ERC or WHO Regional ERCs. Learnings from WHO's current work on regulation and prequalification could be examined to support this work. Ensure that the WHO ERC is also assessed regularly against these same benchmarks.

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Execute the strategy to strengthen policy adherence and coherence, internal consistency, and capacity related to research ethics oversight across the 3 levels of the Organization.	DGO, CRE RDs, HRS	Q3 2025	Not initiated	WHO is organizing a mapping exercise in which, among others: <ul style="list-style-type: none"> – the roles and responsibilities for ethical oversight and research conduct between HQ/DGO & RDs will be defined. – current human resources and capacity in each region will be determined. – redundancies in processes, use of resources, etc. will be identified. In the context of the exercise and given the lack of capacity and resources across all levels, different options will be explored, such as:

				<ul style="list-style-type: none"> - to centralize ethics review at HQ, which would require working closely with a dedicated focal point per region and the use of existing resources at the different levels. - to implement a communication network of all WHO ERCs across the Organization, within the current set up of ethics review across levels. - To prioritise research activities in alignment with organizational mandates to ensure a focus on high-quality/impact initiatives. <p>Based on the mapping exercise, a strategic plan will be developed and finalized to:</p> <ul style="list-style-type: none"> - ensure policy coherence and accountability across all three levels. - identify additional human resources and capacity as needed. - ensure adherence to the strategy: identify several check points throughout the research initiation and implementation process to ensure adherence and compliance to ERC policies and procedures. For example, as part of the internal framework for all departments conducting research, the following actions will be implemented: <ul style="list-style-type: none"> o To showcase leadership by example (e.g., when leaders and managers set standards for junior staff within the organization). o Integrate adherence to ethical processes as a criterion in performance evaluations. o Explore ways to incorporate indicators into the ADG compacts and other senior level TORs, to ensure that all relevant research is subject to ERC oversight. o Investigate methods to include compliance with ERC decisions as part of the corporate internal control framework managed by CRE. o Include the failure to undergo WHO ethics review as a major corporate risk in the corporate risk register.
Improve accessibility of WHO ERC processes, procedures, guidance, templates, trainings and forms on the WHO website.	ERC Secretariat	Q3 2025	In progress	The Secretariat is working on enhancing the SharePoint site to offer Technical Units and ERC members the necessary information and documentation.
WHO ERC will support the dissemination of the benchmarking tool to build capacity and facilitate collaboration including with Regional Offices.	-ERC Secretariat -Regional Offices -AVAREF etc. Peer group with ROS	Q1 2026	In progress	<p>WHO is promoting the WHO Benchmarking Tool at Country and Regional level through workshops supported by Ministries of Health, Collaborating Centers, and other stakeholders. In such context, countries are evaluating their National and/or Institutional Ethics Committees. WHO is also working with partners (e.g. AVAREF, EDCTP, FERCAP etc.) to promote the tool during meetings in which health authorities and representatives of ethics committees are present.</p> <p>WHO is looking for partner with institutions to help on the translation of the Benchmarking Tool into the 6 UN languages.</p> <p>The ERC and its Secretariat will be regularly benchmarked against the WHO tool, for example through mutual evaluation between ERCs at different offices.</p>

Operational/Process Recommendations

Recommendation 3: Continue to build relationships with Responsible Officers through increased communication, awareness-raising and training, and enhance WHO's culture of research ethics.				
<ol style="list-style-type: none"> 1. Focus on increasing capacity development and training at headquarters and regional level to enhance responsible officers' awareness of the process (including requirements, forms and timelines) and of the risk-based approach and decisions. 2. Continue the ERC Secretariat's drop-in sessions which are helping to increase understanding and awareness and monitor the utility and effectiveness of training 3. Consider establishing a working group of responsible officers that meets regularly to discuss challenges and solutions for the ethical review process. 				
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Increase capacity training efforts at HQ and Regional Offices.	-ERC Secretariat -HRT -Regional Offices	Q4 2025	In progress	The Secretariat has produced a course on Research Ethics directed to staff and ERC members. The course is available through WHO Open and currently mandatory for ERC members. WHO is working to establish a WHO-wide policy for mandatory research ethics trainings for responsible officers engaged in WHO research projects (as evidenced by certificate of completion). This is an ongoing activity.
The Secretariat will explore ways of assessing uptake and effectiveness of trainings.	-ERC Secretariat -Open WHO	Q1 2026	Not initiated	The Secretariat will request statistics on the number of staff taking the training course and the scores obtained.
Information will continue to be provided through SharePoint, weekly drop-in sessions, trainings, visiting departments.	-ERC Secretariat	Q3 2025	In progress	The ERC Secretariat provides information through different channels. This work will continue, particularly in areas that require further development as per the information collected through drop-in sessions, meetings with departments, and other opportunities for engagement. This is an ongoing activity.
Technical Units will be regularly invited to provide feedback regarding facilitators and barriers (e.g. Secretariat retreats etc.).	-ERC Secretariat	Q4 2025	In progress	During the annual ERC Secretariat retreats, special sessions for Responsible Officers (RO)/technical units are offered. This will continue and ad-hoc meetings will be scheduled when needed. This is an ongoing activity.

Recommendation 4: Increase the capacity of ERC members for greater effectiveness and efficiency.
<ol style="list-style-type: none"> 1. Ensure that all WHO ERC members have in-depth experience or training in ethics and publish their biographies on the website to increase transparency. Staff/consultant biographies could also be provided to ERC members, so they are aware of individuals' backgrounds, skills and expertise. 2. Consider increasing the number of ERC members, to distribute the workload more evenly. This could be done by requesting technical departments that submit protocols to have volunteers sit on the ERC, which could also help to increase awareness of the research ethics process. The Secretariat

<p>could ensure alignment of ERC members' expertise with protocols being reviewed. Participating in the development of guidance would also help members keep abreast of new trends.</p> <p>3. Consider systematically adding a lay person and/or patient representative to the ERC, as per the RoPs. If a decision is made not to include a lay person and/or patient representative, this decision should be justified.</p>				
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The Secretariat will ensure that the ERC members' backgrounds, skills and expertise are published on the website.	-ERC Secretariat	Q3 2025	In progress	The ERC membership is available from SharePoint. Member's background, skills and expertise will also be made available. This is an ongoing activity.
Enhance ERC membership.	-ERC Secretariat -Directors -DGO	Q3 2025	In progress	The ERC is composed of WHO staff members and external members. The ERC Secretariat will add further expertise to the Committee, e.g. on digital health/AI-related studies, and a lay person/patients' representatives. To maximize WHO staff member involvement a circular is being developed to be sent by the DG asking Directors, Team Leaders and staff in relevant positions to encourage participation. This is an ongoing activity.
The ERC should be enabled to lead /align with on the development of research ethics guidance, policies, and training materials, and be systematically consulted on related documents.	-Dir/RFH SCI -DGO	Q3 2025	In progress	The ERC Secretariat is working with the Science Division to incorporate ERC in relevant approval pathways (e.g. Tulip). This is to enable technical units to engage with the ERC and its Secretariat in the development of research ethics guidance and to ensure alignment with ERC policies and practices. This is an ongoing activity.

<p>Recommendation 5: Step up ongoing efforts to update and streamline ERC processes, procedures and forms.</p> <ol style="list-style-type: none"> 1. Update WHO RoPs to ensure alignment with the latest guidance and review the guidance for ethical review for emergency response post-COVID-19 to ensure lessons learned and good practices are incorporated. 2. Strengthen ERC processes including document management: at a minimum by following up on the UNITAID assessment (2021) and User Survey (2021). This should include dating and version control of all guidance and forms created for the ethical review process, as well as the documentation and archiving of individual protocols. Consider upgrading ProEthos to a more user-friendly and functional platform and automating the ERC cost recovery mechanism to ensure smooth, ongoing access to funding for the ERC Secretariat. 3. Develop specific guidelines to operationalize the open data policy in the WHO ERC processes and raise awareness amongst staff. 4. Formalize the logic model and performance measurement framework (PMF) to ensure alignment with the requirements from the RoPs and expected outcomes. An evaluation needs to be conducted every five years in accordance with the RoPs. 	
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Conduct a review of WHO RoPs, including for emergencies.	-ERC Secretariat	Q3 2025	In progress	The RoPs are being reviewed. The review process is meant to be participatory and include all relevant stakeholders. The Secretariat will therefore involve key actors and propose a new version of the RoPs. This is an ongoing activity.
The Secretariat will engage in regular monitoring of improvement measures.	-ERC Secretariat -IT	Q1 2025	Implemented	<p>In terms of improvement measures, forms for technical units are being reviewed. The ProEthos system is also constantly updated to facilitate submission by units.</p> <p>With regards to monitoring, the Secretariat will adapt the logic model in line with regular monitoring of improvement measures.</p> <p>The Secretariat will develop a briefing note on how to best implement the Open Data Policy with regards to research within WHO. This will require a thorough review of all available material, and the articulation with current WHO practices. A consultative process will be needed to ensure alignment across the Organization. This is an ongoing activity.</p>
A new ERC management software will be developed, based on a business analysis and with the support of a Group of experts.	-ERC Secretariat -SCI -IT	Q2 2026	Not Initiated	A business analysis exercise was completed in 2020. The exercise will need to be updated and based on the results and pending available resources (500k) a new software will be developed.
An external evaluation will be conducted every five years in accordance with the RoPs.	-SCI -DGO	Q3 2029	Not Initiated	WHO will commit financial resources (100,000 US\$) every 5 years.

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