

Summary report on the

**Annual meeting of the
Eastern Mediterranean
Research Ethics Review
Committee**

WHO-EM/RPC/046/E

Cairo, Egypt
17–18 November 2019



REGIONAL OFFICE FOR THE

**World Health
Organization**

Eastern Mediterranean

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Contents

1.	Introduction.....	1
2.	Summary of discussions	2
3.	Recommendations.....	7

1. Introduction

The annual meeting of the Eastern Mediterranean Research Ethics Review Committee (RERC) took place at the WHO Regional Office for the Eastern Mediterranean in Cairo, Egypt, from 17 to 18 November 2019. The meeting was attended by Committee members from Egypt, Lebanon, Palestine and Tunisia, in addition to staff from the WHO Regional Office.

The objectives of the meeting were to:

- review progress on recommendations of the 2018 meeting;
- plan for the RERC's work during 2020 and beyond;
- discuss the status of the upcoming regional bioethics summit; and
- discuss effective means for implementing the expanded agenda for RERC's work in the Eastern Mediterranean Region.

The meeting was co-chaired by Professor Mohamed Salah Ben Ammar (Tunisia) and Professor Gamal Serour (Egypt), while Professor Niveen Abu-Rmeileh (Palestine) served as the meeting's rapporteur.

On behalf of Dr Arash Rashidian, Director, Science, Information and Dissemination, Dr Ahmed Mandil, RERC Secretary, inaugurated the meeting and welcomed participants. Colleagues from the United Nations Educational, Scientific and Cultural Organization (UNESCO) had previously shared a presentation, which was presented on their behalf.

In addition, Dr Andreas Reis from WHO headquarters and Dr Aamir Jafarey from WHO's Collaborating Centre for Bioethics at the Sindh Institute of Urology and Transplantation in Karachi, Pakistan, joined the meeting via teleconference.

2. Summary of discussions

Changes at WHO

The meeting started with a description of the structural changes taking place at WHO headquarters, including departments created or merged, and how these changes are being reflected structurally within the WHO Regional Office for the Eastern Mediterranean, with special reference to research for health and ethics.

Progress on implementation of the recommendations of the 2018 RERC meeting

The Committee reviewed progress on implementation of the recommendations of the previous RERC meeting in 2018. These recommendations included:

1. Support bioethics and research ethics work in the Region, with a focus on capacity-building (including research ethics in emergency settings);
2. Continue to ethically review WHO-funded proposals/protocols, including research in priority areas of public health (RPPH) and the Special Programme for Research and Training in Tropical Diseases (TDR) proposals;
3. Prepare a shortlist of recommended online courses for members of institutional review boards, including background documents (RERC subcommittee comprises: Professor Michel Daher, Professor Aamer Jafarey and Dr Dalia Samhouri);
4. Foster collaboration with UNESCO on bioethics and research ethics in the Region, including: establishing/reinforcing national bioethics committees; enhancing health professional education/curricula; supporting regional bioethics summits (as a follow-up to the Regional Bioethics Summit in Oman in 2017); and promoting networking between WHO Collaborating Centres and UNESCO chairs in the

Region, including co-organizing regional/national courses as part of ongoing interagency collaboration between WHO and UNESCO Arab States region.

5. Work towards achieving the targets of the Sustainable Development Goals 2030 related to health (WHO) and education (UNESCO), with special focus on observing ethical principles in health care delivery, including ethics in health-related curricula and peer education.

The Committee and Secretariat recognized the achievements made in fulfilment of the recommendations, with room for further collaboration. Regarding capacity-building activities, the Committee suggested expanding the target group to include those planning to start research by involving academic institutions and nongovernmental organizations, in addition to health care delivery institutions such as ministries of health.

Proposals submitted for ethical clearance

Extensive discussion took place on sub-dividing proposals submitted for ethical clearance into three categories of review: “full review”, “expedited review” and “exempted from review”.

The Committee felt that proposals that do not involve human participants are beyond the Committee’s mandate, with its current terms of reference. For other types of proposal, the recommendations are as follows.

- If the data (including health care records and specimens) being studied already exist and are either publicly available or are recorded by the investigator in such a manner as to be unidentifiable by the investigator or any member of the research team: expedited review.
- If public officials are interviewed in their official capacity on issues that are in the public domain: expedited review, unless the Secretariat thinks it needs full review.

- If the data for the study are generated by observation of public behavior: expedited review.
- If the relevant activity is limited to public health surveillance or evaluation of health programmes carried out pursuant to statutory or regulatory requirements:
 - cross-sectional surveys (full review);
 - evaluation studies (full or expedited review, as applicable);
 - surveillance activities are beyond the mandate of the RERC, with its current terms of reference; in such cases, the Secretariat will approach internal and external members for support.
- For multi-centre research:
 - in the same country (expedited review);
 - in different countries (full review).
- For research in public health emergencies: the administrative part of the review should be within a short time frame, while maintaining the principle of “no harm to people”.

Since some cases go beyond research, the Committee suggested expanding its mandate from “research ethics” to become an “ethics review committee”.

Activities of the WHO’s Collaborating Centre for Bioethics

The activities of WHO’s Collaborating Centre for Bioethics in Karachi, Pakistan, were presented by Professor Aamir Jafarey (via remote connection). The need to improve collaboration and networking with other collaborating centres, both in the Region and globally, was the main challenge identified, in addition to the limited available funding and staff. The WHO Collaborating Centre held a workshop on ethical deceased organ and donor programmes, and the role of transplant coordinators, in June 2019, which included participants from some countries of the Region (Islamic Republic of Iran, Saudi Arabia and

Tunisia). Participants had benefited from learning about each other's experience, especially regarding the transplantation centres in Islamic Republic of Iran and Saudi Arabia.

Online ethics-related courses

A subcommittee of the RERC, comprising Dr Daher, Dr Jafarey and Dr Samhouri, has reviewed WHO online ethics-related courses and suggests two courses for ethics review committee members and researchers in the Region regarding ethics and research ethics. The courses are [Essential Elements of Ethics](https://globalhealthtrainingcentre.tghn.org/essential-elements-ethics/)¹ and [Research Ethics Online Training](https://globalhealthtrainingcentre.tghn.org/elearning/research-ethics/)².

Ethics committee roles and mandates

The Committee suggested that the Secretariat share with researchers and countries a list of the ethics committees and their roles to reduce confusion about the role and mandate of each committee. The committees are the National Bioethics Committee (NBC), National Ethics Committee (NEC), National Research Ethics Committee (NREC), Ethics Review Committee (ERC), Institutional Review Board (IRB) and Research Ethics Committee (REC).

Research during emergencies

Professor Abu-Rmeileh presented on planning challenges and the outcomes of a workshop on research during emergencies, which took place in Amman, Jordan, in March 2019. She highlighted several challenges faced by ethics review committees in humanitarian settings. These include the lack of ethical guidelines specific to humanitarian

¹ Available at <https://globalhealthtrainingcentre.tghn.org/essential-elements-ethics/>

² Available at <https://globalhealthtrainingcentre.tghn.org/elearning/research-ethics/>

settings and the role of funding and international agencies in obtaining or providing ethical clearance.

The need for capacity-building for ethics review committees was highlighted. There was a suggestion to build a database of all national review committees, or even institutional review committees, and make it publicly available on the WHO Regional Office website.

Charter of Ethics of Science and Technology in the Arab Region and the 13th Global Summit of National Ethics/Bioethics Committees

Dr Mandil provided a progress review, on behalf of UNESCO, on the Charter of Ethics of Science and Technology in the Arab Region. The Charter is ready for dissemination among countries in the WHO Eastern Mediterranean Region.

The first dissemination of the Charter will be during the 13th Global Summit of National Ethics/Bioethics Committees, planned to be held in Lisbon, Portugal, on 18–20 March 2020.

The RERC suggested that participants of the Global Summit be requested to revise and reduce the list of recommendations of the last summit and for an implementation and coordination plan to be devised by participants and countries from the Eastern Mediterranean Region.

The ethics and governance of artificial intelligence for health

Dr Andreas Reis from WHO headquarters gave a presentation to the Committee on the ethics and governance of artificial intelligence for health. The development of an ethical framework for artificial intelligence in health is currently in progress. The process has involved several stakeholders, including academics, human rights experts and

representatives of civil society, international organizations, industry and government.

3. Recommendations

To WHO

1. Review the name and mandate of the RERC to go beyond “research ethics” to “ethics” in general, which would serve an unmet need within WHO and an important demand within countries of the Eastern Mediterranean Region. If approved, the Committee would have the following terms of reference:
 - ensure compliance with WHO’s operational guidelines for ethics committees that review biomedical research and Council for International Organizations of Medical Sciences (CIOMS)/WHO international ethical guidelines for health research involving humans;
 - review protocols of health/research projects involving human subjects recommended for WHO funding in the Region, including randomized controlled trials;
 - support the development and work of ethics review committees/institutional review boards in the Region; and
 - support interagency work on bioethics (especially with UNESCO), and foster the work of national ethics/bioethics committees in the Region.
2. Support bioethics/research ethics work in the Region, including capacity-building.
3. Ethically review WHO-funded proposals/protocols, including RPPH and TDR proposals.
4. Foster work with UNESCO on bioethics and research ethics in the Region.

To Member States

5. Ensure that members of research ethics committees have a minimum of bioethics/ethics training.
6. Use the appropriate nomenclature when establishing ethics committees, including National Bioethics Committee (NBC), National Ethics Committee (NEC), Ethics Review Committee (ERC), Institutional Review Board (IRB) and Research Ethics Committee (REC).



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