

Summary report on the

Annual meeting of the Eastern Mediterranean Research Ethics Committee

WHO-EM/RPC/044/E

Cairo, Egypt
11–12 November 2018



REGIONAL OFFICE FOR THE

World Health
Organization

Eastern Mediterranean

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Contents

1.	Introduction.....	1
2.	Summary of discussions	2
3.	Recommendations.....	6

1. Introduction

In 2010, the Sixty-third World Health Assembly recognized the contribution of research to development of solutions to health problems, and endorsed the WHO strategy on research for health to ensure that the highest norms and standards of good research are upheld within WHO and provide support to Member States in taking relevant actions to strengthen national health research systems.

Research proposals recommended for funding through WHO's different grant schemes require methodological and ethical review. Therefore, in 2017, the Regional Director re-formulated the Eastern Mediterranean Research Ethics Review Committee (RERC) with an essential function to review the protocols of all health research projects involving human subjects submitted to WHO for funding in the Region.

The RERC members meet on an annual basis to follow up and ensure compliance of health research in the Region with the Organization's policies and regulations for conduct of health research. The 2018 meeting was organized by the WHO Regional Office for the Eastern Mediterranean, from 11 to 12 November, in Cairo, Egypt.

The objectives of the meeting were to:

- review progress in implementation of the recommendations of the 2017 meeting;
- plan for the RERC's work during 2019 and beyond;
- discuss the statement of the 12th Global Summit of National Ethics/Bioethics Committees in Dakar, Senegal, in 2018;
- discuss the status of upcoming regional bioethics summits (in Pakistan, 2019, and Islamic Republic of Iran, 2021);
- address new challenges in observing health research ethics during emergencies.

The meeting was attended by RERC members from Egypt, Islamic Republic of Iran, Lebanon, Palestine, Pakistan, Sudan and Tunisia, staff from the Regional Office and WHO headquarters, and a representative from the United Nations Educational, Scientific and Cultural Organization (UNESCO). The meeting was co-chaired by Professor Mohamed El-Sheikh and Professor Michel Daher, and Dr Niveen Abu-Rumeileh served as rapporteur. The meeting was inaugurated by Dr Arash Rashidian, Director, Information, Evidence and Research, who emphasized the key role of the RERC in scaling up ethics in the Region and reviewing selected research proposals for WHO funding that involve human subjects.

2. Summary of discussions

An overview of the structure of the Regional Office for the Eastern Mediterranean was presented, with a special focus on Research Promotion and Development and WHO collaborating centres, including the WHO Collaborating Centre for Bioethics in Karachi, Pakistan. Discussions highlighted the differences between WHO collaborating centres and UNESCO chairs, with respect to requirements and follow-up processes. Networking between UNESCO chairs and WHO collaborating centres should be promoted in order to build on common resources and mandates. In addition, the formulation of a RERC subcommittee to draft a list of recommended online courses for members of institutional review boards in Member States was discussed.

The recommendations of the 2017 RERC were reviewed and discussed. The recommendations, and progress in implementation (in parenthesis), are given below.

- developing terms of reference for the RERC, including the duration of assignment (draft prepared and finalized);

- developing a list of frequently asked questions to be posted online in relation to ethical review as a guide for research applicants (prepared and discussed);
- developing a template for informed consent forms (prepared and discussed);
- identifying a modality to link the RERC with national bioethics/ethics committees (discussed);
- encouraging principal investigators of WHO-funded proposals to publish outcomes of their projects and making manuscript submission (in lieu of final technical reports) conditional for receiving final payments (planned to be applied to upcoming grants);
- organizing side meetings for the RERC during global and regional bioethics summits (proposed).

The following terms of reference were proposed to ensure compliance with WHO operational guidelines for ethics committees:

- review protocols of all research for health projects involving human subjects recommended for WHO funding in the Region, including randomized clinical trials;
- support the development and work of ethics review committees/institutional review boards in the Region;
- support interagency work on bioethics (especially with UNESCO), and foster the work of national ethics/bioethics committees in the Region.

It was suggested to have three levels of review process: full review; expedited review (especially in emergency settings); and, exempted from review. The decision on which level is needed must be made against clear criteria for screening the proposals.

The 12th Global Summit of National Ethics/Bioethics Committees was held in Dakar, Senegal, from 22 to 24 March 2018, with the overall theme of Bioethics, sustainable development and societies. A parallel regional meeting was held, in which 11 representatives from nine countries (Jordan, Islamic Republic of Iran, Lebanon, Libya, Oman, Pakistan, Saudi Arabia, Sudan and Tunisia) of the Eastern Mediterranean Region participated. During the parallel meeting, the venue and proposed dates for upcoming regional bioethics summits were discussed (requests received from Pakistan for 2019, and Islamic Republic of Iran for 2021). Preparations for the second Regional Bioethics Summit, to take place in Islamabad, Pakistan in November 2019, were discussed, although plans are yet to be finalized.

Ethical issues related to vulnerable populations and groups, especially in regional settings, were discussed. Four steps were suggested to move forward in ethical research with vulnerable populations: capacity-building in health research and ethics; resource requirements to conduct and sustain ethical review; linkages and strategies for communication between stakeholders; and creation of novel training and learning opportunities.

A capacity-building activity is planned to be conducted by Birzeit University in Amman, Jordan during 2019, on challenges in conducting ethical research in humanitarian settings. The main aim is building the capacity of researchers engaged in ethics review committees at the national or institutional levels. Target countries for the activity include Iraq, Jordan, Palestine, Somalia, Sudan, Syrian Arab Republic and Yemen.

The concepts and principles for ethical conduct of research during emergencies were discussed. Lessons learned from the Ebola outbreak were debated, where researchers and health professionals faced

several ethical issues since the guidelines were neither comprehensive nor very restrictive.

A short course was conducted on Ethics and bioethics: a global and regional overview. The course covered the ethical guidelines on infectious disease outbreaks, with reference to the online training course on ethics in epidemics, emergencies and disasters: research surveillance and patient care.

Tuberculosis control strategies and goals as well as WHO guidance on ethical issues related to tuberculosis were elaborated. Tuberculosis ethics-related issues among migrants and refugees were deliberated, with the target of avoiding stigmatization and improving access to needed services and treatment as per the legal context of the hosting country.

Public health surveillance and ethics in relation to vectors and vector-borne diseases were discussed. Various vector control measures and their advantages and disadvantages were discussed, linking them with ethical measures. It was noted that vector elimination through genome editing (or gene drives) was controversial, due to the long-term effects and lack of documentation on the vector species, environment and ecosystem balance.

Ethical issues related to big data and artificial intelligence were discussed, including valid consent, privacy and confidentiality, and governance. Related initiatives addressing this area include: United Nations Global Pulse; UNESCO reports; Asilomar AI Principles; national ethics committees; and European Group on Ethics in Science and New Technologies. WHO plans to develop normative guidance for Member States to address the ethical issues for public health raised by artificial intelligence.

3. Recommendations

The RERC members made the following recommendations for the Committee and WHO Secretariat.

1. Support bioethics and research ethics work in the Region, with a focus on capacity-building (including capacity-building for research ethics in emergency settings).
2. Continue to ethically review WHO-funded proposals/protocols, including Research in Priority Areas of Public Health (RPPH) and 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 Aamer Jaafari, Professor Michel Daher 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, 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.
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.

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