

Summary report on the

# Annual meeting of the Eastern Mediterranean Research Ethics Review Committee

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Cairo, Egypt  
12 December 2021



REGIONAL OFFICE FOR THE

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Organization

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## **1. Introduction**

The Eastern Mediterranean Research Ethics Review Committee (RERC) meets annually for strategic planning and to ensure compliance of health research in the Region with WHO policies and international guidance for research on human subjects. Due to the COVID-19 pandemic, the annual meeting was held virtually in 2020. However, in 2021, the RERC co-Chairs and most Committee members were able to participate in person, so the meeting was held on 12 December 2021 at the WHO Regional Office for the Eastern Mediterranean in Cairo, Egypt. Members from Egypt, Islamic Republic of Iran, Lebanon, occupied Palestinian territory, Pakistan and Tunisia, as well as some WHO staff, physically attended in the meeting, while a Committee member from Sudan, a representative from UNESCO headquarters and other WHO staff attended virtually.

The objectives of the meeting were to:

- review the RERC's work during 2020/2021;
- share outcomes of case studies of research ethics governance in three Member States;
- plan future work in light of WHO's Programme Budget 2022–2023; and
- discuss possible contributions to the global bioethics summit and plan for a regional bioethics summit.

The meeting was co-chaired by Professor Mohamed Saleh Ben Ammar (Tunisia) and Professor Gamal Serour (Egypt), with Professor Niveen Abu-Rmeileh (occupied Palestinian territory) and Dr Arshad Altaf (WHO Regional Office) serving as rapporteurs. Dr Ahmed Mandil, (Coordinator, Science, Information and Dissemination, WHO Regional Office) welcomed participants and inaugurated the meeting, on behalf of Dr Arash Rashidian (Director, Division of Science, Information and Dissemination, WHO Regional Office).

## 2. Summary of discussions

### *Progress on implementation of the recommendations of the 2020 RERC meeting*

Dr Ahmed Mandil, as RERC Secretary, presented the progress made on implementation of the recommendations of the 2020 RERC meeting. He pointed out that there are now three WHO Collaborating Centres on bioethics in the Eastern Mediterranean Region: the Centre for Biomedical Ethics and Culture (CBEC) at the Sindh Institute of Urology and Transplantation, Karachi, Pakistan; the Medical Ethics and History of Medicine Research Center at Tehran University of Medical Sciences, Tehran, Islamic Republic of Iran; and the newly designated, Salim El-Hoss Bioethics and Professionalism Program at the Faculty of Medicine and Medical Center of the American University of Beirut, Lebanon. Dr Mandil also described developments related to the Eastern Mediterranean Health Journal. Committee members suggested exploring options for publishing a commentary or editorial on the status of research ethics in the Region and of potentially adding a permanent section on research ethics to the journal.

### *Online system for the RERC's work*

The WHO Regional Office has been exploring the possibility of instituting an online ethics review system for the RERC. Two presenters were invited to the meeting to give a brief demonstration. Ms Marisol Ghuraib (WHO headquarters) provided a demonstration of an online system called [ProEthos](#), which is a public access system and is used by the WHO Regional Office for the Americas and WHO headquarters' Research Ethics Review Committee. Mr Russell Pidmore (United Kingdom) gave an overview of the [Infonetica](#) online ethics review software system, which can be used by researchers and reviewers.

*UNESCO/WHO collaboration: historical and future perspectives*

Dr Orio Ikebe (UNESCO headquarters) presented on collaboration between UNESCO and the WHO Regional Office for the Eastern Mediterranean in research ethics. Since 2017, a series of activities in the form of capacity-building events, virtual webinars and regional summits of national bioethics committees have been jointly organized. The most recent one, on 6 December 2021, was a webinar on the fair, equitable and timely allocation of COVID-19 vaccines in the Arab States/Eastern Mediterranean Region. Dr Ikebe also discussed the UNESCO Chairs programme, describing a UNESCO Chair as a project in a university or higher education or research institution that partners with UNESCO to advance knowledge and practice in an area of mutual interest, such as bioethics or research ethics.

*Health research ethics governance: perspectives from the Islamic Republic of Iran*

Professor Bagher Larijani (Islamic Republic of Iran) presented on Iranian health research ethics governance, describing its implementation in medical universities and academic institutions. The research ethics system is based on three pillars: 1) introduction of research ethics standards; 2) a disciplinary system for research misconduct; and 3) strengthening research ethics committees in the three levels. A national research ethics portal provides details of all accredited committees and the requisite infrastructure and platforms are in place for the implementation and integration of ethics in medical research at the national level. However, there is a need to strengthen the monitoring of trials that involve human subjects and are ethically approved.

*Health research ethics governance: perspectives from Lebanon*

Ms Diana Mikati (Lebanon) presented, on behalf of Dr Thalia Arawi, on a mapping exercise of research ethics governance in Lebanon. The purpose of the exercise was to synthesize prior attempts to map health research ethics governance in the country. Key findings suggest that there is a lack of dedicated policies in Lebanon, with the exception of some decrees addressing clinical and biomedical research. The ethical review process is more formalized in universities, businesses and hospitals, but there is less regulation in community settings, health care services and pharmacies, and of social research. Key recommendations include establishing an accreditation system for research ethics (through ethics research committees), a national health framework to guide health research policies and a network for capacity-building and exchange.

*Health research ethics governance: perspectives from Pakistan*

Professor Aamir Jafarey (Pakistan) explained the mechanisms of research ethics governance in Pakistan, noting that there are research ethics committees in universities, medical colleges and hospitals in both the private and public sectors. At national level, the National Bioethics Committee has a research ethics committee for human subject research, while the Drug Regulatory Authority of Pakistan has a clinical studies committee for clinical trials. A study involving a desk review, pilot survey, structured interviews and a case study, surveyed 18 (14 public and four private) institutions. It identified gaps in the system, including a lack of an accreditation/registration process, no mandatory training on ethical reviews and the unavailability of a national research guidance document. Suggested ways forward included the development of a database, accreditation of research ethics committees, strengthening the national research ethics committee and developing national guidelines.



*Human genome editing: current knowledge and future perspectives*

Dr Katherine Littler (WHO headquarters) described the development of WHO global standards for the governance and oversight of human genome editing. Human genome editing's key areas are: 1) somatic; 2) germline; and 3) heritable genetic alterations. She noted that WHO addresses scientific, ethical, societal and governance issues. The work is overseen by a committee comprising subject experts from around the world. The committee's outputs include a global clinical trials registry on human genome editing, a policy statement by the WHO Director-General, a governance framework for human genome editing and recommendations for governance and oversight. Next steps include a series of regional webinars to understand regional needs, WHO's global guidance framework to harness the responsible use of life sciences, which should feed into the Third International Summit on Human Genome Editing, and a future workshop on "whistleblowing".

*Contributions to the global bioethics summit and plans for a regional bioethics summit 2022*

Professor Michel Daher (Lebanon) and Dr Ehsan Shamsi-Gooshki (Islamic Republic of Iran) presented on the global bioethics summit and made recommendations for contributions from the Eastern Mediterranean Region. The summit will be held from 15 to 17 September 2022 in Lisbon, Portugal. The tentative themes are: 1) strengthening health care systems; 2) access to innovation, prevention and treatments; 3) health education, public engagement and social responsibility; and 4) human vulnerabilities and continuing threats. RERC members made a number of suggestions for the global summit, which included: holding a special session on migrant health and ethics in the Region; advising the Secretariat to be more inclusive and expand into clinical ethics, bioethics and public health ethics; and having a

virtual platform during the summit to increase participation in areas of interest. The regional bioethics summit is proposed to be held in the Islamic Republic of Iran (subject to confirmation). Dr Ahmed Mandil and Dr Ehsan Gooshki agreed to discuss and share a concept note with the RERC in the coming weeks.

### *RERC checklists*

Another issue discussed during the meeting was a review of the RERC checklists for principal investigators and reviewers. Some proposed changes were discussed and approved by the Committee. An updated template of the informed consent form will become part of the principal investigator checklist.

### **3. Recommendations**

- Continue to support bioethics and research ethics in the Region.
- Undertake capacity-building in Member States in ethics and research methodology for aspiring researchers as well as research institutions.
- Ensure more effective utilization of virtual platforms to broaden the scope of capacity-building (particularly for ethics and research methodology) in the Eastern Mediterranean Region.
- Involve WHO Collaborating Centres in delivering training in the Region on ethics and research ethics.
- Encourage collaboration between UNESCO Chairs and WHO Collaborating Centres at national and regional levels.
- Ensure representation from the Region on the WHO expert advisory committee on developing global standards for governance and oversight of human genome editing.



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