

Summary report on the

# Meeting of the Eastern Mediterranean Research Ethics Review Committee

WHO-EM/RPC/041/E

Cairo, Egypt  
22–23 October 2017



**World Health  
Organization**

Regional Office for the Eastern Mediterranean

Summary report on the  
**Meeting of the Eastern Mediterranean  
Research Ethics Review Committee**

Cairo, Egypt  
22–23 October, 2017



**World Health  
Organization**

Regional Office for the Eastern Mediterranean

## © World Health Organization 2017

Some rights reserved. This work is available under the Creative Commons Attribution-NonCommercial-ShareAlike 3.0 IGO licence (CC BY-NC-SA 3.0 IGO; <https://creativecommons.org/licenses/by-nc-sa/3.0/igo>).

Under the terms of this licence, you may copy, redistribute and adapt the work for non-commercial purposes, provided the work is appropriately cited. In any use of this work, there should be no suggestion that WHO endorses any specific organization, products or services. The use of the WHO logo is not permitted. If you adapt the work, then you must license your work under the same or equivalent Creative Commons licence. If you create a translation of this work, you should add the following disclaimer along with the suggested citation: “This translation was not created by the World Health Organization (WHO). WHO is not responsible for the content or accuracy of this translation. The original English edition shall be the binding and authentic edition”.

Any mediation relating to disputes arising under the licence shall be conducted in accordance with the mediation rules of the World Intellectual Property Organization.

**Suggested citation.** [Title]. Cairo: WHO Regional Office for the Eastern Mediterranean; 2017. Licence: CC BY-NC-SA 3.0 IGO.

**Sales, rights and licensing.** To purchase WHO publications, see <http://apps.who.int/bookorders>. To submit requests for commercial use and queries on rights and licensing, see <http://www.who.int/about/licensing>.

**Third-party materials.** If you wish to reuse material from this work that is attributed to a third party, such as tables, figures or images, it is your responsibility to determine whether permission is needed for that reuse and to obtain permission from the copyright holder. The risk of claims resulting from infringement of any third-party-owned component in the work rests solely with the user.

**General disclaimers.** The designations employed and the presentation of the material in this publication do not imply the expression of any opinion whatsoever on the part of the World Health Organization concerning the legal status of any country, territory, city or area or of its authorities, or concerning the delimitation of its frontiers or boundaries. Dotted lines on maps represent approximate border lines for which there may not yet be full agreement.

The mention of specific companies or of certain manufacturers' products does not imply that they are endorsed or recommended by the World Health Organization in preference to others of a similar nature that are not mentioned. Errors and omissions excepted, the names of proprietary products are distinguished by initial capital letters.

All reasonable precautions have been taken by the World Health Organization to verify the information contained in this publication. However, the published material is being distributed without warranty of any kind, either expressed or implied. The responsibility for the interpretation and use of the material lies with the reader. In no event shall the World Health Organization be liable for damages arising from its use.

## Contents

1.	Introduction.....	1
2.	Summary of discussions .....	2
3.	Recommendations.....	5

## **1. Introduction**

The World Health Report 2013: Research for Universal Health Coverage emphasized WHO's role in advancing research that addresses the dominant health needs of its Member States, supporting national health research systems, setting norms and standards for the proper conduct of research and accelerating translation of research findings into health policy and practice. In 2010, the 63th 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 WHO funding through different grant schemes require methodological and ethical review. In 2017 the WHO Regional Director for the Eastern Mediterranean re-formulated the Eastern Mediterranean Research Ethics Review Committee (EM/RERC) with the essential function to review the protocols of all health research projects involving human subjects submitted to WHO for funding in the Region. Such review is meant to protect the dignity, integrity, human rights, safety and well-being of all human participants in research. It entails review of the protocol to ensure "scientific rigour" and "ethical conduct" of research. The Committee has the authority to approve, to request modification as a condition of approval, or to reject proposed activities that are within the scope of its authority. The Committee also has the authority to verify that ongoing studies comply with the Organization's policies and regulations for conduct of health research in the Region, and it may suspend or terminate approval for ongoing studies under its jurisdiction.

The RERC members meet on annual basis to follow up WHO-supported health research in the Region and ensure its compliance with the Organization's policies and regulations for conduct of health research. The 2017 annual meeting was organized by the WHO Regional Office for Eastern Mediterranean from 22 to 23 October 2017 at the Regional Office in Cairo, Egypt.

The objectives of the meeting were to:

- review RERC's work during 2016–2017;
- finalize and adopt a modified checklist (for reviewers and investigators);
- agree on modalities for taking forward the recommendations of recent meetings;
- plan future work in light of the Programme Budget for 2018–2019.

The meeting was inaugurated by Dr Ahmed Mandil, Coordinator, Research Development and Innovation and ERC Secretary, on behalf of Dr Jaouad Mahjour, Acting Regional Director for the Eastern Mediterranean, and Dr Arash Rashidian Director, Information, Evidence and Research. The meeting was chaired by Professor Gamal Serour (Egypt). Dr Mandil served as Rapporteur.

## **2. Summary of discussions**

The Eastern Mediterranean Research Ethics Review Committee has two mandates: reviewing the health research proposals involving human subjects subjected to funding by WHO to ensure protecting dignity, integrity, human rights, safety and well-being of all human participants in research; and ensuring compliance with the International Ethical Guidelines for Biomedical Research Involving Human Subjects.

The mandates of the Review Committee are based in part on the International Ethical Guidelines for Health-related Research Involving Human Subjects and its scope is confined to observational research, clinical trials, bio banking and epidemiological studies. The ethical principles set forth in the guidelines should be held in the ethical review of research proposals especially in: capacity building for research and research review, research involving vulnerable persons and groups, research in disasters and disease outbreaks, requirements for establishing research ethics committees and for their review of protocols. During discussions, participants highlighted the need for bioethics capacity-building in the Region, including further capacity development of ERC members such as through online courses and participation in WHO activities. They also discussed the situation of multi-centre studies and exemptions versus expedited review.

The recommendations of the 2016 ERC meeting were reviewed and discussed with participants. For 2016–2017 the ERC's work covers areas in relation to the ethical review process of WHO-funded proposals. Detailed statistics were presented including the number of reviewed proposals from projects funded by iPIER, RPPH and TDR over the years.

The ethical review process of WHO-funded proposals includes the following components.

- Review package: completed checklist (for principal investigators); research protocol; data collection instrument(s); informed consent form(s); national/institutional ethical clearance
- Review by 2 ERC members using the ERC checklist; communicating feedback to principal investigators; providing written timed ethical clearance

The discussion which followed included the possibility of monitoring ethically cleared research through national mechanisms, in collaboration with the WHO country office. The Committee pointed out the need to design a standard template for informed consent form in English and a standard letter of ethical clearance. It also drew attention to the importance of narrative comments and discussed decision-making about final review.

The ERC checklists for reviewers and principal investigators were thoroughly reviewed based on the modifications recommended by the ERC during its 2016 meeting. More amendments were made to the ERC checklist for PIs, especially for the sections on minors (less than 18 years old), pregnant women and emergency contexts.

The Committee reviewed the recommendations of two recent meetings and their implications for its work: the regional bioethics summit held Muscat, Oman in April 2017; and a national bioethics workshop held in Damascus in September 2017. Both meetings focused on national bioethics and ethics committees, and recommended strengthening their internal mechanisms, their role in promoting bioethics, health and research ethics, and coordination and cooperation. The Committee discussed ways to take forward the recommendations of these meetings and proposed the following actions.

- Liaising with the follow-up committee for the Muscat summit on the recommendations to be reflected in the Global Summit in Dakar
- Communicating the recommendations, through appropriate channels (WHO and UNESCO country offices), to ministries of health, education, higher education, and science and technology



- Sharing outcomes of regional meetings with decision-makers in Member States
- Using the expertise of WHO collaborating centres in conducting regional capacity-building activities

### **3. Recommendations**

Based on the discussions during the meeting, the following actions were recommended for the Committee and WHO Secretariat.

1. Develop terms of reference for the ERC, including the duration of assignment (consider the model of the tuberculosis Green Light Committee).
2. Develop a list of FAQs to be posted online in relation to ethical review as a guide for research applicants.
3. Develop a template for informed consent forms, including for genetic and biobank-related research, and for ERC clearance.
4. Identify a modality to link the ERC with national committees.
5. Encourage principal investigators of WHO-funded proposals to publish their papers and make manuscript submission conditional with receiving payments.
6. Organize side meetings for the ERC during global and regional bioethics summits.



World Health Organization  
Regional Office for the Eastern Mediterranean  
P.O. Box 7608, Nasr City 11371  
Cairo, Egypt  
[www.emro.who.int](http://www.emro.who.int)