Summary report on the

Meeting of the Eastern Mediterranean Research Ethics Review Committee

WHO-EM/RPC/038/E

Cairo, Egypt
6–7 September 2015

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1. Introduction

The WHO Regional Office for the Eastern Mediterranean held a meeting of the Eastern Mediterranean Research Ethics Review Committee (EM-ERC) on 6–7 September 2015 in Cairo, Egypt. The objectives of the meeting were to review the EM-ERC's work in light of its revised membership; ensure compatibility of the Committee's work with international guidelines for review of health research on human subjects; update the current review process for health research supported by WHO; and discuss new health research challenges in the Region, including health policy and systems research.

The meeting was opened by Dr Ala Alwan, WHO Regional Director for the Eastern Mediterranean, who highlighted WHO's role in supporting and promoting health research, as mandated by its constitution. In 2014 he had re-formulated the EM-ERC and included external members (RD's Circular 1105), with an essential function to review the protocols of all health research projects involving human subjects submitted to WHO for funding in the Region. WHO was working in close collaboration with other stakeholders in health research, including the United Nations Educational, Scientific and Cultural Organization (UNESCO) in the field of bioethics applications.

Professor Gamal Serour served as Chairman, while Dr A. Mandil was Rapporteur.

2. Summary of discussions

Misconduct in health research can result in reduced trust in research findings. Examples of serious research misconduct include fraud, fabrication, falsification, plagiarism, ghost-authorship, gift-authorship, failure to disclose conflict of interest and defrauding. The discussions emphasized certain exacerbating factors such as the “publish or perish” culture and the need for peer-review throughout the research process (planning, implementation, publication). Some solutions suggested to prevent or flag misconduct in health research were inclusion of “bioethics” in health-related curricula, enhanced vigilance by journal editors, establishing functional national ethics committees and institutional review boards in countries lacking them and more rigorous ethical review processes.

UNESCO’s work in the field of bioethics includes human reproductive and therapeutic cloning, embryonic stem cell research, genetic testing, human genome and gene analysis, research involving human subjects, organ transplantation, assisted reproductive technologies, pharmaceutical research, medical practice and abortion. UNESCO’s training manuals include Assisting Bioethics Committees, Bioethics Education and Ethics Teachers’ Training Course. Networking is important in bioethics, such as for example the Bioethics Network on Women's Issues in the Arab Region.

Preliminary results of the WHO survey on bioethics in the Eastern Mediterranean Region indicate the need for supporting national ethics committees/institutional review boards/research ethics committees which exist in most Member States, lack of multidisciplinary membership (most members are physicians), and the need for verification of governing laws and for more harmonization between bodies. Challenges in bioethics in the Region include the inclusion of

bioethics in health sciences' curricula, public awareness about bioethics and medical responsibility, resources and conflict of interest.

Egypt's experience and activities in support of bioethics include raising awareness of the health and research communities through organizing multisectoral meetings, establishing a national ethical committee and supporting curricular development on bioethics and networking with national and international organizations. The main assets of biomedical research in the Islamic Republic of Iran include strong political will, enormous progress in different aspects of health care ethics and championship of certain scholars and decision-makers. The main challenges are implementing ethics in provision of health care and medical practice and the conduct of research. In Lebanon, the development of biomedical research ethics included the introduction of governing laws and bodies and collaboration and networking with international organizations. In order to face research ethics challenges, proposed solutions included enhancing education (formal/informal); capacity building; development / enforcement of national laws and regulations; having a national regulatory oversight; establishing a national registry for clinical trials and research in addition to regulation of pharmaceutical companies' influence on research and clinical studies.

The meeting advised that proposals on health policy and systems research should be reviewed using an expeditious process with applicable questions in checklists. It recommended that some members of review committees (especially at national/institutional level) should have training in health policy and systems research, and that different stakeholders be involved with the review process (as applicable). In addition, the Committee carefully reviewed currently used checklists for review of submitted research proposals recommended for WHO funding. It recommended modification some

questions and addition of sections on conflict of interest on an informed consent process for vulnerable groups, including minors, pregnant women, populations in emergencies and intellectually impaired people, which are to be drafted in the near future.

Following the two days of discussions, the meeting made several recommendations for ensuring compatibility of the Committee's work with international guidelines for health research, updating the ethical review process and providing special advice for current challenges in health policy and systems research.

In the closing session, the Regional Director highlighted the role and functions of the EM-ERC in ethical conduct of health research funded by WHO in the Region. He emphasized the importance of collaboration with United Nations organizations working in the field of bioethics, especially UNESCO (with special focus on supporting national bioethics committees and inclusion of bioethics in curricula of health sciences' colleges), and requested that the meeting's recommendations be shared with technical units and Member States.

3. Recommendations

Member States

1. Develop or strengthen enforcement of national laws and regulations which govern bioethics and related research.
2. Emphasize the need for vigilance by editors of scientific journals to avoid fraud and falsification of health research submitted for consideration for publication.
3. Develop and support national bioethics committees which could oversee institutional committees' work, including institutional review boards.

4. Establish different ethical review committees according to need (e.g. for research on human subjects, on animals, etc.).
5. Promote a rigorous ethical review process at all levels (institutional/national/regional).
6. Establish national registries for clinical trials and research.
7. Consider regulating pharmaceutical companies' influence on health research, especially clinical studies.

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8. Use the expertise of current global WHO collaborating centres on bioethics and regional technical collaborating centres.
9. Consider designating a regional collaborating centre on bioethics.
10. Support capacity-building activities in bioethics and ethical conduct of health research.
11. Add sections on "conflict of interest" and "informed consent process for vulnerable groups" in the current checklists for review of submitted proposals.

World Health Organization
Regional Office for the Eastern Mediterranean
P.O. Box 7608, Nasr City 11371
Cairo, Egypt
www.emro.who.int