Research ethics in the Eastern Mediterranean Region

WHO and health research

The 2013 World Health Report, *Research for universal health coverage*[1], emphasized the role of the WHO in advancing research that addresses the dominant health needs of 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.

To help realize WHO's role in health research and target the Region's priorities, the WHO Regional Office for the Eastern Mediterranean supports three types of health research grants:

- Research in Priority Areas of Public Health grant, which address the five strategic health priorities of work in the Region (Health systems strengthening; Maternal, reproductive and child health and nutrition; Noncommunicable diseases; Communicable diseases; and Preparedness, surveillance and response);
- Improved Programme Implementation through Embedded Research (iPIER) grants, offered in collaboration with the Alliance for Health Policy and Systems Research; and
- Tropical Disease Research – Small Grants Scheme, offered in collaboration with the WHO/UNDP/World Bank Special Programme for Research and Training in Tropical Diseases.

Ethical oversight of research: WHO/EMRO Research Ethics Review Committee

A fundamental requirement of research is its compliance with the recognized ethical standards for the conduct of research so as to protect research participants. Therefore in order to ensure the scientific rigour and ethical conduct of health research recommended for funding under the three grants, the Eastern Mediterranean Ethics Review Committee was established in 2007. The Committee was reformulated in 2014 to include external (from Egypt, Islamic Republic of Iran, Lebanon, Morocco, Tunisia, UNESCO) as well as in-house (WHO) members; and was renamed the Eastern Mediterranean Research Ethics Review Committee. Its primary function is to "review the protocols of all health research projects involving human subjects submitted to WHO for funding in the Region" in order to safeguard the dignity, integrity, human rights, safety and well-being of all the human participants. The Review Committee also has the authority to verify that ongoing studies comply with WHO policies and regulations for the conduct of health research in the Region.

During the review process of the health research protocols, the Committee is expected to ensure compliance with the International ethical guidelines for biomedical research involving human subjects[2] as well as other international guidelines which govern ethical conduct of health research[3].

In view of the recent reformulation of the Committee, the WHO Regional Office for the Eastern Mediterranean convened a meeting of the Committee during the period 6–7 September 2015. The objectives were to: review the work of the Research Ethics Review Committee since October 2014, when its functions had been updated; ensure compatibility of the work with international guidelines for review of health research on human subjects; update the current review process for health research supported by WHO; and address new health research challenges in the Region, including health policy and systems research.

The meeting was inaugurated by Dr Ala Alwan, WHO Regional Director for the Eastern Mediterranean, who emphasized the importance of the work of the Research Ethics Review Committee in ensuring that health research funded by WHO in the Region is ethically sound.

Recommendations

Following presentations and active discussion of the key issues concerning the work of the Committee, recommendations were proposed for ensuring compatibility of the Committee's work with international guidelines for health research (including the Council for International Organizations of Medical Sciences, WHO and UNESCO guides), updating the ethical review process and providing specific advice for

1 World health report: research for universal health coverage. Geneva: World Health Organization, 2013.

2 International ethical guidelines for biomedical research involving human subjects. Geneva: Council for International Organizations of Medical Sciences; 1992.

3 International ethical guidelines for epidemiological studies. Geneva: Council for International Organizations of Medical Sciences; 2009.
Standards and operational guidance for ethical review of health-related research with human participants. Geneva: World Health Organization; 2011.
Universal declaration on bioethics and human rights. Paris: United Nations Educational, Scientific and Cultural Organization; 2005.
Bioethics committees at work: procedures and policies (Guide 2). Paris: United Nations Educational, Scientific and Cultural Organization; 2005.

current challenges in health policy and systems research. The meeting's recommendations for Member States and WHO are shown in Box 1.

The Committee also advised that proposals on health policy and systems research should be reviewed using only applicable questions in checklists, and recommended that some members of review committees (especially on a national/institutional level) should have training in health policy and systems research and that different stakeholders should be involved with the review process (as applicable).

In addition, the Research Ethics Review Committee carefully reviewed the checklists currently used for the review of submitted research proposals and recommended adding sections on "conflict of interest" and "informed consent process for vulnerable groups" (including: minors; pregnant women; emergencies; and mentally challenged persons), which are to be drafted in the near future.

Box 1 Recommendations of the Research Ethics Review Committee

To Member States

1. Develop/enforce national laws and regulations which govern bioethics and related research.
2. Urge vigilance by editors of scientific journals to avoid fraud and falsification of health research submitted for consideration for publication.
3. Develop / support/ accredit national bioethics committees which could oversee the work of institutional committees, including institutional review boards.
4. Establish ethical review committees according to need (e.g. for research on human subjects, on animals, etc.).
5. Support institutional clearance (in the absence of national clearance).
6. Establish national registries for clinical trials and research.
7. Regulate/monitor pharmaceutical companies' contributions to clinical studies.
8. Ensure a rigorous ethical review process on different levels (institutional, national, regional).

To WHO

9. Encourage/solicit research on public health priorities in the Region, especially on crises and emergencies.
10. Use the expertise of current global WHO collaborating centres for bioethics-related matters, including capacity building.
11. Establish a regional WHO collaborating centre on bioethics.
12. Support capacity-building activities in bioethics/ethical conduct of health research.