

Biomedical Research in Developing Countries  
**Policy and Practice Challenges for  
Research Ethics in the Muslim World**  
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# Outline of the presentation

- **History of ethics in the Muslim world**
- **Specificity of ethics in the Muslim world**
- **Current state of affairs**
- **Important players and actors**
- **Mapping of ERC capacities**
- **Interventions and plans of WHO EMRO**
- **Next steps**

## Muslim world has a rich history of medical ethics

- **2700 BC - before Oath of Hippocrates:** The first medical ethics guideline ever written on Papyrus (*Have an expectant attitude and trust in nature's healing. Be observant of the patient's condition*).
- **10 AD -** One of the most extensive works dealing with ethics was written by Ishaq ibn 'Ali Al-Ruhawi - "Adab al-Tabib, which has special relevance to the history of medicine all around the Mediterranean countries, including the countries of Northern Africa





# More examples

- **Al-Zahrawi or Albucasis of Cordoba, d. 1013,**
  - first major physician-surgeon of Muslim Spain (*Al-Andalus*)
  - *K. al-Tasrif*, lat. *L. al-saharavi de cirurgia*, one of the first books translated into Latin in Toledo; profusely quoted by European physicians
- **Ibn Zuhr or Avenzoar of Seville, d. 1162**
  - *K. al-Iqtisad* (Book of Moderation), an imitation of Galen
  - *K.al-Aghdhia* (Book on Aliments), a complete regimen of health
  - *K. al-Taysir* (Book of Facilitation), a manual of therapeutics translated into Hebrew and Latin; a companion book to Averroes's *Colliget*
- **Ibn Rushd or Averroes of Cordoba, d. 1198**
  - *K. al-Kulliyat* (On Universals, Lat. *Colliget*); Commentaries on Aristotle
- **Ibn Maymun or Maimonides of Cordoba, d. 1204 in Egypt;**
  - *Aphorisms, Regimen Sanitatis; Guide to the Perplexed*

# **Challenged faced by the Muslim world in research ethics**

- **Religious and cultural challenges**
- **Lack of national ethical guidelines**
- **Lack of regulations. (no punishment for unethical research )**
- **Few REC members with adequate training in research ethics**
- **Insufficient resources (equipment, space and personnel)**
- **No local accreditation for the RECs**
- **Absence of a network to ensure communication between different RECs**

# **Present day scenario of research ethics in the Muslim world**

- **Research ethics is an emergent concept**
- **The role of research ethics and more specifically, research ethics committees (RECs), is in developing phase/state**
- **Several RECs exist, but many lack essential resources for effective functioning**
- **There are little data from Egyptian RECs regarding their Structure & function and resources needs**

# Important players and actors

- **The Islamic Organization for Medical Sciences (IOMS) and the Gulf Cooperation Council (GCC) are the two leading entities currently at the forefront of advocacy and increasing awareness for the need for developing ethical review mechanisms in the Region.**
- **Recently, the Organization of Islamic Conference Standing Committee on Science and Technology (COMSTECH) based in Islamabad, Pakistan established an Advisory Committee on Bioethics with members from different Islamic countries.**
- **The Islamic Educational, Scientific and Cultural Organization (ISESCO) has also been actively promoting ethical norms and values in the Region**
- **Middle East Research Ethics Training Initiative (MERETI), with the support of Fogarty International Center, National Institutes of Health, and the University of Maryland School of Medicine, USA, is operative in enhancing career development of individuals and strengthening institutional training capacity & ethics review systems**
- **UNESCO – An important partner for promotion of bioethics**

# **Capacity mapping of national ethics committees in the WHO's Eastern Mediterranean Region\***

- **Aims of the Study:**
  - **Conduct a survey to determine the characteristics of existing NECs**
  - **Identify perceived resources & capacity building needs of the surveyed countries**

**\* A recent study by the Regional Office (in press)**

## Response of 17 countries regarding presence of national ethics committee

Country Names	Presence of National Ethics Committee
Afghanistan, Bahrain, <b>Egypt</b> , Islamic Republic of Iran, Jordan, Kingdom of Saudi Arabia, Lebanon, <b>Libya</b> , Oman, Pakistan, Syrian Arab Republic, <b>Sudan</b> , <b>Tunisia</b> , United Arab Emirates, and Yemen.	<b>Yes</b> (15 countries, 88% of responding countries)
<b>Djibouti</b> , <b>Morocco</b>	<b>No</b> (2 countries, 12% of responding countries)
Iraq, Palestine, Somalia, Qatar, Kuwait	Did Not Respond (5 countries)

## Composition of national ethics committees

<b>Specialty</b>	<b>Percentage (frequency)</b>
<b>National Ministry</b>	<b>40% (6/15)</b>
<b>Medical Doctor</b>	<b>100% (15/15)</b>
<b>Scientist</b>	<b>33% (5/15)</b>
<b>Social Scientist</b>	<b>27% (4/15)</b>
<b>Public Health</b>	<b>13% (2/15)</b>
<b>Epidemiologist</b>	<b>13% (2/15)</b>
<b>Nurse</b>	<b>20% (3/15)</b>
<b>Pharmacy</b>	<b>13% (2/15)</b>
<b>Legal Expert</b>	<b>60% (9/15)</b>
<b>Religious</b>	<b>33% (5/15)</b>
<b>Community Member</b>	<b>13% (2/15)</b>
<b>Journalist</b>	<b>13% (2/15)</b>
<b>Bioethicist</b>	<b>13% (2/15)</b>
<b>Human Rights Council</b>	<b>13% (2/15)</b>
<b>Other</b>	<b>53% (8/15)</b>

# Activities of national ethics committees

<b>Activities</b>	<b>Percentage (Frequency)</b>
<b>Review of Medical Research Protocols</b>	<b>67% (10/15)</b>
<b>Conduct training activities at the national level</b>	<b>47% (7/15)</b>
<b>Develop publications in ethics</b>	<b>67% (10/15)</b>
<b>Provide an advisory role to policy makers</b>	<b>47% (7/15)</b>
<b>Provide "overseeing" "follow up" to policy makers on ethics issues and decisions</b>	<b>53% (8/15)</b>

# Challenges being faced by national ethics committees

<b>Challenges</b>	<b>Percentage (Frequency)</b>
<b>The need to develop appropriate national ethical guidelines</b>	<b>86% (13/15)</b>
<b>Lack of training of members in medical ethics</b>	<b>67% (10/15)</b>
<b>Lack of ongoing training in medical ethics</b>	<b>73% (11/15)</b>
<b>Inadequate ability to monitor approved protocols</b>	<b>60% (9/15)</b>

# Ethical considerations by national ethics committees

<b>Ethical Considerations</b>	<b>Percentage (Frequency)</b>
<b>Monitoring and oversight</b>	<b>87% (13/15)</b>
<b>Assessment of understanding of informed consent</b>	<b>80% (12/15)</b>
<b>Privacy and confidentiality</b>	<b>80% (12/15)</b>
<b>Provision of appropriate risk reduction measures</b>	<b>80% (12/15)</b>
<b>Assessment of cultural sensitivity for informed consent</b>	<b>73% (11/15)</b>
<b>Placebo controlled trials</b>	<b>73% (11/15)</b>
<b>Determination of appropriate subject selection in vulnerable populations</b>	<b>67% (10/15)</b>
<b>Assessment of anticipated benefits</b>	<b>67% (10/15)</b>
<b>Community participation</b>	<b>67% (10/15)</b>
<b>Determinations to conduct Phase I, II, and III clinical trials in a country or community</b>	<b>60% (9/15)</b>
<b>Incentives for participation</b>	<b>60% (9/15)</b>

# **Interventions and plans of WHO EMRO**

- **The focus of the WHO's drive to strengthen regional research ethics capacities is through advocacy consultations, meetings, seminars, workshops and research through national and regional level activities and in partnership with interested stakeholders**
- **The Regional Office has carried out short-term training programmes for the Member States**
- **The Regional Office in partnership with the University of Toronto in Canada has funded a programme to train health care professionals from the EM Member States for a Masters in Bioethics**
- **A similar short-term training programme has been initiated in collaboration with the University of Maryland, USA**
- **The Regional Office also engages with international organizations such as Council for International Organization of Medical Sciences (CIOMS), Islamic Organization of Medical Sciences IOMS, ISESCO, UNESCO and others to organize international meetings and seminars on key issues related to bioethics.**

## **Interventions and plans.....**

- **Regional expert meeting to develop regional guidelines for ethics of embryo research (February 2008).**
- **First meeting of the forum on bioethics for the Eastern Mediterranean Region of WHO and Arab Region of UNESCO (August 2008)**
- **Mapping infrastructure for ethical review of research in the Region (ongoing)**
- **Provide technical assistance to the Member States to establish national ethics review committees (ongoing)**
- **Second Regional meeting for national bioethics committees (2009)**
- **The Regional Office also recently established a Research Ethics Review Committee and in future all health research proposals involving human subjects that will be conducted or supported by the Regional Office will be reviewed by the Committee**

# Next steps

- **Meeting of interested parties (April 2009)**
- **Making ethics a priority component of RPC**
- **Advocacy and engagement with member states, development partners and civil society**
- **Strengthen capacities of researchers and abilities of policy makers**
- **Networking and developing partnerships with important global partners**

**Thank You**

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