

# **Adequacy of Ethical Review and Informed Consent Documents in Investigations Submitted For Funding To The Eastern Mediterranean Region of the World Health Organization**

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**Background:** Many countries of the Eastern Mediterranean Region of the World Health Organization (EMRO) lack resources and have weak infrastructure for conducting health research. Another concern involves the lack of awareness of the ethical aspects of research, including the need for ethical review and informed consent.

**Aim:** To determine the extent of ethical review and the adequacy of informed consent documents among biomedical researchers in the EMRO countries.

**Methods:** The present study is based on the ethical considerations undertaken/envisaged by 143 health researchers from 12 countries of EMRO. These researchers were applicants for two research Grants in 2006, established by EMRO/WHO: one for research in applied biotechnology and genomics in health and the other grant for research in priority areas of public health. In this study, we evaluated the researcher's awareness of the need for ethical review of his/her research. We also reviewed the informed consent document submitted by applicants and evaluated these documents regarding the inclusion of the basic elements of informed consent.

**Results:** The submitted research proposals intended to involve the participation of human subjects in 85% of cases. Proposals included the use of interviews/surveys (66.7%), collection of biological samples (13.3%), and interventional studies (13%). Ethical review was obtained prior to submission in 30% of the proposals. Of the studies that involved human subjects, only 34.5% of investigators declared that informed consent was not needed from subjects and of those who were aware of the need to obtain informed consent, only 47% submitted the informed consent document, as required by the EMRO application. Evaluation of the submitted informed consent documents showed that the purpose of the study was explained in 50%, a statement that the activity involves research was present in 56%, an adequate explanation of the procedures was present in 38%, risks related to participation in the study were mentioned in only 37% of the documents, mention of benefits occurred in 50% of the documents, a statement that participation is voluntary or that the subject has the right to withdraw from the study was mentioned in 75% of the documents, and a statement regarding confidentiality was mentioned in 94% of the documents with varied degrees of completeness.

**Conclusion:** This study demonstrated that among researchers submitting grant applications to EMRO/WHO, there is a lack of awareness regarding the need for ethical review and in obtaining informed consent. Also, severe deficiencies regarding the inclusion of the basic elements of informed consent were noted in many of the submitted informed consent documents. These findings suggest a need for intensive training in bioethical concepts for researchers of genomics and biotechnology. Training on the ethics of biomedical research will be established at the national level in EMRO countries.