Curriculum Guide for Research Ethics Workshops for Countries in the Middle East
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Topic: Regulations and Guidelines

Problem/Issue Statement

Introduction: Since health research involves the participation of human subjects, it has become increasingly important to offer training in research ethics to those involved in the research endeavor. Such training helps ensure the ethical conduct of research and the protection of the rights and welfare of subjects. International organizations have made explicit recommendations encouraging researchers and members of research ethics committees (RECs) to complete a basic training program. To complement the use of these training programs, interactive workshops have the greatest potential to incorporate the most effective participatory learning styles. To be effective, such workshops should contain the appropriate content and learning styles geared towards the targeted audience. The Middle East Research Ethics Training Initiative (MERETI) has embraced the concept of multi-day workshops in research ethics targeted for different audiences.

Aim: We developed a curriculum training guide and associated learning materials to provide educational training in research ethics.

Description of Program/Research

We started by forming a Workshop Development Team and divided into two groups to develop curricula for members of research ethics committees and investigators. The team held discussions regarding the curriculum of multi-day workshops and then identified a set of core competencies defined as the "ability to perform a complex task or function" and consists of the requisite knowledge, skills, and attitudes to complete the specified task or function which state specifically what the learner should expect to learn (content area) and what the learner will be able to demonstrate upon completion of the program (behavioral action verb). Learning objectives may be classified into three domains: cognitive (knowledge and problem-solving skills), performance skills, and affective (attitudinal). The cognitive objectives, arranged from less to more complex, include knowledge, comprehension, application, analysis, synthesis, and evaluation. Emphases were placed on the higher-order cognitive objectives (e.g. apply, analyze, evaluate) in addition to those involving merely the acquisition of knowledge and understanding (e.g., identify, distinguish). The performance skills include the ability to write an informed consent form and to conduct its discussion with potential subjects without being misleading or coercive. Affective objectives refer to specific attitudes, values, beliefs, biases, emotions expected by learners to develop as a result of the instructional process.

Results: The team achieved consensus regarding the overall goal of workshops and on the basic core competencies needed to achieve this goal. These competencies for investigators and members of research ethics committees are in modular units incorporating the specific learning objectives of the core topics to achieve these core competencies as well as the corresponding instructional activities and learning materials to achieve the learning objectives. These learning materials can be obtained from the Workshop Committee Training website. Instructional activities applicable for the cognitive/knowledge learning objectives include lectures and articles for self-reading, whereas those to achieve objectives in the cognitive-problem solving domain (higher-order cognitive objectives) include the following: case studies, analysis of research protocols/informed consent documents, use of trigger videos to generate discussions. And those applicable for achieving performance skills include: role play involving the informed consent process; the writing of an informed consent form and mock REC review of protocols, while for the affective domain include: presentation of films. Many of these materials are relevant to the Middle East; for example, several articles were co-authored by investigators in the Middle East and several source documents are in Arabic. Many of the PowerPoint slide sets incorporate Arabic phrases and hence, would be suitable for an Arabic audience. Finally, many of the informed consent exercises, case studies, and research protocols are relevant to studies being performed in the Middle Eastern countries. Conclusion Workshops in research ethics have

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been commonly used in developing countries as well as in developed countries. Such short-term training experiences can reach large audiences. We have suggested modular units and model agendas for such workshops that will ensure consistency in content as well as excellence across different developed workshops. The range of content included in the modules in the core curriculum should be sufficient for a broad range of audiences involved in research or the review of research. We expect that these workshop materials will provide a sustainable education resource for educators in research ethics.