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CURRICULUM GUIDE FOR RESEARCH ETHICS WORKSHOPS FOR COUNTRIES IN THE MIDDLE EAST

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Abstract

To help ensure the ethical conduct of research, many have recommended educational efforts in research ethics to investigators and members of research ethics committees (RECs). One type of education activity involves multi-day workshops in research ethics. To be effective, such workshops should contain the appropriate content and teaching techniques geared towards the learning styles of the targeted audiences. To ensure consistency in content and quality, we describe the development of a curriculum guide, core competencies and associated learning objectives and activities to help educators organize research ethics workshops in their respective institutions. The curriculum guide is divided into modular units to enable planners to develop workshops of different lengths and choose content materials that match the needs, abilities, and prior experiences of the target audiences. The content material in the curriculum guide is relevant for audiences in the Middle East, because individuals from the Middle East who participated in a Certificate Program in research ethics selected and developed the training materials (e.g., articles, powerpoint slides, case studies, protocols). Also, many of the activities incorporate active-learning methods, consisting of group work activities analyzing case studies and reviewing protocols. The development of such a workshop training curriculum guide represents a sustainable educational resource to enhance research ethics capacity in the Middle East.

Keywords

bioethics; education; developing world bioethics; research ethics

INTRODUCTION

In order to relieve the burden of disease, the health research agenda in developing countries has grown enormously over the recent decade. Since health research involves the participation of human subjects, it has become increasingly important to offer training in research ethics to those involved in research. Such training helps ensure the ethical conduct of research and the protection of the rights and welfare of subjects. Educational efforts need to be made available at all levels of training and in different formats. 1. For example, research ethics training should be offered at both the undergraduate and postgraduate levels, so that students can learn principles of research ethics prior to and as they become involved in research activities. Intensive certificate and master's level programs in research ethics should also be developed, so that individuals can gain the necessary expertise to become leaders in research ethics in their respective institutions and countries.

International organizations have made explicit recommendations encouraging researchers and members of research ethics committees (RECs) to complete a basic training program on the ethics of research involving human subjects.² Several CD-ROM-based and Web-based curricula are available, but they are mostly designed to meet United States (U.S.) regulatory requirements and might not be appropriate for an international audience.³ Recently, the Collaborative Institute Training Initiative (CITI) program based at the University of Miami, Florida, developed web-based learning modules that were specifically tailored for investigators working in developing countries.⁴ Web-based training, however, lacks an active learning style thought to be needed for enriched learning.

To complement the use of web-based training programs, interactive workshops have the greatest potential to incorporate participatory learning styles. In order to be effective, such workshops should contain the appropriate content and teaching techniques geared towards the learning styles of the targeted audience. Workshops that target members of research ethics committees and research staff (investigators and research coordinators) would complement the more formal training available in academic institutions. Such workshops necessarily embrace a short time-frame due to the time constraints of the intended audiences. Recently, Family Health International, a U.S.-based international research organization, developed a Research Ethics Training Curriculum targeted at an international audience that involved the use of interactive case studies.⁵ This curriculum was designed for group training or to be an interactive self-study program. The case studies, however, are limited, in that they are entirely focused on HIV research issues.

The Middle East Research Ethics Training Initiative (MERETI), a research ethics training program involved in the career development of individuals from the Middle East and funded by the Fogarty International Center (FIC) of the National Institutes of Health, has embraced the concept of multi-day workshops in research ethics that target different audiences in the Middle East.⁶ To ensure consistency in content and quality, trainees from the 2007 MERETI Training Program developed a curriculum training guide and associated learning materials to help educators organize research ethics workshops in their institutions. The development of such a workshop training guide represents a sustainable educational resource to enhance research ethics capacity in the Middle East.

In this paper, we describe the development of this workshop curriculum guide, provide the learning materials that organizers can use in their research ethics workshops, and present sample workshop agendas that take into account the knowledge needs and time constraints of the intended targeted audiences.

METHODS

Participants

The MERETI Training Program in Research Ethics incorporates a 12-month certificate course that includes a two-month academic program held at the University of Maryland, Baltimore (UMB), U.S.A.⁷ In 2007, trainees from the Middle East (Egypt, Jordan, and Sudan) and Pakistan participated in this Certificate Course. The group consisted of seven physicians, two dentists, and one nurse. Funding for the program was provided by the Fogarty International Center of the National Institutes of Health, Bethesda, Maryland; the Eastern Mediterranean Regional Office of the WHO provided funding for two trainees. During the academic program, the trainees, in conjunction with the MERETI faculty, formed a Workshop Development Team that held discussions regarding the design of a curriculum guide for multi-day workshops in research ethics.

Development of the workshop curriculum guide

Core competencies—The Workshop Development Team decided that the targeted audience for the research ethics workshops would include investigators and members of RECs. Once these learners were identified, the Workshop Development Team identified a set of core competencies for the curriculum. A competency is defined as the ‘ability to perform a complex task or function’ and consists of different bundles of knowledge, skills, and attitudes to complete the specified task.⁸ Each competency specifies a learning outcome that can be observed; that is, competencies 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 (behavioural action verb). Finally, core competencies should reflect what the learner needs to know and be able to do (workforce focused) rather than what academics believe learners need to know (teacher-focused).⁹ The Workshop Development Team relied on several sources in developing the core competencies for research ethics training, including the curriculum of the MERETI Certificate Course.¹⁰

Learning objectives—A more specific type of outcome statement consists of learning objectives that describe the more specific knowledge, skills, and attitudes that a learner is expected to demonstrate upon completion of the course.¹¹ A combination of course-specific objectives is usually necessary to achieve the broader core competencies. Learning objectives include only one general learning outcome and may be classified into three domains: cognitive (knowledge and problem-solving skills), performance skills, and affective (attitudinal).¹² The goal of affective objectives is to develop certain human responses to the content. However, given the brevity of the planned workshop courses, it may be unreasonable to achieve appreciable changes in affective objectives. Rather, one may expect changes in awareness or interest (i.e., lower order affective objectives) rather than commitment to an attitude or preference for a value (higher order affective objectives).

Instructional activities—Instructional activities provide the means by which a curriculum’s objectives are achieved. The lowest level of the cognitive domain – the knowledge objectives – can be achieved by a great variety of learning experiences consisting of simple communication of information, for example, readings and lectures. The more complex and higher categories of the cognitive domain – the problem-solving objectives – require far more sophisticated active learning experiences.¹³ In general, learners remember more when they have learned to handle the topic at the higher levels of the cognitive domain. Accordingly, the Workshop Development Team gave attention to the use of active learning methods that would be participatory, interactive (with peers and faculty), and case-based. Such activities would include group work involving problem-solving exercises (i.e., case studies and research protocols in which learners can consider real-world examples of ethical issues).

The Workshop Development Team identified certain instructional activities directed towards the enhancement of performance skills, for example, informed consent writing exercises and role play involving the obtainment of informed consent. Instructional activities to achieve affective objectives over a short time frame would include literary readings and the viewing of film segments.

The Workshop Development Team achieved consensus on the instructional activities and associated materials that were appropriate and relevant to audiences in the Middle East.

Development and consensus process

The Workshop Development Team divided into two groups to develop curricula for the two different targeted audiences: investigators and members of RECs. The groups decided it

would be helpful to break down each core competency into core topics, each with separate learning objectives and instructional activities. Such core topics would represent modular units from which workshop planners would be able to choose a set that would be most appropriate for the intended audience and the time allocated for each workshop. After the members of the Workshop Development Team returned to their home countries, the consensus process continued through informal email discussions.

RESULTS

The Workshop Development Team achieved consensus regarding the overall goal of workshops in research ethics for targeted audiences in developing countries:

To provide educational training in research ethics that will enhance the protection of the rights and welfare of individuals who participate in research.

Consensus was also achieved on the core competencies needed to achieve this goal. The competencies for members of RECs and investigators are shown in Table 1. This table also shows the modular units incorporating the specific topics and associated learning objectives to achieve these core competencies. Finally, Table 1 shows the corresponding instructional activities and learning materials to achieve the outcomes specified by the learning objectives. These learning materials are available electronically from the MERETI website (go to: www.mereti.net and click on Workshop Curriculum on the left-hand side) and can also be accessed from the corresponding footnotes shown in Table 1.

Instructional activities applicable for the lower-order cognitive/knowledge objectives include PowerPoint lectures and articles for self-reading. Table 1 also provides links to videocasts of presentations performed by trainees of the MERETI Certificate Course, which provide the relevant narratives of the PowerPoint slides.

Instructional activities to achieve the higher-order cognitive objectives in the problem solving domain include the following:

- Case studies performed within groups or individually followed by group discussions;
- Analysis of research protocols/informed consent documents;
- Use of trigger videos to generate discussions.

Instructional activities relevant to achieving the identified performance skills include:

- Role play involving the informed consent process;
- The writing of an informed consent form;
- Mock IRB review of protocols.

Instructional activities applicable for learning objectives in the affective domain include:

- Presentation of films, such as:
 - ‘*Extreme Measures*’ (Simian. 1996), a film demonstrating the tension between the goals of achieving scientific progress and respect for human rights; vulnerable homeless individuals are targeted for risky spinal research without their consent
 - ‘*Dr. Jekle and Mr. Hyde*’ (Rouben Mamoulianand, Director, 1931) and ‘*Frankenstein*’ (James Whale, Director, 1931): films demonstrating medical hubris leading to unexpected adverse events from scientific experiments.

- ‘Wit’, beginning segment demonstrating an attending physician obtaining informed consent from a patient with newly diagnosed with ovarian cancer for participation in a chemotherapy clinical trial.

Several of the articles chosen by the Workshop Development Team were co-authored by individuals from the Middle East and several documents are in Arabic. Many of the PowerPoint slide sets incorporate Arabic phrases, thereby enhancing their relevance to an Arabic audience. Finally, many of the informed consent exercises, case studies, and research protocols reflect researches performed in the Middle East.

Table 2 shows examples of workshop agendas for different time-frames and audiences, i.e., investigators and REC members. The Workshop Development Team also developed an evaluation form for participants in the workshop (Figure 1), which can be used by workshop organizers to obtain feedback regarding participant satisfaction with the workshop.

DISCUSSION

We have developed a comprehensive training curriculum for research ethics workshops intended for investigators and REC members. The curriculum is divided into modular units to enable planners to have the flexibility to develop workshops of the appropriate length and content that meet the needs, abilities and prior experiences of the target audiences. Each modular unit is described by learning objectives and contains the corresponding instructional activities and materials. Workshop planners can use the various instructional materials that are suitable to the learning styles and needs of their intended audiences.

All of the training materials (e.g., articles, PowerPoint slides, case studies and protocols) are relevant for audiences in the Middle East, because the Workshop Development Team consisted of individuals from this region and they achieved consensus on what they thought would be most appropriate for the learning needs and styles of their colleagues at their home institutions. Also, several of the articles were written by authors from the Middle East and many of the PowerPoint slides contain Arabic text. Finally, many of the protocols represent research that is typically performed in the Middle East.

Many of the activities incorporate active-learning methods consisting of group work activities, whereby participants work together on a case study or a review of a protocol. Such participatory learning activities, as opposed to passive learning techniques (e.g., lectures), result in the development of critical thinking skills that are often needed in solving ethical dilemmas. Examples of workshops agendas are also presented and have been modeled after workshops that have been performed in the Middle East. These agendas contain modular units that incorporate learning objectives from all of the learning domains: cognitive (knowledge and problem-solving), performance skills, and affective domains.

Also included in the training materials is a sample evaluation form with which organizers can have the participants complete to evaluate the workshops. Such evaluations provide a useful tool to gain invaluable feedback on the adequacy of the content, the performance of the lecturers, and the relevance of the group activities. Such a satisfaction tool, however, does not measure the extent to which the individual participants have achieved any of the core competencies or learning objectives. To be sure, organizers can use pre- and post-quizzes to test for the acquisition of factual knowledge gained from the workshops. Such short answer tests do not, however, assess the acquisition of higher-order problem-solving skills or performance skills. Due to the time constraints of the participants attending these workshops, it might not be feasible to test for these more involved learning skills. Also, workshops organizers should expect that the achievement of the more complex learning outcomes would be modest for the shorter workshops (i.e., one- and two-day workshops).

Acquisition of awareness and basic factual knowledge, however, should be considered a good start, especially in a region where the concept of research ethics has just come to the forefront of the research enterprise. Longer workshops might be expected to be more successful in achieving the higher-order learning objectives. Further research is necessary to test these assumptions.

SUMMARY

Workshops in research ethics have 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 agendas for such workshops that will ensure consistency in content as well as consistency 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 in the review of research. We expect that these workshop materials will provide a sustainable educational resource that will enhance research ethics capacity.

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The image shows a small, low-resolution scan of a form titled "Agenda Evaluation Form". The form contains several sections with headings and corresponding rows for evaluation. The sections include: "1. Agenda Item", "2. Agenda Item", "3. Agenda Item", "4. Agenda Item", "5. Agenda Item", "6. Agenda Item", "7. Agenda Item", "8. Agenda Item", "9. Agenda Item", "10. Agenda Item", "11. Agenda Item", "12. Agenda Item", "13. Agenda Item", "14. Agenda Item", "15. Agenda Item", "16. Agenda Item", "17. Agenda Item", "18. Agenda Item", "19. Agenda Item", "20. Agenda Item", "21. Agenda Item", "22. Agenda Item", "23. Agenda Item", "24. Agenda Item", "25. Agenda Item", "26. Agenda Item", "27. Agenda Item", "28. Agenda Item", "29. Agenda Item", "30. Agenda Item", "31. Agenda Item", "32. Agenda Item", "33. Agenda Item", "34. Agenda Item", "35. Agenda Item", "36. Agenda Item", "37. Agenda Item", "38. Agenda Item", "39. Agenda Item", "40. Agenda Item", "41. Agenda Item", "42. Agenda Item", "43. Agenda Item", "44. Agenda Item", "45. Agenda Item", "46. Agenda Item", "47. Agenda Item", "48. Agenda Item", "49. Agenda Item", "50. Agenda Item", "51. Agenda Item", "52. Agenda Item", "53. Agenda Item", "54. Agenda Item", "55. Agenda Item", "56. Agenda Item", "57. Agenda Item", "58. Agenda Item", "59. Agenda Item", "60. Agenda Item", "61. Agenda Item", "62. Agenda Item", "63. Agenda Item", "64. Agenda Item", "65. Agenda Item", "66. Agenda Item", "67. Agenda Item", "68. Agenda Item", "69. Agenda Item", "70. Agenda Item", "71. Agenda Item", "72. Agenda Item", "73. Agenda Item", "74. Agenda Item", "75. Agenda Item", "76. Agenda Item", "77. Agenda Item", "78. Agenda Item", "79. Agenda Item", "80. Agenda Item", "81. Agenda Item", "82. Agenda Item", "83. Agenda Item", "84. Agenda Item", "85. Agenda Item", "86. Agenda Item", "87. Agenda Item", "88. Agenda Item", "89. Agenda Item", "90. Agenda Item", "91. Agenda Item", "92. Agenda Item", "93. Agenda Item", "94. Agenda Item", "95. Agenda Item", "96. Agenda Item", "97. Agenda Item", "98. Agenda Item", "99. Agenda Item", "100. Agenda Item". Each section has a row of checkboxes or a small table for evaluation.

Figure 1.
Agenda Evaluation Form

Table 1
Core Competencies and Associated Learning Objectives and Instructional Strategies

Core Competency 1 - Ability to explain the importance and role of research ethics in the research enterprise.	
General Introduction to Research Ethics Learning Objectives <ul style="list-style-type: none"> Describe the historical background of research ethics in health research. Explain how a concept of human rights is integral in understanding human research protections. 	Instructional Strategiesⁱ <ul style="list-style-type: none"> Lectures: <ul style="list-style-type: none"> PowerPoint Slide Sets: History of Research Ethics Research and Human Rights Video cast: Why Research Ethics? Self-Study: <ul style="list-style-type: none"> Articles Internet Resource: 'An Apology 65 Years Late - A News Hour With Jim Lehrer; PBS' Films: <i>Dr. Jekle and Mr. Hyde</i>; <i>Frankenstein</i>
International Research Ethics Learning Objectives <ul style="list-style-type: none"> Demonstrate a familiarity with international codes of research ethics (Helsinki, Belmont, CIOMS, IOMS, etc). Identify the problematic issues involved in the ethics of international research 	Instructional Strategiesⁱⁱ <ul style="list-style-type: none"> Lectures: <ul style="list-style-type: none"> PowerPoint Slide Sets: Ethics of International Research International Research Ethics Guidelines Self-Study: <ul style="list-style-type: none"> Articles Research Ethics Guidelines Group Work Exercise
Core Competency 2 – Ability to describe and use relevant concepts in research ethics and research methods	
Therapeutic Misconception Learning Objective <ul style="list-style-type: none"> Distinguish between the ethics in medical practice and the ethics in the research context. 	Instructional Strategiesⁱⁱⁱ <ul style="list-style-type: none"> Lecture: <ul style="list-style-type: none"> PowerPoint slide set: Therapeutic Orientation to Clinical Trials Self-Study <ul style="list-style-type: none"> Articles Group Work Exercises
Research and Clinical Trials I Learning Objectives <ul style="list-style-type: none"> Explain a regulatory definition of 'human subjects' and 'research'. Distinguish between the different phases of clinical trials 	Instructional Strategies^{iv} <ul style="list-style-type: none"> Lecture: <ul style="list-style-type: none"> PowerPoint Slide Set: Clinical Trial Design and Ethics

Core Competency 1 - Ability to explain the importance and role of research ethics in the research enterprise.	
<ul style="list-style-type: none"> Describe the ethical dimensions of different types of research, including clinical trials and qualitative and quantitative studies. 	<ul style="list-style-type: none"> Self-Study <ul style="list-style-type: none"> Articles
Research and Clinical Trials II Learning Objectives <ul style="list-style-type: none"> Identify researches that qualify for exempt from ongoing REC oversight 	Instructional Strategies^v <ul style="list-style-type: none"> Lecture: <ul style="list-style-type: none"> PowerPoint Slide Set: Exempt Research Self-Study <ul style="list-style-type: none"> Articles
Core Competency 3 - Ability to explain and apply the basic ethical requirements for research	
What Makes Research Ethical Learning Objectives <ul style="list-style-type: none"> Describe the basic ethical requirements for health research. Apply the basic ethical requirements for research in the review of a research protocol. 	Instructional Activities^{vi} <ul style="list-style-type: none"> Lecture: <ul style="list-style-type: none"> PowerPoint Slide Set: What Makes Research Ethical Self-Study <ul style="list-style-type: none"> Articles Group Work: Use of a checklist in the review of a protocol Protocol: Multicenter Observational Study to Assess the Safety of Outpatient Treatment of Severe Pneumonia with Oral Amoxicillin in Children aged 3 – 59 months: A Pilot Safety Study
Informed Consent I Learning Objectives <ul style="list-style-type: none"> Identify the basic elements of informed consent. Assess the appropriateness of an informed consent process. Evaluate an informed consent form by the use of a checklist 	Instructional Activities^{vii} <ul style="list-style-type: none"> Lecture: <ul style="list-style-type: none"> PowerPoint Slide Set: Informed Consent; Case on Informed Consent Self-Study <ul style="list-style-type: none"> Articles Template Consent Forms Informed Consent Checklist Group Work Exercises: <ul style="list-style-type: none"> Yellow Fever Informed Consent Consent form: “Biomarkers for detecting active Schistosomiasis” Video cast: Ethics of Bioequivalence Trials
Informed Consent II Learning Objectives:	Instructional Activities^{viii}

Core Competency 1 - Ability to explain the importance and role of research ethics in the research enterprise.	
<ul style="list-style-type: none"> • Demonstrate how to write an informed consent document. • Demonstrate how to obtain informed consent. 	<ul style="list-style-type: none"> • Film: Beginning segment of 'Wit' • Exercise: write a consent form from a previously reviewed protocol • Exercise: Role-play of an informed consent process
Waiver of Informed Consent Learning Objectives: <ul style="list-style-type: none"> • Identify when it is appropriate to waive informed consent. • Analyze cases involving waiver of informed consent 	Instructional Activities^{ix} <ul style="list-style-type: none"> • Lecture: <ul style="list-style-type: none"> – PowerPoint Slide Set: Waiver of Informed Consent • Self-Study <ul style="list-style-type: none"> – Articles • Group Work: Cases on Informed Consent
Vulnerability Learning Objectives: <ul style="list-style-type: none"> • Identify vulnerable groups • Explain what it means to be vulnerable • Analyze issues involved with vulnerability 	Instructional Activities^x <ul style="list-style-type: none"> • Lecture: <ul style="list-style-type: none"> – PowerPoint Slide Set: Research on Vulnerable Populations • Self-Study <ul style="list-style-type: none"> – Articles • Group Work Exercises • Film: <i>Extreme Measures</i>
Research Involving the Mentally Ill Learning Objectives: <ul style="list-style-type: none"> • Describe how the mentally ill can be vulnerable • Identify the safeguards for the mentally ill when they participate in research • Assess a research protocol involving mentally ill patients 	Instructional Activities^{xi} <ul style="list-style-type: none"> • Lecture: <ul style="list-style-type: none"> – PowerPoint Slide Set: Ethics of Research Involving the Mentally Ill Case Study • Self-Study <ul style="list-style-type: none"> – Articles • Group Work Protocol Review
Evaluating Risks and Benefits Learning Objectives: <ul style="list-style-type: none"> • Identify what counts as benefits and risks in a research protocol 	Instructional Activities^{xii} <ul style="list-style-type: none"> • Lecture: <ul style="list-style-type: none"> – PowerPoint Slide Set: "Balancing Risks and Benefits" • Self-Study <ul style="list-style-type: none"> – Articles

Core Competency 1 - Ability to explain the importance and role of research ethics in the research enterprise.	
<ul style="list-style-type: none"> Assess the risks and benefits of a protocol 	<ul style="list-style-type: none"> Group Work Exercise: Case assessing risks and benefits of a clinical trial involving patients with Hepatitis C
Core Competency 4 - Ability to describe the importance of Good Clinical Practice in the conduct of research.	
Good Clinical Practice Learning Objective	Instructional Activities^{xiii}
<ul style="list-style-type: none"> Describe the role of International Conference on Harmonisation List clinical researcher responsibilities Describe the reporting requirements for adverse events. 	<ul style="list-style-type: none"> Lecture: PowerPoint Slide Sets Self-Study <ul style="list-style-type: none"> Articles
Data Safety Monitoring Learning Objective	Instructional Activities^{xiv}
<ul style="list-style-type: none"> Identify the ways in which data safety monitoring can occur during the conduct of research. 	<ul style="list-style-type: none"> Lecture: PowerPoint Slide Set <ul style="list-style-type: none"> Ensuring Investigator Compliance and Improving Performance Ethical Issues Involving Monitoring and Oversight of Research Self-Study <ul style="list-style-type: none"> Articles
Core Competency 5 - Ability to identify and explain the purposes and functions of research ethics committees.	
Research Ethics Committees I Learning Objectives	Instructional Activities^{xv}
<ul style="list-style-type: none"> Explain the reasons for independent review. Describe the functions and roles of an REC 	<ul style="list-style-type: none"> Lecture: <ul style="list-style-type: none"> PowerPoint Slide Set Self reading <ul style="list-style-type: none"> Articles Decision Charts
Research Ethics Committee II* Learning Objectives	Instructional Activities^{xvi}
<ul style="list-style-type: none"> Define typical committee structure Describe the characteristics of effective ethics committee meetings Describe the educational needs of ethics committee members Describe the skills required of ethics committee members 	<ul style="list-style-type: none"> Lecture: <ul style="list-style-type: none"> PowerPoint Slide Set Self reading <ul style="list-style-type: none"> Articles: Egyptian SOPs WHO Document
Core Competency 6 - Ability to evaluate the ethical aspects of research protocols	
Protocol Review*	Instructional Activities^{xvii}

Core Competency 1 - Ability to explain the importance and role of research ethics in the research enterprise.		
Learning Objectives		Protocol for Review
<ul style="list-style-type: none"> Evaluate the scientific and ethical aspects of a research protocol Demonstrate an ability to discuss opinions and listen with respect to the views of others. 		<ul style="list-style-type: none"> Video cast: Example of a Research Ethics Committee Meeting
		<ul style="list-style-type: none"> Protocol Review Checklist

* modules designated only for members of research ethics committees

- ⁱ Middle East Research Ethics Training Initiative (MERETI). 2009. *General Introduction to Research Ethics*. Available at: http://medschool.umaryland.edu/mereti/matrix_historyofresearchethics.asp [Accessed 29 Jun 2009]
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- ^{iv} Middle East Research Ethics Training Initiative (MERETI). 2009. *Research and Clinical Trials I*. Available at: http://medschool.umaryland.edu/mereti/matrix_clinicaltrialdesignandethics.asp [Accessed 29 Jun 2009]
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- ^{viii} Middle East Research Ethics Training Initiative (MERETI). 2009. *Informed Consent II*. Available at: http://medschool.umaryland.edu/mereti/matrix_informedconsentexercises.asp [Accessed 29 Jun 2009]
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- ^{xi} Middle East Research Ethics Training Initiative (MERETI). 2009. *Research Involving the Mentally Ill*. Available at: http://medschool.umaryland.edu/mereti/matrix_researchinvolvingmentallyill.asp [Accessed 29 Jun 2009]
- ^{xii} Middle East Research Ethics Training Initiative (MERETI). 2009. *Evaluating Risks and Benefits*. Available at: http://medschool.umaryland.edu/mereti/matrix_Evaluating%20Risks%20and%20Benefits.asp [Accessed 29 Jun 2009]
- ^{xiii} Middle East Research Ethics Training Initiative (MERETI). 2009. *Good Clinical Practice*. Available at: http://medschool.umaryland.edu/mereti/matrix_good_clncl_practice.asp [Accessed 29 Jun 2009]
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- xv Middle East Research Ethics Training Initiative (MERETI). 2009. *Research Ethics Committee I*. Available at: http://medschool.umaryland.edu/mereti/matrix_researchethicscommittees.asp [Accessed 29 Jun 2009]
- xvi Middle East Research Ethics Training Initiative (MERETI). 2009. *Research Ethics Committee II*. Available at: http://medschool.umaryland.edu/mereti/matrix_rsrch_ethics_commtts2.asp [Accessed 29 Jun 2009]
- xvii Middle East Research Ethics Training Initiative (MERETI). 2009. *Protocol Review*. Available at: http://medschool.umaryland.edu/mereti/matrix_protocolreview.asp [Accessed 29 Jun 2009]

Table 2

Examples of Agendas for Research Ethics Workshops

One-Half Day Workshop	
Audience: Researchers and Members of Research Ethics Committees	
9:00 – 9:30	History of Research Ethics
9:30 – 10:00	What Makes Research Ethical
10:00 – 10:15	Discussion
10:15 – 10:45	Break
10:45 – 11:15	Informed Consent
11:15 – 12:15	Informed Consent Exercise
12:15 – 1:00	Research Ethics Committees: Roles and Functions
1:00 – 1:30	Concluding Remarks
Full Day Workshop I	
Audience: Members of Research Ethics Committees	
9:00 – 9:30	History of Research Ethics
9:30 – 10:00	What Makes Research Ethical
10:00 – 10:15	Discussion
10:15 – 10:45	Break
10:45 – 11:15	Informed Consent
11:15 – 12:15	Informed Consent Exercise
12:15 – 1:00	Research Ethics Committees: Roles and Functions
1:00 – 2:00	Lunch
2:00 – 2:30	Evaluating Risks and Benefits
2:30 – 3:00	Vulnerability
3:00 – 3:15	Discussion
3:15 – 3:45	Break
3:45 – 5:00	Group Discussion of Protocol Review
Full Day Workshop II	
Audience: Members of Research Ethics Committees	
9:00 – 9:30	History of Research Ethics
9:30 – 10:00	What Makes Research Ethical
10:00 – 10:15	Discussion
10:15 – 10:45	Break
10:45 – 11:15	Informed Consent
11:15 – 12:15	Group Work on Informed Consent Exercise
12:15 – 1:00	Research Ethics Committees: Roles and Functions
1:00 – 2:00	Lunch
2:00 – 3:00	Group Work on a Protocol
3:00 – 3:30	Break
3:30 – 5:00	Group Discussion of Protocol Review

Full Day Workshop II	
Audience: Investigators	
9:00 – 9:30	History of Research Ethics
9:30 – 10:00	What Makes Research Ethical
10:00 – 10:15	Discussion
10:15 – 10:45	Break
10:45 – 11:15	Informed Consent
11:15 – 11:45	Research Ethics Committees: Roles and Functions
11:45 – 12:00	Discussion
12:00 – 1:00	Lunch
1:00 – 2:00	Group Work on Informed Consent Exercise
2:00 – 2:30	Vulnerability
2:30 – 3:00	Break
3:00 – 3:30	Evaluating Risks and Benefits
3:30 – 4:15	Good Clinical Practice
4:15 – 4:45	Concluding Remarks