FORMATIVE EVALUATION OF A COURSE ON THE CONDUCT OF CLINICAL RESEARCH FOR HEALTHCARE PROFESSIONALS

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FORMATIVE EVALUATION OF A COURSE ON THE CONDUCT OF CLINICAL RESEARCH FOR HEALTHCARE PROFESSIONALS

By

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Abstract

This master thesis describes the formative evaluation of a clinical research management course for healthcare professionals at the King Faisal Heart Institute (KFHI) in Riyadh, Saudi Arabia. Both the instruction and formative evaluation itself were conducted between November 2007 and May 2008. Sixty learning objectives were set and sequenced based on a needs assessment of KFHI staff (n=102).

The formative evaluation plan was developed in accordance with the published method developed by Dick, Carey and Carey (2005). As a research method, formative evaluation does not purport to assess student learning. Rather its central purpose is to investigate the adequacy of the instructional materials for learning and make suggestions for revision. During the design review stage of this formative evaluation, four design reviewers conducted independent reviews of the instructional materials. During the expert review stage, three reviewers evaluated the methods of instruction and instructional materials, the pre- and post-tests questions, as well as the content, language, and grammar. In the one-to-one review stage, three reviewers evaluated the instruction and instructional material for clarity and impact on learner attitude and achievement. Finally, during the small-group stage of the formative evaluation plan, the evaluator tried out the instruction and instructional materials with 31 learners. The evaluator examined for the effects caused by the changes made in the one-to-one review and identified remaining learning problems.

The results from the research were used to make changes in the instructional materials for the Clinical Research Management Course.

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And mostly to my Mom (1920–2008) for her unfailing love and support of her children, her strength in trying times, and her demand that whatever we do, we do to the best of our ability.

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List of Abbreviations

KFHI	King Faisal Heart Institute
KFSH&RC	King Faisal Specialist Hospital and Research Centre
CRMC	Clinical Research Management Course
CRM	Clinical Research Manger

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Chapter 1: Introduction and Overview

Chapter one is an introduction to this study that focuses on the design, development, and formative evaluation of a course on the conduct of clinical research for healthcare professionals at the King Faisal Heart Institute (KFHI) in Riyadh, Saudi Arabia. Background information is presented as context for the problem under investigation. The purpose of the study is provided, and the significance of the study to the fields of medicine and education are discussed.

Background and Context of the Problem

A common problem confronting numerous hospitals and research centres in Saudi Arabia is that healthcare professionals, clinical research investigators, and support staff members are not provided adequate instruction on how to conduct clinical research in accordance with established regional, national, and international guidelines. Existing professional instruction is minimal in scope and limited in frequency to occasional workshops, lectures, or conferences that are provided when schedules permit. Specifically at the KFHI, biomedical research education has been stochastic and idiosyncratic, with no formal education programs for staff members. Knowledge sharing has been limited to hallway consultations that are usually a result of encountering difficulties when submitting research proposals for approval.

A lack of education and training has been cited by organizations and individuals as a contributing cause to the breach of research regulations, guidelines, and ethical principles when conducting biomedical research. In the United States, a Food and Drug Administration (FDA) audit cited that lack of training of research nurses contributed to

deficiencies and violations in the conduct of research (Yin, 2008). As Jones, Harrison, Catrer, and Jester (2008) stated, in the USA there is a "widespread recognition that training and education of clinical research managers (CRMs) are insufficient" (p. 202). Gorkoun (2007) cited "lack of knowledge of clinical research" as a challenge in conducting medical research globally (p. 27).

A number of options were proposed to make the needed education opportunities available to the staff of the KFHI. The options included: (a) sending staff outside of the country to attend research education programs, (b) adapting a North American or European institution's program and offer it at the KFHI, (c) utilizing existing online programs, or (d) develop and implement an appropriate internal education program. Rather than sending employees out of the country or attempting to determine which parts of the occasional workshops, lectures, and conferences need revision, it was decided by the KFHI administrators that a new course on biomedical research be designed, content developed, and a systematic evaluation conducted to answer one question: "How should these materials be revised?" This is the nature and purpose of formative evaluation as suggested in the educational literature (Dick, Carey, & Carey, 2005; Seels & Glasgow, 1990).

Purpose of the Study

The purpose of this study was to conduct a formative evaluation of a course designed to instruct healthcare professionals at the KFHI on the process of conducting biomedical research. Formative evaluation can be conducted in a variety of education settings and can be an ongoing process or conducted at specific times while a program or

course is being developed (Weston, LeMaiste, McAlpine, & Bordonaro, 1997). It was decided early in the design process of the clinical research administration course to conduct a formative evaluation using the Dick, Carey, and Carey (2005) six-step framework for conducting formative evaluations. Through the formative evaluation, it was anticipated that the strengths and weaknesses in the course would be identified and serve as the basis for making informed changes in the course to improve learning outcomes. A unique feature of this research is that it is the first formative evaluation to be conducted on a research course in Saudi Arabia.

Significance of the Study

For biomedical research to be conducted in a manner that is scientifically sound, legally conducted according to local legislation, compliant with national and international standards, and ethically appropriate, healthcare professionals who participate in research must be knowledgeable in all aspects pertinent to their specific roles. Therefore, providing education that is current and appropriate for the target audience is a responsibility of research institutions. The results of this research will be used to make improvements in the instructional materials of the clinical research mangers (CRM) course, which was designed for healthcare professionals at the KFHI. The resulting course could be used as a model to design similar courses for healthcare professionals conducting research in other regions of Saudi Arabia.

Definition of Key Terms

Throughout this thesis terms are used that may not be familiar to the reader. Therefore, it is necessary to provide definitions of key terms.

Clinical research. Clinical research involves humans as subjects and "proceeds in a systematic way to examine clinical conditions and outcomes, to establish relationships among clinical phenomena, to generate evidence for decision making, and to provide the impetus for improving methods of practice" (Portney & Watkins, 2000, p. 4)

Clinical research coordinator (CRC). The CRC is a healthcare professional who may be involved in different aspects of clinical research such as (a) recruitment and enrollment of human subject; (b) development and management of research protocols, including writing of informed consent documents, reporting of adverse events, construction of case report forms, completion of case report forms, and administrative activities; (c) data collection, analysis and monitoring; (d) protection of subjects and subjects' rights; (e) coordination with or participation in research ethics committees; (f) case management of protocol participants; and (g) maintenance of research drug inventory and accountability records (Society of Clinical Research Associates [SoCRA], 2008)

Clinical investigator. A clinical investigator is a medical researcher in charge of carrying out a clinical trial's protocol. The clinical investigator(s) should be qualified by education, training, and experience to assume responsibility for the proper conduct of the trial and should meet all the qualifications specified by the applicable regulatory requirement(s) (International Conference on Harmonization of Technical Requirements, 1996).

Clinical research management course (CRMC). The CRMC is an 80-hour educational course for healthcare professionals offered by the King Faisal Heart Institute

(KFHI). The CRMC is the subject of this study on the design, development, and formative evaluation of a course on the administration of clinical research.

Formative evaluation. A formative evaluation collects data and information during the development of instruction and uses that information to improve the effectiveness of the instruction (Dick et al., 2005). For this study, research on the design, development, and formative evaluation of a course providing instruction on the conduct of clinical research for healthcare professionals at the KFHI, a formative evaluation was used to provide critical information about how to modify the course to improve student learning.

Instructional design (ID). The ID process includes the systematic development of instructional materials and processes to ensure optimal achievement of the learning objectives. This systematic approach includes analysis, design, development, implementation, and evaluation (Dick et al., 2005).

King Faisal Heart Institute (KFHI). The KFHI is a tertiary cardiac care centre within the King Faisal Specialist Hospital and Research Centre (KFSH&RC), Riyadh, Saudi Arabia. The KFSH&RC is a government-funded, teaching hospital for adult and peadiatric patients serving the citizens of the Kingdom of Saudi Arabia. The King Faisal Heart Institute is this study's research site.

Summary

Chapter one was an introduction to the purpose of this study, namely to conduct a formative evaluation of the instructional materials in a new course on the conduct of clinical research for staff of the King Faisal Heart Institute. The background and context

of the research was described, as well as the purpose and the significance of the research. Key terms were defined for the reader. Chapter two will provide a review of the extant literature on clinical research education, instructional design, and formative evaluation.

Chapter 2: Literature Review

Chapter two is a review of the literature on topics relevant to clinical research education, instructional design, and formative evaluation. The chapter begins with a historical and current description of clinical research and the need for research education. This background provides a context for why and how the clinical research management course (CRMC) was designed. Next, a brief description of instructional design and instructional models is provided (a fuller description of the model used for this study is provided in chapter three). Finally, literature on formative evaluation is presented, including the formative evaluation plan used in this research.

Clinical Research Education

Clinical research, sometimes referred to as clinical trials, involves enrolling patients or health volunteers as the subjects of research aimed at studying outcomes related to diagnostic, treatment , genetic, pharmacological, or other interventions. In the last century, globalization, technological advances in medicine, and advances in communication technology contributed to altering clinical research from an activity conducted in isolation by a single physician-scientist to a multi-national activity involving thousands of people in many different roles. Research in the 21st century may include scientists, physicians, nurses, pharmacists, research coordinators, statisticians, ethicists, and administrators; research participants may have a degree in business administration, education, medical informatics, teaching or other specialties (SOCRA, 2008). This diversity of researchers and support staff—in addition to increasing national and international standards, more complex

research regulations, and the public concerns about research misconduct—has contributed to an increased need for the education of research professionals to help ensure scientifically sound and ethically conducted research (Barnes et al., 2006; University of Chicago Graham School of General Studies). As Jones et al. (2008) explained, "With the increasing cost and complexity of conducting clinical trials, a professional, well-educated, and skilled work force is critical" (p. 208).

Clinical research education is offered in numerous formats and by numerous businesses and institutions around the world. A simple Google search identified over one million hits on research education programs offered through private companies, government agencies, universities, colleges, and hospitals. Programs are offered through traditional classroom settings and various forms of distance learning (e.g., Web-based, computer-based, and correspondence-based). Despite the wide array of forms of clinical research education and providers of education, several key themes are evident in research education programs. Heitman and Bulger (2005) conducted a thorough review of the literature on research education, specifically the responsible conduct of research. This research team identified eight topics that were consistent with the core content of the Office of Research Integrity, US Department of Health and Human Services: (a) data management, (b) mentor and trainee responsibilities, (c) publication practices and responsible authorship, (d) peer review, (e) collaborative science, (f) human subjects, (g) animal research, research misconduct, and (h) conflict of interest and commitment. The Society of Clinical Research Professionals (2008) offers a variety of education courses for research coordinators and investigators that include the topics listed by Heitman and

Bulger, as well as topics on scientific rigor, statistics, project management, the role of research personnel, drug development, study design, adverse events, and standard operating procedures.

Developing education and training programs on the management of clinical research has numerous challenges. The most obvious challenges are related to the diversity of the research personnel and attempts to engage busy hospital staff members in education activities. However, other issues such "a lack of clarity in defining the role and differentiating the many titles that are currently in use [in clinical research]" and "no consensus about certification requirements" make research education inconsistent within a country (Jones et al., 2008, p. 202). Jones et al. reported that of 167 respondents who responded to a survey designed for research coordinators, "72 reported different job titles, illustrating the current level of ambiguity and lack of clarity in the different roles in clinical research coordination nationally" (p. 206). More interesting perhaps, is that only two respondents indicated they had received formal training through a non-college course and one respondent held a master's certificate in clinical research. All other respondents indicated they received training "on-the-job" from other research personnel, professional meetings/seminars/workshops, pharmaceutical companies, self-study of publications, Internet self-study, or audiovisual conferencing. These results are consistent with this researcher's knowledge of the education background of clinical research colleagues in Canada and Saudi Arabia.

This evident lack of education in clinical research practices can have grave long-term outcomes. Jüni, Altman, and Egger (2001) addressed the importance of quality in

clinical research as it relates to "the design, conduct, and analysis of a trial, its clinical relevance, or quality of reporting" (p. 42). If the "raw material" of clinical research is flawed, they argued, "then the conclusions of systematic reviews cannot be trusted" (p. 42). Strohschein, Hagler, and May's (2002) study focused on issues relevant to adult learning theory and the need for change in clinical education practices in the field of physical therapy. Although their review of the literature was limited to a single field of medicine, their findings are relevant to this study because of the emphasis on the importance of the local setting within which the clinical education practices take place. They noted that "Given clear objectives for the clinical education process and appropriate frameworks to guide progress, clinicians should be able to choose the models and tools that will allow them to achieve these goals within the unique context of their setting" (p. 170). By conducting a formative evaluation of the CRMC designed specifically for clinical research staff members at King Faisal Heart Institute, it is anticipated that knowledge will be gained about effective instructional models and tools.

Despite the many challenges in providing clinical research education, it is an expected and required activity in academic and research institutions. For example, the U.S. National Institutes of Health (NIH) requires that research investigators who conduct research involving human subjects complete education that is focused on the protection of research subjects (Barnes et al, 2006). Furthermore, the Canadian Institutes of Health Research (2008) specifically state that a principal applicant for research be "an individual who has completed formal training in research in a discipline relevant to health research,

usually a Ph.D. or equivalent, or health professional degree with research training" (1-B1.3).

Instructional Design Models

An instructional design model is often used to guide the design and implementation processes of instruction and depict the sequence of events and the interconnectivity between components (Diamond, 1998). According to Gustafon and Branch (1997), there are hundreds of instructional design models; some are classroom oriented, product oriented, systems oriented, some represent only parts of the ID process such as needs assessment, media selection, and lesson design. Dick et al. (2005, 2009) and Chang (2006), however, argue that there is no single model of instructional design; specific situations often require adjustments or alternations of a chosen model. For the purpose of this research, the Dick and Cary model for the systematic design of instruction (Dick et al., 2005, 2009) was utilized to design the instructional materials, an instructional strategy, classroom activities, and the formative evaluation processes for the CRMC. A description of the Dick and Carey model is provided in chapter three.

Formative Evaluation

A formative evaluation occurs during the developmental stage of the instructional design process (Seels & Glasgow, 1990). The use of formative evaluation dates back to the 1920s when it was used to improve educational films (Brown & Kiernan, 2001); however, the formative evaluation was not applied in academia until the 1960s when Scriven coined the phrase "to describe an evaluation process for assessing instructional materials", as cited in Weston et al., 1997 (p. 369).

In a formative evaluation, the instructional designer utilizes a variety of reviewers to evaluate instructional materials during the process of instructional development to determine where there are weaknesses in the instruction and thereby make appropriate revisions (Smith & Ragan, 1999). Dick et al. (2005) proposed that the data collected and utilized during a formative evaluation will improve the effectiveness of the instruction and improve student learning. Furthermore, they argued that a formative evaluation is more effective than summative evaluations only.

Formative evaluations can be used to assess all aspects of a course or program. They can also be used to assist in policy making and management decisions by providing information on program management and utilization of resources. This critical information empowers managers to make timely and current changes if needed in the way a program is offered and managed (Wholey, 1996).

A benefit of the formative evaluation is that it can be used in a variety of instructional media including print and multi-media formats. Because a formative evaluation has to be a planned event, the process of conducting one has several additional benefits: (a) stakeholders are identified early, thereby reducing delays during development and implementation; (b) all processes are carefully planned; (c) methods have to be thoughtfully selected; and (d) data is collected prospectively (Savenye, 1992). However, there are also limitations and disadvantages to conducting formative evaluations. Rothwell and Kazanas (2004), while confirming the benefits of conducting a formative evaluation, recognized that the process is time consuming and requires additional resources that may not be available or

supported by institutional administrators. Another disadvantage of the formative evaluation may be the use of qualitative data, which according to Savenye (1992), is controversial in education research.

Despite the advantages and perceived disadvantages of the formative evaluation, the credibility of this evaluation process has been confirmed by research. A meta-analysis of 21 studies on the effectiveness of formative evaluation demonstrated that when learners completed programs that had undergone a formative evaluation, the learning and achievement increased significantly (Fuchs & Fuchs, 1985).

Summary

Chapter two was a review of the extant literature on clinical research administration, instructional design, and formative evaluation. It summarized the historical and current context for the need for research education, introduced the concept of instructional design models, and provided the opinions of experts regarding the structure and need of a formative evaluation as a step in instructional design models. Chapter three describes the research methodology of this master's thesis research which utilized the Dick and Carey (Dick et al., 2005, 2009) model for the systematic design of instruction. Chapter three also describes the steps used in conducting a context analysis and in designing and developing the instructional materials. Finally, chapter three describes the formative evaluation process used to evaluate the Clinical Research Management Course, which was designed to teach

the conduct of biomedical research to healthcare professionals at the King Faisal Heart Institute in Riyadh, Saudi Arabia.

Chapter 3: Methodology

The purpose of this study was to design and evaluate a course for healthcare professionals at King Faisal Heart Institute (KFHI) in Riyadh, Saudi Arabia on the topic of how to conduct biomedical research. Chapter three provides an overview of the Dick and Carey model for the systematic design of instruction (Dick et al., 2005, 2009), which was the instructional design (ID) methodology utilized to design and evaluate the course. Additionally, detailed descriptions are provided for the processes involved with conducting a context analysis, designing and presenting the instructional materials, and conducting the formative evaluation plan for KFHI healthcare professionals enrolled in the clinical research management course (CRMC).

Since the process of designing, implementing, and evaluating an in-house course on conducting clinical research was new to the KFHI, it was decided that a context analysis was a pivotal component for the successful design and implementation of the clinical management course. Choosing an appropriate model for designing the course materials and strategy was also considered a critical component. Lastly, conducting a formative evaluation was necessary to guide instructional decision making and associated revisions. Unlike summative evaluation that is focused on the assessment of student learning outcomes, the purpose of formative evaluation is "to collect data and information that is used to improve a program or product; [formative evaluation] is conducted while the program is still being developed" (Dick, Carey, & Carey, 2007, p. 381).

The Dick and Carey Model for the Systemic Design of Instruction

The Dick and Carey model was chosen for this study for the following reasons: (a) focus is on course design as well as instructional materials, (b) flexibility allows utilization of the model in a variety of settings, (c) systems approach (evaluating all the interrelated parts of a program that may affect learning) for designing instruction is based on the assumptions of Gustafon & Branch (1997), (d) systems orientation is appropriate for creating entire courses and assessing available resources as well as needed resources, (e) appropriateness for developing print and Web-based instruction for groups or individualized learners, and (f) model serves as a scaffold to support instructors and instructional designers in designing specific instructional programs (Chang, 2006; Dick et al., 2005, 2009). Dick et al. (2005) explained, "a model implies a representation of reality presented with a degree of structure and order" (p. 4). The structure and order of the Dick and Carey model is depicted in Figure 1.

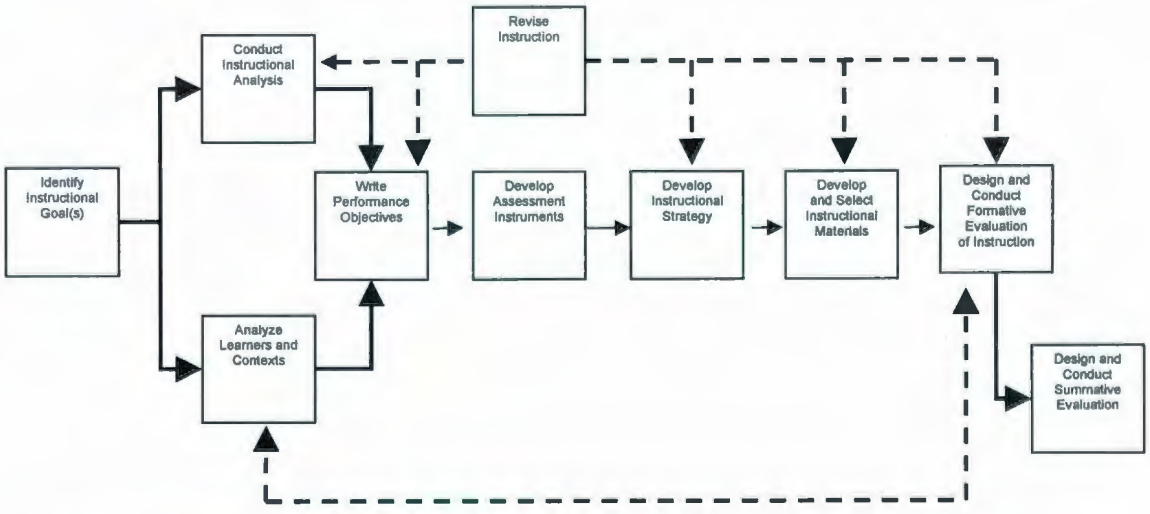

Figure 1. Dick and Carey model for the systematic design of instruction. Source: Dick, Carey, & Carey, 2005, 2009.

In addition to being an essential visual guide for the CRMC designer, the Dick and Carey model served as an effective conceptual and communication tool between the course designer, CRMC instructors, and KFHI administrators. The Dick and Carey model has 10 interrelated components: (a) identify instructional goals, (b) conduct instructional analysis, (c) analyze learners and contexts, (d) write learning objectives, (e) develop assessment instruments, (f) develop instructional strategy, (g) develop and select instructional materials, (h) design and conduct formative evaluation of instruction, (i) revise instruction, and (j) design and conduct summative evaluation. Each component is connected to a subsequent component, and each requires feedback from the earlier component. Following is a brief description of how each of the ten steps in the Dick and Carey model was conducted for this study.

Identify Instructional Goals

A needs assessment was conducted to help identify and articulate instructional goals. Data were collected utilizing three sources: (a) a survey of KFHI physicians and support staff members involved in clinical research; (b) a review of previous and current KFHI research projects for the purpose of identifying deficiencies in the conduct of the research; and (c) a review of newly implemented (within past 5 years) international, national, and local guidelines for conducting research wherein no formal education was offered to staff members. Topics common to courses on conducting research that were offered at international academic, healthcare, and business settings were chosen as topics for the CRMC, as well as topics specifically relevant to conducting biomedical research

in Saudi Arabia (i.e., Islamic ethics and the laws of Saudi Arabia). The instructional designer's experiences in conducting, coordinating, and reviewing biomedical research projects were also helpful when choosing course topics and materials for this study's CRMC.

Based on the needs assessment, the following broad goals were determined for the CRMC:

- To improve the quality of KFHI research proposals submitted for approval.
- To increase the number of KFHI research proposals submitted annually by educating potential research investigators and support staff.
- To assist learners in developing effective research skills in the clinical setting.
- To increase the quantity of KFHI publications submitted for publication in peer-reviewed journals.

Conduct Instructional Analysis

The goals identified in the previous step were converted to instructional goals and subsequently into learning objectives. The learning objectives were classified according to Gagné, Wager, Golas, and Keller's (2004) four domains of learning: intellectual skills, verbal information, psychomotor skills, and attitudes. Furthermore, the major steps required to successfully complete each instructional goal were identified. For example, the instructional goal "To assist learners in developing effective research skills in the clinical setting" was classified as being in the intellectual domain as the skills required to

achieve this goal included unique cognitive activity. Two of the major skills identified to successfully meet this goal were conducting and summarizing an effective literature review and writing a research proposal. Each of these steps was further broken down into subordinate skills. For example, the skill of conducting a literature review included the subordinate skills of (a) choosing appropriate search terms for conducting the review and (b) identifying appropriate resources.

Analyze Learners and Contexts

Since the method developed by Dick et al. (2009) for assessing learning characteristics and learning context de-emphasizes all other factors except learner and content, a more balanced approach to needs analysis between delivery (D), environment (E), content (C), and learner (L) factors was needed. As a result, the DECL method (Mann, 2006) was adopted to assess the learning characteristics and learning context (climate and setting) in the Clinical Research Management Course at the King Faisal Heart Institute. Figure 2 gives a graphic illustration of Mann's "balanced" approach to developing educational materials, which is based on Richey's (2006) recommendations for assessing learners and context. The analysis of the learners and contexts for the CRMC was therefore conducted utilizing Richey's (1986) theoretical instructional design model that examines the factors that comprise learner achievement: delivery, environment, content, and learner (DECL) and Mann's adaptation of the Richey's model for use in distributed learning environments (Mann, 1995, 1997, 2006). The DECL model is further described later in this chapter.

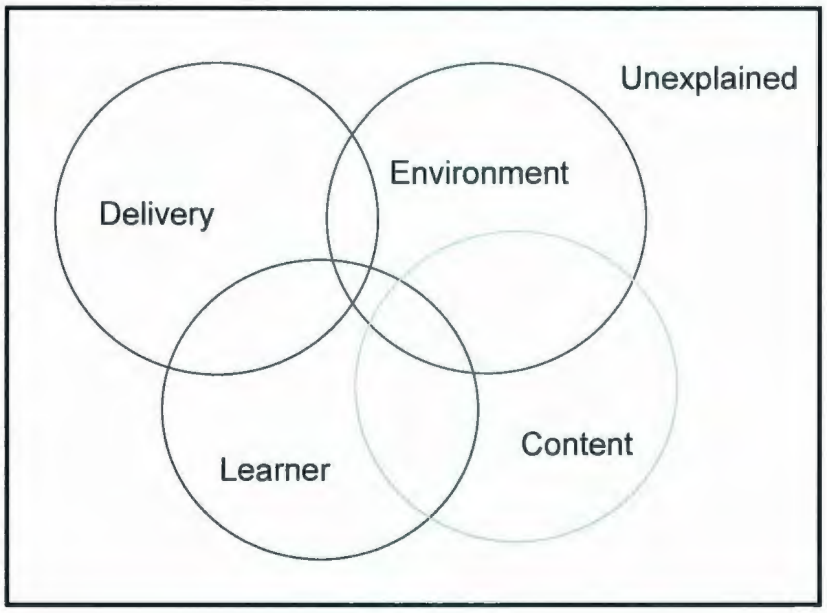

Figure 2. Mann's balanced educational materials development. Source: Mann, 2006.

Write Learning Objectives

From the instructional analysis, learning objectives were written to clearly articulate the skills the CRMC participants would be required to perform, under what conditions the skills were to be performed, and how the performance would be assessed. For example, a learning objective for the subordinate skill "identifying appropriate resources" was "Given a clinical research question, learners will identify at least four appropriate sources that can be used for conducting a literature review."

Develop Assessment Instruments

Criterion-referenced testing was developed to match the two primary domains of the CRMC—the intellectual skills domain and the attitudinal domain. Instructors utilized three evaluation methods: (a) a continuous assessment and remediation process that

included written assignments, (b) evaluation of facilitated discussions, and (c) post-tests on each topic.

Develop Instructional Strategies

The sequencing of instruction and choice of instructional delivery strategies were determined based on Richey's (1986) DECL model context analysis. This process is further described later in this chapter.

Develop and Select Instructional Materials

The DECL method (Mann 2006) was also employed to develop instructional materials because the DECL described more completely than Dick's model, the entire context in which the instructional materials would be employed throughout the Clinical Research Management Course.

Course materials included six sources: (a) pre-class readings and assignments, (b) PowerPoint™ (Microsoft Corporation, 2003) presentations (PPP), (c) participant's workbook, (d) a course reference textbook, (e) a compact disc, and (f) an instructor's manual. These materials were developed to teach healthcare professionals enrolled in the CRMC on biomedical research. Topics for the study's CRMC were based on a systematic review of courses available in other countries on how to conduct biomedical research (see Appendix A).

Design and Conduct Formative Evaluation of Instruction

In the initial planning phase of the CRMC, it was decided that a formative evaluation would be conducted to evaluate the instructional materials and delivery of the instruction. The formative evaluation was based on the Dick et al. (2005, 2009) model for

the systematic design of instruction. Subject matter experts were utilized to develop the formative evaluation. The formative evaluation comprised of one-to-one learner evaluations, small group evaluations, and field trials. The formative evaluation process and results are described in chapters four.

Revise Instruction

Based on data obtained in the formative evaluation, weaknesses and problems in the instructional materials were identified. Based on these findings, the instructional materials were revised accordingly.

Design and Conduct Summative Evaluation

A summative evaluation was conducted to assess the appropriateness and effectiveness of the course and to make decisions about the continued use of the CRMC. The evaluation included results of a survey which was conducted four weeks after the CRMC to assess the impact of the CRMC on learners' current research activities and plans for future research. The summative evaluation and recommendations were presented in a a written report to KFHI administrators.

Critics of the Dick and Carey Model

The Dick and Carey model has been criticized generally for not including specific instructional procedures and the various components of the model have been criticized for not accurately reflecting actual instructional designer functions. Additional criticisms have targeted the model's linear and fixed nature (Dick, 1996). Moreover, others cite the static nature of this older model of instructional design (Boshier et al., 1997; Mann, 1998). Yang, Moore, and Burton (1995) criticized the Dick and Carey model for being

inert, and Wild and Quinn (1998) described the model as being unusable for all educational settings. According to Qureshi (2004), the Dick and Carey model has been criticized for focusing on specific objectives and thereby being ineffective for designing education which supports higher level thinking and learners' construct of new knowledge. Furthermore, Tergan (1998) argued that instructional design models such as the Dick and Carey model are based on educational theories that are too broad and rigid for practical use.

Advocates of the Dick and Carey Model

Dick et al. (2005) defended the Dick and Carey model by explaining that it was designed for the novice instructional designer. The designers of the model further explained that the model was not meant to reflect actual practice but rather to function "as a scaffold" (p. 5) to support instructors and designers. Therefore, the model is not a fixed or linear approach, rather it allows for flexibility and a consistent interaction between the 10 steps of the model (Dick, 1996). "Effective instruction today requires careful and systematic analysis and description of the intertwined elements that affect successful learning," explained Dick et al. (2009); "it requires integral evaluation and refinement throughout the creative process" (p. xxi). Furthermore, Dick et al. (2009) addressed the flexibility of their generic model:

> The elegance of a generic systematic instructional design process is its inherent ability to remain current by accommodating emerging technologies, theories, discoveries, or procedures. For example, performance analysis and needs assessment will reveal new institutional needs and new performance requirements

> that must now be accommodated in the instruction; analysis and description of the performance context will uncover novel constraints and new technologies. Likewise, thoughtful analysis of present learners will disclose characteristics not previously observed, and analysis of new instructional delivery options will enable more efficient and cost-effective combinations of media and teaching/learning methods. The inquiry and analysis phases inherent in each step of a systematic instructional model help to ensure the resulting decisions and designs are current, practical, and effective. (p. xxi)

Chang (2006) cited the effectiveness of the Dick and Carey model for promoting problem solving from multiple perspectives and emphasizing analysis of interrelated instructional components. Other advantages include the appropriateness of the model for developing print and Web-based instruction for groups or individualized learners and the model's ability to serve as a scaffold to support instructors and instructional designers in designing specific instructional programs (Dick, 1996; Chang, 2006). Lastly, Morrison, Ross, and Kemp (2004) advocated the use of the Dick and Carey model for developing formative evaluations at various stages of the instructional design process, and Mann (2006) argued for the effectiveness of the Dick and Carey model for developing formative evaluations for Web-based instructional settings.

Context Analysis

A context analysis is concerned not only with the immediate teaching context but also with the pre-instructional (or orienting) context and the post-instructional (or transfer) contexts in which learners live and work (Richey, 2000). A contextual analysis

of the CRMC was informed by Richey's (1986) conceptual model of instructional design, which includes analysis of the environment in which the content will be offered, the content, and the learners. Richey's model, referred to as the DECL model, has been applied experimentally in both adult learning (Mann, 1995, 1997) and school contexts (Adams, Mann, & Schulz, 2006; Brown & Mann, 2001; Mann, Cui, & Adams, 2002; Mann, Newhouse, Pagram, & Schulz, 2002). Each DECL factor is assessed using the variables illustrated in Figure 3 and described in the following sections.

Delivery	***Environment***	***Content***	***Learner***
Scope	Setting	Mental Operations Required	Attitude
Presentation	Climate	Task	Capacity
Strategy		Domain	Demographics
Sequencing			Competence

Figure 3. DECL factors and associated variables. Source: Mann, 2006.

The Environment Factor

Two variables comprise the environment factor in Richey's (1986) model—the learning climate and its setting. Climate describes where the instruction is held, while setting describes the influences that may affect the design of the instruction. According to Richey, "Instructional climates exist within settings. The settings are structural; the climates are qualitative and can be varied" (p. 159). Given the uniqueness of the climate and setting in which the CRMC was to take place, an analysis of both these variables was detrimental to the successful implementation of the course.

Setting

The setting for the CRMC was the KFHI, a tertiary cardiac-care center located within the King Faisal Specialist Hospital and Research Centre (KFSH&RC) in Riyadh, Saudi Arabia. While the KFHI has fellowship programs for physicians, it is not a traditional educational institution. Participants in the CRMC were not full-time learners in the course and were likely taking time from a busy workday to attend the course. It was difficult to accurately access how this setting would affect learners' achievements; however, it was an important consideration when planning the location of the course and the timing of the course offered.

Climate

Numerous factors influenced the climate in which the CRMC took place. A full description of the climate factors impacting the design and implementation of the CRMC is beyond the focus of this report; however, using Richey's (1986) second level of variable analysis, a broad overview of the factors can be described as follows: (a) external influences (i.e., international standards for conducting research, public demand for safe and effective healthcare, expectations of professional association and the public perception that the KFSH&RC is a leading tertiary care facility in the Middle East); (b) physical materials and arrangements (i.e., location and availability of classroom and meeting rooms, availability of audio-visual equipment, work-schedules of participants and instructors); (c) organizational climate (support of the KFHI administration, education and professional development as values of the KFHI); and (d) participants' characteristics (i.e., education level, clinical research experience, first language, hours of

work). As a result of the climate analysis, important logistical decisions were made that affected the design of the CRMC. For example in assessing the physical materials and arrangements it was noted that the KFHI has a classroom with theater seating and is equipped with audio-visual equipment including a computer, overhead projector, large projection screen, and sound system. The classroom is centrally located within the KFHI and easily accessible by KFHI staff members. However, the physical layout of the room is not conductive to group projects and assignments. There was limited availability of another room that was more appropriate for group seating; therefore, the number of planned group projects was decreased because of this climate limitation.

The Content Factor

Three variables comprise the content factor in Richey's (1986) model of contextual analysis: (a) domains of learning, (b) learning domain tasks, and (c) the mental operations required to engage the learning domain tasks. A task analysis of the skills required for the CRMC showed that learning would primarily be within the cognitive and affective domains.

Domains of Learning in the CRMC

Administering clinical research requires the abilities to coordinate numerous activities, interact with a variety of professional staff, and produce research documents based on applicable laws, regulations and scientific principles, with the end result of conducting a research project according to international standards. Consistent with the revised version of Bloom's taxonomy of learning domains (Anderson & Krathwohl, 2001), these activities are categorized within the cognitive domain. Congruent with these

activities, which also include the ethical conduct of research, is an appreciation for the cultural, societal and religious factors that affect the research being conducted. Therefore, the CRMC included learning exercises in the affective domain (Anderson & Krathwohl, 2001) within which motivation, values, beliefs, and attitudes could be explored.

Learning Domain Tasks

Based on Bloom's taxonomy (Anderson & Krathwohl, 2001), the tasks within the cognitive domain of learning in the CRMC included the abilities to (a) recall pertinent and important information such as ethical principles and legal requirements governing research in Saudi Arabia, (b) demonstrate an understanding of key concepts such as the need for ethical review and the importance of adhering to sound scientific principles, (c) apply the information learned by writing a research proposal correctly, (d) analyze what is needed to conduct a specific research project and organize the various components, (e) evaluate the designing and implementation dimensions of a research project, and (f) create an effective and appropriate research project. The seven tasks within the affective domain were (a) attending to the information presented, (b) participating in class discussion, (c) presenting personal and professional views, (d) sharing knowledge, (e) explaining key concepts, (f) comparing and contrasting ethical views, and (g) displaying a commitment to the principles taught and discussed in class.

Mental Operations

The mental operations required to learn the CRMC content included self-study as well as the ability to attend and participate in class. Learners also needed the ability to transfer what is learned in the course to the real-life workplace.

The topics for this CRMC were identified through a review of courses and programs offered at other institutions (see Appendix A), the results of the questionnaire administered to staff members (see Appendix B), a review of KFHI research projects (see Table 1), and the research experience and education of the program designer. A task analysis was conducted for each topic to identify the tasks involved and the required mental operations needed to complete the tasks (Mann, 2005).

In addition to identifying experience levels with various course topics, KFHI staff members identified their preferred learning format for a course on conducting biomedical research. Of 102 staff members, 61 preferred a short course format (e.g., 1-2 hours per day twice a week over a period of 4-8 weeks). Computer-assisted learning (i.e., computer program/course) was the preferred learning format for 25 staff members. Seven staff members preferred lectures and presentations that were not part of a structured course. Five staff members preferred independent reading (being provided reading material on the topic of their choice). Lastly, four staff members indicated that they preferred individualized self-directed learning (i.e., working with an instructor to develop instructional materials specific to the staff member's needs).

The 102 KFHI staff members who completed the questionnaire identified the following preferred days for attending education sessions on biomedical research as follows: (a) any work day (64 members), (b) Mondays (21 members), (c) Wednesday (5 members), (d) Saturday (4 members), (e) Sunday (4 members), and (f) Tuesday (4 members). The KFHI staff members indicated their preferences for time of day for the

course offerings: (a) 1 p.m.-2:00 p.m. (73 members), (b) anytime (24 members), and (c) 2 p.m. (5 members).

Table 1

A Review of KFHI Research Projects (n = 43)

Research Proposal	
All elements of research proposal and supporting documents written, completed, and submitted according to Hospital requirements	0
Number suspended (after initial approval) because of procedural/administrative issues	9
Deficiencies Noted on First Submission to the Ethics Committee	
Inappropriate research designs	31
Lacking appropriate statistical methods	40
Deficiencies Noted on First Submission to the Ethics Committee	
Informed consent document missing, incomplete, or not at appropriate education level	8/14
Data collection tool not included or not designed appropriately	35
Organizational/work plan missing	42
Ethical considerations not included	41

The content of the course was based on a review of other courses in biomedical research (see Table 2) and included the following 18 topics: (a) defining roles of the investigator, clinical research coordinator, monitor, statistician, external sponsor, and ethics review board in clinical research; (b) selecting the appropriate research methodology and design; (c) developing research questions; (d) conducting a literature review; (e) applying statistical methods in research; (f) writing the research proposal; (g) designing and constructing case report forms; (h) preparing and submitting the research

proposal documents; (i) considering ethical issues when conducting clinical research; (j) writing informed consent documents; (k) collaborating with research ethics committees; (l) being compliant with the International Conference on Harmonization: Good Clinical Practice Guidelines for the Conduct of Biomedical Research; (m) recruiting and enrolling human research subjects; (n) managing research projects; (o) ensuring safety in reporting; (p) collecting, monitoring, and analyzing data; (q) maintaining research drug/device inventory and accountability records; (r) being compliant with the international and local rules and regulations governing medical research.

Table 2

Course Topic Selection: Results of Review of Courses on Biomedical Research

Topic	Number of Courses Presenting Topic	Percentage
Research Ethics	14	73.7%
Research Design	12	63.2%
Project Management	10	52.6%
Good Clinical Practice Guidelines	9	47.4%
Sponsored Research	8	42.1%
Research Regulations	6	31.6%
Data Management	4	21.1%
International Research	4	21.1%
Writing Research Proposals	2	10.5%

Note. Number of courses reviewed = 19.

The Learner Factor

In Richey's (1986) model for context analysis, four variables comprise the learner factor: demographics, competencies, capacities, and attitudes. Determining the characteristics of the learners is an important step in many instructional design models Given the national, religious, professional and age diversities of the learners in the CRMC, a third level of analysis was conducted.

Demographics

Concerning the demographics of the participants in the CRMC, the context analysis showed that the learners would likely be staff members employed at the KFHI who are directly or indirectly involved in the care of pediatric and adult patients with a variety of cardiovascular diseases. Furthermore, it was anticipated that all professional staff members would have a minimum of an undergraduate or associate degree and that a small percentage of them would have research experience. The majority of staff members are Arab and Muslim, the minority are Western and non-Muslim, and the remaining staff members are Muslim Asians or non-Muslim Asians and Western. The demographics of the participants are given in (see Appendix C). Eleven female and 20 male healthcare professionals (n= 31) enrolled in the first CRMC. The participants ranged in age from 22 to 55 years with a median age of 32.8 years. They had responded to a department-wide advertisement and were required to apply to attend the course.

Capacity and Competency

Since the CRMC was designed to teach research administration at the KFHI, it was important to enroll appropriate learners who could demonstrate reasonable capacity

to comprehend and apply the information and complete the course. An analysis of competencies needed to participate in the course revealed that the following required competencies: (a) an associate's degree or a bachelor's degree in science, nursing, medicine, health sciences, pharmacy, or related fields; (b) fluency in spoken and written English; and (c) current employment at the King Faisal Heart Institute. All participants enrolled in the CRMC met the criteria.

The average number of years as healthcare professionals for those accepted into the course was 12.3 years (range 3-25 years). Their occupations within healthcare included: physician (14), clinical research coordinator (6), nurse (3), perfusionist (2), cardiac catheterization technician (2), research data entry operator (1), research administrative coordinator (1), pharmacist (1), and heart transplant coordinator (1). While some of the learners had some experience in biomedical research, none had participated in any formal education relevant to conducting clinical research. Results of a pre-test administered on the first day of class were congruent with the staff survey (see Appendix B) and indicated that the majority of learners were unfamiliar with many of the topics outlined in the course syllabus.

Attitudes

The attitudes of the learners in the CRMC were analyzed in the context of religious, social, and professional factors. Published frameworks for analyzing learners' attitudes are based almost exclusively on Western learning environments. This group of learners is especially unique because of their professional, national, linguistic, religious, social, and cultural diversities that can all impact on teaching and learning. Additionally,

as conducting research includes specific components on research ethics, which is considered to be culturally-sensitive, it is important to acknowledge national and cultural diversity in this group of learners. Therefore, instructional materials were developed with an awareness of cultural, ethical, and linguistic sensitivities in addition to social and professional dimensions.

The Delivery Factor

In the DECL model (Richey, 1986), the organization of the instructional material, including all the printed materials, computer software, and how the material is presented, are all included in the delivery factor. The four variables that comprise the delivery factor are scope, sequence, strategies, and presentation of instruction. Richey described the delivery factor as encompassing a wide range of complex activities and having a large number of delivery processes and procedures.

Scope

The scope of the CRMC is instruction and information on topics relevant to conducting biomedical research. In addition to offering the course content, the CRMC faculty members agreed to act as mentors for new KFHI researchers and research support staff members. The only alternatives available to designing a course on the administration of research to be delivered within the KFHI were to (a) send healthcare professionals to other countries to attend similar programs or (b) contract with an education provider to develop and deliver a course at the KFHI. Both alternatives were considered to be too expensive and would take KFHI healthcare professionals away from professional responsibilities for an extended period of time.

Sequence

The instructional sequence was designed to be congruent with the logical sequence of steps taken when conducting biomedical research. Instructional information was presented from "simple to complex, with increasing diversity, and global before local skills" (Wilson & Cole, 1996, p. 606). For example, the first lecture addressed the rules and regulations of conducting research at the KFSH&RC, the second through fifth lectures covered research methods, and the sixth course lecture focused on project planning. The following lectures dealt with developing a hypothesis, conducting a literature review, implementing statistical methods, determining sample size, preparing the research proposal and supporting documents for submission to the institutional review board, and conducting the research. The fifteenth and final lecture covered the process of reporting and publishing the research results. This sequence is in keeping with teaching subordinate skills first and then progressing to integration and practicing (Dick et al., 2005). The lectures were scheduled as 90-minute sessions conducted twice weekly, which was based on the results of a staff survey indicating staff time and day preferences.

Strategies

A variety of instructional strategies were employed in the delivery of the CRMC: (a) pre-class readings and assignments, (b) PowerPoint presentations, (c) participant workbook, (d) course textbook, and (e) the use of an instructor's manual.

It was recognized during the initial development of the CRMC that healthcare professionals who would enroll in the course would come from a variety of backgrounds with different levels of education and experience in biomedical research. To help

establish a more equitable learning environment and to maximize classroom meeting time, pre-class readings and assignments were incorporated into the course. Prior to the CRMC classroom instruction, learners were e-mailed readings on the upcoming weeks' topics. Learners were asked to review the readings prior to each class session and were informed that this information would be referenced in the relevant class session as well as cumulatively throughout the course.

PowerPoint presentations (PPP) were used to give visual presentation of key issues in biomedical research and to allow for discussion of the points presented. Topics utilizing PPP are provided in Appendix D. Printed copies of the PPPs were disseminated at the beginning of each session on which learners could take notes as needed. The printed PPPs also served as post-course reference materials for the learners. As English was not the first language of the majority of the learners, providing copies of the printed PPP notes helped learners follow more closely what was being spoken in the class; this was considered by the course instructors as a useful and necessary tool for the learners.

The course materials included an electronic version of a participants' workbook, which was divided into sections for each of the topics presented. The objectives and a list of resources were given for each class as well as basic concepts and vocabularies, authentic clinical research scenarios, and open-ended and close-ended questions and activities to help learners think critically and practice applying skills.

The participant workbook was utilized before and during each class. Learners were required to read the workbook material and questions ahead of time to prepare for class discussions. Examples of materials in the workbook included: (a) case scenarios

about conflict of interest in research (for class discussion); (b) descriptions of statistical principles, followed by examples of research questions for which learners were asked to choose appropriate statistical methods and provide rationale for their choices; basic calculations were also demonstrated and practice examples were given, with an answer key provided at the end of the workbook; and (c) a fictitious clinical research proposal, a fictitious patient's medical record, and a case report form (CRF) for exercises to demonstrate designing a CRF, data collection, and data entry.

Utilizing fictitious, but realistically constructed, clinical situations and proposals, medical records and a CRF in authentic formats enhances the application of theory-based information to realistic situations and problems (Graf, Russell, & Stegbauer, 2007). The course instructors facilitated the use of the workbook by lecturing on key points in each of the sections, asking questions pertinent to each section, and engaging learners in discussions. The workbook also contained hyperlinks to Internet Web sites and articles relevant to the conduct of clinical research. These links included: the Nuremburg Code, the Declaration of Helsinki (2002), the Canadian Tri-Council Policy Statement (2002), 45 Code of Federal Regulations Part 46, 21 Code of Federal Regulations Part 50 and Part 312, The Belmont Report, the International Conference on Harmonization: Good Clinical Practical Guidelines, and the Regulations and Guidelines of the Research Advisory Council of the KFSH&RC.

Six references that were written or provided by course instructors were not available on the Internet or the KFSH&RC Intranet. These resources were re-created in Portable Document Format (pdf) and placed on the KFHI Intranet to provide participants

to access them via Web links. The workbook also contained a compilation of other relevant Internet Web site hyperlinks as additional references. Hyperlinks have been described as powerful tools in education that allow learners to view and explore information at a time convenient for the learner and as long as often as the learner wishes. Additionally, the opportunity to visit these Web sites and to potentially communicate with other healthcare professionals involved in biomedical research introduced learners to a wider world of resources available on the Internet, thus supporting their learning and working needs (Gery, 1991) and helping confirm to learners that biomedical research is conducted in a global arena. Specific resources that were identified as self-study components were highlighted in red, and participants were made aware that the course post-test would include the self-study material as well as the material covered in lectures.

The textbook for the CRMC was *The CRA's Guide to Monitoring Clinical Research* by Wooden and Schneider (2003). This text was chosen because of its broad content, easy readability, inclusion of pertinent reference documents, and potential to be used as a general reference that learners could use and share in the workplace. The textbook was used by learners as a reference throughout the course, including the pre-class readings and assignment.

The instructor's manual, also referred to as the course information management system (Dick et al., 2005), contained an overview of all of the instructional materials, the teaching objectives, a daily agenda for presenting topics, a teaching sequence for instructors, the course evaluation plan, and additional resources and suggestions for instructors. The instructor's manual was divided into instructional modules that were

developed for each topic of the course. Instructional modules provided flexibility for healthcare providers who may be unable to attend course sessions because of clinical responsibilities or other professional or personal commitments. As the CRMC will be offered at least annually, the modular format allows participants who missed a particular instructional module to participate the next time the course is offered.

An interactive format utilizing lectures, PowerPoint presentations, printed education material, discussions, and group work was chosen as the primary method for delivery. Selection of these methods was based on (a) preferred choices of the KFHI staff members as indicated in a staff survey (see Appendix B) and (b) a Cochrane Review of educational meetings and printed educational materials that showed that an interactive workshop format was more likely to change professional practice than didactic sessions alone (O'Brien et al., 2001). Additionally, an interactive approach has been shown to promote discussion about a subject and add to the development of participants' critical thinking skills (Gulpinar & Yegen, 2005).

Presentation of Instruction

The field of education has long been known for utilizing learning objectives. Two basic types of learning objectives or learning outcomes were used in the design of the CRMC materials: behavioural objectives and cognitive objectives. Furthermore the learning objectives were stated in "A-B-C-D" format: audience (A), behaviour (B), condition (C) and degree (D) (Mann, 2005). The learning objectives for each lecture are provided in Appendix E. Gagne's (1985) nine events of instruction were used to formulate, organize and present the instruction: (a) gain attention, (b) inform learners of

objectives, (c) stimulate recall of prior learning, (d) present the content, (e) provide learner guidance, (f) elicit learning/practice, (g) provide feedback, (h) assess performance, and (i) enhance retention and transfer. Each event is briefly described as it was incorporated into the course.

Gain attention. Each instructional unit was started with an example or thought-provoking question or statement relevant to the topic. For example, the instructional unit on the topic "Historical Events in Biomedical Research" began with the question "What do you think Nazi Germany and biomedical research have in common?"

Inform learners of objectives. The purpose and objectives of each instructional unit was written in the participants' e-version workbook, included in the printed copies of PPP notes disseminated at the beginning of each session, and listed on the first slide of each PPP lecture used by the instructor.

Stimulate recall of prior learning. As all of the learners were healthcare providers, their common backgrounds were often utilized by the instructor to relate the topics to the learners' prior knowledge and workplace. In addition, to utilize areas of individual learners' specific backgrounds, examples were used to make the relationship between prior knowledge and new knowledge more personally and professionally relatable.

Present the content. The content for each instructional unit was presented using a variety of media, namely lectures augmented by PPP, handouts, self-study materials, videos, role playing, learner presentations, and educational games for review and to stimulate further learning.

Provide learner guidance. All learners were provided with the appropriate course materials as described in the chapter section on course materials, with the exception of the instructors' manual. Instructors were available during regularly scheduled hours to assist learners as needed. The Health Sciences Library of the KFHI was available to all learners who wished to use the resources for class preparation, course research, and study. Learners who stated they did not have access to a computer or the Internet were provided these resources by the KFHI Research and Informatics Office.

Elicit learning/practice. Learners were provided several opportunities to practice what they learned. Role playing (by learners) was used to simulate a convened meeting of a research ethics committee and to simulate obtaining informed consent from a potential research subject. Learners gave presentations to the class based on topics covered in instructional units, and classmates were encouraged to ask questions and discuss the presentation with the presenters. The participants' workbook was used to provide learners with practice sessions, and learners were asked to provide questions for review sessions.

Provide feedback. Course instructors utilized a continuous assessment and remediation process. Learners received immediate feedback on all responses and activities. Feedback was specific with additional learning resources offered when appropriate.

Assess performance. Learners were given frequent opportunities to demonstrate knowledge and newly acquired skills: discussion, presentations, role playing, participation in educational games, and the submittal of a final written project. Criteria were developed for the instructors to use to objectively assess the learners' performance.

Enhance retention and transfer. Throughout the program, learners were encouraged to transfer the knowledge and skills acquired in the course to their present workplace and to other similar research situations. Role-playing and situational analysis aided in making the learning experience as contextual or situational as possible.

Formative Evaluation Plan

The CRMC was unique in the region insofar as there were no other courses previously offered or available for KFHI staff members related to conducting biomedical research. A formative evaluation of the instructional materials of the course was conducted in stages and performed during the development and implementation of the project to inform the course developers about necessary modifications in the instructional materials. Like other types of evaluation, formative evaluation is defined by the question it answers: "How can these materials be revised?" (Patton, 1997). The rationale for conducting a formative evaluation is to allow the instructor or instructional designer to determine whether what was intended to be provided as a learning environment was actually experienced by the learners who were enrolled in the program.

Formative evaluations have been used in a variety of healthcare-related programs including dietetics (Vickery, 1989), a postdoctoral program for nurses (Geunaro et al., 2007), an undergraduate psychiatry program (Chur-Hansen & Koopowitz, 2005), a post-graduate course for healthcare professionals (Coppus et al., 2007), and nurses' practice doctorate programs (Graff et al., 2007). Therefore, it was appropriate to utilize a formative evaluation format in this allied-health course for research administrators. The

formative evaluation of the CRMC was based on the Dick et al. (2005, 2009) suggested framework for designing formative evaluations.

The Dick et al. (2005, 2009) framework is a 6-stage formative evaluation model: (a) design review, (b) expert review, (c) one-to-one evaluation, (d) small group tryout, (e) field trial, and (f) ongoing evaluation. This research utilized the first four stages as it was determined that the field trial and ongoing evaluation were beyond the scope of this master's thesis research.

Design Review Stage

In the design review stage, the researcher seeks answers to four key questions. The first question inquires about the alignment of the instructional goals with the problem(s) identified in the needs assessment. The second question deals with the alignment of the learner and environmental analysis with the targeted audience for the instruction. Third, it is important to determine if the task analysis includes the prerequisite skills that learners will require. Lastly, the researcher must determine if instructional assessment items are reliable and valid as well as aligning with the instructional objectives (Mann, 2006).

Expert Review Stage

In this second stage, an expert—either content or technical expert—reviews the instructional content. This second review stage can take place with or without the evaluator present. The focus of this review phase is five-fold: (a) to determine if the content is accurate and current, (b) to determine if the content is presented from a consistent perspective, (c) to ascertain if examples, instructional practice, and feedback is

realistic and accurate, (d) to assure that the pedagogy (or andragogy) is consistent with current instructional theory, and (e) to determine if the instruction is appropriate for the target audience (Mann, 2006).

One-to-One Evaluation Stage

During this third stage, the evaluator has learners, one at a time, review and comment on the instruction. The evaluator's aim is to make sure the message is clear in all of the instructional materials. Also, the evaluator focuses on discovering how the instruction impacts learner attitudes and achievement of instructional objectives and goals (Mann, 2006).

Small Group Tryout Stage

The purpose of a group evaluation is to duplicate a real-word instructional setting in order to capture learners' actual performances during an instructional episode and learners' feedback on the experience. During the small group evaluation, the evaluator will be focused on tracking the effects of changes made to the instruction as a result of the one-to-one evaluation stage findings. Additionally, the evaluator will be looking for other learning problems associated with the instruction (Mann, 2006).

Summary

Chapter three provided an overview of the instructional design model utilized for the study (Dick et al., 2005, 2009). Descriptions were provided for the processes involved with conducting a context analysis, designing and presenting the instructional materials, and the conducting of the formative evaluation plan for KFHI healthcare professionals enrolled in the clinical research management course (CRMC) at the King Faisal Heart

Institute in Riyadh, Saudi Arabia. Chapter four reports on the study results and provides recommendations for revisions to course instructional materials.

Chapter 4: Results

This chapter reports on the design, procedures, and results of a four-step formative evaluation of the clinical research management course (CRMC) at the King Faisal Heart Institute (KFHI) in Riyadh, Saudi Arabia. The purpose of a formative evaluation is to not to determine learning outcomes, but rather to revise, and make recommendations for revision to instructional materials. The research question for this formative evaluation was "How can the instructional materials designed for the CRMC be revised to make them more efficient and effective?" Conducting a formative evaluation is the ninth step in the Dick and Carey model of instructional design (see Figure 4). Figure 4 provides a graphic illustration of steps of the Dick et al. (2005) formative evaluation plan that were utilized in this research.

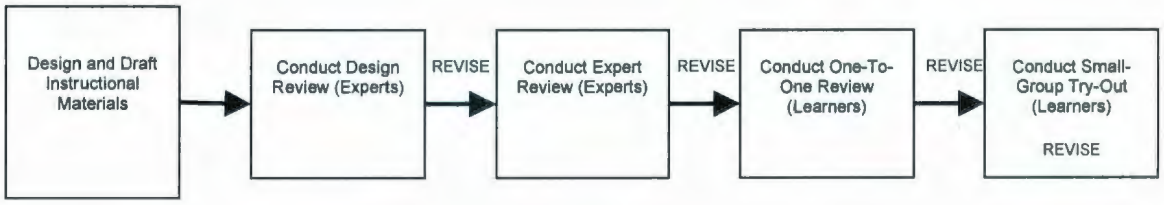

Figure 4. Dick and Carey formative evaluation plan.

The Formative Evaluation Plan

The project selected for this study was a CRMC that was offered to healthcare professionals at the King Faisal Heart Institute (KFHI) in Riyadh, Saudi Arabia. The focus of the course was the conduct of biomedical research. A formative evaluation plan was developed to collect and analyze data during the design, development, and delivery of instruction, rather than evaluating outcomes or assessing learners' evaluations at the

end of the course. Using formative evaluation methods provided the instructors with feedback during all stages of the education program and provided data that are the basis for revisions to the instruction and instructional materials.

According to Dick et al. (2005) "To often instructors have been blamed for poor teaching and learners for poor learning when, in fact, the materials were not sufficient to support the instructional effort" (p. 277). This is supported by the research of Cronbach and Scriven that demonstrated a correlation between low learner achievement and curriculum. Cronbach and Scriven proposed that course evaluations should be designed and conducted to gather data during the design of programs and the information be used to improve instruction before the program is delivered (as cited in Dick et al., 2005). Despite the obviously logical concept of conducting a formative evaluation to help improve instruction during the design process, there has been little empirical evidence demonstrating the positive effects of conducting a formative evaluation (Brown & Keirnan, 2001; Weston et al., 1997). However, conducting a formative evaluation has been generally recommended by the education community as a necessary step in instructional design for evaluating and improving instruction and instructional materials (Russell & Blake, 1988; Baker, Aguirre-Munoz, Wang, & Nieme, 2003; Brown & Kiernan, 2001; Dick et al., 2005; Gagne et al., 1992; Weston, McAlpine, & Bordonaro, 1995).

The Formative Evaluation Model

Dick et al. (2005) defined formative evaluation as "the process designers use to obtain data that can be used to revise their instruction to make it more efficient and

effective" (p. 278) and recommended that it be conducted on all newly designed instructional material and existing materials being adapted for new programs. There is a clear distinction made between a formative evaluation and a summative evaluation. While the former is used to assess and revise instructional materials, the latter is used to evaluate learning outcomes and the effectiveness of a program (Dick et al., 2005).

There are numerous models and processes for conducting formative evaluations and varying recommendations on when is the best time to conduct one (Chambers, 1994; Savenye, 1992; Weston et al., 1995). Gagne et al. (1992), McAlpine (1992), Baker, Aguirre-Munoz, Wang, & Nieme (2003), and Dick et al. (2005) described formative evaluation as occurring throughout the instructional design process, while Komoski and Woodward (1985) and Paloff and Pratt (1999) described formative evaluation as occurring at any time throughout the complete span of the instruction.

An important first step in choosing a formative evaluation model is clarifying the goals of the formative evaluation (Weston et al., 1995). The goal of the formative evaluation of the CRMC was to identify the weaknesses in the instructional materials of the CRMC and to make revisions based on the formative evaluation data. As the CRMC was a new course to the KFHI and all instructors had relatively little teaching experience in the subject matter, it was decided to conduct the formative evaluation during the initial design of the instruction and instructional materials, using the Dick and Carey formative evaluation plan (see Figure 2).

The Dick et al. (2005) formative evaluation plan was applied to the instructional materials to answer the following questions: (a) Is the course content relevant to the

conduct of biomedical research? and (b) Are the learning objectives, events of instruction, length of the program, time devoted to each topic, course materials, methods of instruction, and evaluation processes appropriate? A matrix listing the instructional components and a corresponding list of questions for assessing the areas of interest was designed (see Appendix F).

The full Dick et al. (2005) model of formative evaluation has six stages: (a) design review, (b) expert review, (c) one-to-one trial, (d) small group pilot, (e) field trials, and (f) ongoing evaluation (Mann, 2006). The first four stages of the model were applied to this study. However, the field trial and ongoing evaluation stages were deemed to be beyond the scope of this research project.

Step 1: Design Review

In a design review, the evaluator attempts to answer the following questions: (a) Does the instructional goal match the problem identified in the needs assessment?; (b) Does the learner and environmental analysis match the audience?; (c) Does the task analysis include all the prerequisite skills?; and (d) Are the test items reliable and valid, and do they match the objectives? (Mann, 2006).

Design of the design review. Specific knowledge or skills were required to evaluate the design of the CRMC; therefore, the participants in the design review were selected based on a purposeful sampling rather than randomized selection. The selection requirements for design reviewers included a minimum of a master's degree in education or one of the health sciences, experience as either a research investigator or research coordinator, and experience in teaching. Additionally, because of the multi-national and

multi-language characteristics of the targeted learner population, it was decided that reviewers who had different countries of origin and different native languages would be included. Seven potential reviewers were initially contacted, however, three refused to participate because of heavy workload concerns, feelings of not being competent to act as a design reviewer, or upcoming vacation plans. The demographics of the four design reviewers are provided in . The ARCS model (Keller as cited in Dick et al., 2005) for assessing the quality of instruction was used for the design review. Specifically, reviewers were asked to evaluate the CRMC in relation to attention, relevance, confidence and satisfaction.

Table 3

Demographics of Design Reviewers

Design Reviewer	Education Level	Years of Teaching Experience	Years of Research Experience	Country of Origin	First Language
1	Master of Nursing	15	5	New Zealand	English
2	Ph.D.	10	28	India	Hindi
3	M.D.	1	2	Egypt	Arabic
4	Master of Health Sciences	5	8	Saudi Arabia	Arabic

Reviewer 1 commented that the CRMC is an excellent program overall, however, noted that several lectures appeared to be long and drawn out. So reviewer 1 suggested decreasing the length of four of the lectures. Reviewer 1 further suggested a) adding the

writing of abstracts/publications as a topic, b) decreasing the number of slides, and c) reducing the length of the section on ethics.

Reviewer 2 expressed that the CRMC is a good course and a great idea. The second reviewer recommended changing class time to 60 minutes. It was also suggested that some presentations were too long and that there were too many classes on ethical aspects. Lastly, Reviewer 2 recommended adding more information on statistical analysis.

Reviewer 3 also felt that several of the classes were too long and that there were too many classes, especially on the topics of ethics and Islamic ethics. Reviewer 3 recommended providing more classes on statistics because many people find this to be a difficult topic. It was further recommended that the instructional manual include tips for new teachers or perhaps basic information on adult learning theories. The third reviewer noted several typographical and grammatical errors, but commented positively on the purpose and design of the course.

Reviewer 4 suggested that the CRMC is a "great idea" which includes a great deal of excellent information. This last reviewer suggested that the course was lengthy in places, especially in the area of ethics. Reviewer 4 recommended reducing the PPP slides for some of the classes.

Data collection instruments. Instruments for collecting data in the design review stage were created based on the ARCS Model (Keller as cited in Dick et al., 2005), using closed-ended questions with one question for comments or suggestions (see Appendix C). Closed-ended questions provide greater uniformity in responses, allowing coding and

analysis to be conducted easily (Portney & Watkins, 2000). An open-ended question was useful for probing the reviewers' opinions and suggestions for improvements.

Procedure for the design review. Following the initial contact to solicit their assistance in being a design reviewer for the CRMC, each of the reviewers was sent a package containing a written description of the rationale for the CRMC design and an explanation of what their contribution would be as a design reviewer. Each of the reviewers was also given the results of the needs assessment, a summary of the task analysis, a summary of the contextual analysis, course objectives, participant workbook, the course textbook, copies of all PowerPoint presentations, copies of all pre-class readings, the plan to be used for evaluating learner performance, a copy of the instructor's manual, and the questionnaire. The reviewers were asked to review the material and evaluate them using the data collection instrument provided (see Appendix G).

Results of the design review. The results of the design review are summarized in Appendix H. All reviewers completed the questionnaires. The yes/no responses to the questions under the motivation and characteristics of instruction were counted and summarized.

The results of the reviewers were divided evenly on one questions under the motivation category, "Are learners likely to be confident at the onset and throughout instruction so that they can succeed (e.g., learners informed of purposes and likely to possess prerequisites; instruction progress from familiar to unfamiliar, concrete to abstract; vocabulary, contexts, and scope appropriate; challenges present but realistic;

etc.)?" The following question in the category of intellectual skills under characteristics of instruction was not answered by three of the reviewers, "When appropriate, are follow-through activities such as advancement, remediation, and enrichment present and logical (e.g., address prerequisites, focuses on improved motivation provide additional examples and contexts)?" All reviewers answered "no" to the question, "Are logical mnemonics provided when new information cannot be linked to anything stored in memory?" under the category of characteristics and instructions: verbal information. All reviewers answered "yes" to 18 of the 34 questions, and the remaining 13 questions received "yes" from three reviewers and "no" from one reviewer.

A content analysis of the reviewers' comments revealed the following four themes: (a) class time and length of lectures were too long, (b) information on statistics was inadequate, (c) there were too many classes on ethics, and (d) several lectures overused PowerPoint presentation slides. The suggestion to add writing for publication was considered an excellent idea by the evaluator, and the topic was incorporated into the program. Additionally, under the comments section, all reviewers noted that the course is a worthwhile endeavor.

Revisions were made to the design of the CRMC following feedback from the reviewers. The length of time for individual lectures was revised. The length of class time for ethics was decreased, while the length of class time devoted to statistical analysis was increased. One new topic (writing for publication) was added, and the number of slides for three PowerPoint presentations was decreased. A section on adult learning theories was added to the instructor's manual to provide additional resources for new instructors.

Step 2: Expert Review

During the expert review stage, experts review the instruction with or without the evaluator present. The experts are usually content or technical experts and are asked to assess the following: (a) Is the content accurate and up-to-date?; (b) Does it present a consistent perspective?; (c) Are examples, practice exercises, and feedback realistic and accurate?; (d) Is the pedagogy consistent with current instructional theory?; and (e) Is the instruction appropriate to the audience? (Mann, 2006).

Design of the expert review. Similar to the design review stage, specific knowledge or skills were required to answer the five questions of the expert review described above. Therefore, the participants for the expert review were also selected based on a purposeful sampling rather than randomized selection. Selection requirements for expert reviewers included a minimum of a master's degree in education or one of the health sciences and at least five years experience, including the last two years, as a research investigator, research coordinator, or research administrator. Also, given the international mixture of potential learners and the globalization of clinical research, it was decided that the expert reviewers should come from a variety of countries to help ensure that topics and appropriate ethical issues were included in the CRMC. The demographics of the expert reviewers are provided in Table 4.

Table 4

Demographics of Expert Reviewers

Expert Reviewer	Education Level	Years of Teaching Experience	Years of Research Experience	Country of Origin	First Language
1	Master of Education	22	5	USA	English
2	Master of Health Administration	6	9	Yemen	Arabic
3	M.D.	3	11	Egypt	Arabic

Data collection instruments. The instrument for collecting data during the expert review was designed based on examples given in Dick et al. (2005) and the questions outlined by Williams (2006) at Pennsylvania State University. The instrument included five questions to evaluate the instruction and instructional materials for each of the topics and two questions related to the pre- and post-tests. Nine questions were included to evaluate the overall content, language, and grammar of the CRMC.

Procedure for the expert review. Each of the reviewers was given a course materials package that included the course objectives, participants workbook, the course textbook, copies of all PowerPoint presentations, copies of all pre-class readings, the plan to be used for evaluating learner performance, a copy of the instructor's manual, and the assessment instrument (see Appendix I). The reviewers were asked to evaluate the materials using the instrument provided. According to Dick et al., (2005), the course designer may or may not be present during the expert review. In this research, the

designer was not present but was available at any time to clarify points or answer questions posed by the reviewers. During the expert review, one of the reviewers contacted the evaluator for clarification of Question 4 "Is the pedagogy consistent with current instructional theory?"

Results of the expert review. The results of the expert review are summarized in Appendix J and Appendix K. All reviewers responded "yes" to each of the seven questions in all topic areas, except the question "Is the pedagogy consistent with current instructional theory?" One reviewer felt she was not qualified to answer this question and therefore replied unknown in all topics. These results indicated that the course content and structure were accurate, appropriate, organized and current. Context analysis of the reviewers' comments showed that more culturally appropriate and locally pertinent examples should be used in several classes.

Several revisions were made to the design of the CRMC following feedback from the reviewers (see Appendix J and Appendix K). Most of the case scenarios and examples were based on North American situations; based on the feedback of the reviewers, more local examples and scenarios were incorporated into the material. For example, in a case scenario designed to discuss ethical issues related to genetic research, the reviewers suggested that the case be written to describe the situation in which a Saudi Arabia bedouin may be involved rather than a North American patient or research subject.

Step 3: One-To-One Review

In a one-on-one evaluation, one learner at a time reviewed the instruction with the evaluator and commented upon the two questions. The first question was: Is the message clear? Secondly, what is the impact on learner attitudes, achievement of objectives and goals? (Dick et al., 2005).

Design of the one-to-one review. Unlike the design and expert reviews, specific knowledge or skills are not required to participate as a reviewer in the one-to-one review. Rather the reviewers in this step were selected as representing the learners for whom the CRMC was designed. However, while no specific knowledge or skills were required, as Dick et al. (2005) suggested "The designer therefore selects at least one learner from the target population who is above average ability (but certainly not the top learner), one who is average, and at least one learner who is below average" (p. 283). Therefore, as in the design and expert review, reviewers were selected based on a purposeful sampling rather than randomized selection, with above average, average, and below average as being equated with experience in clinical research. Selection requirements included: (a) having an associate or a bachelor's degree in science, nursing, medicine, health sciences, pharmacy, or related fields; (b) being fluent in spoken and written English; and (c) being an employee of the King Faisal Heart Institute. These selection requirements were the same as the proposed perquisites for entering the CRMC. Also, as in the design and expert reviews, consideration was given to the nationality and linguistic diversity of the targeted learners. Therefore, the one-to-one reviewers were chosen as representative of the three largest groups likely to enroll in the CRMC based on the demographics of the

total staff population at the KFHI. The demographics for the reviewers for the one-to-one review are given in Table 5.

Table 5

Demographics of One-to-One Reviewers (n = 3)

Reviewers	Education Level	Employee of KFHI	Years of Research Experience	Country of Origin	Fluent in Written & Spoken English
1	M.D.	Yes	9 (above average)	USA	Yes
2	Registered Nurse	Yes	4 (average)	Yemen	Yes
3	Registered Nurse	Yes	0 (below average)	Egypt	Yes

Data collection instruments. Instruments for collecting data during the one-to-one review were based on the Dick et al. (2005) "Formative Evaluation Criteria for One-to-One Trials and the Types of Information for Each Criterion." A questionnaire containing 12 open- and closed-ended questions was developed (see Appendix L). In addition to the questionnaire, reviewers were encouraged to use the course materials provided to them to underline, highlight, or in other ways indicate errors and areas of difficulty or ambiguity.

Procedure for the one-to-one review. The course evaluator met with each of the reviewers individually and explained why the course had been designed, how the specific format and sequence were chosen, and how the instructional material had been designed. The evaluator explained that the material for the course was developed specifically for this course and the feedback from reviewers was sought in an effort to correct errors and

improve the course content. Each of the reviewers was provided with the following information and materials: (a) course objectives, (b) participant workbook, (c) the course textbook, (d) copies of all PowerPoint presentations, (e) copies of all pre-class readings, (f) a plan to be used for evaluating learner performance, and (g) the questionnaire. Reviewers were asked to liberally comment, underline, circle, etc., on the written material to indicate suggested changes, or point out errors or inconsistencies. The evaluator interacted with the reviewers at five different sittings and was personally available to discuss the materials and answer any questions. All reviewers were asked to complete the course pre-test and post-test as part of this review process. The reviewers were asked to evaluate the course instruction and instructional materials after each sitting using the questionnaire (see Appendix L).

Results of the one-to-one review. The results of the one-to-one review are summarized in Appendix M, which indicates the reviewers found the information understandable and logically presented. However, all reviewers felt that several English words and phrases may not to be understood by learners whose first language is not English. Additionally, two of the reviewers found that the statistical analysis classes were too difficult. Content analysis of the comments from the reviewers indicated that the course information would be helpful in meeting the learners' professional and personal goals.

Revisions to the CRMC were made as a result of the feedback received from the reviewers. First, 20 of the English words in the PPP were changed as the reviewers believed the words would be unfamiliar to many Arabic participants. Second, the level of

difficulty in the lecture on statistical methods was lowered. Third, minor typographical errors and two links to websites were corrected. Lastly, directions for completing the post-test were clarified.

Step 4: Small-Group Try-Out

In the small-group evaluation, the evaluator tried out the instruction with a group of learners in an environment similar to that which was used for the full field test. The evaluator recorded the small group performances and individual comments. The evaluator focused on (a) looking for the effects caused by the changes made in the one-to-one review and (b) identifying any remaining learning problems.

Design of the small-group tryout. Thirty-one learners were selected for the small-group tryout. Unlike the expert review, design review, and one-to-one review, the learners for the small group tryout were not selected based on purposeful sampling, nor, as would be "in an ideal research setting" (Dick et al., 2005, p.288), were they selected based on randomization procedures. The learners were selected following their response to a department-wide e-mail asking for persons who were interested in receiving education on the conduct of clinical research. Those who met the entrance criteria were asked to contact the KFHI research office. Forty-five KFHI staff members initially responded to the department-wide e-mail, however, only 31 attended the first CRMC class. The demographics of the 31 learners are presented in Appendix N. Coincidently, the learners met the criteria for all of the subgroups outlined in Dick et al. (2005): (a) low, average and high achieving learners; (b) learners with various native languages; (c)

learners who are familiar with a particular procedure and learners who are not; and (d) younger or inexperienced learners as well as more mature learners.

Dick et al. (2005) recommend that 8 to 20 learners be selected for the small group evaluation, citing that more than 20 learners may provide more data than needed to evaluate the course. Given the enthusiastic response to the department-wide e-mail and based on decisions made by KFHI administration, it was decided that all learners who attended the first class would be invited to participate as learner-reviewers.

Data collection instruments. The data collection instrument for the small group try-out was based on the Dick et al. (2005) assessments and questionnaires for small-group evaluation (see Appendix O). The questions provided qualitative data based on learners' perceptions, while test scores provided quantitative data. Also during the small group tryout, the comments and questions of learners outside of the classroom setting were noted, as well as any observations and comments made by the instructors and course evaluator.

Procedure for the small-group tryout. The learners met twice weekly and were administered the course materials in the same fashion as they were intended to be administered in future courses. During the first meeting, the evaluator explained the purpose and importance of this stage of the formative evaluation and encouraged learners to critically evaluate the CRMC to help identify its strengths and weaknesses. Learners were given the course objectives, participant workbook, the course textbook, and copies of all pre-class readings and copies of PPP used in lectures. The data collection instrument (see Appendix O) was administered to learners at the end of each week.

Results of the small-group tryout. Results of the small group tryout are summarized in Table 6. From the results of the small-group tryout, it was evident that difficulties were experienced with a number of topics, including research designs, concepts and methods, statistical in research, and research ethics. Revisions to the design of the CRMC were made following feedback from the reviewers. First, the length of time for each lecture was revised with more time given for the areas of difficulty and other topics slightly decreased. Second, the number of slides for three PPPs was decreased. Lastly, the directions for role-playing, which was utilized in several classes to explore complex issues such as obtaining informed consent from research subjects, were clarified.

The written and verbal comments of the Small-Group Reviewers were grouped under seven broad categories as follows:

- Statistics are too difficult for this level (10 reviewers)
- More time should be spent on statistics (18 reviewers)
- More time should be spent on research ethics (19 reviewers)
- Too much time was spent on research funding (16 reviewers)
- Too much time was spent on collaborative research with industry (19 reviewers)
- Very interesting/worthwhile/needed information (28 reviewers)
- Excellent course (19 reviewers)

Table 6

Summary of Results from Small-Group Evaluation (n = 31)

	Research Design, Concept, Method.		Data Collection		Research Conflicts of Interest		Stats Consideration in Research		Funding Research Project		Collaborative Research with Industry		Good Clinical Practice Guidelines		Research Ethics	
	Yes	No	Yes	No	Yes	No	Yes	No	Yes	No	Yes	No	Yes	No	Yes	No
Was the instruction interesting?	31	0	22	9	31	0	22	9	16	15	15	16	27	4	31	0
Did you understand what you were supposed to learn?	28	3	31	0	28	3	22	9	31	0	30	1	31	0	28	3
Were the materials directly related to the objectives?	31	0	31	0	31	0	31	0	31	0	31	0	31	0	31	0
Were sufficient practice exercises included?	20	11	31	0	25	6	15	16	N/A	N/A	N/A	N/A	29	2	11	20
Were the practice exercises relevant?	31	0	31	0	31	0	31	0	31	0	31	0	31	0	31	0
Did the tests really measure your knowledge of the objectives?	25	6	31	0	30	1	23	8	27	4	23	8	31	0	28	3
Did you receive sufficient feedback on your practice exercises?	31	0	31	0	31		31	0	31	0	31	0	31	0	31	0
Did you feel confident when answering questions on the post tests?	20	11	25	6	25	6	15	16	26	5	26	5	18	13	15	16

Summary

Chapter four reported on the design, the procedures, and results of a four-step formative evaluation of the clinical research management course (CRMC) at the King Faisal Heart Institute (KFHI) in Riyadh, Saudi Arabia. The purpose of a formative evaluation is not to determine learning outcomes, but rather to revise and make recommendations for revision to the instructional materials. The formative evaluation was based on the formative evaluation plan suggested by Dick et al. (2005). A course on the management of clinical research was purposefully designed and was the subject for this research. Data was collected from design and expert reviewers, as well as learners. In chapter five, the research synthesis is provided and discussed; conclusions are drawn, and recommendations are made.

Chapter 5: Discussion and Recommendations

Chapter five is a discussion of the results, implications, and recommendations of the formative evaluation of the instructional materials used with participants in the Clinical Research Management Course at the King Faisal Heart Institute (KFHI) in Riyadh, Saudi Arabia. The aim of a formative evaluation is not to determine learning outcomes, but rather to revise and make recommendations for revisions of the instructional materials.

First, a word regarding the data collected on the instructional materials in the CRMC itself. The data was collected in an objective and informed process utilizing a formative evaluation. The results were encouraging as they demonstrated that the course, with minimal changes, was in fact designed to teach needed course material with appropriate consideration for relevant subject matter, learner diversity, and learning environment.

Was the Dick, Carey, and Carey Instructional Design Model Appropriate?

This master's thesis research utilized the Dick et al. (2005) instructional design model to guide the formative evaluation. Formative evaluation is but a single step within the much larger process of course development called "Instructional Design." There are many models of instructional design; therefore, another relevant and legitimate concluding question is: Was the Dick et al. instructional design model suitable for this task with these participants?

The Dick et al. (2005) model is suitable for a variety of instruction delivery methods (Chang, 2006), and this model was suitable as a framework for identifying key

processes and guiding a systematic approach to designing the instructional materials for the CRMC. This model emphasizes a front-end analysis of learner characteristics and the context in which the learning is to take place, which was especially important in designing the CRMC.

Each of the stages of the Dick et al. (2005) instructional design model that was used in this research is discussed below in relation to the Clinical Research Management Course.

Stage I: Identify Instructional Goals

The plan to provide instruction to KFHI staff on the conduct of biomedical research was an initiative of the KFHI administration. However, the administration did not provide specific instructional goals. To appropriately fulfill this directive it was important to articulate instructional goals to guide the design of the instruction and instructional materials. The DECL model was brought in to lend support to the Dick and Carey model to help identify the goals, especially to confirm that administration did not affect the goals for the CRMC. Opinions of a subject matter expert and an analysis of previous performance were also utilized. Finally, a needs assessment was conducted to identify the instructional goals for the CRMC. This included a survey of KFHI physicians and support staff, a review of KFHI research projects, and a review of international, national, and local regulations. This process resulted in the development of four broad goals for the course and 17 specific instructional goals. However, it became evident throughout the pilot of the CRMC that, while instruction was needed and appreciated, other factors had contributed to the poor quality and quantity of KFHI research projects

and publications. Physicians in particular, described work schedules that were too busy and lack of knowledgeable research assistants as two important factors contributing to their current level of conducting research and publishing. These issues can only be partly addressed by instruction, namely by helping to provide knowledgeable research assistants. Although the front-end analysis did not fully take into consideration the impact of busy work schedules and lack of available research staff, the instructional goals and the learning needs assessment were appropriate for the CRMC and effectively guided the design and development of the instruction and instructional materials. The Dick and Carey model, with support from data obtained through the DECL context analysis, was therefore successful in identifying the instructional goals for an education program for healthcare professionals on the conduct of biomedical research at the King Faisal Heart Institute.

Stage 2: Conduct Instructional Analysis

The instructional analysis provided a description of the skills and knowledge that were required for learners to successfully master the instructional goals, and was used to assist in clearly stating learning objectives. The learning objectives in the Clinical Research Management Course are listed in Appendix H. The Dick and Carey instructional analysis was successful in assisting the designer to determine the skills needed to reach the educational goals, the domains of learning for each task, the steps that should be taken to achieve the tasks, and the sequence in which the steps would be offered in the CRMC. The results of the Expert Review and the One-to-One Review

confirmed that the objectives were clearly stated and the sequence of the instruction was logical.

Stage 3: Analyze Learners and Context

An analysis of the context for the instructional materials was conducted utilizing Richey's (1986) DECL model and Mann's adaptation of Richey's model for distributed learning environments (Mann, 1995, 1997, 2006). A most relevant and legitimate concluding question was: Was Richey's DECL model suitable for this task with these participants?

The Clinical Research Management Course was the first course designed to address the conduct of biomedical research for healthcare professionals at the King Faisal Heart Institute. Several key features made this course especially unique and Richey's (1986) model for contextual analysis provided important data which was essential in designing the instruction and instructional materials.

The data obtained during the analysis of the "Environment Factor" confirmed the directive of the KFHI Administration to provide education to healthcare professionals on the conduct of biomedical research and their commitment to providing the necessary resources. The analysis of the climate in which the course was to take place showed that in order to help facilitate learners' attendance, instruction would need to be provided at a scheduled time and in a location conducive to busy work schedules. Also, additional space was needed for group activities. These logistical considerations allowed the CRMC to be offered in an organized and predictive manner, therefore helping to provide efficient and effective use of resources.

Through the "Content Factor" analysis, the domains of learning, the learning domain tasks, and the mental operations required were identified. The results showed that learning would be primarily within the cognitive and affective domains. This was a lengthy process which resulted in identifying tasks that were primarily within the cognitive and affective domains, mental operations requiring self-study, the ability to attend and participate in class, and the ability to transfer learning from the classroom setting to the workplace. Also, data from the content factor analysis was instrumental in choosing appropriate topics to be taught in the Clinical Research Management Course.

Data obtained through an analysis of Richey's "Learner Factor" provided a description of the learners for the CRMC, including their demographics, competencies, capacities, and attitudes. Given the diversity of the potential learners and the inexperience of the instructors in teaching such a diverse group of learners, this step was of particular importance. The analysis took into account the professional, national, linguistic, religious, social, and cultural characteristics of learners and the resulting data helped to ensure that the instruction and instructional materials were professionally, linguistically, and culturally appropriate. Additionally, having identified that some learners would come from low-context cultures while others would come from high-context cultures, the analysis results helped instructors to prepare for a variety of learning styles and degrees of learner participation. In summary, through this process the designer obtained an understanding of how the design of the CRMC instruction and instructional materials could affect the learners and materials were designed appropriately.

Finally, the analysis of the "Delivery Factor" helped to delineate and articulate the instructional materials and how they would be presented. Data obtained from analyzing the scope, sequence, strategies, and presentation showed that a variety of formats of instructional materials and a variety of instructional strategies would be needed. The effectiveness of using a variety of formats and strategies was confirmed by the one-to-one reviewers and throughout the small-group tryout.

This stage of the Dick and Carey model was weak for the design of the CRMC in that, as stated in Chapter 3, in assessing learning characteristics and learning context, the model de-emphasizes all other factors except learner and content. Therefore, without utilizing a more balanced approach, important factors would not have been considered in developing the CRMC. Richey's DECL model (1986) for conducting a context analysis proved to be an effective tool for assessing a variety of factors that may affect learner achievement in the Clinical Research Management Course. Basic assumptions about the context in which the CRMC would be taught, were either confirmed or refuted as a result of this process and in assessing the delivery, environment, content, and learner factors, the designer was better equipped to offer instructional materials and instructional methods of delivery that were more appropriate and effective.

Stage 4: Write Learning Objectives

Sixty learning objectives, utilizing the A-B-C-D format, were developed for the Clinical Research Management Course following the instructional analysis and taking into consideration the results of the context analysis. The objectives were used to guide instructional strategies, instructional material design, and test development, as well as

communicate to instructors and learners what specifically the learners were expected to master and under what conditions. Only major learning objectives were provided and the results of the one-to-one review and the small-group tryout indicated that the objectives were understood and helpful to the majority of learners.

Utilizing the A-B-C-D format and building on the previous stages, this stage of the Dick and Carey model was effective in helping to translate the goals and instructional analysis into clearly stated objectives that were used in the development of the instructional materials, including assessment instruments.

Stage 5: Develop Assessment Instruments

Criterion-referenced assessment was utilized to help learners evaluate their progress, assist the designer in identifying areas for revision, and provide information to instructors to identify areas for remedial teaching. The results of the written assignments and post-tests and the objective evaluation of facilitated discussions confirmed that criterion-referenced assessment was appropriate and useful in the CRMC.

This stage of the Dick and Carey model was effective in helping the course designer structure test items that were based on the instructional objectives in stage four (writing learning objectives), and therefore avoided ambiguity in learner assessment. The descriptions given by Dick et al. (2005) provided the necessary framework for developing the test instruments that were used to assess learner achievement of the complex skills of the CRMC.

Stage 6: Develop Instructional Strategies

For this stage in the Dick and Carey model, the sequencing of instruction and choice of instructional delivery strategies were determined based on Richey's (1986) DECL model context analysis and incorporating Gagne's conditions of learning (1985), as well as, Keller's ARCS model for learner motivation (1987).

The instructional sequence was designed to be congruent with the logical sequence of steps taken when conducting biomedical research, which is beginning with identifying a research question and progressing to the final step of publishing the research results. This sequence was in keeping with teaching subordinate skills first and then progressing to integration and practicing as described in the Dick and Carey model. A variety of instructional strategies were employed in the delivery of the CRMC, namely pre-class readings and assignments, oral presentations supported by PPPs, participant workbook, course textbook, and an instructor's manual.

This stage of the Dick and Carey model was helpful, effective, and appropriate in designing the CRMC. During this stage, the designer was provided with descriptions and examples of a variety of instructional strategies and was able to examine alternative strategies and choose strategies that would effectively and efficiently affect learner achievement.

Stage 7: Develop and Select Instructional Materials

For this stage of the Dick and Carey model, developing and selecting instructional materials, the designer utilized Richey's (1986) DECL model and Mann's adaptation of Richey's model for distributed learning environments (Mann, 1995, 1997, 2006) in

combination with the guidelines and suggestions given by Dick et al. (2005). This was a particularly important stage as no instructional materials existed for the CRMC and none were available that the designer or instructors could borrow or adapt, with the exception of a published textbook used as a reference for learners. This stage of the Dick and Carey model was a logical step which built on the previous stages and resulted in "tangible" products to be used in the CRMC. Given the financial and time costs of creating instructional materials, this stage was crucial in creating instructional materials that were relevant to the learning objectives, interesting to the learners, and useful for the instructors,

Stage 8: Design and Conduct Formative Evaluation of Instruction

The formative evaluation conducted on the Clinical Research Management Course, designed for healthcare professionals at the King Faisal Heart Institute in Riyadh, was based on the eighth stage in the Dick et al. (2005; 2009) model for the systematic design of instruction. The purpose of the formative evaluation was to provide data that would identify weaknesses and areas for improvements to the instructional materials including "the instruments, procedures and personnel" (Dick et al., 2005, p. 279).

In the Dick and Carey model, the formative evaluation focuses on obtaining data from the learners. The roles of subject matter and design experts are deemphasized with only limited descriptions of their roles given, however, subject matter and design experts were utilized in the formative evaluation of the CRMC. The important question here is "Did conducting a formative evaluation on the instructional materials of the Clinical Research Management Course improve the effectiveness of instruction?"

Each stage of the formative evaluation process provided data that was used to make the revisions in the instructional materials that are described earlier in this Report and summarized in Appendix P. By conducting a formative evaluation, the revisions were made systematically and objectively. Through the Design Review, writing for publication was added as a new topic to the CRMC. This proved to be well received by the learners and they suggested that additional classes be held on the topic outside of the CRMC so other KFHI staff could learn how to improve their writing skills. The reviewers for the Expert Review were given a somewhat formidable task in that none of the reviewers had experience in designing or teaching research education programs. However, each reviewer assessed all the instructional materials, frequently asking for references and conducting their own literature searches on how instructional materials should be effectively evaluated. Reviewers readily acknowledged their inexperience in performing the review but their results and comments demonstrated their commitment and objectivity. The One-to-One Review was the first exposure of the CRMC to a minimal number of learners from the targeted group. This one-to-one teaching provided valuable information that was not only useful in revising the instructional materials, but also provided the designer and the instructors with opportunities to observe learners' reactions to the introduction of certain topics and use of examples and case scenarios based on local situations. This "intangible" information helped the designer to observe learners' reactions to certain aspects of the CRMC in the Small-Group Try-Out and helped instructors prepare for teaching in the larger group. The sample size for the Small-Group Try-Out was larger than recommended by Dick et al. (2005), however, the course

evaluator believed that this larger number did not unfavorably impact on the results. Quite to the contrary, the number of learners who voluntarily participated in the Small-Group Try-Out and enthusiastically provided data added to the credibility and validity of the evaluative process. The importance of obtaining input from learners is a hallmark of this research as obtaining learner input is considered the most important factor in improving learning from the instructional materials (Weston et al., 1997).

In answering the question posed at the beginning of this chapter, "Was the Dick, Carey, and Carey Instructional Design Model Appropriate?" it is important to remember that an instructional designer must select an instructional design model and a method for evaluating the instructional materials that provide sufficient objective data to address the requirements of a particular course and the designer. Different instructional design models focus on different aspects and incorporate evaluation differently. The Dick et al. (2005) model for instructional design was an effective framework for the design of the Clinical Research Management Course for the staff of the King Faisal Heart Institute. Through utilizing the Dick et al. formative evaluation plan, effective instructional materials were designed and delivered to the staff at the King Faisal Heart Institute in a course teaching clinical research management.

Limitations of Formative Evaluation

In concluding, it is important to address the limitations of this research project. Since this study was a formative evaluation and not an experiment, issues of population sampling, experimental validity, and reliability were not relevant. Therefore, any attempt to generalize the findings to similar population is not possible. The sole aim of a

formative evaluation is to recommend improvements to the design of the instructional materials. In this study, the Dick et al. (2005) model of formative evaluation was used to guide the process.

There are numerous models for conducting a formative evaluation of instructional materials and a variety of ways and time-points in which they can be conducted (Dick et al., 2005; Weston et al., 1995). The Dick and Carey model emphasizes assessment by learners with lesser emphasis given to the role of subject matter experts and learning experts. In designing a new course in a unique environment such as the KFHI, the role of subject matter and learning experts is vitally important. As well, the Dick and Carey model prescribes three steps of learner evaluation. Omitting the one-to-one step would have shortened the time for conducting the evaluation and potentially the course would have been completed and offered earlier. The information obtained in the one-to-to step would have, in all probability, been obtained in the small group tryout.

Recommendations

The primary aim of this research was to improve the instructional materials of a course for healthcare professionals on the conduct of biomedical research. Several recommendations were made by reviewers and participants throughout the formative evaluation of these materials. The original instructional materials were revised based on the results of data from design and subject matter experts, as well as samples from the targeted learners. The resulting materials can be used in the future to deliver the Clinical Research Management Course to KFHI staff. However, despite these encouraging reviews, extended interventions with these materials may be required to produce the

information needed to keep the course content relevant and accurate. It may be prudent therefore to augment these measures with a more sensitive instrument. Meanwhile, it is hoped that the results of this evaluation provides some direction for administrators and instructors and the King Faisal Heart Institute.

Summary

Chapter five presented a discussion of the results of the design, expert, and one-to-one reviews, as well as small-group try-out, of the Clinical Research Management Course at the King Faisal Heart Institute in Riyadh, Saudi Arabia. It also discussed the appropriateness of the Dick, Carey, and Carey Model of Instructional Design as a framework for designing and evaluating the course. The information obtained and recommendations provide insight into instructional design the revision process itself.

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APPENDICES

Appendix A:

International Courses and Programs Reviewed For Common Topics

Name of Course	Format	Offering Institution	Topics Covered
Fundamentals of Clinical Research	On-line	Medical Research Management	Food and Drug Administration (FDA), Drug discovery and research, Clinical Research, Good Clinical Practice (GCP), International Conference on Harmonization (ICH), Protocol Design, Case Report Form Design; Clinical Trial Management, Monitoring Clinical Trials, Research Ethics
Research and Practice Fundamental	Web-Based	University of Pittsburg	Research Integrity, Human Subject Research, Conflict of Interest, HIPAA/Confidentiality
Clinical Research	Classroom	University of Texas	Clinical Epidemiology, Statistics, Study Design, Recruitment, Randomization, Data Collection, Quality Control, Data-Monitoring, Proposal Design, Scientific Writing, Research Ethics
Foundations of Clinical Research	Classroom and on-line	Center for Clinical Research Practice	History of Clinical Research, Protocol Design, Implementation and Management
Foundations of Human Subject Protection	Classroom and on-line	Center for Clinical Research Practice	Research Ethics and Regulation
Investigators 101	CD-ROM Self Study	Public Responsibility in Medicine and Research	Research Ethics and Regulation

Name of Course	Format	Offering Institution	Topics Covered
The Ultimate Step-By-Step Guide to Conducting Pharmaceutical Clinical Trials in the USA	Self-Study Textbook	The RAN Institute	Clinical Research Key-Player, Study Phases, Research Terms
Society of Clinical Research Associates Workshops	Workshops; Conferences; Courses	Society of Clinical Research Associate	Good Clinical Practice, FDA, Research Sponsors and Investigators, Data Management, Subject Enrollment, Informed Consent, Research Negligence, Conflict of Interest, Recordkeeping, Research Development, Adverse Events, Research Subjects, ICH, Ethics Committees, Declaration of Helsinki, Research Coordinator, Monitoring, Standard Operating Procedures, Research Ethics and Regulations, Contract Negotiation; Sponsored Research, International Research, Site Selection and Initiation, Study Conduct, Audit Protocol Development
Clinical Research Coordinator Training Program	Classroom: Web-based	Barnett Educational Services	Drug Development, Good Clinical Practice, Clinical Research Team Responsibilities, Institutional Review Boards, Subject Recruitment and Retention, Informed Consent, Study Documents, Monitoring, Adverse Events, Drug Accountability; Budgets, Audits, FDA, Sponsored Research, Research Terminology
Building a Clinical Trials Program	Symposium	Merck and Company	Clinical Research, Good Clinical Practice, Research Regulations, Clinical Research History, Subject Recruitment

Name of Course	Format	Offering Institution	Topics Covered
SOPs for Investigator Sites	Workshop	Association of Clinical Research Professionals	Good Clinical Practices, Research Regulations, ICH, Research Study Team, Research Contracts and Budgets, Monitoring, Study Documentation, Audits, Informed Consent
GCP Training	Workshop	Association of Clinical Research Professional	Drug Development, Phases of Drug Development, ICH, Research Ethics, Research Regulations, Sponsored Research, Conflict of Interest, FDA, Subject Recruitment, Code of Federal Regulation, Audits
Clinical Trial Management Certificate Program	Classroom	University of Chicago	Drug Development, Good Clinical Practices, Statistical Concept in Research, Site Management, Monitoring, Research Writing, Adverse Events, Subject Recruitment, Budgets, Contracts
BS in Health Sciences: Clinical Research	Classroom or Web-based	The George Washington University	Courses in the major include, Biostatistics, Basics of Clinical Research, Processes of Clinical Research, Good Clinical Practices, The Business of Clinical Research, Clinical Research Administration Internship
MS in Health Sciences: Clinical Research	Classroom or Web-based	The George Washington University	Courses in the major include, Biostatistics, Basics of Clinical Research, Processes of Clinical Research, Good Clinical Practices, The Business of Clinical Research, Clinical Research Administration Internship.

Name of Course	Format	Offering Institution	Topics Covered
Building Resources for Randomized Trials	Web-based	Resource Center for Randomized Trials	Research Protocols, Ethics, Consent, Trial Management, Statistics, Research Methodology;
Responsible Conduct of Research	Web-based	The Responsible Conduct of Research Consortium	Research Ethics, Research Guidelines, Regulation, Data Management, Conflicts of Interest, Research Misconduct.

Appendix B:

Results of KFHI Staff Questionnaire (n = 102)

Topic	No experience with topic/ education required	Some experience with topic/ education required	Very experienced topic/ no education required
Research Guidelines and Regulations			
• ICH- -GCP	94	3	5
• KFSHandRC policies and regulations	60	37	5
• KSA laws and guidelines	100	2	0
Research Methods			
• Developing a research question/hypothesis	24	43	35
• Conducting a literature review	7	87	8
• Research design and methodology	60	34	8
• Statistical methods in research	50	45	7
• Writing the research proposal	35	32	35
• Data collection , analysis and monitoring	69	24	9
Ethics			
• Ethical considerations in conducting clinical research	85	12	5
• Protection of vulnerable populations	88	9	5
• Obtaining and documenting informed consent	75	22	5
• Writing research consent documents	87	10	5
• Collaboration with a Research Ethics Committees	80	22	10
• Recruitment and enrollment of human research subjects	81	7	14
Research Project Management			
• Role of each member of the research team	38	42	22
• Preparing and submitting the research proposal documents	52	32	18
• Constructing case report forms/data collection forms	81	15	6

Appendix C:

Demographics of Respondents

	n	Average	Percentage	Range
Female	34		33	
Male	68		67	
Age (years)		32.8		22-55
Years as HCP		12.3		3-25
Direct Research Experience				
• Yes	76		75	
• No	26		25	
Previous Formal Research Education				
• Yes	0		0	
• No	102		100	
English as First Language				
• Yes	4		4	
• No	98		96	
Occupation				
• Physician	46		45	
• Research Coordinator	8		8	
• Nurse	37		36	
• Perfusionist	3		3	
• Cath Lab Technician	4		4	
• Other	4		4	

Appendix D:

Power Point Presentations

	Topic	Name of PP Presentation	Number of Slides
I.	Research Concepts	Research Methods Part 1: Research Concepts	25
II.	Research Regulations	Research Regulations: International, National, Local	20
III.	Research Program Management	Project Planning/Organization and Management	32
IV.	Data Collection	Research Data Management and Processing	30
V.	Research Conflicts of Interest	Conflicts of Interest, Research Misconduct, Privacy and Confidentiality	32
VI.	Preparing the Research Proposal	Research Methods Part 2: When and Where Should you Invest your Efforts? Developing a Hypothesis Statement and Study Aims; Conducting a Literature Review	45
VII.	Statistical Considerations in Research	Statistical Methods in Cardiovascular Research	22
VIII.	Funding the Research Project	Study Budget, Funding, and Contracts	18
IX.	Research Design and Methodology	Research Methods Part 3: Research Design and Methodology	35
X.	Collaborative Research With Industry	Externally Sponsored (pharmaceutical/device company) Research	30
XI.	Good Clinical Practice Guidelines	ICH-GCP Workshop	86

	Topic	Name of PP Presentation	Number of Slides
XII.	Research Ethics	Research Ethics	32
XIII.	Study Drugs and Devices	Maintenance of Research Drug and Device Inventory and Accountability	22
XIV.	Submitting the Research Proposal Package	Bringing it All Together: Preparing the Research Proposal	35
XV.	Critical Evaluation of Medical Articles	Critical Evaluation of Medical Articles	22
XVI.	Writing for publication; International publication guidelines	Preparing Your Manuscript for Submission to Peer-Reviewed Journals	36

Appendix E:

Learning Objectives

Topic	Learning Objectives
Introduction; Research Methods Part 1: Research Concepts **Instructional Goal:** Given a clinical situation in which treatment options are ambiguous, participants will develop a research hypothesis and chose a research design that are testable according to two expert research investigators.	1. Given a description of the potential benefits and risks of conducting biomedical research and following class discussion on the issues, the learner will be able to demonstrate as understanding of the topic by evaluating in writing the benefits and risks of four hypothetical research proposals, as measured by defined elements and with 80% accuracy. 2. Given examples of clinical research questions, the learner will accurately identify two types of research that may be used to answer the clinical question for all questions given, as measured by defined elements and with 100% accuracy. 3. Given examples of four medical diagnosis and histories, the learner will be able to list at least three relevant research topics and one research question for each example given, as measured by defined elements and with 100% accuracy. 4. Given a list of the phases of biomedical research, the learner will be able to describe in writing each phase with key elements included as measured by a checklist and with 100% accuracy. 5. Given a description of the SMART concept, the learner will be able to explain how the concept can be applied to clinical research as demonstrated by the ability to verbally describe one research project in which the SMART can be used, as measured by defined elements and with 80% accuracy.

Topic	Learning Objectives
Research Regulations: International, National, Local **Instructional Goal:** Given examples of clinical research proposals, participants will be able to accurately identify the pertinent regulation or ethical principle governing the research by choosing the correct response in multiple-choice questions, eighteen out of twenty times.	6. Given a list of five key documents relevant to the conduct of biomedical research, the learner will be able to identify in writing the author(s) of each document, as measured by given list and with 80% accuracy. 7. Given a list of five key documents relevant to the conduct of biomedical research, the learner will be able to verbally describe the importance of each document in conducting research, as measured by a checklist and with 80% accuracy. 8. Given a research proposal, the learner will be able to describe verbally the regulations governing biomedical research in Saudi Arabia that are relevant to the research, as measured by a checklist and with 100% accuracy. 9. Given a hypothetical research proposal, the learner will prepare the supporting documents for submitting the research proposal to the KFSH&RC ethics committee, as measured by a checklist and with 100% accuracy.

Topic	Learning Objectives
Research Project Planning/Organization and Management **Instructional Goal:** Given a research proposal, participants will develop a project management plan that includes all the pertinent stakeholders, a workplan, a schedule of events, a reporting system and an evaluation scheme, as measured by a checklist utilized by the instructor.	10. Given a hypothetical research project, the learner will list and describe in writing five key principles of research project management as measured by a checklist, and with 80% accuracy. 11. Given a hypothetical research project, the learner will list and describe five potential causes of project failure as measured by a checklist, and with 80% accuracy. 12. Given a hypothetical research project, the learner will be able to evaluate the project management issues, when conducting research at the KFSH&RC, as demonstrated by the ability to discuss verbally the issues to be encountered, as measured by defined elements, and with 80% accuracy. 13. Given a hypothetical research project, the learner will be able to design a research work plan that includes a timetable of events and the roles and responsibilities of personnel involved in a research study, with 80% accuracy.

Topic	Learning Objectives
Research Data Management and Processing **Instructional Goal:** Given a research proposal, participants will design a case report form and a database that include all the data points of the research project, as measured by a checklist utilized by the instructor.	14. Given a description of the basic principles of Case Report Form (CRF) and a written hypothetical research proposal, the learner will be able to design a CRF that includes all the required data sets, as measured by a checklist, and with 100% accuracy. 15. Given a written hypothetical research proposal, the learner will be able to discuss the relationship between the research question, the CRF, the database design and the documentation, by the ability to verbally describe the purpose of each element in relation to the complete research project, as measured by a checklist, and with 80% accuracy. 16. Given a written hypothetical research project, the learner will demonstrate an understanding of the basics of SPSS by designing a database in SPSS, as measured by a checklist, and with 100% accuracy. 17. Given the data from a hypothetical research project, the learner will demonstrate an understanding of the basics of SPSS by entering the data in the SPSS database with 100% accuracy. 18. Given a SPSS database in which the data has been entered, the learner will conduct basic descriptive data analysis, as measured by a checklist, and with 100% accuracy.

Topic	Learning Objectives
Conflicts of Interest, Research Misconduct, Privacy and Confidentiality **Instructional Goal:** Given a research proposal, participants will identify the potential and actual conflicts of interest that may occur and identify measures to prevent or minimize the conflicts, as measured by a checklist utilized by the instructor.	19. Given three hypothetical research projects, the learner will discuss issues relevant to conflicts of interest, research misconduct, privacy and confidentiality as demonstrated by the by the ability to verbally describe each issue in relation to the research projects, as measured by defined elements, and with 80% accuracy. 20. Given examples of conflicts of interest and research misconduct, the learner will describe in writing, methods to prevent and/or manage each example, as measured by a checklist, and with 80% accuracy. 21. Given a hypothetical research scenario, the learner will define in writing, the terms privacy and confidentiality and describe methods to ensure both in medical research, as measured by defined elements and with 80% accuracy.
Research Methods Part 2: When and where should you invest your efforts? Developing a Hypothesis Statement and Study Aims; Conducting a Literature Review **Instructional Goal:** Given a clinical situation in which treatment options are ambiguous, participants will develop a research hypothesis and write a research proposal that includes the research question, objectives, background and subject selection.	22. Given a hypothetical clinical dilemma, the learner will develop a research question and hypothesis, as measured by defined elements, and with 80% accuracy. 23. Given a research question, the learner articulate in writing, the state research objectives/aims, as measured by defined elements, and with 80% accuracy. 24. Given a research question and research aims, the learner will chose a research methodology and discuss the reasons for choosing the methodology, by the ability to verbally describe his/her rationale, as measured by a algorithm, and with 80% accuracy. 25. Given a hypothetical research question, the learner will demonstrate an effective search of the published literature, as measured by a checklist, and with 80% accuracy. 26. Given a hypothetical research question and aims and a research methodology, the learner will be able to list appropriate inclusion and exclusion criteria with 85% accuracy.

Topic	Learning Objectives
Statistical Methods in Cardiovascular Research **Instructional Goal:** Given a clinical research question, a background of the research topic and the methods to be used in a research study, Learners will describe methods of statistical analysis and state the reason for choosing such methods. The description will include: a) the number of patients; considerations of sample size and assumptions used in calculating sample size based on clearly defined expected outcomes; b) a plan for analysis of dropouts, crossover, and poor compliance; and c) a plan for interim analysis.	27. Given a clinical research question, the learner will formulate a testable, scientific hypothesis to address the questions posed, as measured by defined elements, and with 80% accuracy. 28. Given a hypothetical research protocol, the learner will describe verbally the importance of the sample size requirements as it relates to power, as measured by defined elements, and with 80% accuracy. 29. Given hypothetical research results, the learner will create a Kaplan-Meier survival curve appropriate for the research results, as measured by defined elements, and with 100% accuracy. 30. Given hypothetical research results, the learner will discuss verbally the use of the Cox- regression and its frequent use in cardiovascular research, as measured by defined elements, and with 80% accuracy.

Topic	Learning Objectives
Study Budget, Funding, and Contracts **Instructional Goal:** Given two research proposals, participants will develop a study budget that includes all the expenses related to the study, identify appropriate sources of funding, and complete the research funding applications forms with 90% accuracy.	31. Given a hypothetical research protocol, the learner will list in writing the generally accepted expenditures for the research, as measured by a checklist, and with 80% accuracy. 32. Given a hypothetical research protocol, the learner will list in writing three potential sources of funding for KFHI research, as measured by a checklist, and with 100% accuracy. 32. Given a hypothetical research protocol, the learner will design a budget for a KFHI sponsored research proposal, as measured by comparison to a previously prepared budget, and with 80% accuracy. 33. Given a hypothetical research protocol, the learner will design a budget for an externally sponsored research proposal, as measured by comparison to a previously prepared budget, and with 80% accuracy. 34. Given a hypothetical research protocol, the learner will discuss verbally the elements to be included in an externally-sponsored research contract, as measured by defined elements, and with 80% accuracy. 35. Given a hypothetical research project, the learner will design a basic financial database for documenting research income and expenditures, as measured by a checklist, and with 80% accuracy.

Topic	Learning Objectives
Research Methods Part 3: Research Design and Methodology **Instructional Goal:** Given a clinical situation in which treatment options are ambiguous, participants will develop a research hypothesis and write a research proposal that includes the research question, objectives, background and subject selection.	37. Given the definitions and examples of qualitative and quantitative research, the learner will differentiate between qualitative and quantitative research and explain when one or both should be used in research, as measured by defined elements, and with 80% accuracy. 38. Given the definitions and examples appropriate to biomedical research, the learner will define reliability, internal validly, and external validly and discuss verbally methods to ensure each in biomedical research, as measured by defined elements, and with 80% accuracy. 39. Given the definitions and examples appropriate to biomedical research, the learner will describe verbally, in general terms, how writing qualitative research proposals differ from writing quantitative research proposals, as measured by defined elements, and with 80% accuracy.
Externally Sponsored (pharmaceutical/device company) Research **Instructional Goal:** Given a hypothetical collaborative agreement between a pharmaceutical company and the KFHI, participants will describe the purpose of the investigators' meeting, list and discuss pre-study activities, discuss study initiation and termination activities, and describe two types of study monitoring, as measured by a checklist utilized by the instructor.	40. Given a hypothetical collaborative research agreement between a pharmaceutical company and the KFHI, the learner will describe verbally the drug/device development process and the collaborative role between medical researchers and industry, as measured by defined elements, and with 80% accuracy. 41. Given a hypothetical externally-sponsored research project, the learner will describe in writing investigator/site selection, activities involved in study initiation meetings, preparing a site for study participation, collection and evaluation of research data, and close-out activities as measured by defined elements, and with 80% accuracy. 42. Given a hypothetical externally-sponsored research project, the learner will describe in writing why and how a research study audit is conducted, as measured by defined elements, and with 80% accuracy.

Topic	Learning Objectives
ICH-GCP Workshop **Instructional Goal:** Given a copy of the International Conference on Harmonization: Good Clinical Practice (ICH: GCP) Guidelines, participants will be able to describe the practical application of at least five provisions from each ICH: GCP sections, as measured by a checklist utilized by the instructor.	43. Given a definition and description of ICH-GCP Guidelines, the learner will describe in writing the basic principles of ICH-GCP Guidelines including the responsibilities of the investigators, the sponsor, the institutional review board, and research monitors, as measured by defined elements, and with 80% accuracy. 44. Give a specific example of a research project conducted at the KFHI, the learner will describe verbally how ICH-GCP Guidelines were implemented in the research, as measured by defined elements, and with 80% accuracy.

Topic	Learning Objectives
Research Ethics **Instructional Goal:** Given a clinical research question, learners will be able to discuss the ethical consideration when conducting research and design research proposals that meet international ethical standards.	45. Given examples of clinical research, the learner will describe in writing the ethical considerations of conducting research and who is responsible for ensuring the research is conducted ethically, as measured by defined elements, and with 100% accuracy. 46. Given examples of clinical research, the learner will discuss in writing the importance of research ethics, as measured by defined elements, and with 80% accuracy. 47. Given the definition of Institutional Review Board (IRB) and the opportunity to attend an IRB meeting, the learner will define in writing an IRB and discuss in writing the IRB's role in medical research, as measured by defined elements, and with 80% accuracy. 48. Given the definition and examples of informed consent, the learner will describe verbally the issues related to consent in special circumstances and with vulnerable populations, as measured by defined elements, and with 80% accuracy. 49. Given the background of a research topic, the methods to be used in a research study, the risks and benefits of the research, and a description of the methods of statistical analysis, learners will write an informed consent document for research subjects using the Hospital template and will discuss in writing the ethical considerations of the study, as measured by defined elements, and with 100% accuracy.

Topic	Learning Objectives
Maintenance of Research Drug and Device Inventory and Accountability **Instructional Goal:** Given a research proposal in which drugs are being tested and one research proposal in which medical devices are being tested, participants will design study drug/device inventories and describe the procedures for maintaining the inventories, as measured by a checklist utilized by the instructor.	49. Given a hypothetical research proposal, the learner will describe verbally the importance of study drug/device management, as measured by defined elements, and with 80% accuracy. 50. Given a description of Investigational Drug Services (IDS) at the KFSH&RC, the learner will discuss verbally how the IDS would be utilized in a hypothetical KFHI research project, as measured by defined elements, and with 80% accuracy. 51. Given a hypothetical research proposal, the learner will design documents for a research project's drug inventory, as measured by defined elements, and with 80% accuracy.
Bringing it All Together: Preparing the Research Proposal **Instructional Goal:** Given a research hypothesis and building on the information presented in the course, participants will write a research proposal that meets all the scientific, regulatory, and ethical requirements of the Hospital	52. Given a clinical question, the learner will write a research proposal that meets the scientific, ethical, and regulatory requirements of the KFSH&RC, as measured by defined elements, and with 100% accuracy.
Instructional Goal: Given a research proposal, participants will prepare all the documents required to be submitted with proposal to the Institutional Review Board, as measured by a checklist utilized by the instructor.	53. Given a research proposal, participants will prepare all the documents required to be submitted with proposal to the Institutional Review Board, as measured by a checklist, and with 100% accuracy.

Topic	Learning Objectives
Critical Evaluation of Medical Articles **Instructional Goal:** Given a medical journal article from a peer reviewed journal, which describes the results of a clinical research project, participants will be able to assess the article using the "Manuscript Quality Assessment Instrument" developed by Goodman et al, which will be 80% accurate when compared with the instructor's analysis of the same article.	54. Given a medical journal article from a peer reviewed journal which describes the results of a clinical research project, the learner will ddiscuss verbally what constitutes credible research results, as measured by defined elements, and with 80% accuracy. 55. Given the definition and examples of "rules of evidence" as they apply to biomedical reach, the learner will discuss in writing the rules of evidence in relation to a journal article from a peer reviewed journal describing the results of a clinical research project, as measured by defined elements, and with 80% accuracy. 56. Given a description of the "Manuscript Quality Assessment Instrument" developed by Goodman et al., the learner will ccritically evaluate a medical research article and describe the evaluation in writing, as measured by defined elements, and with 80% accuracy.
Writing for Publication (abstracts; manuscripts) International Publication Guidelines **Instructional Goal:** Given the description and results of a fictitious research study, participants will be able to draft a manuscript that describes the major sections of a medical manuscript including an abstract, introduction, methodology, results, and discussion as evaluated by the instructor.	57. Given a published article reporting the results of research, the learner will discuss verbally how publications reflect the conduct of a research project, as well as, presenting the research results, as measured by defined elements, and with 80% accuracy. 58. Given the description and results of a fictitious research study, the learner will describe verbally how to write the methods and analysis of data, as measured by defined elements, and with 100% accuracy. 59. Given the description and results of a fictitious research study, the learner will write an abstract for publication, as measured by defined elements, and with 100% accuracy. 60. Given the description and results of a fictitious research study, the learner will write a manuscript for hypothetical publication, as measured by defined elements, and with 80% accuracy.

Appendix F:

Matrix Indicating Materials Given to Reviewers of the CRMC

Instructional Component	Expert Design Review	Content Expert Review	One-to-One Review	Small group Tryout
Needs Assessment	X			
Task Analysis	X	X		
Contextual Analysis	X			
Participants Workbook	X	X	X	X
Course Objectives	X	X	X	X
Course Textbook	X	X	X	X
Power Point Presentations	X	X		
Evaluation Plan	X	X		
Instructor's Manual	X	X		
Questionnaire	X	X	X	X
Interview	X	X	X	X

Appendix G:

Questions for Design Review

Please indicate whether the describe principle is present (Yes) or not present (No).

	Yes	No
Motivation		
1. Are strategies used to gain and maintain the learners' attention (e.g., emotional or personal appeals, questions, thinking challenges, human interest examples, etc.)?		
2. Is the instruction relevant for the given target group and are learners informed and convinced of the relevance (e.g., information about new requirements for graduation, certification, employment, advancement, self-actualization, etc.)?		
3. Are learners likely to be confident at the onset and throughout instruction so that they can succeed (e.g., learners informed of purposes and likely to possess prerequisites; instruction progress from familiar to unfamiliar, concrete to abstract; vocabulary, contexts, and scope appropriate; challenges present but realistic; etc.)?		
4. Are learners likely to be satisfied from the learning experience (e.g., relevant external rewards such as free time, employment, promotion, recognition; actual intrinsic rewards such as feelings of success, accomplishment, satisfaction of curiosity, intellectual entertainment)?		
Characteristics of Instruction: Intellectual Skills		
1. Are learners reminded of prerequisite knowledge they have stored in memory?		
2. Are links provided in the instruction between the prerequisite skills stored in memory and new skills?		
3. Are ways of organizing new skills presented so they can be recalled more readily?		
Characteristics of Instruction: Intellectual Skills		
1. Are the physical, role, and relationship characteristics of concepts clearly described and illustrated?		

1. Are application procedures clearly described and illustrated for roles and principles?

2. Are quality criteria (characteristics) directly addressed and illustrated for judging adequate versus inadequate results such as answers, products, or performance?

3. Are obvious but irrelevant physical, relational, and quality characteristics and common errors made by beginners directly addressed and illustrated?

4. Do the examples and nonexamples represent clear specimens of the concept or procedure described?

5. Are examples and contexts used to introduce and illustrate a concept or procedure familiar to the learners?

6. Do examples, contexts, and applications progress from simple to complex, familiar to unfamiliar, and/or concrete to abstract?

7. Do practice and rehearsal activities reflect application of the intellectual skills or merely recall of information about the performance of the skill?

8. Does feedback to learners provide corrective information and examples, or does it merely present a correct answer?

9. When appropriate, are follow-through activities such as advancement, remediation, and enrichment present and logical (e.g., address prerequisites, focuses on improved motivation, provide additional examples and contexts)?

Appendix H:

Results of Design Review (n = 4)

	Yes	No
Motivation		
1. Are strategies used to gain and maintain the learners' attention (e.g., emotional or personal appeals, questions, thinking challenges, human interest examples, etc.)?	4	0
2. Is the instruction relevant for the given target group and are learners informed and convinced of the relevance (e.g., information about new requirements for graduation, certification, employment, advancement, self-actualization, etc.)?	4	0
3. Are learners likely to be confident at the onset and throughout instruction so that they can succeed (e.g., learners informed of purposes and likely to possess prerequisites; instruction progress from familiar to unfamiliar, concrete to abstract; vocabulary, contexts, and scope appropriate; challenges present but realistic; etc.?)	2	2
4. Are learners likely to be satisfied from the learning experience (e.g., relevant external rewards such as free time, employment, promotion, recognition; actual intrinsic rewards such as feelings of success, accomplishment, satisfaction of curiosity, intellectual entertainment)?	4	0
Characteristics of Instruction: Intellectual Skills		
1. Are learners reminded of prerequisite knowledge they have stored in memory?	4	0
2. Are links provided in the instruction between the prerequisite skills stored in memory and new skills?	3	1
3. Are ways of organizing new skills presented so they can	3	1

	Yes	No
be recalled more readily?		
4. Are the physical, role, and relationship characteristics of concepts clearly described and illustrated?	3	1
5. Are application procedures clearly described and illustrated for roles and principles?	4	0
6. Are quality criteria (characteristics) directly addressed and illustrated for judging adequate versus inadequate results such as answers, products, or performance?	3	1
7. Are obvious but irrelevant physical, relational, and quality characteristics and common errors made by beginners directly addressed and illustrated?	3	1
8. Do the examples and non-examples represent clear specimens of the concept or procedure described?	4	0
9. Are examples and contexts used to introduce and illustrate a concept or procedure familiar to the learners?	4	0
10. Do examples, contexts, and applications progress from simple to complex, familiar to unfamiliar, and/or concrete to abstract?	4	0
11. Do practice and rehearsal activities reflect application of the intellectual skills or merely recall of information about the performance of the skill?	4	0
12. Does feedback to learners provide corrective information and examples, or does it merely present a correct answer?	3	1
13. When appropriate, are follow-through activities such as advancement, remediation, and enrichment present and logical (e.g., address prerequisites, focuses on improved motivation, provide additional examples and contexts)? *	1	-

	Yes	No
Characteristics of Instruction		
1. Is new information presented in a relevant context?	4	0
2. Are strategies provided for linking new information to related information currently stored in memory (e.g., presentation of familiar analogies, requests for learners to imagine something, or to provide examples from their own experience?	4	0
3. Is information organized into subsets, and are the relationships of elements within and among subsets explained?	4	0
4. Are lists, outlines, tables, or other structures provided for organizing and summarizing information?	3	1
5. Are logical mnemonics provided when new information cannot be linked to anything stored in memory?	0	4
6. Does rehearsal (practice) include activities that strengthen elaborations and cues (e.g., generating new examples, forming images that will cure recall, reflecting organizational structure?)	4	0
7. Does feedback contain information about the correctness of a response as well as information about why a given response is considered incorrect?	4	0
8. Does remediation include additional motivational strategies as well as rehearsal for recall cues?	3	1
Characteristics of Instruction: Attitudes		
1. Are the desired feelings clearly described or inferred?	4	0
2. Are the desired behaviours clearly described or inferred?	4	0
3. Is the link (causality) between the desired feelings and behaviours, the link between them and subsequent positive consequences clearly established?	4	0

	Yes	No
4. Is the link between the undesired feelings and behaviours, the link between them and subsequent negative consequences clearly established?	4	0
5. Are the positive and negative consequences that are presented true and believable from the learners' perspective?	3	1
6. Are the positive and negative consequences that are presented ones that are likely to be considered important by target learners?	3	1
7. If vicarious learning is involved, are the target learners likely to generate emotions such as admiration, scorn, empathy, or pity for characters and situations presented to tap these emotions?	3	1
8. If vicarious learning is involved, are the contexts and situations presented familiar and relevant to target learners?	3	1
9. In the feedback, are the positive and negative consequences promised for specific actions experienced either directly or vicariously by learners?	3	1

Note. * Not answered by 3 reviewers.

Appendix I:

Questions for Expert Review

Topic: Research Concepts, Design and Methodology **Instructional Goal:** Given a clinical situation in which treatment options are ambiguous, participants will develop a research hypothesis and chose a research design that are testable according to two expert research investigators.	**Class Material**	
	1. Is the content accurate and up-to-date?	☐Yes ☐No
	2. Does it present a consistent perspective	☐Yes ☐No
	3. Are examples, practice exercises, and feedback realistic and accurate?	☐Yes ☐No
	4. Is the pedagogy consistent with current instructional theory?	☐Yes ☐No
	5. Is the instruction appropriate to the audience?	☐Yes ☐No
	Pre and Post-Test	
	6. Are the questions on the pre-test appropriate?	☐Yes ☐No
	7. Are the questions on the post-test appropriate?	☐Yes ☐No
Topic: Research Regulations **Instructional Goal:** Given examples of clinical research proposals, participants will be able to accurately identify the pertinent regulation or ethical principle governing the research by choosing the correct response in multiple-choice questions, eighteen out of twenty times.	**Class Material**	
	1. Is the content accurate and up-to-date?	☐Yes ☐No
	2. Does it present a consistent perspective	☐Yes ☐No
	3. Are examples, practice exercises, and feedback realistic and accurate?	☐Yes ☐No
	4. Is the pedagogy consistent with current instructional theory?	☐Yes ☐No
	5. Is the instruction appropriate to the audience?	☐Yes ☐No
	Pre and Post-Test	
	6. Are the questions on the pre-test appropriate?	☐Yes ☐No
	7. Are the questions on the post-test appropriate?	☐Yes ☐No

Topic: Research Program Management **Instructional Goal:** Given a research proposal, participants will develop a project management plan that includes all the pertinent stakeholders, a workplan, a schedule of events, a reporting system and an evaluation scheme, as measured by a checklist utilized by the instructor.	**Class Material**	
	1. Is the content accurate and up-to-date?	☐Yes ☐No
	2. Does it present a consistent perspective	☐Yes ☐No
	3. Are examples, practice exercises, and feedback realistic and accurate?	☐Yes ☐No
	4. Is the pedagogy consistent with current instructional theory?	☐Yes ☐No
	5. Is the instruction appropriate to the audience?	☐Yes ☐No
	Pre and Post-Test	
	6. Are the questions on the pre-test appropriate?	☐Yes ☐No
	7. Are the questions on the post-test appropriate?	☐Yes ☐No
Topic: Data Collection **Instructional Goal:** Given a research proposal, participants will design a case report form and a database that include all the data points of the research project, as measured by a checklist utilized by the instructor.	**Class Material**	
	1. Is the content accurate and up-to-date?	☐Yes ☐No
	2. Does it present a consistent perspective	☐Yes ☐No
	3. Are examples, practice exercises, and feedback realistic and accurate?	☐Yes ☐No
	4. Is the pedagogy consistent with current instructional theory?	☐Yes ☐No
	5. Is the instruction appropriate to the audience?	☐Yes ☐No
	Pre and Post-Test	
	6. Are the questions on the pre-test appropriate?	☐Yes ☐No
	7. Are the questions on the post-test appropriate?	☐Yes ☐No
Topic: Research Conflicts of Interest **Instructional Goal:** Given a research proposal, participants will identify the potential and actual conflicts of interest that may occur and identify measures to prevent or minimize the conflicts, as measured by a checklist utilized by the instructor.	**Class Material**	
	1. Is the content accurate and up-to-date?	☐Yes ☐No
	2. Does it present a consistent perspective	☐Yes ☐No
	3. Are examples, practice exercises, and feedback realistic and accurate?	☐Yes ☐No
	4. Is the pedagogy consistent with current instructional theory?	☐Yes ☐No
	5. Is the instruction appropriate to the audience?	☐Yes ☐No
	Pre and Post-Test	
	6. Are the questions on the pre-test appropriate?	☐Yes ☐No
	7. Are the questions on the post-test appropriate?	☐Yes ☐No

Topic: Statistical Considerations in Research **Instructional Goal:** Given a clinical research question, a background of the research topic and the methods to be used in a research study, Learners will describe methods of statistical analysis and state the reason for choosing such methods. The description will include: a) the number of patients; considerations of sample size and assumptions used in calculating sample size based on clearly defined expected outcomes; b) a plan for analysis of dropouts, crossover, and poor compliance; and c) a plan for interim analysis.	**Class Material**	
	1. Is the content accurate and up-to-date?	☐Yes ☐No
	2. Does it present a consistent perspective	☐Yes ☐No
	3. Are examples, practice exercises, and feedback realistic and accurate?	☐Yes ☐No
	4. Is the pedagogy consistent with current instructional theory?	☐Yes ☐No
	5. Is the instruction appropriate to the audience?	☐Yes ☐No
	Pre and Post-Test	
	6. Are the questions on the pre-test appropriate?	☐Yes ☐No
	7. Are the questions on the post-test appropriate?	☐Yes ☐No

Topic: Funding the Research Project **Instructional Goal:** Given two research proposals, participants will develop a study budget that includes all the expenses related to the study, identify appropriate sources of funding, and complete the research funding applications forms with 90% accuracy.	**Class Material** 1. Is the content accurate and up-to-date? 2. Does it present a consistent perspective 3. Are examples, practice exercises, and feedback realistic and accurate? 4. Is the pedagogy consistent with current instructional theory? 5. Is the instruction appropriate to the audience? **Pre and Post-Test** 6. Are the questions on the pre-test appropriate? Are the questions on the post-test appropriate?	☐Yes ☐No ☐Yes ☐No ☐Yes ☐No ☐Yes ☐No ☐Yes ☐No ☐Yes ☐No ☐Yes ☐No
Topic: Collaborative Research With Industry **Instructional Goal:** Given a hypothetical collaborative agreement between a pharmaceutical company and the Hospital, participants will describe the purpose of the investigators' meeting, list and discuss pre-study activities, discuss study initiation and termination activities, and describe two types of study monitoring, as measured by a checklist utilized by the instructor.	**Class Material** 1. Is the content accurate and up-to-date? 2. Does it present a consistent perspective 3. Are examples, practice exercises, and feedback realistic and accurate? 4. Is the pedagogy consistent with current instructional theory? 5. Is the instruction appropriate to the audience? **Pre and Post-Test** 6. Are the questions on the pre-test appropriate? 7. Are the questions on the post-test appropriate?	☐Yes ☐No ☐Yes ☐No ☐Yes ☐No ☐Yes ☐No ☐Yes ☐No ☐Yes ☐No ☐Yes ☐No
Topic: Good Clinical Practice Guidelines **Instructional Goal:** Given a copy of the International Conference on Harmonization: Good Clinical Practice (ICH: GCP) Guidelines, participants will be able to describe the practical application of at least five provisions from each ICH: GCP sections, as measured by a checklist utilized by the instructor.	**Class Material** 1. Is the content accurate and up-to-date? 2. Does it present a consistent perspective 3. Are examples, practice exercises, and feedback realistic and accurate? 4. Is the pedagogy consistent with current instructional theory? 5. Is the instruction appropriate to the audience? **Pre and Post-Test** 6. Are the questions on the pre-test appropriate? 7. Are the questions on the post-test appropriate?	☐Yes ☐No ☐Yes ☐No ☐Yes ☐No ☐Yes ☐No ☐Yes ☐No ☐Yes ☐No ☐Yes ☐No

Topic: Research Ethics

Instructional Goal: Given a clinical research question, a background of the research topic, the methods to be used in a research study, and a description of the methods of statistical analysis, Learners will write an informed consent document for research subjects using the Hospital template and will discuss in writing the ethical considerations of the study. The discussion will include: a) the characteristics of the study population (gender, age range, racial and ethnic groups) and justify any exclusion of specific gender, age, and racial or ethnic groups; b) the inclusion and exclusion criteria and whether vulnerable subjects will be involved and if so, what are the special precautions that will be taken to ensure that the consent is freely given and that the rights and welfare of the subjects are protected; c) where and how research data will be stored to ensure confidentiality, and who will have access to information about the subjects that is identifiable; d)how subjects will be identified and recruited for participation in the study, when and where consent will be obtained.

Class Material

1.	Is the content accurate and up-to-date?	☐Yes	☐No
2.	Does it present a consistent perspective	☐Yes	☐No
3.	Are examples, practice exercises, and feedback realistic and accurate?	☐Yes	☐No
4.	Is the pedagogy consistent with current instructional theory?	☐Yes	☐No
5.	Is the instruction appropriate to the audience?	☐Yes	☐No

Pre and Post-Test

6.	Are the questions on the pre-test appropriate?	☐Yes	☐No
7.	Are the questions on the post-test appropriate?	☐Yes	☐No

Topic: Study Drugs and Devices **Instructional Goal:** Given one research proposal in which drugs are being tested and one research proposal in which medical devices are being tested, participants will design study drug/device inventories and describe the procedures for maintaining the inventories, as measured by a checklist utilized by the instructor.		**Class Material**	
	1.	Is the content accurate and up-to-date?	☐Yes ☐No
	2.	Does it present a consistent perspective	☐Yes ☐No
	3.	Are examples, practice exercises, and feedback realistic and accurate?	☐Yes ☐No
	4.	Is the pedagogy consistent with current instructional theory?	☐Yes ☐No
	5.	Is the instruction appropriate to the audience?	☐Yes ☐No
		Pre and Post-Test	
	6.	Are the questions on the pre-test appropriate?	☐Yes ☐No
	7.	Are the questions on the post-test appropriate?	☐Yes ☐No
Topic: Writing the Research Proposal **Instructional Goal:** Given a research hypothesis and building on the information presented in the course, participants will write a research proposal that meets all the scientific, regulatory, and ethical requirements of the Hospital, a measure by the checklist provided by the Hospital's Institutional Review Board.		**Class Material**	
	1.	Is the content accurate and up-to-date?	☐Yes ☐No
	2.	Does it present a consistent perspective	☐Yes ☐No
	3.	Are examples, practice exercises, and feedback realistic and accurate?	☐Yes ☐No
	4.	Is the pedagogy consistent with current instructional theory?	☐Yes ☐No
	5.	Is the instruction appropriate to the audience?	☐Yes ☐No
		Pre and Post-Test	
	6.	Are the questions on the pre-test appropriate?	☐Yes ☐No
	7.	Are the questions on the post-test appropriate?	☐Yes ☐No
Topic: Submitting the Research Proposal to an Institutional Review Committee. **Instructional Goal:** Given a research proposal, participants will prepare all the documents required to be submitted with proposal to the Institutional Review Board, as measured by a checklist utilized by the instructor.		**Class Material**	
	1.	Is the content accurate and up-to-date?	☐Yes ☐No
	2.	Does it present a consistent perspective	☐Yes ☐No
	3.	Are examples, practice exercises, and feedback realistic and accurate?	☐Yes ☐No
	4.	Is the pedagogy consistent with current instructional theory?	☐Yes ☐No
	5.	Is the instruction appropriate to the audience?	☐Yes ☐No
		Pre and Post-Test	
	6.	Are the questions on the pre-test appropriate?	☐Yes ☐No
	7.	Are the questions on the post-test appropriate?	☐Yes ☐No

Topic: Critical Evaluation of Medical Articles **Instructional Goal:** Given a medical journal article from a peer reviewed journal, which describes the results of a clinical research project, participants will be able to assess the article using the "Manuscript Quality Assessment Instrument" developed by Goodman et al, which will be 90% accurate when compared with the instructor's analysis of the same article.	**Class Material** 1. Is the content accurate and up-to-date? 2. Does it present a consistent perspective 3. Are examples, practice exercises, and feedback realistic and accurate? 4. Is the pedagogy consistent with current instructional theory? 5. Is the instruction appropriate to the audience? **Pre and Post-Test** 6. Are the questions on the pre-test appropriate? 7. Are the questions on the post-test appropriate?	☐Yes ☐No ☐Yes ☐No ☐Yes ☐No ☐Yes ☐No ☐Yes ☐No ☐Yes ☐No ☐Yes ☐No
Topic: Writing for publication **Instructional Goal:** Given the description and results of a fictitious research study, participants will be able to draft a manuscript that describes the major sections of a medical manuscript including an abstract, introduction, methodology, results, and discussion as evaluated by the instructor.	**Class Material** 1. Is the content accurate and up-to-date? 2. Does it present a consistent perspective 3. Are examples, practice exercises, and feedback realistic and accurate? 4. Is the pedagogy consistent with current instructional theory? 5. Is the instruction appropriate to the audience? **Pre and Post-Test** 6. Are the questions on the pre-test appropriate? 7. Are the questions on the post-test appropriate?	☐Yes ☐No ☐Yes ☐No ☐Yes ☐No ☐Yes ☐No ☐Yes ☐No ☐Yes ☐No ☐Yes ☐No

Questions to evaluate the overall content of the course.

1. Is all the course content appropriate for teaching scientific and ethical conduct of biomedical research?
   ☐ Yes ☐ No
   If No, please comment.
   _____
   _____

2. Is the information provided in the course complete (i.e. no additional topics need to be included)?
   ☐ Yes ☐ No
   If No, please indicate what topics should be added.
   _____
   _____

3. Are the course objectives clearly stated?
   ☐ Yes ☐ No
   If No, please indicate which objectives are not clearly stated.
   _____
   _____

4. Are important points emphasized?
   ☐ Yes ☐ No
   If No, please comment.
   _____
   _____

5. Is the sequence of lectures logical?
   ☐ Yes ☐ No
   If No, please indicate a logical sequence.
   _____
   _____

6. Is the method of final testing appropriate?
   ☐ Yes ☐ No
   If No, please comment.
   _____
   _____

Language and grammar:

7. Are the language and grammar correct, appropriate, and free from gender, religious, and racial bias?

   ☐ Yes ☐ No

   If No, please elaborate.

   _____

   _____

8. Other comments or suggestions:

   _____

   _____

   _____

   _____

   _____

   _____

Appendix J:

Results of Expert Review: Topic Specific

Material	Topic							
	Research Concepts, Design and Methodology		Research Regulations		Research Program Management		Data Collection	
	Yes	No	Yes	No	Yes	No	Yes	No
Is the content accurate and up-to-date?	3		3		3		3	
Does it present a consistent perspective?	3		3		3		3	
Are examples, practice exercises, and feedback realistic and accurate?	3		3		3		3	
Is the pedagogy consistent with current instructional theory?	3		3		3		3	
Is the instruction appropriate to the audience?	3	2	3		3		3	
Are the questions on the pre-test appropriate?	3		3		3		3	
Are the questions on the post-test appropriate	3		3		3		3	

Appendix J:

Results of Expert Review: Topic Specific

Material	Topic							
	Research Conflicts of Interest		Statistical Considerations in Research		Funding the Research Project		Collaborative Research With Industry	
	Yes	No	Yes	No	Yes	No	Yes	No
Is the content accurate and up-to-date?	3		3		3		3	
Does it present a consistent perspective?	3		3		3		3	
Are examples, practice exercises, and feedback realistic and accurate?	3		3		3		3	
Is the pedagogy consistent with current instructional theory?	3		3		3		3	
Is the instruction appropriate to the audience?	3		3		3		3	
Are the questions on the pre-test appropriate?	3		3		3		3	
Are the questions on the post-test appropriate	3		3		3		3	

Appendix J:

Results of Expert Review: Topic Specific

Material	Topic							
	Good Clinical Practice Guidelines		Research Ethics		Study Drugs and Devices		Writing the Research Proposal	
	Yes	No	Yes	No	Yes	No	Yes	No
Is the content accurate and up-to-date?	3		3		3		3	
Does it present a consistent perspective?	3		3		3		3	
Are examples, practice exercises, and feedback realistic and accurate?	3		3		3		3	
Is the pedagogy consistent with current instructional theory?	3		3		3		3	
Is the instruction appropriate to the audience?	3		3		3		3	
Are the questions on the pre-test appropriate?	3		3		3		3	
Are the questions on the post-test appropriate	3		3		3		3	

Appendix J:

Results of Expert Review: Topic Specific

Material	Topic					
	Submitting the Research Proposal to the IRB		Critical Evaluation of Medical Articles		Writing for Publication	
	Yes	No	Yes	No	Yes	No
Is the content accurate and up-to-date?	3		3		3	
Does it present a consistent perspective?	3		3		3	
Are examples, practice exercises, and feedback realistic and accurate?	3		3		3	
Is the pedagogy consistent with current instructional theory?	3		3		3	
Is the instruction appropriate to the audience?	3		3		3	
Are the questions on the pre-test appropriate?	3		3		3	
Are the questions on the post-test appropriate	3		3		3	

Appendix K:

Results of Expert Review: General Questions and Comments

Question	Yes	No	Comments
Is all the course content appropriate for teaching scientific and ethical conduct of biomedical research?	3		
Is the information provided in the course complete (i.e. no additional topics need to be included)?	3		
Are the course objectives clearly stated?	3		
Are important points emphasized?	3		
Is the sequence of lectures logical?	3		
Is the method of final testing appropriate?	3		
Are the language and grammar correct, appropriate, and free from gender, religious, and racial bias?	1	2	Reviewer 2: Examples and scenarios should be more appropriate for Moslem country. Reviewer 3: Use more local examples to emphasize points and for case studies. For example, discuss genetic research in Saudi Arabia not in the US, what specific conflicts of interests could occur in this hospital/region, discuss consent issues in light of women's rights in this country, etc.
Other comments or suggestions			Reviewer 1: Very comprehensive program. All important topics are covered. Good to see this offered in the

Question	Yes	No	Comments
			region. Reviewer 2: I think you have included all the important things that researchers and support staff should be familiar with. Reviewer 3: You have done a great job in designing this program.

Appendix L:

Questions for the One-To-One Review

1. Was the English clear and easy to understand throughout the course material?

   ☐ Yes ☐ No
   If no, please describe.

   _____
   _____

2. Did you understand the intent and objectives of the instruction from the beginning to the end?

   ☐ Yes ☐ No
   If no, please describe.

   _____
   _____

3. Were the conclusions logical and validated?

   ☐ Yes ☐ No
   If no, please describe.

   _____
   _____

4. Did the use of examples help you to understand and assimilate the material?

   ☐ Yes ☐ No
   If no, please describe.

   _____
   _____

5. Were the examples and practice items relevant and helpful to the specific topic?

   ☐ Yes ☐ No
   If no, please describe.

   _____
   _____

6. The review points were intended to ensure that the more complex and important material content was reinforced. Were there any areas or aspects where gaps were left in the understanding?

☐ Yes ☐ No

If yes, please describe.

_____

_____

7. Was there an adequate summary at the end of each session that encapsulated the key points?

☐ Yes ☐ No

If no, please describe.

_____

_____

8. Were there any areas that you felt did not naturally follow-on from the previous material or session?

☐ Yes ☐ No

If yes, please describe.

_____

_____

9. Were there any learning sessions where it was clear that there was too much or too little time to achieve the learning objective?

☐ Yes ☐ No

If yes, please describe.

_____

_____

10. Were you given sufficient time to take the learning material on board, and was there sufficient opportunity to ask questions?

☐ Yes ☐ No

If no, please describe.

_____

_____

11. Was it easy to navigate through the material?

☐ Yes ☐ No

If no, please describe areas for improvement.

_____

_____

12. How will you use what you have learned?

_____

_____

_____

13. Reviewers overall impression of the course, suggestions (if any), comments.

_____

_____

_____

_____

Appendix M:

Results of the One-to-One Review

Question	Yes	No	Comments
Was the English clear and easy to understand throughout the course material?	1	2	Reviewer 1: A few of the words may not be familiar to Arabic-speaking learners. Reviewer 2: There were some words I did not know what they meant. Reviewer 3: Words and phrases such as "ethical considerations" and collaborative research" may not be familiar to the learners. I underlined the words I found difficult in red.
Did you understand the intent and objectives of the instruction from the beginning to the end?	3		
Were the conclusions logical and validated?	3		
Did the use of examples help you to understand and assimilate the material?			Reviewer 3: Good examples. Really helpful
Were the examples and practice items relevant and helpful to the specific topic?	3		Reviewer 2: More statistical examples may be helpful but the stats part is very difficult.
The review points were intended to ensure that the more complex and important material content was reinforced. Were there any areas or aspects where gaps were left in the understanding?	2	1	Reviewer 2: I didn't understand most of the stats part. Reviewer 3: The statistical section may be too difficult for most people. (It was for me!)
Was there an adequate summary at the end of each	3		

Question	Yes	No	Comments
session that encapsulated the key points?			
Were there any areas that you felt did not naturally follow-on from the previous material or session?		3	
Were there any learning sessions where it was clear that there was too much or too little time to achieve the learning objective?		3	
Were you given sufficient time to take the learning material on board, and was there sufficient opportunity to ask questions?	1	2	Reviewer 2: The class times were long enough but there wasn't always enough time to ask questions.
Was it easy to navigate through the material?	3		
How will you use what you have learned?			Reviewer 1: The information has definitely helped me in writing research proposals and assessing what resources I will need to conduct my research. For example I learned the importance of consulting a statistician and in writing the ethical considerations which before I felt were unimportant. Reviewer 2: Since doing this course I feel I know more about doing research and I want to do my own research if I can get the support of my supervisors. Reviewer 3: I have learned a lot in this course! I can see many mistakes I made before but I know I also did dome things the proper way. I will use all that I learned to improve myself and how I work on research

Question	Yes	No	Comments
			studies and clinical trials.
Overall impression of the course, suggestions (if any), comments.			Reviewer 1: Very interesting and informative. A good job. Reviewer 2: It was very interesting and I learned a lot. Reviewer 3: Excellent course. Really needed in this hospital.

Appendix N:

Demographics of Learners for the Small Group Tryout

	n	Average	Percentage	Range
Female	14		45	
Male	17		55	
Age (years)		43		26 - 61
Years as HCP		15		3 - 36
Research Experience				
• Yes	22		71	
• No	9		29	
Previous Formal Research Education				
• Yes	0		0	
• No	31		100	
English as First Language				
• Yes	4		13	
• No	27		87	
Occupation				
• Physician	14		45	
• Research Coordinator	5		16	
• Nurse	5		16	
• Perfusionist	1		3	
• Cath Lab Technician	2		6	
• Other	4		13	

Appendix O:

Questions for Small-Group Evaluation

1. Was the instruction interesting?	☐ Yes	☐ No
2. Did you understand what you were supposed to learn?	☐ Yes	☐ No
3. Were the materials directly related to the objectives?	☐ Yes	☐ No
4. Were sufficient practice exercises included?	☐ Yes	☐ No
5. Were the practice exercises relevant?	☐ Yes	☐ No
6. Did the tests really measure your knowledge of the objectives?	☐ Yes	☐ No
7. Did you receive sufficient feedback on your practice exercises?	☐ Yes	☐ No
8. Did you feel confident when answering questions on the post-tests?	☐ Yes	☐ No

Comments, if any.

Appendix P:

Revisions to Instructional Materials of the CRMC

	Design Review	Expert Review
Revisions Made	• Length (time) of lectures adjusted • Information on statistical methods increased • Number of hours devoted to research ethics deceased • Use of PPPs decreased • "Writing for publication" added as a topic • Information on adult learning theories added to the instructors' manual	• Case scenarios and examples changed from North American examples to examples based on local culture, situations, and people • Typographical and grammatical errors corrected
	One-to-One Review	**Small Group Tryout**
Revisions Made	• Several English words replaced by less difficult English words • More time provided for information on statistical methods • Typographical and grammatical errors corrected • Directions on completing posttest were clarified	• Allocated time for difficult topics increased • Allocated time for less difficult topics increased • Numbed of power point slides decreased in several topics • Directions for role playing clarified.