JME Online First, published on August 19, 2013 as 10.1136/medethics-2013-101572

Consensus standards for introductory e-learning courses in human participants research ethics

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Received 3 May 2013
Revised 15 July 2013
Accepted 30 July 2013

ABSTRACT

This paper reports the results of a workshop held in January 2013 to begin the process of establishing standards for e-learning programmes in the ethics of research involving human participants that could serve as the basis of their evaluation by individuals and groups who want to use, recommend or accredit such programmes. The standards that were drafted at the workshop cover the following topics: designer/provider qualifications, learning goals, learning objectives, content, methods, assessment of participants and assessment of the course. The authors invite comments on the draft standards and eventual endorsement of a final version by all stakeholders.

INTRODUCTION

This document is the output of a workshop that took place at the Brocher Foundation, Hermance, Switzerland, from 16–18 January 2013. The 22 participants included developers and providers of e-learning programmes from Africa, Europe and North America[1] as well as funders and users of these programmes.[2]

A writing committee, drawn from the participants at the meeting, produced this document. Two drafts were circulated to all other participants and their comments were incorporated in this version. It represents a consensus of those present at the workshop.

OBJECTIVES AND SCOPE

The overall goal of the workshop was to begin the process of establishing standards for e-learning programmes in the ethics of research involving human participants that could serve as the basis of their evaluation by individuals and groups who want to use, recommend or accredit such programmes. In recent years, there has been a proliferation of these programmes,[3] but to our knowledge, this workshop was the first occasion for developers, providers and users of programmes to meet for the purpose of establishing standards.

Preparations for the workshop included fund-raising, identification of and invitations to potential participants and development of a background paper and agenda. The three-day workshop was structured as follows: day 1—introductions, explanation of workshop goals and methods, discussion and agreement on agenda, short presentations on the e-learning programmes represented at the workshop and round-table discussion of standards for such programmes; day 2—round-table discussions of specific standards: objectives, content, methods, evaluation and (briefly) technical aspects; day 3—review of earlier sessions; discussion and agreement on standards for introductory courses; agreement on next steps and who will be involved.

Given the complexity of research ethics and the diversity of e-learning programmes in this area, workshop participants agreed to focus on standards for the introductory course that all programmes offer. Standards for advanced and specialised courses that are tailored to the needs of specific groups (eg, Research Ethics Committee (REC) members, researchers, students, etc) or that treat in greater detail specific research topics or methods (eg, Good Clinical Practice (GCP), vaccine research, epidemiology, etc) may be developed at a later date.

THEORETICAL FRAMEWORK

Standards are consensus-based rules, guidelines or specifications to harmonise or formalise products, services and processes.[4] They are normally developed by associations of organisations that offer the products, services or processes, for example, industry or professional associations, or by organisations established specifically for producing standards, such as the International Organization for Standardization. Where there is no existing association of those who offer a specific product, service or process, as is the case with RECs[5] and e-learning programmes in research ethics, stakeholders can initiate the process of developing standards.

The distinction between standards and guidelines is not always clear. For example, one of the International Council on Harmonization's (ICH) guidelines states, "The objective of this ICH GCP *Guideline* is to provide a unified *standard*…".[6] We have chosen to use the term 'standard' to signify a minimum requirement for e-learning programmes in research ethics. In the future, guidelines can be developed for the implementation of the standards and for identifying best practices to which all programme developers can aspire.

Standards have several objectives. The most important ones for our purposes are:

To cite: Williams JR, Sprumont D, Hirtle M, *et al*. *J Med Ethics* Published Online First: [*please include* Day Month Year] doi:10.1136/medethics-2013-101572

- to identify the essential components of e-learning programmes;
- to specify minimum requirements for such programmes; and
- to provide criteria for the evaluation of programmes by individuals and groups who want to use, recommend or accredit such programmes.

RESULTS

Workshop participants agreed that:

- To maintain the public's trust in the research enterprise, rigorous education stressing the need to protect individuals who participate in human research is essential.
- Research ethics education programmes to promote awareness and appreciation of human research protections must be provided to members of RECs[7 8] and to all members of the research team and must be included at the earliest possible stage of professional training.
- GCP training is essential for all clinical researchers and support staff. However, since GCP training is very process-oriented and procedure-oriented, it does not provide sufficient instruction in the foundations of clinical research ethics. Thus, GCP courses should always be preceded or accompanied by an introductory course in research ethics.
- Ethics training should deal with all forms of research involving human participants, not just clinical research.
- Although not the only appropriate method for providing foundational learning opportunities in research ethics, the on-line, e-learning presentation paradigm can be an extremely cost-effective and time-effective means of achieving this goal.[9]

DRAFT STANDARDS FOR INTRODUCTORY RESEARCH ETHICS E-LEARNING COURSES

A. Developer/provider qualifications
   - Qualifications of the developer/provider are indicated on the programme website together with a description of how the course was developed.
   - Developers have applied e-learning education principles in the design of their courses.
   - All e-learning courses are peer reviewed and pretested before being made available on-line.

B. Learning goals
   - To raise awareness and understanding of the role of research ethics in the protection of research participants and in the promotion of high-quality research that meets the needs of the concerned population.
   - To educate those involved in the conduct of research involving human participants about their roles and responsibilities in the research process.

C. Learning objectives
   - Programme participants will gain the knowledge, understanding and ability to apply basic concepts in research ethics in the evaluation of common ethical issues.
   - The introductory course will provide a common language and ethical framework for everybody involved in research.
   - A needs assessment will determine more precisely the objectives and content of the programme.[10]

D. Content
   - The introductory course includes a treatment of the following topics:
     - Basic concepts: what is ethics, what is research (different types of research), what is research involving human participants, what is ethics review of research
     - A brief history of research ethics
     - The roles and responsibilities of all those involved in research
     - Conflicts of interests and commitments
     - Ethics review by the competent REC
     - Fundamental principles and normative framework:
       - Scientific accuracy
       - Risk–benefit analysis
       - Autonomy/informed consent
       - Justice
       - Vulnerable populations
       - Confidentiality and privacy
       - Societal, religious and cultural factors
       - Local conditions
     - Monitoring post-REC approval

E. Methods
   - The methods and training material are in line with the learning objectives and take into account any technical restraints (eg, low bandwidth) experienced by potential course participants.
     - Course materials are presented at a language level appropriate for the participants.
     - All course materials, including references and hyperlinks, are kept up-to-date.
     - Courses include case studies and other appropriate didactic tools in addition to written text. Audio and video materials, writing exercises and interactive questions and answers are recommended where technically feasible.
   - The introductory course is equivalent to a one-day seminar, that is, it should require, on average, between 4 and 6 h to complete. It should be divided into units or modules that require approximately 30–40 min to complete the basic materials. Longer times might be expected if the learner follows all of the hyperlinks provided or explores all of the suggested additional readings. This limit might also be exceeded if the language of the course is not the learner's first language.
   - The course provides participants with references and links for more in-depth study of the material, including resources in local languages where available. Participants are encouraged to make use of these materials and to regularly participate in other activities (seminars, workshops, refresher courses and informal discussions) to increase their understanding and skills in research ethics.

F. Assessment of participants
   - The course includes an assessment process to ensure that learners have a satisfactory understanding of the materials presented.
   - Assessments are limited to the fundamental elements of the module or course. Questions pertaining to issues not covered in the module or course are avoided.
   - Quizzes or tests for the basic course comprise multiple-choice questions designed and implemented according to internationally recognised standards.[11] Quizzes and other assessments are based on the learning objectives of the course material, including case studies where feasible.
   - Quiz assessment is a learning exercise. After submitting the assessment, the learner is provided with textual feedback about why the answer provided was correct or incorrect.
   - The passing grade is at least 70% correct answers on the first attempt. A more rigorous passing grade is encouraged to ensure careful review of the materials. If learners do not meet the prescribed level of achievement, they are not permitted to advance and are directed to retake the module or course as appropriate.

- Measures are in place to prevent/discourage cheating. Software can be programmed to:
  - Rotate questions presented to the learners from a large pool of questions.
  - Rotate the position of the question in successive quizzes.
  - Rotate the position of the correct answer in successive quizzes.
- A certificate of completion is provided to learners who successfully complete the course.

G. Assessment of the course

- All learners are given an opportunity to provide the course developers/providers written feedback about their on-line learning experiences (good and bad) with the course. This can be done by using open-ended questions or by a voluntary, anonymous on-line survey.
- Such feedback assesses: user friendliness of the software; the quality of the presentation; the appropriateness of the learner assessment method; the value of the course to the learner; and an overall rating of the course.
- Course developers/providers will review the satisfaction surveys and written learner feedback at regular intervals to determine if the course is both well received by the learners and meeting the goals of the course.
- When feasible, the course provider will seek recognition of the course for continuing professional development (CPD) credit by the competent bodies.

VALIDATION

We invite review of these standards by all stakeholders. Comments should be directed to the Writing Committee, c/o John R. Williams (jrewms@yahoo.com). Once a final version of the standards is prepared and distributed, we invite endorsement by all stakeholders.

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Acknowledgements We thank Raluca Ciocan and Paloma Henao, Institut de droit de la santé, Université de Neuchâtel, Neuchâtel, Switzerland, for their assistance in the preparation of a background paper for the workshop.

Contributors DS and JRW planned the workshop. All the authors attended the workshop, participated in the discussions and agreed on the conclusions. JRW drafted the article with assistance from DS and MH. All authors agreed (either explicitly or implicitly) with the final version. JRW is the guarantor.

Funding Swiss National Science Foundation, Brocher Foundation, Université de Neuchâtel (TRREE), University of Miami (CITI Program), University of Maryland (MERETI), Université de Genève (Africabuild—RAFT) and Health Science Training Foundation (HSeT).

Competing interests None.

Provenance and peer review Not commissioned; externally peer reviewed.

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J Med Ethics published online August 19, 2013
doi: 10.1136/medethics-2013-101572