Reviewer's report

Title: Outcome of a training program on research ethics among clinicians and scientists in a Nigerian university

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Reviewer: Michael Kalichman

Reviewer's report:

General
This paper describes a needs assessment for research ethics education, the implementation of a research ethics curriculum, and outcomes for conducting the research course. The target population is clinicians and scientists at the College of Medicine (COM) in the University of Ibadan, Nigeria. Although the authors make the specific case for enhancing research ethics infrastructure at the COM, the principles apply to many developing countries in which research studies are increasing, but in which a history of research ethics may be lacking. This work is important, but several parts of the manuscript raised questions that might be considered:

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Major Compulsory Revisions

1. Data analysis: The authors note using "Chi square test", but it isn't clear how this was done. Were these 2 X 2 analyses, or were multiple factors included in a single analysis? And how were variables categorized to allow for the analysis?

2. Response Rate: Apparently 97 out of 133 persons completed both the pre- and post-test survey. If this is correct, then is it also correct to assume that some people completed only the pre-test and some only the post-test? If so, then those numbers should be provided and it should be made clear how those results fit in with the other results already reported. Also, if the authors know that particular individuals completed both tests, then is it correct to assume that they can identify pre- and post-tests by the individual? If so, then a more powerful analysis might have assessed the change in individuals (e.g., with a paired t test or with a Wilcoxon signed rank test)

3. Case studies: The statements to be ranked in the case studies did not always seem clear. In several instances, it seems that the participants would not have a reasonable basis for judging the statement (e.g., "The study was not reviewed by an ethics review committee" – the fact that a review committee is not mentioned does not mean that it hasn't been reviewed. Is it possible that many/most of those who answered this question incorrectly had marked it "Disagree" simply because they had no way of knowing that a review had not actually occurred?)

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Minor Essential Revisions

4. Endpoints: It appears that big changes were documented in endpoints such as the ability to identify relevant documents. However, more important endpoints (e.g., understanding of ethical principles or knowledge of IRB operations) improved only minimally, if at all. Perhaps this discrepancy should be clearly noted, with an emphasis on the need for particular types of educational approaches different from those used here?

5. Inadequate citation: Ref. [14] is important, but the information given is inadequate for someone who wishes to review the work.

6. Needs Assessment, first paragraph: The authors mention a list of "11 items." It is not clear how this list was created nor is it clear what items are on this list. On the assumption that the next sentence lists the items, it seems that only 10 items are included. What is the correct list and how was the list created?

7. Ethical Challenges (Needs Assessment, item #1): What did the authors mean by "ethical challenges"? Are these supposed to be barriers to good ethical consideration (e.g., "delay in review") or true ethical dilemmas (e.g., how much can you pay a research subject before it becomes coercive?). It seems that the meaning of ethical challenge is not clear here.

8. Ethical Challenges (Needs Assessment, item #3): The content listed here takes many different forms or qualities. It isn't clear how these items can be ranked when some have to do with overriding principles (e.g., "principles of research ethics"), others are specific kinds of principles (e.g., "justice and obligation," which is itself a subset of "principles of research ethics"), and others either overlap are contain the topics (e.g., "informed consent" and IRB).

9. Ethical Challenges (Needs Assessment, item #3): It is disturbing that no "participants considered standard of care, obligations of researchers to study participants and conflict of interest to be relevant contents for training." This is worthy of some comment by the authors. Is this because of a lack of understanding by the participants? Because these issues aren't relevant in these communities (and, if so, why not?) Or for some other reason?

10. Recruitment of trainees: It's worth noting that this recruitment plan looks excellent. However, it isn't clear why the numbers don't add up (32 Departments/Units; 28 responded and 3 did not – what happened to the other Department/Unit?).

11. Implementation of the Workshops and Measures: It isn't explicitly stated, but presumably these studies were conducted in English. Assuming that English is not the first language for the participants, this raises questions about the linguistic and cultural appropriateness of the training and the assessment tools. And, more specifically, it appears that the training heavily emphasized the Belmont Report principles. While those are established as standard in the U.S., is it appropriate or necessary to use those same principles in other countries (e.g., the principle of autonomy may be viewed very differently in other countries). Also, the listed statements in the section on Measures are worded in ways that might be misinterpreted (or "over" interpreted) even by someone for
whom English is a first language.

12. Knowledge of principles of research ethics and guidelines: As listed, it appears that trainees were very consistent in their choice of wording before taking the course. Is this because they had some other common training or because the authors have used some method for categorizing their responses? If the latter, then this should be explained.

13. Knowledge about operations of IRB: In this paragraph, the authors have italicized both the quotations (intentionally) and their own text (unintentionally).

14. Ethics reasoning in case studies: This first sentence is not clear. What is meant by "this" in the statement "but this dropped to 88% at follow-up"? Presumably, the point is that 95% of post-test respondents recognized Madral's conflict, but only 88% did so one month later.

15. Discussion, paragraph 3: On what basis do the author's conclude that the participants' understanding was increased?

What next?: Unable to decide on acceptance or rejection until the authors have responded to the major compulsory revisions

Level of interest: An article of importance in its field

Quality of written English: Needs some language corrections before being published

Statistical review: Yes, and I have assessed the statistics in my report.

Declaration of competing interests:

I declare that I have no competing interests