Author's response to reviews

Title: Identifying Structures, Processes, Resources and Needs of Research Ethics Committees in Egypt

Authors:

Hany Sleem (hanysleem@hotmail.com)
Samer S El-Kamary (selkamar@epi.umaryland.edu)
Henry J Silverman (hsilverm@medicine.umaryland.edu)

Version: 2 Date: 19 May 2010

Author's response to reviews: see over
May 19, 2010

The BioMed Central Editorial Team

Re: MS: 1888512333298723
Identifying Structures, Processes, Resources and Needs of Research Ethics Committees in Egypt
Hany Sleem, Samer S El-Kamary and Henry J Silverman

Dear Sir/Madame:

Please find attached our revised manuscript (including one with track changes). We found the reviewers’ comments very helpful and our point-by-point responses are stated below. We have also addressed the several items requested by the editorial staff.

Reviewer: Reidar Lie
Reviewer's report:
This is an interesting article that gives a good overview of organizational issues with regard to research ethics review in Egypt. I only have some minor comments.

Minor essential revisions
Comment 1: Table 3 and the process of ethics review.
Please clarify exactly what was asked with regard to "use of an expedited review process": Was the question whether the ethics committee has such a system, makes use of it sometimes, or always makes use of it, or some combination of these?

Response #1: We have revised Table 3 and regarding the “use of an expedited review process” we now state: “A system is in place whereby the chair or an authorized person is able to approve protocols by an expedited review process”. However, as we explain in the text, only one of these RECs have used such a system.

Comment #2: In the text it is stated that "less than half require the use of an informed consent form with a stamped expiration date" This is a bit different from the wording in the table, where it says that the REC sends an approved form with a stamped expiration date on it. Please clarify the exact wording used.

Response #2: We have clarified these responses in the revised Table 3. Essentially, 8 of the RECs require the use of the REC-approved consent form, but only 7 of these RECs attach the REC-approved consent form with the letter, whereas one REC require the use of the REC-approved form, but do not attach it and one does not require its use, but attach it to the approval letter. Of these 8 RECs, only 3 has the expiration date stamped on the informed consent form.

Comment #3. Are the 8 RECs that answer yes to the 3 questions about informed consent forms the same ones? If so, that should be stated in the text.

Response #3: This is now stated in the text (see page 8, para 2 ).
Comment #4: Table 4 and the importance of training topics
According to the text a scale was used, but the table only reports the number of ethics committees that identifies topics as very important or important. It might be better to report the mean score of each topic across the RECs, i.e. use of placebo controlled trials gets a mean score of x, determination of methods to use risk gets a mean score of y. I also wondered if there were any other topics suggested in the questionnaire that got very low scores, in particular additional topics related to informed consent, given the perceived centrality of that topic. If such topics were deemed not so important for training, this would also be an important piece of information.

Response #4: We have now clarified in the text that a scale was not used, but rather we asked the RECs to rate the topics according to 4 categories: ‘very important’, ‘somewhat important’, ‘not so important’, and ‘not important’. This is now stated more clearly in the text. All of the topics listed on the survey are presented in Table 4. Accordingly, no one topic was considered “not so important” or “not important” by more than 3 RECs.

Reviewer: Ann Gallagher
Reviewer's report:
I recommend proof reading to correct minor errors.

Response: We have re-proofed read the manuscript

We would be happy to address any further questions.

Sincerely yours,

Henry Silverman