Reviewer's report

Title: Evaluating Institutional Capacity for Research Ethics in Africa: A Case Study from Botswana

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Reviewer: David R Buchanan

Reviewer's report:

I. Major compulsory revisions

The article presents the results of an investigation of “institutional capacity” at the University of Botswana for conducting ethics reviews of health research. The study used multiple methods of data collection, including a 194-item survey questionnaire, in-depth interviews, focus group interviews, archival review and a self-assessment process (based on the so-called “Octagon Model,” an assessment tool originally designed to evaluate the functioning of NGOs across 8 domains). The results are organized into the 8 domains of the Octagon model, and assessments in each domain were based on consensus discussions among the authors regarding the relevant evidence gathered across the multiple methods of data collection to derive a single quantitative score on a 0 – 7 scale (e.g., UB rated a 6 in the domain of Competence) in each dimension. (As an aside, it does not inspire confidence in the validity of the results that the authors note, on p. 19, that the results are “dependent on the team conducting the evaluation.”) The report does not present the results of the survey questionnaire (nor the results of a second survey administered to IRB members that is listed in Table 4 but not discussed in the body of the paper).

Positively, the paper addresses an important gap in the literature and identifies a number of important (if largely unsurprising) problems in the ethical review process at the University of Botswana. As such, the paper should prove useful to concerned readers at other universities in other low income countries in recognizing the challenges of institutionalizing a rigorous ethical review process in similar situations.

I have three concerns. Most importantly, I am not convinced that the Octagon Model is appropriate, necessary or helpful in framing the results of this research. While the effort taken to search for a tool for evaluating institutional capacity is laudable, the identified framework does not appear to be a good match for the purposes at hand. There are significant differences between organizations set up to achieve goals or to meet needs identified by the particular organization’s founders, and the institution or office set up to fulfill universal moral obligations to protect human beings from harm and exploitation in scientific research. The attempt to organize the findings into the Octagon Model feels forced, and at certain points, the “findings” presented under different headings seem incongruous. For example, under “Relevance of Activities” (earlier defined as the
“correspondence between the organization’s activities and goals,” p. 9), the authors present a discussion of the difficulties of convening regular meetings of the IRB and low turnout for trainings (pp. 17-18). Under Relations with Target Groups, there is a discussion of educational scholarships available to the community (p. 20), where, for example, the community might be more interested in the question of whether their interests were being served such that the IRB was protecting them from undue harm and exploitation. Similarly, while NGOs can be set up to achieve a wide range of potential missions, Institutional Review Boards (or Research Ethics Committees) do not have comparable flexibility or choice. While the members of a particular IRB at a particular university may be more or less clear about their responsibilities, the mission of the institution that is granted or that assumes responsibility for assuring the protection of research participants is (relatively) inflexible and based on moral principles derived from the nature of the human condition. I recommend that the authors consider dropping this framework, as it seems to detract more than clarify their findings.

A second concern is the ambiguity inherent in the term, “institution.” For better or worse, the term may refer to a specific organization, or much more broadly, to a set of principles, as in the “institution of law” or “institution of marriage.” The primary focus of the paper is the organizational capacity of the University of Botswana. However, there is both a tacit acknowledgement that their authority must ultimately derive from national legislation, and passing reference to current uncertainties in the respective responsibilities of national research ethics review board and local university-based ethics reviews, in addition to the additional burden of projects now having to go through both levels of review. While I am trying not to impose my own preferred goals for the research conducted (which lie in the larger sense of “institutional” capacity), it would be helpful if the authors could make a clear distinction between issues that arise at the local particular organizational level and those that are external to the local organization (and about which the local university may have little power to resolve, no matter how important and how influential those larger national government legislation and policies may be for the functioning of the local organization), and then, make clear that their report address local “organizational” capacity (my preferred term), and not institutional capacity, with a capital “I” (which the authors may mean by their single reference to a “systems perspective” on p. 27).

Third, the authors should make a clear statement about what is happening or has happened with the quantitative results of their study. The collection of survey questionnaire data is stated as one of the main methods of data collection and the authors indicate that these data were reviewed as part of the assessment process for deriving the Octagon scores. Thus, it is frustrating to learn nothing more about these potentially valuable research results (even if it is merely that these results are being or have been published elsewhere).

II. Minor Essential Revisions

There are several minor inconsistencies that should be addressed: 1) p. 14 “protocols that need some degree of IRB approval”- not clear what “some”
means; 2) p. 16, “about 50 protocols” then 33 + 12 = 45, is “45” what they mean by “about 50”?: and 3) whether or not there is national legislation or national policy guidelines is unclear, with seemingly contradictory statements at different points in the manuscript.

In conclusion, let me reiterate the Discussion section (p. 24 ff) raises many excellent points that may be of great interest and value to potential readers.

III. Discretionary

BMC Criteria

1. Is the question posed by the authors well defined?

See comments above, there is some ambiguity about whether the question that they are seeking to address focuses on the specific organization of the University of Botswana, or the broader question of institutional capacity in the country of Botswana.

2. Are the methods appropriate and well described?

See comments above. The framework for organizing the results is of dubious value, and passing comments that the results may depend on the group conducting the review do not inspire confidence. The lack of information of the quantitative results is puzzling.

3. Are the data sound?

It would improve the paper to know the data from the lengthy survey questionnaire and the second survey of IRB members.

4. Does the manuscript adhere to the relevant standards for reporting and data deposition?

(?)

5. Are the discussion and conclusions well balanced and adequately supported by the data?

Yes.

6. Are limitations of the work clearly stated?

Yes.

7. Do the authors clearly acknowledge any work upon which they are building, both published and unpublished?

No.

8. Do the title and abstract accurately convey what has been found?

Yes.
9. Is the writing acceptable?
Yes.

**Level of interest:** An article of importance in its field

**Quality of written English:** Acceptable

**Statistical review:** No, the manuscript does not need to be seen by a statistician.

**Declaration of competing interests:**
I declare that I have no competing interests.