Reviewer’s report

Title: Ethical challenges for international collaborative research partnerships in the context of Zika in the Dominican Republic: a qualitative case study

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Reviewer: Barbara Mittleman

Reviewer’s report:

This paper addresses important issues regarding the design, conduct and funding of research in the developing and/or under-resourced countries of the world. The work is in the setting of urgent health crises, but is potentially generalizable for not only clinical research but other types of international collaborative research projects. The approach of the authors is to use semi-structured interviews yielding qualitative data, and to work with both individual interviewees as well as focus groups. The authors cite a focus on ethics as the organizing principle for their investigation and write that “the term collaborative research denotes a requirement that the clinical research be considered ethical”.

Although I am very sympathetic to the subject and the importance of both the highest ethical principles in clinical research and the need for collaborative research as a means of addressing critical problem efficiently, especially in low resource environments, this paper has significant deficits. With significant revision, however, it is likely to meet standards for publication.

First, there is a lack of definition in the paper and a failure to set the scene- What ethical principles are the authors addressing, in specific; Why is this methodology suitable to do so?; What is the research funding environment like in the DR and what types of collaborative research are ongoing there? What is the currently existing research infrastructure and to what extent is it supportive of collaboration?

The second set of questions have to do with the sample: why were the interviewees chosen for invitation and who was not invited (e.g., other agencies, NGOs academics, etc.) and why?; was there agreement or discord among the interview responses?; and what categories of stakeholders were not included at all and why (e.g., mothers, pediatricians, vector control, etc.)?

Third are questions about data analysis and portrayal- the paper would benefit from more detailed discussion of how the 5 domains were arrived at, some semi-quantitative analysis of the responses if possible, and a linkage between the data and the ethical principles they are ostensibly discussing. Issues having to do with equity, participation, resource allocation, fairness, capacity building, etc. are present in the discussion and ought to be brought out more clearly. Distinguishing between the ethics of immediate response to crisis and the ethics of clinical research is important and, in this paper, is subject to a confusing conflation.

Finally, although it may be beyond the scope of the research, it does appear that the authors have ideas of how this can be done better. I wish they would say so more explicitly.
This paper, if rewritten, has the potential to not only shed light into what went on research-wise in the DR in response to ZIKA, but also to provide more general and useful insight into how research can be integrated into the response to an urgent health crisis in a LMIC.

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