Author's response to reviews

Title: Linking international clinical research with stateless populations to justice in global health

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Response to Reviewers

We thank the reviewers for taking the time to consider our paper and for providing such constructive feedback to us. We found both sets of comments to be quite helpful and have responded to them below.

Reviewer 1

1. As suggested, we have included more details on the case study research methods, including the direct observation component (see Case study methods sub-section, pp. 10-11). However, we did not provide extensive information because the methods paper in the Journal of Medical Ethics was published under the proviso that we not repeat the same detailed description in future papers and that we refer to the methods paper instead.

2. As suggested, we have included the case study description under the Methods section. However, we have titled the sub-section “The case under study” rather than “Study setting” because it focuses on describing SMRU (what it is, what its research agenda consists of, who its research population is, i.e. the border population) and the VHX trial (its aims, sites, and participants). This comprises the case under study rather than the study setting.

3. As suggested, we have moved the first paragraph of the sub-section “Obligations to stateless research populations” to the “The case under study” sub-section (see pp. 8-10).

4. The instructions to authors on the BMC Medical Ethics website say that the results and discussion sections may be combined. As we felt that doing so was the clearest and most concise way to present these sections in the context of our paper, we chose to merge them. To make this clearer to readers, we have entitled the section “Results and Discussion”.

Reviewer 2

1. We agree with the reviewer that ‘research for health justice’ and international guidelines have different objectives (i.e. addressing justice at the macro-level versus justice at the micro-level). We have noted this in the paper’s introduction (see p. 4). We believe it is useful to demonstrate that these different aims lead to different ethical requirements. As a result, we describe the differences between ‘research for health justice’ requirements and international guidelines’ requirements (see p. 4-5). That the aim of reducing global health disparities is not one addressed by current international guidelines is the reason we chose to use ‘research for health justice’ as the normative framework to analyse our data. The purpose of our research was to
investigate whether and how SMRU’s VHX trial was able to promote global health justice. Thus, we compared it to ethical requirements intended to advance such ends.

We further disagree with the reviewer that ‘research for health justice’ requirements are quite similar to those of international guidelines. How the two differ has been previously discussed in a paper in *Bioethics* (“A framework to link international clinical research to the promotion of justice in global health”). In light of that paper, which we cite, we did not go into detail on how the two differ in the original manuscript submission. We have added more detail on this (see pp. 4-5). We would also note that ‘research for health justice’ includes ancillary care requirements that are not currently part of the *Declaration of Helsinki* or the CIOMS guidelines (see “Ancillary care: Theory and practice in international clinical research”).

2. We agree with the reviewer that the final paragraph in the paper’s introduction is confusing and we have revised the language in the paragraph to address that problem (see p. 7).

We also provide our rationale for using the ‘research for health justice’ framework in the same paragraph, stating: “In this paper, the data are analyzed using ‘research for health justice’ as the normative framework because the aim of our case study research was to investigate whether and how SMRU’s VHX trial was able to promote global health justice. We, therefore, assessed the practices of the VHX trial’s funders, sponsors, and researchers for alignment with a framework that describes how ICR can advance such ends (rather than with ethical requirements designed to promote justice at the micro-level). (The methods paper briefly evaluates researchers’ adherence to international guidelines’ requirements for responsiveness, research capacity strengthening, and reasonable availability.)”

3. As suggested by the reviewer, we have noted that the paper is the latest in a series and have listed the other papers in that series in an endnote (see endnote c).

4. As suggested by the reviewer, we have reviewed the paper for typographic errors and spelling mistakes and addressed those that we found. The reviewer noted that s/he had made some typewritten corrections to the paper, but we were unable to access the reviewer’s copy to see what typographic errors and spelling mistakes s/he found. (We did ask for a copy to be provided though.)
5. We do not think that the two statements identified by the reviewer are contradictory. Statement A states that SMRU has expanded its research agenda to include new topics. Statement B further notes that those new topics comprise a minority of the total research performed by SMRU. We have added the following statement to help clarify this (see p. 20): “These newer research targets (non-malarial illnesses) comprise a minority of the studies currently being performed by SMRU.”