Author’s response to reviews

Title: Engaging Research Ethics Committees to develop an Ethics and Governance Framework for Best Practices in Genomic Research and Biobanking in Africa: The H3Africa Model

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Author’s response to reviews:

The Editor
BMC Medical Ethics

Dear Editor,

Revised Manuscript Submission: Engaging Research Ethics Committees and Regulatory Authorities in the development of an Ethics and Governance Framework for Best Practice in Genomic research and Biobanking in Africa: the H3Africa Model

We are very grateful to the reviewers for their prompt and helpful comments on our manuscript and have revised our manuscript as follows:
Reviewer 1:

The title of the manuscript is somewhat confusing: the official title of the Framework, from what I see, is: Ethics and Governance Framework for Best Practice in Genomic Research and Biobanking in Africa. This should be accurately recorded in the title. The reviewer also notes several inconsistencies in our reference to the Working Group and identified a number of typos.

The title has now been revised as “Engaging Research Ethics Committees and Regulatory Authorities in the development of an Ethics and Governance Framework for Best Practice in Genomic research and Biobanking in Africa: the H3Africa Model.”

The inconsistencies in the names of the H3Africa working groups have also been addressed, the acronym REC has been used consistently in the manuscript and the word Biobanking has been replaced with biobanking with small letters.

• Why not consult other guidance, e.g. international guidance from WHO or other organizations? If these issues are not per se unique to Africa, why the need for Africa-specific guidance?

We would like to note that even internationally, there is very little such guidance available that is specific to genomics and biobanking. To highlight this point we have added ‘on the continent and internationally’.

• In the Background, you write that ‘questions’ were raised about the appropriateness of broad consent in the African research context. Can you elaborate what these questions were?

We summarised the nature of the discussions, including questions about the appropriateness of broad consent in Africa in another manuscript. We have added the relevant reference to that point.

• You write that the H3Africa working groups support ‘empirical studies addressing the [ELSI] of genomic research and biobanking’. Are these empirical studies in Africa only or also elsewhere?

Those studies were conducted within the context of H3Africa research and as such they were conducted only in Africa. We have clarified this in the text.
• You write that the working groups 'deemed it necessary to develop a framework'. Why was it deemed necessary for a framework. Please explain the rationale.

That text now reads “Given the limited ethics guidance available to support these studies, particularly on the African continent and repeated calls for guidance from ethics committees and other stakeholders, the Working Groups deemed it necessary to develop a framework to address the growing concerns about the conduct of genomics studies and biobanking in Africa”

• Are the RECs in Africa all institution-based? None are region-based? If so, this statement is sensible.

We are not aware of any region-based RECs on the continent and so we assume that this did not require changing.

• In describing the second consultation meeting, you write that the meeting 'called for clear guidelines and regulations across the African continent and the need to ensure that there is harmonisation'. You don't make the case for why this is necessary, though. Why is harmonisation so important here?

We have added the following explanation to this text: “The meeting also called for harmonisation of approaches and guidelines across the continent. The reason for this is that much of the research conducted in Africa happens in collaboration between African partners or with non-African partners. In those cases, significant differences in approaches between partners have been known to cause delays and obstruct collaboration. There is also a concern that if only some countries adopt strict regulations (for instance, stipulating that all collaborative research requires a partner for the country) that international partners would avoid those countries and rather work with researchers in countries where regulation is less strict.”

• In the discussion of the third consultation meeting, you mention only 'institutional ethics committees'. Again, does this mean no regional RECs were present?

The reviewer is right – no regional RECs were present (and we have not identified any ‘regional RECs on the Continent to date).

• In your section on 'other matters arising and next steps', you mention that feedback of individual genetic findings 'emerged' as a pertinent ethical challenge. But earlier in the manuscript you wrote that after the first consultation meeting, there was a shift from identifying
ethical issues to exploring how the identified issues should be addressed in practice. This seems inconsistent.

We thank the reviewer for pointing out this inconsistency. The feedback issue was identified more strongly by H3Africa researchers themselves than by ethics committees and other stakeholders. For this reason, we have removed this section from the manuscript.

• Do you have anything to say about efforts to increase communication amongst/between RECs in Africa and encourage harmonization or mutual recognition of their processes/decisions?

We have added the following sentence to the manuscript: “This should inform fostering a harmonised approach to the regulation of genomics and biobanking on the continent and the development of ethics review equivalency agreements between committees.”

We have carefully addressed all the typos and errors noted by the reviewer.

Reviewer 2

• The framework itself is being published separately. I can understand why the authors might wish to break the work into separate papers, but it was a little bit unsatisfying being informed of the process of consultation but not the outcome.

The content paper for the framework has not been published and it is open access. We have referenced this appropriately and hope this addresses the reviewers’ concerns. We had also highlighted the key ethical issues that were raised by the members of the ethics committees and which informed the key elements of the framework.

• The authors refer to the success of the framework and how they have gauged this - are there plans to assess its success more formally? I'm not sure about the framing of RECs as gatekeepers who ensure participant safety (they have limited ability for ongoing monitoring role, so to what extent can we expect them to protect participants?) - sounds like the authors viewed the RECs as needlessly obstructive and a pain for H3Africa (p4). While there can be some truth to this characterisation of ethics committees, in this case I think it might be useful to be more temperate and explain why the RECs might be deeply suspicious of researchers generally and genomic researchers specifically, with reference to relevant historical events.

We have included the texts highlighting the gate keeping role of research which committees.
• How open were the facilitators to dissent? The language used to describe RECs and the framing of 'champions' suggests that there was a clear aim of getting H3Africa projects through the review process. By engaging with communities primarily through the 'champions', do the authors think they received a skewed view of how these REC communities felt about genomic research? Or perhaps inadvertently excluded dissenting or sceptical views?

The consultation meetings happened at a time when most of the H3Africa projects had already gone through the ethics review process. We believe that we took most of the views expressed during the workshop into consideration when drafting the framework document. For example during the third consultation meeting where we aimed to build a consensus on the principles and key elements of framework, we had to reframe the philosophical basis of this framework when it became apparent that our reliance on Ubuntu was not generally supported by the RECs. We have highlighted these changes in the manuscript.

• I would also like to see a bit more critical reflection on what was achieved during this process - the aims clearly evolved over time, and I would be interested to hear what the authors think about the relationships they developed with the RECs - was it about building trust? Education? Demonstrating good governance?

To address reviewer’s concerns, we have included the following reflections in the manuscript: ‘the consultation process provided a great opportunity to clarify some of the disagreements on the definitions of key terms such as broad consent. As these workshops were more consultative, the issues raised by the participants were what informed the key principles and elements outlined in the framework document. We believe that these processes served several purposes; by strengthening understanding of genomic research and the key ethical considerations that should guide the design, review and implementation of these projects. The workshops also demonstrated to the RECs that the H3Africa consortium was not only focusing on the scientific aspects of the project but also concerned about promoting the ethical conduct of these projects by identifying and addressing them as they arise through appropriate governance structures. Trust is built over time and we have suggested that it will be important sustain these consolation worships.

We hope we have addressed the suggestions made by the reviewers and that you will find the revised manuscript acceptable for publication.

Sincerely,

Dr. Paulina Tindana