

Author's response to reviews

Title: Implementation of Clinical Research Trials Using Web-Based and Mobile Devices: Challenges and Solutions

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Author's response to reviews:

Dear Sir;

Dear Madam;

We wish to thank the three reviewers for their kind comments and also especially for their critical review. The comments allow us to improve the paper in a number of ways, which we will outline here, framed within the context of each of the reviewer comments. The changes are highlighted in the manuscript:

Reviewer #1: This paper describes the concerns one needs to address in order to meet issues raised by the ethics committee when designing and testing web- and mobile-based devices for

vulnerable patients (such as overweight and obese young children with congenital heart disease). This is an important area as interventions and participant activities are increasingly getting digitalized. Ensuring the privacy and security of participants' identity and their data is paramount. There are few literatures providing guidance on the concerns raised in an ethics committee, or ways to respond to these ethical questions.

We thank you for your kind comments. Indeed, this is an important issue, and the privacy and security issues were a central concern throughout our study. Accordingly, we appreciate your constructive suggestions for how to present the ways in which we have addressed these concerns – and we have adopted your restructuring suggestions, namely:

- i) We vindicate the concerns of the Ethics Board, frame them within the context of the overarching 10 privacy principles of the Privacy Act, and discuss our approach to addressing them.
- ii) We have restructured our text to highlight our response to the ethical issues, and have downplayed the specific technical solution, as our earlier discussion was tied to the prevalent ASP.NET MVC 4 of the time. Instead, we make use of discussion terms of the underlying principles which generalize to new software platforms.
- iii) The software code that helps explain the issues, and our method of addressing them has been relegated to the Appendix.

Reviewer #2: Thank you for the opportunity to review this very interesting and in many ways sobering 'case report'. It gives insight into the issues to be faced relating to patient data security. Given the growing use of the Web and also cellular phones for both research and service provision in the health sector this paper will provide insight and guidance for those preparing relevant REB/IRB submission. The authors are to be commended on the approaches they have taken, their resolve and determination.

Thank you very much for these kind comments. And with regards to your specific question about PHIP point 9, we have clarified our response in conjunction with the restructuring suggested by Reviewer #1. And with regards to your careful reading, we have corrected the minor grammatical issues and typos – and we will adopt the formatting guidelines of the Journal.

Reviewer #3: Thanks for the opportunity to review this paper. Most interesting. In the introduction, I 'd like to see some reference to the actual risks to privacy (reports, etc). My

investigation into this has led me to believe that the risk, and concerns, are overstated. In other words, everyone says it is a concern - but without any evidence that it is at risk. My context is in large national shared records systems, where patients always say they want their information to be private - but never make use of privacy controls.

We share your observations, and thank you for your interest in our paper. Your comment allows us to improve the paper by citing some of the reports which identify the actual risks to privacy, and we hope that our presentation makes it clear that a 'technical solution' is only one facet of a response to privacy issues.

After some deliberation, and based on the comments from Reviewers, we decided to remove figures 4 and 6 from the manuscript. They contained a lot of extraneous information that did not add value to our results or discussion and was of no benefit to the readers. However, we did add more detailed figure legends for figures 1 to 4 to better help the readers understand the manuscript content.

We hope that our revision is in favour of reviewers and this paper will be published in your esteemed journal.

With best regards