Author’s response to reviews

Title: What Makes Public Health Studies Ethical? Dissolving the boundary between research and practice.

Authors:

Donald J Willison (don.willison@utoronto.ca)
Nancy Ondrusek (nancy.ondrusek@oahpp.ca)
Angus Dawson (a.j.dawson@bham.ac.uk)
Claudia Emerson (claudia.emerson@srcglobal.org)
Lorraine E Ferris (Lorraine.Ferris@utoronto.ca)
Raphael Saginur (rsaginur@ottawahospital.on.ca)
Heather Sampson (heather.sampson@utoronto.ca)
Ross Upshur (ross.upshur@gmail.com)

Version: 3
Date: 14 July 2014

Author’s response to reviews:

Editor, BMC Medical Ethics

Thank you for the opportunity to respond to reviewers’ comments which, overall, we find to be very encouraging. In our response, in the attached file, we have summarized reviewers’ comments in bold text and provided our responses in plain text beneath.

We have provided two versions of the revised manuscript – one clean and the other with changes tracked. Except where indicated otherwise, when referring to line numbers in our responses, these relate to the line numbers in the revised document in the “track changes” version.

Also, one of the reviewers asked for further information about our risk screening tool. We have another paper currently under review with BMC Medical Ethics describing this tool and its application in ascertaining the level scrutiny applied to the ethics review process. If the other paper is accepted for publication in BMC Medical Ethics, it may be worthwhile to publish these concomitantly.

We trust the revisions made will satisfy the reviewers’ and editors’ requirements.

Respectfully submitted,

Don Willison

Reviewer 1: Drue Barrett

Discretionary revisions.

Comment #1. It would be useful to explore in a bit more detail why differentiating between research and practice is so difficult and has been so unsatisfactory.
Response: This is a very reasonable suggestion. On lines 18-22, following the general discussion about the blur between research, QI, and program evaluation, we have added specific reference to challenges with public health.

Comment #2. Are there any real world lessons that can be described regarding the use of the framework since its release? What has been its impact on public health activities conducted by PHO? How has it been received by PHO staff? Is it currently being used or considered for use by agencies other than PHO? What impact has it had on the timeliness of review of evaluative activities? What impact has the framework had on the workload of the ethics review boards? How has its use improved the conduct of activities which otherwise would not have received ethics review? Has there been any impact on the review of research protocols? Also what have been the implications for emergency response activities? Have processes been put in place to evaluate the impact of the new framework?

Response: These are excellent questions. However, it is premature to address the evaluation in this paper, as our ethics review board has been in place only 18 months. While we have preliminary experience with the system, it is our intention to address the questions of impact on the system in a future publication. In terms of its impact on the review process, the framework was implemented concomitant with the establishment of our own ethics review board. Prior to that, we had contracted with the University of Toronto’s Health Research Ethics Board, which used its own (more conventional) review process and only formal research studies were submitted. So, the adoption of the framework is perfectly confounded with the switch of review bodies, and it has been used in the orientation of the Ethics Review Board members and the project review documents. These factors make it difficult to evaluate the “effect” of the framework on the review process.

Currently, we are unaware of other institutions that have adopted the framework. We have not yet had the opportunity to apply the framework in the context of an emergency. We anticipate that researchers in those circumstances will take into consideration these questions, even if not required to submit formally their protocol for review in advance. Text has been added in lines 140 to 142 to this effect.

Comment #2 (part 2). PHO is described as an “arm’s length government agency.” It is not clear what this means and whether this “arm’s length” would mean that non-arm’s length government agencies would have a different experience with the framework. What are the authors’ thoughts regarding using this framework and eliminating the distinction between research and practice at other public health agencies that may be larger than PHO?

Response: We have removed the terminology of “arm’s length” and substituted in lines 56 to 58 a more detailed description of the relationship between PHO and the government. We expect other organizations’ willingness to adopt or adapt our framework would be affected more by their concerns over augmenting the TCPS
2, rather than their relationship with government. We feel it would be valuable for other public health agencies to eliminate the distinction between research and practice and have stated on lines 190 to 194 that we are aware informally that some local public health units are doing this.

Comment #3. Also it is not clear from the manuscript if the framework requires that all evidence-generating initiatives be submitted to the ethics review board. Line 55 and lines 124-127 indicate that level of risk is a factor; however, lines 145-146 indicate that exemptions from ethics review for certain types of activities is not part of the framework.

Response: All evidence-generating initiatives are required to complete an initial risk-screening tool to permit the triaging of level of scrutiny according to risk. This may result in what we have coined a “level 1 delegated review” by the research ethics officer, a delegated review by 2 members of the ethics review board, or a full review. Hence the statements in line 55 and in lines 124-127 [Original submission]. Lines 180 to 184 [current track-changes version] indicate that the system does not support exemption of certain types of evaluative activities “as a class”. Instead, the level of review would be contingent upon the level of risk, as determined by the risk-screening tool.

Comment #3 (part 2) The authors refer to the development of a risk screening tool and the development of standardized protocols for routine evaluative activities, however these are not described. Perhaps a short case example of how the process of using the framework works, from protocol development to ethics board review would be useful (not sure if this would fit given word length requirements).

Response: The risk-screening tool is the subject of a sister paper that is currently under review, also with BMC Medical Ethics. Perhaps it would worthwhile to publish these two papers concomitantly and we could specifically reference that paper in this paper for more details.

Comment #3 (part 3) Also, importantly, as suggested above, it would be useful to discuss how this framework would work with data collections done as part of public health emergency preparedness and response activities.

Response: As mentioned in our response to Comment #2, we have not yet had the opportunity to apply the framework in the context of a public health emergency. We have added text in lines 140 to 142 to speak to this.

Minor essential revision. 4. In the acknowledgements section, the correct title for CDC should be U.S. Centers for Disease Control and Prevention (“and Prevention” was left off).

Response: Fixed. Thanks.

Reviewer 2: Lisa Lee

Major compulsory revisions.
Comment #1a. How the ethical landscape of practice differs from that of research.

Response: Dr. Lee has posed very thoughtful questions about the respective duties and priorities in the practice vs. the research environment. We agree that the primary obligation of the public health researcher to the optimal conduct of the research, but with due consideration of the health of the public and communities being studied. We do not envision this as a dichotomy. Following the equivalent to the Freedman approach of the clinician-researcher, we believe the public health researcher retains a duty to the welfare of the population and may need to temper the design of the research to ensure that the health interests of the population are upheld in the context of the research to be conducted. Hence, the public health researcher who wishes to make secondary use of data collected for a different (clinical or public health) purpose must first identify how the research question will link to potential improvements in public health. Our framework would not support the imposition of research risks upon a community that stood no potential to benefit from the intervention, for the sake of other communities that would, without strong justification and some form of reciprocal support for such an imposition.

Comment 1b. How the proposed framework will be incorporated into the current REB system?

Response: We have made revisions in lines 159 to 164 that address this.

Comment 1c. How the proposed framework will be applied in the non-public-health research context.

Response: Dr. Lee correctly points out that there are challenges to directly applying our framework outside the public health context. We did not envision the framework’s use in Phase 1 biomedical studies or even Phase 2 or 3 biomedical studies. Our thinking is more that this would apply, with appropriate adaptations, to similar kinds of non-public health studies involving program evaluation, quality improvement, etc. in both health care and in other disciplines such as education and social sciences. Accordingly, we have made revisions to the manuscript in lines 211 to 214 to clarify this.

Discretionary revisions

Comment 2. Clarify what is “an arm’s length government agency”.

Response: We have described more explicitly the nature of the relationship between PHO and the government in lines 56 to 58.

Comment 3. It will be important to include not only tools for differentiating high- and lower risk activities but also to assist REBs to differentiate risks taken on for primary benefits of self/community and risks taken on for the sole or primary benefit of others.

Response: Questions 3 and 4 of the framework collect information about the
distribution and benefits while questions 5 and 6 help the reviewer sort through the issue of the appropriateness of those distributions, so we believe we have this issue covered.

Comment 4. Independent review could add a great deal to public health practice activities, but an open question remains about how best to approach review. Will IRBs/REBs, with their focus on autonomy and individual informed consent be adequate? Or would another approach analyzing the unique ethical features of public health activities be preferable? Are IRBs/REBs agile enough to apply ethical analysis with varying emphases on their principles? This is an empirical question that should be studied.

Response: We have taken the approach of analyzing the unique ethical features of public health activities and have used this in the education of our ethics review board members and as the foundation of our ethics review tools. We clarify this in lines 159 to 164 of the revised manuscript. The primacy of autonomy is discouraged in our framework.