Reviewer's report

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

Version: 2 Date: 12 June 2014

Reviewer: Drue Barrett

Reviewer's report:

This manuscript by Willison and colleagues addresses important issues in public health – the distinction between research and practice and the establishment of a mechanism for the ethics review of public health practice activities. The framework proposed by the authors provides useful information to public health practitioners about how to consider a public health ethics perspective rather than just relying on a biomedical perspective reflected in research ethics principles. This includes consideration of relational autonomy, respect for communities, solidarity, social justice, and reciprocity. The framework includes 10 guiding questions which provide practical ways to think about these ethical values. The framework has the advantage of providing guidance for both ethics reviewers and protocol developers and assists in prompting a systematic consideration of ethical issues in both research and practice. Although I think this is a useful document and could be published as is in order to reach a wide audience of public health professionals, it is essentially a condensed version of the framework document that was released in January 2012 (reference 13). Thus, I would recommend that the authors consider the following recommendations in order to improve the usefulness and value of this manuscript. Although I categorize these as discretionary revisions, I hope the authors will give them serious consideration.

Discretionary Revisions:

1. The authors point to the difficulty that the field of public health has had in distinguishing between research and practice. However, the article provides only limited information about why this distinction has been so problematic. 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 (maybe even provide some examples) in order to better frame the argument that this distinction should not be made.

2. I view as a more important omission the lack of a discussion of the practical implications of use of the framework. The framework was released in January 2012. 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?

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?

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. 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). 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.

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).

Level of interest: An article of importance in its field

Quality of written English: Acceptable

Statistical review: No, the manuscript does not need to be seen by a statistician.

Declaration of competing interests:

I have no financial competing interests in this manuscript. I provided comments on the framework in 2011 when it was being developed however I have had no additional contact with any of the authors regarding this work since 2012. I do not perceive that I have any competing interests.