Reviewer's report

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

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Reviewer: Lisa Lee

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The framework presented here is commendable. There is much to be done to integrate ethical decision making into the formulation of programs and research. Posing these 10 questions to guide thinking of public health practitioners and researchers is a concrete tool that should do a great deal to explicate the ethical considerations taken into account when planning and implementing practice and research activities.

Major Compulsory Revisions:

1. The framework discussed in this paper is in the public domain; this manuscript could add substantively to the discussion with the addition of thoughtful analysis of the theoretical basis for what is proposed and wrestling with some of the obstacles of implementation (most importantly how to alter the public obsession with unconditional individual autonomy). Additional conceptual and logistical issues that would be useful to address include:

a] How the ethical landscape of practice differs from that of research: The fiduciary duty of the practitioner is primary in practice (e.g., what is best for this community [the patient]) compared with research where the focus is on what is best for the execution of the study and generation of scientific knowledge. In many/most cases, the primary use of the data collected from practice activities (PH surveillance, program evaluation, etc.) is different than the use of data collected for research purposes; public health activities often are immediately applicable to the persons and communities involved in the data collection. Finally, the risk taken on by communities for their own benefit is morally different than risk taken on for the benefit of others. The ultimate risk:benefit calculus differs when benefits accrue to those bearing the risk. This line is not clear in every situation, but for the majority where it is clear, the ethical difference is real.

b] How the proposed framework will be incorporated into the current REB system: The proposed framework will be helpful practitioners and researchers plan and design ethical data collection and integrate ethical considerations into the fabric of the project. REBs/IRBs provide additional review over and above this type of ethical research design; REB review specifically addresses protection of research volunteers from being used as a means to the scientific end, ensures that the potential harms are minimized, and confirms that participants are aware and fully consenting that they are participating for the benefit of others. How will
the considerations in this framework add to/complement the current (regulated) REB review? What recommendations do you have to motivate the alternative interpretation of REB requirements implied by the framework? IRBs and REBs are focused on individual autonomy and consent, but for many public health practice activities, these are not the primary ethical drivers. How can this reality be folded into the current IRB/REB review process?

c] How the proposed framework will be applied in the non-public-health research context: The authors state that the questions were designed to provide an overall framework to all data collections/systematic activities. The addition of the “public health lens” is helpful for public health activities, but most will not apply to traditional biomedical research/trials where the primary concerns are related to protecting individuals from potential harm they take on for the benefit of others. Thus, it would be helpful to clarify the use of this well-thought out framework. Will the regulations in Canada allow these additional considerations for REB review? What weight will these questions have in REB approval or disapproval of a project? For example, if a Phase I early safety trial is evaluated by an REB using these questions, creating affirmative responses might be a real stretch. Will this “count against” approval of the trial? Is the expectation that the TCPS 2 begin to allow increased value of community benefit over the focus on individual autonomy?

Discretionary Revisions

2. Discussion, The Context, 1st paragraph: “an arm’s length government agency” might be unclear to non-Canadian readers. Does “arm’s length” mean quasi-governmental? Public-private partnership?

3. Section 2.4 Application of the PHO framework, second paragraph: Authors state, “We recognize that extending ethics review to all knowledge-generating activities has major workload implications for an institution’s ethics oversight process.” They mention two promising tools to assist in managing this increased workload. 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.

4. Section 2.5 The PHO Framework in the context of other calls for ethics reform, second paragraph: Authors state, “While we acknowledge that the current research oversight system is often too bureaucratic, we do not agree with calls for exemption from ethics review as a class for surveys, focus groups, and similar research involving competent adults, as has been advocated in some circles.” 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.
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 declare that I have no competing interests.