A Framework for the Ethical Conduct of Public Health Initiatives

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## References
Preface

Public Health Ontario (PHO) is an arm’s length government agency with the mission “to enhance the protection and promotion of the health of Ontarians and to contribute to efforts to reduce health inequities” by providing “scientific and technical advice and support to those working across sectors to protect and improve the health of Ontarians”. PHO is developing a set of services to support the ethical conduct of public health initiatives. The aim is for these services to be responsive to the challenges, needs and responsibilities associated with evidence generation for public health.

To assist with reflection on the ethical issues, this paper presents a framework using a public health lens. It is part of a larger initiative to develop a set of ethics support services for Public Health Ontario and the 36 Public Health Units (PHUs) in Ontario, but it is hoped that the model will be useful more broadly to anyone involved in public health initiatives. The services include educational resources, an ethics advisory, the development of a public health ethics community of practice, and an ethics review process for single site and multi-site initiatives carried out in Ontario. These services are described on the PHO website.

Consultation Process

This framework has been developed by a working group of public health and ethics professionals and scholars, in consultation with individuals representing a wide range of public health roles. The ideas in this paper were presented at various forums, and early drafts were circulated to public health practitioners and ethicists for comment. The resulting feedback was incorporated into the first completed version of this paper, which was released broadly for discussion in June 2011 to public health units across Ontario, independent academics working in the areas of public health and ethics, and individuals at the Canadian Institutes of Health Research, the Public Health Agency of Canada, the Panel on Research Ethics, the Registered Nurses Association of Ontario, and the U.S. Centres for Disease Control. PHO greatly appreciates the effort that went into reviewing the various drafts and first full version and providing the very thoughtful, detailed and useful feedback. These comments were used to inform the revision of the paper into the version presented here.

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Executive Summary

Evidence generation is integral to the work of public health. Evaluation routinely accompanies the introduction of new public health programs and services or the modification of established programs. Public health surveillance programs monitor indicators of health status as well as social and environmental conditions that may affect public health. Quality improvement activities collect data to ensure that ongoing programs and services are being implemented to appropriate standards. Research serves to address broader knowledge gaps to inform all of these activities.

All these initiatives involve the systematic collection of data about individuals or communities, their environments, and the health and social services they receive or provide. They require either the primary collection of new data or the secondary use of existing data for these purposes. Ethical issues may arise at any point in the conduct of these activities.

Public Health Ontario (PHO) has developed a model for the ethical conduct of public health initiatives that:

- is to be applied throughout the lifecycle of those initiatives, from the initial development of an inquiry through to knowledge exchange;
- fosters a culture of ethical integrity among all those conducting the initiative, rather than a culture of compliance with an external ethics review body; and
- is to be applied to all evaluative activities, proportionate to the risks involved.

This report provides a framework to guide the ethics review of evidence-generating public health initiatives. It begins by interpreting the Canadian Tri-Council Policy Statement 2, Ethical Conduct for Research Involving Humans (TCPS 2) through a public health lens. The three core principles of the TCPS 2—respect for persons, concern for welfare, and justice—are examined with an emphasis on the inter-relatedness of the welfare of individuals and communities and a positive obligation to promote equity and reciprocity. So, for example, while respect for autonomy is still valued, autonomy is interpreted in the context of the dynamic relation between the individual and his/her community. As well, respect for communities generally invites the question of when community engagement is warranted and at what level of engagement.

In the latter half of the document, we pose ten questions that should be considered by both the investigator when planning an initiative and the evaluator responsible for reviewing an initiative for ethics issues. The two boxes that follow list the ten questions and some key points to consider when using them. These are summaries only. The reader intending to apply these questions is encouraged to read the full text, as it provides a greater contextualization of the questions to public health circumstances.

As with all frameworks, the guiding questions are not algorithms to provide the “right” answer. They are meant to help with the systematic examination of the issues, including appropriate consideration of the interests of all stakeholders. In addition, as the questions are applied to more and more cases, we anticipate refinements to the questions and interpretive text. We encourage any users of this framework to share with us any refinements they introduce, in the spirit of continual improvement of this document.
Guiding Questions: Points to Consider

1) **What are the objectives of the initiative? How are they linked to potential improvements in public health?**
   - A clear link must be provided between the initiative and potential public health improvements; potential benefits may be immediate or future. Collection of data where public health value is more speculative may be permissible with justification.
   - This question serves as an anchor for review, as many of the questions below relate back to the original objectives.

2) **Can the objectives be achieved using the proposed methods?**
   - Initiatives lacking sufficient methodological rigour may lead to data that is of poor quality or invalid, wasting resources and potentially causing potential harm through misinformation.
   - Requirements for scientific rigour must be balanced with sensitivity to the context in which an activity is implemented.
   - Judgment regarding the design of an initiative requires relevant methodological expertise as well as some knowledge about the participating populations and other contextual details, as relevant.

3) **Who are the expected beneficiaries of the knowledge gained or other benefits?**
   - Beneficiaries may include individuals and/or communities, whether or not they are directly participating in the proposed initiative.
   - Individual and collective interests may be shared or competing, or both, depending on the circumstance.

4) **What are the burdens and potential harms associated with the proposed initiative? Who bears them?**
   - Harms associated with evidence generation in public health frequently arise from collection, use or disclosure of information; potential consequences include stigmatization, discrimination, psychological distress or economic loss. Other harms, such as threats to health, may also occur.
   - Burdens generally are borne by those participating in an initiative. Harms may affect individuals and/or communities, whether or not they are directly participating in the proposed initiative.
   - Potential harm to relationships should be considered.
   - Where possible, an effort must be made to mitigate or minimize risks and burdens, balancing against any loss in potential benefit.

5) **Are burdens and potential harms justified in light of the potential benefits to participants and/or to society?**
   - Burdens and potential harms should be weighed against not only potential benefit from conducting an inquiry, but the harm in not carrying out that inquiry.
   - Burdens or harms may accrue to different individuals/groups than those receiving the benefit but, where this is the case, there should be some justification.
   - “Fair procedures” such as transparency and stakeholder participation should be used to guide decision making regarding balancing of burdens, harms and benefits.
6) **Is selection of participants fair and appropriate?**
   - Fair distribution of burdens, risks and potential benefits includes paying special attention to vulnerable or disadvantaged populations, to be included where there is potential benefit, excluded where certain groups face greater burden or risk, or preferentially included because of increased probability or magnitude of benefit.
   - The principle of reciprocity requires finding ways to give back to individuals or communities that bear a disproportionate share of burden or risk for the benefit of others.

7) **Is individual informed consent warranted? Is it feasible? Is it appropriate? Is it sufficient?**
   - While important, individual autonomy does not always take priority over other ethical concerns, such as welfare of populations.
   - For many public health initiatives, obtaining individual consent may not be required, feasible or appropriate. Where departure from individual informed consent is proposed, consider alternatives such as broad consent, notice with opt out, and consultation with a representative sample of the population of interest.
   - In certain cases, such as examination of illegal behaviour, alternative approaches such as use of verbal consent or pseudonyms may be appropriate.

8) **Is community engagement warranted? Is it feasible? What level of engagement is appropriate?**
   - Community engagement is encouraged where feasible and might be used in lieu of, or in addition to individual consent.
   - Engagement may range from informing to consultation, collaboration and empowerment.
   - Community engagement may include some form of collective consent or consensus process authorizing the initiative in the community.
   - Challenges include determining what level of engagement is appropriate, what counts as a community, and who the appropriate representatives are.

9) **What are the social justice implications of this initiative?**
   - Projects that reinforce existing inequities should be avoided and opportunities to promote social justice should be considered where possible.
   - Extra resources or special measures may be needed to promote social justice, for example to ensure that disadvantaged groups are appropriately considered in the development of project objectives, or to remove barriers to their participation in public health initiatives.

10) **What are the potential longer-term consequences?**
    - Where possible, potential negative long-term consequences of an initiative should be considered and plans for mitigating these risks should be developed prior to implementation.
    - Community engagement can be helpful both in identifying potential long term harms, and in devising methods to address them.
1.0 Introduction

1.1 What is public health?

There is no universally accepted definition of “public health.” For this paper, we define the practice of public health as interventions by a collective that aim to promote and protect the health of the public.\(^2\) Public health activity involves both a particular kind of end (the health of the public as a group or population) and a particular kind of action directed towards that end, carried out by individuals, groups or entities within governments or on behalf of governments. While the ethics framework that we describe in this document is intended for use by public health organizations, we believe the core elements are also useful for others engaged in public and population health evaluative activities.

Key aims of public health policy and practice include:

- **Protection of citizens from threats to health**
  - through, for example, disease prevention initiatives such as vaccination programs, control of infectious diseases, and food inspection programs;
  - by monitoring known threats to health and detection of novel threats, through surveillance programs for chronic and acute diseases.

- **Promotion of individual, societal and environmental factors likely to make a positive impact upon health**
  - through programs to prevent chronic disease (e.g. tobacco control);
  - through injury prevention (e.g. through promotion of helmet use for skiing and snowboarding); or

- **Promotion of greater health equity**
  - through identifying the barriers to achieving maximum health potential for individuals and populations; and
  - by aligning public health programs and services with those of other partners to address the societal influences on health.\(^3\)

1.2 The role of evidence in public health

Evidence generation is integral to the work of public health. Evaluation routinely accompanies the introduction of new programs and services or the modification of established programs. Public health surveillance programs monitor indicators of health status as well as social and environmental conditions that may affect public health. Quality improvement activities collect data to ensure that ongoing programs and services are being implemented to appropriate standards. Research serves to address broader knowledge gaps to inform all of these activities. All these initiatives involve the systematic collection of data about individuals or communities (including patients, healthy community members, populations, and health care workers), their environments, and the health and social services they receive or provide. They involve either the primary collection of new data or the secondary use of existing data for these purposes.

1.3 Ethical conduct of public health initiatives

The application of ethical principles to the design and implementation of public health initiatives can play an important role in:

- supporting the ethical conduct of these initiatives;
• protecting the rights and welfare of participants (individuals, communities or broader populations) and employees; and
• preserving public trust in public health.

While there have been significant developments in research ethics over the last two decades, the ethical principles traditionally employed tend to focus on protecting individuals. This does not always transfer readily to public health initiatives, which frequently target populations rather than individuals, and which often aim to prevent or reduce harm in those populations, rather than treat illness. In Section 2 of this paper, we interpret the core principles in the Tri-Council Policy Statement (TCPS 2) from a public health perspective. This perspective considers the individual in interplay with the broader community in which that person lives. It ascribes considerable importance to the promotion of justice and the common good. Section 3 then poses ten questions to be considered when developing or reviewing a new public health evidence-generating initiative.

It is our intention that this framework will guide ethical reflection for public health initiatives throughout the lifecycle of an initiative, beginning with the initial development of an inquiry and carrying through to the exchange or application of knowledge generated. The goal is to develop a culture of ethical reflection among investigators, reviewers and decision makers, rather than a culture of compliance with an external ethics review body.

1.4 An integrated approach to ethical analysis of public health initiatives

Traditionally, ethics has been managed differently in research projects, as compared with quality improvement, program evaluation, and surveillance, with only research requiring formal review by a research ethics board (REB). However, these various initiatives frequently use common methods and, therefore, may pose common risks to those who participate. In this section we present the argument why these various initiatives should be handled in the same fashion when it comes to ethical considerations.

There is significant agreement that some form of ethical reflection or review is important for all types of evidence-generating initiatives, whether or not they constitute formal research. For activities that fall outside the definition of research, however, there is no consensus regarding who should be responsible for making these ethical judgements, or what process should be used. It is widely suggested that review of activities not labelled as research falls outside the purview of the REB. However, the establishment of separate review processes for different types of evidence-generating initiatives is problematic—it requires one to differentiate between research and non-research initiatives, but efforts to develop criteria that cleanly make this differentiation have been unsatisfactory. As Fairchild and Bayer (p 632) note:

> The recent efforts to provide definitional solutions to the question of research and public health practice involve twists and turns that inevitably produce results that are riddled with inconsistencies and that are conceptually unsatisfying.

The setting up of different processes for research and non-research activities also creates an incentive among those wishing to avoid the burden of submission to an REB for review, to try to present the project as non-research. In addition, considerable time is often spent on determining whether or not an initiative meets the requirements for REB review. This consideration often involves multiple conversations between investigators—

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1 The inclusion of employees may be somewhat contentious, as protections for this group are covered under various occupational health provisions. We suggest that consideration of risk to evaluators is nevertheless appropriate, as activities that pose unreasonable risks to evaluators cannot be considered ethical. The identification of risks to investigators in the course of ethics review is supported by the TCPS 2, Article 2.9: “While it is not a formal part of its responsibilities, an REB may raise concerns about the safety of student researchers as part of its communication to the student researchers, and to their supervisors. Based on the level of risk, the REB may consider referring these concerns for review by an appropriate body within the institution.”

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and the ethics office. Frequently, no definitive answer is reached, and the “play it safe” option of submitting the project for research ethics board review is chosen—either just to be sure, or “in case we want to publish”. In the end this wastes time and does not guarantee that all initiatives that should be reviewed are considered.

To address the challenges identified above, PHO has developed a model of ethical reflection and review that takes an integrated approach for all evidence-generating public health initiatives involving people, their biological materials or their personal information, whether or not the information is identifiable. The use of a single system avoids the problems associated with trying to distinguish research from non-research described above, and ensures that all initiatives receive ethical assessment proportionate to the degree of risk. Out of scope are initiatives involving monitoring of non-personal data in public spaces—e.g. direct monitoring of air and water quality—unless data are being displayed at a particular level of geographic granularity such that there may be an adverse effect on individuals or communities. Ethics services to support implementation of the new model are described on the PHO website. The current paper describes the ethics framework that will be used to guide the reflection and review.

1.5 Public health, ethics and the law

The work of public health is enabled, guided and in some cases mandated by a number of different laws. It might be argued that the existence of enabling or mandating legislation obviates the need for ethics review of many public health activities such as surveillance. Ethics and law, however, perform complementary, rather than interchangeable, functions. In general, laws give representatives or agencies of the government the duty and authority to protect and promote the health of the public, and also specify certain limitations on that authority. The question of how to carry out these functions—particularly when there may be competing mandates or interests and more than one course of action that is possible—becomes an ethical issue that requires consideration of the risks and benefits to various stakeholders. For example, the requirement for an individual’s consent to medical care can be overridden when “a person who is infected with a communicable disease has failed to comply with an order by a medical officer of health.” Determining whether the public health risk is sufficient to justify such restriction of an individual’s autonomy is, however, an ethical issue. A court of law may review a case to determine if there was “overreaching” or disproportionate risk/benefit ratio, but the use of ethics guidelines or frameworks can help ensure that deliberations regarding how to act in these situations include reasoned consideration and weighing of the interests of relevant stakeholders.

2.0 Ethics review of public health initiatives

The remainder of this paper describes a framework to guide ethical reflection on public health initiatives. It builds on the second edition of the Tri-Council Policy Statement on Ethical Conduct for Research Involving Humans (TCPS 2). The decision to use the TCPS 2 and its three core principles of respect for persons, concern for welfare, and justice as the starting point was based on a number of considerations:

- In Canada, research projects involving human participants and carried out at institutions that receive Tri-Council funding must be compliant with TCPS 2. As we are developing a unified system for review of research and non-research initiatives the most appropriate approach is to build on the TCPS 2.

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ii The three national funding agencies: Canadian Institutes of Health Research, Social Sciences and Humanities Research Council of Canada, and Natural Sciences and Engineering Research Council of Canada.
• Users know and trust the TCPS 2. Many of those responsible for ethics review, as well as many investigators, have invested significant time in knowing and applying the Policy.

• There is wide acceptance for the three core principles. The foundational principles of TCPS 2—respect for persons, concern for welfare and justice—very closely mirror other internationally accepted principles that underlie research protections, such as the US Belmont Report, which has been in use for over 30 years. While additional principles that are particularly relevant to public health may also be introduced, the three core principles of the Policy remain relevant.

• Concerns about the limitations of the TCPS 2 largely relate to misapplication. Concerns have been voiced that the TCPS 2 is not an appropriate starting point for public health initiatives, because it reflects an individualist orientation and is founded on presumptions that hold true for biomedical research, but not for other contexts. We suggest that perceived challenges with the applicability of the TCPS 2 in many instances reflect overly rigid interpretations amidst a cultural bias towards individual autonomy and a focus on avoiding risk rather than doing good, and not limitations in the actual guidance provided by the Policy.

2.1 Interpreting the Tri-Council Policy Statement, 2nd Edition through a public health lens

As noted above, at the foundation of TCPS 2 are three core principles—respect for persons, concern for welfare, and justice. These principles provide fundamental guidance, but require interpretation and specification to be used to inform decision-making in a specific context. The TCPS 2 provides interpretation and specification for different types of research activities and for research involving special populations, such as Aboriginal communities and vulnerable individuals. With the exception of a brief section on research in the case of public health emergencies, however, application of the core principles to the public health context has not been covered.

In this section we discuss how the core principles of the TCPS 2 might be interpreted in the context of public health. In particular, we consider how these core principles may be read in the context of community or population interests, including the relational interests of the individual as part of a community. Additional principles often associated with public health, such as common good, solidarity, social justice and reciprocity will be considered as they relate to the core principles.

The need to consider groups and communities is recognized in the TCPS 2. The community lens, however, is not carried through in many of the more specific interpretations in later TCPS 2 chapters. An exception to this is Chapter 9, which provides a detailed examination of community considerations in the context of research with First Nations, Inuit and Métis peoples, much of which is very relevant to the public health context more generally. Thus, the public health interpretation offered below is not a departure from but an expansion of that community lens.

2.1.1 RESPECT FOR PERSONS

According to the TCPS 2, “Respect for Persons incorporates the dual moral obligations to respect autonomy and to protect those with developing, impaired or diminished autonomy.” Autonomy can be interpreted in many ways, but is generally seen as guaranteeing individuals the right to make decisions about their own lives. Protection for those with diminished autonomy may involve measures such as “seeking consent from an authorized third party” and special conditions for including vulnerable persons in research.

The TCPS 2 notes that individual expression of autonomy may be influenced by relationships with others, including family, community, and other social groups. A public health interpretation might take this notion further, to a concept of “relational personhood” that “not only makes evident that all persons are (at least partially) socially constructed, it also reminds us that we are not all constructed as equals.” Thus, a public health lens brings into focus forms of disadvantage such as the impact of social determinants that may...
affect autonomy. Poverty, for example, may reduce choice or the opportunity to express a preference. It may even affect the perception that an individual has a choice. Consequently, persons with limited means may, for example, find it difficult to participate in community forums.

The interpretation of respect for persons in the sense of respect for autonomy has led to an emphasis on individual interests. Respect for individual autonomy has often dominated discussions of ethical issues in many areas of health care. In the chapter on research involving the First Nations, Inuit and Metis peoples of Canada, the TCPS 2 provides an interpretation of respect for persons that extends beyond individuals to respect for communities, recognizing concern “for their continuity as peoples with distinctive cultures and identities.”5 [p 109] This concept of respect for communities can be extended further, to consideration of all communities or groups that might be affected by an evidence-generating public health initiative.

Gostin has suggested that respect for communities requires investigators “to observe choices made by local communities, and to avoid any activity which stigmatizes, demeans, harms or disintegrates human populations, intentionally or inadvertently.”19 [p 192] In addition to harming communities directly, failure to show respect may erode trust between communities and those delivering public health services, such as local public health units. This loss of trust may create barriers to acceptance in the community and a loss of potential public health benefit that extends well beyond the boundaries of a specific initiative.

An important mechanism for demonstrating respect for communities is through consultation or collaboration with the affected community, to learn their perspectives and choices. Community participation may augment individual consent. It may also be indicated where individual consent is not sufficient, feasible or appropriate. Individual consent is not feasible, for example, for participation in a study of water fluoridation, an intervention that is administered regionally rather than individually.iii With the exception of research with Aboriginal peoples, community engagement is not explicitly required by the TCPS 2, which allows a waiver of consent where individual consent is not feasible.

Engaging communities raises a number of challenges. Bringing decision making to the community may surface conflicts and damage relationships that are already in tension—for example if members become polarized regarding whether to take part in a particular initiative. Other challenges include how to identify relevant communities and how best to engage them. (These challenges are considered in more detail below in Section 3.8) The challenges should not be used as an excuse to avoid community engagement, but to encourage thoughtful planning before engagement.

Respect for communities also raises the issue of competing voices—both with individual members of that community and with the public at large. In such circumstances, one must take care to avoid the tyranny of the majority, in which the views of the majority always trump those of the individual or marginalized sub-populations. At the same time, one must be alert to tyranny of the minority, in which the views of narrow well-organized minorities are asserted over those of the majority.

2.1.2 CONCERN FOR WELFARE

The TCPS 2 states that welfare “consists of the impact on individuals of factors such as their physical, mental and spiritual health, as well as their physical, economic and social circumstances.” Moreover, “harm includes any negative effects on welfare, broadly construed.”5 [p 9] To protect the welfare of human subjects, ethics boards and investigators are required to ensure that the risks and benefits of initiatives are favourably balanced, and that risks are minimized. Although the emphasis appears to be on individual welfare, the TCPS 2 does acknowledge that concern for welfare also applies to communities or groups, and notes that individual welfare may be affected by various factors including the welfare of “those who are important to them.”5 [p 9]

A public health perspective recognizes that the welfare of individuals is affected by the welfare of those in their environment more generally, rather than only “those who are important to them.” In addition, a public health interpretation of concern for welfare recognizes that individual and collective welfare are often not
Clearly distinguishable, so that consideration is not simply about determining whether individual or collective interests get priority, but identifying the interactions or relationships between the welfare of individuals and their social environment.

Many public health threats risk the health of the whole population and not just that of individuals. The idea of a common good might be used to capture the idea that we all benefit from a society with strong public health facilities to address, for example, control and treatment of certain communicable diseases. Public health is founded on the recognition that there are certain common goods that ought to be promoted. Such common goods are often related to those conditions necessary for human flourishing, such as clean air, clean water, adequate nutrition and removal of radiation.

Recognition of the common good acknowledges the interdependence among members within and between communities. The principle of solidarity recognizes a commitment to standing together as a group, community or nation to promote our collective welfare. It is often appealed to in discussion about justifications for the welfare state or the sharing of costs through insurance pooling, and in thinking about how states might defend the interests of vulnerable groups within their population.

Differences of opinion may exist, however, regarding what measures are appropriate to achieve such goods, or how best to define them. For example, in the minds of some communities, fluoridation of the water supply is not consistent with access to “clean water”. Limitations on the sale of raw milk will interfere with some individual’s perceptions of adequate nutrition. Therefore, if someone justifies an initiative on the basis that it promotes “the common good”, one must recognize that there may be a diversity of opinions regarding how goods are to be realized. Article 9.6 of the TCPS 2 notes that, in engaging communities “researchers should ensure, to the extent possible, that they take into consideration the views of all relevant sectors—including individuals and subgroups who may not have a voice in formal leadership” and that “special measures” may be needed to ensure inclusion of “those who have been excluded...in the past.”

2.1.3 JUSTICE

The TCPS 2 summarizes the principle of justice as “the obligation to treat people fairly and equitably.” In the policy, fairness and equity are considered in terms of the distribution of the benefits and burdens of research, to individuals or in some cases, to communities. Justice also requires recognition of pre-existing vulnerabilities and power imbalances, and the need to ensure that, as a result, some individuals or groups are protected against being routinely: i) denied the benefits of research, or ii) overly burdened as participants. Inclusion of vulnerable groups as study participants requires justification in terms of direct benefit to those groups and scientific merit, and exclusion of groups requires justification in terms of risks and scientific merit. TCPS 2 distinguishes equity from equality, and notes that vulnerable or marginalized people or groups “may need to be afforded special attention in order to be treated justly in research.”

A public health interpretation recognizes the above obligations, but also emphasizes a positive obligation to intervene where injustice or inequity exists. This focus on social justice is seen by many as one of the central roles of public health. Reduction of health inequities may at times require “focussing on the needs of the most disadvantaged.” Groups may suffer from health inequities as a result of a wide variety of factors including income and social status, social support networks, education, employment, early childhood health, gender and culture. Consequently, unequal shares of resources may be expended to compensate for existing inequalities.

Reduction of health inequity and taking care not to worsen existing inequities may be considered throughout the lifecycle of an initiative, from the choice of objectives and outcome measures, to selection of participants and considerations regarding how to facilitate participation of disadvantaged groups, to the development of strategies to promote dissemination and uptake of knowledge among those most in need. The positive obligation to reduce inequity also requires that the risks associated with public health initiatives should be weighed against not only the potential benefits of the study, but also against the harm to a population of failing to conduct initiatives that may lead to the reduction of existing inequities.
A public health conceptualization of justice also emphasizes reciprocity—i.e. the idea of “giving something back” for those who put themselves at risk or bear substantial burden for the benefit of others. It might include an obligation to compensate if any harm or burden is caused while working on behalf of others. Compensation may include, for example, planning to make available to control groups interventions that are found to be beneficial after a study is completed.

3.0 A Framework to Guide the Application of Core Principles to Public Health Initiatives

In the preceding section of this paper we interpreted the TCPS 2 core principles through a public health lens. In this section we propose a set of ten questions to help apply the core principles in the planning and review of evidence-generating public health initiatives. These questions are informed by several earlier frameworks developed for clinical research, public health and health services research. The first seven items in the list are also reflective of the guidance provided by the TCPS 2, and the kinds of questions that REBs typically ask when reviewing a research protocol. For these items, the difference from previous approaches is evident mainly in the discussion regarding how to interpret and apply the questions to a public health initiative. Items eight through ten are the most novel and reflective of the public health perspective. In all cases, it is important that the guiding questions not be used in isolation from the discussion regarding their interpretation and application.

Guiding Questions

1) What are the objectives of the initiative? How are they linked to potential improvements in public health?

2) Can the objectives be achieved using the proposed methods?

3) Who are the expected beneficiaries of the knowledge gained or other benefits?

4) What are the burdens and potential harms associated with the proposed initiative? Who bears them?

5) Are burdens and potential harms justified in light of the potential benefits to participants and/or to society?

6) Is selection of participants fair and appropriate?


8) Is community engagement warranted? Is it feasible? What level of engagement is appropriate?

9) What are the social justice implications of this initiative?

10) What are the potential longer-term consequences?
3.1 What are the objectives of the initiative? How are they linked to potential improvements in public health?

An important requirement for any public health initiatives is that the objectives are stated clearly and, consistent with the principle of concern for welfare, are explicitly linked to the promotion and protection of the health of the public. Initiatives may have public health value whether the potential benefit is proximal or distal to the population or participants involved. For example, evaluation of a program designed to increase awareness of risk behaviours associated with sexually transmitted infections may be used immediately to improve that same program, whereas research into biomarkers may be used to design better vaccinations at some point in the future.

All proposals for evidence-generating initiatives claiming a public health objective should include a discussion of how any of the findings could contribute to improvements in public health by supporting one or more of the aims described in Section 1.1. A surveillance proposal, for example, should include suggestions for the potential usefulness of the data collected. What would not satisfy this requirement is collecting information only out of curiosity, without a link to potential public health benefits.

3.2 Can the objectives be achieved using the proposed methods?

Poorly designed studies can yield poor quality data and may result in invalid conclusions, which could reduce their usefulness or possibly create harm. Scientifically invalid initiatives fail to show concern for welfare because they waste limited resources, can put participants and others at risk while offering limited or no benefit, and delay knowledge generation, thereby depriving a population of potential benefit. Poorly designed initiatives also fail to respect persons, because participation in these initiatives is justified by the expected knowledge benefits. Many approaches and methods are used to conduct public health initiatives, including, but not limited to:

- experimental and observational research designs;
- qualitative, quantitative and mixed method approaches;
- empirical and modelling methods;
- microbiological assays; and/or
- economic analyses.

Reviewer requirements for scientific validity must be realistic and take into account the design limitations that public health initiatives present. Where there is not the opportunity for a methodologically optimal study design, investigators need to articulate the methodological limitations, potential threats to scientific validity, and how they have attempted to address these threats. Where such limits result from careful consideration of ethical issues, reviewers should not necessarily see this as inherently inferior. On the other hand, a project design that is compromised to the point that it presents significant threats to scientific validity should be considered unethical and should not be permitted to proceed as designed.

Privacy considerations require that no more data be collected than required to accomplish the stated purpose and are reflected in legislation and privacy codes. It is recognized that under some circumstances, an argument may be made for collection of more information than is immediately necessary, based on anticipated relevance for future questions. This is particularly relevant when setting up ongoing surveillance systems for which specific future questions cannot necessarily be articulated. In such cases, justification for a broader scope of data collection should be included with the proposal. Scientific need for the information must be balanced against the risks and costs of more extensive data collection.
3.3 Who are the expected beneficiaries of the knowledge gained or other benefits?

Identification of who are the expected beneficiaries of public health initiatives has several purposes: i) to ensure that the study is focusing on a population consistent with the public health objectives of the initiative (Question 1); ii) to inform the consideration of whether risks and potential benefits are balanced (Question 5); and iii) to inform justice considerations (Questions 6 and 9).

Public health initiatives may benefit participants directly, and non-participant members of the same or different populations indirectly. For example, testing of a novel anti-smoking campaign may benefit:

- the target population directly;
- non-participants through decreased exposure to passive smoking; and
- society more generally through knowledge gained.

Expectations regarding who reasonably stands to benefit from a public health study must be clearly articulated.

Consideration of who is the beneficiary of a public health initiative is often framed as a conflict between the interests of a population and the interests of individuals. While such conflicts may at times exist, it is important to recognize the common good as well as the inter-relatedness of individual and community welfare. For example, benefits to a community are also likely to benefit individual members of that community. Alternatively, benefits to a community may also contribute to a common good. Privacy, for example, is often thought of as an individual interest, but can be seen as meeting a broader societal interest because: i) everyone values some degree of privacy; ii) it is essential to a democratic political system; and iii) in contemporary society it is hard for any one person to have privacy without all persons having a similar minimum level of privacy.

3.4 What are the burdens and potential harms associated with the proposed initiative? Who bears them?

While anticipated benefits are the driving force for conducting public health initiatives, the welfare of some individuals or groups may be negatively affected by the activity. “Burdens” refer to various costs or inconveniences, such as demands on time, resulting from participation in an initiative. Burdens associated with participation should be identified and minimized, unless they are clearly trivial. Unnecessarily burdening a participant is disrespectful, and may harm the goals of an initiative by discouraging participation or prompting early withdrawal.

The term “harm” is used here to refer to a broad range of potential adverse occurrences (foreseen and unforeseen) related to involvement in public health initiatives. Public health initiatives may be associated with physical or psychological hazards, but the collection, use and disclosure of information, which is the focus of many public health initiatives, can also cause harm to individuals or communities. These “informational harms” may include:

a) Harms to initiative participants
   The collection or disclosure of information may lead to psychological distress, discrimination, or stigmatization of individuals or communities. For example:

   - Surveys that ask about sensitive issues may cause participants psychological distress.
   - Disclosure of study results may cause an individual or community to suffer psychological distress, damage to reputation, discrimination, stigmatization, or economic loss.
There may also be “dignitary harm”, by failing to show respect for persons (individuals or communities), even where no consequential harm or injury has occurred, such as through privacy breaches or use of information without consent. Because they are abstract, dignitary harms may be difficult to identify, and thus may be overlooked.

b) Harms to trust relationships
Public health initiatives that harm individuals or communities or cause dignitary harm as described above, may also lead to loss of trust in public health service providers, with negative consequences extending beyond the initiative in question.

Where possible, an effort must be made to mitigate or minimize risks and burdens, balancing this against any loss in potential benefit. Appropriate planning is important to managing risks. For example, given the public health purpose of a particular initiative, it may not be possible to avoid asking sensitive questions. However, it may be possible to reduce the risk by:

- collecting the minimum information necessary to achieve the objective of the initiative;
- including a mechanism for referral for counselling if needed;
- collecting non-identifying information or anonymizing the data collected;
- employing appropriate data security measures; and
- publication of findings in a manner that avoids stigmatization of communities.

As with benefits, it is also important to identify who bears the burdens and potential harms associated with evidence generation in public health, in order to consider questions about the distribution and balancing of burdens, risks and benefits. As noted in the discussion for Question 5 below, these may accrue to different individuals or groups. While those participating in an evidence-generating initiative are the most likely to bear the burdens and potential harms, non-participants may also be affected. As noted elsewhere throughout this document, members of a community may be negatively affected by an initiative or the findings generated. In addition, individuals may bear burdens or potential harms as a result of their decision not to participate. The few children who elect not to take part in a classroom survey, for example, may be subject to challenges, ridicule or speculation as to their reasons for non-participation. Consideration of who bears the burdens and potential harm must take into account the differing contexts of those affected and a customized approach to addressing any negative impact may be required.

3.5 Are burdens and potential harms justified in light of the potential benefits to participants and/or to society?

Once potential harms are managed either by eliminating or mitigating them, there remains a question as to whether the potential benefits of the initiative are sufficient to justify remaining burdens and risk. Although there is widespread agreement that the benefits must be proportionate to or outweigh the burdens and risks, as Kass notes “disagreements are all but guaranteed over the details.” Disagreements may occur at several points, including: i) assessment of how burdensome or risky an initiative is, ii) how beneficial the initiative may be, and iii) whether the positive effects outweigh the negative. Although there is no formula to resolve these inevitable differences, a system of “fair procedures” can guide their resolution. Procedural approaches that can be used to promote fairness include transparency, and participation of stakeholders in decision-making. Simply going with the majority opinion is not appropriate, however, and caution must be taken to ensure adequate representation of the views of the minority.

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iv There are different uses of the term “harm” in the literature. Some use it to refer specifically to those things that impact negatively on the set of human interests. Others expand the category of harm to include other kinds of wrongs, including rights violations. The former position does not dismiss other kinds of wrongs as being morally unimportant but suggests it is incorrect to label them as harms.
Public health is built on a foundation of positive action to promote health, prevent harm, and to reduce health inequities. Recognition of these positive goals suggests that inaction, such as not evaluating a program or not conducting surveillance may be regarded as harmful, and so the burdens and potential harms of an initiative should be weighed against not only the added benefits, but also the harm of doing nothing.\textsuperscript{26}

In some cases a public health initiative may offer important potential benefits to a particular group, but the potential harms are borne by another group, further complicating the weighing of these consequences. For example, studies are ongoing to assess whether aggressive early treatment of HIV-positive individuals, before the appearance of symptoms, can reduce the spread of the virus. Early results suggest reduced spread, benefitting the uninfected, but it is not clear whether such early treatment will be beneficial or harmful to those receiving the anti-viral treatment.\textsuperscript{27} Where competing interests must be balanced, the principle of proportionality may be helpful in deciding on the appropriate course of action. Proportionality refers to the requirement that an activity that infringes on the interests of individuals or communities must be sufficiently important to warrant the infringement, and incorporate means that are reasonable and justifiable to meet the circumstance. It must infringe on the interests of others only as much as necessary.

\subsection*{3.6 Is selection of participants fair and appropriate?}

Concern for justice calls for a fair distribution of the potential harms and benefits among participants in a public health project. Participant selection should be guided first by the goals of the initiative, and not by convenience, or other factors not related to the study question.\textsuperscript{24} Appropriate selection should also be driven by prior evidence about harms and benefits to subgroups.

Within the potential pool of scientifically appropriate participants, consideration should also be given to minimization of risk and maximization of benefit. This may mean avoiding inclusion of vulnerable or deprived individuals or populations, if they are at greater risk of study-related harm relative to other potential participants. Similarly, if certain vulnerable or deprived individuals or populations are more likely to benefit from participation, they might be given priority for inclusion in a study.\textsuperscript{24}

It has been noted that evaluations of public health programs often explicitly select for communities or groups that are the most motivated, organized, and ready for change.\textsuperscript{28} Selecting participants based on such criteria may generate results that lack external validity, as these highly motivated settings may not be representative of the majority of settings to which the results will be applied. In addition, as the more difficult to reach groups may be those that are most disadvantaged or marginalized, selection of the “easiest” participants may exacerbate existing inequities.\textsuperscript{28}

\subsection*{3.7 Is individual informed consent warranted? Is it feasible? Is it appropriate? Is it sufficient?}

Respect for persons means that, where appropriate, individuals (or their authorized representatives in case of incapacity)\textsuperscript{7} are given the opportunity to make informed choices about participation in public health initiatives. The traditional default action in the context of formal research is to require individual consent from all participants, with exemption from this requirement if certain criteria are met:

- the research involves no more than minimal risk to the participants;
- the lack of the participant’s consent is unlikely to adversely affect the welfare of the participant;

\textsuperscript{7} For the remainder of this document, reference to “individual consent” includes consent by a legally authorized third party where appropriate.
• it is impossible or impracticable to carry out the research and to answer the research question properly, given the research design, if the prior consent of the participant is required;
• whenever possible and appropriate, after participation, or at a later time during the study, participants will be debriefed and provided with additional pertinent information in accordance with TCPS 2 Articles 3.2 and 3.4, at which point they will have the opportunity to refuse consent in accordance with Article 3.1; and
• the research does not involve a therapeutic intervention, or other clinical or diagnostic interventions. (Article 3.7).5

In making a judgment about practicability, the cost of obtaining consent and its impact on scientific validity must be taken into consideration. Further discussion of when it may be impracticable or inappropriate to obtain individual consent may be found in the CIHR’s Best Practices for Protecting Privacy in Health Research.29

While individual autonomy ought, in general, to be respected, framing the question in terms of whether consent is warranted allows for the possibility that consent is not always called for, and may not be the most ethical approach. Within public health, data collection (e.g. for certain communicable diseases) may be mandated by law. Similarly, in the event of an emergency, the Chief Medical Officer of Health may request that necessary data be collected to manage the emergency. In these cases, consent is not warranted.

For some routine surveillance activities, informed consent for the indirect collection of information for public health studies is not required. On the other hand, for non-routine surveillance activities or when collecting information directly from individuals, consent may be required because the purpose of information collection has moved beyond the initial public health service purpose. In other cases, notification of the opportunity to opt out may be warranted.

Informed consent may also be inappropriate when it creates additional privacy risk for participants. For example, requiring individual consent may create a privacy threat by requiring that “otherwise useable coded data” be linked with identifiers so that individuals can be contacted for their consent.29(p 40) In some circumstances, it is the documentation of consent that creates a problem, such as when collecting data about illegal activities. In such cases other approaches, such as forgoing signatures and the use of code names to allow participants to remain anonymous, may be required.30,31

Where a departure from individual initiative-specific consent is proposed, alternatives include:

• carrying out the study with no notification or consent;
• notification of the participants or community with no opportunity to opt out;
• notification with opportunity for individuals to opt out; or
• broad opting into a range of studies, possibly with restrictions.

Justification should be provided for the approach chosen.

Whatever the approach, plans must be described to promote a process that will reasonably accomplish its purpose. Consent processes need to be free and informed. Notices must be made in a way that ensures a reasonable probability that they reach and are understood by the intended audiences. Where individual consent is not practicable, investigators would be wise to consult with relevant representatives of the community or affected parties. Even where individual informed consent will be obtained, it may not be sufficient, and additional consultation with relevant communities may be warranted, as discussed below.
3.8 Is community engagement warranted? Is it feasible? What level of engagement is appropriate?

Community engagement may be used in lieu of, or in addition to individual consent, depending on the circumstances, and like informed consent, is based on the principle of respect for persons. Community engagement can also promote welfare, by giving communities the opportunity to identify potential benefits and risks of proposed initiatives, and providing insight into how community welfare might best be defined.

A community can be defined as “a collectivity with shared identity or interests, which has the capacity to act or express itself as a collective”. Community engagement can also promote welfare, by giving communities the opportunity to identify potential benefits and risks of proposed initiatives, and providing insight into how community welfare might best be defined.

In general, these range from notifying and informing, to greater involvement through consultation, consent or consensus, collaboration and empowerment.

Community “consent or consensus” is used here to refer to some type of authorization or agreement to participate, given by a subset of individuals on behalf of a community. As Gostin notes, “Clearly, community leaders cannot realistically give consent on behalf of the population, for they have no way of knowing what decision each person would make” and suggests the term “community consensus” is more appropriate. Higher levels of engagement allow communities to play a more active role—not only authorizing planned initiatives, but identifying public health priorities and defining objectives, planning, implementation, analysis and publication of results.

Communities may be defined by many different factors including geography, and biological or social relatedness, although in many instances identifying what constitutes a discrete community remains a challenge. Communities with an interest are those that “may benefit from, be harmed by or otherwise affected by” a study.

There is no simple answer to the question of when community engagement is warranted, or what the appropriate level of engagement is. Since communities vary in social cohesiveness, the challenge frequently is in identifying: i) when it may be appropriate to engage with local communities; ii) who are the appropriate representatives of the community; and iii) the appropriate level of engagement of the community (e.g. consultation vs. collaboration). In the interests of respect for persons and transparency, at a minimum, notification or informing should be considered wherever a community is identifiable that has an interest in a study.

Factors which may warrant greater engagement with a community include:

- the nature and probability of harms to the community (i.e. all other things being equal, greater risks may increase the required level of engagement);
- any norms or traditions that should be respected;
- past experience of the community that may require specific attention; and
- the social structure of the community, such as whether it is well-defined with clear leaders or other governance structures.

Other factors, such as geographic localization, common economy/shared resources, a communication network and a health-related common culture may also facilitate, and therefore create an obligation to consider, community involvement in decision making. Attention should also be paid to how communities will be approached (e.g. respecting their own values, cultural protocols within the community). Determining what approaches are most appropriate may require preliminary consultations with a few community members, or others who have experience working with a particular community.
3.9 What are the social justice implications of this initiative?

Question 6 considers fairness and equity in terms of the benefits or burdens associated with public health initiatives. Social justice pushes us to go further, however, and consider the positive obligation to intervene where injustice or inequity exist. Initiatives that reinforce existing inequities should be avoided and opportunities to promote social justice should be considered where possible. Populations may be disadvantaged socially, economically, in terms of access to public health services, or in terms of health outcomes.

Social justice should be considered at multiple stages in a public health initiative. For example, at the point of developing objectives, one should consider how the expected knowledge generated might promote health equity and which outcomes are particularly relevant to disadvantaged or vulnerable groups. Community consultation may play an important role in helping develop relevant objectives, although special efforts may be needed to ensure that the perspectives of disadvantaged or disenfranchised groups or individuals are represented.

Similarly, plans for data collection should include mechanisms to ensure adequate representation of disadvantaged groups. Extra resources or special measures may need to be devoted, for example, to ensure inclusion of populations who don’t routinely seek health or social services, and who therefore might be missed if recruitment or data collection strategies are linked to service providers.

Providing it is scientifically appropriate, disadvantaged individuals or populations may be given priority for inclusion in an initiative, if such inclusion has the potential to improve their health status. This is justifiable in the context of an intervention that is known to have equal or greater effect among those who are disadvantaged, or initiatives where data collected (e.g. surveillance data) might be of immediate use to a disadvantaged population. Inclusion motivated by social justice would not be appropriate, however, for initiatives developed to evaluate the effectiveness of an unproven intervention. Prioritization of disadvantaged groups should also extend to the development of strategies for knowledge translation after a study is complete, to increase the potential for those with the greatest need to benefit from the knowledge generated.

3.10 What are the potential longer-term consequences?

This question is asked explicitly as there is a tendency to focus on the impact of activities directly related to the evidence-generating initiative itself and not so much on the use of the evidence to alter policy and practice. Potential beneficial long-term consequences are usually given consideration in the early stages of the development of an initiative, as these potential benefits are the rationale for undertaking the evidence-generating activity in the first place. The discussion here will focus on the potential harmful longer-term consequences of evidence generating public health initiatives.

Negative consequences may arise as an unintended result of initiatives. For example, property values may drop following findings of environmental toxins in a neighbourhood, or a program may be cut when the results of a formative evaluation are used not to improve it, but as justification for eliminating it. As with more immediate risks, where harms can be anticipated, attempts must be made to mitigate or minimize them, and a judgment must be made as to whether the potential benefits of carrying out the initiative are sufficient to justify the potential longer-term harms. Careful attention to how and when findings are released may help reduce a potentially negative impact.

Community engagement can be helpful both in identifying potential longer-term harms, and in devising methods to address them. For example, a study may discover that there has been a problem in a particular community with retaining primary care physicians. Immediate publication of these findings in a scientific journal runs the risk of discouraging new physicians from setting up practice in that region. If, instead, one were to delay release of this information and work with the community to identify and address the root
causes of the problem, then the delayed publication may be able to identify both the initial problem and the solution introduced, thereby reducing the potential harm.

In an extreme case, results may be suppressed indefinitely to avoid serious long-term harms. The U.S. government, for example, has asked scientific journals not to publish details of studies showing how bird flu viruses could be modified so that they could easily be transmitted between humans, out of concern that this information could be used for bioterrorism.\(^3\) This approach is controversial, however, and has generated calls for less extreme measures for managing the information risk, so that the potential public health benefits of the research are not lost.\(^3\)

It is generally accepted that investigators have some ethical obligation to address short term harms occurring as a direct result of an initiative. However, the degree to which ethical obligations extend beyond the conclusion of an initiative is a matter that requires further consideration, both for anticipated and unanticipated consequences. For example:

- How far into the future should one project when assessing the consequences of an initiative?
- What resources, if any should be put into monitoring the longer-term consequences of an initiative? The further into the future one projects, the more speculative the consequences generally become. How should these more speculative consequences be weighed against more immediate competing risks or potential benefits?
- What is considered sufficient effort at risk-mitigation?
- What is sufficient compensation for long-term harms? Who bears the responsibility for these long-term harms? Resources for carrying out an initiative do not usually extend beyond the reporting of results. In addition, individual investigators may not have the power to address many types of harms such as the use of findings to develop policy in an unanticipated way.
- Who would represent the interests of those who are harmed in the long term as a result of an initiative, or are existing mechanisms sufficient?
- To what extent should these potential long-term consequences be raised during the informed consent process?

Much empirical and conceptual work must be done to address the above questions.

### 3.11 Framework summary

This framework portrays a web of responsibilities and relationships between the investigator and those whom he/she is studying. Not all of these concerns will be relevant to every situation. Conflicts occur and one principle or concern may need to be promoted over another on a particular occasion. For example, in the context of an infectious disease outbreak, a temporary compromise in autonomy, such as collecting certain health data without individual consent, might be acceptable in light of a significant concern for welfare to participants and the broader community. Such a decision might not be acceptable in the case of a similar study on a chronic disease, where the same urgency is lacking.

There are no simple rules regarding how to balance principles when they conflict with one another in a specific circumstance. No one principle has any predetermined value over any others, and judgment is required in making a decision about what ought to happen in response to individual circumstances.

*Ethical principles, like other practical principles, state abstract requirements…we cannot expect any practical principles—whether ethical or legal, social or technical—to provide a life algorithm…but the fact that principles always underdetermine action means only that they must always be complemented and implemented by the exercise of judgment.*\(^4\)
4.0 Conclusion

The purpose of this framework is to consider how a public health lens might be applied to the ethical examination of public health initiatives. It is not meant to be an exhaustive list of issues to consider, but to provide a starting point for ethical reflection. This framework can be used by those developing a new public health initiative, to guide the design, implementation and dissemination of results, by those responsible for determining the ethical acceptability of an initiative, and as a guide in the development of policies and procedures aimed at ensuring the ethical conduct of evidence generation in public health. It is hoped that this document will be useful in providing guidance in its current form, but also in stimulating further discussion and work in the area of public health ethics, both for evidence generating initiatives and public health more generally.
References


