

# A Survey of Research Ethics Practices in Ontario Public Health Units

Prepared on behalf of the Provincial  
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(PHRED) Program

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## A Survey of Research Ethics Practices in Ontario Public Health Units

### Executive Summary

#### Purpose

The TriCouncil provides guidelines for ethics review, yet these guidelines may be unknown or not used in public health research and evaluation. This survey of provincial health units was conducted as part of an initiative of the Public Health Research Education and Development (PHRED) Program. The focus of this survey was to determine the need for a Public Health Research Ethics Toolkit and identify specific areas of needs related to the ethical review of research proposals.

#### Methods

A contact was made in each of the 36 health units; 35 health units agreed to participate. The survey was conducted by telephone and audio taped. Descriptive statistics were used in the quantitative analysis.

#### Results

- Health units differed in their definitions of research and the processes used for ethics review; only 43% had a documented definition of research
- Almost all health units conducted satisfaction surveys and internal program evaluations; 86% reported conduct of externally funded research proposals.
- Health units varied in the extent to which they conduct research; although 96% reported conducting research
- Health units varied in the extent to which they have formalized their practices for ethical review; 30 (86%) had criteria of which 25 (83%) had it in writing and 22 (73%) set in policy
- 31 (89%) reported having a process to determine if a project must go for ethics review
- PHUs 17 (49%) health units had an internal review process; 7 (20%) had external review, 7 (20%) had both internal and external process, and 4 had no process
- 12 (34%) health units indicated that their ethics review process conforms to the Tri-Council Policy Statement, 12 (34%) did not conform and 11 (31%) did not know
- Some respondents had not heard of the TriCouncil Statement on Ethics Review
- 27 (77%) agreed that a centrally developed Research Ethics Toolkit would be useful

### **There were three key areas of strength in this survey:**

- the very high response rate
- accurate recording of responses through the use of audio tapes, and
- verification of the results by providing respondents with the opportunity to check their responses.

### **Recommendations**

1. An Ethics Review Toolkit would be useful for all health units in Ontario, and should include:

- i. Definitions of research and program evaluation
- ii. Relevant excerpts from PHIPA Legislation
- iii. The TriCouncil Statement Policy Statement, emphasizing:
  - A clearly articulated process for ethics review
  - An outline of who should be on the ethics review committee
  - A list of recommendations for ethics review committee member preparation e.g. research background, PRE tutorial certificate
- iv. Criteria for deciding what needs to go for ethics review with examples
- v. Recommendations for dedicated ethics review committee staff
- vi. Pros and cons of using internal and/or external committees
- vii. Sample documents and /or strategies for the recruitment, professional development and retention of ethics review committee members

2. The need for dedicated resources and expertise in ethics review is such an important issue for health units it is recommended that ethics review should be dealt with at a provincial level.

## A Survey of Research Ethics Practices in Ontario Public Health Units

### Introduction

*Public health research provides the foundation upon which evidence-based practice can be built...Health units should develop, enhance and strengthen in-house capacity and resources for research and knowledge-exchange in order to support evidence-based practice and decision-making*

(Capacity Review Committee, May 2006 pages 43,47).

This provincial health unit research ethics survey was conducted as part of an initiative of the Public Health Research Education and Development (PHRED) Program to provide inquiry into the needs of Ontario public health unit's (PHU's) for information related to the ethical review of research proposals. The Tri-Council provides guidelines for ethics review, yet there was concern that these guidelines were unknown or not used in public health research (Canadian Institutes of Health Research, Natural Sciences and Engineering Research Council of Canada, Social Sciences and Humanities Research Council of Canada, 1998). PHRED contributes to health promotion, health protection and the prevention of health problems among the residents of Ontario by facilitating the integration of research, education, policy and public health practice through a range of strategic initiatives. One of these initiatives is to develop a Public Health Research Ethics Toolkit as an electronic resource to all PHU's in Ontario.

For several years, some of the PHRED PHU's have been repeatedly approached by PHU's, academia and local health care institutions across Ontario to provide guidance with respect to research ethics. Questions from the field have been broad, specific and plentiful – all attesting to the PHRED program that there is a need to be addressed. Below is a sample of questions generated from the field?

*Can we have a copy of your Research Ethics Review Policy and Procedures?  
What should undergo research ethics review?  
If our health unit is just a recruiter for subjects for a university study, do we need REB review?  
How long should we keep raw data generated from research?  
What about doing research with First Nations communities?  
Can we just use your Research Review Committee rather than set up our own in-house committee?  
Does the province have a system in place to do research ethics for all health units?  
What exactly is the Tri-Council Policy Statement – does it cover health units?  
What about the privacy legislation?*

*What do we do with electronic data and electronic research documents and final fate?*

*What form of consultation and ethical review should take place when partnering with First Nations communities?*

Further, inconsistencies in the ethical review process undertaken by PHU's might pose a potential agency liability.

Building on earlier successful deliverables such as the Program Evaluation Toolkit and the Benchmarking Toolkit, the provincial PHRED program began to address this need for guidance. In 2005 a provincial Public Health Research Ethics Working Group was established, with an external advisory committee composed of Research Ethics Board Chairs, academics and privacy officers to work on a Public Health Research Ethics Toolkit. A comprehensive literature review, supplemented with key informant interviews, was conducted to assess research ethics resources and their applicability to public health practice in Ontario. An essential next step was to conduct a scan of all PHU's in Ontario to determine current practices with respect to research ethics and to determine their future needs in this area.

This report presents the results of the environmental scan, with participation from 35 of the 36 Ontario PHU's.

### **Research Ethics Toolkit Working Group (Working Group)**

A Working Group, consisting of individuals' from PHRED and non-PHRED PHU's who had an interest in contributing to the creation of a Research Ethics Toolkit, conducted this study. Members have met regularly since 2005 by teleconference, and consulted on all aspects of data collection, analysis and reporting.

### **Methods**

The Working Group considered paper and electronic questionnaires and telephone interviews as potential data collection tools to gather information about the processes for ethical review in place in Ontario PHU's. A telephone survey was selected to maximize response rate. In addition, it was expected that there would be a wide range of ethics review processes in place; the telephone interview provides a good opportunity for a full description of the process and for the clarification of responses.

### **Development of the Interview**

The Working Group in the spring of 2006 drafted the survey. Revision and refinement was done by a smaller working group of three members. The survey was reviewed and approved by the Working Group before pilot testing, which began in early July 2006.

The survey intended to scan Ontario PHUs' current practice; identify gaps and future resource and educational needs related to research ethics. The following topics were included:

#### Definition of Research

Types of research and evaluation activities conducted by the health unit

A description of the health units ethics review process

Degree of compliance with the Tri-Council Policy Statement

The absence or presence of an ethics review committee

The absence or presence of formal documentation to guide the ethics review process

The absence or presence of process for determining need for ethical review

Number of proposals reviewed annually

Degree of satisfaction with current ethics review process

Practices around dissemination of research results

Known sources of support when dealing with difficult ethics questions

The absence or presence of a privacy officer

The absence or presence of a person to oversee the ethics process

Willingness to share the health unit's current resources related to ethics review

Degree of interest in PHRED research ethics initiative

The interviewer's version of the questionnaire contained additional instructions to provide the rationale for questions, and to ensure that all needed information was gathered and that skip patterns were clear. A copy of the interview with the interviewer instructions is attached as Appendix A.

#### **Pilot Testing of the Interview**

The Working Group agreed that the survey was complex and reliance on closed-ended questions would result in the loss of information. Audio recording of responses was therefore instituted to reduce transcription error, and comments were encouraged.

The interview was pilot tested with 5 participants and found to require 20 to 30 minutes to complete. Some changes were recommended as a result of the pilot study. Some questions were re-ordered and others refined for clarity. Response options were added or amended as needed. A question was added concerning the privacy officer and how this position relates to research ethics.

#### **Data Collection**

In 2005 each PHU was telephoned to obtain the name and contact information of an individual likely to be knowledgeable about research ethics. These contacts were verified just prior to the commencement of the survey.

Interviews took place in the summer of 2006. A copy of the interview questions with a covering letter was sent out electronically to each potential participant one week in advance of a telephone contact (Appendix B). The electronic copy of the questions gave the participant a chance to look them over and gather additional information if required.

The research assistant telephoned a week later to set up an appointment for the interview. The interview was conducted by telephone; with the consent of the respondent. Interviews were conducted in English and all responses were recorded.

Following transcription, completed surveys were returned to all respondents to verify the information for accuracy. Respondents were invited to make corrections where necessary.

## **Data Analysis**

### *Responses to Closed Ended Questions*

Closed ended questions were coded and entered into the computer using the Statistical Package for Social Sciences (SPSS V 13.0). Descriptive statistics were used.

### *Responses to Open Ended Questions*

Comments were pasted into word files for each question or sub question. Each comment was then colour coded for themes, allowing main themes to emerge. These themes were identified on a summary document. The questions were divided between two members of the working group, who reviewed each other's coding. A third member of the group reviewed the findings and identified key items, which expanded the quantitative results and provided depth to the discussion.

## **Confidentiality**

All information was considered confidential and was analysed and reported without identifiers. Tapes were kept to allow responses to be verified but will be destroyed following the acceptance of the draft report by the PHRED Operations Committee. Completed questionnaires will be kept for one year following dissemination of the report, and then will be destroyed.

## **Results**

### *Response Rate*

Responses were obtained from 35 of the 36 Ontario Health Units (97%).

### *Scope of Research Conducted in Ontario Health Units*

Of 35 responding health units, 15 (43%) have a documented definition of research, and three additional health units (9%) have a definition, which is not documented. The remaining 17 health units do not have or did not provide a definition of research.

Definitions of research used by health units often included the systematic collection of data for the purpose of generating new knowledge or further development of knowledge. Respondents reported often struggling with the difference between program evaluation and research. Some definitions of research mentioned specific study populations including the community, program respondents, and/or public health professionals.

All but one of the health units (n=34 (97%)) reported conducting research, although the one in which research is not conducted reported that satisfaction surveys are carried out.

Almost all health units conducted satisfaction surveys and internal program evaluations, and a large proportion (86%) reported externally funded research projects. *Table 1* presents the types of research reported in participating health units.

**Table 1: Types of research conducted in Ontario Health Units**

<b>Types of Research (n=35)</b>	<b>n (%)</b>
Satisfaction surveys	34 (97)
Internal program evaluations	33(94)
Externally funded research projects	30 (86)
Internally funded research projects	27 (77)
CQI or quality assurance projects	25 (71)
Other: Collaborative research	2 (6)

All 35 health units disseminated research results internally, and 33 (94%) disseminated results externally as well. *Table 2* presents the methods used in the dissemination of results.

**Table 2: Methods used for the dissemination of research results in Ontario Health Units**

<b>Methods of Dissemination (n=35)</b>	<b>n (%)</b>
Reports	34 (97)
Presentations, posters	32 (91)
Publications	29 (83)
News releases	26 (74)
Internet postings	26 (74)
Other: Dissemination by research partner	2 (6)

Thirty-one of the 35 respondents (89%) report that there is a process for ethical review in their health unit. In 17 (49% of all health units), only an internal process exists, in 7 (20%) only an external process exists, and in 7 (20%) there are both internal and external processes. Twelve health units indicated that their ethics review process conforms to the Tri-Council Policy Statement, while 12 did not conform; 11 respondents either did not know or indicated that the question was not applicable.

Twenty-one (60%) respondents were aware of who their privacy officer or designated trained privacy person was, some suggested that this person had no relation to the ethics review process. Five (14%) did not have a privacy officer, one of whom questioned whether health units required a privacy officer. Two (6%) were unsure if there was a relationship or the link to research ethics. Three (9%) commented:

*Not aware of that position, but that doesn't mean it's not around  
Check with legal services if we have questions, not sure about privacy officer role  
I was aware that there was a link but I do not know what that is, how that is meant to function.*

Two (6%) respondents used the privacy officer for the region or city and two (6%) did not respond.

Of the 35 health units, 30 (86%) have criteria to determine if a project must go for ethical review. In *Table 3*, the existence of criteria for deciding what must go for review, is cross tabulated by the ethic review process. All health units with an internal process of ethical review have criteria to determine what should go for ethical review. Two health units with only an external process do not have such criteria to determine eligibility. Size of health unit and skill of staff members were identified as reasons for the lack of criteria for deciding what projects require ethical review.

**Table 3: Existence of criteria for deciding what must go for review, by ethical review process**

<b>Ethical Review Process in Place in the Health Unit (n=35)</b>	<b>Criteria</b>	<b>No Criteria</b>
	<b>n (total %)</b>	<b>n (total %)</b>
Internal process only for ethical review	17 (49)	--
External process only for ethical review	5 (14)	2 (6)
Both internal and external processes for ethical review	7 (20)	--
No process for ethical review	1 (3)	3 (9)
<b>TOTAL</b>	<b>30</b>	<b>5</b>

Of the 30 health units with criteria for ethical review, criteria are written in 25 (83%) and set in policy in 22 (73%). *Table 4* describes how criteria are documented, according to the process of ethical review in place. Each column entry of *Table 4* presents the number of health units eligible for the next column.

**Table 4: Documentation of criteria for deciding what must go for review, by ethical review process**

<b>Ethical Review Process in Place (n=35)</b>	<b>Have Criteria<sup>1</sup> n (row%)</b>	<b>Criteria are written<sup>2</sup> n (row %)</b>	<b>Criteria are set in policy<sup>3</sup> n ( row%)</b>
Internal process only (n=17)	17 (100)	15 (88)	13 (76)
External process only (n=7)	5 (71)	4 (57)	4 (57)
Both internal and external processes (n=7)	7 (100)	5 (71)	5 (71)
No process (n=4)	1 (25)	1 (25)	0 --
<b>TOTAL</b>	<b>30</b>	<b>25</b>	<b>22</b>

<sup>1</sup> Of health units reporting each process

<sup>2</sup> Of health units with criteria

<sup>3</sup> Of health units with written criteria

The existence of written criteria or criteria set in policy was unrelated to the nature (internal/external) of the ethical review process. It was interesting that one of the health units without a process has written criteria as to what should go for review.

Table 5 presents the ease with which respondents were able to decide what was appropriate for ethical review, according to the degree to which criteria exist or are documented.

**Table 5: Ease of deciding what should go for review, by documentation of criteria for ethical review**

<b>Ease of Deciding What Should Go for Ethical Review (n=35)</b>	<b>Have Criterion (column %)</b>	<b>Criteria are written (column %)</b>	<b>Criteria are set in policy (column %)</b>
Very easy (n = 6)	6 (20)	3 (12)	2 (9)
Fairly easy (n = 17)	17(57)	16 (64)	15 (68)
Fairly difficult (n = 5)	5 (17)	4 (16)	4 (18)
Very difficult (n = 0)	--	--	--
Not applicable (n = 7)	2 (7)	2 (8)	1 (5)
<b>TOTAL</b>	<b>30</b>	<b>25</b>	<b>22</b>

Seventy-five percent of respondents found it very easy or fairly easy to decide what to send for ethical review, regardless of whether the criteria were written or set in policy. Written criteria appeared to focus on the appropriate group to conduct the ethical review (internal or external committee) and the type of projects requiring ethical review. The most common criteria for projects requiring ethical review were the use of human subjects. The most common projects not requiring ethical review were standard program evaluations. Distinguishing research from program evaluation, surveillance and routine data collection was an underlying theme in the written criteria for projects requiring ethical review, and the most common challenge in deciding what projects go for ethical review.

Table 6 presents the ease of deciding what should go for ethical review, cross tabulated by the ethical review process.

**Table 6: Ease of deciding what must go for review, by ethical review process**

Ease of Deciding What Should Go for Ethical Review  (n=35)	Ethical Review Process in Place in the Health Unit			
	Internal Only n (column %)	External Only n (column %)	Both Internal and External n (column %)	No Process
Very easy (n = 6)	4 (24)	1 (14)	1 (14)	0
Fairly easy (n = 17)	10 (59)	4 (57)	3 (43)	0
Fairly difficult (n = 5)	2 (12)	0 --	3 (43)	0
Very difficult (n = 0)				
Not applicable (n = 7)	1 (6)	2 (29)	0	4 (100)
TOTAL	17	7	7	4

An internal process for ethical review appeared to make it more difficult for staff to determine what should go for ethical review, although the numbers are very small. Where only an external process was available, respondents felt it was very easy or fairly easy to decide what should go for review.

In Table 6, seven respondents did not assess the ease of deciding what should go for ethical review. No research is done in one of these health units, and three others have no process for ethical review, even though respondents indicated that research is done. Two have an external process for ethical review, but no criteria for assessing what should go for review. The last non-respondent to this question indicated that the MOH and senior epidemiologist would review proposals for scientific merit and ethical considerations; although a policy is in place, it is not followed because no committee exists.

The likelihood of a proposal being sent for review varied with the type of research activity. Some respondents indicated that projects seen as usual or routine public health practice such as satisfaction surveys, program evaluations or CQI projects did not require ethical review. Projects involving external organizations as funders, research partners or users of the results were more likely to go through an ethics review process.

*...Any project... deemed to be program evaluation, (doesn't) need ethics review.*

*No (ethics review not required), because we see it as usual public health practices.*

For these types of projects, a few respondents also indicated that limited resources influenced whether or not an ethical review was conducted.

*If everything had to go through an ethical (review) process, no research would get off the ground; (we have) limited resources.*

For some health units, the decision to request ethical review was influenced less by the type of project than by its purpose and the sampling and data collection procedures involved.

The ethical review is not attached to the type of research project, but to how information is collected and whether privacy and other issues are respected.

*Depends on nature of the evaluation, if it is something that is more intrusive then it could (go for ethical review).*

*Our policy states that any systematic investigation to establish facts, principles, or general knowledge involving humans is to go through this ethical review process.*

Respondents also indicated that projects going through an ethical review process were reviewed by a variety of health unit staff members such as management teams, epidemiologists, planning and evaluation staff including program evaluators and information analysts, evaluation and research committees and privacy and policy officers. These reviews appeared to assess multiple dimensions including scientific merit, burden on staff and ethical issues. However, the extent to which these reviews consistently took ethical concerns into account was unclear.

Table 7 presents the degree to which meetings to perform ethical review are formalized, by the ethical review process.

**Table 7: Formalization of meetings, by ethical review process**

Ethical Review Process in Place in the Health Unit (n=35)	Regular Meetings n (row%)		Meets when proposal is ready n (% of those without regular meetings)
	Yes	No	
Internal process only for ethical review (n=17)*	3 (19)	13 (81)	11 (85)
External process only for ethical review (n=7)*	4 (80)	1 (20)	1 (100)
Both internal and external processes for ethical review (n=7)	3 (43)	4 (57)	3 (75)
No process for ethical review (n=4)*	0	2 (100)	1 (50)
TOTAL	10	20	

\* Some responses are missing from the cross tabulation. Percentage calculations exclude missing.

The majority of health units conducted the ethical review of an individual project in less than 4 weeks. A few health units could take as long as 10 weeks for ethics review. The majority of health units 27 (77%) provided an estimate of how many proposals reviewed per year two reviewed none and 21 (78%) indicated they reviewed less than 15 proposals per year and 9 (33%) of these reviewed 5 or less.

It was reported that internal ethical reviews were conducted by the manager of the epidemiology program or team (10), epidemiologist (9), researcher (3), PHRED director (2), or another staff member, such as the director or chair of the research advisory or program leadership committee (4). There were eight non-respondents.

It is clear from comments made by respondents that a clearly articulated process is important in helping staff to know what proposals need to go for review and how to go about obtaining a review. This theme is evident in their comments about what was working well, what was missing, and what improvements they felt could be made.

When asked what was working well, 18 (51%) identified concrete components, in the form of a process, criteria, checklist or guideline. Two (6%) felt the local university provided them with the process they needed. Eight (23%) were unable to say what worked

well, mainly because they lacked experience with the process of ethical review or were revising the policy. Others said that one person did ethical review or they were just piloting their process. One stated that the process was based on the USA Food and Drug Administration Guidelines.

Nineteen (54%) respondents did not identify anything missing from the ethical review process in their health units. However, 7 (20%) thought that there was a lack of process, of criteria or have expertise to conduct these reviews, or were unsure if they were doing the right thing. Two felt the process could be better or were looking to improve it, three expected the process to work well, one had a good working relationship with a local PHRED (although not a formal process), and one respondent was unsure.

Comments about improvements to the process were consistent with the comments about what was working well; 16 (46%) felt there could be improvements to criteria, policy, guidelines, structure, procedures, terms of reference or checklists. They felt that “grey areas” should be addressed to determine what needs review. Six (17%) identified unspecified needs for improvement; 2 (6%) wanted more personnel and 2 (6%) suggested diverse activities including involvement with more external partners.

Table 8 presents the number of health units with a person dedicated to the ethical review process, by the process in place (internal/external). In nine (29%) of 31 health units with an ethical review process, there is a position dedicated to coordinating ethical reviews. This table also shows whether they feel the process provides the services they need.

**Table 8: Presence of a dedicated position for ethical review, by ethical review process**

Ethical Review Process in Place in the Health Unit*	Dedicated position		Provides the services needed	
	n (row %)		(n (row %))	
	Yes	No	Yes	No
Internal process only for ethical review (n=17)*	5 (29)	12 (71)	15 (94)	1 (6)
External process only for ethical review (n=7)*	2 (33)	4 (67)	5 (100)	0
Both internal and external processes for ethical review (n=7)*	2 (29)	5 (71)	3 (50)	3 (50)
No process for ethical review (n=4)*	0	2 (100)	0	1 (100)

\* Some responses are missing from the cross tabulation. Percentage calculations exclude missing.

Twenty-three respondents (74%) felt that the process in place provides the services that are needed.

Satisfaction with the ethical review process in place is presented in *Table 9*.

**Table 9: Satisfaction with the ethical review process, by process**

<b>Ethical Review Process in Place in the Health Unit</b>	<b>Satisfaction with the ethic review process</b>				
	<b>(n (row %))</b>				
	<b>Very Satisfied</b>	<b>Quite Satisfied</b>	<b>Quite Unsatisfied</b>	<b>Very Unsatisfied</b>	<b>Other</b>
Internal process only (n=17)	3 (18)	9 (53)	1 (6)	1 (6)	3 (18)
External process only (n=7)*	2 (33)	2 (33)	1 (17)	0 (--)	1 (17)
Both internal and external processes (n=7)*	2 (33)	0	2 (33)	0	2 (33)
No process (n=4)*	0	0	1 (100)	0	0

\*Some responses are missing in the cross tabulation. Percentage calculations exclude missing.

Seven respondents (23%) reported that they are very satisfied with the process of ethical review, while 11 (35%) are quite satisfied and 5 (16%) are dissatisfied (*Table 9*). There was a broad range of qualitative comments from 13 (37%) respondents that indicated they were not entirely satisfied with their process.

Table 10 presents who or where respondents go to when they have a complex research ethics question.

**Table 10: Resources used for complex research ethics questions**

	<b>Resource for complex research ethics question (n=35)</b>	<b>N</b>
1	University	10
2	Other health units, PHRED	7
3	Individual within their own health unit (MOH; Senior Management, Chief Operating Officer, privacy commissioner, colleagues)	7
4	Association of Public Health Epidemiologists in Ontario (through the listserve)	5
5	Research Ethics Board	8
6	TCPS (Tri-Council Policy Statement)	3
7	Other (Internet, Center for Excellence in Ethics, local PHIPA, provincial agency responsible for program, researchers, consultant)	5
8	No response	6
9	Don't have anywhere to go	1

30 participants responded, some respondents provided multiple answers

Of the 30 participants who responded in Table 10, 10 (33%) respondent's provided multiple answers

Twenty-one (60%) respondents were able to identify their privacy officer or designated trained privacy person. Some suggested that this person was unrelated to the ethics review process. Five respondents indicated that their PHU (14%) did not have a privacy officer, one of whom questioned whether health units are required to have a privacy officer. Two (6%) were unsure if there was a relationship or of the link to research ethics. Three (9%) commented:

*Not aware of that position, but that doesn't mean it's not around*

*Check with legal services if we have questions, not sure about privacy officer role*

*I was aware that there was a link but I do not know what that is, how that is meant to function.*

Two (6%) respondents used the privacy officer for the region or city and two (6%) did not respond.

Twenty-seven (77%) of the respondents indicated that having a Research Ethics Toolkit was important. They said not all health units have the level of expertise or access to the resources necessary for research ethics reviews. Others indicated access to existing reliable resources with which to compare their own documentation would be useful. It was felt that it would be an important resource to have if ever research ethics was included in the accreditation process. The need for dedicated resources and expertise is such an important issue for health units it is recommended that PHU's ethical review should be dealt with at a provincial level.

## **Discussion**

Health unit practices were very heterogeneous with respect to the definition of research, conduct of research and ethical review process. There is considerable variability as to whether they have an internal process, an external process or a combined approach.

While PHU's varied in the extent to which they conduct research almost all health units conducted satisfaction surveys and internal program evaluations. Most PHU's reported having a process to determine if a project must go for ethics review, they varied in the extent to which they have formalized their practices for ethical review.

Decisions for ethical review are sometimes based on the type of project. This then becomes a challenge when health units have to determine whether a proposal is program evaluation or research. Some have based ethical review decisions on issues such as sensitivity of subject matter and how the information is collected. These practices often fall far short of the requirements of the TCPS. This is demonstrated by comments from some respondents that they have not heard of the TCPS.

Survey results demonstrated overwhelming support for a provincial Research Ethics Toolkit that would provide the Tri-Council Policy Statement, define research, provide guidelines for determining which proposals need to undergo ethics review, and guidelines on who should be involved in ethics review. Health units expressed the need for guidance and resources, which could be provided by a Toolkit. There is also a need for health units to examine their policies and procedures and it would be advantageous and efficient if there were a way of coordinating this across the province.

Finally, inconsistencies in the ethical review process undertaken by PHU's might in some instances pose a potential agency liability. This inconsistency in practice may be seen as a detriment for the PHU to identify and be adequately informed about risks during the course of providing consultative and ethical review services. Liability potential could be managed through the standardization of research ethics practice. The research ethics tool kit was seen as one strategy that would benefit public health.

## **Limitations of the Study**

Challenges of this study included the complexity of the topic area, differing levels of understanding of the ethical review process among respondents and the wide range of processes in place in Ontario PHU's. The interaction of these factors contributed to the limitations in adequately describing practices currently in place.

The study team attempted to identify the most knowledgeable contact in each PHU. Responses to the interview were sometimes provided by this person alone and sometimes in consultation with other staff. Although some respondents were very knowledgeable, others had very limited experience with ethical review. "*Lots of questions were difficult.*" was a closing comment of one such respondent. The range in knowledge among respondents was a reflection of the range in practices among the PHU's--from no process at all to one which conforms to the TCPS.

There were often discrepancies and contradictions between the qualitative and quantitative data. The research assistant conducting this survey was relatively inexperienced in research ethics and therefore had difficulty providing definitions or examples for some of the respondents' questions. She was limited, also, in her ability to detect and resolve discrepancies in the data.

In spite of these challenges, this survey has succeeded in describing a wide range of practices and identifying areas in which PHU's need support.

## **Strengths of the Study**

There were three key areas of strength in this survey: the very high response rate, accurate recording of responses through the use of audio tapes, and verification of the results by providing respondents with the opportunity to check their responses.

## **Conclusion**

This survey represents a first attempt to conduct a scan of research ethics practices in Ontario PHU's. It has provided rich data and demonstrates some of the issues that confront health units.

The results have provided support for the need for a resource such as a Research Ethics Toolkit. The Toolkit will involve interpretation of the Tri-Council Policy Statement, and offer samples of approved documentation this will help standardize public health's approach to ethical review.

## **References**

Capacity Review Committee. (2006, May). Final report of the Capacity Review Committee: Revitalizing Ontario's public health capacity. Toronto, ON: Queen's Printer for Ontario.

Canadian Institutes of Health Research, Natural Sciences and Engineering Research Council of Canada, Social Sciences and Humanities Research Council of Canada. **Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans**. 1998 (with 2000, 2002 and 2005 amendments). Last accessed March 2007 from <http://www.pre.ethics.gc.ca/english/policystatement/policystatement.cfm>

## APPENDIX A

### Ontario Public Health Department Research Ethics Survey Interviewers copy

#### *Instructions to the Interviewer*

***When setting up the appointment, you should ask the respondent to assemble any relevant documentation there might be on this topic, for easy reference during the interview.***

***Before beginning the survey explain that you may ask some of the questions out of the order that they received to follow a more logical flow of information however you will cover all of the questions. Remind them that they have the right to stop the survey at any time or not respond to any question they prefer not to.***

***If the respondent wants our address or FAX here it is:***

7 West,  
100 Constellation Crescent,  
Ottawa, Ontario K2G 6J8  
FAX: 613-580-9601

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### Ontario Public Health Department Research Ethics Survey

1. How does your health unit define "research"?

2. Is this definition documented?

\_\_\_ yes:

Where and how is it recorded:  
(ie policy, working document)

Are you willing to send us a copy?

\_\_\_ no

***Question 2:*** This question is to find out whether there is a standard, recorded definition, as opposed to a definition created "on the spot" by the respondent.

3. Does your health unit conduct research?

\_\_\_ yes:

What kinds of research are done in your health unit? (Check as many as apply.)

- satisfaction surveys (*ie workshop evaluation*)
- internal program evaluations
- internally funded research projects (other than program evaluations)
- externally funded research projects
- CQI or QA projects (*continuous quality improvement, quality assurance*)
- other:

Transfer responses to question 3 to column 1 of question 6 to avoid asking again

Are results of this research disseminated internally?

- yes
- no

Are results of this research disseminated externally?

yes: How are results disseminated externally? (Check as many as apply.)

- news releases
- presentations, posters at conferences or meetings
- reports (grey literature)
- internet postings
- publications
- other:

no

**The following appears on the participant survey but don't ask at this point do it under question 4 for table 1.** Does your health unit have an internal ethics committee or REB or access to an external committee or REB or both (**circle appropriate response(s)**)

no:

Why does your health unit not conduct research?

4. Please describe your process for ethical review. (Please ensure that respondent has touched on or been asked about all criteria in Table 1.)

INTERNAL

EXTERNAL

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**Question 4:** We are asking for a full description of the ethical review process. **Use Table 1 as a guide** to ensure that all dimensions are covered. Transfer the response from Question 1 to the top of this table. Ask everyone the first 5 items in Table 1.

If the process involves a REB which conforms to the Tri-Council Policy Statement, you do not have to ask any of the subsequent questions following item 5.

However, if the respondent indicates that proposals are reviewed by a committee but does not know whether the committee conforms to the Tri-Council Policy Statement, or knows that the committee does not conform to the Tri-Council Policy Statement, then subsequent questions must be asked in order to determine what requirements are met. Try to determine if staff members sit on the committee.

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During your discussion, all items on Table 1 should be covered (subject to the comment above). The column on the left should be checked as each item is discussed. If the respondent does not volunteer the information, please ask specifically, checking the column as you do so. The column on the right is to be used to indicate the respondent's answer to the question. Use "Y" for yes, "N" for no and "DK" if the respondents does not know and "C" if there other comments. Record comments verbatim, in the space given for the description in question 4.

The other four questions in the table should be asked to find out if there is any other review (eg. scientific review) of this kind of project.

5. Do you have criteria to determine whether a project must go for ethical review?

\_\_\_ yes:

Are these written criteria? \_\_\_ yes: Are you willing to send us a copy?

\_\_\_ no: Please list criteria:

Are these criteria set in policy? \_\_\_ yes: Are you willing to send us a copy?

\_\_\_ no

How difficult is it to decide what goes for review and what does not? (Pick one)

\_\_\_ very easy

\_\_\_ fairly easy

\_\_\_ fairly difficult: → Please describe where the difficulties arise:

\_\_\_ very difficult: →

If you have a complex research ethics question where would you go to seek help?

\_\_\_ no:

What is the reason why the Health Unit does not have ethical review criteria?

6.

Type of Activity	1. Is this activity done in your Health Unit? (Y/N/DK)	If not checked in first column, ask these questions:		
		2. What kinds of research currently require ethical review?	3. Why does this activity <b>NOT</b> receive an ethical review?	4. Is there any review of these? Please describe.
satisfaction surveys				
internal program evaluations				
internally funded research projects (other than program evaluations)				
externally funded research projects				
CQI or QA projects				
Other (please specify):				

**If there is no process, Please skip to Question 16**

**Questions 7 to 15:** These questions can be skipped if all of the following conditions are met:

- no research is done in this health unit (“no” to question 3)
- no projects require ethical review (“none” to question 6 column 2)
- there are no criteria for ethical review (“no” to question 5)
- there is no process for ethical review (“nothing” in response to question 4)

7. Can the decision made using the process described in question #6 be reversed?

\_\_\_ yes:

\_\_\_ an approved study can be vetoed at another level

Please indicate level: \_\_\_\_\_

\_\_\_ a study not receiving approval can be considered elsewhere (internally or externally) for approval

\_\_\_ other: \_\_\_\_\_

\_\_\_ no: decision is final (ie. approved study will not be considered elsewhere, and a study not receiving approval will not be done)

**Question 7:** The intent of this question is to determine whether a decision made during the ethical review process can be appealed to another process, that is, **other than** the appeal process that is built into the Tri-Council Policy Statement.

8. Is there a regular meeting schedule for the ethics review process?

\_\_\_ yes:

\_\_\_ \_\_\_ times per

\_\_\_ no:

\_\_\_ whenever there is a research proposal

\_\_\_ other:

9. How many weeks does the process of ethical review take?

(i.e. from submission to receiving letter)

10. How many research proposals are reviewed annually, on average?

11. Do you have a dedicated position to manage projects requiring review?

\_\_\_ yes: Title or % FTE (**individual not organization**)

\_\_\_ no: Who ensures that ethical review is done?

12. Does the review process provide you with the service you need?

\_\_\_ yes:

\_\_\_ no: What is lacking from the process?

13. What is working well about the process of ethical review which you follow?

14. How could the ethical review process be improved?

15. How satisfied are you with the ethical review process that has been established? (Pick one) \_\_\_ very satisfied

- \_\_\_ quite satisfied
- \_\_\_ quite unsatisfied
- \_\_\_ very unsatisfied

Further comments:

16. All Health Units are required to have a privacy officer, are you aware of the relationship of the privacy officer formally or informally and how it relates to the ethical review process?

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**16 is a new question and does not appear in their survey.**

17. The PHRED program is considering preparing an online research ethics toolkit to assist health units. This would include templates for the process, standard letters and forms used in the research ethics process, as well as articles, websites and other key documents. How important would an online research ethics toolkit be to your health unit.

- 1 – not important      2 – no opinion      3 – important      4 – very important

18. Considering the potential for increased research contained in both the capacity review and the agency taskforce, what can be done centrally by the Province, or designated agency to make research ethics review easier?

19. To recap, if you have not already done so would you share a copy of the policy or documentation?

\_\_\_ yes:

- \_\_\_ to help in analysis of survey results
- \_\_\_ for inclusion in the ethics toolkit

\_\_\_ no:

20. May I contact you again if I need further information?

\_\_\_ yes

\_\_\_ no

Other Comments:

Table 1

(Check off criteria as they are mentioned or as information is solicited)

Legend: **Y**= yes, **N** = no, **DK** = don't know **C** = comments

Asked	Ethics Review Quality	Y/N/DK/C
1.	Does the Health Unit have a formal definition of research?	
2.	Does proposal go to a committee or individual reviewer[s]?	
3.	If committee, is it an ethics review committee (REB)?	
4.	Is this committee internal or external? If external, please obtain name and institution to which it is affiliated. If internal, are there terms or reference and can these be shared?	
5.	Does the committee conform to the Tri-Council Policy Statement?	
	If They do not have a process you can stop here	
6.	At least five members: how many?	
7.	Both men and women	
8.	At least two members with broad expertise in the methods or areas of research	
9.	At least one member knowledgeable in ethics	
10.	At least one member knowledgeable in relevant law	
11.	At least one community member, with no affiliation with the institution	
12.	A process for including Ad Hoc members as required?	
13.	Established at highest level of the institution: what level?	
14.	Ethical review includes assurance that scholarly (or scientific review) is done	
15.	Procedures are in place for a full REB review, an expedited REB review or a departmental review of undergraduate student projects, depending on the degree of invasiveness proposed	
16.	Regular meetings, with dates communicated to researchers	
17.	Face-to-face meetings	
18.	Minutes of meetings	
19.	Communication of problems to researchers, with suggestions for improvement	
20.	An opportunity for re-submission of an application which has been judged to be unacceptable	
21.	An appeal board, for review of proposals on which the REB is unable	

	to make a decision	
22.	Withdrawal of a REB member in a “conflict of interest” situation	
23.	Continuing review of ongoing research projects	
24.	A certificate of ethical review is sent to investigators for approved research studies. If not, how is decision communicated?	
25.	The process of obtaining consent is examined	
26.	Privacy and confidentiality are considered	
27.	Secondary use of data issues are examined?	
28.	Risks and benefits are considered	
29.	Risks and benefits are monitored	

**Thank you for taking the time to complete this questionnaire**

## APPENDIX B

Date: July 10, 2006



Hamilton  
Public  
Health

Kingston,  
Frontenac  
and Lennox  
&  
Addington  
Public  
Health

Middlesex-  
London  
Health Unit

Ottawa  
Public  
Health

Sudbury  
and District



### Re: PHRED Public Health Research Ethics Needs Assessment Survey

Dear Colleagues:

I am writing to you on behalf of the Public Health Research Education and Development Program (PHRED) to ask for your assistance in completing a needs assessment survey of public health units about current practices and future resource needs related to research ethics. The survey has been developed to conduct a scan of what public health units in Ontario are currently doing with respect to research ethics and to determine your future needs in this area.

This Provincial organization (PHRED) contributes to health promotion, health protection and the prevention of health problems among the residents of Ontario primarily through applied research in a range of strategic initiatives. One of these initiatives is a project to develop a Research Ethics Toolkit to be available electronically to all public health units in Ontario.

A working group, consisting of a representative from each of the five PHRED health units, with expertise in research ethics and experience in the management and functions of a Research Ethics Board has been collecting best practice resources to this end. An Advisory Committee provides grounded advice and has the capacity to provide guidance in the selection of current, useful and relevant materials to ensure a high quality of final product.

The Research Ethics Tool Kit will present tools and resources for public health staff and decision makers to develop some specific competencies and to understand research ethics and ethical considerations when working with human research participants and/or within the public health field. It will assist in ethical planning when considering research, evaluation and quality assurance projects. The tool kit will provide templates for the process, standard letters and forms used in the research ethics process, as well as articles, websites and key documents. Ultimately, the tool kit will assist public health staff in the standardization of approaches to research ethics within their organizations based on best practices.

When the results of the survey have been analyzed and a report has been completed we will be happy to share this with you. Please be assured that all responses will be treated as confidential, and that no health unit will be identified in the reports resulting from this evaluation.

We would appreciate your taking the time to review the accompanying survey and perhaps collect some of the documents that you may need to help complete it. Our research assistant Jessica Watts will contact you to arrange a time at your convenience to complete the survey by telephone. We hope you can complete the survey on behalf of your health unit by August

15, 2006. If you have any questions related to this project or survey please do not hesitate to contact me.

Sincerely, Susan Moxley B.Sc.N., Med.

Secretariat, Ottawa Public Health Research Ethics Board,  
Secrétariat, Comité d'éthique de la recherche de Santé publique Ottawa,

7 West,  
100 Constellation Crescent,  
Ottawa, Ontario K2G 6J8  
Tel: 580-6744 x26108  
FAX: 580-9601  
email: [susan.moxley@ottawa.ca](mailto:susan.moxley@ottawa.ca)