



Interagency Advisory Panel on Research Ethics (PRE)



*REB Community Member
Educational Needs:
A PRE Pilot Project*

Report

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Standing Committee on Education
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The Interagency Advisory Panel on Research Ethics (PRE) has been created by the Canadian Institutes of Health Research, the Natural Sciences and Engineering Research Council of Canada and the Social Sciences and Humanities Research Council of Canada, to provide independent and interdisciplinary advice to these three Agencies on the interpretation, evolution and use of the *Tri-Council Policy Statement: Ethical Conduct of Research Involving Humans* (TCPS).

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REB COMMUNITY MEMBER EDUCATIONAL NEEDS: A PRE PILOT PROJECT

REPORT¹

1.0 BACKGROUND

The Interagency Advisory Panel on Research Ethics and Secretariat on Research Ethics (PRE/SRE) were created in 2001 by the Canadian Institutes of Health Research (CIHR), the Natural Sciences and Engineering Research Council of Canada (NSERC), and the Social Sciences and Humanities Research Council of Canada (SSHRC) (“the Agencies”). PRE’s primary role is to provide independent, multi-disciplinary advice to the Agencies on the evolution, interpretation, implementation and education dimensions of the *Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans* (TCPS). To advance policy initiatives under its education mandate, PRE created a Standing Committee on Education. The *REB Community Member Educational Needs: A PRE Pilot Project* is one initiative of the Standing Committee on Education.

2.0 PROJECT RATIONALE AND OBJECTIVES

Section 1, Article 1.3(d) of the TCPS specifies that one of the members on a research ethics board (REB) must be from the community the institution serves. The TCPS explains that this REB community member is essential to “help broaden the perspective and value base of the REB beyond the institution, and thus advance dialogue with, and accountability to, local communities.” At the REB level, there is general agreement that community members play an important role on REBs by contributing a perspective during the research ethics process that is both unique and at arm’s length from the institution. However, very little empirical or other information exists about the education resources and supports that community members need. This is why the Standing Committee on Education, on behalf of PRE, undertook the pilot project on the REB Community Member Educational Needs. This pilot project set out to:

¹ This document has been prepared by PRE’s Standing Committee on Education as a follow-up to the pilot focus group discussions which were held to explore community members’ perspectives on their roles on REBs as defined in the TCPS, and to understand their educational and other resource needs. The views expressed in the document represent those of the participants in the *REB Community Member Educational Needs: A PRE Pilot Project*. They do not necessarily reflect the views or the policy of the PRE or SRE. They were included to show some elements of the discussion on this topic.



- explore community members' perspectives of their roles on Canadian REBs
- further PRE's understanding of the education and other resource needs of REB community members inform PRE on the need for further study, based on the results of this pilot project.

3.0 METHODOLOGY

In December 2004, PRE approved the conduct of focused discussion groups on REB Community Member Educational Needs, to take place in Ottawa and Quebec City. These locations were selected because of proximity to the SRE office and cost considerations. Subsequently, ethics approval was obtained from REBs at the University of Waterloo and Université Laval for the conduct of the focus groups at the chosen locations.

A total of 15 local REBs were identified in Ottawa and Quebec City: at universities, government agencies and hospitals. Invitation letters were distributed through REB chairs to current and former REB community members. Through this process, 12 community members offered to volunteer as participants in the focus group discussions. Bilingual information packages—including an agenda, a set of questions and the TCPS definition of community members—were mailed to the community members who agreed to participate.

The three-hour focus groups, moderated by Standing Committee on Education members, consisted of an informal presentation about the Online TCPS Tutorial and discussions on the role and resources needs of community members. With consent of the participants, the focus group discussions were audiotaped for later analysis.

A number of direct benefits were anticipated from this small-scale project. It would provide opportunities for community members to meet and discuss common issues and to offer their thoughts and reflections on the education and other resources needed at the beginning and throughout a community members' term on an REB.

Although demographic information was not specifically requested, of the 10 community members who actually participated in the focus group discussions, the number of men and women was equal and the great majority of the participants were “retired.”

Participants in the REB Community Member Educational Needs pilot project were associated with REBs as follows:

- hospitals: 5
- universities: 4
- government agency: 1



Participants in the REB Community Member Educational Needs pilot project came from the following areas of expertise:

- teaching: 2
- nursing: 1
- public administration: 3
- university research: 1
- university administration: 1
- law: 1
- ethics: 1

4.0 FOCUS GROUP RESULTS

The questions that formed the basis of the focus group covered a range of topics, including recruitment of community members on REBs, a person's role and responsibilities as a community member, and how they should be prepared for this role. Details of findings are presented below.

4.1 Process for Volunteering on an REB

The Standing Committee on Education wanted to know how community members learned about the opportunity to volunteer on an REB. Most community members who took part in the focus group discussions had a prior connection with their REB. They were linked either through a current or former REB member who was a friend or former community member, or they knew someone on the REB, such as the chair or REB coordinator.

4.2 Reasons for Volunteering on an REB

Community members joined REBs for a range of reasons. Some believed that through membership on the REB they would learn about research in general and research ethics specifically, because they had time available, or they wanted to give back to the system because they or family or friends had benefited as participants in research. Others wanted to learn more about the institutional structure.

4.3 Mandates of REB Community Members

Community members felt that their primary role on the REB is to ensure that the community members' voice is heard and their experiences are recognized and understood. Some did this by taking the perspective of the research participants. The following comments from community members illustrate this view:



“I have to put myself in the role of being the patient or client...I pretend to be in the shoes of a research subject.”

“It’s not scientific, but I ask, ‘How would it affect me?’”

“What would you want to know if you were the participant?”

Community members also indicated a secondary role: to provide an arm’s-length perspective on research involving humans. Since community members do not have an affiliation with the institution and the research enterprise, they may be able to be more objective about research in general. This is particularly important when research participants are vulnerable and/or risks to research participants are high. The following comment illustrates this important role:

“You see things that they (other REB members) don’t see because you’re not dealing with that environment.”

4.4 Community Members’ Contributions to REB Work

Community members reported that they enjoyed their work on REBs and held a positive view of their role and contributions. They viewed themselves as bringing pragmatism and humility to the ethics review process. Further, by asking questions from their own unique perspectives, community members can help ensure that the research is of the highest possible quality. These views are illustrated by the following comment:

“You want someone from outside the institution who will do a reality check on the research.”

Community members also reported that they play a valuable role in assessing the quality and the content of the information letters or brochures and the consent forms written by researchers for participants (length, type of language, etc.). They check that the content and language are neither too technical, nor simplified to the point of losing accuracy. The following statements reflect this commitment:

“I spend time to rephrase sentences....”

“If I have to go to a dictionary, I strike that word.”



4.5 Importance of REB Community Members' Familiarity with the TCPS

Community members commented that the TCPS is an important reference document, though they noted that only one section addresses the practical side of REB work (that is, the REB review process). They also mentioned that an introduction to the TCPS should be complemented by other components of an orientation program for community members (see section 5.0 of this report).

4.6 Type of Orientation and/or Training Received by REB Community Members

The background, training and experiences of community members in research ethics varied considerably; some community members already had an understanding of research ethics from previous roles/jobs, while others did not. In spite of this, few community members were provided with a formal orientation program. In most cases, training consisted of receiving a copy of the TCPS and a binder of forms and procedures to read, with no opportunities for discussion about the materials or for mentoring by another REB member. In reality, community members learned on the job.

Community members suggested that institutions should ensure that all REB members receive adequate initial and continuing education, including formal training in the ethics review and protocol review processes. The value of educating community members in research ethics and the ethics review process is illustrated by the following comment:

“The more I learn, the more I can be comfortable in my role.”

5.0 FOCUS GROUP FINDINGS AND PARTICIPANTS' RECOMMENDATIONS

The community members provided the following clarifications to the sections of the TCPS related to community members, and they suggested support that would better prepare them in their role as members on an REB.

5.1 Formalizing the Role of REB Community Members: Position Description

Participants suggested that a community member job description be developed. This would be useful both to community members and other REB members in describing and clarifying the community member's roles, responsibilities and expectations. This description would also enhance recognition of the community member's valuable role within the institution's culture.



5.2 Regular and Ongoing Communication with REB Community Members about Training Opportunities

Participants pointed out that REB community members have special resource requirements, and since they are not part of the institution, they may have only limited access to announcements about education and training opportunities. Thus, institutions should ensure that information distribution mechanisms include community members and that information about education and training be readily accessible to them.

5.3 Provision of a REB Community Member Mentorship Program

Participants suggested that a formal mentorship program be developed for new community members. Each community member could be matched with an experienced, current REB member willing to mentor a community member.

5.4 Provision of a Formal Orientation Program for REB Community Members

Participants recommended that a formal orientation program be developed and offered to new REB community members. In recognition of the diverse educational and cultural backgrounds and life experiences of community members, the program should offer a range of options and include face-to-face discussion meetings on the following:

- i) *Understanding the REB Meeting Process*: An overview of the process and procedures involved in an REB meeting.
- ii) *Training in Research Ethics Review Process*: How to critically read and review research proposals from an ethical perspective.
- iii) *Training in Research Ethics Guidelines and Policies*: Education in, and understanding of, guidelines and policies related to research with humans, including provincial, federal and international perspectives, as well as professional codes of ethics.
- iv) *Completion of the TCPS Online Tutorial*: Increased awareness about the TCPS Online Tutorial, with opportunities for discussions and dialogue about the content of the tutorial.
- v) *Understanding the Research Environment*: An overview of the research environment of the particular institution, including the institution's annual research report.



- vi) *Feedback from REB Community Members on the Orientation Program: An opportunity to provide written feedback on the effectiveness of the orientation program.*

5.5 Establishing Contacts within REBs

Community members suggested that having opportunities and mechanisms for direct contact with all REB members would be helpful. This would facilitate communication and sharing of knowledge and expertise with other members on the REB.

5.6 Facilitating Opportunities for Networking with REB Community Members at Other Institutions

Community members suggested that providing opportunities for networking and communicating with community member colleagues at other institutions would foster discussion and increase the sharing of experiences.

5.7 Providing Balanced Representation on REBs

Participants commented that REBs with more than 10 members should include more than one community member and suggested that 20 percent of the REB membership should be community members. This suggestion relates to the commentary following TCPS Article 1.3 which specifies: “as the size of an REB increases...the number of community representatives should also increase.”

5.8 Providing Professional Development for REB Community Members

Community members would benefit from attending annual national and regional meetings of CAREB and NCEHR. Cost of their attendance should be covered by the institution where they serve as REB members.

5.9 Education and Training of All Members of REBs

Ongoing education and training for all members of an REB, including community members, should be an institutional priority. The contributions and commitment of community members who volunteer their time and expertise while having no affiliation with the institution should be recognized by the institution’s senior administration.



6.0 OTHER CONSIDERATIONS ON THE TCPS DEFINITION OF REB COMMUNITY MEMBERS' ROLES

During the community member focus group discussions, participants raised other important questions related to the TCPS definition of community members' roles on REBs. These points merit further attention.

6.1 Need for a Clear Definition of “Community” in REB “Community Member”

The TCPS does not adequately inform REBs on how to identify a person to fill the role of community member. Section 1, Article 1.3(d) specifies that on an REB, “at least one member has no affiliation with the institution, but is recruited from the community served by the institution.” The TCPS also indicates that community members on an REB are essential to “help broaden the perspective and value base of the REB beyond the institution, and thus advance dialogue with and accountability to, local communities.” Participants were unclear about the meanings and intention of “no affiliation” and “community served by the institution.” They raised concerns about the required number of community member representatives on an REB, and they had a number of other related questions.

6.2 Need for Further Examination of the Issue of REB Community Members' Qualifications/Profile

Considerable variability exists across REBs in terms of the educational background and experience of community members. Further research and dialogue are required to determine if REBs use specific procedures to recruit community members; in particular, whether REBs seek out people with specific qualifications and experience.

6.3 Need for Closer Association with Experience of Research Participants

Some community members have personal experiences in decision-making related to their own participation in research and/or through family members or friends. Thus, future research and dialogue should occur to determine whether experience as a research participant is an important characteristic for serving on REBs, and to what extent this experience can enrich the quality of the REB's deliberations during the ethics review process.



7.0 CONCLUSION

Community members play an important and valuable role on REBs. The Standing Committee on Education, on behalf of PRE, conducted focus groups for the REB Community Member pilot project from January through April 2005 to explore community members' perspectives on their roles on REBs as defined in the TCPS, and to understand their educational and other resource needs.

During the pilot project, the participants provided recommendations for potential clarification of the TCPS and for resources and supports that could better prepare them in their role as community members on REBs. In particular, participants noted the need for institutions to provide orientation, training, mentorship and professional development to REB community members, and the need for REBs to increase the communication and/or the networking opportunities with other REBs.

The pilot project raised many important questions that merit further attention. These suggestions should be considered, to support not only the community members' educational needs, but also those of all REB members.

