

Research Ethics Boards and Challenges for Public Participation

Denise Avard, Michèle Stanton- Jean, Roberta L. Woodgate,
Daryl Pullman & Raphael Saginur

Background

Governments increasingly emphasize the importance of public input in processes related to policy and decision making.¹ Over the last decades, public input has become standard practice in, for example, prioritizing the funding of research,² health service planning,³ public health,⁴ and on research ethics boards.⁵

Prior to implementing a research study, all research protocols must be reviewed and approved. Furthermore, as established by the Nuremberg Code⁶ (1947) and the World Medical Association Declaration of Helsinki⁷ (1964), potential research participants are expected to have sufficient knowledge of the research project to make voluntary and informed choices. Research Ethics Boards (REBs) have been instituted to assess the risks and benefits of the research,⁸ to review the rights and welfare of the participants, to monitor the informed consent process, and to safeguard the privacy and confidentiality rights of the participants.⁹ The principal role of the REB historically has been to review whether the research protocol respects these ethical standards so as to protect the interests of research participants. However, it has become incumbent upon REBs to embrace a wider mandate that includes enhanced transparency and accountability towards the public, to increase public understanding of the issues at hand, and to ensure respect for broader community values. UNESCO's guidance documents for establishing and operating REBs serve as a case in point as they embrace this broader vision. In their Guide No. 1 *Establishing Bioethics Committees*, and

in Guide No.2 *Bioethics Committees at Work: Procedures and Policies*,¹⁰ research ethics reviews are deemed the public's business. In Guide no. 1, UNESCO states that,

In an increasingly open and critical society, institutions are concerned for their public image. They are concerned about their integrity and reliability. In some countries it creates anxiety to minimize the risk of lawsuits. Committees demonstrate that scientists and health professionals seek guidance from peers, groups and committees in order to share responsibility.¹¹

Moreover, UNESCO continues that,

... scientific decision-making is no longer simply a one-on-one affair and that researchers and health care personnel must be responsive to a variety of publics. When there are bioethical conflicts, their resolution may not be achieved simply by appealing to scientific and medical judgements alone. Policy decisions will have to be taken that extend far beyond a single researcher or physician's expertise.¹²

In light of these statements and to gain a better understanding of the role of community members on REBs, this paper explores several questions: i) Who is the public? ii) Why involve the public? iii) What role should the public representatives play on the REB? iv)



Does the public representative need a certain level of education and training to participate on the REB? and v) How are the contributions of the public representatives to the REB evaluated? Each of these questions may have important implications for REBs in determining how best to implement the recommendations regarding the presence of a public or community member on a research ethics board. Although the focus of this article is on these questions, we begin with an overview of the situation of community representation in REBs in Canada.

The *Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans (TCPS)* advocates the inclusion of “at least one person not affiliated with the organization... who are using the services.”¹³ Article 1.3(d) states:

The Agencies consider it essential that effective community representation be maintained. Thus as the size of an REB increases beyond the minimum of five members, the number of community representatives should also increase.¹⁴

In Canada at least one community member is required on the REB, while other countries like the United Kingdom and Denmark respectively recommend that one third and one half of the members on the committee are from the community.¹⁵

The “community representative” requirement under Article 1.3(d) is essential to broaden the perspective and value base of the REBs and thus advance dialogue and accountability to local communities. Similarly, at the provincial level, the Québec Ministry of Health and Social Services (MSSS) indicates in the *Plan d’action ministériel en éthique de la recherche et en intégrité scientifique*, that transparency and shared responsibility between government, institutions, and individuals is crucial.¹⁶

The National Council on Ethics in Human Research (NCEHR) inquired about the ‘public representation’ on the REB during their 76 site visits (50 universities and 26 hospital/health settings) conducted between September 1998 and November 2007.¹⁷ Their findings showed some discrepancies between the *TCPS* recommendations and existing REB composition. While the *TCPS* requires that each REB have at least one community/public member, only 67% of the committees visited by NCHER had community members on their REB.

The observations made by Henry B. Dinsdale in a 1997 address titled *The Composition of Research Ethics Boards*, are as valid today as they were more than a decade ago:

What qualities should one seek in lay committee members? [...]If (in Canada) a national committee was established to provide advice to local REBs who should serve on that committee? The ideal REB lay member is without a vested interest, has good judgment, is interested and able to listen to both sides of an argument. [...]The quality of local REB work depends to an inordinate degree on the conscience and commitment of committee members.¹⁸

In the same vein, in a presentation “*Le recrutement d’un membre de la communauté*” to the General Assembly of NCEHR, Hubert Doucet¹⁹ stressed similar questions regarding the selection of participants, their subsequent diversity of values, and the expectation of REBs.

To begin to address the many challenges regarding the value and role of public participation on REBs there is a need to consider the ‘Who?’ the ‘Why?’ and the ‘What’ of public participation. Although we do not provide definitive answers to these questions here, our discussion addresses some key points that need to be clarified if the idea of public participation is to amount to something more substantial than mere window dressing for the ethics review process.

Who is the public?

The terminology used to describe the public varies tremendously. A descriptive list of “public representatives” might include: non-scientific members; associates; a representative from the community served by the institution; a non affiliated person from outside the organization but who still uses the services of the organization; an outside consultant; an outsider; lay persons and so on.²⁰

For example, the *TCPS* states that REBs shall consist of at least one member who has “no affiliation with the institution”, but is recruited from “the community served by the institution.”²¹ This statement is vague and unclear. What is meant by “no affiliation with the institution?” Does “no affiliation” exclude ex-patients, a disease support group, a patient who has experienced a



similar research protocol or had a similar life experience? To require a public representative from the community served by the institution is no less ambiguous. Does this refer to people in a geographic area surrounding the institution, or would it include someone who has a family member who is at the institution or a student at the university in the case of university REBs?

“Community” is also an elusive concept with differing degrees of complexity and a multitude of interests. Community is an informally organized association of people, more or less cohesive, who are unified by a number of shared characteristics including, for example, culture, religion, race, common language, political or geographic boundaries, social economics status, as well as communication networks.²²

The broad mandate of the REB includes a responsibility both to protect the interests of individual research subjects and to promote the broader public good by ensuring that valuable research moves ahead expeditiously.

Why Involve the Public?

There are many definitions of public involvement,²³ but in the context of this paper we will focus on the active “process” whereby public involvement infers inclusion in the decision making process, and not just consultation.

The broad mandate of the REB includes a responsibility both to protect the interests of individual research subjects and to promote the broader public good by ensuring that valuable research moves ahead expeditiously. Included in this mandate is a responsibility to “judge community attitudes, community competence, and to identify what the patient/participant would want to know about the research.”²⁴ In order to achieve this, it is critical to include individuals with no vested interest in the review process. An REB consisting of only researchers might focus too much on promoting science since there is a natural tendency for investigators on REBs to take the

perspective of the investigators rather than the point of view of potential research participants.²⁵ Public participation can thus help to promote principles of justice by allowing the committee member to represent the interests of research participants since the public member is more likely responsive to the concerns of the participants or population from which the participants are recruited.²⁶ However, when examining the contribution of a lay member it is important to realize that their personal experiences, cultural background, level of education, and membership in a patient organization may contribute to some variability in the assessment of the protocol. However, public involvement in REBs has been criticised on the grounds that a member’s perception will reflect, for example, a certain worldview or cultural affiliation which, in turn, can generate conflicting viewpoints ranging from supporting research to trying to stop it.²⁷

What is the Role of the Public?

Even if all would agree on a precise definition who is a lay member, the role of these public members on the REB is vague. On a more practical level lay members often describe their role as representing “the man or woman on the street” or as providing an outsider view.²⁸ Schuppli and Fraser describe a range of roles such as providing: a perspective that is independent of the research agenda; input from the public in the decision making process; a window on the outside world; greater integrity and transparency about the review process; a bridge between the researcher and the general public; protection to research participants; and, guidance for scientists regarding ethical issues relevant to the public.²⁹ Other roles described by the lay representatives include reviewing the content and process of informed consent. Interestingly, 94% of respondents in a study by Sengupta and Lo indicated that their principal role was to improve the clarity and language level of the consent forms.³⁰ However, reviewing the consent process was given less attention. Other roles described by the lay representatives include balancing between risks and benefits, protecting vulnerable populations such as children, judging the value of the research, and sensitising members of the committee to the needs of the public.³¹

Others see their role as representing the public.³² Sengupta and Lo³³ indicated that 53% of “non-affiliated and non-scientist members” of REBs perceived their



roles as representatives and voices of the community. Some respondents (10%) indicated they were hesitant to accept the community representative role, feeling they were unable to stand in for the broad concerns of the community or public in general. Public representation on the REBs has been criticised on these grounds because it is felt that the person who takes part in the review process cannot be a representative of all participants in research or represent community values, however defined.

Overall, the range of roles listed illustrates the lack of consensus about the role of the lay person on the REBs. Further research is needed to understand what are the roles, the extent to which they apply and how these various roles are assumed.

Training and Education

Public members may be disadvantaged during REB committee discussions because of a lack of familiarity with the technical language due to a lack of training.³⁴ Training and educational background for public members, as well as for other members of the committee,³⁵ is an important issue, even more so because it has been mentioned that the informational sessions in REBs is often varied, vague, and unsystematic.³⁶ As a result, lay public members are sometimes unsure of the essential points they need to focus on when reviewing a protocol.³⁷ While “on-the-job training” is recognized as valuable, applied and interactive training, a mentorship programme having new members working with senior members of the REB, and a formal process of accreditation, are other means to support the process towards education and training.³⁸ However, training does engender some risks. How does one reconcile the concern that the more training a public member receives, the more the person becomes professionalized, thereby seeing issues from the viewpoint of the researcher or the institution?³⁹

UNESCO notes that very few countries have formally established educational programmes for REB chairs and members. They propose a curriculum for future REB members addressing criteria to carry out sound ethical research and to study principal ethical concepts produced by agencies whose mandate is to regulate the recruitment of participants for surveys and clinical investigations.⁴⁰ In Canada, the TCPS recommends that REB public members participate in general meetings, retreats, and

educational workshops to inform themselves. In addition, they should discuss any general issues arising out of the REB’s activities with other committee members.⁴¹ This could help to reduce uncertainty and confusion.

Evaluation and Monitoring

Involving the public in REBs is a relatively new concept and little is known about who the members are and their contribution to the review process.⁴² One study concluded that lay members are primarily white, male and highly educated.⁴³ Their role on the committee focused primarily on the review of the consent forms rather than in assessing what risks are acceptable.⁴⁴ While this descriptive information is useful, it is also important to assess whether the diversity of roles described earlier

Involving the public in REBs is a relatively new concept and little is known about who the members are and their contribution to the review process.

has been achieved. However, the vagueness of the community member’s role makes it difficult to evaluate the effectiveness of their participation on REBs,⁴⁵ whether they do in fact represent the public’s interests, and whether their input is valued by the REB.

UNESCO has released international guidelines to evaluate the effectiveness of national REB’s setting the following criteria:⁴⁶(i) Has the REB invited or included experts which are considered independent of the research to be evaluated?; (ii) Is the REB recording its strengths and weaknesses?; (iii) Is there a willingness to change?; and, (iv) Has the committee publicized policy changes to maintain credibility?

Challenges

REBs have a mandate to include the public in their consideration, commentary, and evaluation of research protocols. However, as noted above, involving the public presents a number of challenges. The TCPS provides little guidance for REBs as to how to implement the recommendation of ‘community representation’ in the



review process. Implementation of existing guidelines is problematic. We have identified numerous questions that need further examination through research and public debate. We believe that the role the public plays on the REB should be properly evaluated to enhance the legitimacy of the policies in place. Clear definitions would be helpful so as to better assess who the public is, what their role is, and how they are expected to perform. Moreover, in order for public members to make meaningful contributions, they need to receive

We believe that the role the public plays on the REB should be properly evaluated to enhance the legitimacy of the policies in place.

education and training concerning the technical and ethical aspects of their responsibilities, without neutralizing the concerns from the community. Identifying educational programmes that are available for the public members can be a powerful mechanism for promoting action.

Finally, there are several other crucial questions to be considered: How will the public members be recruited? What are the terms of office? How many public members are needed on the committee? Should different public representatives be available to review different kinds of health research? While a cancer survivor may be an appropriate lay representative for the review of clinical trials research, she may not be the best community representative for a qualitative social science research study conducted in a remote northern community. Finally, how does an REB select an individual to represent the values of the heterogeneous population of an urban centre, and does such heterogeneity even matter in any particular study?

There is no readymade recipe for involving the public in research ethics board. However, to succeed in protecting the interests of research participants further evaluation is needed to show how the public's point of view is heard and that they are not the 'unsung heroes' of the ethical review committee.⁴⁷

Denise Avard., is an Associate Researcher at the Centre de recherche en droit public, Faculté de Droit, Université de Montréal, Montreal, Quebec.

Michèle Stanton-Jean is an Invited Researcher at the Centre de recherche en droit public, Faculté de Droit, Université de Montréal, Montreal, Quebec.

Roberta L. Woodgate, is an Associate Professor, Faculty of Nursing, University of Manitoba, Winnipeg, Manitoba

Daryl Pullman, is a Professor of Medical Ethics, Division of Community Health & Humanities, Faculty of Medicine, Memorial University, St. John's, Newfoundland

Raphael Saginur, MD, Ottawa Hospital and University of Ottawa, Ottawa, Ontario.

*Correspondence: Denise Avard, PhD, Associate Researcher, Centre de recherche en droit public, Faculté de Droit, Université de Montréal, C.P. 6128, succ. centre-ville, Montreal, Québec H3C 3J7
Email: denise.avard@umontreal.ca*

Endnotes

- 1 Herbert Gottweis, "Participation and the New Governance of Life" (2008) 3 *Biosocieties* 265.
- 2 Australia, Bill C2006B00036, *National Health and Medical Research Council, Amendment Bill 2006*, (Cth), online: Parliamentary library <www.aph.gov.au/Library/Pubs/bd/2005-06/06bd126.htm>.
- 3 Julia Abelson & John Eyles, *Public Participation and Citizen Governance in the Canadian Health System*, Discussion Paper No. 7 (Ottawa: Commission on the Future of Health Care in Canada, 2002).
- 4 Denise Avard *et al.*, "La participation du public dans la santé publique: l'implication des communautés culturelles dans le dépistage des maladies héréditaires(2008)" 39 *Pratiques et Organisations des Soins* 231.
- 5 Marcia Kelson, "The NICE Patient Involvement Unit" (2005) 9 *Evidence-Based Healthcare and Public Health* 304; See also Vicki A. Entwistle *et al.*, "Lay Perspective: Advantages for Health Research" (1998) 316 *British Medical Journal* 463.
- 6 Germany (Territory under Allied occupation, 1945-1955: U.S. Zone) *Military Tribunals, Trials of War Criminals before the Nuremberg Military Tribunals under Control Council Law No. 10*, vol. 2 (Washington



- D.C.: U.S. Government Printing Office, 1949) at 181.
- 7 World Medical Association, *Declaration of Helsinki: Ethical Principles for Medical Research Involving Human Subjects*, online: WMA <<http://www.wma.net/e/policy/b3.htm>>.
 - 8 Robert Veatch, "Human Experimentation Committee: Professional or Representative?" (1975) 5 *Hastings Center Report* 31.
 - 9 Raymond DeVries & Carl P. Forsberg, "Who Decides? A look at Ethics Committee Membership" (2002) 14 *HEC Forum* 252.
 - 10 UNESCO, *Establishing Bioethics Committees: Guide No.1* (Paris: UNESCO, 2005); UNESCO, *Bioethics Committees at Work: Procedures and Policies, Guide No.2* (Paris: UNESCO, 2005).
 - 11 UNESCO, *Establishing Bioethics Committees, ibid.* at 14.
 - 12 *Ibid.* at 15.
 - 13 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* (Ottawa: Public Works and Government Services Canada, 1998 with 2000, 2002 and 2005 amendments) [*TCPS*], online: Interagency Advisory Panel on Research Ethics (PRE) <<http://www.pre.ethics.gc.ca/english/policystatement/policystatement.cfm>>.
 - 14 *Ibid.* at Article 1.3.
 - 15 C.A. Schuppli & D. Fraser, "Factors Influencing the Effectiveness of Research Ethics Committees" (2007) 33 *Journal Medical Ethics* 294.
 - 16 Ministère de la santé et des services sociaux, *Plan d'action ministériel en éthique de la recherche et en intégrité scientifique*, (Québec: Ministère de la santé et des services sociaux, 2008) at 8.
 - 17 National Council on Ethics in Human Research, *Report on Findings from NCEHR Site Visits 1998-2004* (Ottawa: NCEHR, 2005), online: NCEHR <http://www.ncehr-cnerh.org/pdf/publications/site_visits/ReportSiteVisitsFinal3_June_2005.pdf>; Personal Communications with Richard Carpentier, Executive Director, NCEHR & Felicetta Celenza, Coordinator of Educational Visits, NCEHR.
 - 18 Henry B. Dinsdale, "The Composition of Research Ethics Boards", online: Canadians for Health research <<http://www.chrcrm.org/main/modules/pageworks/index.php?page=015&id=231>>..
 - 19 Hubert Doucet, 'Le recrutement d'un membre de la communauté' (Presentation to the General Assembly of NCEHR 5-6 March, 2001 [Unpublished]).
 - 20 Joan P. Porter, "What are the Ideal Characteristics of Unaffiliated/Nonscientist IRB Members?" (1986) 8:3 *IRB: Ethics & Human Research* 1.
 - 21 *TCPS, supra* note 11 at Article 1.3. It should be noted that the Statement did not want to create a section dealing with research involving Aboriginal Peoples considering that they did not held sufficient discussions with them. They included a Section 6 with a review of the literature on that topic as a starting point.
 - 22 C. Weijer & E.J. Emanuel, "Protecting Communities in Biomedical Research" (2000) 289 *Science* 1142.
 - 23 Health Canada:Health Products & Food Branch, *Public Involvement Framework* (Ottawa: Office of Consumer and Public Involvement, 2004), online: Health Canada <<http://www.hc-sc.gc.ca/ahc-asc/pubs/cons-pub/piframework-cadrepp-eng.php>>.
 - 24 Veatch, *supra* note 6.
 - 25 Emily E. Anderson, "A Qualitative Study of Non-affiliated, Non-scientist Institutional Review Board Members" (2006) 13 *Accountability in Research* 135; Mildred K Cho & Paul Billings, "Conflict of Interest and Institutional Review Boards" (1997) 45 *Journal of Investigative Medicine* 155.
 - 26 Sohini Sengupta & Bernard Lo, "The Roles and Experiences of Non-affiliated and Non-scientist Members of Institutional Review Board" (2003) 14 *Academic Medicine* 212.
 - 27 Jonathan Kimmelman, "Valuing Risk: The Ethical Review of Clinical Trial Safety" (2004) 14 *Kennedy Institute of Ethics Journal* 369.
 - 28 Sarah Dyer, "Rationalizing Public Participation in the Health Services: the Case of Research Ethics Committee" (2004) 10 *Health & Place* 339.
 - 29 Schuppli & Fraser, *supra* note 13.
 - 30 Sengupta & Lo, *supra* note 26.
 - 31 Joan P. Porter, "How Unaffiliated /Non-scientist Members of Institutional Review Boards See Their Roles" (1987) 9:6 *IRB: Ethics & Human Research* 1.
 - 32 *Ibid.*
 - 33 Sengupta & Lo, *supra* note 26.
 - 34 Patricia E. Bauer, "A Few Simple Truths about Your Community IRB Members" (2001) 23:1 *IRB: Ethics & Human Research* 7; Sengupta & Lo, *supra* note 26.



- 35 Gary L. Chadwick & Cynthia M. Dunn, "Institutional Review Boards: Changing with the Times?" (2000) 6:6 Journal Public Health Management Practice 19.
- 36 Anderson, *supra* note 24.
- 37 *Ibid.* at 145.
- 38 National Council Ethics Health Research, *Promoting Ethical Research with Humans Report of the Task Force for the Development of an Accreditation System for Human Research Protection Programs*, (Ottawa: NCEHR, 2002), online: NCEHR <http://ncehr.org/english/Task%20Force%20Report_FINAL_18%20July%202006.pdf>; Sponsors' Table for Human Research Participant Protection in Canada, *Moving Ahead: Final Report* (2008), online: Sponsors' Table for Human Research Participant Protection in Canada <<http://www.hrppc-pphrc.ca/english/movingaheadfinalreport2008.pdf>>.
- 39 Steven Epstein, *Impure Science: AIDs, Activism, and the Politics of Knowledge* (Berkeley, University of California Press, 1996) at 445.
- 40 UNESCO, *Establishing Bioethics Committees*, *supra* note 8 at 48-49.
- 41 *Ibid.*, Article 1.7.
- 42 Kimmelman, *supra* note 26.
- 43 Sengupta & Lo, *supra* note 26.
- 44 *Ibid.*
- 45 *Ibid.*
- 46 UNESCO, *Establishing Bioethics Committees*, *supra* note 8 at 57
- 47 Bauer, *supra* note 33.

ARTICLES FOR SUBMISSION

The *Health Law Review* has a wide audience of subscribers and welcomes articles from all health disciplines, ethics, philosophy, and law. Articles should be submitted by email to hli@law.ualberta.ca.

Check our website at <http://www.law.ualberta.ca/centres/hli> for specific information on formatting prior to forwarding your paper.

Endnotes **must** comply with the Canadian Guide to Uniform Legal Citation (6th ed.).

Submission deadlines for are, August 15, October 15, 2009 and February 15, 2010.

Tel: 780.492.8343 email: hli@law.ualberta.ca

