Giving Voice to Research Participants: Should IRBs Hear From Research Participant Representatives?

By Michael R. Hadskis

Abstract
The current decision-making model for the review of human research contains inadequate mechanisms to ensure that the interests and perspectives of research participants are considered by Institutional Review Boards, whose decisions may profoundly affect the safety and well-being of participants. As a result, this model is far from being optimized to realize Institutional Review Boards’ principal mandate and undermines the credibility of the research review process. This article proposes a procedural mechanism that would ameliorate these systemic deficiencies by allowing “research participant representatives” to give voice to participants during the research review process.

Introduction
The primary purpose of Institutional Review Boards (IRBs) is “to protect the rights and welfare of human research subjects recruited to participate in research activities conducted under the auspices of the institution with which [they are] affiliated” (OHRP, 1993). This lofty mandate is supposed to inform any decision made by an IRB to approve, require modifications in, or reject proposed studies or to require ongoing studies to be altered or terminated. IRBs render such decisions after considering the information that has been put before them, which typically consists solely of documentation submitted to the board by the researchers who are proposing (or carrying out) the research in question. With this information in hand, IRBs deliberate on a number of complex issues, including: whether the foreseeable risks to participants outweigh the anticipated benefits; whether risks to participants have been minimized by the researcher; whether the proposed consent process will properly inform prospective participants of the risks, benefits, and true nature of the research; and whether participant selection criteria are equitable and justified (45 CFR §46.111 and 46.116).

In view of the principal purpose of IRBs and the types of matters they are called upon to decide, it is striking that the only individuals who will necessarily have the opportunity to make submissions to these boards are the very people whose proposed (or ongoing) activities may adversely affect the rights and well-being of research participants. Researchers are afforded ready access to the decision-maker and are given the chance to
advance their interests by influencing the decision that will ultimately be reached. However, the adoption of this decision-making model is deeply problematic given the reality that the interests and perspectives of researchers and participants are not necessarily congruent and may, in some instances, clash.

The first half of this article critically examines the decision-making methodology currently being employed for the review of biomedical research and concludes that it falls well short of being optimized to furnish IRBs with sufficient information respecting the interests and perspectives of research participants. With that as a backdrop, the remaining portion of the article explores the viability of creating a mechanism that would allow persons who are able to represent the interests and perspectives of research participants to make submissions to IRBs. Such a mechanism would promote the attainment of IRBs’ primary objective and would evince greater respect for research participants.

The analysis that follows largely focuses on the IRB decision-making process, although some comparison is made to the prescribed procedures for IRBs’ Canadian counterparts, Research Ethics Boards (REBs), which share the same primary mandate as IRBs (Glass and Lemmens, 1999). The term “research board” will be used to refer to both boards generically.

**Researcher and Research Participant Interests**

The review of human participant research by research boards is a “political process as much as it is an ethical process” given its chief concern with “balancing one set of interests in the community against another set of interests: the interests of science and scientists (principally) on the one hand and the interests of the human subjects of experimentation on the other” (McNeill, 1993). Before discussing how the IRB decision-making process has been structured to adduce information to carry out this balancing act, it is appropriate to first identify the various interests of researchers and research participants. My gaze is narrowly set on the interests of participants and researchers because it is researchers who are seeking authorization from research boards to disturb the status quo and who generally enjoy an exclusive opportunity to influence these boards, and it is the participants whose integrity and well-being are typically most directly and profoundly affected by board decisions.

So, what are the interests of research participants? Regulatory norms require that the free and informed consent of prospective participants (or their legally authorized surrogate) be secured by researchers before participants can be enrolled in a study (45 CFR, §46.116; TCPS, Art. 2.1). As a result, it is expected that the consent process will include, among other things, measures to effectively impart information to prospective participants regarding the potential risks and benefits associated with participation in the research. Thus it follows that a key interest of participants is not to be exposed to a less favorable potential harm-benefit ratio than they accepted during the consent process. Participants also have an obvious interest in researchers taking all reasonable precautions to safeguard their safety and well-being. Depending on the specifics of the research protocol and the participants’ particular circumstances, a number of other interests may be in play: the receipt of financial incentives for their participation; receipt of diagnosis and treatment of a medical condition (Lemmens and Miller, 2002); the desire to benefit a general patient population to which the participant may or may not belong; or the wish to advance scientific knowledge. A decision to approve or reject proposed research or to terminate ongoing research can directly affect any of these interests.

Not surprisingly, researchers’ interests are also affected by research board decisions. The primary interest of all researchers “should be valid answers to research questions, since scientific progress which contributes to improved health care is the final goal of research,”
and where they “are also treating physicians, the well-being of individual patients/research participants is a concurrent primary interest” (Glass and Lemmens, 1999). Secondary interests of researchers may include, among others: career advancement through the publication of study results in reputable journals; peer recognition; pleasing research sponsors; financial gain arising from funding acquisition, honoraria, subsidized overhead, and patents; satisfaction of intellectual curiosity; and scientific development (Glass and Lemmens, 1999).

The interests of research participants and researchers can intersect or conflict. A shared desire to advance scientific knowledge for the benefit of health care consumers is an example of intersecting interests that may exist in some instances. The expanding body of literature devoted to exposing the negative impacts of the commercialization of biomedical research on researchers’ design and conduct of studies, as well as the way study results are interpreted, provides a bountiful source of examples of clashing interests (Barnes and Florencio, 2002; Thompson, 1993; Thompson et al., 2001).

**Existing Decision-Making Model and Its Limitations**

The main regulatory instrument in the U.S. for federally-funded research and research conducted within government departments is Title 45, Part 46 of the Code of Federal Regulations (CFR), with Subpart A of these regulations (the “Common Rule”) providing the basic decision-making framework for the protection of research participants. Also of significance is Title 21, Part 50 of the CFR, which governs research involving products such as drugs and medical devices that are regulated by the Food and Drug Administration (FDA). Both instruments establish formal legal standards for the conduct of ethics reviews by IRBs. The rough equivalent to the Common Rule in Canada is the Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans (TCPS), which sets out the standards and procedures applicable to the review of research undertaken by researchers or institutions receiving financial support from the main national funding agencies. Unlike the Common Rule, the TCPS is not a formal legal instrument; nonetheless, there are factors which mandate or encourage compliance with its standards (Downie and McDonald, 2004). Canada’s Food and Drug Regulations are the counterpart to the FDA’s regulations. This article will pay particular attention to the Common Rule and the TCPS, which for the most part parallel the requirements found in the regulations pertaining to food and drugs in the U.S. and Canada.

Commonalities exist respecting the procedural requirements prescribed by the Common Rule and the TCPS. Research boards must have memberships that reflect diversity in terms of experiences and expertise and that are at least five members strong (45 CFR, §46.107; TCPS, Art. 1.3). There must be a set number of individuals that have expertise in scientific areas, that possess knowledge of the relevant law, that are not affiliated with the institution, and that have nonscientific areas as one of their primary concerns. As will be discussed, certain other individuals may be added to this basic membership.

Specific process requirements must be satisfied before a research board can render its decision. These requirements reflect the fact that researchers have a clear interest in the decision outcome and, therefore, are owed certain procedural protections. Researchers provide written submissions to the board in support of their applications. The submission package includes the research protocol and participant consent forms, among other documents. Embedded within one or more of these documents is the researcher’s opinion regarding the study’s attendant risks and benefits for participants, and the researcher’s express or implied opinion on why the benefits of the research would outweigh any harm that might be occasioned by participants. In Canada, researchers are given the opportunity
to be present for and participate in board discussions (but not the board’s deliberations) regarding their research proposal. When a researcher-negative decision is being considered by the board, he or she must be supplied with all the reasons for why it is considering to do so, and the researcher must be given the chance to reply before a final decision is made (TCPS, Art. 1.9). In the U.S. and Canada, a researcher has the right to written communication of the board’s decision, including reasons for a decision to disapprove the study, and the researcher is entitled to seek reconsideration of the decision if he or she is unhappy with it (45 CFR, §46.109(d); TCPS, Arts. 1.9 and 1.10). Finally, in Canada, a researcher has a right of appeal to the institution’s internal appeal board if the researcher is dissatisfied with the reconsideration outcome (TCPS, Art. 1.11).

It would seem that the current process requirements in the U.S. and Canada give researchers an effective voice. What about research participants? Generally, the only persons who are given the opportunity to address research boards are the researchers whose studies are under review. Because the specific individuals who will ultimately be enrolled in a particular study – if it is approved – are typically unknown at the time of the review, this acts as an obvious impediment to airing their perspectives and interests before a decision is reached.

Any contention that the prospective participants’ right simply to refuse to participate in a board-approved study adequately compensates for their lack of voice would ring hollow. Consider the example of a study that employs a consent process which promotes therapeutic misconception (Dresser, 2002) on the part of participants. Participants who would not have enrolled in the research had they been properly informed that no benefits would actually accrue to them are unlikely to view their right of refusal to be meaningful.

A claim that the researchers, the research board membership, and board consultants, either alone or in combination, will necessarily lay bare participant interests and perspectives should also be resisted for the reasons set out below.

Researchers Cannot Be the Voice of Participants

Drawing on the controversial 1999 gene-therapy trial that led to the death of Jesse Gelsinger in the U.S. (Gelsinger, 2006), Dettweiler and Simon identify several lessons for research boards (Dettweiler and Simon, 2001). Included among them is a caution respecting researchers’ ability to achieve impartiality when assessing and communicating gene-therapy risks, even where they strive to act in the best interests of the participants/patients. Any expectations of impartiality on the part of researchers are unreasonable and unattainable as the participants’ “health is by definition not the primary focus of the research enterprise, and the compatibility of interests [between researchers and participants] is often compromised by hazardous uncertainties in gene therapy clinical trials.”

Just as impartiality cannot be expected when researchers communicate risks to participants, it would be naïve to expect neutral or interest-free communication by researchers to the very body that will decide whether they can proceed with the proposed study, either at all or at least as initially framed by the researchers. Researchers’ submissions to the board are, to be sure, a form of self-advocacy and this must always inform the weight that boards afford them. In light of the great potential for actual or perceived conflicts of interest between researchers and participants, it would be unwise to suggest that researchers can effectively advocate before research boards on behalf of participants. Of course, the idea that researchers can act as conduits for the expression of participants’ interests and perspectives presupposes that researchers are even aware of the various interests and perspectives that may be present in the pool from which they seek to draw participants for their studies. This knowledge may not exist and certainly cannot be presumed to exist.
The Research Board May Not Be an Effective Voice for Participants

The existing process requirements provide that the membership of the research board must include at least one person whose primary concerns are in nonscientific areas and an individual who is not affiliated with the institution. Knowledge of the local community is also required. However, knowledge of the local community, the absence of institutional affiliation – which frequently does not actually exist (McNeill, 1993) – and the lack of direct experience in a scientific area does not equate to competence in providing insight into the interests and perspectives of research participants. On this score, a 2000 Law Commission of Canada Study concluded that although “there are supposed to be ‘lay’ or ‘community’ representatives on many REBs, there is no requirement that lay representatives be knowledgeable about research subjects, let alone have been involved in research as subjects or as parts of groups that are often studied” (McDonald, 2000). The same observation is of equal application in the U.S. The Office for Human Research Protections (OHRP) furnishes examples in its IRB Guidebook of persons who fit the community member bill, with ministers, teachers, attorneys, business persons, and homemakers being among those listed. Interestingly, no reference is made to persons who would necessarily be knowledgeable about research participants.

Under the Common Rule, a board that regularly reviews research involving a vulnerable category of participants (e.g., children, pregnant women, or persons with mental disabilities) must consider including in its membership individuals who are knowledgeable about and experienced in working with these participants (45 CFR, §46.107). However, for the most part, this only applies to boards that regularly review such research and, where this is the case, the only thing required is that the board consider including one or more persons with the requisite knowledge and experience. Although there are two situations that require the inclusion of persons knowledgeable about certain participants under U.S. regulations (namely, research involving prisoners and research for a Department of Education program), these exceptions are of extremely limited application. As well, because the particular vulnerable population concerned can vary from study to study, it is unrealistic to think that boards will always have such representatives in their midst (Baren et al., 2005).

Even if research boards were required to appoint lay/noninstitutional members who are knowledgeable about research participants, this is far from a guarantee that participant voices will be heard. Pursuant to quorum rules, the attendance of such members at convened meetings is not mandatory (45 CFR, §46.108). Consequently, this member may not be at the table to put forward participant perspectives during a given meeting. In any event, attendance of this member would not mean that he or she would have an effective voice for a variety of reasons. The member may be afraid to take a “researcher unfriendly” position, particularly where the meeting environment is dominated by other board members who themselves are actively engaged in biomedical research at the institution (OIG, 1998). This apprehension may be fueled by assumptions that many of the board members have strong commitments to the productiveness of the institution’s research program and that they have close professional and/or personal relationships with the researcher whose proposal is under review.

Also, an imbalance of power between the scientist and lay members may exist that, in part, springs from an asymmetrical distribution of scientific knowledge between them. McNeill has observed that “non-research members of [research boards are] dependent on their research members for information about current research practices and the likely effect of the particular experimental interventions proposed” (McNeill, 1993) and may therefore be inclined to readily defer to the experts. The OHRP IRB Guidebook’s admonition that “nonaffiliated member(s) should not be vulnerable to intimidation by professionals on the IRB” appears to telegraph a concern about lay members being potentially strong-armed by
the research members. American and Australian studies have yielded evidence indicating that lay members play a less active and effective role than their scientist counterparts, “are seen as less important to [boards] in reaching their decisions” (McNeill, 1993), and do not effectively counterbalance institutional and scientific interests (OIG, 1998).

The presence of lawyers and ethicists on research boards does not ensure that the interests and perspectives of participants will be articulated. Their training allows them to speak to relevant legal standards and ethical principles, but this hardly qualifies them to address the specific concerns and viewpoints of research participants. Indeed, for at least a fair number of studies, their backgrounds, experiences, and socioeconomic status will not even approximate those of the individuals who will likely be enrolled as participants. Moreover, many legal and ethics members may also be affiliated with the research board’s host institution, thereby raising apprehensions about their independence.

Merely modifying the current rules regarding the composition of the voting board membership and the quorum rule for convened meetings by requiring a person knowledgeable about participants to serve on the board and to be present at all convened meetings would fall short of the mark of ensuring that participants’ interests and perspectives are heard. As already discussed, participant representatives could be marginalized or simply outvoted by the other board members. Perhaps these obstacles could be overcome if, as suggested by some (Waring and Lemmens, 2006; McNeill, 1993), research boards were required to contain equal numbers of science and participant-knowledgeable members. Nonetheless, other problems would endure.

Unlike participant representatives who would be given the chance to make vigorous representations under the alternative model that is proposed later in this article, board members of any stripe must assiduously guard against making comments or engaging in behavior that is incompatible with being perceived as impartial. This is so because impartiality (and the appearance of it) on the part of research boards is essential for stakeholder confidence in the research oversight system. The importance of research board impartiality finds expression in the regulatory instruments (TCPS, commentary under Art. 1.10; 45 CFR, §46.107(e)) and is emphasized in the OHRP’s IRB Guidebook, wherein it is stated that “the IRB must be and must be perceived to be fair and impartial...” I do not mean to suggest that appointing persons to the board because of their prior association with particular points of view or with health advocacy groups offends the impartiality requirement. In fact, some boards such as those that make labor relations decisions have persons in their folds with labor or management backgrounds so that differing perspectives can enrich the decision-making process. However, it is unlikely that participant-knowledgeable research board members could pursue an advocacy role with unfettered vigor as this may well depart from an acceptable threshold of impartiality.

I hasten to clarify that my position is not that the community member convention has universally failed and should be abandoned, though I do believe that action needs to be taken to make it more effective. What I am positing is that, even if this convention were made more robust, the current decision-making methodology would still need to be modified. Thus, the proposal put forth in the second half of the article ought to be regarded as being in addition to, not in replacement of, having community members serve on research boards.

**Existing Consultative Mechanisms Do Not Offer Sufficient Voice for Participants**

Mechanisms presently exist that allow research boards to invite individuals with competence in special areas (e.g., knowledge of a particular participant population) to assist in the review of issues which require expertise beyond that available on the board (45 CFR, §46.107; TCPS, Art. 1.3). Of course, in order for a board to be motivated to seek
appropriate consultation, it must be aware of its lack of competence in a particular area. Furthermore, should the board be aware of its limited understanding of a particular category of participants, it is not required to fill the knowledge gap since invitations to consult the board are, subject to the exception noted below, at its discretion. Indeed, it has been observed that outside expertise is not commonly sought by many boards (Coleman, 2003).

A noteworthy requirement for consultation with research participant representatives is set out in the FDA regulations. Under these regulations, researchers wishing an exemption from informed consent requirements for emergency research must satisfy a host of conditions. “Consultation (including, where appropriate, consultation carried out by the IRB) with representatives of the communities in which the clinical investigation will be conducted and from which the subjects will be drawn” as well as prior “public disclosure to [these communities]…of plans for the investigation and its risks and expected benefits” (21 CFR §50.24(a)(7)) form part of these conditions. This provision laudably reflects the pressing need to provide voice to participant communities (Baren and Fish, 2005; Lo, 2006) in order to “serve the important ethical purposes of promoting trust, ensuring justice, and protecting research participants” (Richardson et al., 2005). However, the provision has been criticized for: being ambiguous (i.e., it lacks definitions of “consultation” and “community representative” and is not clear about what researchers and research boards are to do with consultation results); requiring extensive time and effort; and impeding emergency research (Contant et al., 2006; Kremers, 1999). Some believe that best practice guidelines would alleviate these problems and that research is needed to verify assertions that the quality or quantity of emergency research has been negatively affected by the community consultation requirement (Ernst and Fish, 2005).

The consultation requirement for emergency research bears resemblance to the procedural mechanism that is recommended later in this article. However, my reform proposal is not as narrowly circumscribed (it extends beyond emergency research involving products regulated by the FDA where informed consent requirements will be waived), the role of the participant representative under my proposal is clearer, and these representatives would play a more direct and extensive role in the research oversight process.

Negative Consequences Arising from the Existing Decision-Making Model

The current decision-making model is problematic for a number of reasons, not the least of which is a reduced likelihood of achieving the primary objective of research boards. How can research boards protect the safety and well-being of participants if they do not have full and accurate information about participants’ interests and do not know what specific interests among the many they may have that the participants actually want protected? The existing procedural scheme hands researchers ample opportunities to influence the decision-makers in ways that advance their interests, yet there is great potential for participants’ voices to go unheard. Therefore, the door is wide open for unbalanced information to reach the board’s ears – a disturbing prospect since any decision-maker’s determinations are only as strong as the informational foundation on which they rest.

This situation is all the more alarming in view of the exceedingly low probability that ill-informed decision-making will be challenged. The present process allows for researchers to seek reconsideration of board decisions (and, in Canada, an internal appeal) if they feel aggrieved by a board decision and, possibly, to seek redress through the courts in respect of a research board operating within a public institution where the board violates procedural due process standards defined by American (Noah, 2004; Halikas v. The University of Minnesota, 1994) or Canadian (Hadskis and Carver, 2005) regulatory instruments. But, aside from individuals who may bring lawsuits after they sustain research-related injuries, who will respond to participant-negative board decisions?
Other significant consequences are possible. The process may be regarded as displaying a lack of respect for research participants by not incorporating sufficient measures to at least attempt to inform research boards of the potential interests and perspectives of the very persons who may be adversely affected, in the extreme, by board decisions. Heavily skewing the ethics review process in favor of researchers’ interests can engender public distrust in medical research, which in turn could diminish both the willingness of individuals to enroll in research and the public’s commitment to financially support it (Coleman, 2003).

An Alternative Approach
The remainder of this article will be devoted to outlining the basic framework for a modified decision-making methodology in the U.S. and Canada that would, where appropriate, allow individuals to advocate on behalf of prospective research participants before research boards render their decisions.

To facilitate discussion regarding the possible adoption of an alternative decision-making process, I propose the following wording for a procedural rule that could be incorporated within the existing regulatory instruments:

Research boards shall provide a reasonable opportunity to an appropriate representative of research participants to make submissions to the board, where such an opportunity is deemed warranted by the board. In those instances where a research participant representative makes submissions, the board shall provide written notification of its decision to the representative and give the representative an opportunity to respond in person or in writing.

This rule begs a number of questions: What role should participant representatives play? Who should be considered an "appropriate" representative? When should submissions from representatives be deemed warranted? What needs to be done to provide representatives with a reasonable opportunity to make submissions? Each question will be addressed in turn.

Role of Participant Representatives
Participant representatives would be charged with a number of functions including, most fundamentally, speaking to the core ethical issues associated with the research project under review from the perspective(s) of the community from which the participants will be drawn. Not only would they concern themselves with issues regarding the proper disclosure of possible harms, but would also potentially offer submissions on matters such as possible conflicts of interest on the part of researchers, the fair distribution of the benefits and burdens of the research, the balancing of the harms and benefits, and the ownership of study data.

The representative would define exactly what participants want protection from. It is a mistake for research boards to presume that they know the answer on this basic issue. Indeed some authors have noted that “protection may become ‘over-protection’” (McNeill, 1993), the peril being that paternalism on the part of research boards can lead to the exclusion of some segments of the population, such as women and children, from research that may benefit them personally or the groups to which they belong. Research boards would profit from participant representatives weighing in on the relevant communities’ perception of just how harmful they regard possible negative consequences of participation or their position on the conditions precedent for their acceptance of potential harms. Participant representatives would also be able to provide current information about a community’s attitude or attitudes toward certain types of research. The importance of this is demonstrated by the fluid nature of perspectives on the FDA’s accelerated approval program.
for antiretroviral drugs where some “HIV/AIDS activists have qualified their early enthusiasm for expanded access” (Waring and Lemmens, 2006).

Execution of the participant representatives’ role would entail thoroughly reviewing the information/documentation that researchers put before the board in order to determine its adequacy and accuracy. Critically, they would review the material in an effort to ascertain whether any other relevant information may exist; if so, representatives could request that boards obtain such (in many instances this would simply involve the board asking the researcher for the information, particularly when it is in the researcher’s possession or control) or, where appropriate, representatives could independently seek additional information. The importance to any decision-maker of having another person before them who will carefully review submissions and produce relevant material should not be underestimated. Overburdened research boards (OIG, 1998) should welcome the participation of others who are motivated to ensure that things are not missed through inadvertence.

In order to fulfill this role, representatives would need to receive the researcher’s written submissions to the board. However, this could raise confidentiality concerns on the part of some researchers and research sponsors. In some circumstances, measures including the removal of sensitive information from the researchers’ submissions (where this would not impair the ability to meaningfully respond to the submissions) or requiring research representatives to enter into agreements to maintain the confidentiality of these submissions could address these worries. Coleman, in answer to a related concern arising from a proposal he has advanced that calls for research boards to prepare written decisions and to make them available to the public, notes that “sponsors’ and investigators’ desire for confidentiality should not come at the expense of constructing an effective system for disseminating information that could facilitate better reviews.” He goes on to observe that confidentiality “should not be used as a shield to limit the public’s ability to participate in and oversee the decision-making process” (Coleman, 2003). I agree.

It is imperative that participant representatives not be cast in a role that necessarily pits them against researchers. Representatives should be at liberty to, in whole or in part, oppose or support the research project being reviewed by the board.

Where the representative is dissatisfied with the board’s decision, he or she would need to decide whether to pursue any of the possible remedies discussed earlier in this article. Representatives’ decisions to seek any such redress should, in appropriate instances, be made in consultation with members of the relevant participant community.

Participant representatives could also play an important role in ongoing studies. Research boards could facilitate this by requiring researchers to disclose the name and contact information of the representative to prospective participants during the recruitment process. Establishing a continuing line of communication between participants and participant representatives could result in timely information being given to the board by participant representatives in those cases where representatives receive notice of participants encountering significant problems during or after study participation. In essence, it would act as an informal mechanism for monitoring the safety and well-being of participants after studies are approved by research boards and would, in part, address concerns raised by the United States Office of Inspector General (OIG, 1998) and others (Morse et al., 2001; Weijer, 2001) about research boards having no or limited knowledge of what happens to participants after they are enrolled in studies.

In many respects, the role and authority of the representative would parallel that of the researcher. This is entirely apt. Neither individual would form part of the board’s membership and therefore would not have voting rights, but both would have the opportunity to influence the decision-maker by presenting information that is colored by
their differing perspectives, each would have the chance to respond to decisions for which they take issue, and both would play a role in post-approval safety monitoring.

Appropriate Representatives

Let me start by confessing that determinations as to who will qualify as an appropriate representative may sometimes be a very difficult undertaking for research boards. The difficulties boards would face could be mitigated by the development of selection guidelines, although criteria capable of definitively sorting out those individuals who are “appropriate” from those who are not would doubtlessly remain elusive. Most importantly, representatives would need to have sufficient knowledge of the relevant research participant community to allow them to speak meaningfully to the core issues that the research would raise for the community. This would demand knowledge of the interests and perspectives held by a significant portion of the community. It is appreciated that not all communities can be readily defined in terms of the characteristics they must share in order to “belong” to the community. Furthermore, even if a particular community is definable, homogeneity of perspective and opinion within the community is unlikely.

McNeill’s discourse on appointing participant representatives to research boards confronts such challenges. He argues that it is not unusual for the majority of studies that are reviewed by many boards to draw on a common, defined participant pool. This undoubtedly holds true for a great many hospital and university research boards that routinely deal with research that draws from patient and student pools, respectively. In those contexts, groups or bodies representing patients (e.g., patient advocates) or student associations could nominate representatives. Anticipating that sufficiently-defined communities may sometimes not exist, McNeill goes on to suggest that people from “broadly representative groups” could fulfill this role, such as participant advocacy groups (e.g., Alliance for Human Research Protection and Citizens for Responsible Care and Research), health care consumer organizations that represent the interests of persons with certain health conditions, or civil rights groups (McNeill). While some may find it hard to muster the same degree of optimism about always being able to locate suitable representatives as McNeill, there may well be many cases where representatives would be ready, willing, and able to take on a research participant advocacy role. In the context of the community consultation requirement for emergency research, commentators have noted that suitable community representatives can be selected from existing community organizations (Richardson et al., 2005; Baren and Fish, 2005) and community advisory boards, which are becoming quite common in research (Davis, 1998). Participant representatives under my proposal could be selected from among the ranks of such organizations.

Ideally, representatives would be directly accountable to the relevant research participant community, perhaps through a nominating process or a reporting obligation created by a relevant health care consumer organization. Drawing on McNeill’s work, Waring and Lemmens note that “community group affiliation is required to give participant representatives ‘some ground and support for their views’” (Waring and Lemmens, 2006). Whereas the presence of direct lines of accountability should weigh heavily in favor of allowing a representative to make submissions to the board, making it obligatory may be unduly restrictive. For example, a representative’s regular engagement in meaningful dialogue with members of the potential participant pool may suffice.

Another necessary criterion to be met in order for a representative to be deemed “appropriate” is the absence of an actual or reasonably perceived conflict between the interests of the participant community and the representative. Representation would be precluded where an association exists between the representative and the research institution, the researcher, or the sponsor of the research being proposed. Therefore, boards
would need to ask prospective representatives about such things as their funding sources in order to ensure that veiled associations do not exist.

There is no doubt that research boards would be faced with the sometimes trying task of identifying different representatives for different kinds of studies, and of deciding who should be given the chance to speak on behalf of a markedly heterogeneous participant community. Ultimately, a pragmatic standard for selecting representatives will need to be embraced. It should not be necessary for representatives to be able to speak on behalf of all constituents, nor should they be expected to be able to voice all possible perspectives. Boards should merely be required to ask themselves whether a representative can reasonably be expected to represent the views of a significant portion of the community on issues central to the review. It would be shortsighted to excuse boards from receiving the perspectives of non-researchers because an ideal research representative cannot be found, or because the task of selecting suitable representatives cannot be carried out with ease.

When to Receive Submissions from Research Representatives

It is not practical or advisable to simply throw the doors open to all who may want their views known to research boards respecting particular studies since allowing others to make submissions would increase the already sizeable administrative loads that many boards are presently shouldering (OIG, 1998), and would potentially slow the decision-making process. On the other hand, these concerns should not be permitted to eclipse the previously provided rationale for hearing from participant representatives in those cases where this is warranted. I suggest that participant representatives not be given the opportunity to address the board unless the particular study poses high risks for participants and the representative is likely to be able to provide relevant information. A few words about each of these preconditions are offered below.

High-risk research

Research representative participation should, at least initially, only be available for “high risk” studies. Research that carries a considerable risk of serious harm to participants would qualify. Gene-therapy studies (Marshall, 2000), stem cell research (Kimmelman, 2006), and some research on highly vulnerable populations (e.g., clinical drug trials involving persons with HIV/AIDS or cancer whose therapeutic options have been exhausted) could present such risks to participants.

Admittedly, my rationale for inclusion of participant representatives would support a lower threshold of risk. However, given that the alternative approach being proposed here represents a marked departure from the current process, it seems reasonable to start with the riskiest studies (perhaps as a pilot project at selected research institutions) and then, after a suitable trial period, determine the impacts of the approach. For instance, evidence could be gathered on how often appropriate representatives actually participated and, where they did so, viewpoints on the constructiveness of their engagement with the process could be sought from the relevant boards, researchers, and participant representatives. Other data would also be informative. Did their participation present an administrative burden? Did it create an adversarial climate? If after answering these and other questions the alternative approach appears useful and workable, consideration should be given to extending its application to less risky research.

Ability to provide relevant information

The representative must be positioned to furnish the research board with information relevant to the central issues raised by the study from the perspective of a significant portion of the participant community. Boards would need to be satisfied that it is more likely
than not that the person seeking to address the board can provide meaningful information – a judgment call to be sure, but one that may be made easier by requiring prospective representatives to provide the basis on which they are equipped to speak on behalf of the participant community. If after giving due consideration to a request to make representations the board determines that this would unlikely further the main objective of the review process, the board would be at liberty to deny the request.

Research boards may encounter situations where more than one appropriate representative asks for the chance to respond to a proposed research project. Unless boards are able to control the number of persons permitted to make submissions, the process could quickly become cumbersome. Consequently, research boards must be explicitly given the discretion to limit the number of representatives that can take part in the process in order to avoid duplication of information on the core issues raised by the research proposal, and to prevent the review process from becoming impracticable. In order to minimize the opportunity for boards to be criticized for favoring some representatives over others (perhaps on the alleged basis that the selected representatives are “researcher-friendly” or have been co-opted), boards should be required to make reasonable efforts to distribute submission opportunities across a roster of potentially appropriate representatives.

**Providing a Reasonable Opportunity to Make Submissions**

Research boards have control over information regarding the studies that are before them at any given time. This information is typically not within the public domain. For this reason, boards must bear responsibility for making reasonable efforts to facilitate participant representatives’ access to their decision-making processes. Boards may foster involvement of participant representatives by launching public information initiatives aimed at communicating the types of research studies they review and inviting persons and groups to provide them with a statement of interest in providing submissions on specific issues. Some representatives may then self-identify by advising the board of their knowledge and experience with particular participant communities and of their desire to be informed of opportunities to address studies that may impact such communities. Over time, boards may successfully generate and share rosters of participant representatives. Boards could also generate publicly-accessible electronic bulletin boards that would provide very brief descriptions of the “high risk” studies that have been submitted to them. Interested participant representatives could review such information and make study-specific requests to be heard.

Limited financial resources and/or training in research ethics and basic scientific concepts may act as access barriers for potential participant representatives. To remedy this problem, the OHRP could be required to provide needed financial support to representatives so that they could meaningfully pursue an advocacy role, which for some may mean securing adequate training in areas such as research ethics and research methodologies. Comprehensible, culturally appropriate, and unbiased education modules could be developed and distributed to relevant communities (Richardson et al., 2005).

Consideration would also need to be given to providing some measure of compensation to participant representatives for their contribution to the process or, at a minimum, reimbursing them for reasonably incurred expenses. Approaches to minimizing associated costs would need to be developed; for instance, research participants could file standard/generic submissions with the board on important, recurring issues and request that the board refer to them in apposite cases.

These suggestions will doubtlessly be decried by some as being implausible in an already financially-strapped research oversight system. I would rejoin by observing that the need to protect research participants is reason enough to find ways to foot the bill. It is difficult to
bring to mind another system “entrusted with life-or-death decisions [that] is dependent almost entirely on the efforts of unpaid volunteers” (Coleman, 2003).

Conclusion

It would seem incontrovertible that any decision-making body which bears the high charge of reviewing human research with the principal aim of protecting research participants must strive to ensure that the interests and perspectives of such persons are heard before critical decisions are made to approve the commencement of research. Yet, as argued in this article, research boards in the U.S. and Canada lack adequate procedural mechanisms to inform board members of participants’ interests and perspectives. This stands in stark contrast to the procedures currently entrenched in both countries to ensure that researchers are afforded full opportunity to sway research boards. Allowing participant representatives to also influence these decision-makers in appropriate circumstances is a potentially viable remedy for this systemic deficiency. It would increase the likelihood of achieving the primary mandate of research boards and would address the manifest unfairness of extending the opportunity to be heard to only one directly affected class of research stakeholders (researchers).

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Author

Michael R. Hadskis, B.Sc., LLB., LLM, is Assistant Professor of Law at Dalhousie University. Contact him at 1.902.494.2534 or michael.hadskis@dal.ca.