

RESEARCH ETHICS

Factors influencing the effectiveness of research ethics committees

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J Med Ethics 2007;33:294–301. doi: 10.1136/jme.2005.015057

Research ethics committees—animal ethics committees (AECs) for animal-based research and institutional research boards (IRBs) for human subjects—have a key role in research governance, but there has been little study of the factors influencing their effectiveness. The objectives of this study were to examine how the effectiveness of a research ethics committee is influenced by committee composition and dynamics, recruitment of members, workload, participation level and member turnover. As a model, 28 members of AECs at four universities in western Canada were interviewed. Committees were selected to represent variation in the number and type of protocols reviewed, and participants were selected to include different types of committee members. We found that a bias towards institutional or scientific interests may result from (1) a preponderance of institutional and scientist members, (2) an intimidating atmosphere for community members and other minority members, (3) recruitment of community members who are affiliated with the institution and (4) members joining for reasons other than to fulfil the committee mandate. Thoroughness of protocol review may be influenced by heavy workloads, type of review process and lack of full committee participation. These results, together with results from the literature on research ethics committees, suggested potential ways to improve the effectiveness of research ethics committees.

been conducted on these topics, although a few studies have identified concerns about committee composition,^{1–3} the role of community members^{2–5} and heavy workloads.⁶

This ethnographic study used four AECs as a model to identify structural and procedural factors (committee composition and dynamics, member recruitment, motivation for joining, workload and participation levels) that may influence the effectiveness of the protocol review process. We define effectiveness as achieving the mandate of the committee to protect research subjects. This includes meeting procedural standards of committee independence, broad expertise, sufficient depth of review, commitment of members to the mandate, and fair and respectful committee discussion. The research identified problems for AECs and, partly through additional analysis of the literature, suggested possible remedies for both AEC and IRB functioning.

METHOD

We interviewed 28 members of AECs at four universities in western Canada between 2001 and 2002 to learn about a range of experiences, so committees were selected to represent variation in the number and type of protocols reviewed. All committees reviewed proposals for biomedical research, teaching and product testing; some also covered biological, wildlife, agricultural and veterinary research. All committees reviewed a mixture of protocol severity levels. Where possible, participants were selected to include the different types of committee members at each university. Participants (11 women, 17 men) were voting members and included 6 community representatives, 13 university scientists experienced in animal research, 4 university animal-care technicians, 3 university veterinarians and 2 university non-animal users. Participants included one current chairperson and two former chairs.

An ethnographic approach was used to gain understanding of the AEC protocol review process from the perspective of their members. Thus, CAS interviewed most (13) committee members from University A where CAS was a participant observer,⁷ serving as the student member from September 2000 to April 2003. This allowed her to take advantage of the relationships and trust she had developed with these members. These members acted as “key informants”⁷ to help shape the direction of the research. The sample included at least one of each type of member at the

Abbreviations: AEC, animal ethics committee; IRB, institutional research board

Since the 1960s, research ethics committees are being widely used in research governance for the protection of research subjects. Committees include animal ethics committees (AECs) for research using animals and institutional review boards (IRBs) for research on human subjects. These two models have many similarities in their function, structure and processes, and insights into improved research governance can be gained from both. Understanding how AECs and IRBs function is essential for identifying problems and suggesting possible improvements in research governance.

A major responsibility of these committees is to review proposed research protocols. Decisions during protocol review are influenced by policy and guidelines, institutional culture and by the views, values and decision-making processes of individual members. Aspects of committee structure and process—committee composition, deliberation process, group dynamics and training—can also affect decisions. Little empirical research has

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Received 7 November 2005
Revised 1 April 2006
Accepted 6 April 2006

remaining universities, although only two committees included non-animal users and only three included animal technicians as voting members. Participants were recruited through the Director of Animal Care at each university.

Interviews were semistructured and lasted 'on average' 1.3 (range 1–2.25) h. Interviews were taperecorded and transcribed verbatim. Questions were open-ended and allowed members to reflect and elaborate on points that they considered to be important. CAS had a list of interview questions based on two major themes (evaluation of protocols, and committee structure and process). Most participants answered all questions in the same sequence, but given that the interviews were semistructured and participant driven, this was not always the case. Interviews began with factual questions on how and when members joined the committee, how they were trained, what was the typical meeting format, how long they prepared for meetings, what was the typical length of meetings, whether they thought the workload was reasonable and whether there was adequate time to review protocols during a committee meeting. Members were then invited to talk about how they reviewed and evaluated protocols (not discussed in this paper). Interviews concluded with questions on committee composition ("How well balanced is the committee in terms of expertise?"), the role of the chairperson, their personal experiences as a member ("Are your concerns adequately addressed or acknowledged?") and how interpersonal dynamics change at meetings. To document institutional variations in AEC decision-making, CAS observed one committee meeting at each university.

Transcript data were analysed and interpreted using a system of inductive coding.^{8–10} Possible interpretations of data, relationships between codes and emerging themes were noted. On completion of analysis, results were sent to participants for comment. A separate paper (in preparation) examines how the decision-making processes of members affect committee effectiveness.

The Behavioural Research Ethics Board at University A approved the study. Pseudonyms for participants were used in field notes and interviews to ensure anonymity and confidentiality, and all participants gave informed consent. In this paper, participants are identified with codes beginning with letters representing their group (C, community member; N, non-animal user; S, scientist; T, technician; V, veterinarian).

FINDINGS

Committee composition

Committees varied from 7 to 17 voting members (table 1). All committees were similar in composition, with scientists being the majority (3–10) of the voting members, followed by animal technicians (0–4), student members (1–2), community representatives (1–2), veterinarians (0–1) and non-animal users (0–1). Of the four current chairs, three were scientists and one was a non-animal user.

Although members generally reported having sufficient expertise on their committee, several expressed concern that the preponderance of scientist members could affect committee function. In particular, although all committees made decisions by consensus,¹ there was concern that community members would carry little weight in discussion because they were outnumbered by affiliated and mostly scientist members. One animal technician (T3) stated that her committee "lacked a layman's voice" because of such an imbalance, and one community member (C2) expressed doubt that her single opinion would carry weight. On the other hand, one scientist member (S10) considered that community members have considerable influence, noting a protocol that was rejected by an AEC because the single community member dissented.

Committee dynamics

Most members reported being content with their committee atmosphere, that their views were valued and that group dynamics were comfortable and respectful. However, two of six community members (C2 and C6) reported negative experiences with other participants, and three (C4, C5 and C6) commented that they found the committee atmosphere intimidating at first, although this decreased with time for two members. Common problems were feeling intimidated by scientists (although this was not seen as intentional), being perceived as having insufficient expertise, the difficulties of being an "outsider" and a perceived lack of appreciation for their contribution. Given the preponderance of scientist members, committee discussion often centred on technical issues that fell outside the expertise of non-scientists. Nonetheless, in committee B, all members believed that one of their community members had a strong influence on the substance of committee discussion. A non-animal user (N2) supported the view that community members can play a valuable part in posing the "obvious" and "unsophisticated" questions.

Another minority member (T2) had felt that her opinion was discounted by the rest of the committee and was "not 100% confident" that her concerns were passed on to the investigator. However, a second technician (T4) thought that support from the AEC gave him authority to request changes to animal care in the workplace, where he felt his opinions were often discounted by researchers with "doctorates".

Three members (T3, C2 and C5) believed that a less intimidating atmosphere for community members could be achieved by appointing more such members.ⁱⁱ They also noted the importance of choosing community members with appropriate confidence and outgoing personalities to ensure their voices are heard. One community member (C6) thought that she would benefit from being able to discuss issues with other community members, perhaps through a mentor system or "chat group" for community members from different committees.

Generally, members saw the chairperson as particularly important in keeping the meetings efficient, maintaining an open and respectful atmosphere where all views are accepted, having a neutral role by participating in the discussion without influencing decisions, ensuring that issues are not missed, keeping the investigator's interests in mind and helping the committee to reach a consensus. Only at University B was the chairperson a roughly equal participant in discussion and decision-making, and members thought this worked well. The single institutional non-scientist chairperson (N1) stated that the chairperson should have an arm's-length relationship with the committee and institutional scientists. Five members (S1, S11, V2, N1 and C2) commented that every member, regardless of whether he or she is the chairperson, can influence committee functioning, both positively and negatively.

Recruitment of members and motivation for joining

University administrators, such as the vice president of research, were formally responsible for appointing members, but the committees themselves tended to put names forward. Traditionally, all four universities recruited a representative from each university department that used animals for

ⁱOne committee's policy stated that decisions were to be made by majority vote. However, committee members reported making decisions by consensus.

ⁱⁱIn Canada, the Canadian Council on Animal Care¹¹ requires that the AEC includes "at least one person representing community interests and concerns, and who has no affiliation with the institution".

Table 1 Number of protocols reviewed per meeting and per year between 1999 and 2001, and composition and size of animal ethics committees from four universities in western Canada

Feature	University			
	A	B	C	D
Protocols reviewed per meeting (range)	6–34	0–4	10–32	15–49
Protocols reviewed per year (range)	239–267	7–19	173–203	309–313
Type of member				
Scientist	10*	3	10*	5*
Animal technician	2	1†	4	1
Non-animal user	0	1*	0	1
Veterinarian	1†	1	1	2‡
Student	1	1†	1	2
Community	2	2	1	2
Total voting members (2002)	15	7	17	12

*Chairperson of committee is from this group.

†Ex-officio and non-voting members.

‡One veterinarian was an ex-officio and non-voting member.

research. In all, 9 of 13 scientists were nominated by their departments and 2 were nominated by an AEC member; 4 of 6 community members were recruited as friends, relatives or neighbours of committee members or animal-care staff. Two community members (C2 and C5) noted that recruitment of community members was challenging, because the institution may be sensitive to drawing attention to its animal research activities. By contrast, two community members were recruited through a local animal protection organisation. One of those members opposed all use of animals in research, but other members (N1, V1, S10 and C4) reported that he was an active and well-respected contributor to meetings. In fact, this community member reported that he volunteered because he thought that he could make a contribution to implementing the Three Rs (widely accepted utilitarian rules of the thumb for minimising suffering of research animals).¹² He also said that he did not “obstruct” the consensus-based decision-making process of his committee.

Five members volunteered to join the committee because they were unhappy about some aspect of the AEC protocol review process and were hoping to change it. These included two animal technicians (T1 and T2) who thought that the AEC was not scrutinising protocols sufficiently, and three animal users (S7, S4 and S12) who reported previous frustration with the AEC and wanted to find out how the process worked or to “make sure that they [the AEC] don’t overdo it”. Several comments by scientists suggested that they viewed their role as representing their departments, to ensure the process was fair to them or to “feel that someone is in there fighting for your corner, or at least representing your corner” (S10). One scientist (S2) was nominated by the university veterinarian because he was perceived, in his own words, to be a “complainer” who thought that the AEC protocol review process was bureaucratic and wasted time, and it was felt that “the best way to get complainers to engage is to get them on the committee”.

Workload and participation

All committees typically had one meeting per month. From 1999 to 2001, they reviewed an average of 18 (range 0–49) protocols per meeting and an average of 191 (range 7–313) protocols per year (table 1). Apart from University B (where all members read all protocols), protocols were assigned for detailed review to two members who obtained any necessary information and presented a summary to the committee. The

chairperson, veterinarian and community member were also responsible for reading all protocols in detail. In preparation for meetings, most other members briefly scanned protocols that were not assigned to them by reading titles and lay summaries, scanning for anything that “stood out”, reading protocols that were more invasive, or written by “problem” investigators, or ones for which they thought they had specific expertise. One community member (C2) did not read the procedures section because she believed she did not sufficiently understand the technical aspects. Several members from two different committees (C2, S1 and S12) deferred their review of minimally invasive protocols to meeting times and they felt able to keep up with discussion.

Members expressed concern about the effect of member absence on this type of review process. One scientist (S1) noted that the two members assigned to a protocol were sometimes absent from the meeting and provided the committee with only a written submission or none at all. Another scientist (S7) suggested that her AEC be expanded to compensate for frequent absenteeism among scientists.

Members also voiced concerns that committee discussion was influenced by variable attendance at meetings. An animal technician (T2) and a scientist (S1) thought that a sizeable attendance was necessary for discussion and effective review, and one veterinarian (V2) believed that “face-to-face” discussion was essential for thorough review. On the other hand, one scientist (S3) thought that his committee worked more slowly because his committee (of 15) had expanded.

In general, those who read all protocols in detail spent more total time preparing for the meetings but less time per protocol than those who read only their assigned protocols in detail (table 2). For community members who read all protocols in detail, preparation time ranged from 0.75 to 8 h or from 4 to 60 min per protocol; two of these members had a small workload (average one protocol per meeting), and a third reviewed protocols briefly (4 min per protocol), mainly to check “how the form is filled out, or things that are missing”. Although policy required that community members read all protocols, one did not. Chairs (S1, S6 and N1) spent 6–10 h in preparation (not included in table 2).

Despite the variation in preparation time, when asked, all members except one scientist (S8) reported that they had enough preparation time to do the job well. S8 spent 2–3 h preparing, and thought that he was rushing. Thus, members differed widely in the preparation time they considered to be sufficient.

Turnover

Length of membership averaged 6.5 (range 0.5–25) years. Normally, committees allowed either 2-year or 3-year renewable terms, but all universities had at least two members who

Table 2 Reported time spent in preparation for monthly animal ethics committee meetings

Type of member	Preparation time	
	Hours spent per meeting	Minutes spent per protocol
Read all protocols in detail	6.7 (0.75–9.0)	23 (4–60)
Read several protocols in detail	3.0 (0.75–7.0)	45 (21–150)

Values are median (range).

Committee members who read all protocols in detail include 3 animal technicians, 2 veterinarians and 4 community members.

Committee members who read several protocols in detail and scanned the remainder include 10 scientists, 1 animal technician, 1 non-animal user and 1 community member.

Chairs are not included.

served longer than two terms. University B nominally limited members to a maximum of 4 years, although one non-animal user had served for 22 years. Three members (T2, C2 and C6) commented on the importance of turnover. An animal technician (T2) noted: "There is dead weight on there. There's people who never come to the meetings, so why are they on it? ... There are people who just sit around and don't say anything." One community member (C2) felt that she needed to quit after 6 years to maintain a "lay" perspective.

DISCUSSION

Many of the fundamental ethical issues and principles in research on animals are similar to those for research on humans. In both cases, the governance system assumes that research is acceptable if it benefits humans or animals, or advances knowledge, as long as the work is achieved in an ethically appropriate manner; this included meeting substantive standards related to potential harm, benefit and social value, as well as procedural standards such as independent ethical review. Procedural and structural requirements for IRBs and AECs are also quite similar. Committee membership varies with the needs of each institution, but usually includes institutional researchers, other institutional members (legal experts on IRBs and veterinarians, and animal-care staff on AECs) and community members. Committees of both types are required or encouraged to meet regularly for face-to-face meetings to review protocols. Decisions are based (at least nominally) on a proportionate harm-benefit analysis, and a process of expedited review exists for protocols of no more than minimal risk (referred to as lower categories of invasiveness for animals). Because of these similarities, we will discuss the results with respect to both AECs and IRBs.

Participants in this study identified six potential problems in the structure and process of AECs. For each problem, review of the AEC and IRB literature helped to clarify the issues and suggest possible solutions (table 3). As the study includes few committees, it is impossible to know how widespread the problems are, but the literature on AECs and IRBs shows that similar problems have been found elsewhere. The proposed solutions in table 3 represent a mixture of common-sense ideas, solutions proposed by study participants and solutions gleaned from the literature on AECs, IRBs and group deliberation.

Problem 1. Committee composition creates bias towards institutional or research interests versus interests of research subjects and the community

The committees in this study were similar in size and composition to AECs¹³ and IRBs in the US,¹⁴ with scientists and institutional members dominating the membership, compared with one or two community representatives. At least one community member is generally required for both AECs and IRBs in Canada^{11 15} and in the US,^{16 17} and for AECs in the UK.^{18, iii} In contrast, the UK requires one third community members on IRBs.¹⁹ For AECs, Sweden requires an equal number of scientists and community members, including one third animal welfare representatives,²⁰ and Germany requires one third animal welfare representatives.²¹

Various critics have claimed that an imbalance in membership in favour of researchers and other institutional members biases the process towards the interests of researchers versus the interests of research subjects. As in this study, community members from ethics committees have reported feeling that they had limited power because they were outnumbered, especially in majority vote systems.^{2 22 23} However, even in Germany, where animal protection members made up one third

of AEC membership, most of these members thought that committees were unduly allied with the institution.²⁴ Adding to the potential bias is that chairs are often institutional scientists in AECs² (as in this study) and in IRBs.¹

Research on group deliberation in other settings has shown how social influence affects decisions. These include "polarisation" (whereby initial views of individual group members become more aligned in the attitudinal direction favoured before group interaction and discussion²⁵) and "groupthink" (the concurrence-seeking tendency of moderately or highly cohesive groups²⁶). Both processes may be occurring in ethics committee deliberation. These processes may be problematic if they lead to incomplete review of protocols, where not all views and relevant information are considered. Mechanisms that have been proposed to explain these processes include informational,²⁷ normative²⁸ and self-categorisation^{29 30} influence, and research in these areas points to factors that may negatively influence the review process by an ethics committee. For example, group composition and member status (see the next section) have been identified, and both might be particularly relevant to challenges faced by community members.

Conformity to group judgements is sometimes influenced by the number of "compatriots" (like-minded people), such that people are less likely to make decisions independent of group judgements when they are alone with no others who agree with their views.³¹ In addition, discussions in groups of members who share an identity—researchers or institutional members in this case—are more likely to result in more extreme group polarisation and suppression of dissent.^{29 32} Both cases may marginalise the views of community members. However, when groups have equal proportions of members with opposing opinions, convergence rather than polarisation can occur.³³ Thus, it seems that attention needs to be paid to composition to avoid processes that may result in biasing the committee by excluding the views of some members. One solution is to increase the number of community members so that they can become more effective contributors in group discussion. Awareness of these pitfalls might also improve committee decision-making.

Other possible solutions are to move to greater independence from the institution—for example, by using regional committees as in Sweden,²⁰ choosing a chairperson who is not an institutional scientist or increasing the proportion of research subject advocates. A related solution would be to increase participation of non-institutional members at meetings through improved committee dynamics as discussed later.

Choice of decision rule will also be important. Consensus might be preferred to a voting system, so that the majority does not rule. However, a requirement for unanimity may produce a shift towards the most extreme points.³⁴ Therefore, a consensus-based decision rule with some allowance for dissent might be preferable.

The preponderance of institutional scientist members was partly because all four committees traditionally included a member from each university department that used animals. Hence, committee composition was partly a byproduct of an attempt to achieve representation in the institution. However, this may not produce the ideal composition for achieving the committee's mandate. A clear consensus and policy on the function of the committee could help to clarify the most appropriate membership structure.

Problem 2. Committee dynamics prevent full participation of members

Effective protocol review may be hampered if some members fail to participate fully because of feelings of intimidation or

ⁱⁱⁱIn the UK, face-to-face meetings may not be necessary in ethical review processes, but a regular deliberation of committee members is required.¹⁸

Table 3 Checklist of potential procedural and compositional problems of research ethics committees, and possible solutions

Problem 1. Committee composition creates a bias towards institutional or research interests versus interests of research subjects and the community

Solutions:

- Increase the number of community members
- Make committees aware of problems of group deliberation, such as polarisation, concurrence-seeking tendency and suppression of dissent
- Use a committee that it is not affiliated with the institution
- Choose a chairperson who is not an institutional scientist
- Increase the number of research subject advocates
- Use a consensus approach for decision-making but without a requirement for unanimity to allow for dissent by clarifying functions expected of the committee and designing composition accordingly

Problem 2. Committee dynamics prevent full participation of members

Solutions:

- Increase the proportion of minority members to reduce feelings of isolation or intimidation
- Recruit animal technicians who do not work for other committee members
- Provide respectful and open committee atmosphere so that members do not feel intimidated and feel their views are valued. Could be achieved by
 - Clarifying policy on the roles of minority members, particularly community members
 - Training members on the roles of minority members so that their distinctive contributions are valued
 - Training members on the mandate of the committee
 - Providing leadership training for the chairperson to ensure all information and views are considered
- Appoint members to serve as devil's advocate to challenge majority views and prevent "groupthink"

Problem 3. Recruitment methods create a bias towards institutional or research interests versus interests of research subjects and the community

Solutions:

- Recruit community members who are fully independent of the institution by
 - Advertising broadly for members
 - Approaching community organisations for nominations
 - Establishing an intake interview process that is independent from the committee
- Recruiting members from animal protection or patient advocate groups
- Reducing barriers to joining by providing an honorarium or by recruiting from organisations that recognise volunteer work by their employees

Problem 4. Motivation for joining is to pursue agendas other than the committee mandate

Solutions:

- Consider applications from all people interested in joining, to avoid excluding important views
- Achieve a greater balance in the proportion of different types of members, so that no one perspective dominates
- Ensure, perhaps through interviews, that all prospective members know and accept the mandate of the committee

Problem 5. Excessive workload or inadequate participation for adequate review

Solutions:

- Establish realistic level of time commitment per member and design committee functioning to stay within this limit
- Form another committee to share the workload or divide workload between members
- Develop an expedited review process for proposals of minimal risk or invasiveness
- Ensure prospective members agree to the required time commitment including meetings, preparation and training
- Monitor and limit absenteeism
- Increase committee size to allow members time off
- Ensure that the institution rewards participation of committee members—for example, provide honorarium

Problem 6. Low turnover limiting new ideas and risk of indoctrination

Solutions:

- Limit term in office
- Reassess contributions of members on renewal of their term

isolation, problematic power dynamics or poor leadership by the chairperson.

As in this study, a survey of US AEC community members showed that only a minority felt intimidated by other members.⁴ Nonetheless, some community members report experiencing hostility from other committee members and lack of respect for, or recognition of, their concerns, both on AECs^{2 4 22 24 35} (in this study) and IRBs.^{3 5} The proportion of community and minority members that would be needed to reduce feelings of intimidation has not been studied, although this study and research on group deliberation (see previous section) suggest that more than one community member is desirable.

A clear and shared understanding of the role of the community members is required for their effective participation.^{5 36} Unfortunately, policy on their role is generally

vague^{15–18 37} and diverse views have been proposed.^{2 3 22 35 36 38} These fall into the following seven categories. Community members should

1. provide a perspective that is independent of institutional and research agendas;
2. provide a broad perspective to committee discussion and decision-making, which includes public input;
3. serve as a reminder of the outside world;
4. help ensure the integrity of the process by making research institutions more open and accountable to the public;
5. provide an interface between the institution and the general public;
6. protect research subject interests; and

7. raise ethical issues and thus make scientists more reflective about their work.

Unlike categories 1–4, categories 5–7 might require choosing people with particular skills or connections. Overall, given the vagueness in policies (particularly in Canada, the US and the UK) and the variety of interpretations found in the literature, it seems that further clarification and consensus about the role of the community members could be helpful in designing an appropriate committee and creating realistic expectations for them. Increasing their number would reduce the need for individual members to meet the excessively diverse expectations of their role.

Members in this study and several authors^{2 3 36} suggest that a confident and outgoing personality in a community member helps to overcome problems of intimidation and facilitate effective community membership. However, it seems unsatisfactory if an extraordinary personality is required for a community member to be effective.

Inadequate participation by other minority members, such as animal technicians, is also a concern. Some animal technicians may be employed by investigators who may themselves be members; this can introduce a power dynamic that may hinder open participation.³⁹ Other non-scientist members may face similar challenges, and even scientists may be reluctant to raise objections to protocols of their colleagues. Membership by other institutional minority members could provide views different from those of scientists. Therefore, the appropriate proportion for all these members should also be considered. In healthcare, participants in heterogeneous groups often give least weight to the views of low-status members such as nurses.⁴⁰ Community members and animal technicians might fall into the category of low-status members, because they may have less training than scientists or because they are outsiders.

Adjusting composition is not likely to solve all these problems. Other solutions include providing a respectful and open committee atmosphere so that members do not feel intimidated and feel that their views are valued. This could be achieved by providing specific training to members on their roles, which might help to clarify the distinctive contributions expected of non-scientist members so that their participation is more valued. In some cases, better understanding of the official mandate of the committee may provide weight to arguments by non-scientists—for example, by enabling minority members to frame their arguments in terms of committee policy such as the Three Rs of Russell and Burch.¹²

The style of leadership is also important because a forceful chairperson can control discussion and discourage frank debate.⁴¹ However, skilled chairs can improve the committee atmosphere by encouraging all members to voice their concerns so they are less likely to feel isolated or overwhelmed, and by preventing individual members from dominating discussion. They can also help to overcome feelings of apprehension, which may prevent members from expressing their fundamental ethical views.⁴² Therefore, training the chairperson might improve committee functioning.

Creating an open atmosphere where all views are respected will also help to prevent “groupthink”.²⁶ The chairperson also has an essential role in integrating all information from all members to offset the tendency for the group to focus on shared information.⁴⁰ Another solution is to assign the role of devil’s advocate to one or two members to ensure that views are challenged.⁴¹

Problem 3. Recruitment methods create a bias towards institutional or research interests versus interests of research subjects and the community

Recruiting new members through word of mouth is a common strategy,^{2 43} but it runs the risk of recruiting members who are

perceived and motivated to “fit in” with the committee and their views, perhaps to the exclusion of other views. Recruiting friends or relatives as community members also reduces the arm’s-length relationship between institutional and community members, and raises the issue of whether community members are truly acting independently of the institution. In this situation, community members may not feel at ease to criticise their friend’s institution or they may accept their friend’s views, without truly bringing a community view. However, familiarity with another member may also provide an opportunity for members to discuss concerns outside meetings, especially for members who may be reluctant to bring up certain concerns in a meeting.

To achieve broad representation and independence from the institution and research agendas, committees could broaden their search for new members. Generally, the community has no say in who represents it; this makes it difficult to claim that the community members really represent community interests. Ways to engage the community in choosing a representative are approaching community organisations for nominations or advertising, through organisations or local media, followed by an interview, as is done in Australia and New Zealand.⁴⁴ This process could include publishing the mandate of the committee and inviting applications from those who accept and want to further the mandate. The interviews could be structured to gain an understanding of the applicant’s motivations and commitment. Committee members (including the current community member) could participate in the interview process. Alternatively, the nomination procedure could be removed further from the committee’s control. For example, a university could establish nomination and interview procedures that include people who are external to the ethics committees and possibly the institution itself. Recruiting members from animal protection or patient advocacy groups will also promote the interests of research subjects.

Recruitment of suitable members may also be limited by practical barriers. Many potential members may be unable to serve because of their employment, demands of child care and so on. The potential pool of participants might be increased by an honorarium or by recruiting from organisations that recognise volunteer work by their employees. Further investigation on what barriers exist would be helpful.

Problem 4. Motivation for joining is to pursue agendas other than the committee mandate

Committee effectiveness may be reduced if members join for reasons other than to promote the committee mandate. This could happen in two ways. First, animal rights advocates on AECs could oppose all research, not participate in discussion^{2 43 45} or use confidential information in a subversive manner. In reality, in this study and another,⁴³ a committee member who opposed animal research proved not to create these problems. Finsen⁴⁵ suggested that excluding the abolitionist perspective on AECs insulates committees from philosophically confronting an important perspective. Thus, committees should consider applications from all people interested in joining to avoid excluding important views. A second and perhaps a more relevant concern is that some scientist members in this study joined to promote their own or their department’s agendas, particularly to limit the committee’s actions. A better balance in composition on the committee might mitigate concern over people unduly influencing decisions.

For all types of members, the primary criterion for membership should be to support the committee in fulfilling its mandate. Although mandates may vary, in general they all include the aim of protecting research subjects via substantive and procedural standards. For all prospective committee

members, interviews could be used to help screen out community, scientist or other potential members who are seeking membership to pursue goals others than the committee mandate.

Problem 5. Excessive workload or inadequate participation for adequate review

Three of the committees in this study reviewed about three times as many protocols per meeting and per year than many AECs in the US (<100 per year for 70% of Institutional Animal Care and Use Committees¹³) and than AECs in Germany (72 per year²⁴), and similar numbers to an IRB in the UK (302 per year⁶). However, some universities review many more (>500 per year^{13 46}).

Concern about the workload of committee members is common,^{46 47} but little information is available about actual workloads. In this study, estimates of preparation time per protocol indicated a degree of trade-off between time spent per protocol and the number of protocols reviewed. Comments in this study raise the question of whether protocols are receiving ample review by people with different views and expertise.

Some upper limit probably exists to what members are willing or able to invest, and the level of attention to protocol review probably varies depending on workload. Hence, consensus is needed on what constitutes a realistic commitment of time and effort, and committee functioning needs to be tailored so as not to exceed that level. If the workload exceeds realistic expectations, a committee could divide the protocols between members (risking no or little review by the remaining members, as was the case in this study) or the institution can increase the number of committees to compensate for increased workload (with the challenge of recruiting enough volunteers). Expedited review, whereby one or a few members of the committee review proposals of minimal risk or invasiveness, can be used to save time.

Some AEC members in this study were not adequately fulfilling their role as reviewers: some members were regularly absent from meetings, some reviewers did not review their assigned protocols and some members were satisfied with spending relatively small amounts of preparation time. Lack of participation by members may lead to a less thorough review of protocols, because there will be less discussion and fewer members participating. Similar to solutions for recruitment, when members are nominated to join the committee, all members need to support a clearly articulated mandate of the committee. Possible solutions are ensuring that prospective members agree to the required time commitment including meetings, preparation and training; monitoring and limiting absenteeism; increasing numbers of members to make up for those who cannot attend on occasion; increasing the recognition given to committee members by the institution so that they can devote the necessary time to committee work; and offering an honorarium to compensate for lost time.

Problem 6. Low turnover limiting new ideas and risk of indoctrination

Low turnover may stifle the introduction of new ideas through new membership, limit the possibility of new volunteer membership and increase the risk of indoctrination. Thus there might be a trade-off between the length of membership needed to train members and a reduction in new ideas or challenges to the committee's views. To avoid these problems, committees could limit the terms of office for its members, or at least reassess the contributions of members before renewing a term. Bradshaw⁴⁴ suggested limiting terms of office of community members to 3–4 years.

CONCLUSIONS

This study identified aspects of committee composition, dynamics, recruitment methods, motivation for joining, workload and member turnover as factors that could influence the effectiveness of research ethics committees. For each of these areas, possible ways of improving committee functioning were identified. The findings provide a framework that would assist AECs and IRBs to reflect on their own effectiveness and select possible improvements. The findings also provide a basis for developing standards for performance assessment of committees by oversight bodies, which is important to assure quality and performance of a system for protection of research subjects.

One of the assumptions for the creation of research ethics committees is that decisions made by groups are superior to those made by individuals. Research in this area and results from this study have pointed to some potential shortcomings of group decision-making³⁴—committee structure, social influences and recruitment processes leading to biases or polarisation—all of which call the assumption into question. Testing whether these processes actually occur would provide valuable insight in improving ethical review processes.

ACKNOWLEDGEMENTS

We thank the members of the animal ethics committee who generously donated their time as participants in this study; the directors of animal care at each university who helped recruit participants; the members of the committee on which CAS served; Dr Fern Brunger and Dr Susan Cox who provided guidance on the design of the study and on data analysis; and Mary Dearden, Terry Dennis, Harold Herzog, James Love, Lynn Macdonald, Michael McDonald, Colleen Myers, Loekie van der Wal and Dan Weary for input and assistance.

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Funding: This research was funded by The International Foundation for Ethical Research (IFER) through a postgraduate fellowship; by the UBC Animal Welfare Program that is funded by the Natural Sciences and Engineering Research Council of Canada; the BCSPCA; the BC Veterinary Medical Association; and other sponsors listed on the programme website at www.landfood.ubc.ca/animalwelfare/. The sponsors had no role in the study design; in the collection, analysis and interpretation of data; in writing of the report; and in the decision to submit the paper for publication.

Competing interests: None.

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