



Ethical Review of the Use of Animals in Research: A Reflection on the Journey

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Summary

It is nearly forty years since the first committees were established to review the ethical acceptability of research using animals. Modelled on comparable committees concerned with human subjects, the establishment of animal ethical review committees recognized that such activities presented ethical challenges and that, given the level of controversy in the wider community, scientists needed to demonstrate responsibility and accountability for their actions. These committees now have been established in many countries, albeit with differences in their charter and standing; in some countries, the role of the committee is mandated in legislation.

There have been few reviews into the operation of animal ethical review committees, but available evidence raises questions as to the outcomes of the ethical review process and effective engagement with the wider community.

The ethical review process would be strengthened by reflection upon and reaffirmation of expected goals and a better understanding and recognition of the broader context within which a committee operates.

Keywords: ethical review, animal research, committee processes, social context

1 Introduction

It is nearly forty years since the first committees were established to review the ethical acceptability of research using animals. Drivers for the establishment of these committees were the recognition that such activities presented ethical challenges and that, given the level of controversy in the wider community, scientists needed to demonstrate responsibility and accountability for their actions. There are some parallels in the establishment of these committees with human research ethics committees, which have been integral to acceptable standards for the conduct of human research since the 1960s. Notably, in both human and animal ethical review committees, the involvement of the wider community has been seen as important. However, unlike the situation for human research ethics committees, the ethical principles underlying the deliberations of animal ethical review committees have not been clearly enunciated.

Animal ethical review committees now have been established in many countries, albeit with differences in their charter and standing reflecting historical experiences and cultural differences. These committees are variously referred to as Animal Care Committees, Institutional Animal Care and Use Committees, and Animal Ethics Committees.

For the purposes of this paper these committees will be referred to collectively as animal ethics committees (AEC), with a specific focus on evidence of ethical review being either explicit or implicit in their charter. An overview of the development of

AECs will be presented and the case made that, based on published reviews and reports, there are opportunities to strengthen this ethical review process significantly.

2 Ethical review of animal research

The beginning

During the 1970s Canada, Sweden, and Australia became the first countries to establish committees to review the ethical acceptability of animal research.

Under the auspices of the Canadian Council on Animal Care (CCAC), Canada was the first country to require institutions to establish a local animal care committee charged with the responsibility of reviewing ethical aspects of research protocols (CCAC, 1980). The establishment of these institutional committees was the cornerstone of the program of voluntary self-regulation that was developed in Canada. The other key component was the Assessment Program undertaken by the CCAC. It is of note that from the early stages the importance of public input into all aspects of this program was acknowledged and incorporated into the development and implementation of various components, including committee membership (Rowell, 1986).

The placement of the animal care committee within the broader context of the way in which an institution conducts the business of animal research was integral to how the program in



Canada was conceived. The intention was that by placing these committees within an institution they would act as the “conscience” of that institution in the ethical use of animals and, further, that through the processes established, contentious issues could not simply be avoided (Rowse, 1981). Moreover, an effective working relationship between the committee and researchers was key, not only in terms of deciding the ethical acceptability of a research proposal but also in the day-to-day conduct of research; the educational role of these committees was seen as paramount (Rowse, 1984). Thus the AEC was not only embedded into the operation of the organization but, through public involvement, it provided an outreach to the wider community. The AEC process was accountable to the wider community and was able to respond to changing community views.

Australia took a similar approach to Canada. Since 1969, the use of animals for scientific purposes has been governed by the *Australian Code of Practice for the Care and Use of Animals for Scientific Purposes* (the Code) and based on a system of self-regulation with the underlying principle that “*the lives of animals, especially vertebrates, should be treated with respect and care and their welfare catered for at all times.*”

The second edition of this Code in 1978 required institutions to establish an Animal Experimentation Ethics Review Committee, the role and functions of which were further developed in subsequent editions of the Code (Rose, 2008). As detailed in the 1990 edition, the Code established an ethical framework for the review of animal research by setting out the guiding principles that informed the deliberations of the institutional AEC. Experiments using animals could only be performed if it was determined that they were justified, weighing the scientific or educational value against the effects on the welfare of the animals involved. To bring a diversity of views to the AEC determinations, membership had to include representatives of both animal welfare interests and the wider community – both being external to the institution.

As in Canada, the effective implementation of the Code in Australia necessitated a good working relationship between the committee and researchers, noting that in this way the committee would raise awareness of the ethical issues involved and assist researchers in fulfilling their responsibilities for the welfare of animals involved in their work (Anderson, 1990).

In 1984, the Australian Federal Government initiated a national inquiry into animal welfare by a Senate Select Committee. The Report (SSCAW, 1989) identified the need to insure that the use of animals is justified through ethical review and the application of the principles of the 3Rs (Replacement, Reduction and Refinement of animal use). Transparency of process, public participation in ethical decision-making, and mechanisms for accountability were all seen as important.

The Report is notable for the in-depth consideration it gave to the role of the AEC. It was concluded that the AEC was the “lynch pin” in any system of ethical review, arguing that it was the collective wisdom of a committee, with each member

bringing their own expertise and values to bear on deliberations, that would enable broadly-based, collective judgments to be made. The Senate Committee concluded that AECs served a major societal benefit by bringing together people of differing views. The Committee saw a pivotal role for lay/non-scientist members.

Sweden took a different approach. Following a three-year, voluntary pilot program, committees to review the ethical acceptability of animal research were established by law in 1979. Six regional committees were established, external to research organizations, with the mandate to review experiments that were likely to cause pain or suffering to the animals involved; the researcher was to be responsible for so classifying proposed experiments prior to committee review. Committee membership comprised equal numbers of researchers, technical staff, and laymen. Subsequently, this system was reviewed and the law amended in 1988, requiring that all experiments be reviewed by a committee chaired by a judge with equal representation of research interests and laymen (including animal welfare representatives). Although these committees were designated “ethics” committees, as noted by Forsman (1993) the ethical principles that were applied were not explicitly stated in legislation, although the weighing of costs and benefits was implicated in associated guidelines.

Challenges

Despite these early initiatives, the uptake of AECs in other countries has met with challenges. During the 1980s, arguments for and against the establishment of institutional AECs were widely debated, particularly in the United States (US) and the United Kingdom (UK).

In the US, the 1985 edition of the *Guide for the Care and Use of Laboratory Animals* (the Guide) required institutions to appoint a committee that would be responsible for evaluating the animal care and use program within the institution, and the committee was to include “a person not affiliated with the institution” in its membership. In many ways these committees replaced animal care committees that had operated in some research institutions for many years, and there was a view that the former committees, which relied on the professional knowledge and expertise of specialist veterinarians, would better achieve animal welfare goals (Steneck, 1997).

Ambivalence as to the basis for the ethical review of animal research was highlighted in the report by the Office of Technology Assessment of the US Congress (OTA, 1986) in which it was argued that “*animals are morally entitled to be treated humanely; whether they are entitled to more than this is unclear.*” Although there were those who argued for institutional committees to undertake ethical review (for example, Dresser, 1985), the primary focus of Institutional Animal Care and Use Committees (IACUC) in the US was to review experimental protocols and, where appropriate, recommend modifications to improve animal welfare (Orlans et al., 1987).

In the UK, where animal research had been regulated

through the Home Office since 1876, the need for the introduction of AECs was widely contested. Even when there was agreement as to the potential benefits of establishing AECs, there was much trepidation about using the word “ethical” or including lay membership (Liverpool Animal Ethical Group, 1986). However, in 1995, the Boyd Group published a discussion paper on *Ethical review of research involving animals: A role for Institutional Ethics Committees?* This paper concluded that the establishment of such committees would improve the ethical review of this research by providing a clearer institutional focus on ethical issues (Boyd Group, 1995).

One important development during the 1980s was the publication of the *International Guiding Principles for Biomedical Research Involving Animals* by the Council for International Organizations of Medical Sciences (CIOMS, 1985), which were endorsed by the Advisory Committee on Medical Research of the World Health Organization and incorporated into national policy in many countries, including the US. While recognizing that different countries would take different approaches in the regulation of these activities, the CIOMS sought in these principles to provide a conceptual and ethical framework that would be widely acceptable. Although arguing that the advancement of biomedical sciences should not be unduly restricted, the moral obligation to treat animals humanely, to prevent pain and discomfort as far as possible, and to replace animals where possible was highlighted.

Introduction of new legislation in the UK and Europe in the 1980s, while not requiring the establishment of AECs, paved the way for subsequent developments. In the UK, the Animals (Scientific Procedures) Act 1986 replaced the 1876 Act, and the European Union issued a Directive (EU86/609) to protect animals used in scientific procedures (Council of Europe, 1986). In 2000, the Home Office in the UK introduced a requirement for institutions to introduce an ethical review process to compliment the activities of the Inspectorate and, it was envisaged, to provide on-going support to researchers (Home Office, 2000).

Today

Canada and Australia have continued to develop their processes for self-regulation through institutional AECs. Importantly, in both countries the regular revision of policies and the publication of science-based guidelines have enabled the AEC process to develop and respond to emerging ethical issues and to be informed by scientific advances. Moreover, public participation remains a key element and processes to strengthen this involvement have been introduced in both countries (Gauthier and Griffin, 2007; Rose, 2007).

Recent changes to the US Guide and the introduction of the new Directive by the European Union indicate significant developments in recognizing the need for a process for ethical review of animal research. While not requiring this to be undertaken by a committee, the new Directive on the Protection of Animals Used for Scientific Purposes (European Commission, 2010), mandates comprehensive project evaluation prior

to authorization to commence, noting that on both moral and scientific grounds, the likely harm to the animals should be balanced against expected benefits.

In anticipation of these amendments to the Directive of the European Union, in 2006 the Federation of European Laboratory Animal Science Associations (FELASA) undertook a review of then current practices in 20 member countries (FELASA, 2006). Sixteen were identified as having in place a mandatory requirement for ethical review, although the mechanisms to do so and the scope of activities covered varied. In this detailed review, FELASA recommended that “*ethical review should aim to ensure that, at all stages in scientific work involving animals, there is adequate, clearly explained ethical justification for using animals.*” Further, such a review needed to take into consideration the balance of the predicted (or actual) benefits over harms caused and the likelihood that such benefits would be achieved. Further, FELASA concluded that the ethical review process needed to reflect a diversity of views.

The publication in 2010 by the International Council for Laboratory Animal Science (ICLAS) of the guideline *Ethical Review of Proposals to Use Animals in Science* indicates the level of international consensus that has been reached on the need for an ethical review process and the underlying principles. While recognizing that countries will approach this in different ways, the need to weigh expected benefits against the likely harm to the animals involved is cited as a foundation principle (ICLAS, 2010).

3 Published reviews and reports

An extensive search of Medline, PsycINFO, CAB Abstracts and Reviews, Biosis, Sociology Abstracts and Philosopher’s Index databases was undertaken to identify publications that reported an evaluation of the operation of or outcomes from the ethical review of animal research, including AECs. Unlike the situation for human research ethics committees where there is a substantive body of literature (Abbott and Grady, 2011), very few publications that provided empirical evidence of the workings of AECs were found. Most of these reports concerned the operation of the AEC, in terms of either the outcomes or the process, and they involved committees in Sweden, Canada, the UK, and the US.

There were three reports concerning the workings of committees in Sweden. Forsman (1993) reviewed the outcomes of the ethical review process from 1979 to 1989. Based on her analysis of documentation relating to the day-to-day working of these committees, including applications for ethical approval, minutes of committee meetings, and associated correspondence, Forsman noted that what was understood as the basis for the ethical review process was unclear and that, unlike the situation with human research ethics committees, there was not a clear ethical code. However, she concluded that the introduction of AECs had been beneficial in raising



awareness of the issues, facilitating discourse, and enabling people of differing views to find common ground. Importantly, she cited substantive evidence that AECs had increased ethical consciousness and awareness of responsibilities on the part of researchers. Nevertheless, she also concluded that AECs acted primarily as technical committees, with refinement of procedures being the predominant focus of AEC deliberations. For the most part, weighing the balance of the predicted benefits and harms could not be substantiated.

Hagelin and colleagues reviewed the minutes of AECs in Sweden in a later period (1989-2000) with the purpose of evaluating how the AECs modified applications (Hagelin et al., 2002). They found that approximately 18% of applications were approved without modification, and they classified the majority of modifications as addressing the goals of Refinement, concluding that AECs were being effective in improving animal welfare.

An ethnographic study of AEC members in Sweden found differing views on what the term “ethics” means, and there was no consensus on what constitutes an ethical problem in relation to animal research (Ideland, 2009). Ethical considerations within the AEC meetings were found to be situated in the committee culture and were characterized by the personal views of members and hierarchies within the committee, i.e., the committee culture significantly influenced the outcomes. Although the mix of views should provide the basis for an exploration of the complexity of ethical issues, this study showed that AECs focused on technical questions. One reason suggested is that this is an area where committee members can reach consensus. The limitations to this ethical evaluation were noted, and it was argued that an AEC process that recognizes and evaluates differences would provide a better basis for ethical review.

There were three reports relating to committees in Canada.

A twelve-month observational study of AECs at three Canadian institutions aimed to provide empirical data that the authors concluded had not been provided in previous publications (Houde et al., 2003). Based on an analysis of the type of protocol, the final decision, and a verbatim record of the committee’s discussions in relation to a specific protocol, data indicated that most comment was of a technical nature, with 16% related to what had been defined as the “explicit ethical categories” of the 3Rs. The complexity of the ethical review process in relation to animal research was noted, and on further analysis the authors concluded that ethical concerns were implicit in both scientific and technical comments. Schuppli and Fraser (2005) investigated the interpretation and implementation of the 3Rs through in-depth, open-ended interviews of committee members at four Canadian universities. Although few mentioned the 3Rs per se, there was substantive evidence that the underlying principles were applied. However, they noted a lack of consensus as to the nature and ethical significance of pain and suffering.

In a further ethnographic study, Shuppli and Fraser (2007) sought to examine the effectiveness of the committee process

at four Canadian universities and to identify factors that may influence outcomes, such as the possible influence of committee composition and meeting dynamics. The limitations of this study in terms of the number of committees involved was recognized, but it was concluded that there was evidence of bias towards institutional and scientific members, and the dynamics within a committee prevented full participation by all members, particularly community members. Various strategies to encourage full participation were discussed and reference to the wider literature on group deliberations was suggested.

Purchase and Nedeva (2001) evaluated the impact of the introduction of the ethical review process in the UK through a postal survey of the various institutional stakeholders, e.g. Licence Holders and Named Veterinarians, from the perspective of their attitudes to alternatives. They concluded that the ethical review process had had a positive effect, particularly on the culture of institutions with the establishment of formal mechanisms to review the application of alternatives. Notably, they found a high level of awareness of the importance of alternatives, with 80% of respondents holding the view that alternatives should be used on moral and ethical grounds.

Two reports in relation to US committees investigated the reproducibility of the institutional committee review process. Dresser (1985) surveyed the responses of 32 IACUCs when asked to review four hypothetical protocols. While there was broad agreement on the need to refine particular procedures, the author concluded that assessing the justification for using animals was problematic and presented major difficulties for committees. Plous and Herzog (2001) assessed the reliability of decision-making across 50 randomly selected IACUCs by comparing the evaluation by each committee member of three protocols, each of which was reviewed by two committees. Their analysis revealed significant variability in the determination, both between and within IACUC members. Notably, this variability related to key components of the protocol review process, such as justification for the type and number of animals. The authors argued that such variability challenged the credibility of the IACUC review process.

In his discussion of the potential difficulties of using a committee for ethical review of animal research, Caplan (1987) argued that some inconsistency in determinations was inevitable when participants bring a diversity of values to such discussions. Differences in the outcomes of the ethical review process also have been reported in a number of studies of human research ethics committees (Edwards et al., 2007), and there is an argument that such differences should be expected if the ethical review process is effective and not simply endorsing the *status quo*.

4 Discussion

Although there are few published studies providing empirical evidence on the operation of AECs, those available do



show that the process is supporting and informing awareness and implementation of the principles of the 3Rs. However, evidence questions the foundations and effectiveness of the ethical review process, not only in terms of the application of a framework for ethical review but also as to the underlying ethical principles.

Evidence suggests that consideration of the ethical justification for a particular project based on a full consideration of expected benefits and predicted harms is problematic and supports the contention that ethical justification is neglected by AECs where the primary focus is the 3Rs (Kolar, 2006). The reasons for this are not extensively explored, but contributing factors could include a pervasive view that there is a fundamental justification to use animals to benefit human or animal health and welfare, a committee culture that seeks to find consensus and avoid differences, the attraction of dealing with “practical” outcomes, e.g. the 3Rs, rather than exploring questions of value, a view that the AEC members do not have the necessary expertise to assess the scientific merit of a proposal, or a lack of agreed ethical principles upon which to base broader consideration of ethical questions.

The limitations of the current framework for ethical review of animal research have been argued by several commentators (for example, Forsmann, 1993; Delpire et al., 2000). Further, within the context of a process that focuses on technical and scientific issues, there is the risk of a cost/benefit analysis (as this is often described) being utilized in a formulaic manner and so avoiding ethical considerations.

Reiss (2003) has argued that to achieve confidence in the validity of an ethical decision by a committee, a number of criteria need to be met, i.e., that conclusions are supported by reason, arguments are conducted within an established ethical framework, and a degree of consensus arises from genuine debate.

Delpire and colleagues (2000) reviewed extant guidelines for the cost-benefit analysis of research involving transgenic animals and concluded that these did not provide adequate guidance for ethical review. Rather, they argued, there was a need for a framework that guided a broad and systematic assessment of ethical issues, such as the ethical matrix developed by Mepham (2000). Such a framework would provide a practical procedural tool to support sound ethical considerations by inclusion of all values at stake, engagement with a multiplicity of viewpoints, supporting discussion of case-relevant ethically relevant aspects, allowing inclusion of ethical argument, and enabling transparency of process (Kaiser et al., 2007). Thus, the adoption of this broader framework would strengthen the ethical review process, avoid the pitfalls of a simplistic cost/benefit approach, and align the outcomes to the criteria proposed by Reiss.

The lack of agreed ethical principles underlying the ethical review of animal research is likely to be a major contributing factor in the difficulties identified (Rollin and Loew, 2001). This is the significant difference between the ethical review of research involving humans and that concerned with animals

(Forsmann, 1993; Mepham et al., 1998; Houde et al., 2003). The basic ethical principles applied in the ethical evaluation of human research are respect for persons, beneficence, and justice, as detailed in the Belmont Report (1979) – respect for persons being paramount as a necessary component of the other two (Gillon, 2003). The development of comparable ethical principles for animal research has been suggested by Mepham et al. (1998). Such a proposal was developed by van Hoosier (2000) but has not to date received further attention.

One of the obstacles, which has long been recognized, is the lack of a consensus as to the ethical basis for such principles (Tannenbaum and Rowan, 1985; Donnelley and Nolan, 1990), and the consequences of applying different ethical positions to decisions concerning animal research are well argued in the 2005 report of the Nuffield Council on *The Ethics of Research Involving Animals* (Nuffield Council, 2005).

Respect is a term frequently found in discussions about our responsibilities towards other animals but, to date, exploring this as an ethical principle has been argued against on the basis that, as such, the notion of respect is based upon reciprocity and thus requires recognition of reciprocal rights. This is the focus of the ethical argument for an alternative approach to respect for animals developed by Markie (2004).

Adopting “respect for animals” as an ethical principle would recognize that an animal has inherent value and would provide an ethical benchmark against which a proposal to use animals for research could be tested. The interests of the animal would not be considered as equal to those of human beings but would need to be considered, and an argument to override their interests must be carefully appraised. Further, Markie’s argument that respect is a form of duty (Markie, 2004) fits well with Jonas’s argument for responsibility in an ethical context (Jonas, 1976). Jonas argued that, in the context of human relationships, responsibility arose when the well-being, interests, or fate of others came under the control of another person. This disparity in power then carries an ethical obligation on the part of the person who is in control and, because of that superiority, is responsible. Further, he argued that responsibility is a function of power and knowledge, where the responsible person has control over their actions and can, to some extent, foresee the consequences of their actions in terms of how they would affect others. There are striking parallels between the circumstances outlined by Jonas and the notion of responsibility towards animals as it is widely represented in policies and guidelines concerning animal research.

If we take the ethical principles of respect for animals and responsibility as the basis for consideration of the ethical justification of the use of animals in research, this allows the development of agreed criteria against which the outcomes of the application of these principles can be judged. Notably, it is in this way that agreed ethical principles outlined in the Belmont Report (1979) have served to underpin the ethical review of human research.



In relation to animal research, evidence that these principles underpin any decision regarding whether and how to use animals would be that a proposal has scientific merit, is designed to achieve realistic outcomes that have potential benefit, that the goals cannot be achieved in any other way and the promotion of the wellbeing of those animals involved is the benchmark, so that any factors likely to cause pain, suffering, or lasting harm have been identified and justified. Further, there is evidence of a broad consideration of the ethical issues and high standards of research integrity are evident in the conduct of such research.

In this way, respect for animals and pursuant responsibilities are demonstrated, and there would be evidence that a thorough assessment of the breadth of ethical issues has informed the ethical review process; the principles of the 3Rs are embedded in the outcomes achieved. Further, through this approach there would be better engagement of all members in committee deliberations, and the involvement of researchers would be integral to demonstrable outcomes.

Two of the foundation concepts in the development of AECs were that there should be involvement of the wider community and that these committees would have a strong collaborative relationship with researchers. Although community involvement also is held as fundamental to the ethical review of human research (Warnock, 1984), similar issues to those identified by Schuppli and Fraser (2007) have been evident in studies of human research ethics committees. A common theme in all these studies has been an identified need to clarify the role of community/lay members (for example, Weblert and Tuler, 2002; White and Bourne, 2007). In a detailed consideration of these questions, Dyer (2004) supported the conclusions of Schuppli and Fraser regarding the need to better define and understand the role of community/lay members on ethical review committees so as to fully realize the potential value from their involvement.

One of the arguments put forward for the diversity of AEC membership was to bring a broader perspective to committee deliberations. Ideland's study provided an important illustration that this diversity of values and views is maintained and the opportunity to harness these differences in the deliberations of the AEC could be beneficial to ethical review (Ideland, 2009).

AECs are situated in a broad community within an organization, and they provide important links to the wider community. The challenges for an AEC in fulfilling expectations as to its various roles are many, not least the complexity of its relationships with various stakeholders. A number of commentators (for example, Forsmann, 1993) have expressed concern that the AEC process would disengage researchers from their responsibilities. Although the available evidence does not indicate this to be so, it is important to ensure a balance between the respective roles and responsibilities of AECs and researchers and to be alert to the potential for processes to influence this balance (Rose, 1996). Further, within the broader influence of the AEC, recent commentary is of

note as to how institutions should promote a culture of ethics and integrity and the concomitant risks of an undue focus on compliance (Geller et al., 2010; Bergsteiner and Avery, 2010) in developing and supporting ways by which the AEC can meet these broader social goals.

5 Conclusions

Deciding if and how we use animals for research purposes presents significant ethical challenges. Placing the principle of respect for animals with our pursuant responsibilities as the ethical basis for our reflections upon and analysis of these questions will strengthen the ethical review process, inform the identification of outcomes against which the application of these principles can be affirmed, and influence a broader consideration of issues. Animal ethical review committees are integral to achieving these outcomes. By bringing a diversity of views to these deliberations these committees can be agents for change and fulfil an important societal role by challenging the status quo and prompting us to critically evaluate our views and values in relation to our responsibilities towards other animals.

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