

THE ETHICAL REVIEW PROCESS IN THE UK AND AUSTRALIA: THE AUSTRALIAN EXPERIENCE OF IMPROVED DIALOGUE AND COMMUNICATION

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Abstract

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A study was carried out in Australia and the UK of the legislation and procedures relating to the welfare and use of animals in scientific research. In Australia, a National Code of Practice for the Care and Treatment of Laboratory Animals has been adopted and it is a legal obligation for all Institutions to adhere to the Code. Each institution has an Animal Ethics Committee (AEC) responsible for ethical review and animal welfare which must include, within certain stipulated parameters, a veterinarian, a research scientist, a member of a rights/welfare organisation and an additional lay member. In the UK the situation is different, as the Home Office directly administers the law regarding the use of animals in research. In April 1999 the Ethical Review Process (ERP) was introduced; every Institution must establish an ERP which must include a named veterinarian and representatives from the Animal Care and Welfare Officers and others. In both countries great emphasis is placed on the principles of replacement, reduction and refinement in experimental research. Substantial differences in culture and ethical review structure between the two countries are identified. However, various recommendations are outlined, based on the Australian experience, to build on existing structures and further develop the UK ERP. These recommendations should be seen as long-term aims and seek to further improve animal welfare through facilitating communication, increasing accountability and creating an environment conducive to open discussion.

Keywords: *animal welfare, Australia, communication, ethical, laboratory, review, UK*

Introduction

During the course of the last century, there has been a vast increase in scientific research and in our endeavours to combat hitherto untreatable human diseases. This increase in research has resulted in a greater number of animals being used in experiments, which, in turn, has resulted in concern over their rights and welfare. The use of animals in research is a controversial issue in the UK and there is considerable polarisation among the various stakeholders in the debate, such as scientists, welfare and rights campaigners, and the Government. The result has been a somewhat besieged mentality by all concerned and a resultant lack of dialogue. There have been constructive attempts to break the impasse (eg The Boyd Group 1995) but any system, such as an ethics committee, which seeks to improve animal welfare and human dialogue would be of considerable benefit to the welfare of all groups of people and animals involved.

One effect of the concern for animal welfare among scientists has been the increase in the study of animal welfare as an academic discipline. This discipline seeks to apply scientific

methods in order to assess welfare and has gained ground in recent years, allowing the legislators evidence upon which to base their deliberations. Over the last two decades, there has therefore been a substantial increase in the body of evidence relating to animal welfare (eg Dawkins 1980, 1990, 1993; Fraser & Broom 1990; Broom & Johnson 1993) and considerable research has been focused on farm animals, zoo animals and laboratory animals. However, no amount of evidence can influence the debate unless there are well-established methods in place to facilitate dialogue, to encourage a sharing of knowledge and to improve animal welfare.

Since April 1999, a framework has been put in place with the establishment of the UK local Ethical Review Process (although a number of UK establishments have had a process in place for many years). Broadly, the purpose of this process is to review — by consultation with appointed parties — all animal experiments before they proceed, in order to establish their ethical and scientific validity and to improve animal welfare. A similar, although not identical, system has existed in Australia for over a decade and appears to work well. In this study, I sought to investigate the methods of ethical review adopted there and focused on the design and implementation of systems of ethical review at various institutions in four states of Australia: Queensland, South Australia, Victoria and New South Wales. Discussions with representatives focused on problems, solutions and the applicability of their system to the UK.

This study begins by outlining the background legislation in Australia (Section 1). The current legislation in the UK is briefly described (Section 2), and the two systems (the UK and Australia) are then contrasted and compared (Section 3). A series of recommendations are drawn up based on the Australian model with a view to further enhancing the system already existing in the UK (Section 4).

SECTION 1 — Australian legislation for the use of animals in research

The political system of Australia and the history of the development of the country have given rise to a federal structure with a Parliament for each of the six states and the northern territories. Each state varies in both the legal basis of the legislation and its implementation. However, every state has a form of legislation that makes cruelty to animals a criminal offence (in some, this is long-standing and brief, whereas in others it is recent and detailed).

A National Code of Practice for the Care and Use of Animals for Scientific Purposes (the *Australian National Code*) has existed since 1969 (see Commonwealth of Australia 1997). This Code may be seen as one of the great strengths of the Australian system and has evolved over a period of time and with the publication of a number of editions. The current 6th edition was arrived at after consultation with all relevant parties (scientists, welfare/rights organisations, funding bodies and government officials) and provides the main guidelines and controls on animal experimentation for investigators, teachers, technicians and Animal Ethics Committees (AECs). The *Australian National Code* is either incorporated into legislation or has legal standing in all states and territories. All states therefore follow the same guidelines on the care and treatment of animals in scientific research.

The Australian National Code

The *Australian National Code* outlines guidelines and stipulates the exact minimum requirements for setting up local Animal Ethics Committees (AECs). This system relies on the implementation of procedures on the ground along with a substantial element of self-regulation. The two overall aims set out in the Code are: first, to limit the number of animals

used in scientific research; and second, to safeguard the welfare of animals involved in research. Full consideration is given to alternatives or *replacement* of procedures with others that do not use animals, *reduction* of the number of animals used, and the *refinement* of procedures to minimise pain and suffering (as originally elaborated upon by Russell and Burch [1959] and referred to hereafter as the principle of the Three Rs). Full details of the scope of the Code may be found therein, and they have most recently been outlined by Baker (1999).

The Code stipulates that responsibility for monitoring the welfare of animals in research rests with the institutions themselves through the establishment of AECs and details the terms of reference, membership and operation of Institutional AECs (a policy that has been progressively implemented since 1979 and has been mandatory in most states and territories since the mid-1980s). The function of the AEC is to review every application for the use of animals for scientific purposes, taking particular account of the requirements of the Code to implement the Three Rs.

Since this study focuses on laboratory animal ethics and welfare, two specific matters relating to the *Australian National Code* merit specific attention: first, the consultation process by which the Code was established; and second, the composition, stipulated in the Code, of the compulsory AECs. Both of these aspects are essential to its successful implementation.

The consultation process by which the Australian National Code was established

The Code was first produced by the National Health and Medical Research Council (NHMRC) in 1969 and has been revised six times. Its revision is inclusive, as a wide variety of organisations from both the scientific and welfare community are consulted (including scientific organisations, funding bodies, welfare and rights organisations, lay people and Government representatives). The last revision was published in 1997. The organisations involved are the NHMRC, the Commonwealth Scientific and Industrial Research Organisation (CSIRO), the Agricultural Resource Management Council of Australia and New Zealand, the Australian Research Council (ARC), the Australian Vice-Chancellors Committee (AVCC), the state/territory governments of Australia, and welfare organisations (RSPCA and Animals Australia, discussed later). Thus, all stakeholder groups are represented.

The Animal Ethics Committees (AECs) as stipulated in the Australian National Code

The system of AECs in Australia is the 'backbone' of the Australian system. The process was set up with a view to encouraging openness, increasing accountability and providing communication channels directly (or indirectly) with the general public. AECs have particular design features in their structure and in how they operate which make them effective in monitoring the use of animals and ensure the animals are properly treated. The Code specifically states that an AEC must have a membership that will allow it to fulfil its terms of reference. It must therefore comprise at least four people including an individual from each of the following four categories:

Category A: A person with qualifications in veterinary science, with experience relevant to the activities of the institution or, in special circumstances, a person with qualifications and experience to provide comparable expertise.

Category B: A person with substantial recent experience in the use of animals in scientific or teaching activities.

Category C: A person with demonstrable commitment to, and established experience in, furthering the welfare of animals, who is not employed by or otherwise associated with the institution, and who is not involved in the care and use of animals for scientific purposes. The person should, where possible, be selected on the basis of active membership of, and nomination by, an animal welfare organisation.

Category D: An independent person who does not currently and has not previously conducted scientific or teaching activities using animals, and who is not an employee of the institution except under defined circumstances.

The Code also states that a person responsible for the daily care of animals within the institution should have membership of the AEC, and additional members can be included to ensure that it can function effectively (the needs of institutions will vary based on internal lines of authority and the nature of the research under consideration).

The Australian and New Zealand Council for the Care of Animals in Research and Teaching (ANZCCART)

One of the key elements to the success of the Australian system is an organisation called the Australian and New Zealand Council for the Care of Animals in Research and Teaching (ANZCCART). ANZCCART was originally established in 1987 as ACCART (The Australian Council for the Care of Animals in Research and Teaching) and expanded to include New Zealand in 1993. This non-profit-making umbrella organisation is an independent body with offices in both Australia and New Zealand. Through its varied activities, ANZCCART seeks to promote excellence in the care of animals in research and teaching and thereby minimise any discomfort that the animals may experience, to ensure that the outcome of the scientific uses of animals are worthwhile, and to foster informed and responsible discussion and debate within the scientific and wider community regarding the scientific uses of animals. ANZCCART has 19 member organisations (national, state and territorial governments, research and funding bodies, and professional scientific associations including universities), which provide access to virtually all animal-based research in Australia and New Zealand. ANZCCART reinforces the Three Rs and their implementation through annual conferences, workshops (eg for members of AECs), seminars by visiting speakers, an annual award, lectures at biomedical conferences, a quarterly newsletter and published monographs.

SECTION 2 — UK legislation for the use of animals in research

In the UK, animal research is controlled by the Animals (Scientific Procedures) Act 1986 (abbreviated to ASPA 1986; see Home Office 1990), which puts into effect the European Union Directive 86/609 EEC. This Act is designed to regulate the way animals are experimented upon in research, education and toxicology, and is administered by the Home Office. This contrasts with the Australian system, which is mainly administered through AECs within the institute with a strong element of self-monitoring. The UK system is outlined in the two leaflets entitled *The Use of Animals in Scientific Procedures* (Home Office 1999a) and *The Animals (Scientific Procedures) Inspectorate* (Home Office 1999b). A synopsis is provided here for clarity and to allow subsequent comparison with the Australian system.

The licences and certificates

Every research protocol involving the use of living vertebrates (and their foetuses if more than half way through gestation, and *Octopus vulgaris*) and which may harm the animals in some way must be granted a 'project licence' by the Home Office. The licence details those scientific procedures that may be carried out. The researcher must outline their justification for the use of each species, along with the severity of any distress likely to be caused and the steps that will be taken to minimise pain and distress. In addition, the individual scientist must apply to the Home Office for a 'personal licence', which can only be used under the authority of a project licence. Both project licence holder and personal licence holder must attend a series of compulsory training modules designed to educate and to test understanding. Licensing is designed to ensure that those carrying out the research are suitably qualified, aware of the ethical issues and know the law, that alternatives to animals are used wherever possible, that the number of animals used is minimised, and that any suffering or other harmful effects experienced by the animals is minimised. Finally, the adverse effects on the animals have to be weighed up against the potential benefits to humans or animals before a project licence is granted.

In addition to these two licences, each 'site' that intends to carry out experimental research on animals must be licensed by means of a 'certificate of designation' and registered as suitable with the Home Office following their inspection of the animal facilities. There must be a named person legally responsible for animal care and welfare, a named veterinary surgeon available to provide advice and support on issues relating to animal health and welfare, and a certificate holder to be responsible for various aspects of the Act.

The Animals (Scientific Procedures) Inspectorate

The Home Office inspectors assess applications for licences and certificates and advise the Home Secretary whether they should be granted. They are employed as full-time civil servants to provide professional medical, veterinary and scientific advice to the Home Secretary and his/her officials. When assessing proposals, the Inspectorate ensures that full consideration is given to the principle of the Three Rs. Inspectors visit establishments, often without notice, to ensure that the terms and conditions of licences and certificates are being met. All inspectors are qualified in medicine or veterinary sciences. Approximately 2500 visits, by 20 inspectors or so, are made annually to establishments for inspection purposes.

The Animal Procedures Committee (APC)

The Animal Procedures Committee includes individuals from welfare organisations and scientists, and is an independent body set up under ASPA 1986 to advise the Home Secretary on matters relating to the Act. There must be a minimum of 12 members (although usually there are more); one must be a lawyer and at least two thirds must be medical practitioners or veterinary surgeons or have related biological qualifications. At least half of the committee must not have held a licence to carry out animal procedures within the last six years and representatives of animal welfare organisations must be adequately represented. All appointments (and vacancies) are publicly announced. The Home Secretary may seek the advice of the APC in deciding whether to licence a particular procedure. Each year the Committee submits a report on its activities to the Home Secretary, which is then published (eg Home Office 2001).

In November 1998, the number of animal welfare experts on the APC was increased, and a dedicated and enlarged secretariat was provided to help the committee to take a more proactive and independent role. Thus, the APC is developing into a highly independent consultative committee, with representatives from the scientific community and welfare organisations, which advises the Home Secretary on aspects of the implementation of the Act.

Guideline publications

The Act requires the Home Secretary (with the support of the APC and working groups) to publish guidance on the operation of the controls and codes of practice. These publications include *Guidance on the operation of the Animals (Scientific Procedures) Act 1986* (Home Office 1990); *Code of practice for the housing and care of animals used in scientific procedures* (Home Office 1989); *Code of practice for the housing and care of animals in designated breeding and supplying establishments* (Home Office 1995); and *Code of practice for the humane killing of animals under Schedule 1 to the Animals (Scientific Procedures) Act 1986* (Home Office 1997). In addition, statistics of scientific procedures on living animals are published annually. Although these Codes are not strictly law, the Home Office expects designated sites and certificate holders to follow these guidelines in their implementation of ASPA 1986.

The Ethical Review Process(es)

In April 1999, the Home Office made it a requirement for all institutions conducting research involving animals to have a local Ethical Review Process (ERP). This requirement is in addition to the existing controls under the Act. The ERP was drawn up after extensive consultation with all stakeholder groups (eg scientists, welfare organisations). There have been a number of recently published studies (eg Jennings 1994; Jennings *et al* 1998) and key meetings (eg The Boyd Group 1995; Jennings 1998) in the lead-up to its introduction.

The Home Office has stipulated that the local ERP should be satisfactory to inspectors employed to enforce ASPA 1986 and has indicated that flexibility in the form of ethical review is an important feature. Details of the requirements for the ERP are set out in an Annex of ASPA 1986 entitled *The Ethical Review Process* (Home Office 1998), hereafter referred to as the Annex.

The aims of the ERP are: first, to provide independent ethical advice to the certificate holder, particularly with respect to project licence applications and standards of animal care and welfare; second, to provide support to named people and advice to licensees regarding animal welfare and ethical issues arising from their work; and third, to promote the use of ethical analysis to increase awareness of animal welfare issues and develop initiatives leading to the widest possible application of the Three Rs.

The Annex states that all institutions (certificate holders) must set up an Ethical Review Process within certain guidelines and that the certificate holder, through an established local framework, should involve as many staff as possible. There must be full consideration and justification for the use of animals in research as regulated by ASPA and adherence to the principle of the Three Rs. In addition, high standards of accommodation and care for the animals must be provided. The role of the ERP includes, among its stated aims, retrospective project reviews throughout the duration of the project, and advice on how staff can be appropriately trained and their competence ensured. Receipt of a project licence application

signed by the certificate holder is taken by the Home Office to mean that the application has been through the ERP for that establishment.

The certificate holder (under ASPA 1986) is responsible to the Home Office for the local ERP and is also the person who appoints those to implement the procedure. The process must include a named veterinarian, representatives from the Named Animal Care and Welfare Officers appointed within the institution, a project licence holder and a personal licence holder. As many people as possible should be involved in the ERP and views of those who do not have responsibility under the Act should be considered. Consideration should also be given to the inclusion of lay people independent of the institution. Home Office inspectors retain their inspection role, and may also attend any Ethical Review Process meeting and read through associated documentation.

SECTION 3 — Contrasting the legislative approaches of the UK and Australia

Considerable differences immediately become apparent between the processes in the UK and Australia. In order to clarify these differences in terms of legal regulation, Skene (1994) has helpfully classified the systems as ‘at the top’ in the case of the UK (with a statute enforced by a publicly appointed monitoring authority) and ‘at the bottom’ in the case of Australia (with controls being enforced by the state mainly from within the institution whose activities require monitoring; see Figure 1).

Thus, the UK has a system that has strong external inspection and is administered ‘at the top’ in terms of it being the Government that administers the law relating to institutional compliance with ASPA 1986. Non-compliance with the Act can ultimately result in disciplinary action and even imprisonment for statutory offences. The Australian system relies on a high degree of self-regulation within the institution (ie ‘from the bottom’). However, in Australia, all systems are ultimately regulated by the Australian National Code and non-compliance can result in disciplinary action. Thus, the two systems aim to achieve the same end from very different approaches: under both systems, the animals and their welfare are controlled and scientists are subject to sanctions for non-compliance.

SECTION 4 — Key elements of the Australian system and their applicability to the UK

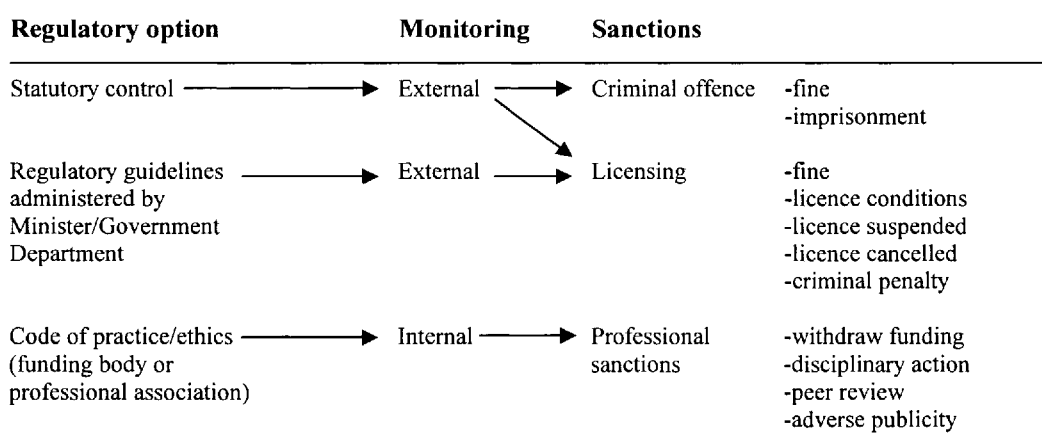
It is noteworthy that the main differences between the UK and Australian ‘top down’ and ‘bottom up’ systems seem to reflect real differences in the overall political systems of the two countries whose histories, although intertwined, are very different. The UK has a unique history involving the early development of a focused set of animal protection groups, which grew out of the concern for animal welfare in the nineteenth century. Thus, the issues have been debated over a long period and a much more acrimonious environment has developed. While acknowledging these considerable cultural differences, various aspects of the Australian experience may be of value to the UK in the further ‘evolution’ of the ERP over the long term.

Methods

This study used a qualitative approach consisting of semi-structured, open-ended discussions with individuals who were identified as belonging to key stakeholder organisations in Australia and the UK (two individuals from the US were also included). Individuals representing as many different points of view as possible were chosen and contacted (eg scientific organisations, welfare and rights organisations, lay people and Government

representatives). Discussions were held with twenty-one individuals in Australia and seven individuals in the UK.

Each person was visited and individual discussions were held which lasted on average for 50–60 min. On some occasions these discussions were considerably longer, however, and on three occasions more than one stakeholder was present. Stakeholders helped to create the substance and direction of each discussion which focused on issues of animal experimentation, particularly the history and design of ethical review processes and issues relating to the practical implementation of policy. Notes were taken during or shortly after the discussions (as appropriate) and important aspects were highlighted. Recurring themes and key elements were identified.



Taken from Skene (1994)

Figure 1 Options for regulating the use and welfare of animals in scientific procedures as outlined by Skene (1994). The figure shows not only the supervisory mechanism for statutory and voluntary regulation, but also the available penalties for non-compliance. ‘At the top’ of the regulatory scheme are strict statutory controls or delegated legislation such as regulations or guidelines monitored ‘externally’ by government inspectors with stringent punishment for non-compliance. ‘At the bottom’ regulatory schemes employ ‘voluntary’ controls (self-regulation) which include guidelines and codes of practice prepared by a funding body with compliance generally monitored by a Committee within the institution itself (although it may have members from outside the institution and itself be monitored by a central committee); sanctions for non-compliance are of a ‘professional’ kind — withdrawal of funding, demotion, dismissal, reprimand or loss of reputation through peer criticism.

Recommendations

Based on my findings from the discussions with stakeholders, I make eight recommendations, which are summarised below. These recommendations, based upon the Australian experience, should be viewed as integrative to the established UK ERP. Any

changes to the UK ERP should be introduced incrementally and with due process (as previously indicated by Jennings *et al* 1998). It is clear that the newly introduced local Ethical Review Process requires time to 'bed down' before further development.

1. Maintenance of an inclusive consultation process and the importance of lay members

Since the UK does not have a national Code equivalent to that in Australia which is binding in law, it has a number of procedures which facilitate consultation and provide guidelines for the care and welfare of laboratory animals. It would be misleading to assume that the absence of a national Code is a major flaw in the UK system. The structure of the legislation and political system in Australia is so different from the UK that the approach adopted in the UK appears to be the best suited to the society here. Nonetheless, there are two main elements of the Australian National Code that appear highly beneficial: first, the inclusive consultation process which led to its establishment and revision; and second, the aspects of the Code specifying that Animal Ethics Committees include representatives from all stakeholder groups.

In the UK, similar processes exist but they are arrived at by a very different route. The consultation process occurs at the level of the Animal Procedures Committee. In addition, guidelines on the care and treatment of animals are drawn up by the APC (with relevant working groups) and these are then published. One recent working group is investigating the care of animals used for xenotransplantation. While these guidelines are not strictly laws, all relevant institutions will be expected to adhere to them. One such guideline that is already published is the *Code of practice for the housing and care of animals used in scientific procedures* (Home Office 1989). There are also several additional publications available, for example *The UFAW Handbook on the Care and Management of Laboratory Animals* (UFAW 1999). Finally, the Home Office has recommended that the ERP be constituted to include as many interested parties as feasible in each institution. Thus, the UK system aims to achieve the same ends as the Australian consultation process and Code but by a different route.

In Australia, the presence of lay members appears to enhance dialogue, stimulate interest and facilitate communication, and the long-term outcome of this appears to be improved animal welfare and working conditions for scientists. The importance of their inclusion wherever possible within certain agreed parameters (see recommendation 2, below) cannot be overstated. Their presence alone may be seen as an important stimulus for change to a more cooperative rather than confrontational environment.

2. The make-up of the Ethical Review Process (ERP) and the inclusion of specified lay members

In the interests of providing the best possible framework to allow smooth implementation of the ERP, it is best to remain flexible and not too prescriptive. However, the possibility of including representatives from various groups, as prescribed by the categories A–D used in the Australian Code, may be of benefit in long-term planning. The responsibility for setting up such an ERP should remain with the certificate holder.

Category A: In Australia, a category A member is a veterinarian. The UK system assigns a Named Veterinary Surgeon, who could be considered a category A member.

Category B: In the Australian system, a category B member is a person with recent experience in the use of animals in research. In the UK, the equivalent of category B members are representatives of project licence holders and personal licensees.

Category C: In the Australian system, a category C member is a lay person selected on the basis of active membership of, and nomination by, an animal welfare organisation. The nomination procedure is important to maintain 'transparency'. In the UK, provision has already been made in the Annex to allow the inclusion of such a person but is not directly specified in these terms (and few ERPs include such members).

Category D: In Australia, a category D member is a lay person who does not currently conduct, and has not previously conducted, scientific or teaching activities using animals, and who is not an employee of the Institution. In the UK, provision has already been made in the Annex to allow the inclusion of such a person but is not directly specified in these terms. Suitable category D individuals may include retired professionals such as teachers of humanities, lawyers, and accountants.

Category E (animal care technicians): Although animal care technicians are not explicitly named in the Australian system as a category, it is stated in the Australian National Code that they should be members of the AEC. The UK system assigns a representative from the Named Animal Care and Welfare Officers. The role of animal technicians is very important and should not be undervalued.

Category F: An additional individual may be designated as a person who is a qualified applied animal behaviour scientist (eg someone with an MSc in applied animal behaviour and welfare or with an applied ethology doctorate). The number of individuals with such qualifications continues to increase, and they have specialised training in the field of animal behaviour which is important in the assessment of animal welfare.

Chairs: Ideally, over the long term, there should be an aim to implement policy such that the Chair is a non-scientific senior member of the institution. This approach may be difficult to implement and not appropriate in all cases. In Australia, however, it appears to work well. There are three main reasons: first, they know the institution and the procedures therein; second, they are impartial and will be seen as such; and third, they provide credibility when explaining the institute's decisions concerning the use and treatment of animals. The Chair could be a legal professional, senior professional, accountant, or similar person from within the institution. The Chair can be pivotal to the success of any process. Workshops for Chairs are also recommended (see recommendation 5, below).

Issues relating to the inclusion of Category C and D lay people

Reason for inclusion

In the UK, the inclusion of lay people should be stipulated (provision having already been made for their inclusion in the Annex) for a number of important reasons. First, they provide an unbiased view during the review of research proposals. Second, they provide a degree of public accountability in terms of the functioning of the ERP as well as the expenditure of research funds. Third, they have the tendency to improve animal welfare through applying pressure on the Committee. Fourth, their presence demonstrates good will on the part of institutions. In the long term, their inclusion should improve dialogue between all stakeholders and ultimately, through relevant channels, the wider society as a whole.

Reason for two categories

One of the strengths of assigning two categories of lay people is to provide representation from the public as distinct from welfare groups. In addition, while the ERP allows for more than one lay person, stipulating the inclusion of two such individuals allows for a more

supportive environment for lay representation. An individual lay person may feel isolated and unable to speak out.

Locating candidates

In the case of any potential difficulties in finding enough category C welfare representatives, institutions may have to select individuals from non-scientific departments within their institution (but this situation would not be ideal). In Australia, an organisation called Animals Australia is a key player (in addition to others, such as the RSPCA). This organisation is the Australian arm of ANZFAS (Australian and New Zealand Federation of Animal Societies Inc.), and speaks for some 40 member groups. Animals Australia wishes to eliminate animal suffering but recognises that to achieve a change in attitude it is necessary to have a long-term view. Its members therefore reluctantly agree to sit on Animal Ethics Committees. Similar 'umbrella' systems for welfare organisations in the UK should be encouraged.

As regards category D members, it may also be difficult to identify suitable and willing candidates. In Australia, an advertisement would be placed in the local paper; three referees would then be called, and a panel would meet in order to interview candidates. Lay people must have the ability to speak up and to work with others who have a different opinion.

Balance of numbers

It was clear in Australia that the balance of any committee is important. Ideally, this balance should be stipulated as 50 per cent of members from categories A, B, E and F and 50 per cent from categories C and D. This may not always be appropriate, for example when there is a requirement for additional specialists (eg statisticians) because of the nature of the research under consideration. The way to enhance ethical discussion is to strive for a more balanced perspective of different viewpoints (Orlans 1997).

Payment

It is important to separate the issue of expenses (eg travel costs) from remuneration (fees paid for attendance), as it is clearly reasonable that individuals should not be expected to pay expenses in order to attend. However, it seems unlikely in the near future that lay people will receive remuneration for attendance at ERPs. It can be argued either that members of categories C and D should not be expected to give their time for nothing or that such payments are undesirable (resulting in a conflict of interests).

Plain English summary

The lay statement included in the submission to the ERP is very important. Emphasis should be placed on the use of plain English within lay summaries, so that lay members will be able to comprehend the basic issues from the main proposal despite complex specialist terminology.

Timing of meetings

Timing of meetings should suit all concerned. Lay people may have a different schedule to those in the institution that they are attending.

Length of service

The period of time for which a lay member should serve requires clarification. After a certain specified period (eg 3–4 years), it may be argued that a lay person has developed a certain expertise which, by definition, should preclude that person from continued inclusion in the

process. One possible solution may be to include an 'experienced' lay member (so as to retain their expertise) along with an additional 'novice' lay member (both within category D). This would also add further support for the lay membership while retaining the expertise of long-serving lay members. Ultimately, however, certain lay members may have to be asked to step down after a period of service.

Access to institutional counselling services

In order to assist in support, all lay members should have access to the confidential counselling services of the institution at which they are members. Some members of ERPs may be unfamiliar with the use of animals in research and may require support.

3. General issues surrounding the working of the ERPs

Ultimate authority to block an application

It is clear that the ERP should maintain the authority to prevent an application from going forward if the submission is poor, if insufficient justification is provided or if the predicted suffering for the animals is deemed to be too great in relation to the potential benefits of the research. The maintenance of such authority may actually be in the interests of all concerned in order to avoid any external accusations of procedural 'rubber stamping'. Currently, proposals that receive funding tend to be judged on the quality of the science rather than on the ethics involved in conducting the experiments.

The maintenance of confidentiality agreements

The maintenance of confidentiality agreements is necessary for two reasons: first, it is important to allow people to air their views without concern about being quoted in the media; and second, it is important to protect the intellectual property rights of the scientists or industries whose proposals are being considered. All parties involved in the process in both countries are currently required to sign a confidentiality agreement which is binding in law.

The issue of confidentiality is far from straightforward. On the one hand, the ERP risks the criticism of everything being 'in house' and secret. On the other hand, there is the problem of individuals or groups deliberately exploiting their position in an attempt to force others into change which could undermine the whole process. On balance, only those who are willing to adhere to confidentiality agreements should be included in the process.

The need for training of ERP members and researchers

The membership of the ERP needs to be taught about the function of the process and their role. It is also essential to provide induction procedures and to publish guidelines for new lay members. These should eventually include specific guidelines that provide some form of standardisation for the cost-benefit analysis performed as part of the ethical review. Training for all applicants for a licence under ASPA 1986 is also very important and is carried out using a series of accredited modules covering aspects such as ethics, legislation, recognition of well-being, handling, an introduction to anaesthesia, and health monitoring (laid out in the guidance provided by the Home Office 1992). The important ethical aspect of this training has recently been given careful and balanced consideration by Smith and Jennings (1998) and Jennings and Hawkins (1998).

Standardisation of submission procedures

All forms to be submitted by scientists for clearance by the ERP should be standardised as appropriate and be available electronically. Although this issue was of concern in Australia

(and repeatedly emphasised) because of their decentralised system, it is not a problem in the UK, where procedures are overseen by the Home Office and standard forms are available electronically.

4. Internal and external assessment

A hybridisation of the UK 'top down' and the Australian 'bottom up' systems seems the best way forward in the UK — an emphasis on the role of the inspectorate combined with the gradual creation of a culture conducive to an institutional ERP with elements of self-regulation. The current system in the UK involving the Inspectorate is one of the great strengths of the existing process. External assessment via the Inspectorate will also assist in maintaining objectivity and eliminating lack of consistency. With this in mind, the following recommendations can be made:

(a) Emphasis should be placed on local self-monitoring. A principle focus of this form of assessment would be a follow-up on whether the ERP recommendations were being adhered to. Although inspectors can visit without notice, members of the ERP are on the spot all the time. Such a system may exist informally in the spirit of the ERP (and retrospective project reviews are stipulated in the Annex) but a formal acknowledgement of an expectation of internal monitoring may be designed to complement the role of the Inspectorate.

(b) The Home Office should clearly maintain their current advisory role and continual routine inspection of the procedures that are in place in relation to the Act. This will include all existing powers under ASPA 1986.

This approach, if carefully designed, may also help to remove any bureaucratic burden and free the Home Office to concentrate and further enhance their inspection role; inspections need to be carried out as regularly as possible in order to be effective. This mix of the 'bottom up' and 'top down' approaches is already in place in the UK since the introduction of the ERP and these recommendations therefore simply seek to build on the existing system.

5. The need for a non-Government ANZCCART equivalent

Facilitation and communication between all interested parties may be greatly enhanced in the UK by the development of an organisation similar to ANZCCART with a similar mandate. It could be called UK-CCART, the United Kingdom Council for the Care of Animals in Research and Teaching. This may be possible through an existing organisation such as UFAW (or administered by, but not part of, UFAW); alternatively, a new body could be incorporated with a similar mandate to ANZCCART. This organisation should receive funding to maintain a forum for scientists, welfare/rights groups and other interested parties, publish a newsletter free to members, conduct workshops (eg for Chairs, welfare/rights groups, lay members and others) and look to assist in other ways (eg the payment of the registration fees for attendance at conferences/workshops for those who cannot pay).

6. Introduction of the issues to undergraduates and secondary school pupils

In Australia, emphasis is placed on the need for a balanced education of the issues involved. The following recommendations merit consideration:

(a) Undergraduate science courses which include information relating to the use of animals should incorporate some form of introduction to ethics and animal welfare. Some have already introduced such courses and others should be encouraged. There are now standard textbooks on the subject.

(b) Issues relating to the use of animals in experiments should be addressed at all secondary school and further education colleges.

7. Inclusion of the term 'animal welfare'

Eventually an Animal Ethics Committee should include the term 'welfare' in its title (eg Animal Ethics and Welfare Review Process — AE&WRP) with a view to further emphasising the welfare issues surrounding the housing and maintenance of animals. It is clearly not just the use of animals in experiments that requires emphasis (ie the ethics of whether the animals should be used or not) but the housing and husbandry before, during and after experiments (ie their welfare).

8. Dissemination of information relating to ERPs

Another consideration is the need for careful dissemination of information relating to an inclusive Ethical Review Process through relevant channels such as UK-CCART. It is clearly also important for the Home Office to continue the policy of publishing all necessary statistical information relevant to the debate.

Overall conclusions

Although many may argue the imperfections of any one system — for no system is perfect — the Australian system appears to provide an appropriate framework. The inclusion of diverse segments of society is highly encouraging. In Australia, many individuals have found ways to 'bridge the divide' despite all the difficulties encountered, and their system has provided a highly constructive model.

The newly established UK local Ethical Review Process also follows the principles of inclusive dialogue. In the early stages, it appears to be benefiting from a bedding-down period while maintaining a degree of flexibility. It is clear that any changes would be best implemented through a series of long-term incremental steps. To this end, it is important for interested parties to offer further guidelines as appropriate. The key to the advancement of the ERP in the UK lies in the development and maintenance of an inclusive process of dialogue within specified parameters (which includes the creation of a 'culture' able to tolerate this approach). Certain key elements of the Australian system, as outlined above, may help in the further development of the UK ERP.

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