A resource book for lay members of Ethical Review Processes

2nd edition
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Acknowledgements

We are especially grateful to the numerous people who have contributed to the development of this resource book, including lay members of Ethical Review Processes, scientists, Named Veterinary Surgeons, animal care staff and the Home Office Inspectorate.

The RSPCA and the Ethical Review Process (ERP)

The RSPCA is a long-standing advocate of ERPs as a means of promoting ongoing consideration of ethical aspects of the use of animals in research and testing, wider involvement in decisions regarding the justification for animal use, and advancing more active implementation of the Three Rs. The Society's Research Animals Department has been involved in the development of ERPs from the early 1990s, when it produced its first report[1] advocating that ethics committees should be set up in all establishments designed under the Animals (Scientific Procedures) Act 1986. Further publications followed, produced jointly with other interested parties. In 2003, the first edition of this ERP resource was published. This updated and revised edition is now one of a series of RSPCA resources developed to facilitate the work of ERPs, and particularly their lay members, in the UK and in equivalent bodies worldwide.

[1] Jennings M. (1994) *Ethics committees for laboratory animals: a basis for their composition and function.* RSPCA, Horsham, UK.

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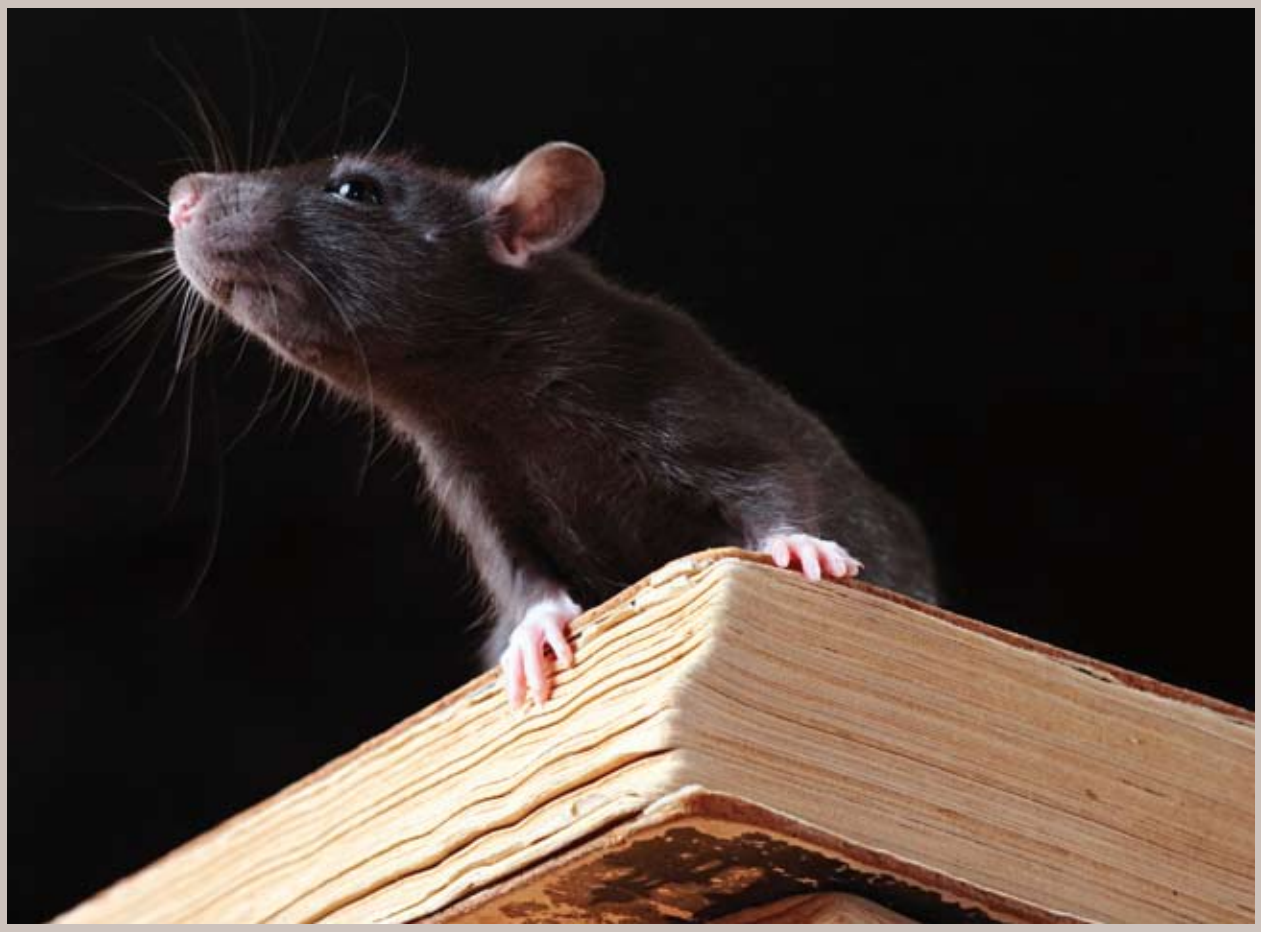

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INTRODUCTION

The first edition of this resource book was published in 2003 (Smith and Jennings, 2003). It was prepared in response to requests from lay members attending an inaugural meeting of the UK RSPCA Lay Members' Forum for information and advice to support them in their roles within local Ethical Review Processes (ERPs) (Jennings and Smith, 2000). Since it was first published, the booklet has been widely disseminated and used by lay members and other ERP participants, not only in the UK but also in similar ethical review processes around the world.

It is now ten years since local ERPs became mandatory in the UK as an adjunct to the Home Office system of licensing and control of scientific procedures on animals (Home Office, 1998), and six years since the publication of the first edition of this resource book. During that time, understanding of the ERP's role and functions has developed considerably, in the light of experience and the publication of a number of influential reports and guidance. This revised edition takes the same basic format as the first, but brings all the material up to date, includes additional resources, and provides more detailed advice on the valuable contributions that lay (and other) participants can make to the ERP.

Lay members of ERPs

The Home Office recommends that local ERPs should involve "as many people as possible" from the establishment and include lay (and preferably external) participants. It recognises the important role that lay members can play:

> "Lay members of ERPs have asked questions from a different perspective. They have constructively challenged existing assumptions and practices, with the result that improvements have been made with respect to licence applications and animal care and use." (Home Office, 2001)

A wide diversity of people may be regarded as 'lay' participants in the ERP. They come from a variety of disciplines and fields of work, within or outside establishments in which laboratory animals are kept and used.

Some have expertise in ethics *per se* (including moral philosophers and theologians), others in animal behaviour and welfare, including representatives of animal welfare organisations. Although it is a moot point whether these groups can, strictly speaking, be described as 'lay', some, at least, may have little specific expertise related to laboratory animals.

Others, more readily identifiable as lay, include managers in areas unrelated to animal use, academics from the arts or social sciences, lawyers, administrative support staff, librarians and safety officers. These people may have no special knowledge of the ethics of laboratory animal use, but bring wisdom gained through experience in their own particular fields to the ERP discussions.

This means that a broad range of people might begin to read this resource book. For those who are just starting out as participants in ERPs and/or have little knowledge of the field, most of the information and ideas will be totally new; whilst for others, much of the material may already be familiar. Nevertheless, it is hoped that all who use the booklet will find its resources useful in supporting and developing their thinking on the issues that the ERP engages with, and that it will help them make an active contribution to, and continue to develop their role in, the process.

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Contents of the resource book

The contents of this book are arranged as a series of resources, each of which addresses a particular aspect of the ERP and can be read as a 'stand alone' section.

RESOURCE 1	discusses the benefits that lay participants can bring to the ERP and lists some procedural issues for consideration when starting work as a lay member.
RESOURCE 2	is a brief guide to the main provisions of UK law on animal experiments: the Animals (Scientific Procedures) Act 1986.
RESOURCE 3	is intended to help develop an understanding of the role and organisation of the ERP and to obtain a feel for the work and ethos of the particular establishment.
RESOURCE 4	examines one of the ERP's main functions – ethical review of new scientific projects involving animals – and the part that lay members can play in this.
RESOURCE 5	explores the ERP's role in retrospective project review.
RESOURCE 6	looks at the wider functions of the ERP (beyond ethical review of specific projects), all of which can have significant impacts on standards of animal care and welfare within establishments.
RESOURCE 7	is a brief guide to preparing for and reflecting on visits to animal facilities.
APPENDIX	The resource book concludes with an appendix that considers what is meant by the 'ethics' with which the Ethical Review Process is involved.

Developing the ERP

After ten years' experience, ERPs are still evolving, especially in their approach to functions such as the retrospective review of projects and consideration of more general issues relating to laboratory animal housing and care. An RSPCA and Laboratory Animal Science Association (LASA) project is currently considering these and other issues, and is working on a series of guidelines, covering all aspects of ERP work. When these are ready, they will be available via both the RSPCA and LASA websites (www.rspca.org.uk/ethicalreview and www.lasa.co.uk).

RSPCA ERP Lay Members' Forums and other resources

In addition to publishing this book and associated resources for lay members, the RSPCA also organises annual Lay Members' Forums, which enable participants from a range of establishments to come together and share experiences of their work in the ERP. The forums include presentations on a variety of topics relevant to ERPs and provide plenty of opportunity for discussion. Reports of past meetings are published on the RSPCA's website, where you can also join an e-mail list to receive information about forthcoming events and relevant publications. (Go to: www.rspca.org.uk/ethicalreview and follow the lay members' link).

Feedback requested

This resource book is not a static document, fixed for all time, but one that grows and develops in response to ideas from people who are integral to the ERP. Input from lay and other members is essential to ensure that the material it contains is relevant and helpful in supporting their work. Comments, criticisms, suggestions for changes and ideas for further resources are welcomed; in fact, they are required!

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RESOURCE 1: Participating in the ERP

The lay member's role

The Home Office Guidance on the Animals (Scientific Procedures) Act 1986 (2000) states that "one or more lay persons independent of the establishment should be considered" as participants in UK ERPs. Lay involvement is also common practice in other countries that have broadly equivalent review processes (such as Australia, Canada, Sweden and the USA).

Participants in RSPCA Lay Members' Forums have suggested that lay members add value to the ERP in the following ways.

- **Providing an independent and novel perspective**
  Lay people can ask the kind of insightful questions that people directly involved might not consider asking. They can bring a 'fresh eye' by questioning established practice and challenging accepted norms, which in turn can help to stimulate new or different ways of thinking about the ethical, animal welfare or scientific issues.
- **Acting as an advocate of animals and science**
  Lay members can ask questions from the animals' point of view, with the aim of making a positive difference for animal welfare. Similarly, they can ask questions about the science, with the aim of understanding the benefits that are sought, how these can be achieved with the least possible impact on animals and why alternatives cannot be used. They will also want to ensure that the justification for using animals is critically evaluated.
- **Helping to ensure the integrity of the process**
  Lay members can also play a more procedural role, helping to ensure that the ERP's procedures are rigorous and that all the members play their proper parts, thereby helping to promote transparency in the ERP's work.
- **Supplying a measure of public representation**
  Lay involvement can provide a societal input into decisions on animal experiments, which are often funded by public money and carried out in the public's name. This in turn can help scientists see how members of the public might view their work. It is of course unrealistic to expect individual lay members to represent the full spectrum of public perspectives, but nevertheless their inclusion can be viewed as a contribution to openness.

See also APC (2003) and FELASA (2007) for further discussion.

Comparison with lay involvement in other similar contexts

Similar roles are proposed for lay participants in local research ethics committees for clinical (medical) research in the National Health Service and in scientific advisory committees at the government's Department for Environment, Food and Rural Affairs. Empirical studies of the part that lay members play in these contexts indicate that there is a general feeling that lay perspectives are important and can bring substantive procedural benefits, helping to ensure the rigour of the review process itself (Dyer, 2004; Stilgoe *et al.*, 2006). However, it is also acknowledged that it is not always easy for lay members to contribute in the ways listed above (see also Entwistle *et al.*, 1998). For example, it can be difficult to ask pertinent and stimulating questions when complex scientific issues are discussed, or to 'challenge accepted norms' when visiting the establishment and/or its animal facilities relatively infrequently.

In this respect, it is important to remember that it is not only lay people who can face such difficulties, and that other members of the ERP are likely to be in a similar position when the discussions fall outside their own specialist areas. Indeed, some commentators argue that the term 'lay' is unhelpful, because it suggests that there are two classes of member (lay *cf.* expert), rather than a group of equal but diverse experts to which lay members bring wisdom gained in other fields that can complement the expertise already on the committee (Stilgoe *et al.*, 2006).

Feeling confident in the role

It is clear that to achieve any of the benefits listed left, lay members need to feel confident and comfortable in their work. The following practical steps, again suggested by participants in the RSPCA's Lay Members' Forums, should help in this.

- ### Do not feel apologetic about a lack of expertise in the particular issues under consideration
  Lay participants need to understand the issues, but are not expected to have any special expertise related to laboratory animal use. There is not a strict dichotomy between lay and expert within the ERP, and at times the roles are overlapping and interchangeable.

- ### Ask any question you feel is important
  A point that might seem obvious from an outside perspective, could be the very thing that the people closely involved in the situation have not yet spotted. Furthermore, asking for clarification can enable not only you but also other members of the ERP to enter more fully into the discussions. The resources in this booklet include ideas for questions to ask in a range of different contexts.

- ### Draw support from other lay members, as well as other members of the ERP
  Getting to know the other participants in the ERP, as well as other members of the establishment, can help you to develop confidence in your role. Talking with other lay members can be especially helpful, and the annual RSPCA Lay Members' Forums enable lay people from a range of different establishments to meet one another and compare perspectives and approaches (RSPCA, 2008). Experience also shows that the support of a challenging ERP chairman is very valuable, particularly when that chair is also a layperson.

- ### Obtain as much information as possible to help you in your work
  In order to participate effectively, all members of the ERP need to understand as much as possible about the ERP itself, the work presented for review, how animals are used and cared for in the establishment more generally, and where to go to for advice on issues such as the Three Rs (see page 14). Good non-technical summaries of projects that have been through the ERP, visits to animal facilities and discussions with relevant staff are also particularly helpful.

All these aspects, along with other thoughts on obtaining information and developing understanding, are explored in more detail in subsequent sections of this resource book.

Some procedural issues

Trust and confidentiality

As in similar situations, a relationship of mutual trust has to exist between members of the ERP and the establishment. The confidentiality of research proposals and ongoing work has to be respected and the actions of the ERP and its individual members must not jeopardise security.

Moreover, in order to safeguard freedom of expression within ERP discussions, members usually work on the understanding that 'who said what' in meetings is not divulged outside the ERP without its authority.

Some ERPs make formal minutes available to other members of staff within the establishment. In addition, the ERP may have to respond to more public requests for information about decisions, minutes, or synopses of them, under Freedom of Information legislation.

Consensus, compromise and disagreement

For the ERP to be effective, it is important that participants work together to try to achieve consensus. However, there may be times when some members disagree with the majority view and feel unable to compromise their position. Expressing and standing by a difference of opinion can be difficult, but is important, since always compromising in such circumstances diminishes the value of involving a diversity of perspectives.

Whether and how best to record disagreement is something that the ERP and its individual members will have to decide for themselves. In this context, it is important to remember that the ERP's role is to advise the establishment's Certificate Holder (the person who bears ultimate responsibility for the care of all animals bred, supplied or used within the establishment – see Resources 2 and 3), and that it is perfectly legitimate for the advice offered to include different opinions.

For its part, the ERP should enable participants who have reservations to feel that their concerns have been taken seriously, and should not subject lay or other members to cross examination that can close down, rather than open up, discussion of differences of opinion.

TO DO

Participants in the annual RSPCA Lay Members' Forum have suggested a number of questions that are helpful for potential lay members to think about when considering joining or beginning work in an ERP, and these are set out below. Matters relevant to these questions are also explored in Resource 3: Getting to know the establishment and its ERP.

Some questions to think about when considering becoming a member of an ERP

- Are you clear about the roles and responsibilities of lay members within the ERP?
- What do you hope to achieve by participating in the ERP?
- How far does your perception of, and hopes for, your role match the expectations of the individual ERP itself?
- Do you have strong views on animal experiments, and is reaching consensus within the ERP likely to involve compromising your personal principles?
- Would you have any concerns about the minutes of meetings being made more widely available, within or outside the establishment?
- As well as attending formal ERP meetings, would you be able to commit time to reading what might be a large volume of written material prepared for the ERP, and also to visiting animal facilities and getting to know the work of the establishment?

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RESOURCE 2: UK law on animal experiments in a nutshell

Much of the specialist terminology heard in ERP discussions comes from the law on animal experiments – the Animals (Scientific Procedures) Act 1986 (ASPA) – and the majority of the ERP's work is related to this Act. It seems most helpful, therefore, to begin these resources with a guide to its main provisions. Key terms that will appear elsewhere in this resource book are in orange. All quotations are from Home Office (2000) and/or the ASPA itself.

The European legislation on animal experiments (Directive 86/609) is also relevant since individual member states have to implement this through their own national laws. The Directive is under review at the time of writing (in 2009) and the revised text is likely to establish the requirement for local ERPs throughout Europe.

Scope of UK regulation

The ASPA regulates the use of vertebrate animals (mammals, birds, reptiles, amphibians and fish) and one species of invertebrate (*Octopus vulgaris*) in: "Any experimental or scientific procedure applied to a protected animal which may have the effect of causing that animal pain, suffering, distress or lasting harm".

Developmental stages of animals covered

Mammals, birds and reptiles are covered from halfway through gestation or incubation. Fish, amphibians and octopuses are covered from the time they become capable of independent feeding. This means that, for example, foetal rats, chickens' eggs, fish larvae and frog tadpoles may all be covered depending on their stages of development.

Level of adverse effect that is regulated

Under European and UK law, regulation of scientific procedures on animals starts at the level of pain and stress that would be caused by "skilled insertion of a hypodermic needle". In Britain, the Home Office decides thresholds at which other kinds of procedure, such as psychological stress and environmental changes, become regulated. Acts of "commission" (e.g. blood sampling) and of "deliberate omission" (e.g. withholding food) are both included.

Licences required

Before scientific procedures can be carried out on animals, three kinds of licence must be obtained, covering the place, the project and the personnel involved.

- The **certificate of designation** licenses establishments in which scientific procedures are carried out on animals and also establishments that breed and/or supply animals for research and testing – these are **designated establishments**.
- The **project licence** (which has to be obtained for every scientific project in which animals are used) licenses a specific "programme of work" for up to five years.
- The **personal licence** licenses a "suitable and sufficiently competent" individual to carry out specified procedures on animals within the context of a project licence.

Administration of the law

The law is administered by the Home Office, through a team of **Home Office Inspectors**, who:

- review applications for new project licences and any later amendments, advising the Secretary of State for the Home Office whether to grant them
- visit designated establishments to monitor compliance with ASPA and to advise on laboratory animal welfare and implementation of the **Three Rs** (see box overleaf).

A statutory, independent **Animal Procedures Committee (APC)** also advises the Home Secretary on matters concerned with the ASPA. Members of the APC must, in law, include two-thirds medical practitioners or veterinary surgeons or biologists, with at least one lawyer. At least half of all members must not hold, or must not have held within the past six years, any licence under the ASPA. Other members have various areas of expertise and usually include licence holders, scientists who do not use animals, animal welfarists, anti-vivisectionists and philosophers.

Legal responsibilities

The Certificate Holder

The establishment's **Certificate Holder** (who holds the certificate of designation) bears overall responsibility for "standards of [animal] accommodation and care" and must "actively establish, nurture and reflect a culture of care" at the establishment. The Certificate Holder is also responsible for ensuring that only "authorised [i.e. licensed] regulated procedures" are performed at the establishment and is required to set up and maintain the establishment's local ERP (see Resource 3).

Named persons

Every designated establishment must nominate the following **Named persons**:

- a **Named Veterinary Surgeon (NVS)**, who is responsible for "providing advice on animal health and welfare"
- one or more **Named Animal Care and Welfare Officers (NACWOs)**, who are responsible for "the day to day care of the animals".

Project licence holders

Project licence holders take: "overall responsibility for the scientific direction, management and control of the programme of work" specified in the project licence and must ensure compliance with its terms and conditions. They are also responsible for the "supervision, training, conduct and performance of personal licence holders" working under the licence.

Personal licence holders

Personal licence holders bear: "primary responsibility for the welfare of the animals on which they perform regulated procedures".

Ethical framework of the ASPA

The ASPA sets out an ethical framework for deciding whether or not particular uses of animals are acceptable and justified and can be authorised by a project licence. The broad principles are as follows.

- A **harm-benefit assessment** must be carried out for every project, weighing "the likely adverse effects on the animals concerned against the benefit [to humans, other animals or the environment] likely to accrue from the programme of work".
- The purpose of the work cannot be "achieved satisfactorily" by "any other reasonably practical means" that does not use animals covered by the ASPA.
- The procedures used must involve the minimum number of animals, with the "lowest degree of neurophysiological sensitivity", and cause the least pain, suffering, distress and lasting harm.
- Additional justification is required for the use of cats, dogs, primates and equidae.

The Three Rs

The Three Rs are principles of humane experimental technique that were first set out by Russell and Burch in 1959. These principles are now widely accepted in the international scientific community and encompassed in UK and European legislation. They are defined as follows.

Replacement: using methods or strategies that replace or avoid the use of animals in research and testing.

Reduction: employing strategies that reduce the numbers of animals used to achieve the scientific objectives, for example, by improving experimental design and statistical analyses.

Refinement: refining scientific and other procedures (for example, transport, housing, restraint) to reduce suffering and improve the animals' welfare at every stage of their lifetime.

Codes of Practice and guidance notes

In addition to the ASPA itself, the Home Office has published two Codes of Practice on the required standards of animal husbandry and care in establisments where animals are used in scientific procedures (Home Office, 1989) or bred and supplied for such use (Home Office, 1995). There is also a *Code of Practice for the Humane Killing of Animals* (Home Office, 1997).

From time to time the Home Office also issues policy statements and additional guidance on matters relating to the ASPA and its interpretation in practice. Examples include policies on the education and training of personnel and on the ERP itself. These, and other helpful information on the legislation surrounding the use of laboratory animals, are available via the Home Office's website: scienceandresearch.homeoffice.gov.uk/animal-research and, in particular, in the detailed publication *Guidance on the Operation of the Animals (Scientific Procedures) Act 1986* (Home Office, 2000). Further information about the work of the APC can be found at: www.apc.gov.uk

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RESOURCE 3: Getting to know the establishment and its ERP

As a new lay member, it can take a while to gain a clear picture of the role of the ERP, how it operates and the research that it covers. To help with this, Resource 3 includes information about the organisation and work of ERPs in general and suggests some practical steps that can assist in finding out more about the work of your particular establishment and its ERP.

Note that specific terms relating to the law on animal experiments are explained in Resource 2.

ERPs in general

The ERP is set up and maintained by the establishment's Certificate Holder, to whom it provides advice. It is a local framework that should work to ensure that all use of animals within the establishment, as regulated by the Animals (Scientific Procedures) Act 1986, is carefully considered and justified; that proper account is taken of all possibilities for replacement, reduction and refinement (the Three Rs); and that high standards of accommodation and care are achieved.

The Home Office (1998; 2000a) lists three key aims for the process, and defines seven core functions that should be undertaken to fulfil these.

The ERP's three key aims

1. To provide independent ethical advice to the Certificate Holder, particularly with respect to project licence applications and standards of care and welfare.
2. To provide support to Named persons and advice to licence holders regarding animal welfare and ethical issues arising from their work.
3. 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 ERP's seven core functions

1. Promoting the development and uptake of reduction, replacement and refinement alternatives within animal use, where they exist, and ensuring the availability of relevant sources of information.
2. Examining proposed applications for new project licences and amendments to existing licences, with reference to the likely [welfare] costs to the animals, the expected benefits of the work and how these considerations balance.
3. Providing a forum for discussion of issues relating to the use of animals and considering how staff can be kept up to date with relevant ethical advice, best practice and relevant legislation.
4. Undertaking retrospective project reviews and continuing to apply the Three Rs to all projects throughout their duration.
5. Considering the care and accommodation standards applied to all animals in the establishment, including breeding stock, and the humane killing of animals covered by the ASPA.
6. Regularly reviewing the establishment's managerial systems, procedures and protocols where these bear on the proper use of animals.
7. Advising on how all staff involved with the animals can be appropriately trained and how competence can be ensured.

The Home Office also provided initial guidance on who should participate in the ERP (Home Office, 2000a).

Participants in the ERP

Required participants

- "A Named Veterinary Surgeon (NVS) and representatives from among the [establishment's] Named Animal Care and Welfare Officer(s) (NACWO) should be involved."
- Project and personal licence holders "should also be represented".

Suggested participants

- "Where possible, the views of those who have no responsibilities under the Act should be taken into account."
- "One or more lay persons, independent of the establishment, should also be considered."

In addition

- Home Office Inspectors "should have the right to attend any meetings and have access to the records of the ERP."
- All licence holders and NACWOs "must be informed of the ERP and should be encouraged to bring matters to its attention."
- The process should also "allow for input by colleagues and other people from outside the establishment."

Note that many establishments now also employ a Home Office Liaison Officer (HOLO) who, amongst other tasks, helps to administer the ERP – but this is not a Home Office requirement.

The value of involving lay members was subsequently emphasised as follows:

> "Lay members of ERPs have asked questions from a different perspective. They have constructively challenged existing assumptions and practices, with the result that improvements have been made with respect to licence applications and animal care and use." (Home Office, 2001)

Your local ERP

General organisation

Establishments vary considerably in size, in the nature and diversity of their scientific studies and animal work, and in their management structures. It was therefore emphasised at the outset that: "It is for each establishment to design, implement and maintain a process suited to its particular needs and resources" (Home Office, 2000b). There is no standard Home Office-prescribed way of organising an ERP and no requirement for a formal committee structure, though most, if not all, do involve committees of some kind.

This means that ERPs vary in how they are designed to meet the aims and objectives described left. For example, in a small research institute with relatively few project licence holders working in broadly similar areas, the ERP might comprise a single, central committee. In a large university, a single committee would find it difficult to cope with the volume and diversity of issues that the ERP has to address and so a more complex structure is needed, perhaps a central committee plus a range of departmental sub-committees or other working groups.

TO DO

Every establishment has to submit details of the structure and operation of its ERP to the Home Office and any subsequent changes also have to be notified. If you have not received this information already, you should be able to obtain an up-to-date copy from the establishment (e.g. from the HOLO / ERP administrator if there is one, the establishment's Certificate Holder, or the ERP chairman).

Membership

The categories of people who participate in the ERP are listed on page 17. It is important to understand their roles within the establishment, the experience and expertise they bring, and the perspectives they represent.

Effective, open and trusting communication between members of the ERP is essential but, as with any committee or similar process, this can take time to develop. Opportunities for informal discussion with other ERP participants are particularly valuable, and lay members should feel able to approach scientists, Named persons, and others with relevant expertise to ask questions and discuss issues arising in the work of the ERP.

TO DO

To help you get to know other members of the ERP, you should be able to obtain the names, affiliations and, if necessary, their contact details from the HOLO / ERP administrator, or the establishment's Certificate Holder or ERP chairman.

The work of the establishment

The establishment's research interests and use of animals

It is important to appreciate the context in which the ERP operates. That is, to understand the establishment's research interests and why and how animals are used, and to gain a feel for the culture of the place. This includes the priority given to animal welfare and the Three Rs and the many factors that impact on these. It can take time to acquire a strong sense of these aspects, particularly when coming from outside the organisation.

TO DO

The box below lists some factors that can help in building up a picture of the animal work carried out within the establishment, which you might explore with other members of the ERP. It is also very valuable to visit the animal facilities and view the animals whenever possible (see Resource 7).

Building up a picture of animal work within the establishment: some points to consider

- The **type of establishment**, for example whether it is predominantly an academic, industry or contract research organisation. This will influence the type of work and the reasons it is done, for example, the balance between fundamental and applied research and whether tests are carried out to satisfy regulatory requirements.
- The **diversity of research interests** across the establishment as a whole and within individual departments, and the **lines of responsibility** involved in managing animal care and use.
- The **scale of animal research**, for example the number of project licences and personal licensees, and the frequency of submissions of new project licence applications and amendments to the ERP.
- The variety of **animal species used**, how the animals are **housed and cared for**, and the numbers of each kept at the establishment.
- The broad range of **types of scientific procedures** carried out, and whether the establishment has decided **any absolute limits** on the kinds of work that can be done. For example, some establishments will not use primates or dogs, or carry out safety testing of certain categories of non-medicinal products.

The wider context within which the ERP operates

Local ERPs should aim to "add value" by "targeting their resources at aspects of animal care and use *not already provided for by other means*" (Home Office, 2000b; our italics). In particular, the ERP should not duplicate the work of the Home Office Inspectorate and should aim to complement, not replicate, other activities that affect whether and how animals are used within the establishment. It is therefore helpful to have an understanding of these other activities in order to appreciate where and how the ERP can add value.

TO DO

Some activities that can impact on the work of the ERP are listed below. It might be helpful to ask someone involved in your ERP (perhaps the HOLO / ERP administrator, ERP chairman, or the NVS) to talk you through these and to explain where and how they relate to the ERP's work.

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Examples of activities that can impact on the use of animals and the work of the ERP

Groups that review or discuss animal care and use in the establishment

- Animal users' groups; animal house management/policy committees; NACWO discussion forums; ongoing project review carried out by project teams involving animal care staff.
- Internal or external audits of standards of animal care and welfare.

These activities can all have positive impacts on both animal welfare and science. In fact, they may be regarded as part of the ERP and provide it with information, advice or feedback.

Activities that help decide the animal research that is done in the establishment

- Review of research proposals and ongoing projects by internal or external funding bodies.
- Research priority-setting by senior management within the establishment.
- Business processes in Contract Research Organisations.
- Audits of research quality, carried out by internal or external assessors.

The outcomes of these processes clearly have impacts on whether and how animals are used. However, their focus is on scientific quality and research priorities, and they vary as to whether, and in what detail, they consider animal use and associated ethical issues.

The work of the Home Office Inspectorate

- Formal review of project licence applications once they have been through the ERP.
- Announced and unannounced visits to inspect animal facilities and check compliance with the Animals (Scientific Procedures) Act 1986.
- Meetings with licensees and/or animal care staff to discuss issues and provide advice.

Processes that review the results of research

- Editorial peer review prior to publication in journals or other media.
- Other peer reviews, for example, by scientific peers or senior management within the establishment, externally at conferences and/or by the bodies that fund the work.

These processes can influence animal use in a number of ways, for example, if a reviewer requires replication of a study before publication or further funding, or if particular methods or approaches are required to meet reviewers' expectations.

The ERP's outcomes

It was emphasised from the start that the outcomes and effects of the ERP are more important than how it is done. ERPs therefore need to be clear about their objectives in relation to each of the seven functions. They also need to evaluate their effectiveness and efficiency in achieving their aims and consider whether the process can be improved in any way.

TO DO

It is important to be clear what the aims and objectives are for your individual ERP. You also need to find out how the decisions and advice provided by the ERP are implemented in practice, what feedback is asked for by the ERP, and how the impacts of the ERP's work are evaluated.

Looking at the ERP's work in more detail

The ERP's seven core functions (see page 16) fall into two interrelated categories:

- project licence review (both prospective examination of new licence applications and amendments, and retrospective review of existing licences) – ERP Functions 2 and 4 respectively
- consideration of wider aspects of animal care and use within the establishment – ERP Functions 1, 3, 5, 6 and 7.

The balance of time spent by ERPs on fulfilling these two roles varies considerably, depending in part on the number of project licences operating at the establishment and the frequency of licence applications. Some ERPs focus mainly on the assessment of project licences. However, more general aspects of animal care and use and the application of the Three Rs, together with the wider ethical and educational issues, all have a significant impact on animal care and welfare across the establishment and the ERP must consider these as well (see Home Office [2007] for a recent review of ERP activities).

The two facets of the ERP's work (project review and consideration of wider aspects of animal care and use) are considered in more detail in the next three resources.

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NOTES

RESOURCE 4: Reviewing scientific projects involving animals

Consideration of project licence applications forms a major part of the work of most ERPs, and can be the most difficult task for lay members to engage in because of the level of scientific detail and the complexity of the issues involved. Resource 4 examines the ERP's role in the review of new project licence applications and amendments, describes some factors for consideration, and discusses ways in which lay members can contribute.

The ERP's role in project review

The ERP's main functions with respect to project licences are as follows.

ERP project review functions

- Examining proposed applications for new project licences and amendments to existing licences, with reference to the likely [welfare] costs to the animals, the expected benefits of the work and how these considerations balance. (ERP Function 2)
- Undertaking retrospective project reviews and continuing to apply the Three Rs to all projects, throughout their duration. (ERP Function 4)

These activities help to implement the ethical framework of the Animals (Scientific Procedures) Act 1986 (ASPA) described in Resource 2.

A number of different stages and processes are involved in the development and review of a project licence from its initial preparation through to its authorisation, operation and completion. This includes the following (with the ERP's roles **in bold**).

- Scientists prepare project licence applications and any later amendments, usually in conjunction with appropriate staff (such as the Named Animal Care and Welfare Officer [NACWO], Named Veterinary Surgeon [NVS] and statistician) and with advice from the local Home Office Inspector. In so doing, they should make their own assessments of likely harms and benefits, and how these balance.
- **Licence applications are reviewed by the ERP, which provides advice to the Certificate Holder, who is responsible for signing the applications, thereby indicating the establishment's support for the project.**
- Signed applications are submitted for review by the local Home Office Inspector, who advises the Home Secretary whether or not to grant the project licence under the ASPA.
- A small number of applications are also referred by the Home Office for review by the national Animal Procedures Committee (APC) (see Resource 2 and APC [2004], pages 1–2).
- Home Office Inspectors visit establishments to monitor and advise on standards and compliance with the ASPA, its codes of practice and the terms of each project licence.
- **ERPs carry out ongoing/retrospective reviews of licensed work** (see Resource 5).

In addition, scientific aspects of projects may be reviewed by scientific peers (for example, by funding body review panels when deciding whether or not to provide funds for the research) and/or by senior management within the establishment. This can take place before or after a project licence is obtained, and varies in whether and to what depth the use of animals is taken into account, compared with other factors such as the quality of science.

The benefits of ethical review of project licence applications by the ERP

The ERP operates at a local level, so its review of project licences differs from that of the Home Office Inspectorate in that it looks at applications from the *local perspective* of the establishment in which the work will be carried out. It can therefore add value by:

- reviewing project licence applications and amendments in light of the establishment's own goals and ethical values
- involving a wider range of perspectives and expertise from within and outside the establishment, including animal care staff, licence holders, other scientists, and lay people
- basing reviews on first-hand knowledge of local factors that impact on animal care and use, such as the facilities and expertise available to carry out the work, and how, in practice, the use of animals will be managed (for example, local processes for monitoring animals and implementing humane end-points)
- facilitating communication between scientists and Named persons (NVS and NACWOs, see Resource 2) on animal care and welfare issues arising in new projects (for example, regarding refinements to techniques or special husbandry needs)
- drawing on other local expertise, advice and resources that can help to reduce or replace animal use, enhance animal welfare and improve scientific aspects of projects (for example, providing advice on alternative approaches, experimental design and statistics, animal accommodation and care, and other Three Rs issues)
- providing a forum for consideration of any wider ethical issues arising in project reviews
- ensuring that, where relevant, advice given and lessons learned in review of project licence applications (e.g. examples of Three Rs initiatives) are disseminated more widely within the establishment.

See Home Office (2000b; 2001) and APC (2003) for further discussion.

Local procedures for ethical review of project licence applications

Procedures for ethical review of project licence applications vary between establishments. In some establishments, a single, central committee reviews all licence applications and amendments. In others, this is done by one or more smaller 'project review groups' with feedback and any applications of particular concern or contention (for example, those involving procedures that have the potential to cause substantial suffering to the animals) being brought to a central, overarching committee.

In some establishments, the people involved in project review always meet face to face, whereas in others much of the business is conducted via e-mail. The project licence applicant may attend the meeting to present the project, and this is particularly helpful in facilitating discussion of applications and resolving concerns swiftly.

In addition to consideration of new project licence applications, some establishments also review individual studies carried out under a licence as they arise, for example when the establishment holds relatively few project licences or where a licence is very broadly framed.

There may also be 'fast track' procedures for the review of certain categories of work, such as minor amendments to existing licences.

Establishments also vary in how they deal with applications for secondary availability[1] for a project licence application that has already been through the ERP of the establishment in which the majority of the work will be carried out. Some ERPs carry out a (second) full review of the licence, whereas others focus on the particular work that will be done at their site and whether the overall 'ethos' of the project fits with their own culture and standards.

[1] Project licences specify the establishment(s) where the regulated work will be performed. Sometimes a licence holder may want to carry out the work in more than one establishment. The first named place where the majority of the work is performed is known as the "primary availability". The other place(s) listed are described as places of "additional" or "secondary availabilities" (Home Office, 2000a, page 27).

Some establishments provide members of the ERP with guidance on particular issues they might wish to address, and some require project licence applicants to provide additional material to help the ERP gain a better understanding of the project. This may include a 'lay summary' of the application, including a brief outline of the likely benefits and harms of the work and how the researchers have 'weighed' them.

TO DO

Information about your ERP's procedures for project review should be found in the document describing the ERP, submitted by the establishment to the Home Office. This should be available from the Home Office Liaison Officer (HOLO)/ERP administrator, Certificate Holder or ERP chairman.

It is essential to make sure you are clear what the establishment hopes to achieve through its review of project licence applications and amendments, including what outcomes it expects and how these are evaluated in practice, so do always ask the ERP to explain this to you at the start.

Participating in ethical review of project licence applications

What lay members should expect

The review process should enable you to understand the potential benefits of projects and all of the harms likely to be caused to the animals throughout their lifetime. It should explain why the researchers believe that the goals of the project justify using animals, what efforts they have made to avoid or replace procedures involving animals, how the numbers of animals have been minimised and how suffering will be reduced and welfare improved.

There should be plenty of opportunity for you to ask questions and to engage in discussion with other participants in the ERP, in order to form your own views and work towards consensus, and so provide feedback to the researchers and advise the establishment's Certificate Holder on two key inter-related aspects:

- whether any changes can and should be made to the work, to reduce its impact on animals and enhance the science, and
- whether the ERP feels that the balance of benefit over harm is sufficient for the establishment to support the work.

At the end of the process, you need to feel comfortable that the review has been carried out with care and rigour and has addressed any concerns, and that the advice provided to the Certificate Holder has benefited from the range of expertise and perspective represented.

Three steps in prospective project review

People involved in the ERP will develop their own particular approaches to the review of licence applications, but everyone will need to do the following.

- Gather information: find out about the project, what it entails and how the researchers have weighed the harms and benefits and applied the Three Rs.
- Clarify and discuss issues with other participants in the ERP: ask questions about harms and benefits, application of the Three Rs and any specific ethical issues that arise.
- Draw conclusions: both personally and with other members of the ERP in order to provide feedback to the researchers and advice to the Certificate Holder.

(Each of these three steps is considered in more detail on the following pages.)

Gathering information

'Lay' summaries of applications

Formal applications for project licences should include all the information needed for ethical review of the proposals. However, applications are often complex and are written in technical language that can make it difficult to ask constructive questions and enter fully into discussion.

To help readers understand and identify ethical, scientific or animal welfare issues arising in project licence applications, some ERPs ask researchers to provide summaries that explain the salient features of their projects in non-technical terms, highlighting the main issues of harm and benefit that the ERP has to consider. If these are well written, they can be very useful for any member of the ERP, not just lay members. A synopsis of advice on preparing project summaries for local ERPs is given in the first edition of this resource book (Smith and Jennings, 2003) and its key points are given in the box below.

In addition, since 2005, project licence applicants are asked to produce abstracts of their licences, which cover similar information and are published by the Home Office on its website as a contribution to greater openness (Home Office, 2008a). If properly prepared, these abstracts can serve the same purpose as a summary specifically prepared for the ERP, and using them means that there is no need for additional paperwork. However, although current project licence abstracts are generally strong on the perceived benefits of projects, they are often weak in describing the scientific procedures and their effects on the animals, and sometimes do not even give the species of animals and numbers used (see RSPCA, 2006; Hudson, 2006; Phillips and Jennings, 2008).

TO DO

If you do not receive good quality 'lay' summaries or abstracts as part of project review it would be worth asking for these to be provided. If you do receive summaries, your views on their clarity and helpfulness should provide useful feedback to researchers before they submit their abstracts for publication on the Home Office website.

To be useful to ERP members, a summary needs to include sufficient detail to clarify the likely harms to animals as well as the potential benefits of the project, and to highlight what the main ethical issues are likely to be.

Guidance on preparing project summaries

In about two pages, provide a paragraph or two under each of the following headings, writing in non-technical language and avoiding jargon.

Objectives and potential benefits of the project

- Distil the *key* objectives and perceived benefits and say why these should be pursued now.
- State why the *particular* project is important, not merely the general field of research.
- Outline the general sequence of the work, indicating how different approaches, including non-animal studies, contribute.

Why animals are needed

- State the *key* reasons why the project requires the use of animals, including:
  - why animals are needed at this particular stage in the work and why alternative methods cannot be used
  - why the particular species/strains of animals have been chosen.

Continued . . .

Anticipated number of animals involved

- Indicate the means by which the experimental design and number of animals have been decided – for example, by taking statistical advice.
- Where maximum numbers of animals are stated in the licence application, if possible note the numbers that are *actually* likely to be used if all goes to plan.

What happens to animals during the project

- Provide a candid synopsis of the main adverse effects, covering the experience of the animals from birth to death:
  - include any adverse effects due to the methods of housing, husbandry and supply of animals, as well as the effects of the scientific procedures themselves
  - note the likely level and duration of suffering
  - state what will happen to the animals at the end of the procedures (e.g. euthanasia, re-use[2], rehoming).
- Outline efforts made to minimise adverse effects, for example, improvements in technique or husbandry, humane end-points, and any special arrangments for monitoring and caring for the animals.

Explain (briefly) why you think that the benefits outweigh the harms and the research is justified

State the source of funding and any collaborations

Project licence applications

A summary only provides an overview of the work proposed, so it is usually necessary to turn to the full project licence, either to look up specific details relating to points in the summary or to read the whole thing. You should therefore expect to see full project licence applications, since these documents should include details of all the aspects needed to understand and assess the justification for the work and the care taken to minimise its impacts on the animals.

Other sources of information

Discussion with researchers also helps you to gain a clearer understanding of the project. It is helpful for project licence applicants to attend ERP meetings at which their work is reviewed since this enables them to respond to questions directly, thereby promoting open discussion and dialogue and helping to resolve any problems quickly.

TO DO

Informal discussions with scientists, Named persons and others, as appropriate, can help you gain a better understanding of issues raised in project review. This also helps others see things from your perspective. Discussions with other lay members can also be useful in identifying any points of concern and questions to ask.

Other members of the ERP can also answer queries and clarify points of concern. For example, the Named persons can help you to understand the potential effects of scientific procedures on animals, possible ways of refining procedures and issues of animal care and husbandry.

Information about projects need not be confined to paperwork and discussions in committee. It can be difficult to envisage what effects the written protocols will actually have on the animals in practice, and so it is very valuable to see the animals for oneself, especially if the ERP feels there is a particular cause for concern. Sometimes, experimental or other constraints mean that this is not possible, but the researchers and Named persons can nevertheless provide insights into the animals' likely experiences. More generally, visits to animal facilities can help to ensure that project review is rooted in wider understanding of animal husbandry and care at the establishment (see Resource 7).

[2] Re-use of animals is only allowed under certain carefully controlled circumstances and must be authorised in the project licence (see Home Office, 2000a, page 34).

TO DO

You should be provided with sufficient information to enable you to get a good sense of the full impact of the proposed work on the animals throughout their lifetime, and of the expected scientific benefits and how these will be applied. If not, you should ask for more explanation – you will rarely be alone in doing this. It is important that everyone involved understands what is presented so that they can participate fully in discussion and come to informed decisions.

Clarifying the harms and benefits of projects

The notes in this section have been prepared in response to lay members' requests for help in identifying and asking pertinent questions about the harms and benefits of projects. They draw on a range of other available guidance on harm-benefit assessment and ethical review (including the first edition of this resource book), which are described under 'Some sources of further information' at the end of this chapter (page 36). Some establishments have also drawn up their own guidance, including lists of factors for consideration, to assist ERP members in project review. This may be circulated with each licence application and as part of the paperwork for review of work in progress, and may also be found in documentation describing the operation of the particular ERP.

A wide range of factors can contribute to the harms and benefits of projects, and it is useful to bear these in mind when approaching project review. 'Reminder lists' of questions for consideration, such as those presented at the end of this resource (pages 32–35), can be very useful in guiding thought and can help to ensure that reviews are as pertinent and comprehensive as possible. However, they should not be used in a mechanical, box-ticking manner.

Benefits: points to consider

Members of the ERP need to understand the aims and objectives of the research, at least in broad terms, to help them evaluate the arguments used by scientists to justify the use of animals in their projects and to make their own judgements. However, asking questions about the benefits of projects and interpreting the answers can be difficult because the science involved is often very detailed, the wider context into which the specific project fits may be difficult to see, scientific outcomes are by their nature uncertain, and perceived benefits may only be realised a long way in the future.

It is sometimes suggested that ERPs should not assess benefits when the scientific work involved has already been peer reviewed and supported by reputable funding bodies. Clearly, it is important to take into account the value that funding bodies place on the science involved, along with any commercial or regulatory reasons for the work. However, the focus of the funding body review is on quality of science, and, although the use of animals may be considered, animal welfare and associated ethical issues are not the main priority. The ERP by contrast considers the likely benefits *in relation to the particular harms* likely to be caused to the animals and with *knowledge and understanding of local factors* that need to be taken into account. It therefore delivers a different and valuable perspective on questions of benefit.

See APC (2003) for further discussion; see also the list of benefits of ERP review on page 23.

Questions relevant to likely benefits can be especially helpful in identifying practical issues that could influence the success of the project (for example, in respect of experimental design, possible alternative approaches, and resources available for the project). It is particularly important that such issues are addressed at a *local* level, so that, wherever necessary, appropriate safeguards and practical responses can be put in place by the establishment itself. For example, the ERP could advise the Certificate Holder of any staff training needs or requirements for particular facilities, equipment or expertise that the establishment needs to address; or if the project involves a method new to the

establishment, the ERP could ask for a pilot study and regular feedback, especially in the early stages of the work.

A list of questions to help in thinking about the potential benefits of projects and the likelihood that these will be achieved in practice is included at the end of this resource (see page 32).

TO DO

Experience shows that by using these sorts of questions non-specialists can provide helpful perspectives on issues of benefit, even though they do not have in-depth knowledge of the particular field of research.

Harms to animals: points to consider

In order to 'weigh' the benefits in light of the likely harms to animals, it is essential that all the various adverse effects (harms) and their sources are identified and that everything possible is done to reduce and preferably avoid these. The adverse effects caused by scientific procedures may be obvious, particularly if physical pain is involved. However, there are many other potential sources of harms and other types of suffering (for example, psychological distress, anxiety, boredom) that also need to be recognised and dealt with.

Sources of harms

Adverse effects can occur at any stage from birth to death of the animals and may be caused by:

- animal sourcing and transport, whether long distance or between laboratory buildings
- housing and husbandry, and how far this allows the animals to perform a wide range of normal behaviours
- handling, which can cause stress in many species, or other methods of restraint that confine the animals more closely for longer periods
- scientific procedures and their effects
- what happens to the animals at the end of the procedures (for example, how they are killed or whether they are re-used or rehomed).

The nature and degree of adverse effects may also be influenced by the species, strain, and even individual animal involved. For example, some species can be trained to accept handling more easily than others, and some have behavioural needs that are more difficult to satisfy in the laboratory environment.

Clearly, the overall harms likely to be caused in any given project will also be determined by the numbers of animals involved.

Types of harms and their description

Harms range from the largely physiological (for example, nausea, fever, skin irritation, convulsions, pain) to the more psychological (for example, distress, behavioural disorders, fear, anxiety, boredom).

It is important to consider the nature, degree and duration of any adverse effects and to ensure that the harms are described in terms of what they actually mean for the animals. For example, in a study where, say, dogs are singly housed, the harm is not 'single housing'; that is just a description of what will happen to the animals. The real harms are lack of comfort and stimulation from social contact, together with associated boredom and frustration. Identifying the nature of harms in this way gives everyone a better understanding of the impact of the research on the animals and can help in identifying ways of reducing or avoiding the adverse effects.

Recognising and reducing harms in practice

In order for harms to be minimised, they must first be recognised and assessed. To achieve this, it is important that:

- the staff who use and care for the animals are appropriately trained and experienced in recognising adverse effects and assessing their severity in the particular species concerned
- procedures for monitoring the animals (for example, frequency of checking, specific signs to look for, use of score sheets or other recording systems) are agreed in advance of studies
- the steps to be taken to relieve or reduce any adverse effects are clear and agreed in advance by all involved, including the circumstances in which humane end-points[3] will be applied, with a clear definition of who has responsibility for implementing these actions.

Severity of harms: severity limits and severity bands of project licences

Under UK law, the adverse effects caused by scientific procedures are classified as "mild", "moderate" or "substantial" severity, or "unclassified" for procedures carried out under anaesthesia from which the animal is not allowed to recover (see Home Office, 2000b, page 32, for brief examples of each category).

Each protocol[4] described in a project licence is given a "severity limit" (unclassified, mild, moderate or substantial), which sets an upper limit to the suffering that an animal used in that protocol is allowed to experience. Severity limits help in managing and minimising adverse effects. For example, if a protocol is allocated a mild rather than a moderate limit, the licence holder must ensure that the adverse effects do not progress further than the permitted mild limit (APC, 2003; Boyd Group/RSPCA, 2004).

In addition, each project licence is assigned an overall "severity band", which reflects the "overall level of cumulative suffering [likely] to be experienced by each animal" across the whole project (Home Office, 2000a, page 33). This is sometimes described as an assessment of the experience of the 'average' animal used in the project. The severity band is also categorised as mild, moderate, substantial or unclassified. Unlike severity limits, it is widely believed that severity bands are of little value in minimising or managing the severity of adverse effects caused to animals. Neither are they useful in weighing harms and benefits of the research in licence applications (see Boyd Group/RSPCA, 2004, for further discussion).

Strategies for reducing harms: the Three Rs

In addition to understanding the potential adverse effects of projects and their sources, the ERP also needs to consider the steps that have been, or will be, taken to minimise the adverse effects, and whether there are any further opportunities for reducing the overall impact on animals by implementing the Three Rs (see page 14).

A wide range of literature is available on the Three Rs, some of which is listed under 'Sources of further information' at the end of this resource. As a lay person, you are not expected to be acquainted with the detailed, practical possibilities for applying the Three Rs (other members of the ERP should provide this expertise), but you should feel free to ask questions that can help you understand both the harms to animals and the possibilities for minimising or avoiding these.

TO DO

Some general questions relevant to harms to animals and the Three Rs are listed at the end of this resource. You might use these to satisfy yourself that all the potential harms have been identified and minimised and that there is no further scope for applying the Three Rs.

[3] The earliest point at which there will be specific intervention to end an animal's suffering, e.g. by removing the animal from the study, humanely killing the animal and/or terminating the study.

[4] A 'protocol' is a combination of scientific procedures carried out on an animal for a single specific purpose. In most cases a protocol will cover everything that happens to an individual animal, from issue from stock until killed or discharged from the controls of ASPA.

Deeper questions about harms and benefits: moving ethical thinking on

Answers to specific questions about harms and benefits are often underlain by deeper, yet frequently tacit, assumptions held by researchers, Named persons and other participants in the ERP (see Appendix: What is – or are – ethics? for further discussion of 'levels' of ethical issue). Discussions within the ERP can help to identify and make these assumptions more explicit and so in turn suggest more fundamental, and general, questions for the ERP to explore.

Examples of questions include the following.

- Is it possible to distinguish the 'value' of different kinds of scientific knowledge and are all potential benefits equally 'worthwhile'? See Jennings and Silcock (1995) and APC (2003) for further discussion of ethical issues.
- If a particular use of animals is said to be 'necessary', what exactly does this mean and how has necessity been determined?
- Can an economic or career benefit ever form part of the justification for using animals?
- Is there an assumption that it is it 'better' to use some species (say mice) than others (say dogs or pigs) in research? If so, what (if any) are the grounds for according different species different status?
- How far is the humane killing of an animal regarded in itself as a harm?
- What do people actually mean by 'best possible' animal welfare or 'best practice'; and what exactly is meant when it is said that a particular technique is 'better' or 'worse' than another for the animals concerned?

Being alert to, and exploring, such questions challenges the assumptions and arguments that underlie practical ethical decision making and so helps strengthen the decisions that are made. It also ensures that ethical thinking develops alongside scientific advances and improvements in understanding of the capacity of animals to suffer and of animal welfare generally. This helps ensure that the ERP's deliberations and advice do not merely rest with the *status quo*.

Local ERPs provide useful forums in which to consider these more general issues because their discussions involve a range of different specialist and non-specialist perspectives and are informed by detailed understanding of the benefits sought, and the adverse effects caused, in scientific projects involving animals.

TO DO

Lay members, from their 'uninvolved' and independent perspectives can play a valuable role in identifying wider ethical issues and stimulating discussion of these, so do take advantage of opportunities to do so.

Drawing conclusions on ethical aspects of project licence applications

Having examined likely harms and benefits and explored ways of maximising the benefits and minimising the harms, members of an ERP will then need to decide whether they are convinced that sufficient benefits are likely to come from the project and the individual studies within it to justify the harms caused to the animals, and advise the Certificate Holder accordingly. This can be a difficult task, and there is considerable debate about what exactly the 'weighing' of harms and benefits should mean in practice.

Some people argue that no amount of benefit can permit the infliction of any form of suffering on animals, and thus that the benefits of using animals in research and testing are *never* sufficient to sanction the harms. Other people feel that it would be wrong to forgo potential benefits of animal use and accept that at least *some* uses of animals in research and testing should take place, provided that the benefits are judged sufficiently worthwhile and no alternatives are available that could reduce or avoid harm to animals. For people in the latter group, the justification (or lack of) for using animals varies with context, and so they must make their judgements on the issues case by case.

At the (theoretical) extremes, it is likely to be relatively easy to reach consensus on what definitely should *not* be done. If the benefits are unlikely to be achieved, for example because the experimental design is poor, then animal use should not be sanctioned, even where the adverse effects on the animals are only mild. The same applies if the benefits are considered to be very low, or if there are alternatives that can be used, as is the case with testing cosmetics in the UK, which has not been allowed since 1997. At the other end of the spectrum, there are harms that are so high that no benefit is considered to justify their use. For example, in 1997 the UK government also decided that it would no longer allow the use of great apes on moral grounds because of the level of suffering they were likely to experience. However, when one begins to enter the grey area between the obvious extremes, both personal and consensus judgements about the balance of benefit over harm become more difficult.

A particular difficulty is that the factors to be weighed together are not directly comparable. *Animal suffering* must be weighed against *benefit to humans* (or, in some cases, *other animals*). It is therefore debatable whether it is possible, or indeed desirable, ever to say that the predicted benefits 'exceed' the harms to animals.

Here, it is worth remembering that the 'weighing' that members of ERPs are asked to carry out is not in any sense a quantitative procedure. Rather, it is a matter of *moral judgement*, which, by its nature, depends on the particular circumstances involved (see Appendix: What is – or are – ethics? for further discussion). In this sense, the weighing required of the ERP does not seem a unique or even unusual process of judgement:

> "In everyday life... personal, professional and political judgements on moral issues normally require the weighing of factors and considerations which cannot be quantified with mathematical precision. A judge, for example, weighing a plea for mitigation of sentence in the 'scales of justice' carries out a procedure of this kind."
>
> Smith and Boyd (1991)

In such situations, confidence in the quality of the judgements depends on the approach of the people who make them, and especially on whether and how far such people are *trusted* to come to balanced, informed decisions that take into account all reasonable perspectives on the issues (Smith and Boyd, 1991). Involving a diversity of people in the decision-making process, and especially lay members who are widely regarded as having no vested interest in the outcomes of the review, can be considered an important step in achieving and enhancing such trust.

At the end of all the thinking and debating, you will still need to make judgements, both personally and collectively with other participants in the review. Because the judgements will arise from the kind of searching and comprehensive thinking described above, they will not rest on 'gut feelings' alone, though it should be noted that emotions *can* play an important part in ethical decision making, as a useful guide to identifying areas of ethical concern. Rather, the judgements, and associated advice, will be supported by arguments that are well-informed and sensitive to the different ethical nuances and perspectives brought before the ERP.

As Donnelley (1990), writing as part of a US project that explores issues in ethical review of animal research, neatly concludes:

> "The mere asking of the right questions and demanding full or detailed answers goes a long way toward promoting ethical science. But not the whole way. The final problem of assessing the strength of the many competing obligations... remains... For there is no overarching theory, but the ongoing need for broadly sensitive, ethical judgement".

Some questions to help in thinking through the harms and benefits of projects

Using the questions

The questions below are informed by a number of published sources listed at the end of this resource, including the first edition of this lay members' resource book. The issues they cover should be addressed in the licence application and/or in written material provided to the ERP and/or in discussion with the researchers concerned.

The questions are offered as a 'reminder list' to help you identify any points of uncertainty or concern that you or others feel should be considered and/or wish to ask about. They are not intended to be used as a 'check list' of questions that must be asked.

Similar points will be covered in the Home Office Inspectorate's reviews of project licence applications and so, when thinking about the questions, it is important to bear in mind that the ERP's review needs to 'add value' rather than duplicate the Home Office's role (see also pages 22–23). The points raised therefore need to be set in the context of the individual ERP's objectives for project review. Bear in mind also that some of the issues, particularly in relation to the Three Rs, may be dealt with under other ERP functions (see Resources 6 and 7).

Questions about the benefits of projects

Potential benefits

- Has the written information provided to the ERP, and the ERP's discussions with the applicant, given you a clear sense of the objectives of the project and its potential benefits? If not, do ask for clarification.
- Particular questions to help in thinking through the potential benefits and the research team's justification for using animals include the following.
  - What kinds of benefits are anticipated (for example, scientific, clinical, environmental, educational regulatory, economic)?
  - What makes the work original, relevant, realistic and timely?
  - If the project is part of ongoing work, what progress has been made previously?
  - If the project involves repetition of previous studies, what are the reasons for this?
  - What are the project's potential links to, and implications for, other areas of research?
  - How will the results be used?
  - Will the findings be published or otherwise disseminated?

Likely benefits (i.e. whether potential benefits will be achieved)

- Do you and the ERP as a whole feel comfortable that, given the experimental approach, it is likely that the potential benefits will be achieved in practice?
- Specific questions to help in thinking through the likelihood that the potential benefits will be achieved include the following.
  - How will the chosen scientific approach and animal model(s) help in achieving the objectives?

- What steps have been taken to ensure the validity of the experimental design (for example, that optimum numbers of animals are used – neither too many nor too few – and that the use of control and experimental groups and subsequent statistical analyses are appropriate)?
- Are facilities (for animal housing and husbandry, laboratory space, equipment) available to meet the requirements of the project and will any special arrangements be needed?
- What is the project team's experience of the methods and is all the required expertise available?
- Are other resources for the project – for example, time and funding – sufficient to meet its aims?
- Has there been consultation/collaboration with others working in the field, to learn from their experiences, optimise the experimental approach and avoid unnecessary duplication of effort?

Questions about harms to animals and the Three Rs

- Is it clear to you what will happen to the animals throughout their lifetime?
- Are all the potential adverse effects clearly identified and described in terms of what they will actually mean for the animals? If not, do ask for clarification.
- Are you, and the ERP as a whole, satisfied that everything possible has been or will be done to minimise and avoid harms to animals in the project?
- Specific questions to help in thinking about harms and the implementation of the Three Rs might include the following.

Replacing or avoiding the use of animals

- Why is it considered necessary to use animals to achieve the objectives of the work? Why are non-animal methods or alternative approaches to the scientific questions considered unsuitable?
- Are non-animal methods also used as part of the overall approach to the objectives and, if so, how do the different methods relate to and build on one another? Is there any further opportunity for non-animal methods to be used as part of the research programme?
- What efforts have been made to search for and consider alternatives?
- How would the research questions be addressed if the use of animals was not possible and what would be the limitations of possible alternative approaches?

Reducing the use of animals

- How have the numbers of animals (for example, experimental and control group sizes) been decided and how has the experimental design been optimised?
- Has a statistician been consulted? Have the results of other similar studies been used to inform the approach?
- Are there strategies that could enable use of fewer animals yet still provide meaningful results?
- Do pilot studies need to be performed to optimise the experimental approach and the strategy for minimising adverse effects on the animals?
- Will there be ongoing evaluation of the need to use as many animals as first predicted?

Refining the use of animals

- What efforts have been made to refine the scientific procedures and husbandry and care of the animals, so that adverse effects on the animals are minimised as far as possible?
- Are there any possibilities for further refining the procedures and other aspects of animal care and use?

These two general questions about refinement should be used to cover everything that happens to an animal, from birth to death, and which could impact on the nature and severity of adverse effects that the animal experiences. There are many more specific questions that could be relevant, some of which are listed in the box below. They might help you think further about the potential harms to animals and identify and articulate any specific concerns.

More-in-depth questions regarding harms and refinements

Species and strain of animal involved

- Why is the particular species and strain of animal considered the most appropriate for the work in question?
- If genetically altered animals are to be used, why are they needed? What are the potential and likely adverse effects of the genetic alteration, and what are the plans for monitoring and minimising them?
- Do the animals involved have particular behavioural or physiological needs that might be difficult to satisfy, or are they particularly sensitive to the proposed techniques?
- Could the adverse effects be reduced by using a different species, strain or genetic alteration?

Source and transport of animals

- Have the animals been bred or previously maintained under laboratory conditions? If not, will the laboratory represent a particularly stressful environment for them and how is it proposed to limit/reduce the stress?
- If the animals are to be supplied from outside the establishment, what additional stresses will be caused by their transport to the laboratory, and how is it proposed to limit these?
- If the animals are wild-caught, what harms are likely to be caused during their capture, how will these be reduced, and will additional stresses be caused by any requirement to quarantine the animals?
- Could the adverse effects be reduced by obtaining animals from a different source?

Housing and husbandry of animals

- How will the animals be housed and cared for? Could the housing and husbandry system be improved in any way, so as to minimise any adverse effects caused by confinement of the animals and to enrich their environment?
- Will social animals be housed singly at any time? If so, why is this considered necessary and can it be avoided? If not, will the animals be housed within sight, sound and smell of others (assuming this is appropriate for the species and individuals concerned)?
- Will the procedures impose any special husbandry requirements, for example use of metabolism cages, which are designed to allow collection of the animals' faecal and urine output? If so, why are these considered necessary, what adverse effects will be caused, and how is it proposed to reduce or alleviate them?

Pain, distress, anxiety or other harms likely to be caused by the procedures

- Will any pilot studies be carried out? If so, how will the results be used in designing the full studies so as to minimise animal suffering?
- How will the animals be acclimatised to the experimental set-up, and to the laboratory itself, and would better acclimatisation help to reduce the harms (and enhance the science)?
- Will the animals be restrained during any of the procedures? If so, why is restraint considered necessary, what method will be used, and is any refinement of the method possible? How far could the animals be trained to cooperate in the experiments, as a means of reducing stress?
- What efforts will be made to mitigate the adverse effects of the procedures on the animals? For example, is there use of pain relief (analgesia) wherever necessary and will special nursing or other care be provided to reduce particular adverse effects, for example use of especially soft bedding, softened food, warmth from a heat lamp?

Monitoring and implementation of humane end-points

- What are the humane end-points for the procedures? Could any milder end-points be used? How often will the end-points be reviewed for appropriateness and refinement? How will it be ensured that the agreed end-points are not exceeded?
- What are the plans for monitoring the animals' condition? For example, how frequently will they be checked? Are score sheets used? What signs will be looked for? What particular observations will be considered to give cause for concern, and what action will be taken?

What will happen to the animals at the end of the experiments?

- If the animals are to be killed, will a standard method be used, as laid out in Schedule 1 of the ASPA? If not, what is the scientific justification for using a non-Schedule 1 method, and is the proposed method the most humane?
- Could any of the animals be rehomed? If so, how does the establishment ensure that this is in the best interests of the animal?
- When animals are killed at the end of experiments, are there opportunites for collaboration with other researchers to ensure that maximum information is obtained from each animal, for example by collecting and using as many of their organs and tissues as possible in other studies, perhaps avoiding additional animal use?

Facilities, expertise and competence to carry out the procedures

- Are all members of the team trained and/or experienced in the proposed approach and with the particular species and techniques? If not, how will experience be gained, what arrangements are there for supervision, and how will competence be ensured?
- How far do the available facilities (animal housing, laboratory space, equipment) meet the requirements of the project, and are any special arrangements or resources required?

Some sources of further information

Home Office and APC guidance on harm-benefit assessment[5]

Home Office thinking on harm-benefit assessment under ASPA is described in a useful paper by a chief Home Office Inspector (Home Office, 1998). The paper describes general principles and explains how the Home Office applies these in practice. The APC has also published an extensive report on the weighing of harms and benefits, which includes detailed lists of factors for consideration (APC, 2003).

Other published schemes for ethical review of projects

A variety of such schemes have been published, listing questions that can be asked during ethical review. These include those compiled by the Institute of Medical Ethics (Smith and Boyd, 1991), Delpire *et al.* (1999) and those compiled for lay members in the first edition of this resource book (Smith and Jennings, 2003). More recently, a report from the Federation of European Laboratory Animal Science Associations (FELASA) (Smith *et al.*, 2005; FELASA, 2007) makes a series of recommendations on principles and practice in ethical review of animal experiments.

Implementing the Three Rs

Further information about the Three Rs is available from the RSPCA research animals website: www.rspca.org.uk/researchanimals. The Universities Federation of Animal Welfare (UFAW) also produces useful information and advice on animal welfare: www.ufaw.org.uk. The Fund for Replacement of Animal Experiments (FRAME) specifically addresses replacement: www.frame.org.uk

The National Centre for the Three Rs' (NC3Rs) website: www.nc3rs.org.uk is a good central point for specific information on the Three Rs and details of other sources of information and organisations working on these topics.

In addition, some useful general 'overview' papers on each of the Three Rs have been published by the journal *Laboratory Animals* and are available via: la.rsmjournals.com/. These are: Balls (1994) on replacement; Festing (1994) on reduction; and Flecknell (1994) and Lloyd *et al.* (2008) on refinement. Despite being rather elderly, the 1994 references are still highly pertinent.

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[5] Note that both of these reports refer to 'costs' to animals, rather than 'harms'.

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NOTES

RESOURCE 5: Retrospective review of projects

As well as examining new project licence applications and amendments to existing licences, ERPs are required to "undertake retrospective project reviews and continue to apply the Three Rs to all projects, throughout their duration". Resource 5 examines the goals and potential benefits of retrospective review and suggests some ways in which lay participants can help to achieve them.

Objectives and benefits of retrospective project review

There is little formal guidance on retrospective review, other than the brief statement shown in the box below.

Home Office (2001) description of the purpose of retrospective review

"Retrospective project review seeks to look back on the animal welfare costs [harms] encountered and the benefits realised", in order to:

i. assess "the extent to which the original assumptions, including the severity limits of protocols [see Resource 4, page 29] were correct" when the licence was applied for, and

ii. "consider if additional Three Rs strategies can be identified and incorporated".

"This information is of value to licensees and ERPs in planning future work and, as ERP records are available to the Inspectorate, may also help influence future Home Office assessments."

Guidance notes prepared by the Laboratory Animal Science Association (LASA) and the RSPCA elaborate further, and recommend that retrospective project reviews should cover the following.

Harm/benefit aspects: to determine whether the actual harms and benefits of a project are in line with those anticipated, and to use the information and experience gained during the course of the project to inform future judgements.

Practical aspects: to identify, build on and promote good practice and advances in the Three Rs during the course of a project and, where relevant, to ensure that these are applied to other work in the establishment.

Management aspects: to help with project licence management issues, such as licence amendments, staffing, resources, training, communication and dissemination of information.

Benefits of retrospective review

Retrospective review should be a positive and constructive experience that is designed to benefit both animal welfare and science and to advance ethical thinking (see also Resource 4). The review should assist project licence holders and the wider establishment, including its ERP, in a number of ways, including:

- comparing the actual harms and benefits with those predicted at the application stage, re-evaluating the ethical 'weighing' and so helping to inform the ERP's future judgements
- providing feedback to the ERP and the establishment's Certificate Holder on progress with the project, its achievements and any problems or difficulties
- bringing together a range of expertise (including Named persons and other scientists) in order to provide targeted advice to project licence holders and their research teams, to assist in:
  - addressing any technical or scientific difficulties not yet resolved
  - raising awareness of any actions that can be taken to more fully implement the Three Rs
  - planning ahead, particularly regarding the need for any future amendments to the licence

- identifying and addressing any issues related to project or animal facility management or performance and any resource issues, for example:
  - recognising and meeting any training requirements
  - providing support to the project licence holder to enable more efficient supervision of personal licensees working on the project
  - putting in place systems, where needed, to help the animal facility better meet the project's needs
- identifying examples of good practice or advances in the Three Rs developed in the project and ensuring that these are communicated to other licence holders within the establishment, and, where appropriate, publicised more widely.

See Jennings and Howard (2004), Jennings *et al.* (2007) and RSPCA/LASA (2009) for further discussion of these points.

Your ERP's approach

The ERP is allowed flexibility in deciding when and how retrospective reviews are carried out, so establishments vary in how they deal with this function. Feedback from lay members suggests that, at the time of writing, some ERPs are still developing and refining their approach (RSPCA, 2007).

Retrospective reviews may be carried out at a fixed time for all project licences held at the establishment (for example, halfway through a project or at its completion) or at different time points for different licences, depending on the pattern of work involved. Reviews may also be triggered on an *ad hoc* basis, such as when unexpected events occur during the course of a project (for example, unanticipated adverse effects) or when an amendment to a licence is applied for.

As well as variation in timing, there are differences in the factors that are addressed during retrospective review, the way the process itself is carried out, how the outcomes are recorded, and to whom these are communicated. The amount of written documentation that ERPs require from licence holders also varies. Some ask for written feedback on specially designed retrospective review forms of varying complexity, while others rely more on oral presentations from project licence holders.

Whichever approach is used, the focus should be on the *outputs* of retrospective reviews, and every effort should be made to maximise the benefits of the process whilst minimising paperwork and other bureaucracy. Everyone involved needs to have a clear idea of what the process is intended to achieve, the issues that are to be considered, the questions that need to be addressed and how any actions are to be taken forward.

TO DO

It is essential to find out what the establishment hopes to achieve through retrospective review, and how the ERP's procedures help to attain those goals. Your ERP's procedures for retrospective review should be laid out in the document describing the ERP, submitted by the establishment to the Home Office – available from the Home Office Liaison Officer/ERP administrator, Certificate Holder or ERP chairman.

Lay members' contributions to retrospective project review

The retrospective review process should be designed to enable lay and other ERP participants to ask any question they feel is important, and which might help in achieving the benefits indicated above. It should enable members to gain a clear sense of the scientific outcomes of the project and its effects on the animals to date. You should feel confident that any difficulties or concerns have been identified and that the ERP has provided advice and support to help the animal care staff, researchers, and/or others to address them. Also, that any developments in the Three Rs, or other lessons learned in the project, have been communicated (where relevant) to others in the establishment or more widely.

In addition to playing a part in achieving the benefits of retrospective review, lay members can also help to ensure that those benefits match the efforts put into the process. For example, from their independent perspective, they can help the establishment audit the outcomes of retrospective reviews and consider whether there are any further steps that can be taken to maximise the benefits and minimise the costs of the process in terms of the time and other resources needed.

TO DO

Some questions designed to help think through the process of retrospective review are presented below. They are intended to help lay (and other) members check that all pertinent issues are identified and addressed during the review and that, wherever appropriate, the process results in helpful recommendations that are implemented in practice. The latter point is especially important and lay members can contribute by requesting feedback on how actions have been progressed.

Some questions to help in thinking through the process of retrospective review

Using the questions

The questions below indicate the range of issues that retrospective review should cover. Not every topic will be relevant in every case, but the list should help identify any aspects that might have been missed, and which you could ask about. It should also help check that the process has led to practical advice and actions that can assist the research team in addressing any difficulties or concerns, and that any relevant developments, including Three Rs initiatives, are shared with others in the establishment or more widely.

The questions are informed by the following sources: Jennings and Howard (2004); Jennings *et al.* (2007); and RSPCA/LASA (2009).

Harm/benefit aspects

- Have the researchers clearly explained the results of the project so far, and are they as anticipated?
- Is everyone satisfied that the adverse effects on the animals, and the numbers of animals used, are in line with predictions? Has the ERP explored the reasons for any differences and any action that is needed if the adverse effects are greater than expected?
- Does the research team and the ERP feel that the particular animal models and study designs are still the most appropriate for achieving the aims of the project?
- Has the ERP explored whether there have been any recent developments in science or technology that could or should influence the future direction or conduct of the work and, especially, any developments that might help to avoid or replace the use of animals in some or all of the project, or cause less suffering?

Practical aspects

- Has the review process revealed any further possibilities for implementing the Three Rs in the project (for example, could housing and husbandry or experimental procedures be further refined, or experimental design improved)? If so, has appropriate action been agreed within the research team?
- Is everyone satisfied that monitoring regimes and scoring systems are working well and that humane end-points are as refined as possible?
- Has the supply and use of animals been balanced so that none are wasted?
- Have any special housing and care needs arisen? If so, how have these been addressed?
- Has the research team or ERP identified any advances relevant to the Three Rs that it would be beneficial to communicate to others in the establishment, or more widely?

Management aspects

- Are the researchers, Named persons and others satisfied that facilities for procedures and animal housing and care are still appropriate for the work? Are there any difficulties that need addressing?
- Do the Named persons have any concerns about the work? Does there seem to be good communication between Named persons, other animal care staff and the researchers working on the project? Has the ERP helped to address any difficulties or concerns?
- Has the review process identified any additional needs for staff training or supervision?
- Has the ERP helped to identify and plan for any future amendments to the licence?
- Have there been any particular developments or lessons learnt that should be communicated to others in the establishment?

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RESOURCE 6: Other ERP functions

It is important to recognise that there is much more to the ERP than consideration of project licences and that the other functions of ERPs can have as much, if not more, impact on animal use and welfare throughout the establishment. This resource explores these wider ERP functions and how lay members can help address them.

The ERP's functions other than project review

Providing advice specifically on project licences is only one of the ERP's three key aims (see Resource 3); the other two are:

- to provide support to Named persons and advice to licence holders regarding animal welfare and ethical issues arising from their work (ERP Aim 2)
- 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 (ERP Aim 3).

There are five functions other than project review that contribute to these aims.

The ERP's five functions, other than project review

- Promoting the development and uptake of reduction, replacement and refinement alternatives (the Three Rs) in animal use, where they exist, and ensuring the availability of relevant sources of information (ERP Function 1).
- Providing a forum for discussion of issues relating to the use of animals and considering how staff can be kept up to date with relevant ethical advice, best practice and relevant legislation (ERP Function 3).
- Considering the care and accommodation standards applied to all animals in the establishment, including breeding stock, and the humane killing of protected animals (ERP Function 5).
- Regularly reviewing the establishment's managerial systems, procedures and protocols where these bear on the proper use of animals (ERP Function 6).
- Advising on how all staff involved with the animals can be appropriately trained and how competence can be ensured (ERP Function 7).

(Home Office, 2000a and 2000b; see also Resource 3)

In practice, these five wider functions for ERPs are closely related and overlap, both with each other and with project review, and so they should not be viewed or implemented in isolation. For example, review of a particular project licence might raise questions about the best way to carry out a procedure that is also used in a number of other projects within the establishment. These questions are discussed by the ERP (Function 3). As a result, the ERP decides to draw up establishment-wide guidance on how the procedure should be performed (Function 6) and to provide some training for staff (Function 7). This helps to refine the procedure so that it causes less harm to the animals, which, in turn, leads to a reduction in the number of animals needed to achieve the scientific goals (Function 1).

The importance of the ERP's wider functions

All these functions are concerned with promoting good animal welfare and humane science and so help to develop and maintain a *culture of care* within the establishment.

As the box below explains, good animal welfare is vital not only because of its positive effects on the animals, but because it is essential to good science. In this context, the ERP's wider functions are crucially important because they relate to all aspects of animal production, care and use within the establishment, not just to specific projects.

Good animal welfare and good science go hand in hand

Good animal welfare and good science are closely linked. When animals are stressed, they may appear outwardly 'normal' but their physiology may be affected in a number of ways, for example by changes in heart rate and the levels of 'stress' hormones in the blood. This can influence the variability, reliability and reproducibility of experimental data. Reducing animal suffering and improving welfare can therefore contribute significantly to reducing animal use. It increases the reliability and reproducibility of data, which helps to reduce the likelihood that experiments will have to be repeated, and can reduce the variability of results, allowing smaller group sizes to be used.

Addressing the wider functions in practice

The ERP's role

The ERP's wider functions are tasks that any responsible organisation using laboratory animals should be carrying out, regardless of whether an ERP exists. Indeed, before ERPs were initiated in 1999, many establishments already had systems in place to deliver many of them. However, the ERP has brought considerable benefit by providing a *focal point* for efforts to address the wider functions within the establishment, its role being to mobilise institutional expertise and resources and to *drive* and *coordinate* the various local systems and processes needed to ensure good animal welfare and sound, humane science (Home Office, 2000b; see also RSPCA/LASA, 2009).

Examples of approaches to the different functions

As with project review, ERPs differ in how they deal with the five wider functions. Review of licence applications and ongoing projects will often raise relevant issues for the ERP to address, as will reports from Named persons, visits to animal facilities and/or viewing work in progress (see Resource 7).

Importantly, the ERP should also play a *proactive role* in identifying issues of concern and developing strategies for enhancing animal welfare and implementing the Three Rs within the establishment. A common approach, particularly in larger establishments, is to establish specific working groups, or sub-committees, to identify and address particular issues (for example, Three Rs sub-committees, husbandry and care, and training groups).

TO DO

It may take a while to get a good sense of the ways in which the ERP addresses the wider functions in practice – but do satisfy yourself that they are fully covered. To help in this, some of the things that an ERP might do or coordinate in respect of each function are listed at the end of this resource. In addition, the ERP's general procedures for addressing these functions, including any special working groups, should be described in the ERP document submitted by the establishment to the Home Office – available from the Home Office Liaison Officer (HOLO) / ERP administrator, Certificate Holder or ERP chairman.

Balance of time spent on wider functions

The time spent on wider functions compared with project review varies between establishments. This may be related to the number of projects that the establishment has to deal with and the time that takes, but it may also be because ERPs differ in how they prioritise these two main facets of their work. However, given the central importance of the wider functions, it is important that sufficient time and effort is devoted to them all (Home Office, 2000b and 2007; APC, 2008; RSPCA/LASA, 2009).

Lay members' input to the wider functions

Perhaps the most important way in which lay members can contribute is to ensure that the five wider functions are firmly on the ERP's agenda, both literally and metaphorically. The ERP needs to be alert to issues relating to the wider functions, regard them as important, and have systems in place to deal with them, proactively as well as reactively. In particular, lay members can help by:

- reminding the ERP of the need to devote sufficient time to consideration of wider issues related to promoting good animal welfare and humane science (i.e. that the ERP is about more than just project review)
- asking that each function appears as a regular item on the meeting agenda
- taking an interest in issues that could have wider significance across the establishment that are raised during ERP work (including visits to animal facilities – see Resource 7), then helping to ensure that these are picked up and dealt with by the ERP
- thinking about ways in which the wider functions can be addressed most effectively (perhaps using the lists at the end of this resource to help) and checking that the ERP is using and making the most of the various strategies at its disposal
- requesting feedback on what the ERP is doing to address the wider functions proactively, including what benefits have been achieved in these areas.

Examples of ERP activities on the five wider functions

Using the examples

The examples in the boxes illustrate how some ERPs and their establishments currently deal with the five wider functions. The lists should provide you with some ideas for your own establishment if needed. Note that not all the suggestions will be appropriate in all circumstances.

Function 1: Promoting the Three Rs and ensuring availability of relevant information
Function 3: Providing a forum for discussion and keeping staff up to date

- Developing an intranet website, special library collections of papers and/or organising regular mailings of information on the Three Rs, ethical issues, good practice, legislation and guidelines for scientists, animal care, and other, staff. Organising seminars or similar events (open to all relevant staff) to explore these issues.
- Ensuring there is a good mechanism for researchers to receive information and advice on the above issues from Named persons, statisticians and other scientists within or outside the establishment (particularly when preparing project licences), perhaps through a dedicated Three Rs group.

- Ensuring that there is appropriate training for research teams in searching for information relevant to the Three Rs.
- Collecting examples of successful Three Rs approaches developed within the establishment, for example through an annual survey of project licence holders; communicating these more widely, for example through a Three Rs day.
- Encouraging and supporting staff in applying for grants for the development of the Three Rs.
- Advertising relevant meetings and conferences to scientists and animal care staff and encouraging and supporting their attendance.
- Awarding a Three Rs prize for the best advance in any given year.
- Setting up formal or *ad hoc* Three Rs groups to, for example, refine procedures commonly used, starting with the more severe, and developing establishment-wide refined methods.
- Enabling any member of staff to raise a question or concern for consideration within the ERP, for example, via an ERP post box or e-mail facility.
- Inviting staff who are not formally involved in the ERP to sit in on ERP discussions from time to time and to feed back their impressions to the ERP.

Function 5: Considering standards of animal care, accommodation and humane killing

- Ensuring that all members of the ERP visit the animal facilities regularly and, where possible, see animals under procedure so that everyone has a feel for what happens to them in practice (see Resource 7 for further discussion).
- Organising audits/reviews of facilities and methods of animal care and welfare at the establishment, perhaps involving independent external experts.
- Assessing animal suppliers, contracted organisations, or research partners abroad against the establishment's own standards of animal housing and care.
- Reviewing what happens to animals once they have been used in scientific procedures (for example, to ensure that as many as possible of the tissues are used, so that additional animals are not killed).
- Reviewing whether there is any possibility of rehoming animals and, if so, developing a robust system to ensure that this is in the best interests of each individual animal (see LASA, 2001 for some general principles and specific details regarding rehoming dogs).
- Inviting Named Animal Care and Welfare Officers (NACWOs) to make presentations to the ERP on their animal facilities, for example, on how the animals are housed and cared for, how their environment is enriched, and whether there are any concerns or issues that the ERP could help to address.
- Encouraging and supporting animal care staff in developing and evaluating potential refinements in husbandry and care, including environmental enrichment, and ensuring that these are published more widely.
- Awarding a husbandry and care prize for the best advance implemented in any given year.

Function 6: Reviewing management, procedures and protocols relevant to animal use

- Providing visible management support for Named persons and a framework for their dialogue with other stakeholders, and ensuring that they have adequate resources to fulfil their statutory roles.
- Providing a HOLO, ERP administrator, or similar, to advise scientists with drafting licence applications, communicating with the Home Office and/or coordinating the ERP.
- Developing in-house procedures for considering the justification for certain uses of animals on a study-by-study basis.
- Developing in-house guidelines or standard methods that help to implement current 'best practice' for particular procedures or uses of animals.
- Playing a role in strategic planning, for example in considering the need for new facilities and developing these, and coordinating joint bids for expensive equipment.
- Reviewing the ERP's own procedures and outputs, to help to ensure that the benefits of the ERP's work match the efforts put into it.

Function 7: Advising on staff training and competence

- Considering what comprises 'good' training and supervision through to competence for different categories of staff, and ensuring that there are systems in place to deliver this.
- Recognising the importance of ongoing training, bearing in mind that mandatory modular training for licence holders (Home Office, 2000c) is only an introduction to the issues and cannot ensure licensees are fully competent in all the topics and procedures covered (APC, 2006).
- Ensuring that opportunities for continuing professional development on matters related to animal care and use are an integral part of training for all categories of staff, and are adequately resourced.

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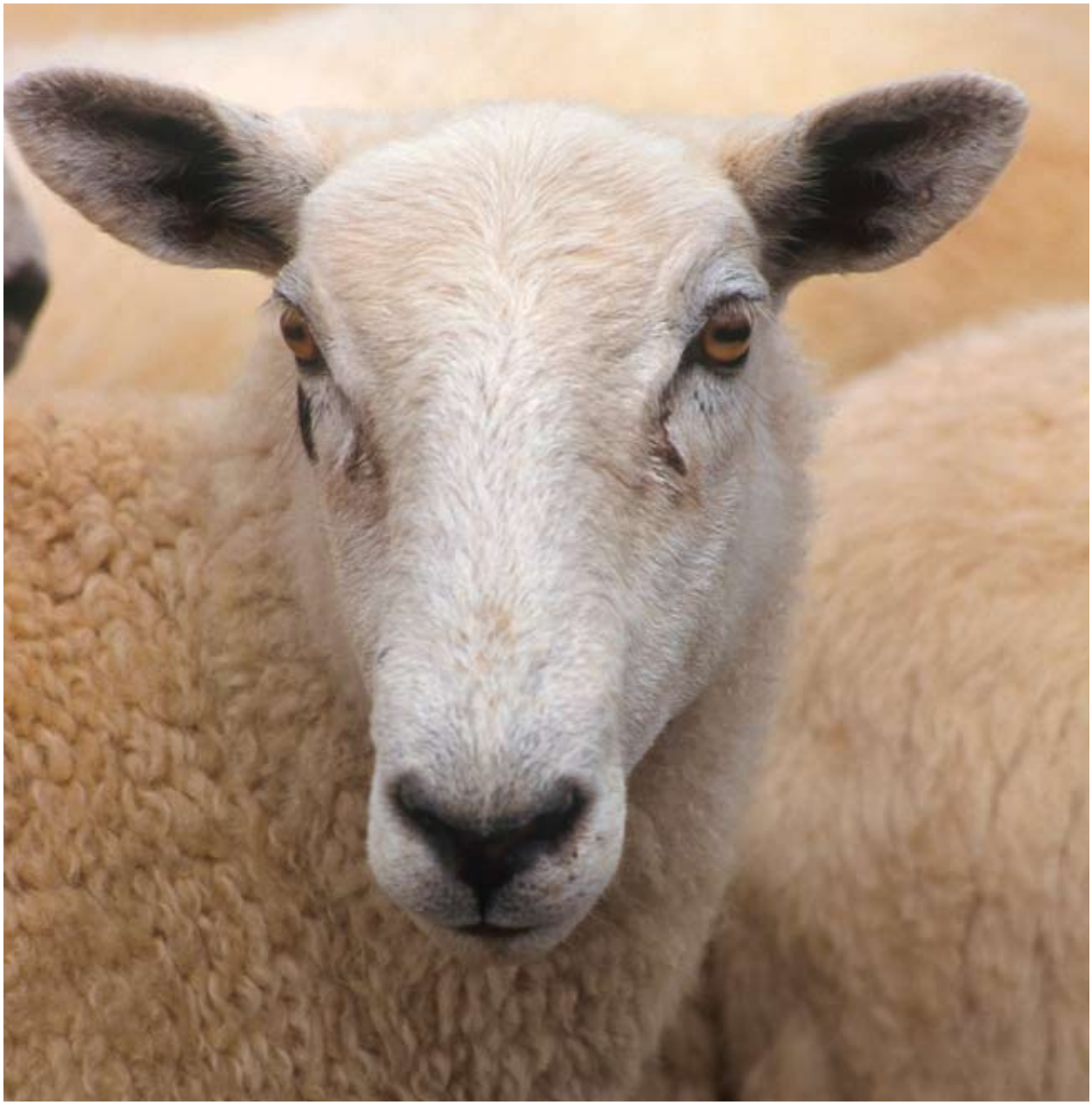

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RESOURCE 7: Visiting animal facilities

Laboratory animals spend most of their time in cages or pens, and so their immediate environment and the care they receive has a major impact on their welfare, as well as on the science in which they are used. It is therefore important that all ERP members are able to visit the establishment's animal facilities, talk to relevant staff and raise any issues that may concern them. Resource 7 lists some sources of advice and presents a series of points to think about when preparing for and reflecting on such visits.

Background: standards in laboratory animal housing and care

Codes of practice and other guidance

Standards of laboratory animal housing and care across Europe are governed by both a European Council Directive[1] (CEC, 1986) and a European Convention (Council of Europe, 1986), and in the UK by Home Office Codes of Practice (1989 and 1995), which specify the *minimum* standards that establishments must comply with. The standards of husbandry and care set out in the European Convention have recently been revised and updated (Council of Europe, 2006) and are helpfully summarised in a 'Euroguide' published by the Federation of European Laboratory Animal Science Associations (FELASA, 2007).

The Home Office Codes of Practice cover basic requirements relating to lighting regimes, intensity, environmental temperature, humidity and minimum enclosure dimensions. However, the codes are around 20 years old and much can be done to improve upon their basic provisions. For example, much more is now known about the behavioural needs of animals and how to provide for these with environmental and social enrichment than was understood when the codes were written.

There is, in addition, a large and increasing volume of literature on laboratory animal housing and welfare, which is constantly evolving. This published material is not always easy for non-specialists to interpret and so the RSPCA's Research Animals Department has produced a series of guidance notes (RSPCA, 2009). These summarise the scientific literature and set out good practice for laboratory animal housing and care (for commonly used species) in an easy-to-use format.

The ERP's role

Good animal housing and care are recognised as important for scientific as well as animal welfare and ethical reasons, and many establishments already work to exceed the minimum standards in the Home Office Codes of Practice. The need to address housing and care is recognised in ERP Function 5:

> "Considering the care and accommodation standards applied to all animals in the establishment, including breeding stock, and the humane killing of protected animals".

ERPs respond to this function in a variety of ways, for example through sub-groups of the main ERP or groups of animal care staff, who get together specifically to consider housing and care issues. Examples include moving to more group housing of social species, challenging perceived needs to keep animals in barren environments for some types of study, reviewing rodent cage cleaning protocols, and developing positive re-enforcement training of animals to reduce the stress associated with handling and restraint. These sub-groups will then report their ideas and conclusions to the main ERP for discussion and appropriate action (see also Resource 6).

[1]At the time of writing, Directive 86/609 is under revision.

Preparing for and reflecting on animal facility visits

Visiting the establishment's animal facilities allows ERP members to see for themselves how the animals are cared for and used, and therefore to consider animal care and welfare issues from a more informed perspective. It is also helpful to ask to see animals undergoing or experiencing the effects of procedures, where this is possible, especially if initial or retrospective project review (see Resources 4 and 5), or other feedback to the ERP, raises specific concerns.

TO DO

You should be invited to visit your establishment's animal facilities as part of your role within the ERP. If this is not the case, do ask to visit; it is vital to see the animals and their husbandry for yourself. When viewing procedures, it is helpful if the project or personal licence holder, a member of the animal care staff and/or the Named persons are available to explain the procedure and answer any questions, so ask for this too.

Some practical matters

- It can be very helpful to visit with one or two other members of the ERP. However, many animal facilities can only accommodate small numbers of visitors at a time.
- Usually you will be given protective clothing to wear during the visit, such as a lab coat or boiler suit, latex gloves, overshoes and a face mask. This is to avoid infection entering the animal house and to protect staff and visitors from allergy. Sometimes you will need to shower before entering a particular area, for the same reason.
- If you have visited another animal facility recently, you may be asked to delay your visit for a set time afterwards, to avoid any possibility of contamination.

Some questions for consideration

As well as viewing the animals and the facilities, the visit should provide an opportunity to talk informally with the animal care staff and Named persons and so help you to get a better feel for the culture of the establishment.

TO DO

The RSPCA's housing and care guidelines for particular species (RSPCA, 2009) provide a useful guide to what to look for when preparing for a visit to the animal facility. In addition, some general questions that you might wish to ask or think about are listed at the end of this resource.

Reporting back

The ERP should be interested in how you, as a lay member, view the housing and care that the animals receive, so reporting back is important. The visit might also suggest particular questions for consideration by the ERP, either in relation to specific projects (see Resources 4 and 5) or with respect to more general matters (see Resource 6).

TO DO

After each animal facility visit, you should have the opportunity to feed back your impressions to the ERP and ask any further questions or raise any concerns or issues for further discussion.

Some questions to consider when visiting animal facilities

Using the questions

There are many issues to think about when visiting the animal facilities, and not all can, nor should, be addressed in a single visit. The following questions are suggestions for particular points to think and enquire about, to help you understand the system. They are not intended to be used as a check-list. It can be helpful to read the RSPCA good practice guidelines for the species you will see before your visit. These will help you judge for yourself how well the animals' needs are catered for.

Note that there is some overlap with the questions on the Three Rs presented on pages 34–35.

General organisational issues

- Is there good interaction and understanding between animal care staff, Named persons and scientists?
- Do the animal care staff feel that their perspectives are valued and do they have clear and effective channels for expressing any concerns over the use of animals?
- How are housing and care standards assessed, and against what benchmarks?
- Are innovative animal welfare ideas encouraged and, if so, how?
- Are there any aspects that the animal care staff would like to see changed or improved?
- Overall, do you feel comfortable with the environment and care provided for the animals and with the culture of the place?

Carrying out procedures and monitoring animals

- How is compliance with project licences monitored when procedures are performed?
- Who carries out procedures? (In some establishments almost all the procedures are carried out by the animal care staff; in others, researchers carry out more of the work. There are pros and cons for both approaches, which you could discuss.)
- Do staff receive the specific training that they feel they need (for example, for certain techniques and care of individual species)? How is the competence of people carrying out procedures monitored and assessed? What processes are there for supervising inexperienced staff?
- How is refinement of procedures addressed?
- How are animals monitored for adverse effects during and after procedures, and how are humane end-points developed and implemented?

Animal supply and breeding

- What sources do the animals come from and what steps are taken to reduce any stress when they are transported to (or within) the establishment?
- Where animals are bred in-house, what steps are taken to try to ensure that supply matches demand? If there is any over-production, requiring culling of animals, could this be reduced by some means?
- What steps are taken to ensure that when animals are killed they are used to maximum effect (for example, that as many as possible of the tissues and organs are taken and used, so that additional animals are not killed)?
- Are any animals rehomed or released from the establishment in some other way (for example, to a farm or sanctuary)? If so, is there a system in place to ensure that this is always in the best interests of the animals concerned?

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APPENDIX: What is – or are – ethics?

The ERP's three key aims all emphasise the ERP's role in 'doing ethics', – the ERP is required to provide ethical advice and support on ethical issues and to promote the use of ethical analysis. To provide some background to the use of 'ethics' terminology, this appendix explores what is meant by 'doing ethics' in practice and the benefits this can bring.

Different uses of the term 'ethics'

'Ethics' concerns ideas of right and wrong, what is good and bad, and how people ought and ought not to behave, both generally and in particular cases. The term ethics is used in at least four different but related ways to describe:

- particular patterns or ways of life – as in, say, Buddhist ethics or Christian ethics
- sets of rules or guidelines for good, right or correct behaviour – as in professional codes of ethics or general ethical guidance, such as the ten commandments, or the Declaration of Helsinki, for medical research (World Medical Association, 1964, last amended 2008)
- general, theoretical inquiry into what it means to live a good life and do the right things
- exploration of how these ideas translate into practice when people are faced with dilemmas or decisions about what should (and should not) be done in specific situations.

In the last two senses, the term is being used as a verb – to 'do' ethics.

Ethics *cf.* morality

Morality (from the Latin *mores,* meaning customs, manners) also encompasses questions of right and wrong, what ought and ought not to be done. Nowadays, the terms 'ethical' and 'moral' are frequently used interchangeably, both in everyday conversation and in philosophical literature.

Nevertheless, ethics is often the preferred term in a *professional* context. Codes of principles for professional conduct are usually described as codes of *ethics*, not codes of morals:

> "Anyone can be described as immoral", but only doctors, lawyers, scientists and "others who fail to live up to publicly professed obligations tend to be called 'unethical'." (Boyd, 1997a)

This particular perspective might encourage a narrow view of ethics, but the subject is not limited to professional practice – it includes all aspects of (everyday) morality (Downie and Calman, 1994). Moreover, professional codes of practice do not provide an escape from the need to make moral judgements, because they cannot cover all circumstances and are open to interpretation in different contexts.

Ethics *cf.* law

Behaving ethically (or being moral) "involves more than keeping on the right side of the law" (Boyd, 1997b). Laws lay down certain rules, or boundaries, which must not be breached; yet within these boundaries there can be considerable room for judgement about what is right and what is wrong.

The Animals (Scientific Procedures) Act 1986 is not an easy-to-follow code of dos and don'ts in animal use. Rather, it sets out a framework within which *ethical judgements* must be made about what is and is not acceptable. Some guidance notes are provided (Home Office, 2000), but it is recognised that these are not static and will evolve alongside advances in both scientific and moral understanding.

Identifying ethical questions

Ethical issues are most often encountered when there are difficult choices to be made about which courses of action *ought* to be taken in particular situations. We enter the realm of ethics when we move from consideration simply of what *can* be done (i.e. what is *possible*) in a given situation, to consideration of what *ought* to or *should* be done in that situation. For example, whether or not a particular research project that can provide knowledge to benefit humans or other animals, but which will involve causing pain, distress or suffering to animals, *ought* to go ahead.

The most dramatic dilemmas tend to make the headlines and it is sometimes forgotten that more day-to-day decisions and judgements can have ethical components. For example, in animal research, even a decision about how frequently to clean a mouse cage could have an ethical as well as a practical dimension, because it might involve balancing competing animal and human interests in order to decide what ought to be done. For example, the decision could involve weighing scientific evidence about what would promote the best possible mouse welfare, against constraints of technician time and costs (if the evidence suggests that more frequent cleaning would be beneficial), or against human health hazards due to odour/allergen build-up (if the evidence points to less frequent cleaning).

'Doing ethics' in practice

The kind of practical decision making mentioned above is the visible "tip of the [ethics] iceberg" (Seedhouse, 1988). Practical decisions in particular cases are influenced by deeper, more fundamental questions that we run into as we think more deeply about the reasoning behind our ethical choices. For example, more fundamental and often unspoken questions that underlie and influence decisions on whether, and how, animals should be used in experiments, might include the following:

- whether animals have 'rights' not to be harmed (either at all or in certain ways) by humans
- what value we should place on an animal's life – how far, and in what ways, is killing an animal ethically similar to killing a human?
- whether it is more or less acceptable to use some species than others in experiments and, if so, on what grounds?
- what in practice should 'good animal welfare' mean?

At a deeper level still, there are ever-present questions, common to all moral choices, about how we should live our lives, what it means to be a good person and how, in the most general terms, we should decide how we ought to behave.

One useful working definition of 'doing ethics' is that this involves the *"critical evaluation of assumptions and arguments"* used to arrive at such value judgements as described above (Raphael, 1994).

Ethical questions often crop up in everyday lives, both private and professional, and we frequently make judgements or decisions on them. 'Doing ethics' involves careful consideration of the reasoning on which such judgements and decisions are based, so as to:

- make sure that the judgements are sound and consistent
- attempt to resolve disagreements, and
- promote better ethical decision making in future.

Inevitably, 'doing ethics' involves balancing competing arguments, trying to find out where exactly the disagreements and any points of agreement lie. Ethical judgements need to take into account a range of different perspectives, and this might involve engaging in debate with people who hold different views. Sometimes, consensus judgements can be reached; in other cases disagreements will remain, but better understanding of the reasons for the disagreements can help to strengthen the decisions that are eventually made.

Some benefits

Ethical questions, by their very nature, are difficult questions on which people's opinions and judgements tend to differ. 'Doing ethics' can help to remove both muddle and intolerance from difficult debates by discouraging a rush to judgement and taking the time to think more clearly, deeply and precisely about the reasons for opinions and decisions (Sorell, 1987).

In particular, doing ethics can help to:

- avoid being swayed by ill-founded, but at first sight persuasive, arguments, that is, to recognise bad rhetoric[1]
- develop a deeper understanding of the range of perspectives on the issue, and use this understanding to inform judgements
- make sure that decisions and judgements take into account all relevant features of the issue at stake
- engage in debate with people who hold different views and, by pin-pointing exactly where the agreements and disagreements lie, learn from each other, identify any common ground and move towards consensus
- feel more confident in the decisions that are made, knowing that, at the very least, all involved have done their best to identify the most acceptable standpoint or solution to a problem.

Ethics, however, cannot positively prove that one judgement is 'the correct solution' compared with all other possibilities, and choices must still be made. Indeed it can be argued that studying ethics:

> "makes it more necessary, not less, to stand on your own feet, to be self-critical, and to be obliged to choose for yourself. It makes you more rational, more responsible, more of a human being." (Raphael, 1994, page 10).

Approaching ethical judgements in practice

As discussed above, the quality of ethical judgements depends largely on the depth and breadth of thought that those involved put into them. Higgs (1997) has set out a list of possible aims of ethical discussion that are important elements in the process of arriving at decisions, or ways forward, on ethical issues.

- Identification of issues at stake, whom they affect, and in what way.
- Further exploration of morally relevant facts, together with a reasonable attempt to assess the perspectives and purposes of all involved.
- Clarification of the concepts and arguments being used (including asking whether any person or group is distorting the discussion by manipulation, misuse of language, or distortion of concepts and arguments).
- Interaction and dialogue between the various parties to ventilate feelings, share points of view, and make sure everyone feels 'heard'.
- Analysis or synthesis of different points of view and arguments in order to create a response or way forward.

[1] Rhetoric attempts to persuade others to adopt a particular point of view – in this case about what is right and what is wrong. Bad rhetoric is based on poor argument – it might merely play on the emotions, or it might exploit incomplete, disputable or incorrect facts, or it might use logically inconsistent arguments, for example.

This list emphasises that good ethical judgement requires:

- as comprehensive and accurate an understanding of the issues at stake as possible
- consideration of all the relevant factors and interests involved.

The latter includes an understanding of the *context* in which the judgement is made. This, in turn, includes any legal framework or relevant professional codes, historical precedent, range of current perspectives (both amongst people directly involved in the issue under consideration and perhaps across society more widely), and possible general frameworks for thinking on the issue.

Approached in this way, judgements will not result from 'gut feelings' alone. However, emotions do still play a part. Such feelings can, at least, help in identifying areas of ethical concern, suggesting a need to 'pause' and allow time to consider the issues in depth (Gillett, 1988; 1997).

Role of ethics 'experts'

Good ethical judgement is not limited to a 'specially trained elite' but can be claimed by anyone with sufficient wisdom, intelligence and experience, who is prepared to make the effort to understand the issues and seriously consider the different perspectives involved (Sorell, 1987).

Nevertheless, people trained in ethics have expertise that is particularly helpful in challenging others to think in new ways and in ensuring that the *process* of ethical reasoning is comprehensive, logical and consistent. Moreover, initial and/or continuing training in ethical reasoning can be helpful for everyone involved in considering ethical questions, such as those related to the use of animals in science. This is part of the long-term process of developing the experience needed to understand and evaluate the arguments, appreciate their context, and balance conflicting demands.

Suggestions for further reading

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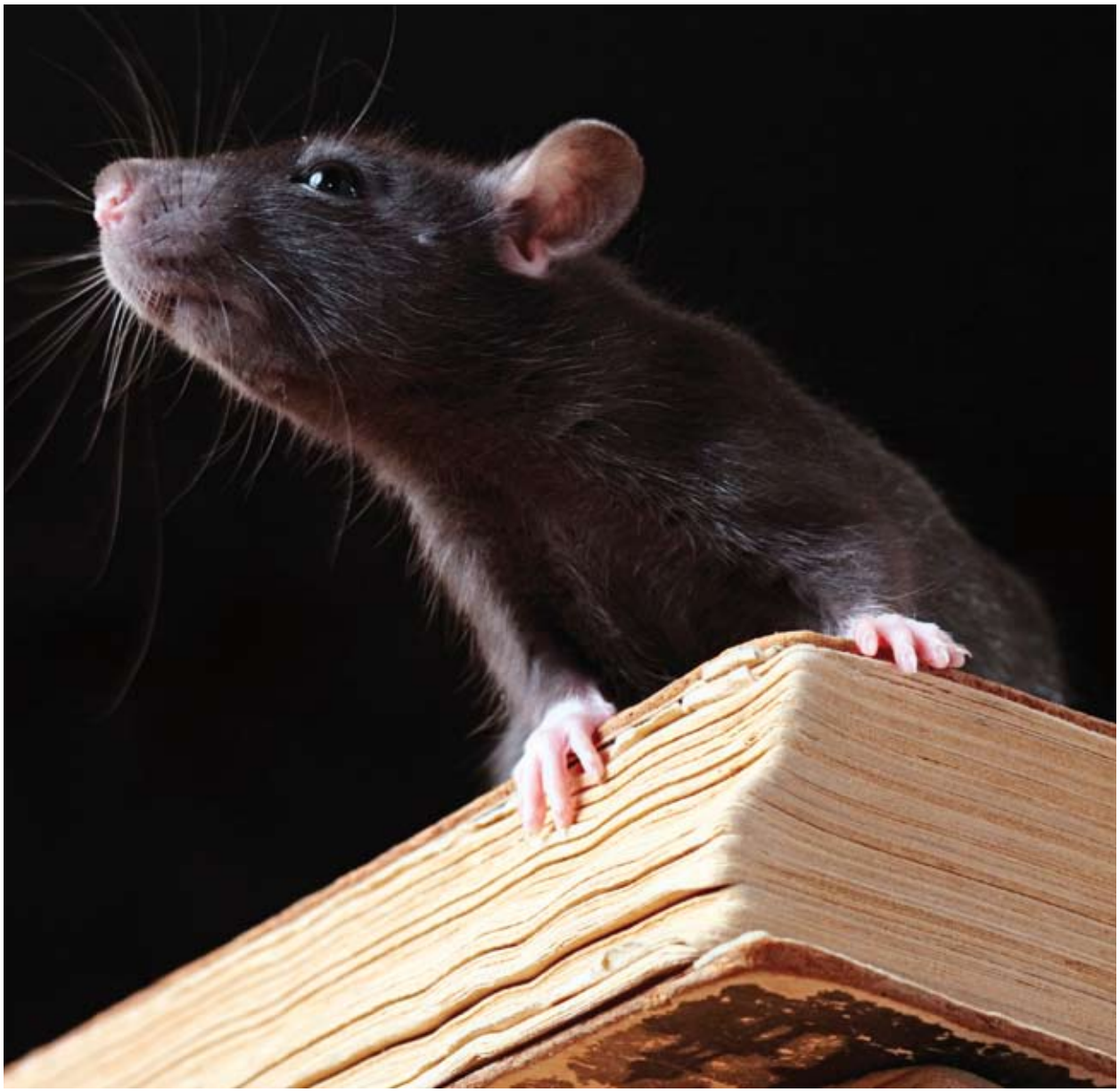

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