



Lay Members' Forum

22nd May, 2007

Research Animals Department





RSPCA LAY MEMBERS' FORUM **22nd May, 2007**

PROGRAMME **Chair: Dr Jane Smith**

10:00-10:30 **Registration & Coffee**

10:30- 13:00 **Morning Session**

Welcome and introduction

Dr Jane Smith (The Boyd Group etc...)

The Ethical Review Process and Better Regulation

Dr Derek Fry (Home Office)

Training animals as a refinement technique - why, what, where, when and how?

Dr Mark Prescott (NC3Rs)

The fate of experimental animals - euthanasia and its alternatives

Dr Penny Hawkins (RSPCA)

Is your Process fully functional?

Dr Maggy Jennings (RSPCA)

A lay member's guide to retrospective review

Dr Manuel Berdoy (University of Oxford)

13:00-14:00 **LUNCH**

14:00-16:15 **Afternoon Session**

Update on outcomes of the last Lay Members' Forum workshop

Dr Jane Cooper (RSPCA)

Workshop and discussion - The seven functions of the Ethical Review Process



The Ethical Review Process and Better Regulation

Dr Derek Fry, Chief Inspector, Home Office

The Government Better Regulation initiative extends to all Departments, and within the Home Office a particular focus is on the operation of the Animals (Scientific Procedures) Act 1986. The initiative is for more efficient regulation, not for removal of important controls, and any simplification and streamlining of processes for licensing under the 1986 Act should not compromise animal welfare. This presentation will discuss the better regulation issues and consider how any changes and other developments in the UK and Europe may affect the role and functioning of local Ethical Review Processes.



Training animals as a refinement technique – why, what, where, when and how?

Dr Mark Prescott (NC3Rs)

Training, using positive reinforcement techniques which reward desired behaviour, is a valuable tool for refining the husbandry, management and use of laboratory animals. Non-human primates, dogs, cats, rodents, farm species and birds can be trained in a variety of situations and for a variety of scientific, veterinary and husbandry procedures (e.g. for capture, blood sampling or administration of substances).

Encouraging animals to voluntarily co-operate with such procedures, where appropriate, can reduce any potential stress and improve animal welfare (e.g. by reducing the need for physical restraint and/or sedation and thus avoiding the risks associated with such procedures). It can also enhance quality of science, since suffering in animals can result in physiological changes that may increase variability in experimental data and could even invalidate the research. However, training is in itself not without an ethical element - some people are instinctively troubled by the idea of training animals to co-operate with procedures that may cause them harm. This is a legitimate viewpoint but the deciding factor should be the welfare of the animals.

This presentation will use examples to illustrate the benefits of training as a refinement to animals, staff and science. It will outline some common problems encountered with training attempts and give guidance for developing and implementing effective training programmes, highlighting suitable resources for support. Finally, it will comment on appropriate training techniques and give suggestions for what lay members of Ethical Review Processes can do to encourage refinement through training animals.



The fate of experimental animals - euthanasia and its alternatives

Dr Penny Hawkins (RSPCA)

It is often assumed that all experimental animals will be killed when procedures have ended, but this is not necessarily the case. Animals do have to be euthanased if a project requires their tissues or if remaining alive would cause them to suffer. This applies to the majority of studies, but not all, and it is very important from an ethical point of view to consider what is the best fate for each individual rather than to routinely kill animals.

Possible alternative fates for experimental animals under the ASPA are:

- re-use,
- rehoming, or
- release.

The Act includes controls on re-use, rehoming and release that are all intended to prevent animals from suffering avoidably. These provide the legal context for the ERP to consider the scientific, practical, ethical and - most importantly - animal welfare issues that apply in each case. In the case of re-use, the life experience and potential future suffering of the animal who has already been used must be considered and balanced against the ethical and welfare issues associated with bringing in a naïve animal. For rehoming and release, the Secretary of State must be satisfied that the maximum possible care has been taken to safeguard the wellbeing of the animal and s/he will not be at a biological disadvantage if released to the wild. It can be difficult to decide whether it is in an animal's best interests to be rehomed or released and people can have very strong opinions on the issue. This talk will set out the key factors to consider when making a decision.

If animals must be killed, Schedule 1 to the ASPA sets out permissible euthanasia techniques that are designed to minimise any pain, anxiety or suffering that animals may experience. This talk will focus on the use of carbon dioxide (CO₂) because many, if not most, rodents are killed using this technique. CO₂ is effective and easy to use, but its acceptability is being increasingly called into question as it can cause discomfort and distress. It is recognised that placing animals into 100 % CO₂ is painful - and this is not allowed under Schedule 1 - but there is controversy as to the ideal protocol for CO₂ euthanasia that will minimise suffering.

The use of carbon dioxide has been reviewed by a number of groups including the Animal Procedures Committee and a meeting of researchers in the field who aimed to achieve a consensus about CO₂ euthanasia protocols, but despite this it is unfortunately still not possible to make definitive recommendations. This talk will set out and explain the issues, as they are currently understood, to help local ERPs decide what is acceptable at their own establishments.



Further reading:

- Animal Procedures Committee (2007) *Review of Schedule 1 of the Animals (Scientific Procedures) Act 1986. Appropriate Methods of Humane Killing.* <http://www.apc.gov.uk/reference/reports.htm>
- Hawkins P et al. (2006) *Newcastle Consensus Meeting on Carbon Dioxide Euthanasia of Laboratory Animals.* <http://www.nc3rs.org.uk/downloadaddoc.asp?id=416&page=292&skin=0>
- Home Office (2000) *Guidance on the Operation of the Animals (Scientific Procedures) Act 1986.* London: The Stationery Office.
[Guidance on re-use (paras 5.60 to 5.66), release from the controls of the Act and “disposal” (8.13 and 8.14, 8.17).]
- Home Office (1997) *The Humane Killing of Animals Under Schedule 1 to the Animals (Scientific Procedures) Act 1986.* London: The Stationery Office.
- Jennings M and Howard B (undated) *LASA Guidance on the Rehoming of Laboratory Dogs.* http://www.lasa.co.uk/position_papers/publications.asp
[Contains useful principles that can be applied to other species.]



Is your Process fully functional?

Dr Maggy Jennings (RSPCA)

When local ERPs were first established in 1999, the Home Office listed seven core functions that the process should cover. These are:

1. promoting the development and uptake of **reduction, replacement and refinement alternatives** in 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 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 3Rs 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 protected animals;
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.

Many ERPs seem to interpret their role as mainly related to Point 2, project review, and discussion sessions at previous Lay Members Forums have focussed on issues around harm/benefit assessment. However, the other six functions are also important in achieving the goal of local ERP and helping to develop each establishment's overall culture of care.

Some ERPs have set up good systems for addressing the additional functions, for example by setting up separate groups to cover issues such as the 3Rs, animal husbandry, environmental enrichment, and staff training, which feed into and inform the work of the main ERP.

In the afternoon discussion session we will be able to compare notes on how different ERPs deal with functions 1 and 3 – 7, and how lay members have been able to contribute to such activities. If sufficient information is available this may enable us to produce some guidance notes on performing these functions. As a prelude to this, the next presentation will explore one of the more difficult issues - retrospective review - in more depth.



A lay member's guide to retrospective review

Dr Manuel Berdoy (University of Oxford)

Retrospective review of research projects is one of the seven core tasks of the local Ethical Review Process that will be discussed later in the afternoon session. It is perhaps the task that has been most difficult to define and interpret and as a consequence the way it is done varies considerably between individual establishments. For example, some ERPs review projects at set intervals throughout the lifetime of the project, whilst others carry out an end of project review, and yet others may receive reports on individual experiments within a project once each is completed.

The way retrospective review is done and exactly what is 'reviewed' also varies, and thus so do the outcomes and the usefulness of these. The Home Office have stated that the purpose is to:

"...look back on the animal welfare costs encountered and benefits realised. This permits assessment of the extent to which the original assumptions, including the severity limit of protocols, were correct when the request for authority was originally considered, and to consider if additional 3R strategies can be identified and incorporated. This information is of value to licensees and the ERP in planning future work and, as ERP records are available to the Inspectorate, it may also influence future Home Office assessments."

The LASA Ethics and Training Group have published guidelines on retrospective review and are engaged with others in ongoing work on the issue. This presentation will summarise current thinking on the purposes and objectives of retrospective review and provide ideas on how to develop an effective system.

The best processes are the most likely to lead to the best outputs, so it is hoped this information will provide lay members with ideas to implement within their own ERPs.

Reference:

LASA (2004) *Guidance notes on retrospective review: A discussion document prepared by the LASA Ethics and Training Group*. Available from:

http://www.lasa.co.uk/position_papers/publications.asp



Workshop and discussion session: The Seven Functions of the ERP

According to the Guidance on the Operation of the Animals (Scientific Procedures) Act 1986, the ERP should allow (where appropriate) the following:

1. promoting the development and uptake of reduction, replacement and refinement alternatives in 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 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 3Rs 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 protected animals;
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.

Workings within your groups, consider function 1 and 3-7 as allocated and explore:

- Does your ERP perform the function? If so, how and what does it achieve?
- Are there any difficulties in performing the function?
- Do you think your ERP could improve the process? If so, how?
- What role do you think the lay member can play in this function and how can/do you input?

There is space provided at the back of this booklet for you to record the outcome of your discussions.



Useful resources available at: www.rspca.org.uk/ethicalreview

RSPCA resources for members of ERPS:

- A resource book for lay members of Local Ethical Review Processes
- Projects involving genetically modified animals - explains the technology, terms and welfare implications relating to creation and use of GM animals
- Good practice guidelines for laboratory animal housing and care:
 - The mouse
 - The rat
 - The guinea pig
 - The rabbit
 - The dog
 - The ferret
 - The pig
 - The sheep
 - The domestic fowl
 - Ducks and geese
 - The pigeon
 - Finches, including the zebra finch
 - The quail, including *Coturnix spp*
 - African clawed frogs, *Xenopus laevis*

Other useful resources:

- Animal Procedures Committee review of the cost-benefit assessment in the use of animals in research
- Guidance notes on retrospective review
- Categorising severity of scientific procedures on animals report
- Nuffield Council on Bioethics report on “The ethics of research involving animals”

Links to useful information provided by other organisations

Guidance on the operation of the Animals (Scientific Procedures) Act 1986:

www.archive.official-documents.co.uk/document/hoc/321/321.htm

Home Office documents relating to the Ethical Review Process:

<http://scienceandresearch.homeoffice.gov.uk/animal-research/publications-and-reference/publications/guidance/ethical-review-process/>

Animal Ethics Infolink – Australian site with information useful to members of ethics committees and links to other sites with useful info:

<http://www.animaethics.org.au/reader/whatsnew/6>

National Centre for the 3Rs:

www.nc3Rs.org.uk



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RSPCA, Research Animals Department
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