



ERP Lay Members' Forum 2010







Programme

Chair: *Bryan Howard*

09.45 **Registration and coffee**

10.30 **Welcome and introduction**

Implementing the Three Rs...

10.40 **Approaches to alternatives**

Vicky Robinson

11.00 **‘Reduction’ through good statistics and
experimental design**

Simon Bate

11.20 **Understanding severity classification**

Anne-Marie Farmer

11.40 **Assessing pain, suffering and distress - how and
why**

Penny Hawkins

12.00 **Coffee followed by discussion group session**

Three discussion groups to cover topics above, led by
the speakers

13.10 **Lunch**

continued ...



continued ...

14.00 **Home Office issues**
Judy MacArthur Clark

14.25 **Implementing ERP function 2: examining project
licence applications**

- *Debs Flack*
- *Dawn Parkins*
- *Nic Wells*
- *Caroline Bergmann*

15.30 **Plenary session: for input, questions and discussion
from the floor**

16.00 **Close**



Presentations

Approaches to alternatives

Vicky Robinson

Replacing the use of animals is inherently difficult. There are scientific, technological, regulatory and often attitudinal obstacles to overcome. The ethical review process has replacement as part of its remit yet its impact in this area is not clear. This presentation will focus on the challenges faced by the ERP in promoting replacement and using examples from the work of the NC3Rs and experience as a lay member will review opportunities for putting replacement higher up the ERP's agenda.



Reduction through good statistics and experimental design

Simon Bate

It is generally understood that appropriate experimental design and statistical analysis methods can contribute to the 'R' of Reduction by reducing sample sizes in animal experiments. Good experimental design also contributes to Refinement and is integral to good project design and obtaining good quality scientific data. Members of the ERP will therefore want to feel confident that these issues are well addressed in the projects that come for review - or retrospective review - and that their establishments have the means to make sure they are generally dealt with adequately.

However, experimental design and statistical analysis are quite specialised topics and it may not be easy to know what questions to ask, or what points to raise, and therefore to enter into discussions. For example, apparently simple factors such as whether animals will be housed in more than one room, be tested on different days or be assessed by different operators, can have a significant effect on results and so need to be taken account of in experimental designs.

This talk will provide some real practical examples of how using efficient experimental design has helped reduce animal numbers and will show how a non-statistician, equipped with a little common sense, can help identify and solve design problems.



Understanding severity classification

Anne-Marie Farmer

What is meant by unclassified, mild, moderate and substantial severity and what sorts of procedures fall under the different categories? Should the “life time” experience of a research animal be assessed and if so how? Do you know the difference between a severity band and a severity limit and when each is used?

This presentation will expand on each of these issues and with the use of practical examples will illustrate how project licence applications are assessed and how conclusions are reached as to the most appropriate limits and band to apply to a project licence application.



Assessing pain, suffering and distress - how and why

Penny Hawkins

Assessment of pain, suffering and distress in laboratory animals is a necessary step towards achieving the goal of reducing animal suffering. Considerable progress has been made in recent years, particularly in the recognition of more subtle behavioural and physiological signs of suffering, enabling animal suffering to be picked up much earlier so that pain relief can be given and earlier endpoints can be applied. This progress in identifying, monitoring and interpreting animal behaviour has also contributed towards better evaluation of husbandry and care refinements.

Alongside these changes, emphasis has shifted from focusing on minimising negative feelings such as discomfort, pain or anxiety, with more thought now being given to improving welfare by facilitating a good quality of life in experimental animals.

Better ways of monitoring animals' welfare are also being developed and people are beginning to think in terms of setting up welfare assessment teams for individual projects and/or more generally within the establishment.

This presentation will provide examples of some recently identified subtle indicators of animal pain, suffering or distress and explain some commonly used approaches to assessing and recording welfare. It will also provide ideas on how to contribute to the development of good practice, both within project review and in conjunction with the broader ERP functions.



Home Office issues

Judy MacArthur Clark

This presentation will provide an update on Home Office issues, in particular in relation to the revision of the EU Directive regulating animal experiments. The revision of the Directive was completed in September this year and it now needs transposition into UK law. This session will provide the latest information on this process and describe possible implications for local ERPs.



Project evaluation at a small unique research establishment

Debs Flack

At the Trust our aim is to improve animal welfare through development of new technology and knowledge for the better diagnosis, prevention and cure of disease in companion animals.

As part of this remit there is a requirement at times to use animals in research. The Trust expects this research to be executed not only to Home Office standards but to the highest possible standards of care and welfare, which are paramount to the running of our institution.

With this goal in mind our ERP was founded using a 3 tier system to evaluate animal care and welfare, 3Rs and finally, ethics. This approach was considered unique at the time and is managed with 3 separate committees, mixed key internal personnel, external experts and lay people. The Committees also provide a learning process by exposing research staff to the ethical and animal welfare implications of their research, and thereby seeks to permeate a culture of animal care and respect throughout the Trust.

The Trust has a relatively small number of project licences and although these are considered in full by the ERP, the process focuses more on individual studies as these are developed within the overall programme of work. In addition, there are a number of interesting ethical questions that arise at an establishment where the focus is on companion animal health and welfare. Input from the project licence holder is considered extremely helpful in addressing these and they usually attend meetings when their studies are discussed.

This presentation will outline the Trust's process and its benefits and highlight some of the points that arise in ethical debate.



ERP experiences at a large university and a smaller college

Nic Wells

At a large university and at a smaller college, the ERP functioned in a largely similar fashion - project licence applications were assessed by a panel of the NVS, NACWO, scientific peer reviewer and lay person. Amendments were assessed in most cases by the NVS and NACWO. In both institutions this was done via electronic communication unless problems were identified that could be best addressed by face to face meetings. Similarly in both cases the ERP reported to a central committee which could follow up any concerns. Electronic communication has great advantages as it removes potential delays and ensures that questions are answered and revisions are made accordingly. In most cases the issues raised by the ERP related to humane end points and the standard protocols adopted by the institution (for example ear biopsy instead of tail biopsy in identifying GA mice). The lay member(s) can play an important role in questioning standard procedures and the ethical value of the proposed work.

Although the ERP plays an important role in assessing whether the work meets good ethical and institutional standards, it is without doubt the relationship with the animal facility staff and NACWO dealing directly with the PPL Holder's animals and research staff that are key to the successful implementation of ethical experimentation. Examples of the role played by staff will be given to reinforce this view, with particular emphasis on a recent substantial protocol.



An example of an Ethical Review Process within a pharmaceutical company

Dawn Parkins

Project Licence Review Committee (PLRC) meetings are held on a monthly basis to review new project licence applications and amendments to existing licences. In addition to this, meetings are used as a forum to discuss other related information, such as ethical issues and practical/technical issues linked to Home Office compliance.

The full licence application process comprises of an initial meeting with the project licence holder, named veterinary surgeon and the company Home Office Liaison Officer. In conjunction with this, proposals are discussed with the Home Office Inspector at the earliest opportunity. After this there is a technical review of the application, and then the ethical part of the review process begins as follows:

The full application, along with any supporting documents, is placed in an electronic forum area and the internal members of the panel are invited to post comments. External lay members are sent details of the application via a secured method. Questions and issues are raised during this ethical review and the project licence holder is invited to give a presentation addressing these at the PLRC meeting. During the review, considerations are given for refinement, reduction and for replacement. Evidence of statistical input into experimental design is requested and the cost (severity, animal numbers) and benefits are discussed.

This PLRC face to face meeting also gives a chance for further ethical discussions and a chance for lay members to raise questions.

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Once all the ethical discussions are exhausted, the members of the committee are asked if they support the application going forward. There are three possible outcomes:

- application supported
- application supported following agreed amendment(s)
- application deferred

The PLRC consists of animal technologists, scientists, veterinary staff, personal and project licence holders, non-animal using scientists, NACWOs, lay members, Home Office Liaison Officers, and a statistician. The meetings are chaired by the Certificate Holder. There is a separate 3Rs sub-committee and a NACWO group, both of which link into the PLRC.

From the start of the technical review, until submission to the Home Office, the process is typically completed within 6 weeks.

During this presentation I will look more closely at the ERP, how it interacts with other groups within the company and give examples of other topics which are covered during PLRC meetings. I will also share with you learnings from previous meetings and ideas for the future.

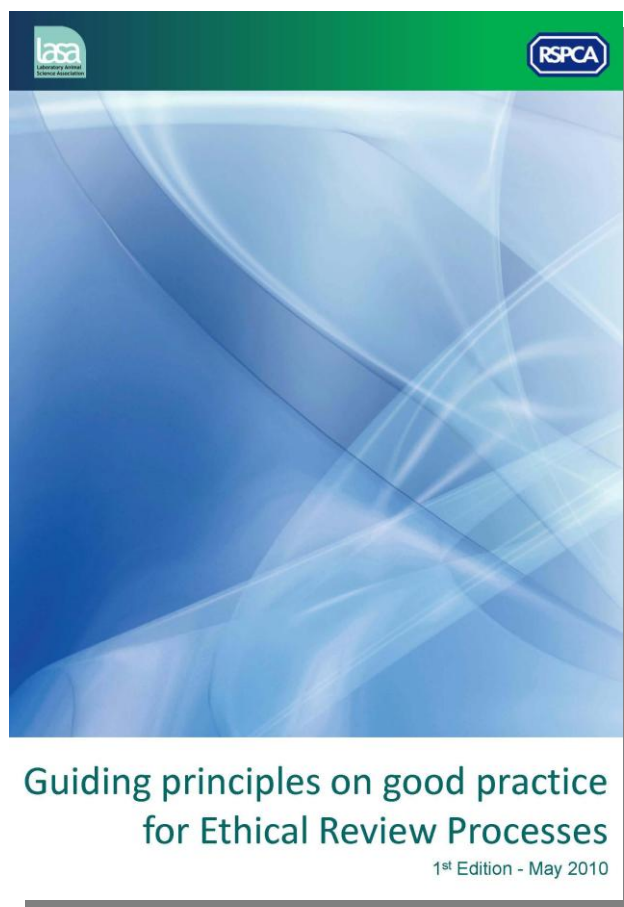


Ethical review of project licence applications in a large academic institution

Caroline Bergmann

The local ethical review process operates through two principal elements: a central committee on Animal Care and Ethical Review (ACER) and a network of five departmental ethical review committees. The Committee on Animal Care and Ethical Review meets six times a year, has overall responsibility for the University's ethical review process and for monitoring standards of animal health and welfare. It has two sub-committees responsible for matters relating to non-human primates and promotion of the 3Rs. The committee reviews the more complex applications for project licences, defined as those involving the use of non-human primates, protocols of substantial severity or novel procedures. All other applications are considered by one of the departmental committees. Ethical review committees advise the Certificate Holder on whether the benefits of research outweigh the costs to the animal. The final decision on ethical review rests with the Certificate Holder.

□ New resource: Guiding principles on good practice for Ethical Review Processes

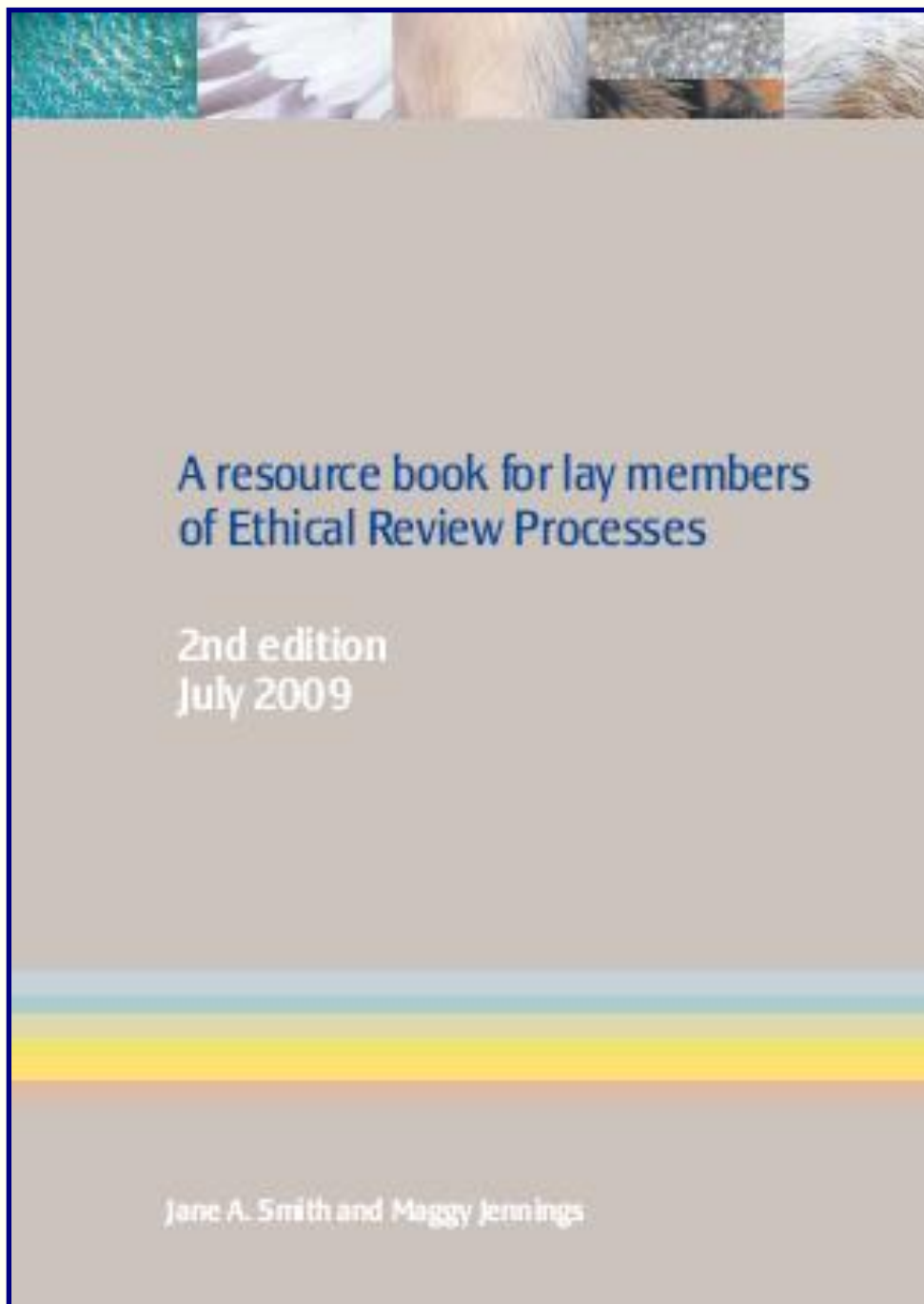


The report is based on the output of two workshops involving staff from around 50 establishments, with a diverse range of roles, all of whom were closely involved with the work of their ERP. It starts with 'Ten Top Tips' for a successful ERP, then subsequent sections help to interpret each of the ERP's seven main functions, exploring in more detail their purpose, some recommended approaches, and ideas on issues and topics to cover. The report is intended to be a 'dynamic' document, so feedback is very welcome - please send any comments to: erp-laymembers@rspca.org.uk

This year the RSPCA and LASA completed their joint project to develop a set of 'Guiding principles on good practice for ERPs' and the report is now available on the RSPCA and LASA websites:

www.rspca.org.uk/ethicalreview
www.lasa.co.uk/publications.html

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Copies are available from the RSPCA Research
Animals Department - email:
erp-laymembers@rspca.org.uk



□ Good practice guidelines on housing and care

- ◆ Mice
- ◆ Rats
- ◆ Guinea pigs
- ◆ Hamsters
- ◆ Rabbits
- ◆ Ferrets
- ◆ Dogs
- ◆ Cattle
- ◆ Pigs
- ◆ Sheep
- ◆ African clawed frogs
- ◆ Ducks and geese
- ◆ Domestic fowl
- ◆ Pigeons
- ◆ Finches
- ◆ Quail



□ Poster on retrospective review with key questions to consider together with the original LASA Guidance notes [see: www.lasa.co.uk]

□ www.rspca.org.uk/ethicalreview

The RSPCA website contains an area dedicated to aspects of ethical review. It includes information on ethical review around the world, downloadable resources including all of those above and details of our events for lay members.

