



# ERP Lay Members' Forum

3<sup>rd</sup> December  
2009



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## Programme

Chair: Bryan Howard

### 09:45 Registration opens

10:00 Informal introductory session for new lay members  
*Bryan Howard, Maggy Jennings, Jane Smith*

### 11:00 Meeting proper starts - Welcome to formal sessions

Harms and benefits - brief introduction  
*Jane Smith*

11:10 Harms and benefits of surgical instrumentation of animals  
*Tony Webb*


11:30 Harms and benefits in projects involving transgenic animals  
*Sarah Johnson*

11:50 Harms and benefits of re-use of animals  
*Anne-Marie Farmer*

12:15 Coffee and discussion group session  
Three topics (transgenics, instrumentation, re-use and general harm/benefit issues led by the speakers and other participants)

### 13:15 Lunch

Continued ...



14:15 Feedback session on any key points from the morning

14:25 Dealing with retrospective review: examples of common practice from different types of establishment  
*Sarah Wolfensohn*  
*Sue Thorpe-Jones*  
*Sarah Lane*  
*Angela Kerton*

Panel discussion with questions from the floor

15.35 News and comments since last year - update on the European Directive; Home Office issues; any other issues

### 16:00 Close



## Harms and benefits

### Harms and benefits: a brief introduction.

Jane Smith

Assessment and weighing of harms and benefits are matters of judgement, which by their nature are contestable. Opinions will differ on what should count as a harm or legitimate benefit, and on the relative weights that should be accorded to different kinds of harms and benefits. This short presentation will introduce some of the key points to consider; the three presentations that follow will then provide some examples of the way the harms and benefits of specific areas of animal use can be addressed in practice.



### Harms and benefits of surgical instrumentation of animals.

Tony Webb

Surgical preparation of animals may be performed to implant devices that facilitate a number of experimental techniques, including physiological data collection, administration of compounds by specific routes and sampling of body fluids. Typical examples are listed in the table below.

Physiological data	Blood pressure Blood flow Electrocardiogram (ECG) Electroencephalogram (EEG) Electromyogram (EMG) Motility Body temperature (core/peripheral)
Compound administration	Intravenous - long term or repeated infusions Intra-arterial Regional circulation (e.g. portal vein infusion) Intracerebral (bypassing blood brain barrier) Intrathecal (spinal cord)
Biological sampling	Blood withdrawal - systemic Blood withdrawal - regional (e.g. hepatic portal vein) Bile Urine Lymph Gastrointestinal content Cerebrospinal fluid

Potential harms to animals undergoing surgical preparation include acute and chronic pain or discomfort, infection, adverse reactions to the implant, thrombosis from vascular implants, and alteration to normal structure or function. Harm will be increased where serial (multiple) surgeries are performed and where surgery is performed in animals with induced or genetic diseases. In addition, distress may be caused by isolating normally social animals to prevent damage to implants by cage mates, tethering to permit infusions or data collection by "hard wired" methods, and the use of jackets in some species.



Surgical instrumentation can also provide benefits for animals, often by reducing the need for stressful repeated handling and restraint. For example, instrumentation for biological sampling reduces the need for repeated puncture of blood vessels. Telemetry can be used as a refinement to replace tethered recordings, and implantable infusion pumps with back packs can replace the use of restrictive tethers for administering substances.

However, the benefits of such preparations need to be carefully weighed against the harms - for example, it is difficult to justify a surgically implanted catheter for small numbers of blood samples where used to compensate for lack of skill in handling! There may also be technical issues relating to wastage, where device failure following implantation can mean that animals have undergone procedures without producing any data.

Experimental surgical procedures can be a very technically complex area for ethical review for a lay member. It is suggested that lay members can make their greatest contribution by viewing the broader picture of the whole project and critically evaluating the justification for surgical instrumentation. It is also essential to ensure that consideration is given to likely adverse effects in the project licence application and provision made for treatment of these should they arise, including humane endpoints or euthanasia as appropriate. A growing number of "best practice" documents are available to assist review.

It is also possible for instrumented animals to be kept for several years and undergo reuse, so careful consideration must be given to assessing overall lifetime severity. Finally, special consideration should be given to the fate of animals, especially where they may be released from the control of A(SP)A.



## Harms and benefits in projects involving transgenic animals.

Sarah Johnson

Over the past few years the production and use of genetically altered animals (GAAs), in particular mice and zebrafish, has expanded rapidly. GAAs are used to research the regulation of gene expression, cellular and physiological processes, in a variety of fields including fundamental research, toxicity testing, in human (and veterinary) disease and as a source of cells, tissues or other reagents.

There are a wealth of scientific benefits that can be reaped from the use of this technology, yet the creation and use of these animals gives rise to specific animal welfare concerns. Harms include those associated with the procedures used to produce the animals, and both the predicted and unknown adverse effects of the genetic alteration. More general harms associated with all laboratory animal use also apply, such as those that may be associated with husbandry, restraint, identification and euthanasia.

The harms and benefits of each project need to be weighed carefully, and this is best done from an informed viewpoint. Gathering information on the reasons for GAA use in particular circumstances, understanding the most appropriate use and choice of production method, ensuring that processes for specific welfare checks are in place and that establishments provide practical solutions to deal with any special needs, are necessary for the harm-benefit analysis. Similarly, ensuring there is a culture where new and improved knowledge and methodology is sought out and disseminated is essential to minimise the harms associated with the use of GAAs.



## Harms and benefits of re-use of animals.

Anne-Marie Farmer

This presentation will define what is meant by re-use and set it in context with continued use. It will explain the relevant provisions made for the further use of animals in the Animals (Scientific Procedures) Act 1986, and Guidance on the use of the Act.

Having set the base line parameters, a number of scenarios will be diagrammatically presented for consideration and to stimulate discussion.



## Retrospective Review

### Retrospective review: a methodology from academia.

Sarah Wolfensohn

The objective in undertaking retrospective project reviews is to continue to apply the 3Rs to all projects throughout their duration. The University's web site states that it "is committed to ensuring that all those involved in animal-based research (scientists, veterinary surgeons and animal technicians) are pro-active in pursuing the replacement, reduction and refinement of animal use (the 3Rs), engage fully in the ethical review process, and fulfil their moral and legal responsibilities for the care and welfare of animals", and it goes on to say that it "meets this commitment by reviewing regularly all project licences to ensure that ethical review is an on-going and dynamic process that keeps pace with new developments".

Reviews are carried out at the two and four year stage of the project licence by the Ethical Review Committee following submission of a written report from the licence holder. This report contains an overview of progress against the objectives, a report on each 19b, the application of the 3Rs and the management of the licence. Details of the process before, during and after the meeting will be described and an overview given on the outcomes of retrospective review.



## Retrospective review: example of common practice in a contract research organisation.

Sue Thorpe-Jones

Before a project licence expires and a replacement licence is written, retrospective review needs to be conducted to ensure that refinement, reduction and/or replacement of procedures is incorporated within the new licence.

A 'prompting proforma' has been developed within the establishment to help the project licence holders focus on 3Rs aspects of their licence. This presentation will look at the proforma and outline the types of prompting questions, with some examples of the responses that have been given.

It takes a team effort to write a replacement project licence, beginning with the scientific staff conducting the programme of work. The draft licence is then submitted to the ERP, which involves scientists, animal care staff, personal licence holders, the NACWO, the NVS and lay members. The submission is scrutinised by the ERP to ensure the members understand why and how the animals are to be used. The questions they ask may trigger those involved with the programme to rethink their approach. Alternatively, the reviewers may suggest different, refined methods for carrying out procedures. This approach helps to disseminate new methodology across the multiple disciplines working within a contract research organisation.



## Retrospective review in a pharmaceutical company.

Sarah Lane

Retrospective reviews are performed at the mid term point on all project licences held on site. A harm/benefit spreadsheet is undertaken both at the start of the licence, whether it be a draft project licence or a renewal, and then again at the mid term point. Although this simple spreadsheet aims to provide the reviewers with a method of arriving at a numerical score, it should also stimulate the reviewers to ask further questions. A sub group of the ethical review committee is responsible for the review, which is then reported back to the full committee. The project licence holder also presents a review of the licence, including the total numbers and species used to date and which 19bs are most commonly used. The review also highlights any welfare issues or opportunities for advances in the 3Rs.



## **The ERP's role in retrospective review at a large academic institution.**

**Angela Kerton**

The presentation will outline how retrospective reviews are performed at a large academic institution, which has over 180 project licences and >1000 personal licences. The institution is involved with research in a range of species across multiple campuses. The main drive for the use of experimental animals is medical research and to further scientific understanding and knowledge to the benefit of society.

At this academic establishment, the ERP undertakes retrospective reviews of all existing project licences at least once in their duration. Such reviews request information from the licence holder which may include the number of times each procedure has been carried out and the results of such work to date. This provides the ERP with feedback and enables continuing consideration of the cost-benefit analysis and opportunities to further the implementation of the 3Rs. It also aids in the identification of any specific problems or issues unanticipated at the application stage and enables them to be addressed by the ERP. In addition, a retrospective review may be initiated following a request for amendment of a current licence and may then be combined with consideration of such amendment. Retrospective review also gives the ERP a chance to consider the data arising and/or progress made under the project licence to date. The project licence holder may be asked to present such results to members of the ERP, which enables particularly the lay people to feel part of the on-going process of research.

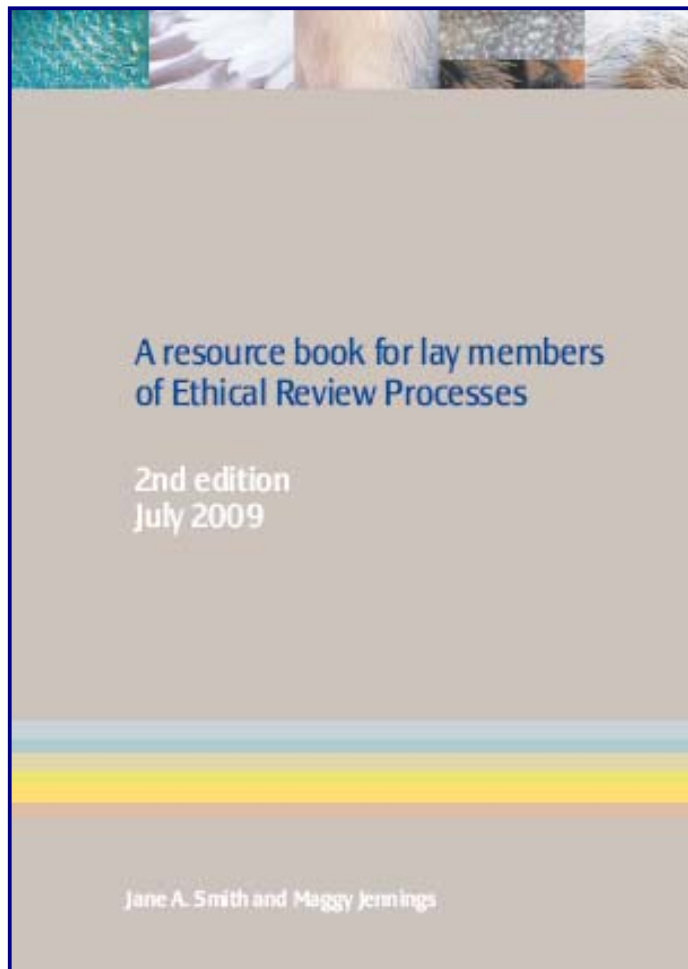
Examples of topics and issues which have been raised during retrospective reviews will be discussed, along with details of how these have been resolved. The retrospective review is an opportunity for the ERP to promote the 3Rs within the research field. By promoting best practice locally as part of the review, scientists and staff work will ensure that animals are kept and cared for using the highest standards of husbandry. Also, if all concerned keep abreast of new developments



in refining techniques, research animals will experience the least pain, suffering or distress.



## Resources



- The RSPCA's handbook for lay members has been completely revised and updated. The new edition includes additional material on each of the seven functions of the ERP and how lay members can play a role in implementing them.
- Copies are available from the RSPCA Research Animals Department – email [erp-laymembers@rspca.org.uk](mailto: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



- **Refining rabbit care** [see: [www.rspca.org.uk/researchrabbits](http://www.rspca.org.uk/researchrabbits)]
- **A poster on retrospective review with key questions to consider together with the original LASA Guidance notes** [see: [www.lasa.co.uk](http://www.lasa.co.uk)]
- **A paper assessing the abstracts of project licences on the Home Office website**  
Barry Phillips and Maggy Jennings; published in ATLA, 2008, 36 (4), 465-471

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.

[www.rspca.org.uk/ethicalreview](http://www.rspca.org.uk/ethicalreview)





## GA animal resources

- A resource on **GA Passports: the key to consistent animal care**, which explains what a GA animal passport comprises, why and when to use one, and what to include.
- A pair of posters entitled **Transgenics and the 3Rs - what's it all about?** which provides an overview of current best practice in the production, care and use of GA mice?
- A booklet on **Sharing and archiving of genetically altered mice: opportunities for reduction and refinement**, which discusses why it is good practice to archive and share resources; what, when and how to archive; and how to share.

**Transgenics and the 3Rs**  
What's it all about?

**Transgenics and the 3Rs**  
Good practice and care

**Sharing and archiving of genetically altered mice: Opportunities for reduction and refinement**

**GA passports: The key to consistent animal care**

For further information on these GA resources, email [GA@rspca.org.uk](mailto:GA@rspca.org.uk)

Our website:  
[www.rspca.org.uk/ethicalreview](http://www.rspca.org.uk/ethicalreview)



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