ERP Lay Members' Forum 2011

RSPCA ERP LAY MEMBERS FORUM 2011

'Making difficult decisions .....'

Chair: Bryan Howard

09.45 Registration and coffee

10.30 **Welcome and Introduction**

10.40 **Humane endpoints: where science and welfare conflict**
- *Maggie Lloyd, Red Kite Veterinary Consultants*

11.00 **Harms and benefits in behavioural pharmacology**
- *Clare Stanford, University College London*

11.20 **Harms and benefits of new technologies: refinement vs reduction**
- *Penny Hawkins, RSPCA*

11.40 **Challenges of a global ethical review process**
- *Doug Brown, Syngenta*

12.00 **Coffee followed by discussion group session**

13.10 Lunch

14.00 **Cumulative suffering: presentation with interactive 'turning point' session**
- *Sarah Wolfensohn, 1789*

15.00 **ERPs and the revised UK law – points of contention and agreement**
- *Jane Smith, Boyd Group*

15.30 **Comments, questions and discussion**

3.45 Close

Humane endpoints: where science and welfare conflict

Maggie Lloyd, Red Kite Veterinary Consultants

Considerable progress has been made in recent years in assessment of pain, suffering and distress in laboratory animals, particularly in the recognition of subtle behavioural and physiological signs of suffering. Animal suffering can now be detected at an early stage. This knowledge has meant that pain relief can be given and endpoints can be applied in good time, and has also enabled scientists, vets and animal technicians to develop a deeper understanding of the actual impact of scientific procedures on animals. As this understanding develops, it raises questions about the ethical justification for some models, in which the degree of suffering experienced by the animals is found to be perhaps greater than was previously considered. In this presentation, a number of ‘difficult’ models will be presented, and strategies for balancing animal welfare against scientific requirements considered.

Harms and benefits in behavioural pharmacology

Clare Stanford, UCL

The aim of studying animal behaviour in the laboratory is to help us to develop better treatments for neurological diseases and mental illnesses. In drug development, the growing options for high-throughput screening of surrogate markers *in vitro* is helping to ensure that only the most promising drug candidates go on to be tested in animals. However, it may never be feasible to replace animals completely because it is unlikely that *in vitro* systems can tell us all we need to know about the regulation of complex functions, such as emotions or memory.

When assessing the merit of behavioural experiments, perhaps the most important role for ERP should be to decide whether the research is really necessary at all. Evidence confirms that scientists' view of what is a worthy research objective is not shared by the wider community. For instance, many people question the justification for using animals in experiments aimed at improving humans' quality of life, which encompasses much of the research into mental illness. This controversy is exacerbated by the widespread scepticism about the benefits of medicines that emerge from this research and concern about inappropriate use of medication to manipulate human behaviour. An even more difficult dilemma is how to evaluate the harm and benefit of research aiming to develop treatments for medical problems that are apparently self-inflicted: e.g., obesity or drug dependence.

Above all the ERP must consider the validity of the research. This rests on ensuring that the procedures enable measurement of the intended variable. There is no way of knowing whether rats are hearing voices in their head, or whether they experience anxiety, but there is a strong rationale for using stimuli that have well-established effects in humans to study their effects on animal behaviour (back-translation). But this approach is fraught with potential pitfalls: whereas pharmacological stimuli are easy to define and reproduce, it is more difficult to confirm the etiological relevance of environmental stimuli. The choice of a laboratory stressor is a case in point. By contrast, the impact of the stress of some procedures on animals' behaviour is often ignored altogether.

The rationale for all behavioural experiments is based on the assumption that studying animals can tell us something useful about the human brain. In behavioural research, especially, the validity of that assumption rests on the experimental procedure in the context of the research objective. However, given that similar stimuli shape the behaviour of all animals, including humans, it is clear that we are not as special as we would like to think.

Harms and benefits of new technologies: refinement vs. reduction

Penny Hawkins, RSPCA

The application of new technologies in animal research and testing is rapidly increasing. Examples include imaging (for example MRI scanning); biotelemetry, in which data such as heart rate are transmitted from devices attached to or implanted into animals; repeated 'keyhole' surgery; and automated blood sampling.

There can be both scientific and animal welfare benefits associated with the use of these techniques; for example, with repeated imaging animals can be used as their own 'controls' and studied in the long term, which means that numbers can be reduced. Endpoints can also be refined using imaging, for example because tumour growth can be monitored more accurately. Telemetry facilitates the collection of data from freely-moving animals, so that stressful restraint is not needed, and automated blood sampling removes the requirement for repeated capture, handling and needle sticks.

However, there can also be harms associated with the application of these technologies. Some, such as automated blood sampling and telemetry, can result in single housing of social animals, which is a major stressor. Repeated anaesthesia for scanning sessions, which can be for long periods, can also affect welfare. There is a risk that the 'cumulative' effects of repeated procedures, such as 'keyhole' surgery, may not be taken into account in the drive to reduce animal numbers.

The talk will focus on how these harms and benefits can be considered against one another, to help ensure that decisions on techniques and protocols are in the animals' best interests. For example, can we judge, from a rat's point of view, whether being repeatedly caught and blood sampled, then returned to a group, is 'better' or 'worse' than having an indwelling cannula and living alone? Is reduction more important than minimising harms to each individual?

The aim is to help you contribute to ERP discussions on projects involving the use of new technologies, with respect to whether use of a particular technique is justified, how to refine the animals' experiences and how to strike the important balance between refinement and reduction.

Challenges of a global ethical review process

Doug Brown, Syngenta

Cultural diversity and differing legislation throughout the world on the use of animals in research give global ERPs particular challenges and potentially difficult decisions if they are to "do the right thing".

As a global company we are committed to using animal studies only when appropriate. We aim to develop alternative techniques that replace and reduce the use of animals and to adopt a humane and compassionate approach to the care and use of animals. We try to operate to the highest professional standards.

There are plenty of challenges! Whether to do work in the UK or China? What standards can or should be set for a company around the world? Global imperatives like food security may look very different if you are a member of an ERP looking at the world through a lens located in Bangladesh rather than Belgium!

We will share a little of how we manage these issues and hopefully take the opportunity to listen and learn from the forum's participants their thoughts on how best we may deliver our duty to the highest professional standards.

Cumulative suffering

Sarah Wolfensohn, Seventeen Eighty Nine

The new Directive 2010/63/EU requires that all procedures are assigned a “severity” which should take into account the “cumulative suffering”. The Directive also requires taking into account the life-time experience of the individual animal, enhancing the life-time experience of the animals, and reducing the duration and intensity of suffering to the minimum possible. The severity category should take into account the nature of pain, suffering, distress and lasting harm, its intensity, the duration, frequency and multiplicity of techniques and the cumulative suffering within the procedure.

Many factors can impact negatively on animal welfare and these need to be considered individually and in combination to determine the overall suffering/severity for each procedure, and to identify areas where refinements can be implemented both in advance of, and during, the course of studies. Using case studies, typical of industry and academia, the presentation will explore approaches to the assignment of severity and opportunities for introducing refinements during the design and application of procedures.

Implications of revised EU law for ERPs: points of contention and agreement

Jane Smith, Boyd Group

The new *European Directive on the protection of animals used for scientific purposes*[1] came into force on 9 November 2010. EU member states have to transpose its provisions into their national laws by 10 November 2012, and the revised legislation will go live on 1 January 2013.

Many of the requirements of the new Directive are similar to those of current UK legislation. However, there are also a number of important differences – including two that could affect the operation of ERPs:

- the Directive requires establishments to set up local animal welfare bodies (AWBs) not ethical review processes. Whilst most of the tasks assigned to AWBs map onto current ERP functions, they do not explicitly include "ethical" review functions. In particular, there is no requirement for AWBs to carry out ERP Function 2 (harm-benefit analysis of proposed project licence applications).
- the Directive sets minimal requirements for membership of AWBs, which could comprise just two members (the person responsible for animal care and welfare and, at a 'user' establishment', a scientist).

It remains to be seen how the Directive will be transposed into UK law. However, in a recent public consultation on options for transposition, the Home Office suggested that it will support establishments that "opt to model their AWBs on their current ERPs".[2]

There has been vigorous debate about the possible effects of the Directive on the operation of ERPs and how establishments should respond. This presentation will:

- explore points of contention and agreement within the debate, drawing on recent discussions within the Boyd Group (a forum that brings together a wide range of expertise and perspective on the use

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1 Directive 2010/63/EU. For further information about the new regulation and its development see: http://ec.europa.eu/environment/chemicals/lab_animals/home_en.htm

2 Home Office (2011). *Consultation on options for transposition of European Directive 2010/63/EU on the protection of animals used for scientific purposes*, page 36, para. 164.See: http://tinyurl.com/cnhztef

of laboratory animals)[3] and recent RSPCA/LASA *Guiding principles on good practice for ERPs*[4]; and

- highlight some questions that lay members might raise within their ERPs, to prompt discussion of the benefits of current practice and plan for implementation of the Directive.

[3] The points are summarised in the Boyd Group's response to the Home Office consultation, which can be found at **http://boydgroup.wordpress.com/** along with further information about the Group.

[4] Available on the RSPCA and LASA web-sites: **http://www.rspca.org.uk/sciencegroup/researchanimals/ethicalreview** and **http://www.lasa.co.uk/GP%20ERP%20July%202010%20print%20FINAL.pdf**

The RSPCA sees the involvement of lay perspectives as essential to the integrity of a successful ethical review process (ERP) and is committed to supporting and developing the role of lay members.

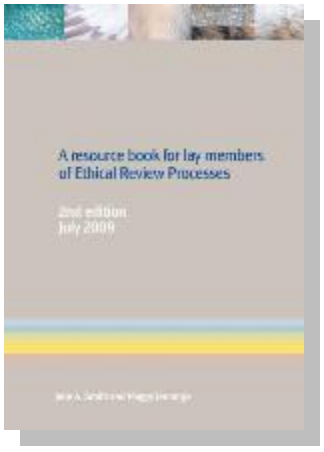
The research animals department organises an annual meeting for lay and other members of local ERPs. The meeting provides a forum for people to come together and share experiences of their work. They combine presentations on some of the many important issues that ERPs cover, with opportunities for group discussion.

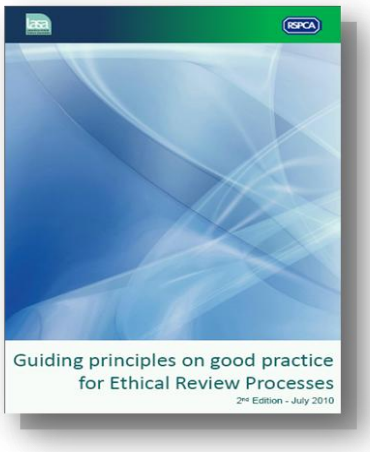
For further information, see
http://www.rspca.org.uk/sciencegroup/researchanimals/ethicalreview/laymembers

… where you can download two useful resources:

- A resource book for lay members of Ethical Review Processes, 2nd edition (2009). This is also available as a hard copy by emailing the address below.
- Guiding principles on good practice for Ethical Review Processes, 2nd edition (2010). This was produced by the RSPCA and Laboratory Animal Science Association (LASA) and sets out guidance on each of the seven functions of the ERP.

Both documents will be updated to take account of the revised EU Directive and its transposition into UK law.

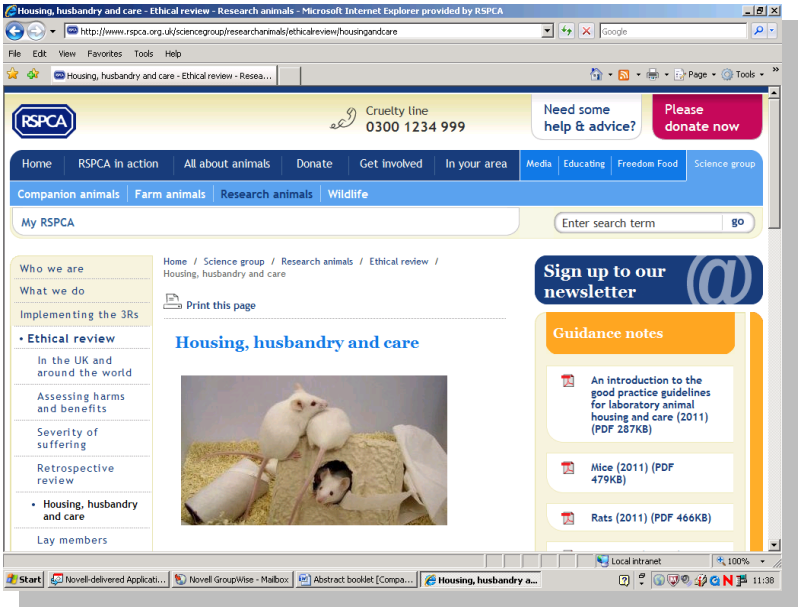




If you would like to register on our mailing list or have any questions regarding the ERP please email us at:
erp-laymembers@rspca.org.uk

http://www.rspca.org.uk/sciencegroup/researchanimals/ethicalreview/housingandcare

On the RSPCA website:



Our guidance notes on good practice for housing and care have all been reviewed and updated this year – all can be downloaded from the RSPCA website (URL on the left of this page). Species currently included are:

Mice	Rabbits	Cattle	Quail
Rats	Ferrets	Sheep	Pigeons
Hamsters	Dogs	Ducks and geese	Zebra finch
Guinea pigs	Pigs	Domestic fowl	*Xenopus laevis*

There are also information sheets on **cage cleaning mice and rats** and **humane killing**, with more to come, including **welfare assessment**, so please check our site regularly.