AWERB
Lay Members' Forum

RSPCA AWERB Lay Members' Forum 2014

Monday 8th December 2014, The Royal Society, London

10.15	**Registration and coffee**
11.00	**Introduction**
11.10	**Assessing the harms and benefits of project licences** ***Peter Thornton, Home Office***
11.40	**Plenary discussion session on assessing harms and benefits - 'How does your AWERB compare with others?'** ***Led by Jane Smith, Boyd Group***
12.15	**Experimental design and translatability – what are the key issues for AWERBs to consider?** ***Gillian Currie, CAMARADES, University of Edinburgh***
12.35	**Working with fish** ***Felicity Huntingford (University of Glasgow)***
12.55	**LUNCH**
14.00	**Giving animals a good life – promoting positive welfare** ***James Yeates, CVO, RSPCA and University of Bristol***
14.20	**Consideration of the fate of animals – the role of the AWERB** ***Penny Hawkins, RSPCA and ASC***
14.40	**Retrospective assessment of actual severity and how this fits with retrospective review** ***Sue Sparrow, GSK*** ***Debs Flack, University of Cambridge***
15.20	**Updates on current topics including progress and guidance documents from Europe** ***David Anderson, European Commission***
15.35	**Final discussion**
15.45	**CLOSE**

Assessing the harms and benefits of project licences

Peter Thornton, Home Office Inspectorate

The conduct of a harm-benefit analysis is at the heart of the regulatory framework that controls the use of animals in science and research under the Animals (Scientific Procedures) Act 1986.

One arm of the licensing mechanism is the programme of work which is delivered via the project licence. The project licence application process is intended to capture the required information for the various elements of the Act in order that the Secretary of State can grant licences for programmes of work that meet the criteria of the Act and thereby ensure the harms are justified by the benefits (a favourable harm-benefit analysis) and the 3Rs have been duly considered and embedded in the application. It is, therefore, essential that sufficient and relevant information, including clear humane endpoints, is submitted in order for the Home Office to conduct this process with due diligence, accuracy and robustness.

This presentation will outline the information required and how it is used to conduct the harm-benefit analysis.

Turning Point discussion of project evaluation/harm-benefit analysis

Led by Jane Smith, Boyd Group

Following on from the Home Office presentation, this interactive session will explore lay members' thoughts on how their AWERBs approach project evaluation/harm-benefit analysis in practice. To start the discussion, an interactive voting system (TurningPoint) will be used to explore how methods of evaluation and lay members' involvement vary between AWERBs, so that members can compare this with their own experiences.

Topics will include:

- understanding harms and benefits;
- whether and how far harms are *actually* weighed against benefits in practice;
- range of perspectives involved in project review; and
- from a lay member's perspective, what, in general, makes for a good approach.

Experimental design and translatability – what are the key issues for AWERBs to consider?

Gillian Currie, CAMARADES, University of Edinburgh

CAMARADES (Collaborative Approach to Meta-Analysis and Review of Animal Data from Experimental Studies) was initially set up to try and understand why data from animal models of stroke failed to translate into success in human clinical trials. We provide resources and support for those involved in the systematic review (where all relevant literature for a given topic is identified) and meta-analysis (where statistical techniques are used to summarise experimental findings) of data from animal studies. Although stroke was the initial focus, CAMARADES has carried out reviews across a range of fields of research including stroke, glioma, pain, Alzheimer's disease and multiple sclerosis. Some of our work has focused on issues that contribute to poor design and reporting of experimental studies and this had led to the development of recommendations to encourage the research community to improve in these areas.

Good experimental design and appropriate statistical analysis increase the validity of scientific results. Previous research from our group and others has shown that measures which might protect a study from bias - such as randomisation and blinding - are often lacking in reports of animal studies and this can lead to an over estimation of effect size.

Work from our group has also highlighted the importance of sample size calculations (power analysis), where the appropriate number of animals is used to gather valid results. Improving experimental design by using the appropriate number of animals fits well with the 3Rs concept of Reduction as this prevents the waste of animals in small underpowered or large overpowered studies.

In this talk I will summarise the key principles of good experimental design and reporting as applied to animal experiments.

See: **www.camarades.info/**

Working with fish

Felicity Huntingford, University of Glasgow

In the last 15 years some 190,000 articles have been published that describe research on fish, many involving laboratory experiments. With this statistic in mind, this session will start by specifying the characteristics that define a fish. Fish have many features in common with other vertebrates, but they are also different in ways that have implications both for their suitability as subjects of scientific experiment and for their welfare in this context.

Many studies motivated by concern for human health use fish as subjects because of the features they have in common with mammals. However, it is important to note that fish are not used merely as replacements for mammals. Besides the fact that special features may limit the value of fish as models in medical research, there are many other important reasons for using fish as experimental subjects. Thus fish are widely used to answer important fundamental questions in a range of biological disciplines from molecular genetics to evolutionary biology and, additionally, much experimental work is aimed directly at a better understanding of fish themselves and their aquatic environment.

The widespread use of fish in experimental studies throws into focus the key question of whether fish are capable of feeling and suffering. This can be approached from the top down, asking whether the fish brain contains the same structures that are involved in emotion and feeling in mammals, and from the bottom up, using the behaviour of fish to probe their mental capacities. This is a difficult and controversial topic, but it is one that must be addressed if legitimate public concern about the welfare of captive fish is to be addressed properly.

Further reading

- Fish intelligence, sentience and ethics by Culum Brown, *Animal Cognition* (June 2014): **http://tinyurl.com/mzual6r** (open access)

Giving animals a good life – promoting positive welfare

James Yeates, RSPCA and University of Bristol

The welfare of animals used in research and testing is usually considered in terms of minimising harms, and public concerns often focus on the harms caused by experimental procedures. But there are other issues that relate to animals' welfare, some of which can be discussed within the concept of 'quality of life'. The terms 'quality of life' (QOL) and 'animal welfare' are often used interchangeably, but considering an animal's QOL can give a different focus.

QOL is a 'broad' concept in terms of content, extending beyond health and suffering. In particular, it can also include 'positive' aspects to an animal's life, such as being able to satisfy motivations and have pleasant experiences.

QOL is also a 'broad' concept with respect to time, because it can include an animal's welfare over an extended period. This idea of QOL suggests that long-term conditions, and chronic welfare compromises, may be particularly important (although acute problems will have an impact too). This makes it important to consider:

- 'cumulative' effects such as sensitisation (e.g. hyperalgesia, where pain is exaggerated, or learning to associate something with pain or distress); and
- 'anti-cumulative' effects such as habituation (e.g. reducing the alarm response because an animal has become accustomed to a stimulus); as well as
- 'coping mechanisms' and other forms of learning and ways in which animals interpret what they perceive.

There can be trade-offs with respect to the overall QOL; for example, veterinary treatment can reduce welfare in the short term (because the animal may be anxious or the treatment may hurt) but have a net effect of increasing QOL because the condition has been treated. This can allow us to consider concepts such as *compensation*, whereby those caring for or using animals can try to ensure that the harms the animals suffer are counterbalanced with positive

experiences. This may involve giving the animal items or resources they personally prefer, to try to outweigh any experimental harms.

Humans are often asked to rate their own QOL, but an animal's QOL can only be inferred by considering how the particular individual is affected by positive and negative aspects of their life. Most animals may have similar responses to some welfare compromises (e.g. injury), but there may be inter-individual variations (e.g. in how much pain-related behaviour is displayed or how much fear the animal experiences). The animal's behaviour can also be assessed, to evaluate what they choose and prefer, how anxious they feel, whether they are interested in playing or how they interpret neutral stimuli.

These considerations of all an individual animal's experiences and choices over time can help to assess their lifetime welfare. In particular, we can consider whether the animal has a 'life worth living'. This concept can inform decision making in many important areas such as breeding practices, husbandry and humane killing.

Consideration of the fate of animals – the role of the AWERB

Penny Hawkins, RSPCA

Most animals used in research and testing are humanely killed at the end of the procedure, usually because their tissues are required as part of the project or in order to prevent further suffering. However, if neither of these conditions apply, the Animals (Scientific Procedures) Act 1986 (ASPA) permits other options including reuse, rehoming and release. Animals have 'intrinsic value', as recognised by The European Directive that regulates animal use, so alternative fates should be given full consideration by the AWERB. The aim should be to minimise the number of healthy animals who are humanely killed.

The AWERB can play a role in preventing 'wastage' by monitoring the fates of animals and ensuring that measures are in place to avoid the generation of surplus animals. For example, it could review whether it is ethically preferable to breed or buy in specific lines, or challenge requirements for a certain age, sex or weight of animal.

The AWERB can also help to determine the fates of 'surplus' animals, for example those who are healthy following a procedure, or have been bred but are not required for a project. In some cases rehoming, or humane killing followed by tissue sharing, may be a feasible and ethically preferable option.

If humane killing is unavoidable, the AWERB can play vital roles in considering the chosen technique within each procedure and in reviewing local practice. There is currently some debate regarding commonly-used techniques and it is important to ensure that staff are aware of the potential animal welfare issues.

Further reading

- LASA Overbreeding Task Force Report: **http://www.lasa.co.uk/PDF/Surplus.pdf**
- LASA Guidance on Rehoming Laboratory Dogs: **http://tinyurl.com/nbr5juj**
- MRC Code of Practice for Rodent Supply: **http://tinyurl.com/lmgambx**

Retrospective assessment of actual severity and how this fits in with retrospective review

Sue Sparrow, GSK & Debs Flack, University of Cambridge

An industry perspective:

GSK is a global organisation performing animal studies to meet drug discovery and regulatory needs in diverse therapeutic areas. Our challenge has been to meet the requirement for Actual Severity Reporting and Retrospective Review, ensuring a thoughtful process which adds value to both science and animal welfare, while not imposing a heavy administrative burden on our staff. We have worked to involve the right people with the appropriate expertise for both activities; time will tell how successful we have been.

An academic perspective:

The University of Cambridge is a large, hierarchical system at the cutting edge of global academic research. Its scientists, within a broad range of disciplines, strive to be innovative and dynamic in order to achieve the highest rated grant funding and to fulfil their purpose. The challenge for our Named People and AWERB processes is to ensure that actual and retrospective review is achieved as part of a culture of care within the diversity of project licences and species – without stifling the ability of the scientists. Communication, people and the right processes to allow the appropriate levels of scrutiny to achieve consistency is challenging and we rely on the observational skills of good animal technicians, named people and the transfer of information to ensure it is happening across all sites.

Updates on current topics including progress and guidance documents from Europe

David Anderson, Technical Advisor to European Commission, Pentlands Management Systems, Edinburgh

This presentation will provide a brief update on progress being made towards a common understanding and implementation of Directive 2010/63/EU, which regulates animal care and use, within the European Union.

The European Commission has convened a number of Expert Working Groups (EWGs) to prepare guidance for those involved in the care, use and regulation of animals used in scientific procedures, on specific topics requested by Member States. Members of the EWGs are nominated by Member States and relevant stakeholder organisations. Their recommendations are subsequently considered and endorsed, subject to any requested modifications, at National Contact Point (NCP) meetings of the Member States.

Of particular interest to AWERBs will be the guidance for Animal Welfare Bodies and National Committees (endorsed at the October 2014 NCP meeting and soon to be available at the EC website), the guidance on Project Evaluation and Retrospective Assessment, and on Severity Assessment. Other available guidance includes Education and Training and Information sources on the Three Rs.

This information can be found at the EC website - **http://ec.europa.eu/animals-in-science**

The RSPCA sees the involvement of lay perspectives as essential to the integrity of successful ethical review 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 AWERBs. 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 AWERBs cover, with opportunities for discussion.

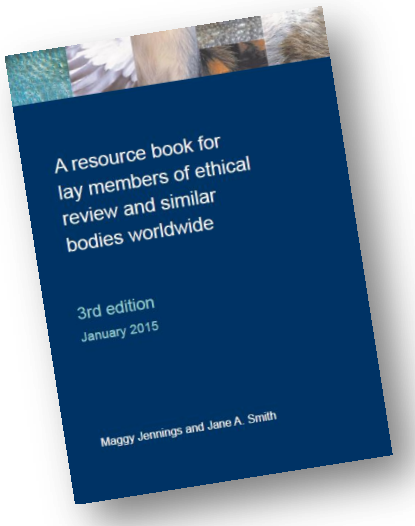
For further information, see: science.rspca.org.uk/laymembers

… 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. **The 3rd edition will be available in the new year** (below left).

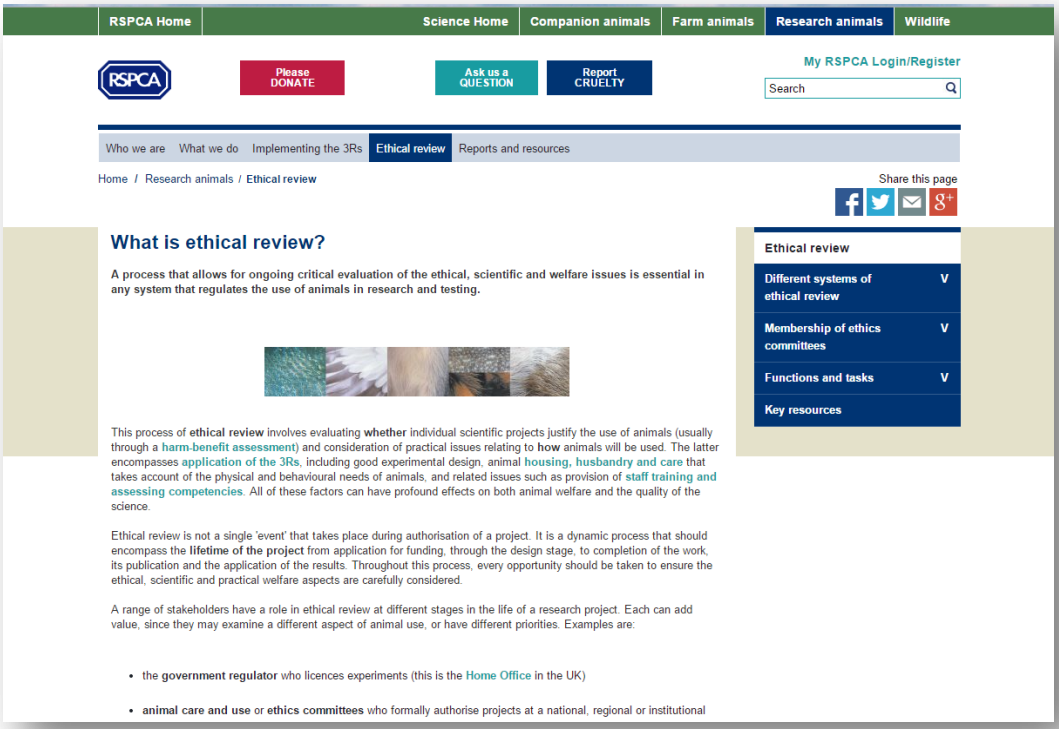
- **Guiding principles on good practice for Ethical Review Processes**, 2nd edition (2010). This was produced by the RSPCA and Laboratory Animal Science Association (LASA) and sets out guidance on each of the seven functions of the ERP.

Both documents are currently being updated to take account of the revised EU Directive and the revised Animals (Scientific Procedures) Act 1986.



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

New, improved RSPCA website:



We have revised the RSPCA website on ethical review to make it more informative and international, including useful links, reports and resources – see **science.rspca.org.uk/ethicalreview**

Tackling severe suffering

We are developing and promoting ways of avoiding or reducing severe suffering, including some reports and resources that are relevant to AWERB tasks which can be downloaded at **http://tinyurl.com/lncgpdo**

The 'Road Map' poster opposite sets out an approach to tackling severe procedures that can be implemented locally, with input from the AWERB; if you would like a PDF of the poster please email **research.animals@rspca.org.uk**

We are also able to visit establishments to give a presentation on targeted approaches to avoiding and reducing severe suffering and discuss the 'Road Map' – to find out more, email **research.animals@rspca.org.uk**

A 'road map' towards ending severe suffering

Elliot Lilley, Penny Hawkins & Maggy Jennings

Abstract

Revision of the EU Directive controlling experiments on animals has focussed attention on the need to reduce animal suffering in scientific procedures. Classification of levels of suffering into mild, moderate and severe and the need to report actual levels of severity has provided added impetus to the drive to refine the most severe models and procedures, as has greater recognition that high levels of suffering impact on an animal's physiological responses, increasing variability of experimental data. So ending severe suffering is a desirable goal for scientific, ethical and legal reasons.

This is therefore an excellent time to look at the sources and nature of suffering within the research context (to perform a 'severity audit'), to evaluate the effectiveness of current refinement practices and to seek more effective ways of avoiding or minimising all unnecessary pain and psychological distress experienced by animals. Central to the success of such an initiative is a receptive institutional culture and a robust and challenging ethical review process.

This poster will outline the key questions and practical considerations that establishments need to address in order to reduce suffering for all animals and to work towards ending severe suffering.

Analysis

Perform an in-house 'severity audit' of all protocols, procedures and 'models'. Establish where there is the *potential* for severe suffering *(prospective assessment)* and then what *actual severity* is experienced by individual animals *(retrospective assessment)*.

Evaluation

For procedures where severe suffering occurs, ask:

1. *Why* the procedure is used and *what* factors contribute to it being severe?
2. Is severe suffering really *necessary* to achieve the scientific objective?
3. What *proportion* of animals in each protocol, procedure or 'model' experienced severe suffering?
4. What refinements are already in place, how *effective* these are and whether there is *potential* for further application of the 3Rs?

Define Obstacles

What are the scientific obstacles to ending severe suffering?
Set these out clearly and assess the genuine impact of stopping severe protocols, procedures or 'models'.

The Road Map Process

Every establishment should ensure there is a process to achieve the following for severe 'models' or procedures:

1. Culture
   Establish and maintain a progressive, open minded and caring research culture
2. Analysis
   Establish to what extent severe suffering occurs
3. Evaluation
   Look at why severe suffering occurs and what current approaches are used to avoid it
4. Define obstacles
   Establish what the impact of ending severe suffering would be
5. Overcome obstacles
   Set out a plan to overcome issues and to end severe suffering

"what would happen if severe suffering was banned tomorrow?"

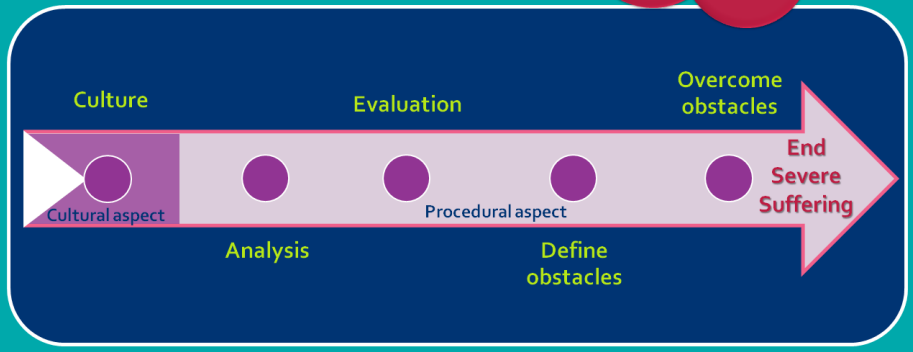
An institutional 'culture of care' an essential prerequisite of effective implementation of the 'Road Map'. Components of such a culture include:

1. A *collective responsibility* and accountability for the welfare of animals, shared by all staff.
2. Demonstrable *commitment to high standards of housing, care and welfare above the legal minimum* from senior management.
3. Internal openness including the ability to *raise, share and resolve concerns*.
4. Support for '*Named Persons*' (such as Animal Care and Welfare Officers, Veterinary Surgeons, Information and Training and Competency Officers).
5. A robust framework for *training, assessment of competence and continued professional development* of all staff.
6. Effective and *well-supported institutional ethical review* of scientific work.
7. An *effective ethics or animal care and use committee*, e.g. the Animal Welfare and Ethical Review Body (AWERB) in the UK.

Overcome Obstacles

Take an alternative approach e.g.:
Use a non-severe model
Re-frame the research question to avoid a severe model
Use a mechanism-based approach rather than a disease-model approach

Apply Refinement e.g.:
Refine every element of the lifetime experience of the animal
Establish, validate and implement humane endpoints



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