RSPCA Lay Members' Forum 2015

The Royal Society, London

8th December, 2015

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Tuesday 8th December, 2015

The Royal Society, 6-9 Carlton House Terrace, London, SW1Y 5AG

Chair: Penny Hawkins

10:15	Arrival and registration, with tea, coffee and biscuits
11:00 - 11:10	Welcome and introduction - *Penny Hawkins, RSPCA*
11:10 - 11:35	What do you think of it so far? A Home Office view on the performance of the AWERB during its first two years - *Peter Thornton, Home Office - Animals in Science Regulation Unit*
11:35 - 11:50	Q&A
11:50 - 12:10	Training, supervision and competence – what should the AWERB expect? - *Manuel Berdoy, University of Oxford*
12:10 - 12:30	Working with wild animals – a case study - *Julie Lane, APHA – National Wildlife Management Centre*
12:30 - 12:40	Update on the Animals in Science Committee and AWERBs - *John Landers, ASC*
12:40 – 13:50	Lunch
13:50 - 14:10	Organ-on-a-chip technology – the potential for replacement - *Anthony Holmes, NC3Rs*
14:10 - 14:30	Key issues when reviewing projects aiming to develop disease therapies - *Nic Wells, Royal Veterinary College*
14:30 - 15:30	Interactive session on aspects of project review - *Jane Smith, The Boyd Group*
15:30-15:45	Concluding remarks
15:45	Close

WHAT DO YOU THINK OF IT SO FAR? A HOME OFFICE VIEW ON THE PERFORMANCE OF THE AWERB DURING ITS FIRST TWO YEARS

Peter Thornton, Home Office - Animals in Science Regulation Unit

The Animal Welfare and Ethical Review Body, or AWERB, was incorporated into the amended Animals (Scientific Procedures) Act 1986 from January 1st 2013. It replaced the Ethical Review Process, and in doing so implemented a number of changes in structure and function, and roles and responsibilities, underpinned by a more robust legal foundation.

The AWERB has a number of functions and these will be reviewed in the context of what is being seen to be done well and what appears to not be done so well. Opportunities for improving will be presented together with examples of good practice.

The role of lay members in supporting improvements to AWERB function will be explored.

TRAINING, SUPERVISION AND COMPETENCE – WHAT SHOULD THE AWERB EXPECT?

Manuel Berdoy, University of Oxford

Behavioural change, it turns out, is the hardest thing. Yet it is the root of real progress and, arguably, must be steeped in appropriate Education and Training. I will address some relevant developments in that area, including:

- the European Commission's *Education and Training Framework Consensus* document[1], and its relevance to the UK;

- the RSPCA/LASA *Guiding Principles on Good Practice for AWERBs*[2] and the LASA *Guiding Principles for Supervision and Assessment of Competence*[3]; and

- the challenges, and some initiatives, in a large institution like University of Oxford.

References:

1. **ec.europa.eu/environment/chemicals/lab_animals/pdf/Endorsed_E-T.pdf**
2. **tinyurl.com/RSPCA-LASA-AWERB**
3. **lasa.co.uk/PDF/LASA_GP_Supervision_&_Competence_2013_final.pdf**

WORKING WITH WILD ANIMALS – A CASE STUDY

Julie Lane, National Wildlife Management Centre, Animal and Plant Health Agency

Wildlife studies under A(SP)A

Wildlife research covers a wide range of subject areas including behaviour and ecology, species conservation, population management and disease control. This research is usually conducted with free-living animals in their natural habitat and, more occasionally, with wild-caught animals in various captive settings. Wildlife studies vary in their invasiveness, with many studies falling under the regulation of A(SP)A, but the exact numbers of wild animals used in regulated procedures are difficult to ascertain, as are not collated specifically.

Although the original definition of the 3Rs (Replacement, Reduction and Refinement) was developed with laboratory studies in mind, the principles and philosophy of this concept can be extended to many other areas in which there are human-animal interactions as a means of promoting high standards of welfare (Cuthill 2007). Unfortunately most of the information readily available with respect to the 3Rs tends to be aimed at their implementation in laboratory studies with many examples not easily applicable to wildlife research (e.g. replacing *in vivo* studies with cell culture). This, however, should not lead to the conclusion that 3Rs implementation within wildlife research is not necessary or relevant.

Case Study: Fertility control

Fertility control has the potential to be an attractive alternative to lethal methods for reducing population size in overabundant populations of birds and mammals. Both avian and mammalian fertility control agents have been shown to induce infertility in a wide spectrum of species. However, the duration of infertility and the potential side effects of these agents on animal behaviour, physiology and welfare needed to be assessed. Our study aimed to develop systems to deliver fertility control agents to target populations and investigate the long-term effectiveness, and possible side effects, of fertility control agents in model species (e.g. Rose-ringed parakeets, grey squirrels, wild boar and badgers). This involved both captive and free-living studies, which each bring their own challenges with respect to ensuring the welfare of the animals in the study. These type of projects often require novel approaches and 'thinking out of the box' to ensure that high welfare standards are maintained whilst not affecting the integrity of the study.

The implementation of 3Rs in this programme of work have included a number of refinements similar to those used in laboratory-based research (e.g. providing appropriate anaesthesia), albeit with slight differences of approach.

Wild animals undoubtedly suffer a range of markedly inhumane fates in the wild, and some populations are in grave need of intervention for conservation and management reasons. However, the ethical/moral absolute of the welfare of the individual animal means that research using wild animals requires an approach to ethical issues, and an implementation of the 3Rs, that is as rigorous as for laboratory animals.

Further reading:

- Cuthill IC (2007) Ethical regulation and animal science: why animal behaviour is not so special. *Animal Behaviour* **74:** 15-22
- *Lane J & MacDonald R* (2010) Chapter 7: Welfare and Best Practice in Field Studies of Wildlife. In: *UFAW Handbook on the Care and Management of Laboratory and Other Research Animals (Eighth Edition)* Publishers – Wiley, pp. 92-106

UPDATE ON THE ANIMALS IN SCIENCE COMMITTEE AND AWERBS

John Landers, Animals in Science Committee

The legislation setting up the ASC tasks it with 'advising' AWERBs on matters relating to the remit of A(SP)A and taking steps to 'ensure the spread of best practice'. In order to put this in practice the Committee is establishing a national communications network for AWERBs. This will be organised regionally with a designated 'Hub' AWERB in each region. The presentation will explain how this network is planned to function and provide an update on the Committee's wider work programme in relation to the Animal Welfare and Ethical Review Body.

www.gov.uk/government/organisations/animals-in-science-committee

ORGAN-ON-A-CHIP TECHNOLOGY – THE POTENTIAL FOR REPLACEMENT

Anthony Holmes, NC3Rs

The development and launch of new products in areas such as human and veterinary medicine, agrochemicals, personal care products, and food additives requires evaluation of the safety and efficacy of the substances used in them. Currently, with the exception of personal care products, this is mostly determined by testing in animal 'models' prior to potential exposure or use in humans. However, these models are not always accurate predictors of the effects of a new substance in humans, animal species or the environment. The failure to translate findings from animal models has led to questions about the utility of *in vivo* studies and to demands for more predictive models and tools based on the latest technologies.

Organs-on-chips are one such technology, offering exciting opportunities for reducing animal use and improving the predictivity of efficacy and safety testing of chemicals across a range of industries. This presentation will describe the different drivers for the development and application of these technologies, some of the current and future capabilities, what hurdles remain and opportunities for accelerating their development and application.

nc3rs.org.uk

KEY ISSUES WHEN REVIEWING PROJECTS AIMING TO DEVELOP DISEASE THERAPIES

Nic Wells, Royal Veterinary College

One of the reasons for conducting animal research is to develop treatments for human disease. These may be relatively common diseases such as metabolic syndrome, diabetes, cardiovascular disease, asthma and cancer. Alternatively these may be one of the over 7,000 'rare' diseases (those diseases that affect less than 1 in 2000 people). Two problems with some of the animal research in this area are lack of reproducibility and a relative poor success rate in translating this work to the clinic. The reasons for these problems will be discussed. Some problems can be overcome by common methods for reducing bias, such as randomisation and assessment blind to the treatment group, but surveys suggest that such assessments are not often routinely reported (Macleod et al. 2015). In addition, experimental design may be suboptimal leading to problems with statistical interpretation. Guidance on experimental design is now available from the NC3Rs with the new Experimental Design Assistant. A third problem is that many investigators do not critically analyse the animal model(s) they are proposing to use and experiments are performed with doses and routes of administration that are not translatable to man (Wells 2015).

In reviewing project licence proposals, it is useful to use the ARRIVE guidelines (for publishing the results of animal experiments) as a guide to elements that should be in the ideal project licence. These include but are not limited to:

1. Animal numbers required for a robust statistical result (power calculations). With novel work this may not always be possible, in which case investigators should plan to perform a limited pilot experiment to gain an idea of the likely variation before doing the larger study.

2. An explanation of the animal model and methods of assessing experimental outcomes can demonstrate careful thought about the appropriateness of the animal model.

3. Statements about experimental design including control groups, randomisation and analysis of the effects of treatment that is blind to sample identity.

References:

- **ARRIVE guidelines: nc3rs.org.uk/arrive-guidelines**
- **Macleod MR et al. (2015) Risk of bias in reports of in vivo research: A focus for improvement. *PLoS Biol* 13(10): e1002273 doi: 10.1371/journal.pbio.1002273**
- **NC3Rs Experimental Design Assistant: nc3rs.org.uk/experimental-design-assistant-eda**
- **Wells D (2015) Improving translational studies: lessons from rare neuromuscular diseases *Dis. Model Mech.* 8(10): 1175-7 (PubMed ID: 26438690)**

INTERACTIVE SESSION ON ASPECTS OF PROJECT REVIEW

Jane Smith (Boyd Group), Penny Hawkins (RSPCA), Peter Thornton (Home Office) & Nic Wells (RVC)

Based on responses to last year's questions about potential difficulties in project review, this year's discussion will focus on:

1. Evaluation of harms and benefits, using a series of potentially contentious examples, plus lay members' own thoughts on where they have experienced difficulties in evaluating harms and benefits; and

2. Advantages and difficulties in visiting animal facilities, and how to overcome the latter.

There will be plenty of opportunity for discussion with neighbours, alongside plenary comments from the panel.

To prepare for these discussions, please would you identify any specific examples of difficulties you have encountered in the above areas, and whether/how you think the difficulties can be overcome.

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Focus on severe suffering

Last month we launched a new web resource which brings together practical guidance, information and resources to help scientists, animal technologists and members of AWERBs to reduce and avoid severe suffering. The website has been produced in conjunction with the Laboratory Animal Science Association (LASA), Laboratory Animal Veterinary Association (LAVA) and the Institute of Animal Technology (IAT).

- Please have a look at the 'AWERB members' pages (you can access the others too) and let us know what you think at **research.animals@rspca.org.uk**
- If there are projects involving severe procedures at your establishment, please ask if you can use the web resource and downloadable 'Road Map' to focus on refining or avoiding them – feedback on this would be much appreciated.

The RSPCA sees the involvement of lay perspectives as essential to the integrity of a successful AWERB and is committed to supporting and developing the role of lay members.

For further information, see: rspca.org.uk/ethicalreview

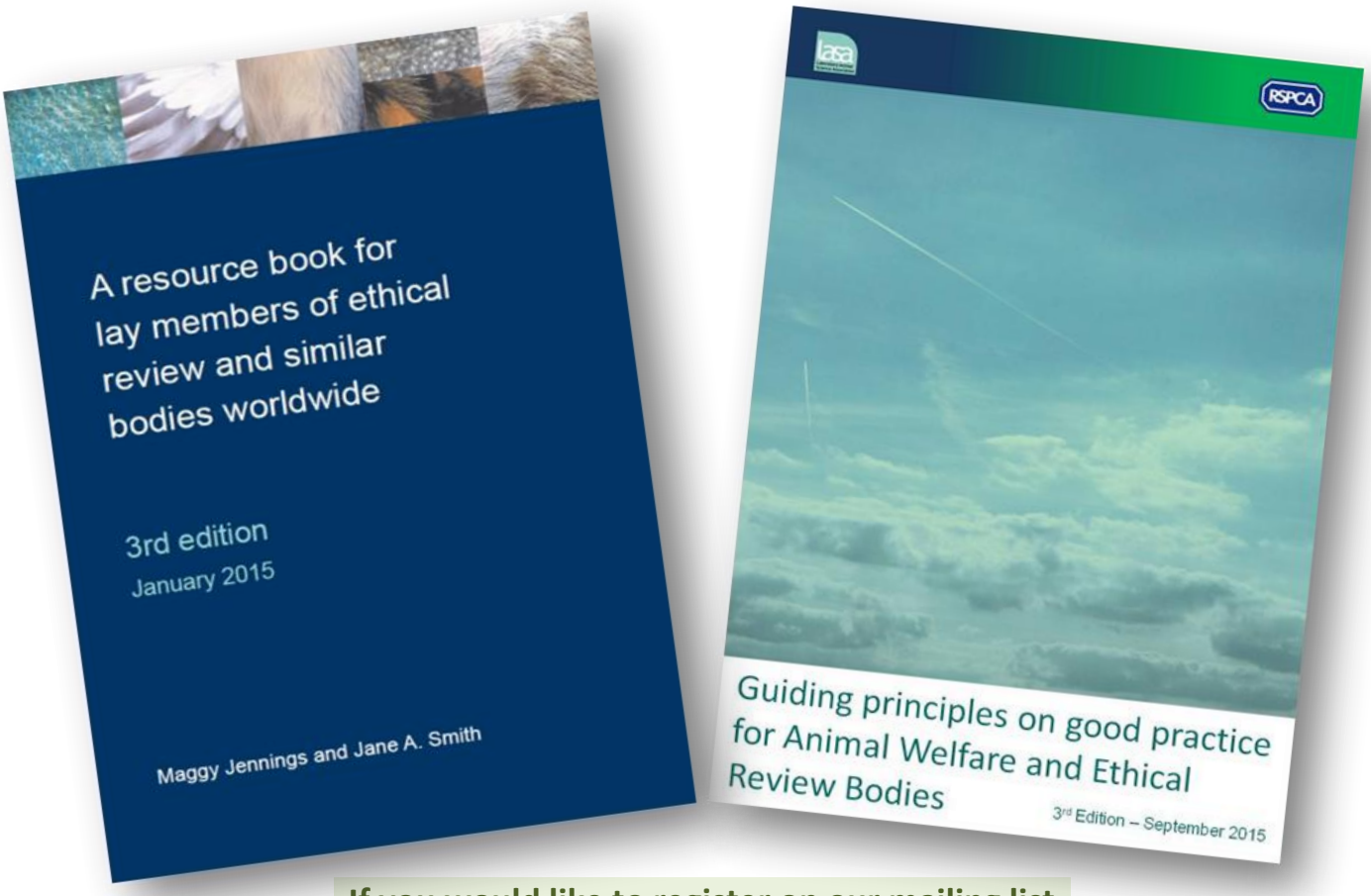
Two useful resources to download for free are:

- **A resource book for lay members of ethical review and similar bodies worldwide, 3rd edition (2015). tinyurl.com/RSPCALMH**

  This is also available as a hard copy by emailing the address below.

- **Guiding principles on good practice for Animal Welfare and Ethical Review Bodies, 3rd edition (2015). tinyurl.com/RSPCA-LASA-AWERB**

  This was produced by the RSPCA and LASA and sets out guidance on each of the seven functions of the AWERB.



If you would like to register on our mailing list or have any questions regarding the AWERB please email us at:

research.animals@rspca.org.uk

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