

ASPA e-Newsletter: October 2011

Launch of the Animals in Science Regulation Unit

We are pleased to announce the formation of the Animals in Science Regulation Unit (ASRU) bringing together the Animals Scientific Procedures Division (ASPD) and Animals Scientific Procedures Inspectorate (ASPI) into a single, integrated organisation. The new unit has been created as part of our drive to develop and improve the service we provide to stakeholders and Ministers. ASRU will be led by Judy MacArthur Clark, supported by Sue Houlton as Chief Inspector and Martin Walsh as Head of Policy and Administration.

Public consultation on the transposition of Directive 2010/63/EU

The public consultation on the UK implementation of Directive 2010/63/EU closed on 5 September. During the 12 week consultation period, we received over 13,000 responses of which about 150 substantively responded to the majority of the questions. We are very grateful for all the careful consideration which has gone into these responses. A detailed analysis of these responses is underway and we plan to publish a summary in due course. Meanwhile we are continuing our regular meetings with stakeholder groups as we develop a draft of the new legislation together with guidance and a code of practice.

Bateson Report

The report of a retrospective review of the use of non-human primates in research was published on 27 July. The review was commissioned by the Wellcome Trust, the Medical Research Council and the Biotechnology and Biological Sciences Research Council and was headed by Professor Sir Patrick Bateson. The review report is available at

<http://www.mrc.ac.uk/Utilities/Documentrecord/index.htm?d=MRC008083>.

Two of the recommendations are directed at the Home Office as the regulator of animal testing.

Recommendation 10: The Home Office should review its performance with the regard to the operation of the Animal (Scientific Procedures) Act to ensure that inefficiencies of processes or inconsistent advice to researchers do not create unreasonable delays or obstacles to appropriate NHP research. Accreditation of the enforcement processes to the appropriate ISO standard should be considered.

Recommendation 14: The Home Office should reconsider their advice to research workers to destroy records after five years.

As to Recommendation 10, we welcome any practical suggestions to improve our processes and the advice we provide. We already review our performance and have made a number of improvements to processes. For example, the new project licence application form which has been well received by applicants as quicker and easier to complete, with the required information more clearly explained.

Recommendation 14 appears to be based on a misunderstanding as the Home Office does not give any such advice. For the avoidance of doubt, we require researchers and establishments to keep records for at least five years; when those records are destroyed after that is a matter for decision locally.

Ensuring Standards of Aseptic Surgery in Designated Establishments: a Current Topic for Inspection

Attached as an annex to the newsletter is an explanation of the current themed inspections on aseptic surgery.

OECD Guidelines

Five new Test Guidelines were adopted by the OECD Council on 28 July 2011 and can be found at:

[234 Fish Sexual Development Test](#)

[235 Chironomus sp., Acute Immobilisation Test](#)

[443 Extended One-Generation Reproductive Toxicity Study](#)

[456 H295R Steroidogenesis Assay](#)

[488 Transgenic Rodent Somatic and Germ Cell Gene Mutation Assays](#)

It is recommended that licence holders become familiar with the Fish Sexual Development Test, the Extended One-Generation Reproductive Toxicity Study and the Transgenic Rodent Somatic and Germ Cell Gene Mutation Assays which require the use of protected species.

The Extended One-generation Reproductive Toxicity Study has the potential to decrease animal numbers used in report safety and the Transgenic Rodent Somatic and Germ Cell Gene Mutation Assays offers a more refined method of determining the effects of potential mutagens.

As regulatory requirements evolve, all project licence holders are expected to move into compliance with the latest relevant guidelines. There is no requirement to submit licences for detailed amendments, but studies should be conducted to the most refined relevant protocols.

NC3Rs

The latest newsletter can be read in full at:

<http://www.nc3rs.org.uk/news.asp?id=1643>

Understanding Animal Research

The latest newsletter can be read in full at:

<http://www.understandinganimalresearch.org.uk/homepage>

RSPCA ERP Lay Members' Forum

This year's ERP Lay Members' Forum will be held on Tuesday 22 November 2011 in central London. The meeting will start at 10.30am and finish around 3.45pm.

The theme for the meeting will be 'Making difficult decisions'. Topics to be covered include: assessing harms and benefits of new technologies; issues relating to humane endpoints and cumulative suffering; harms and benefits in behavioural

pharmacology; and, the challenge of ethical review in a global context - an issue which is increasingly important in both industry and academia.

Although the Forum is primarily for lay members, other ERP members are also welcome to attend. There will be the usual mix of presentations and interactive discussion sessions, with plenty of opportunity for networking.

The cost of registration (including a buffet lunch) is £55 per delegate. For further information, or to register, please contact us at: erp-laymembers@rspca.org.uk

The closing date for registration is Tuesday 8th November.

EUPRIM-Net Course on General Primate Biology

The upcoming EUPRIM-Net Course on General Primate Biology for scientists, veterinarians and students will be held on November 14-17 2011 at the German Primate Center (www.dpz.eu), to provide lectures and interactive seminar sessions on a variety of different topics related to primate biology. These will include:-

- Primate taxonomy/diversity
- Feeding strategies & competition
- Functional anatomy and locomotion
- Non-invasive endocrine assessments
- Primate behaviour & communication

The last date for registration is 28 October 2011 and further details can be found at: <http://www.euprim-net.eu/network/courses.htm> ,

Annex

Ensuring Standards of Aseptic Surgery in Designated Establishments: a Current Topic for Inspection

Background

Guidance from the Home Office that surgery from which animals are to recover should be carried out under appropriate clean or aseptic conditions, has been built on by Guidelines published by Laboratory Animal Science Association (LASA) on the general principles for aseptic surgery.

In order to encourage and assist those persons holding authorities at designated establishments in discharging their responsibilities, Inspectors will be conducting themed inspections to ensure surgical work is carried out to meet these standards

As a reminder to all those involved, there are key responsibilities for different duty holders under the Animals (Scientific Procedures) Act 1986 (ASPA).

Responsibilities

Holders of Certificates of Designation

Certificate holders must ensure that the use of rooms or other areas at their Establishment is as specified on the Schedule to the Certificate and details of the approved areas should be made available to those with responsibilities under the Act.

Certificate holders must ensure that the fabric and environment of the approved areas meet or surpass the minimum provisions of the appropriate Home Office Code of Practice, unless specific exemption is granted by the Secretary of State.

With respect to the provision of facilities for aseptic surgical procedures, certificate holders are responsible for ensuring that facilities, training of staff and retention of relevant records meet the expectations of the Secretary of State.

Named Veterinary Surgeons

Key roles are played by Named Persons, especially the Named Veterinary Surgeons. They should lead in advising on good surgical, anaesthetic and analgesia practices. It is recognised as good practice for Named Veterinary Surgeons as well as the project licence holders themselves, to observe the range of surgical procedures undertaken by licensees.

Named Animal Care & Welfare Officers

The Named Animal Care & Welfare Officer has a unique position of oversight in day to day activities at establishments. They are responsible for the overall day to day care of the animals. Where surgical procedures are undertaken with licence authorities, the appropriately designated rooms (for Sterile Experimental Procedures - SEP) are often shared between several users/ Licensees. The rota for use, cleaning and reserving the SEP room is frequently managed by the Named Animal Care & Welfare Officers or a Deputy.

Project Licence Holders

Project licence holders are responsible for procedures undertaken on their Licences and for ensuring that the appropriate level of supervision is given to all those working under the Project Licence. They should have sufficient contact with personal licence holders to remain confident that appropriate standards of aseptic surgery are being practised.

Periodic direct inspection (during the conduct of surgery) is recommended to help identify good and poor practices during surgery. Where personal licence holders meet to review study plans, etc, it will be useful for the project licence holder to review surgical risks and to emphasise the necessary control measures.

Personal Licence Holders

Personal licence holders should ensure they have completed the relevant training and have licence authority to undertake the proposed surgical procedures. Sufficient time for preparation and checking of resources should be allowed prior to commencing surgery.

Preparation includes the facilities and equipment; the animal; and, most importantly, the surgeon themselves. Sterile sets of instruments; adequately clipped, draped and disinfected, anaesthetised animals; and a gowned and gloved surgeon are usually the minimum requirements to perform aseptic surgery.

Inspection Activities during this Period

Home Office Inspectors will be encouraging the named Veterinary Surgeons to lead in-house review of the surgical expertise and practices at each establishment and will be paying special attention to the conduct of surgical work during visits of inspection.

These initial activities will be intended to encourage the use of appropriate levels of aseptic surgery at all establishments where surgical procedures under ASPA are carried out.

Resources & References

<http://tna.europarchive.org/20100413151426/http://www.archive.official-documents.co.uk/document/hoc/321/321.htm>

http://tna.europarchive.org/20100413151426/http://scienceandresearch.homeoffice.gov.uk/animal-research/publications-and-reference/publications/code-of-practice/code_of_practice_part1/index043d.html?view=Standard&pubID=428573

http://www.lasa.co.uk/LASA_Guiding_Principles_Aseptic_Surgery_2010.2.pdf