

THE UNIVERSITY OF LEEDS

THE COUNCIL

## Annual report of the Animal Welfare and Ethical Review Committee, 2015-16

*This is the second annual report from the Animal Welfare and Ethical Review Committee, which was reconstituted as a committee of the Council from the 2014-15 academic year. The report reminds the Council of the University's policy on animal use, summarises the regulatory framework, and includes data on the number and species of animals used during the year.*

*There are no issues of concern to draw to the Council's attention: the Committee is positive about standards of animal care and welfare, there were no infringements of the relevant Act during the year, and the Home Office has classified Leeds as a low-risk establishment.*

### Background

1. The University carries out medical and biological research using animals in accordance with the Animal (Scientific Procedures) Act 1986 (as amended in 2012). The following policy statement, which appears on the University's website, summarises the University's overall position on such research:

The University of Leeds carries out research on animals to improve the health and welfare of human beings and animals, and to provide a better understanding of the animals themselves. It uses animals only when there are no alternatives, and is firmly committed to the principles of replacement, reduction and refinement of animals in research<sup>1</sup>.

Research using animals is driving fundamental advances in understanding, treating and curing a range of health problems including cancer, heart disease, diabetes and mental illness, and continues to enable fundamental advances in our understanding of diseases.

The University will use alternatives to animals wherever possible, such as computer modelling, tissue culture, cell and molecular biology, and research with human subjects. But these cannot yet properly reproduce the complex biological characteristics of human beings and animals and nor can they replicate the study of wild animals in their natural environment.

All research involving animals is carried out to high standards of humane care and treatment within a strict framework of legal controls. Projects must also be approved by an ethical review committee, and researchers are trained in the ethical dimensions of their work and in standards of animal care, welfare and accommodation.

2. The regulatory framework was summarised in the Committee's first annual report (CL/14/86), available on the intranet or from the Secretariat on request. In a nutshell (and at the risk of over-simplification), any scientific work with animals is unlawful unless it is covered by three licences from the Home Office: an **establishment licence** (which designates the premises on which scientific procedures may be carried out<sup>2</sup>); a **project**

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<sup>1</sup> The principles of replacement, reduction, and refinement – the 3 Rs – were developed over fifty years ago; they are now embedded in national and international legislative requirements.

<sup>2</sup> Provision also exists for work to be carried out in some circumstances at a Place Other than the Designated Establishment (PODE). Such PODE work normally covers observational studies in the wild or in a farm setting.

**licence** (which sets out the purpose of the particular line of research, the techniques to be employed and the predicted severity limits of those techniques), and one or more **personal licences** (granted to individual scientists working on the project after they have satisfactorily completed appropriate training).

3. The main focus of animal use in Leeds continues to be translational research targeting cancer, heart disease, diabetes, mental illness, pain management and spinal cord injury models.

### Data on animal usage

4. There are currently 42 project licences held by University staff, and 211 personal licences.
5. The numbers of animals used in regulated ASPA procedures in each of the calendar years 2013 to 2015 were as follows:

	<b>2013</b>	<b>2014</b>	<b>2015</b>
Rats	830	778	743
Mice	19715	25469	24354
Pigs	15	24	19
Birds & poultry	134	183	147
<i>Total</i>	<i>20694</i>	<i>26454</i>	<i>24993</i>

### Meetings in 2015-16

6. The Committee held six meetings in 2015-16 (on 15 September, 20 November, 25 January, 13 April, 27 May and 27 July). We welcomed the Home Office Inspector to one of our meetings and received positive feedback on our approach and engagement.

### Project licences

7. Since the last report, the Committee has considered eleven applications for new project licences. In each case a number of amendments to the proposed project were suggested. Five of these applications have been approved by the Home Office, four are currently being reviewed by the Home Office, and two are in the process of being amended by the applicants prior to submission. We regularly have the project licensees in attendance at the Committee.
8. In addition, eleven mid-term reviews of existing project licences were carried out in order to review progress and identify any animal welfare issues that may have arisen during the work. No material concerns emerged.
9. The attendance of project licence holders at the committee has been a positive development and there has been learnings for the project holders and the Committee through this engagement.

### Animal welfare

10. There were no infringements of the Animal (Scientific Procedures) Act in 2015-16.
11. Regular inspections of animal facilities by the Named Veterinary Surgeon (NVS), and by

the Named Animal Care & Welfare Officers, as well as a visit by the lay chair of the Committee, identified no animal welfare concerns and confirmed the high standard of animal care maintained by unit staff. The Home Office itself classified Leeds as a low-risk establishment in 2015-16.

12. To improve animal care and welfare, a request to increase the number of Named Animal Care and Welfare Officers (NACWOs) from three to four was submitted to the Home Office in May 2016. The change, intended to facilitate the alignment of operations on both sites and to improve animal welfare provision, was approved by the Home Office in June. The increase in NACWO support, along with the additional training and professional development successfully completed by the staff concerned, was welcomed by the Committee.

### 3Rs

13. Researchers at Leeds continued to pursue 3Rs initiatives. For example, funding secured from the NC3Rs<sup>3</sup> for the development of an in-vitro system to 'determine the causes of aberrant, leukaemogenic V(D)J recombination reactions' successfully generated a number of cell lines from transgenic mice in which production of antibody genes can be induced. Another 3Rs research project carried out at Leeds is targeted at the development of methods for reducing the number of donor and recipient female mice for embryo transfer and to replace the need for vasectomised male mice in transgenic production of animals.

### Condition 18 reports

14. During the year, twelve 'condition 18' reports, from five project licences, were submitted to the Home Office to report an increase in the severity experienced by an animal greater than authorised by the relevant project licence<sup>4</sup>. In every case the Home Office accepted the explanation offered, and no further action was taken.

### Openness and transparency

15. In November 2015 we invited a senior member of the RSPCA's Research Animals Division to tour one of the animal facilities and received some extremely positive feedback following the visit.
16. Arrangements are currently being made to publish on the University's website the minutes of the Committee, statistics on animal use at Leeds, and accessible lay summaries of new project licences granted to staff at Leeds.
17. During the year, the \_\_\_\_\_ (who holds the Establishment Licence) published a blog about the governance of animal research for the Association of Heads of University Administration

### Unit Management

18. Following a procurement process during which a number of potentially suitable systems developed for the animal research community were considered, the University has placed an order for an integrated unit management software package to meet the current

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<sup>3</sup> National Centre for the 3Rs

<sup>4</sup> Project Licence Condition 18 requires that "The licence holder shall ensure adherence to the severity limits as specified in the project licence and observance of any other controls described in the licence. If these constraints appear to have been, or are likely to be, breached, the holder shall ensure that the Secretary of State is notified as soon as possible."

and ongoing requirements of the animal facilities and research staff. The system chosen will enable the University to maintain and manage data in a number of main areas:

- ~ animal breeding, care and veterinary treatment records;
- ~ receipts from external suppliers and internal supply, along with chargeable services, allocated to specific research grants for charging/invoicing;
- ~ research records;
- ~ training, supervision, competence and CPD records; and
- ~ cryopreservation records (cryopreservation of mouse embryos and/or sperm is used to minimise the number of genetically altered animals that have to be kept to maintain colonies that are not in continuous use but may be needed in future).

19. This purchase is welcome as it relies on a single point of data entry which will assist the University in maintaining compliance with Home Office licensing and other requirements for record keeping and data retrieval. With the routine input of data the system will ensure that personal and project licences and relevant protocols are in place before any animals can be issued to anyone registered; the system will automatically generate correctly formatted annual returns of procedures carried out at the University under authorised project licence protocols; it will enable the NVS to monitor and review animal care and treatment regimens; and it will enable key personnel to have access to contemporaneous training, supervision and competence records, improving management oversight. All of this information was previously held on paper, in spreadsheets or in separate unrelated databases so the single-entry system will be a significant improvement in providing up-to-date, complete and detailed management information across both sites.

## **Training**

20. In-house training courses for animal researchers continue to run at full capacity. Three courses have been run, in October, January and March, and course provision was independently reviewed by the Universities Accreditation Group<sup>5</sup> in July 2016.

21. This training – the core of which includes training in the legislation and in ethics – is mandatory for anyone wishing to apply for a Personal or Project Licence under the Act or to undertake the humane killing of any animal protected by the Act. For the majority of courses the species covered were rats and mice but some other species were included, upon request of the trainees; these were pigs, birds and poultry, rabbits and guinea-pigs. During the year from 1 August 2015 to 31 July 2016 a total of 41 staff and students were trained.

September 2016

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<sup>5</sup> The Universities' Accreditation Group is one of three UK accreditation bodies (the others being the Royal Society of Biology Accreditation Board and Scottish Accreditation Board), responsible for the accreditation of mandatory licensee training. These organisations are recognised by the Home Office Animals in Science Regulation Unit as authorised accreditors for this training. Individuals are unable to apply for personal or project licences under the Animals (Scientific Procedures) Act without first having successfully completed the prerequisite training modules and being issued with a certificate by or with the permission of (processes vary) one of these accrediting bodies. The entry of full details from the certificate, including modules successfully completed and species for which the individual has been trained, forms part of a very rigid electronic application process. Details are verified by the University's Named Training and Competence Officer prior to submission of each application.