

The University of Leeds, The Council, Annual report of the Animal Welfare and Ethical Review Committee, 2018-19

Introduction

This is the fifth 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, and the Home Office Inspector has indicated that Leeds continues to be regarded as a low-risk establishment.

Background

1. The University carries out medical and biological research using animals in accordance with the Animals (Scientific Procedures) Act 1986 (as amended in 2012), normally known as ASPA. The following policy statement summarises the University's overall position on such research:
 - The University of Leeds carries out research using animals to improve the health and welfare of human beings and animals, to provide a better understanding of the animals themselves, and for educational purposes.
 - We use animals only when there are no alternatives, and are firmly committed to the replacement, reduction and refinement of the use of animals in research (the 'three Rs').
 - Research involving animals is driving fundamental advances in understanding, treating and curing a range of health problems including cancer, heart disease, diabetes and mental illness, thus reducing unnecessary suffering. In addition, our researchers continue to develop new strands of thinking to tackle future issues.
 - We use alternatives to animals wherever possible— including computer modelling, synthetic tissue culture, cell and molecular biology, and research with human subjects – and we are actively involved in developing alternatives to animal tissue use.
 - However, these alternatives cannot yet properly reproduce the complex biological characteristics of human beings and animals, and nor can they replicate the study of animals in their natural environment.
 - Whenever animals do have to be used as part of a study, they are treated with dignity, and cared for by professionally qualified staff. All research programmes using animals are carried out to high standards and with recognition that living species are involved.
 - Research programmes using animals operate 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 out¹); a project 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, including one that is specifically for educational purposes; and there are 279 personal licences; both numbers have remained stable since last year when there were 42 and 275 respectively.
5. The numbers of animals used in regulated ASPA procedures in each of the calendar years 2015 to 2017 were as follows:

	2016	2017	2018
Rats	396	593	734
Mice	21,927	21,616	19,641
Rabbits	18	2	0
Pigs	91	358	174
Birds & poultry	14	156	480
Total	22,446	22,725	21,029

Rodent use has shown a slight fluctuation during the period 2017 to 2018 with a slight increase in the number of rats and a drop in the number of mice. Similarly, the number of pigs has reduced and the number of birds used for research has increased. The majority of pigs used in 2018 (144) were under a mild protocol in which one blood sample was taken as part of a dietary study, while 30 pigs were used on a moderate protocol involving wound healing studies. The birds used were also on a mild protocol under which they had blood and saliva samples taken as part of a conservation study.

¹ 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.

Import and export of experimental animals:

6. Occasionally, animals are exported from Leeds to researchers overseas. While most transgenic lines provided to researchers overseas are shipped as frozen embryos or sperm, a small number of genetically altered mice produced at the University are shipped to researchers overseas when there is a good case for so doing. Having reviewed the arrangements, the Committee is satisfied that all necessary requirements are in place from both ethical and welfare perspectives. During this reporting period, consignments of 12, 26 and 11 mice were exported to the USA, Spain and Italy, respectively. During the same period, 7 consignments totaling 120 mice and one consignment of 11 mice were imported from the USA and Canada, respectively.

Meetings in 2018-19

7. The Committee held six meetings in 2018-19 (on 26 September, 5 November, 30 January, 27 March, 6 June and 24 July).

New project licences

8. Since its last report, the Committee has considered thirteen applications for new project licences; in each case a number of amendments to the proposed project were required. Four of the thirteen have since been granted, four are currently being reviewed by the Home Office and five are in the final stages of drafting following comments from the Committee.
9. Project licence applicants (or, on occasions when the applicant is not available, an informed principal investigator involved in the project) meet the Committee to explain their work and to discuss issues of animal welfare and ethics. This was possible for all of the applications considered over the past year. Information is sent to applicants in advance of the meeting to help them to prepare for the meeting.

Reviews of existing project licences

10. As well as considering applications for new project licences, the Committee also carries out mid-term and final reviews of existing project licences to review progress and identify any animal welfare issues that may have arisen during the work. These are in-house reviews except in cases (a) where a licence is for education and training, and (b) where a licence includes procedures which are classified as 'severe'. In such cases, referred to as Retrospective Assessments, the University is obliged under Section 5B of the ASPA to return to the Home Office a formal report and an amended non-technical summary for the licence. Having revised the guidance for formal Retrospective Assessment, the Home Office now requires them to be submitted at the end of the licence.
11. The Committee requires written reports from licensees for all mid-term and final reviews, and, in addition, licensees are expected to attend the Committee in cases when a report has to be made to the Home Office.
12. During 2018-19, two mid-term reviews of existing project licences and four final project licence reviews were carried out. In the event, no material concerns emerged.

13. One formal retrospective assessment was done in July and submitted to the Home Office.

Animal welfare

14. There were no infringements of the Animals (Scientific Procedures) Act during 2018-19.

15. Regular inspections by the Named Veterinary Surgeon and Named Animal Care and Welfare Officers identified no animal welfare concerns. The Home Office Inspector inspected the animal facilities on two occasions (viewing procedures under way), and raised no concerns relating to animal welfare.

Condition 18 reports

16. During the year, ten 'condition 18' reports from three project licences were submitted to the Home Office to report an increase in the severity experienced by an animal above the level authorised on the relevant project licence. (There were four such reports in 2017-18 and ten reports in 2016-17.) In each case, the Home Office accepted the explanation offered, and no further action was taken. In addition, an incident that caused animal welfare concern was also reported to the Home Office. This incident was thoroughly investigated internally as well as by the Home Office and a Standard Operating Procedure for working in animal facilities was amended. The incident was reported and discussed by the AWERC, and the Home Office was similarly satisfied that this was an isolated incident and not as a result of any systemic failure.

Assurance

17. As usual, the Committee has during the year reviewed its terms of reference and has satisfied itself that it has access to sufficient information and advice to enable it to assure itself that it is discharging its remit appropriately.

18. Traditionally, the remit of Animal Welfare and Ethical Review Bodies (AWERBs) has been confined formally to work regulated under the ASPA. In common with some other institutions, however, the Committee has begun to review arrangements for ensuring that no ethical or welfare concerns arise in respect of non-regulated work carried out by the University's staff and students. (Non-regulated work is typically work which falls below the ASPA threshold, but also could include work carried out abroad.) The Committee will report further on this matter in its next report.

Openness

19. The corporate webpage that deals with animal research now contains published minutes and reports of the Committee, statistics on animal use at Leeds, and accessible lay summaries of project licences granted to staff at Leeds [www.leeds.ac.uk/animalresearch].

Benchmarking

20. In order to ensure that Leeds keeps abreast of emerging best practice, the Committee continues to be represented at various national events, including meetings of the Laboratory Animal Science Association, the Laboratory Animal Veterinary Association, Home Office consultations meeting to improve licensing systems, and regional meetings. Leeds hosted a successful 'AWERB Hub' meeting in November 2018, bringing

together members from Animal Welfare and Ethical Review Bodies (AWERBs) in the North of England.

Unit management

21. The Committee is being kept informed about plans to rationalise the University's animal holdings and experimental facilities.

Training

22. The University runs mandatory licensee training courses – accredited by the Universities' Accreditation Group² and recognised by the Home Office – for anyone wishing to apply for a personal or project licence and anyone wishing to undertake the humane killing of any animal protected by the Act. The courses are modular and include training and relevant legislation and in the ethics of animal research.
23. Three courses were run in 2018-19, in October, January and April respectively. A total of forty-one staff and students were trained plus two external delegates from Swansea University who required training for birds; the species covered were mice, rats, pigs and wild birds.
24. In addition, continuous professional development (CPD) events are organised annually. In January 2019, this took the form of a regional workshop on the 3Rs.

Work at the University Farm

25. Apart from occasional blood sampling, research involving the commercial pig herd at the Farm does not fall within the scope of the ASPA. Essentially, the research is non-invasive, mainly involving studies of pig diet. The welfare of the pigs has to be assessed through a framework set by the Animal and Plant Health Authority (APHA). Although the welfare of the pig herd does not therefore strictly fall within the jurisdiction of the Committee, it has been agreed that an annual report will be made available to the Committee from a veterinary surgeon who specialises in work associated with pig production.
26. The reports submitted to the Committee by the veterinary surgeon in February 2019 confirmed that the building and equipment provision 'is of a high quality' and that husbandry practices 'ensure [that] the highest standards of pig welfare are maintained'. The vet concludes that the Farm 'complies fully with all relevant welfare legislation, codes of practice and relevant quality assurance standards'.

18 September 2019

² The Universities' Accreditation Group is one of three bodies recognised by the Home Office for the accreditation and quality audit of mandatory Home Office licensee training courses in the UK. The others are the Royal Society of Biology and the Scottish Accreditation Board