

# The University of Leeds, The Council, Annual report of the Animal Welfare and Ethical Review Committee, 2020-21

## Introduction

This is the seventh annual report from the Animal Welfare and Ethical Review Committee (AWERC), 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 2020.

There are two compliance issues, described in section 15 below, to draw to the Council's attention. Despite these, and the lockdown engendered by the coronavirus pandemic, the Committee remains positive about standards of animal care and welfare.

## 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. We are committed to maintaining and enhancing a comprehensive culture of care.

2. 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>1</sup>); 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).

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<sup>1</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.

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. In addition, there is some research on pig diets at the University Farm but this work, as in previous years, has remained under the ASPA threshold for regulation.

### Data on animal usage

4. There are currently 35 project licences held by University staff,; and several more applications are in preparation or with the Home Office for approval. There are currently 239 personal licences. There were 38 project licences and 267 personal licences at the same point last year. Recent Home Office policy has been to request shorter, more focused project licences so there is a likelihood that the number of project licences will increase in future, with research programmes being split across a number of smaller licences. However, this would not in itself signify an increase in overall animal research at the University.
5. The numbers of animals used in regulated ASPA procedures in each of the calendar years 2018 to 2020 were as follows:

	<b>2018</b>	<b>2019</b>	<b>2020</b>
Rats	734	513	244
Mice	19,641	18,555	11,440
Rabbits	0	0	0
Pigs	174	441	6
Birds & poultry	480	533	250
<i>Total</i>	<i>21,029</i>	<i>20,042</i>	<i>11,940</i>

A considerable reduction in the use of rodents during 2020 can be seen. This is of course attributable to the restriction of animal research during the Covid-19 lockdown periods, when the focus was primarily on the maintenance of colonies. Similar reductions in the number of pigs and birds are apparent, reflecting restrictions on the movement of staff. The birds used were on a mild protocol under which they had blood and saliva samples taken as part of a conservation study. (The reduction in animal use across the UK is reflected in the Home Office Annual Statistics for 2020 which were published in July.)

### 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, one consignment of six mice was exported to the USA, 4 to Spain, 8 to China and 58 to Belfast. In addition, 126 mouse embryos were exported to the USA. During the same period, five consignments totalling 344 mice were imported from the USA, and one consignment of 40 mice imported from Italy. Six mini-pigs were also imported from Denmark during this reporting period.

### Meetings in 2020-21

7. The Committee held six meetings in 2020-21 via Microsoft Teams (on 30 September, 2 December, 15 February, 8 April, 13 May, 15 June and 28 July).

8. In addition, members of the Committee attended virtual meetings with the wider animal research and welfare community including the Animal Welfare and Ethical Review Body (AWERB) UK meeting on 8 February, the AWERB Northern Hub meeting on 5 May 2021, the Laboratory Animal Science Association Establishment Licence Holders' Forum and Home Office Liaison, Training and Information Forum meetings.

### **New project licences**

9. 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. One application was expedited by the Committee (via email correspondence) to enable the maintenance of breeding genetically altered mice under a project which was due to expire. The extension not only avoided any need to cull animals unnecessarily and lose colonies of unique genetically altered animals, but also provided additional time for two new applications to be prepared to include research protocols to continue the work. The work in question had previously been covered by one project licence, but was split at the request of the Home Office to facilitate easier assessment of the animals' experience within the separate licences. During this reporting period, twelve project licences have been granted, two are currently awaiting review by the Home Office and six are in the final stages of drafting following comments from the Home Office inspectorate. Significant delays in the processing of project licences have been experienced across the sector because the Home Office prioritised applications relating to Covid-19 research and has been dealing with a backlog of applications as a result. We have continued to work closely with the Home Office Inspector who has been very supportive in prioritising applications to facilitate the continuation of work and ensure that animal welfare issues can be avoided.
10. It is the Committee's practice to meet project licence applicants (or, when the applicant is not available, an appropriate deputy) to have the work explained and to discuss issues of animal welfare and ethics with the applicants.

### **Reviews of existing project licences**

11. 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 where a licence includes procedures which are classified as 'severe'. In such cases, the University is obliged under Section 5B of the ASPA to return to the Home Office a formal report, referred to as a Retrospective Assessment, and an amended non-technical summary for the licence. The Home Office now requires these to be submitted following expiry of the licence via the e-licensing system.
12. The Committee requires written reports from licensees for all mid-term and final reviews, and, in addition, for Retrospective Assessments, licensees are expected to attend the Committee.
13. A sub-group, with a balance of expertise, continues to consider project reviews and reports to the Committee on a regular basis. During 2020-21, five mid-term reviews of existing project licences were carried out. One final project licence review was carried out at the same time as a new application for a project licence to continue the work. In the event, no material concerns emerged.
14. One formal Retrospective Assessment was carried out in July and submitted to the Home Office.

## **Animal welfare**

15. There were two infringements of the Animals (Scientific Procedures) Act during 2020-21. Both incidents were self-reported by the University. The first compromised animal welfare, in that three mice were found dead. However, taking into account mitigating circumstances, the Home Office decided to deal with this incident administratively, without imposing any sanctions on any licence holder and without raising the University's risk assessment category. The second incident is still under investigation: it relates to one project using more mice than were authorised on the project licence, but without any animal welfare issues.

## **Condition 18 reports**

16. During the year, nine 'condition 18' reports from five 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 six such reports in 2019-20 and ten reports in 2018-19.) In each case, the Home Office accepted the internal investigations and the explanations offered, and no further action was taken.

## **Covid-19**

17. At the start of the Covid-19 related lock down in March 2020, a review of ongoing and planned animal work was carried out. In order to ensure that only routine animal care and husbandry was carried out – and in keeping with the principles of the 3Rs – it was decided to halt all new work and to finish ongoing work early, assuming that scientific outcomes could be achieved without wasting animals. The breeding of animals was either suspended or effectively put on 'tick-over'. Culling of animals was kept to a minimum, limited to neonate mice and rats that would not be used within a designated timescale. Regular animal work was resumed from the summer of 2020 onwards.

## **Assurance**

18. 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.
19. 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 reviewed the arrangements for ensuring that no ethical or welfare concerns arise in respect of the use of animals for research by the University's staff and students at other establishments either in the UK or abroad, or in the field. The Committee was satisfied that sufficient safeguards exist to address this aspect of animal work.

## **Openness**

20. 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](http://www.leeds.ac.uk/animalresearch)]. In March this year we appointed a student to the committee.

## **Benchmarking**

21. In order to ensure that Leeds keeps abreast of emerging good 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 meetings to improve licensing systems, and regional meetings

of representatives from Animal Welfare and Ethical Review Bodies (AWERBs) in the North of England. During the pandemic, meetings of these professional bodies have continued to take place virtually as scheduled and the organisations have been active in liaising with the Home Office; sharing good practice for management of facilities during lockdown to maintain high standards of animal welfare; and as lockdown measures have eased sharing experience and providing advice for re-opening and re-starting animal research. Our establishment's Named Persons under the Act have frequently engaged with Home Office staff during the last year, obtaining advice consultation and discussion with regards to regulatory and compliance advice, as well as advice of project licence applications submissions.

## **Training**

22. The University runs mandatory licensee training courses – accredited by the Universities' Accreditation Group<sup>2</sup> 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. A decision was taken to cancel in-house courses during 2021 because of ongoing Covid-19 restrictions on teaching and access to facilities. Trainees have been provided with details of commercial, virtual, licensee training theory courses and separate arrangements for practical in-house training have been made for anyone completing an external theory course at a time when permission was given for their work in the animal facilities to commence.

## **Work at the University Farm**

24. No ASPA related work was carried out at the Farm during this reporting period. Feeding trails not involving any invasive procedures and outside the scope of ASPA were conducted under the supervision of the Farm's veterinary surgeon.
25. The report submitted to the Committee by the veterinary surgeon in March 2021 confirmed that 'the building and equipment provision – at a time of major building within the indoor unit – for both herds is of a high quality and husbandry practices ensure satisfactory standards of pig welfare are maintained'. The vet concludes that 'current standards of welfare on the farm are good' and that 'the farm complies fully with relevant welfare legislation, current codes of practice and relevant quality assurance standards'.

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<sup>2</sup> 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