

# **The University of Leeds, The Council, Annual report of the Animal Welfare and Ethical Review Committee, 2019-20**

## **Introduction**

This is the sixth 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. Despite the lockdown engendered by the coronavirus pandemic, the Committee remains positive about standards of animal care and welfare, and the annual risk assessment carried out by the Home Office Inspector in February 2020 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 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).
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 36 project licences held by University staff, including one that is specifically for educational purposes; and several more applications are in preparation or with the Home Office for approval. There are currently 260 personal licences. There were 42 project licences and 279 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 2017 to 2019 were as follows:

	<b>2017</b>	<b>2018</b>	<b>2019</b>
Rats	593	734	513
Mice	21,616	19,641	18,555
Rabbits	2	0	0
Pigs	358	174	441
Birds & poultry	156	480	533
Total	22,725	21,029	20,042

There has been a reduction in the use of rodents, both rats and mice, during the period 2018 to 2019, whereas the number of pigs and birds used for research has increased. Of the 441 pigs used in 2019, the majority (427) were under a mild protocol in which one blood sample was taken as part of a dietary study, while 6 pigs were used on a moderate

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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.

protocol involving wound-healing studies and 8 were used in a terminal procedure for the investigation of human gastrointestinal disorders. The birds used were also on a mild protocol under which they had blood and saliva samples taken as part of a conservation study.

### **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, 18 mice in two consignments were exported to the USA, 28 mice in two consignments were exported to Spain, and 11 mice were exported to Italy in one consignment. During the same period, three consignments totalling 236 mice were imported from the USA and one consignment of six Gottingen Mini-Pigs was imported from Denmark.

### **Meetings in 2019-20**

7. The Committee held three face-to-face meetings in 2019-20 (on 20 September, 4 December and 28 January) and two meetings were held via Microsoft Teams (on 1 June and 29 July). The meeting due to have taken place on 19 March had to be cancelled as the University moved into lockdown; however, urgent business was conducted via e-mail. The Home Office Inspector attended two meetings during the year and commented favourably on the way in which the Committee operated.
8. In addition, members of the Committee attended a workshop on 28 January “Ethical reflection on harms and benefits in animal research” to discuss ethical considerations in the use of animals for scientific research.

### **New project licences**

9. Since its last report, the Committee has considered six applications for new project licences; in each case a number of amendments to the proposed project were required and one application was returned to the Committee for further review following amendment by the applicant. During this reporting period, six project licences have been granted, two are currently awaiting review by the Home Office and one is in the final stages of drafting following comments from the Committee. Significant delays in the processing of project licences have been experienced across the sector because the Home Office has been prioritising applications relating to Covid-19 research. The Home Office accordingly returned a number of applications to the applicants in March saying that it could not consider them during the pandemic. However, we have been able 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 are avoided.
10. It is now the Committee’s established practice to meet project licence applicants (or, when the applicant is not available, an appropriate deputy) to have the work explained first-hand and to discuss issues of animal welfare and ethics. Information is sent to applicants in advance of the meeting to help them to prepare for the meeting.

### **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 (a) where a licence is for education and training, and (b) 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, known as a Retrospective Assessment, and an amended non-technical summary for the licence. Having revised the guidance for formal Retrospective Assessment, the Home Office now requires these to be submitted following expiry of the licence.
12. The Committee requires written reports from licensees for all mid-term and final reviews, and, in addition, licensees are expected to attend the Committee.
13. During 2019-20, two 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. The disruption caused by the coronavirus pandemic led to three mid-term reviews being deferred. A sub-group, with a balance of expertise, was set up by the Committee to bring the project reviews up-to-date; the deferred reviews have now been completed with no concerns.
14. One formal Retrospective Assessment was carried out in January and submitted to the Home Office; and a further return was submitted, as required, for a project licence under which no work had been done.

### **Animal welfare**

15. There were no infringements of the Animals (Scientific Procedures) Act during 2019-20.
16. 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**

17. During the year, six '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 ten such reports in 2018-19 and four reports in 2017-18.) In each case, the Home Office accepted the outcome of internal investigation and the explanation offered and took no further action.

### **Covid-19**

18. At the start of the Covid-19 related lockdown in March, 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, if scientific outcomes

could be achieved without wasting animals. The breeding of animals was either suspended or effectively been put on 'tick-over'. Culling of animals was kept to a minimum, limited to neonate mice and rats born that would not be used within a designated timescale.

19. The Committee is satisfied that animal welfare was not compromised during the period of lockdown, and has recorded its thanks to all of the staff for everything they have done during what had been a difficult and demanding period.

### **Assurance**

20. 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.
21. 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 been confined that sufficient safeguards exist to address this aspect of animal work.

### **Openness**

22. 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)].

### **Benchmarking**

23. 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 eased, sharing experience and providing advice for re-opening and re-starting animal research.

### **Training**

24. 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

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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.

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.

25. Two courses were run in 2019-20, in October and January for prospective personal licence applicants. The course scheduled to take place in April had to be cancelled because of the Covid-19 lockdown. Trainees who were registered for this course (6) were offered places on the next course that is provisionally scheduled to run at the University in October and also provided with details of commercial, virtual, theory courses in the event that an urgent need for training should arise before October. Separate arrangements for practical animal handling training will have to be made once it is possible for this to be provided safely in-house. A total of 23 staff and students were trained plus one lay member of the Committee who attended the legislation and ethics module. Two external delegates attended the course, one from the University of York who attended the Surgery and anaesthesia modules and one from the University of the Highlands and Islands who required training to work with sea birds. The species covered were mice, rats, Guinea-pigs, pigs and wild birds.
26. In addition, continuous professional development (CPD) events are organised annually. In January 2020, this took the form of a one-day workshop covering subjects including 3Rs, animal welfare, experimental design, enhancing the reproducibility, reliability and translatability of research, and the culture of care.

#### **Work at the University Farm**

27. 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, representatives of the Committee do visit the Farm, and 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.
28. The report submitted to the Committee by the veterinary surgeon in March 2020 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'.

#### **Chair**

29. The Committee has recorded its great gratitude to its first Chair, who stepped down in 2020 after five years in office.