

THE UNIVERSITY OF LEEDS

THE COUNCIL

Annual Report of the Animal Welfare and Ethical Review Committee, 2014-15

The Animal Welfare and Ethical Review Committee was reconstituted as a committee of the Council at the beginning of this session. This is the first annual report from the reconstituted committee, and, as such, starts by explaining the purposes of animal research, outlining the regulatory framework and describing the University's arrangements for securing animal welfare and for the ethical review of proposed projects using animals. The report goes on to describe the Committee's work over the past year, and to provide data on animal use in 2014.

Background

Overview

1. Like most other research-intensive universities, Leeds uses animals for scientific research. 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, refinement and reduction of animals in research¹.

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 man 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. Some of the areas in which advances are being sought through the use of animals are summarised in **Annex 1**. Some specific examples of scientific progress achieved through the use of animals are being collated for inclusion in the University's annual report for 2014-15.)

¹ 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.

Legal framework

3. In the UK, the use of animals in scientific experiments is regulated by the Animals (Scientific Procedures) Act 1986 (ASPAs), which was revised in 2012 to transpose European Directive 2010/63/EU on the protection of animals used for scientific purposes. The revised legislation came into force on 1 January 2013. ASPA is implemented by the Home Office in England, Scotland and Wales.
4. 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.
 - ❖ First, an establishment licence is required; this licence designates the premises on which scientific procedures may be carried out². The Establishment Licence is typically held by an individual – at Leeds by the University Secretary.
 - ❖ Secondly, there needs to be 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. Project licences are granted after an ethical review process within the establishment (see below) and after scrutiny by the Home Office itself acting on behalf of the Secretary of State.
 - ❖ Finally, a scientist working on a licensed research project normally needs a personal licence, granted after the scientist has satisfactorily completed appropriate training. (The establishment is responsible for providing appropriate training and maintaining associated records.)

Arrangements at the University of Leeds

5. The University has two animal facilities, one located on _____ and the other on _____. The two facilities were brought under common – unified – management in January 2015.
6. Scientific research involving animals is regulated and administered by the following, who have special responsibilities under ASPA.
 - ~ The Animal Welfare and Ethical Review Committee, which *inter alia* has a responsibility to promote the 3Rs and the welfare of animals generally, and to evaluate proposals to carry out work involving animals;
 - ~ The Establishment Licence Holder (PEL), who is responsible for ensuring that the requirements of ASPA and conditions of the licence are complied with;
 - ~ The Named Veterinary Surgeon (NVS), who is responsible for advising on the health, welfare and treatment of the animals (and who must be a member of the Royal College of Veterinary Surgeons with expertise in laboratory animal medicine for the species being used in the establishment);
 - ~ At least one Named Animal Care and Welfare Officer (NACWO), who is responsible for overseeing the welfare and care of the animals;
 - ~ The Named Training and Competence Officer (NTCO), who is responsible for ensuring that those dealing with animals are adequately educated, trained and supervised until they are competent and that appropriate further training continues;

² 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.

~ The Named Information Officer (NIO), who is responsible for ensuring that those dealing with animals have access to any information they need about the species they are using.

7. There are currently 42 project licences held by University staff, and 178 personal licences.
8. The numbers of animals used in regulated ASPA procedures in each of the calendar years 2012 to 2014 are as follows:

	2012	2013	2014
Rats	825	830	778
Mice	20547	19715	25469
Pigs	5	15	24
Birds & poultry	101	134	183
<i>Total</i>	<i>21473</i>	<i>20694</i>	<i>26454</i>

Reconstitution of the AWERC as a Council committee

9. The existing Animal Welfare and Ethical Review Committee (AWERC) was reconstituted last year as a committee of the Council, chaired by a lay member of the Council. (Previously, the committee was chaired by the Establishment Licence Holder. The new arrangement came into effect from 1 January 2015; the Committee's terms of reference are reproduced in **Annex 2**.)
10. There were two main reasons why the AWERC was made a committee of the Council.

➤ *Assurance*

Responsibilities and accountabilities under the ASPA are held by named individuals rather than by the University corporately. Nonetheless, research involving animals is potentially controversial and, if things go wrong, has the potential to be damaging to the University's reputation. It is therefore appropriate that the governing body has a direct line of sight to the committee which has a responsibility for monitoring compliance with the ASPA, for promoting animal welfare and for undertaking ethical review of animal work. That the committee is chaired by a lay member of the Council rather than someone with ASPA responsibilities provides some independence and gives a greater measure of assurance.

➤ *Openness and transparency*

Mindful of the risk of violent 'direct action' by animal rights extremists, universities and scientists have tended over the past few decades to be reticent about their work with animals. Though the climate has improved lately, the need for discretion still remains. There is, however, a general recognition that the climate of discretion has perhaps conduced towards a culture of secrecy, one which is at odds with the values of science and of universities. The reconstitution of the AWERC as a committee of the council is set in this context: it is intended to give effect to – and indeed to symbolise – a determination to be as open and transparent about animal use as is consistent with protecting the safety and security of individuals.

Work of the Committee in 2014-15

11. As noted above, the new arrangements for the AWERC came into force with effect from 1 January 2015. Since then, the Committee has held four meetings (on 5 February, 16

March, 19 May and 2 July); three of the meetings were chaired by the Chair and one by the Establishment Licence Holder.

Openness and transparency

12. In the spirit of securing openness and transparency on the basis indicated in 9 above, the Committee has agreed to suggestions from the Establishment Licence Holder that from this summer the following documents should be made publicly available through the University's website:

- (a) the Committee's minutes (without the names of individuals, location of facilities or matters relating to intellectual property);
- (b) the non-technical summaries of any new project licence granted by the Home Office for work under ASPA at the University of Leeds;
- (c) data on the numbers of animals used, by species, year by year.

In addition, non-technical summaries of existing project licences will be added after redaction of any information which might compromise the safety of individuals; and the feasibility is being explored of collating and publishing data about the severity of different lines of animal work.

Concordat on Openness on Animal Research in the UK

13. Following discussion in the Committee, the University has now signed the Concordat on Openness on Animal Research in the UK, which sets out the ways in which signatories – mainly scientific bodies of one sort or another – will be more open about the ways in which they use animals in scientific, medical or veterinary research.

14. There are four specific commitments in the Concordat, as follows.

- We will be clear about when, how and why we use animals in research
- We will enhance our communications with the media and the public about our research using animals
- We will be proactive in providing opportunities for the public to find out about research using animals
- We will report on progress annually and share our experiences.

15. The first annual report on the way in which the University fulfils its commitments will be included in the Committee's 2015-16 report. In the meantime, it should be noted that the Committee has agreed in principle that we should arrange an opportunity for accredited journalists and MPs to see round the University's animal facilities. The Committee was clear, however, that, given such visits might disturb animals used to relative quiet, there should be no more than one or two such visits in any one year. To complement these visits, the Committee is encouraging the Communications team, when resources allow, to prepare a short film on the University's work with animals – a film which would be available through the University's website.

Sources of assurance

16. The Committee has begun a review of the way in which it can best discharge its terms of reference – and thus how it can gain and give assurance about the promotion of animal welfare and about compliance with the ASPA. This work is not yet complete, but the Committee has to date been reassured by the procedures and processes in place. The intention is to codify arrangements, and copies will be available to members of the Council when this exercise is complete.

Internal audit

17. PricewaterhouseCoopers, the University's internal auditors, carried out an audit during the year of record keeping in ASPA work. The audit concluded that arrangements were generally satisfactory, but made three recommendations to tighten record keeping.

New project licences

18. Since its reconstitution, the Committee has considered five applications for new project licences. In each case, it suggested a number of amendments to the proposed project; in two cases those amendments have been made and the applications are currently with the Home Office for review the remaining three applications are in the process of being amended. Non-technical summaries of the projects will be published on the website if and when the licences are granted.

Animal welfare

19. Since its reconstitution, the Committee has been informed of one welfare issue – though not one where any responsibility or culpability attaches to the University. In January 2015 some diabetic mice were ordered from a laboratory . Responsibility for the welfare of the mice rested with the supplier and the freight carrier until the consignment was delivered. On arrival, sixty-four of these mice (out of a total of 148) were found to be dead, while two further animals died within an hour of arrival. The matter was reported to the supplier and to the Home Office, and an investigation involving the supplier, the freight company and the University was launched. The investigation concluded that the cause of death of these animals was exposure to extremely low environmental temperature during transit at one of the airports en route. The supplier accepted responsibility on the basis that it had not taken cold weather conditions into account, and had therefore failed to place enough bedding in the animal transport cages to keep the animals warm during transit. Unfortunately, despite assurances from the supplier, a similar problem affected the next consignment, in February 2015: on this occasion, forty-three out of 160 animals were found dead on arrival. As a result, the supplier has changed its standard operating procedures for transporting this relatively sensitive strain of mice in extreme weather conditions. For its part, the University has decided not to order any consignments of these mice in extreme weather conditions. (There was no problem with the third consignment.)
20. Since July 2014 the University has been subject to seven inspections by the Home Office, of which three were unannounced. No animal welfare issues were identified during any inspection; however, during one inspection procedural deficiencies in aseptic surgical technique were observed. As acknowledged by the Home Office Inspector on a subsequent visit, these deficiencies were dealt with promptly.
21. The Committee has endorsed a conclusion reached by the Establishment Licence Holder, that, for welfare reasons, no animal should be housed overnight other than in the main animal facilities.

Training

22. The University runs Home Office licensee training courses, primarily for University staff and students, to provide mandatory prerequisite education and training for prospective Home Office licensees, animal care personnel and those who will be involved in the humane killing of animals. These courses have been re-developed with effect from January 2015 to reflect the modular structure outlined in the relevant EU framework and also to correspond with Home Office requirements for licensee training.

23. Two courses have been run under the new modular structure, in January and April this year, and a total of twenty-one people have been trained in order to apply for new or to amend existing personal licences.
24. Demand for places has remained relatively steady since 2014 following an increase in the uptake of anaesthesia and surgery modules during 2012/13.
25. One further development in training for prospective licensees is the Home Office requirement for project licence applicants to have successfully completed all relevant personal licensee training as well as the project design and management modules before they are able to apply for a project licence. Along with the recent introduction of mandatory training for those who will be involved in humane killing of animals, this is likely to lead to a gradual increase in demand for Home Office training courses in future.

10 July 2015

Areas of research using animals at the University of Leeds

A. *Cancer development, mapping, diagnosis and treatment*

- Mouse models for tumour stem cells and anti-tumour efficacy studies
- Gene function in tumorigenesis (**leukaemia, sarcoma, lung, prostate and breast cancers**)
- Mechanisms regulating growth of brain metastasis
- Renal Cancer Biology and Therapy
- Immune and Biological Therapies for Cancer
- New approaches to radiosensitisation of brain or spinal tumour
- The potential for new treatments, or strategies for developing them, to address problems of cardiovascular disease and cancer in people.

B. *Cardiovascular studies*

- Mechanistic basis of cardio-metabolic disease. **Diabetes and Cardiovascular Disease**
- cardiovascular and respiratory function in disease
- Right Heart failure
- Statin effects on heart and skeletal muscle
- Molecular mechanisms regulating normal and disease cardiovascular physiology

C. *Applied research:*

- Biocompatibility of Tissue Engineering Scaffolds
- Biological Response to Prosthetic Nanoparticles
- Wound healing

D. *Neurological /psychiatry/anxiety /drug addiction research*

- To evaluate potential novel pharmacological therapies for the treatment of Alzheimers's disease
- Mechanisms and treatment of anxiety
- Behavioural Neuroscience of Drug Addiction
- Neurobehavioural disorders: causes and therapies (autism and schizophrenia)
- Neuronal function and psychiatric disorders (autism and schizophrenia)

- Genetic Causes of Neurological Disorders (mainly brain disorders e.g. Ataxic cerebral palsy , Optic nerve hypoplasia)
- Pharmacological regulation of appetite

E. Surgical models

Development and testing of a novel cardiac assist device.

Minimally Invasive Surgical Technology

Surgical treatment of congenital bladder defects in neonate

Surgical treatment of congenital urethral abnormalities in male neonate

Identifying time-sensitive biomarkers that correlate with the development of abdominal sepsis.

F. Ecology and conservation

Disease ecology in wild bird populations

Bat conservation

G. Pain research

Molecular mechanisms of pain

Rehabilitation of patients after spinal cord injuries

Farm animal research

Effect of food manipulation on farm animal production (pigs and chicken)

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Animal Welfare and Ethical Review Committee

Terms of reference

1. To promote the welfare of animals held or used by the University under the Animals (Scientific Procedures) Act 1986 and, in particular
 - (a) to advise staff dealing with animals on all matters concerning animal welfare – covering in particular the acquisition, accommodation, care and use of animals;
 - (b) to promote awareness of animal welfare and the 3Rs (the replacement, reduction and refinement of animal experimentation);
 - (c) to review management and operational processes for monitoring and reporting on the welfare of animals housed or used in the University, for following up any issues arising and for training staff who work with animals;
 - (d) to follow the development and outcome of projects carried out in the University, taking into the account the effect on the animals used, and to identify and advise on elements that could contribute further to the 3Rs;
 - (e) to advise where appropriate on re-homing schemes, including the appropriate socialisation of animals to be re-homed;
 - (f) to promote a culture of animal care within the University, supporting named persons and other staff dealing with animals as appropriate.
2. To provide independent ethical advice to the Establishment Licence Holder, particularly with respect to new project licence applications and amendments to existing licences - in both cases with reference to the likely cost to the animals, the expected benefit of the work and how these consideration balance.
3. To monitor the University's compliance with the Animals (Scientific Procedures) Act 1986, and to report at least annually to the Council.

Membership

A lay member of the Council (in the Chair)

The Establishment Licence Holder

The named veterinary surgeon

The named animal care and welfare officers (NACWOs)

Up to four members of the University who do not work with animals, at least half of whom should be scientifically qualified

Up to four members of the University who hold personal project licences

The Committee may co-opt additional members at its discretion.