

# Gazette Supplement



## Committee on Animal Care and Ethical Review

### Annual Report 2019–20

The University's Local Ethical Review Process was set up in 1999 to ensure that all aspects of research involving animals conform to the requirements of the Animals (Scientific Procedures) Act 1986. The process remains in place and is aligned with the latest revision of the Act that was completed in 2012. For the purposes of this report the Act is referred to as A(SP)A. The Animal Care and Ethical Review Committee (ACER) is required to report annually to Council and, through it, to Congregation on activities concerned with research management, compliance and licensing of procedures involving the use of animals in scientific research. The ACER Committee, supported by six Animal Welfare and Ethical Review Boards (AWERBs) at cross-department and faculty level, provides assurance to the Establishment Licence Holder on the ethical treatment and welfare of animals used in conjunction with scientific, medical and zoological research projects that are undertaken across the University. Animal-based research at the University takes place mainly within the Medical Sciences Division (MSD) but the Department of Zoology, the Department of Engineering and other associated operations are often involved or collaborate with animal-focused research projects as the integration of technology and computing capability expands. This report summarises the range of work carried out and the support measures in place to ensure compliance with A(SP)A and the requirements of the Home Office Animals in Science Regulation Unit.

A(SP)A requires that all research using animals is properly justified and that any viable alternatives to their use are fully considered. In all cases where animals are subjected to invasive or non-invasive procedures that cause

any pain, distress, suffering or lasting harm this is mitigated through the application of anaesthetic and analgesia and kept to an absolute minimum. The University's Animal Use Policy requires that anyone involved in research that includes the use of animals is proactive in pursuing refinement, reduction and replacement (usually referred to as the 3Rs) in procedures involving live animals wherever possible. In addition, all researchers and animal care staff must ensure they engage fully in the approved ethical process of review and monitoring of animal-based research. The University of Oxford Animal Use Policy also commits the University to providing standards of accommodation and care that exceed, wherever possible, the minimum standards required by UK national legislation. The responsibility for provision and maintenance of the accommodation and facilities is devolved by the Establishment Licence Holder to the Director of Biomedical Services (BMS) who, with animal care staff and researchers, is charged with ensuring that animal facilities are managed and maintained efficiently and to as high a standard as possible.

### Home Office inspections

The Home Office Inspectors conducted unannounced visits to the University animal housing and research facilities during the current reporting period.

There has been a change in the inspectors over the past year, with three inspectors covering research projects and licences across the University. We have had non-compliances that resulted in a focus by the Home Office. This focus has resulted in close monitoring and an action plan initially commissioned by the Establishment Licence Holder that has been extended as part of the overall review of animal-related activity. We continue to work

closely with the Home Office and continually review and adapt our processes to ensure compliance.

During this period, the Home Office Inspectors have also been monitoring the effects of COVID-19 and the restrictions lockdowns have had on the performance of the facilities. We have been open with them on how this has affected the animal numbers and reduced the scientific output. There have been weekly meetings between the Director of the Biomedical Services department and key members of his staff. The Establishment Licence Holder has also had regular meetings to address any issues of compliance and to reassure the Inspectorate of our drive to run a compliant organisation.

### The Animal Welfare and Ethical Review Bodies

There are seven AWERBs<sup>1</sup> that consider applications for new project licences, amendment requests for current project licences, retrospective reports on current project licences and any other welfare and ethical review matters relevant to animal-based research involving staff working at the University. In addition, there is a process for the review of collaborative projects in animal-related research that fall outside of A(SP)A and the countries covered by the European Directive 63/2010<sup>2</sup>. Collaborative ventures involving Oxford-based researchers that take place elsewhere in the world are reviewed and recommendations made to ensure compliance with local ethical and welfare standards. Wherever possible collaborative research projects that fall outside the jurisdiction of A(SP)A and the EU

<sup>1</sup>This includes Animal Care and Ethical Review Committee (ACER).

<sup>2</sup>Directive 2010/63/EU on the protection of animals used for scientific purposes is the legislative document.

Directive are required to demonstrate that they meet a similar or acceptable standard of welfare. Where there is any doubt about the quality of facilities or standards of animal welfare at the distant site or establishment, the ACER Committee requires the aspects of collaborative research involving Oxford-based researchers to comply as nearly as possible with the welfare and ethical standards, and 3Rs requirements, that apply across the University.

The Animal Care and Ethical Review (ACER) Committee is the overarching ethical review board and acts in collaboration with the six AWERBs and a subcommittee that considers the application of the principles of the 3Rs in research. The ACER Committee considers project licence applications that have severe category protocols or employ novel techniques in the type of research undertaken, and any projects that use what are deemed to be sensitive species, such as non-human primates. The Local or Departmental AWERBs review project licence applications that involve mild or moderate protocols in the planned programme of research.

#### **AWERB Hub**

An initiative by the national Animals in Science Committee (ASC), a non-departmental public body sponsored by the Home Office, set up a series of AWERB Hubs with Oxford nominated as a hub for nine research establishments in the region. The concept of AWERB Hubs is to provide a discussion forum for sharing best practice, information and collaboration. In practice it proved difficult to coordinate a range of very different establishments and organisations, both in terms of size and research facilities, to achieve a meeting, common aim or viewpoint. After discussion with the ASC it was agreed that Oxford would seek to align itself with a similar establishment both in terms of size and research philosophy.

#### **Home Office Licences**

The Home Office computer-based application, ASPeL, continues to be upgraded and the Establishment Licence and Approved Areas, all Personal Licences (PILs) and the majority of Project Licences at Oxford are managed through the online system. The few remaining paper-based Project Licences will be transferred to

the online system early in 2021 by the Animals in Science Regulation Unit at the Home Office. All Project Licence (PPL) applications and Personal Licence (PIL) applications are made online. The Home Office Administration Unit, a section within Biomedical Services, comprises three Home Office Liaison Contact Officers and a Home Office Liaison Administrator. Their role is to provide guidance on the Ethical Review Process for new PIL and PPL applicants and coordinate the review and submission process that takes place before applications are considered by the AWERBs and manage approved applications for subsequent submission to the Home Office. The Home Office Administration Unit maintains oversight and management of all applications and guides applicants on submission of their approved application to the Home Office using the ASPeL system and, after the granting of licences, during the review and amendment procedure.

The Home Office Liaison Contacts also act as Committee Secretaries for the ACER Committee and the six Departmental AWERBs managing the regulation and membership of each committee, the annual schedule of 34 review meetings, and all compliance and legislative aspects of the ethical review process.

#### **Personal Licences**

During the period of the report the number of PILs held by researchers at Oxford averaged 1,165. The PIL authorises the holder to undertake various procedures according to their individual training and supervision qualifications. Each PIL Holder is required to qualify at Home Office-approved training courses before being permitted to handle or perform surgical or non-surgical procedures on animals. Animal care staff are also required to undertake training on approved courses run by the Institute of Animal Technology in order to fulfil their duties. Home Office-approved training courses are run within the BMS at regular intervals. During the year a total of 158 new PILs were issued to University staff and students, while 201 PILs were revoked for staff and students who ended their courses, completed their research or moved to other establishments.

#### **Personal Licence Activity October 2019–September 2020**

Month	PILs Issued	PILs Revoked
Oct 2019	10	8
Nov 2019	23	14
Dec 2019	17	20
Jan 2020	23	8
Feb 2020	11	9
Mar 2020	9	109
Apr 2020	28	16
May 2020	8	2
Jun 2020	7	6
Jul 2020	9	0
Aug 2020	6	7
Sep 2020	7	2
<b>Total</b>	<b>158</b>	<b>201</b>

#### **Project Licences**

The maximum number of active PPLs held by researchers at the University during the period of the report was 153, compared to 160 active PPLs during the previous reporting period. PPLs authorise the holder to undertake a research project that has clearly defined objectives and anticipated outcomes; each is valid for a period of five years. PPL Holders are responsible to the Home Secretary for the compliance and conduct of all researchers working under their project and for compliance with the closely defined procedures that may be carried out in pursuit of their research goals. The University's Home Office Liaison Officers in BMS are involved throughout the PPL applications process in their role as secretary to the AWERBs and provide guidance to applicants in the initial stages of drafting a new project licence prior to the Named Veterinary Surgeon (NVS) and Named Animal Care and Welfare Officer (NACWO) review. The Home Office Liaison Officers continue to support applicants after the Ethical Review Committee Process by providing feedback and guidance on the submission process and once licences are granted.

During the reporting period a total of 21 new project applications were approved and granted by the Home Office, compared to 33 applications in 2018-19, representing a decrease in licences issued. A total of 58 amendment requests for existing projects were approved, compared

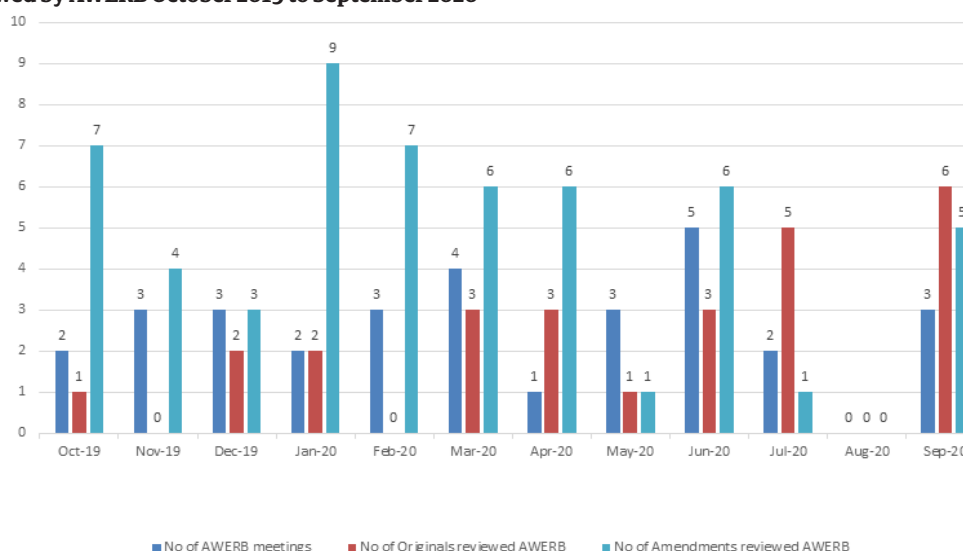
to 67 amendment requests in the previous year, representing a decrease in amendments to licences. It should be noted that more than half the reporting period was subject to restrictions and a reduction in active research due to the COVID-19 pandemic.

The chart below shows Project Licence applications and amendments reviewed at AWERB meetings across the reporting period October 2019 to September 2020. The slight difference in numbers reviewed when compared to the number of new licences and amendments approved and issued by the Home Office in the same period is due to the lead and lag time between AWERB meetings and the online

submission to the Home Office. In some cases, the Home Office Inspector reviewing the submission may require further changes to a licence application before approval, and this review and amendment process will add to the time delay between the start of the application process and the granting of the licence. In complex cases the delay can be between six and twelve months after submission. In the case of Project Licence applications where continuation of current research is necessary, the Home Office Administration Unit within BMS ensure that reminder notices are sent to applicants at least twelve months before the current Project Licence

expires. The applicant is also advised of the date of AWERB review to ensure the application writing process is completed in good time so as not to compromise continuity of research. All applications and amendments are subject to full ethical review by the NVS or Veterinary Surgeons, NACWOs and the Home Office Liaison Contacts/AWERB Secretaries before consideration in committee. A number of amendments may be approved by the chair of an AWERB without being reviewed in full committee, but only for minor changes that do not have welfare or ethical considerations. An example of a chair's approval might be a change of contact information or similar.

#### Applications reviewed by AWERB October 2019 to September 2020



The distribution of active Project Licences between the AWERBs at the end of the reporting period is shown in the table below.

Animal Welfare and Ethical Review Body	Total (160)	% PPLs
Animal Care and Ethical Review Committee	45	29.4
Clinical Medicine	69	45.1
Physiology, Anatomy & Genetics/Experimental Psychology	17	11.1
Pathology	9	5.8
Pharmacology	9	5.8
Zoology	4	2.6

Processing time for applications and amendments includes the internal review by the NVS, NACWO and AWERBs, and final granting by the Home Office. During the period of this

report the average processing time was 96 working days for original Project Licence applications, and 27 working days for a Project Licence amendment.

#### Species used and severity of procedures

Animals are used in research only where there is no viable or satisfactory alternative available. All projects are subject to assessment by internal review within the University and by the Home Office, where the potential benefits are considered against the adverse effects and potential cost to the animals concerned. The University pursues research using a number of non-animal methods such as computer modelling, tissue culture, cell and molecular biology, and research with human subjects. These methods continue to be used and integrated into research projects wherever possible and appropriate, and new technology will be incorporated if it is deemed to offer a useable alternative; however, animal experimentation continues to remain

necessary in certain circumstances where technology is currently lacking.

Projects where the use of animals is necessary include research into the prevention and treatment of human diseases (eg cancer, HIV, tuberculosis, Parkinson's, diabetes and heart failure), and the study of host-parasite interactions (for example in malaria) continues to be an area where it is necessary to understand the interaction

between systems (including the effects that chemical or neural changes may have on circulation, respiration or other functions). Similarly, studying behaviour or complex brain functions, transplantation and musculoskeletal systems still necessitates the use of animals, though restricted to the minimum number required. The involvement of a broad range of individuals in the ethical review process, including lay members and

animal care staff, ensures that it remains proactive in pursuing the adoption of best practice, promoting a culture of care, and encouraging education and training to enhance staff skills and raise awareness of ethical issues.

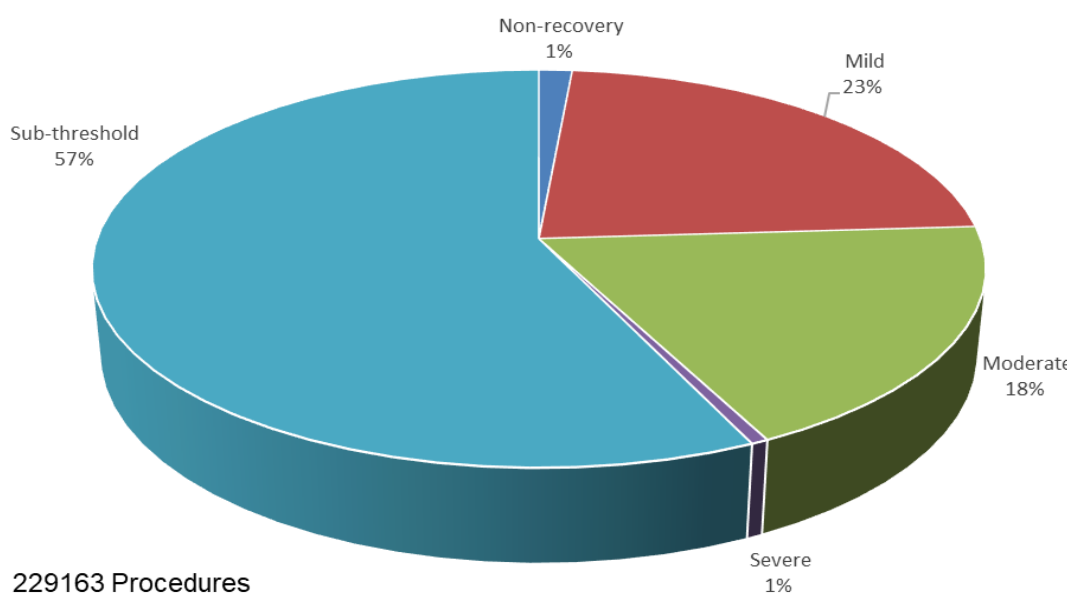
A variety of different species of animals is used in research projects at the University, as may be seen from the table below left.

Species	Number used in 2019	Number used in 2018
Mouse	222,206	208,057
Fish (zebrafish)	4235	7847
Other fish	358	155
Rat	2197	2913
Frog	0	89
Guinea pig	61	81
Ferret	13	24
Rabbit	0	0
Non-human primates	8	10
Jungle fowl	7	291
Pig	15	20
Badger (observation only)	63	0

(Note: The number of animals used is collected annually in January and covers the previous calendar year. Figures shown cover the year 2019 only and do not include usage in 2020.)

The actual severity of procedures reported during 2019, drawn from the Return of Procedures forms sent to the Home Office, were as shown in the diagram below.

#### Percentage of animals used under each severity category in 2019



(Note: This period covers 2019 only as figures for 2020 have not yet been collated.)



The changes in animal numbers used during the year reflects a reduction in some species where alternatives have been identified, for example in terms of different types of fish, or where more in vitro research has been undertaken.

#### **Veterinary and Named Animal Care and Welfare Officer staff**

The current Veterinary Team is made up of three Named Veterinary Surgeons (NVS) with support from locum veterinarians. A primary duty is the provision of advice on the welfare and treatment of the animals. The team interacts closely with the Named Animal Care and Welfare Officer (NACWO) to provide direct support for the animals and those carrying out experimental procedures. The roles act together to ensure we provide a compliant environment when managing the animals under our care.

The NVS, veterinary and NACWO functions continue to support the training needs of the University, providing expert tutorials on a range of subjects relating to the Animals (Scientific Procedures) Act. Most of this sits with the Veterinary Team and includes background, ethics, concepts around the experimental effect on the animal, anaesthesia and Project Licence preparation. An additional role for the NVS is that of the Named Training and Competency Officers. The NVS role has the practical aspect of training in surgical and new procedures to ensure that researchers can achieve and maintain competency when carrying out procedures.

As in previous years, a high proportion of the team's effort was directed at Project Licence and ethical review. Each licence amendment or new application involves meeting with the applicant, advising researchers on health and welfare matters relating to the use of animals, and attendance at the relevant ethical review committee. The Veterinary and NACWO teams actively contribute to the termly Departmental Animal Welfare meetings to provide timely updates to the research community on various topical and practically relevant issues which relate to animal welfare, compliance and the 3Rs. Advising on suitable animal health monitoring programmes is also an integral aspect of regular responsibilities.

#### **Training**

The Training Director and lead NTCO oversees a comprehensive range of training courses provided through BMS for researchers to gain Home Office-accredited qualifications in procedures involving animals and associated skills in animal research. The courses are run at regular intervals throughout the year and are designed to cater for delegates within the University and from other establishments. Normally the BMS Team teach the majority of the accredited modular Laboratory Animal Management and Welfare course (successful completion of which is a requirement for new Personal Licence Holders), which runs five times a year, either delivering lectures or running practical sessions.

Overall, over 200 delegates attended relevant training for Animal and Biomedical Sciences Researchers, including Modular Training Courses for researchers and those intending to apply for Project Licences. This has been achieved despite the double threat of various levels of COVID-19-induced confinement and the level of veterinary staff shortage at BMS. The range of training provided has also continued to include advice on writing a Project Licence application and Experimental Design in preclinical research, in conjunction with the MSD skills section.

In addition to being accredited by the UK Universities Accreditation Group, the training courses have achieved accreditation by the Federation of Laboratory Animal Science Associations (FELASA). This is recognised as a mark of quality in Europe and facilitates movement of researchers within the European Union, including in the post-Brexit period. Oxford has been accredited for 10 years and was joined this year by Cambridge University (currently the only two institutions in the UK with accreditation).

The Course Director, the two NVSs and a member of Biomedical Services act as Named Training and Competence Officers under the Home Office Establishment Licence. Additional support for training is provided by NACWOs and BMS Support Staff as necessary to facilitate the training programme. The objective is to provide comprehensive and approved training for all licence holders and a high level

of assurance for the University that appropriate training is undertaken.

We continue to lead and/or collaborate with UK (eg RSPCA, LASA) and international organisations in the fields of animal welfare, experimental design and the ethical conduct of biomedical research. In a number of cases these collaborations have led to the publication of guiding principles that have been endorsed by the UK (Home Office) and Europe-wide.

All Licence Holders have to be endorsed by a competent trainer or supervisor in order to be able to complete any type of procedure or animal care work. The Oxford Online Supervision and Competency Recording database (OSCR), the internal online system that was used to record details of training and levels of competence, is no longer supported by the developers and has not been operational this year. A new system has successfully been developed with urgency and will be operational this year.

#### **Engagement with internal structure and other external organisations**

Recording of training course attendance and recording of competence is undertaken by members of the Home Office Administration Unit. NVSs, veterinary clinicians, NACWOs and other staff from Biomedical Services attend the Departmental Animal Welfare Meetings each term to promote best practice, the 3Rs and aspects of ongoing research, and to discuss the importance of compliance with A(SP)A. The Departmental Animal Welfare Meetings provide an opportunity to share best practice and deliver updates on a number of topics such as Annual Return of Procedure Guidance, the Refinement initiative, access to and information on guidance available via the bms sharepoint site, effective breeding according to the Home Office GAA toolkit, international collaboration on animal research projects, and various procedural changes.

The University of Oxford remains a signatory (one of over 250) to the statement supporting the EU Directive on the protection of animals used for scientific purposes.

Unfortunately, the annual Oxford 3Rs Research Day was cancelled this year due to COVID-19-related restrictions. Instead, there have been a series of online discussions and presentations to promote the 3Rs and best practice in

research. Though not ideal, the online options have provided a platform for participation by a wide range of delegates: Project Licence Holders, Personal Licence Holders, Veterinary Surgeons, Animal Welfare Staff and others with an interest in animal-based research. The University continues to promote engagement with replacement technology, the importance of public engagement in animal research, non-invasive methods in animal research, and experimental design.

The 3Rs Subcommittee and the Home Office Administration Unit have continued to liaise throughout the year with the National Centre on the 3Rs (NC3Rs)<sup>3</sup> to promote best practice and to incorporate the 3Rs principles in animal research projects. The chair of the University's 3Rs Subcommittee is a member of the NC3Rs Grant Assessment Panel and participated in briefings to NC3Rs-coordinated projects. Oxford students and researchers are actively encouraged to participate in NC3Rs grant programmes, with positive results in the form of research grants to date. Biomedical Services funds 50% of an NC3Rs post located within the University. The post holder divides their time between University training and welfare meetings, and sits on the 3Rs Subcommittee of ACER. The rest of their time is spent monitoring and interacting with external groups, bringing new concepts, techniques and shared best practice into the University to be reviewed and adopted where appropriate.

Visits to animal areas of the Biomedical Services Building have been cancelled this year. It is intended that the opportunity to visit the facilities will be once again extended to family members, University staff with an interest in animal-based research and other groups as soon as the restrictions imposed by the pandemic are lifted.

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<sup>3</sup> The NC3Rs is the UK's national organisation for the discovery and application of new technologies and approaches to replace, reduce and refine the use of animals for scientific purposes.