

Gazette Supplement



Committee on Animal Care and Ethical Review

Annual Report 2021

The University of Oxford 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 has been revised to align with the latest revision of the Act that was completed in 2012 and subsequent changes in the Home Office Animals in Science Regulation Unit (ASRU) process. For the purposes of this report the Act is referred to as A(SP)A. The Animal Care and Ethical Review Committee (ACER) is the overarching ethical review committee. The ACER Committee 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, the Named Person Responsible for Compliance (NPRC) and the Project Establishment Licence Holder (PEL Holder) on the ethical treatment and welfare of animals used in conjunction with scientific, medical and zoological research projects. 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.

A(SP)A requires all research using animals to be 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 the effects are mitigated through the appropriate use of anaesthetic and analgesia and are 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, through cooperation 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

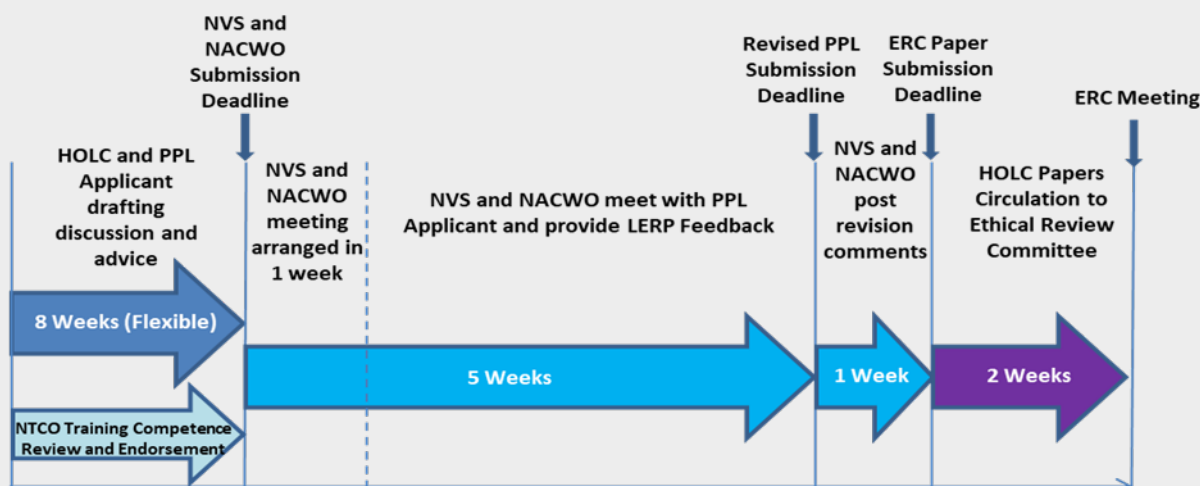
The Home Office is entitled to conduct unannounced visits to the University animal housing and research facilities at any time. Visits have not taken place during the current reporting period due to the implementation of COVID-19 control measures.

ASRU has implemented a revised licensing process during the reporting year that removed establishment-specific Home Office Inspectors and changed the process for personal and project licensing. The University continues to work closely with ASRU at the Home Office and continually reviews and adapts internal processes to ensure compliance.

The Ethical Review Process

HOME OFFICE LICENCES

The Home Office computer-based application ASPeL is now used for the majority of licensing activities including submission of PIL (Personal Licence) and PPL (Project Licence) applications, PPL annual returns, PPL transfers and secondary availability at other establishments, and final retrospective report submission where required. The Home Office Administration Unit (HOAU) is a section within Biomedical Services comprising three Home Office Liaison Contact Officers (HOLC), a Home Office Liaison Administrator and a part-time Project Licence Writing Advisor. The HOAU has responsibility for providing guidance on the Ethical Review Process for new PIL and PPL applicants and coordinating the review and submission process that takes place before applications are considered by the AWERBs. HOAU also manage and process approved applications for subsequent submission to the Home Office. The Home Office Administration Unit maintains oversight and management of all applications and guides applicants both 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 pre-AWERB process is illustrated in the diagram below.



The HOLCs also act as Committee Secretaries for the ACER Committee and the six other AWERBs managing the regulation and membership of each committee, the annual schedule of more than 34 review meetings, and all compliance and legislative aspects of the ethical review process.

THE ANIMAL WELFARE AND ETHICAL REVIEW BODIES

There are seven AWERBs¹ 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 63/2010². 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 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 require the aspects

of collaborative research involving Oxford-based researchers to comply as much as possible with the welfare and ethical standards, and 3Rs requirements, that apply across the University.

The ACER Committee also has a subcommittee that considers the application of the principles of the 3Rs in research. The 3Rs subcommittee considers aspects of the 3Rs reported to AWERBs through the retrospective review process and circulates best practice information and recommendations to the research community. There is a proposal being considered to review the current AWERB structure and division of responsibilities to streamline the ethical review process.

Personal Licences (PILs)

At the end of the reporting period the number of PILs held by researchers at Oxford was 1,137. 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 also are 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 245 new PILs were issued to University staff and students, while 222 PILs were revoked for staff and students who ended their courses, completed their research or moved to other establishments.

PERSONAL LICENCE ACTIVITY JANUARY-DECEMBER 2021

Month	PILs issued	PILs revoked
January 2021	22	9
February 2021	10	6
March 2021	12	13
April 2021	37	53
May 2021	10	13
June 2021	15	0
July 2021	14	5
August 2021	14	5
September 2021	23	4
October 2021	19	34
November 2021	39	43
December 2021	30	36
Total	245	222

Project Licences

The maximum number of active PPLs held by researchers at the University during the period of the report was 169, compared to 153 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

¹ This includes the Animal Care and Ethical Review Committee (ACER).

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

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 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 49 new project applications were approved and submitted to the Home Office, compared to 33 applications in the previous reporting period, representing an increase of 48% in licences held. A total of 72 amendment requests for existing projects were approved, compared to 64 amendment requests in the previous year, representing an increase in amendment applications of 12.5%. The period of the report 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. Any 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 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.

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

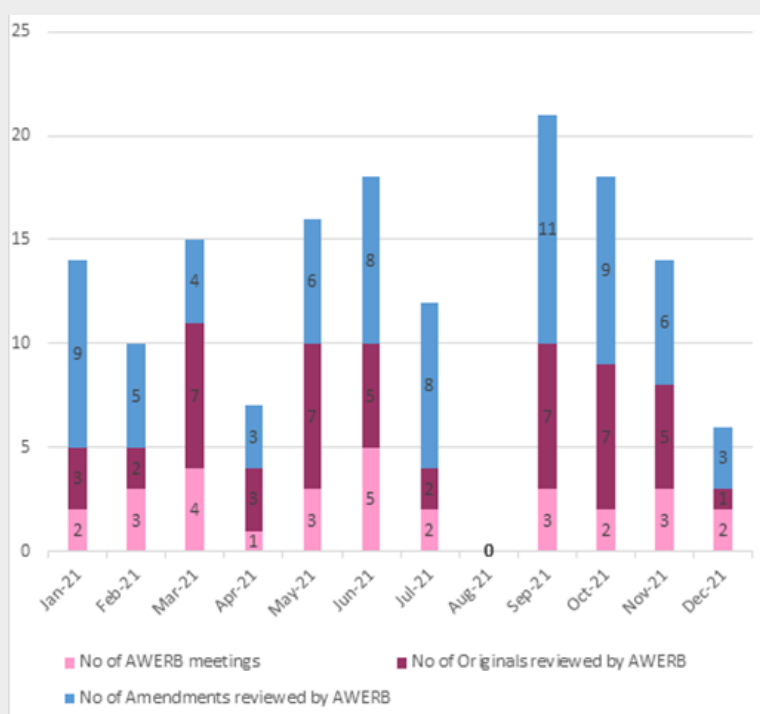
Animal Welfare and Ethical Review Body	Total (169)	% PPLs
Animal Care and Ethical Review Committee	48	29
Clinical Medicine	77	46
Department of Physiology, Anatomy and Genetics with Experimental Psychology	20	12
Pathology	8	5
Pharmacology	12	7
Zoology	4	2

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), which 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,

APPLICATIONS REVIEWED BY AWERB JANUARY–DECEMBER 2021



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.

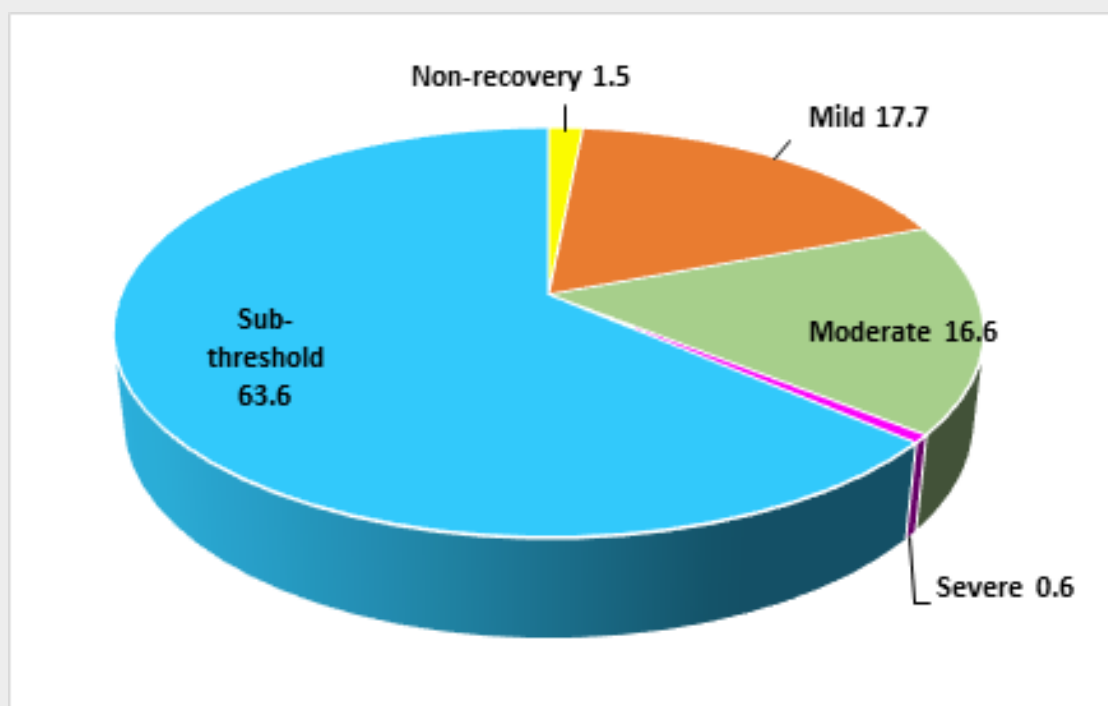
A variety of different species of animals are used in research projects at the University. Data on animal numbers used was not available when compiling this report as the Home Office Return of Procedures exercise was in progress for 2021 and will not be complete at the time of submission. In order to provide

continuity of reporting the data on the number of animals used and severity recorded in procedures from 2020 is provided.

Animal Use

A total of 169,511 animals were used in 2020, down by 59,625 compared to 2019 (229,163). The species and total number of each along with the severity experienced is given in the table.

Severity	Mice	Ferrets	Pigs	Rats	Non-Human Primates	Other birds	Guinea-Pigs	Zebra fish	Other Fish	Other Rodents	Grand Total	% severity
Non-recovery	1,986	3	7	508			7	46			2,557	1.5
Mild	27,567			84	1	46	16	2,333	4	17	30,068	17.7
Moderate	27,565	7		171	10			292	2	19	28,066	16.6
Severe	695			10	4			300	76		1,085	0.6
Sub-threshold	105,925			182				1,628			107,735	63.6
Grand Total	163,738	10	7	955	15	46	23	4,599	82	36	169,511	
% of species	96.5943	0.0059	0.0041	0.5634	0.0088	0.0271	0.0136	2.7131	0.0484	0.0212	100	



The percentage of animals used under each severity category is shown. The majority of animals used experienced sub-threshold actual severity.

Veterinary and Named Animal Care and Welfare Officer staff

The current Veterinary Team is made up of five Named Veterinary Surgeons (NVS) that equate to four full-time equivalent posts. 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 Officers (NACWOs) 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 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 (ASPA). A large proportion of this training is delivered by the Veterinary Team and includes the background to ASPA, ethics, concepts around the experimental effect on the animal, anaesthesia and Project Licence preparation. The NVS role has a practical aspect too and involves 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

Biomedical Services continues to offer a suite of Home Office-approved training courses to provide the necessary skills and qualifications for researchers in animal research. Delivery of training has continued despite the restrictions imposed by the COVID-19 pandemic, with the majority of training delivered online.

Biomedical Services training courses are 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. Biomedical Services at the University of Oxford has held FELASA accreditation for more than 10 years.

The Training Director also acts as the lead Named Training and Competence Officer (NTCO); an appointment required under A(SP)A in establishments where animals are used in research. There are a further eight NTCOs: one administrative officer and seven who are also NACWOs that assist in the assessment of training and competence of research staff. All Licence Holders and some other animal care staff have to be endorsed as competent by an approved trainer or supervisor in order to be able to complete any type of procedure or animal care work. The migration of training and competence records to the Mouse Colony Management System was completed this year.

Collaboration with UK (eg RSPCA, LASA) and international organisations in animal welfare, experimental design and the ethical conduct of biomedical research continues.

Engagement with internal structure and other external organisations

NVS, 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.

The annual Oxford 3Rs Research Day was held online this year due to COVID-19-related restrictions. The event was well attended and 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 with the National Centre on the 3Rs (NC3Rs)³ throughout the year to promote best practice and to incorporate the 3Rs principles in animal research projects. Oxford students and researchers are actively encouraged to participate in NC3Rs grant programmes and award schemes with positive results in the form of a Global 3Rs Award for vaccine development and Honourable Mentions for two Oxford-based researchers during the reporting period.

Visits to animal areas of the Biomedical Services Building were again 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.

³ 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.

