This Handbook will be updated from time to time to reflect current advice from the Home Office and as the Home Office and University processes evolved from a paper based to electronic process.

Everyone using this document is advised to check with either their Deputy Director/Named Training and Competence Officer or the UBS Website to make sure they have the most up to date version.
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1. Introduction

The University of Cambridge expects the use of animals in research to be conducted with exemplary care and welfare, which are paramount to the running of this institution.

The local Animal Welfare and Ethical Review Body [AWERB] Process has been set up with the strictest possible ethos to fulfil this particular emphasis of ethical review of animals in research. The committees that make up the University AWERB are formed to advise the holder of a section 2C (establishment) licence [PELh] on all science, aspects of animal welfare and ethical issues relating to the use of animals in research at the University the majority of which is conducted under the Animals (Scientific Procedures) Act 1986 Amendment Regulations 2012 (SI 2012/3039) [ASPA].

The AWERB will serve as a learning process by emphasising to research staff the ethical and animal welfare implications of their research, thereby permeating a culture of animal care and respect throughout the University of Cambridge.

The aim of this induction document is to introduce AWERB members and lay people, scientists especially those writing project licences, research assistants, animal technicians and care personnel to the AWREB processes applied with respect to the use of animals in research at the University of Cambridge, set locally and within UK Legislation.

Contained within this document is information on ASPA, the University AWERB process, the project licence writing process and information on key personnel at the University who are employed to advise and help, or who have legal responsibilities under ASPA.

2. Animal Welfare Policy

The University of Cambridge recognises that research using animals has made, and continues to make, a vital contribution to the understanding, treatment and cure of major human and animal diseases. We realise that we must not be complacent and therefore will actively promote, investigate and use new methods of research that can replace animals and only ever use animals where these alternatives are currently not viable. Our scientists are instrumental in devising humane alternative methods to animal models that can effectively reproduce the complex biological characteristics of man and animals to challenge the need for animal use with the goal of eventually ending the use of animals in medical and veterinary research.

In the UK, research with animals is governed by a range of legislation, including ASPA and, in the case of teaching to veterinary students, the Veterinary Surgeons Act 1966.

Our research compliance is regulated by ASPA and is monitored by University staff, including the Named Veterinary Surgeons [NVS] and by the assigned Home Office inspectors. All members of the University carrying out procedures regulated under ASPA must by law have prior training, relevant experience, be assessed as adequately competent to work with animals and their programme of work must be licenced by the Home Office. All animal research project licences are subject to robust assessment and consideration by the University AWERB process consisting of independent lay-members, veterinary surgeons, animal welfarists, animal care staff and academic representation from outside the animal research field. Only where a programme of animal research is necessary and considered justified by this body and with due consideration to Reduction, Replacement and Refinement [the 3Rs] will it be submitted to the Home Office for assessment and processing.
To this end, we strictly adhere to the principle of law which demands that where a non-animal approach to research exists, it should be used. The principles of the 3Rs underpin all related work at the University; ensuring that if animals have to be used then the numbers are minimised and that procedures, care routines and husbandry are refined and under constant review to maximise welfare. All involved are charged with bringing to our attention, including to the highest level of management, without fear of personal negative consequence, any animal welfare concerns or issues that jeopardize our commitment to these principles and must therefore follow the University procedures for whistleblowing and escalation of concerns. The University is committed to openness and transparency regarding its use of animals in research and will make every endeavour to deliver on its registration to the Concordat (see Appendix B: Links).

Where wild animals need to be observed and studied in their natural habitat, our responsibilities will extend outside of the UK legislation and country borders to ensure research in non-laboratory settings is also undertaken with full consideration of our robust ethical justification and animal welfare. University staff undertaking regulated procedures, or collaborating with scientists, abroad or at other ASPA licensed user establishments, or work performed elsewhere during sabbaticals will employ the same standards required under UK legislation.

Where no alternative exists to work involving animals of protected species, the University will adhere to high standards of humane care and treatment of those animals and adhere with all relevant laws and guidelines. Wherever possible and feasible, rehoming laboratory animals once they have been released from the controls of the Act is investigated. The University expects everyone involved in animal research to follow the Laboratory Animal Science Association [LASA] guiding principles as set out in their published documents (see Appendix B: Links) and apply the use of analgesia and anaesthetic regimes together with applying a robust welfare ethos.

The key principles governing all our animal research are:

a) It is conducted only when it will contribute to the advancement of knowledge that is likely to lead to improvement of the health and welfare of animals or human beings or involves observations that will lead to a greater understanding of the animals themselves.

b) It is undertaken on the basis of well-defined scientific objectives and the advancement of knowledge, giving due consideration to the welfare of the animals, minimising the number of animals employed in each experiment and avoiding unnecessary duplication.

c) The University will actively support the development, validation and adoption of appropriate alternatives to the use of animals, aimed at eliminating the need for animals in research.

d) Animals are transported, housed and cared for by dedicated and appropriately trained staff under professional supervision in a manner designed to maximise health and wellbeing of the animals, with provisions for environmental enrichment.

e) A Named Veterinary Surgeon is contactable at all times for consultation, care and attendance.

f) The University of Cambridge considers that the use of animals in research is not a right, but a responsibility that must be earned by demonstration of our staff’s commitment to achieving the highest standards of animal welfare and an ongoing commitment to replacement, reduction and refinement.
### 3. Glossary of Terms

<table>
<thead>
<tr>
<th>Term</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>2C Licence</td>
<td>A licence issued by the Home Office which specifies where animals may be housed which are intended for or are used in regulated procedures and names those with responsibilities under ASPA</td>
</tr>
<tr>
<td>3R’s</td>
<td>The principles of replacement, reduction and refinement</td>
</tr>
<tr>
<td>Actual severity</td>
<td>The actual intensity of pain, suffering, distress or lasting harm experienced by an animal in a procedure or series of procedures. It should be the highest level experienced at any point during the course of the procedure and should take into account any cumulative effects</td>
</tr>
<tr>
<td>ASC</td>
<td>The Animals in Science Committee – the independent, non-departmental public body set up under ASPA sections 19 and 20</td>
</tr>
<tr>
<td>ASPA</td>
<td>The (Scientific Procedures) Act 1986 as amended by the Animals (Scientific Procedures) Act 1986 Amendment Regulations 2012 incorporating changes brought in by the European Directive (2010/63/EU) on the protection of animals used for scientific purposes – also referred to as the Act</td>
</tr>
<tr>
<td>ASRU</td>
<td>The Animals in Science Regulation Unit. ASRU is the unit of the Home Office responsible for implementing ASPA and comprises inspectors, licensing officers and those responsible for policy</td>
</tr>
<tr>
<td>AWERB</td>
<td>Animal Welfare and Ethical Review Body</td>
</tr>
<tr>
<td>Cumulative effect</td>
<td>The effect which occurs where, in a series of procedures, a second or subsequent procedure has a compound effect, which may be positive or negative, in terms of causing pain, suffering, distress or lasting harm</td>
</tr>
<tr>
<td>Harm–benefit analysis</td>
<td>An analysis in which the likely adverse effects in a procedure within a project are weighed against the potential benefits of the project for people, animals or the environment</td>
</tr>
<tr>
<td>HOI</td>
<td>Home Office Inspector</td>
</tr>
<tr>
<td>HOLC</td>
<td>Home Office Liaison Contact. This title is often used by establishment licence holders to denote one or several key contacts for communication with the Home Office</td>
</tr>
<tr>
<td>Humane end-point</td>
<td>Clear, predictable and irreversible criteria that allow early termination of a procedure before an animal experiences harm that is not authorised or scientifically justified</td>
</tr>
<tr>
<td>IAT</td>
<td>Institute of Animal Technology</td>
</tr>
<tr>
<td>LASA</td>
<td>Laboratory Animal Science Association</td>
</tr>
<tr>
<td>NACWO</td>
<td>Named Animal Care and Welfare Officer</td>
</tr>
<tr>
<td>NC3Rs</td>
<td>National Centre for Replacement, Refinement and Reduction of Animals in Research</td>
</tr>
<tr>
<td>NCO</td>
<td>Named Compliance Officer – a term sometimes used for the Named Person Responsible for Compliance – also see NPRC</td>
</tr>
<tr>
<td>NIO</td>
<td>Named Information Officer</td>
</tr>
<tr>
<td>NPRC</td>
<td>Named Person Responsible for Compliance (the preferred term, also sometimes referred to as a Named Compliance Officer)</td>
</tr>
<tr>
<td>NTCO</td>
<td>Named Training and Competency Officer</td>
</tr>
<tr>
<td>NVS</td>
<td>Named Veterinary Surgeon</td>
</tr>
<tr>
<td>PELh</td>
<td>The holder of a section 2C (establishment) licence under ASPA</td>
</tr>
<tr>
<td>PILh</td>
<td>The holder of a personal licence under ASPA</td>
</tr>
<tr>
<td>POLE</td>
<td>Place other than a licensed establishment (formerly known as a ‘PODE’)</td>
</tr>
<tr>
<td>PPLh</td>
<td>The holder of a project licence under ASPA</td>
</tr>
<tr>
<td>Procedure</td>
<td>An act of commission, deliberate omission or permission applied to, or having any effect on, an animal</td>
</tr>
<tr>
<td>Prospective Severity</td>
<td>The intensity of pain, suffering distress or lasting harm which any animal subjected to a protocol is likely to experience during the course of that protocol after applying all the appropriate refinement techniques</td>
</tr>
<tr>
<td>Protocol</td>
<td>A procedure or series of procedures carried out for a particular purpose as part of an authorised project</td>
</tr>
<tr>
<td>Regulated Procedure</td>
<td>A procedure which is regulated under ASPA</td>
</tr>
</tbody>
</table>


<table>
<thead>
<tr>
<th><strong>Retrospective assessment</strong></th>
<th>The formal assessment required in the Directive 2010/63/EU (Article 39) of specific types of projects, either during or at the end, to determine, amongst other things, whether the objectives have been achieved and whether lessons can be learnt to further the implementation of the 3Rs</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Retrospective review</strong></td>
<td>One of the tasks set out in the Directive (Article 27(d)) requiring the AWERB to follow the development and outcome of all projects carried out at the establishment and identify and advise on the implementation of the 3Rs</td>
</tr>
<tr>
<td><strong>RSPCA</strong></td>
<td>Royal Society for the Prevention of Cruelty to Animals</td>
</tr>
<tr>
<td><strong>Severity</strong></td>
<td>The intensity of the pain, suffering, distress or lasting harm experienced by an animal during a procedure</td>
</tr>
<tr>
<td><strong>Severity classification</strong></td>
<td>The process of assigning a severity category to a protocol. It may be sub-threshold, mild, moderate, severe or non-recovery. It is based upon the greatest degree of pain, suffering, distress or lasting harm likely to be experienced by any animal within that protocol after applying all appropriate refinement techniques</td>
</tr>
<tr>
<td><strong>Severity limit</strong></td>
<td>The highest level of pain, suffering, distress or lasting harm that may be experienced by any animal undergoing an authorised procedure (or series of procedures). It should normally be expressed as a humane end-point in relation to an adverse effect which may be expected to occur. Hence a procedure may have a number of severity limits which apply at different times in relation to different adverse effects</td>
</tr>
<tr>
<td><strong>Technique</strong></td>
<td>A single action carried out on an animal as part of a procedure or series of procedures</td>
</tr>
<tr>
<td><strong>The Act</strong></td>
<td>The Animals (Scientific Procedures) Act 1986 as amended by the Animals (Scientific Procedures) Act 1986 Amendment Regulations 2012 incorporating changes brought in by the European Directive (2010/63/EU) on the protection of animals sued for scientific purposes – also referred to as ASPA.</td>
</tr>
<tr>
<td><strong>UBS</strong></td>
<td>University Biomedical Services</td>
</tr>
</tbody>
</table>
4. Animals (Scientific Procedures) Act 1986

The use of animals in scientific procedures in the UK is regulated by ASPA, which is widely viewed as the most rigorous piece of legislation of its type in the world. It puts into effect, and in some aspects exceeds, European Directive 2010/63/EU (regarding the protection of animals used for experimental and other scientific purposes) and offers a high level of protection to animals whilst recognising the need to use animals in biomedical research, the development of new medicines and scientific testing. It also has sufficient flexibility to allow the latest ideas and technology to be taken into account when deciding whether the use of animals is justified.

1. What is a Protected Animal?
All living vertebrates (other than a human, including certain immature forms) and any living cephalopod.

Embryonic and foetal forms of mammals, birds and reptiles are protected animals once they have reached the last third of their gestation or incubation period. Larval forms of fish and amphibians are protected once they are capable of feeding independently. Cephalopods are protected animals from the point when they hatch. A procedure carried out on a foetal, larval or embryonic form at an earlier stage of development may be regulated if the immature form is allowed to live until it reaches the stage of development when it becomes protected and if the procedure may cause the animal to suffer distress or lasting harm above the lower threshold.

2. What is a Regulated Procedure?
A procedure is regulated if it is carried out on a protected animal for a scientific or educational purpose and may cause that animal a level of pain, suffering, distress or lasting harm equivalent to, or higher than, that caused by inserting a hypodermic needle according to good veterinary practice. This is referred to as the ‘lower threshold’.

Regulated procedures may be acts of:
   a) commission, for example an action such as dosing or sampling; or
   b) deliberate omission, for example withholding food or water; or
   c) permission, for example the natural breeding of animals with harmful genetic defects.

3. What Licences do you require to use animals in research?
Under ASPA, both personal and project licences are required. These ensure that those undertaking research using animals are qualified, suitably trained, supervised and assessed for competence; that alternatives to animals are used wherever possible; that the number of animals used is minimised; and that any suffering or other harmful effects experienced by the animals are minimised and the harms caused to the animals are weighed against the potential benefits (to humans, animals or the environment). Standard licence conditions add further controls and are aimed to minimise pain and suffering. In addition, work can only be carried out at licensed establishments which meet high standards of care and accommodation and which have appointed suitable Named Persons (veterinary, animal welfare, training, compliance and information personnel; see Section 5).
5. Named Persons under ASPA

Establishment Licence Holder [PELh]

2C licences are issued to persons occupying positions of relevant authority at the establishments. Communication with those holding responsibilities under the Act and co-ordination of their activities are key functions for the PELh. They must implement and maintain local AWERB processes acceptable to the Secretary of State [SoS].

2C licences may be held by a natural person (an individual) or a legal person (a corporate entity such as a pharmaceutical company, university or research institute with corporate status).

A PELh must be subject to jurisdiction within the UK which means the PELh must have either personal residence or company registration in the UK. Where the holder is a corporate entity, the ultimate legal responsibility of the establishment licence holder will be carried out by the individual legally accountable for the corporate entity (usually a Company Secretary). However where that person is remote from work under ASPA the responsibility for compliance will lie with the Named Person Responsible for Compliance [NPRC]. Nevertheless, ultimate legal responsibility lies with the corporate entity.

Where the PELh is a corporate entity an individual must be appointed to serve as the NPRC. In all other circumstances the individual named as the PELh will be the same as the NPRC. The NPRC should therefore be of similar standing in terms of authority and seniority.

PELhs must specify named individuals who are responsible for the following activities:

a. Ensuring that the requirements of ASPA and the conditions of the establishment licence are complied with – the NPRC. This will usually be the holder of the establishment licence;

b. Advising on the health, welfare and treatment of the animals – the Named Veterinary Surgeon [NVS] with expertise in laboratory animal medicine. Exceptionally it may be possible to nominate other suitably qualified experts where the PELh can show that the nominated person(s) are more appropriate for this role;

c. Overseeing the welfare and care of the animals – Named Animal Care and Welfare Officer [NACWO];

d. Ensuring that those dealing with animals are adequately educated, trained and supervised until they are competent and that they continue to undertake appropriate further education - the Named Training and Competency officer [NTCO]; and

e. Ensuring that those dealing with animals have access to information they need about the species they are using – the Named Information Officer [NIO].

Named Veterinary Surgeon [NVS]

The NVS is responsible for monitoring and providing advice on the health, welfare and treatment of animals and should help the PELh to fulfil responsibilities under ASPA. The NVS should be entrusted with the necessary management authorities to carry out their role effectively, and be seen to have senior management’s support. NVSs should be provided with appropriate training, and should expect that appropriate facilities and resources are made available for adequate veterinary care of the protected animals at the establishment, including adequate support to ensure that veterinary care can be provided at all times.

The NVS must be a member of the Royal College of Veterinary Surgeons (RCVS) with expertise in the species being used in the establishment. The NVS is accountable to the PELh for fulfilling their duties and responsibilities. In addition, NVSs should also observe their professional responsibilities to the animals
under their care, to other veterinary surgeons, to the public and to the Royal College of Veterinary Surgeons, as set out in the RCVS Code of Professional Conduct for Veterinary Surgeons.

For the role and responsibilities of the NVS see the Home Office Guidance to ASPA Section 8.6.2.

**Named Animal Care & Welfare Officer [NACWO]**

The NACWO is responsible for overseeing the day-to-day husbandry, care and welfare of the protected animals held at their establishment. They should be a source of independent advice on welfare and care to minimise suffering and optimise the welfare of all animals that are bred, kept for use or used at the establishment.

A suitable person might, for example, be a senior animal technician with an animal technology qualification or an experienced stockperson with a qualification in agricultural science. The Institute of Animal Technology [IAT] maintains a Register of Animal Technologists who may be appropriate to fill a NACWO post. Further details are available at www.iat.org.uk.

NACWOs should have appropriate personal authority to promote high standards and will need good communication and diplomacy skills to champion a culture of care amongst both scientific and husbandry staff.

NACWOs are expected to have appropriate managerial authority to enable them to ensure that high standards of husbandry and care are practised, meeting or exceeding the minimum standards set out in the Home Office Code of Practice.

This responsibility extends into all areas named on the establishment licence.

For the role and responsibilities of the NACWO see the Home Office Guidance to ASPA Section 8.8.2.

**Named Training and Competency Officer [NTCO]**

The NTCO is responsible for ensuring that all those dealing with animals are adequately educated, trained and supervised until they are competent and that they continue to undertake appropriate further training to maintain their expertise. The role may be undertaken by a single person or by a number of people at a large establishment. It is important that all tasked with this role at an establishment should work to the same principles and standards and that, where more than one person in an establishment is an NTCO, each understands their own individual responsibilities, e.g. for a particular animal unit, species or type of work.

The NTCO needs to be sufficiently senior to influence others and make decisions on training issues. It is likely that this role will require significant resource and the support of senior management.

The NTCO may or may not be directly involved in the provision of training; instead the role is to oversee the process, making sure that training is taking place, that standards are acceptable and that a consistent approach is being adopted and delivered. Role holders require good communication, management and organisational skills.

NTCOs are required to endorse each application for a new or amended personal licence which is requesting primary availability at the establishment. However, they may not endorse their own application for a personal licence or amendment. If an NTCO holds or wishes to hold a personal licence, the establishment licence holder must nominate a second NTCO to independently endorse such applications.

For the role and responsibilities of the NTCO see the Home Office Guidance to ASPA Section 8.9.2.
Named Information and Officer [NIO]
The NIO is responsible for ensuring that those dealing with animals in the establishment have access to information they need about the species held at the establishment and procedures being performed. The NIO must have good communication and networking skills.

For the role and responsibilities of the NIO see the Home Office Guidance to ASPA Section 8.10.2

6. Home Office Licensed Personnel

Project Licence Holder [PPLh]
A project licence is a licence granted by the SoS which specifies a programme of work and authorises the application, as part of that programme, of specified regulated procedures to animals of specified descriptions at a specified place or places.

Each project licence is granted to a single, named individual. The Home Office does not grant project licences to organisations or research groups, nor does ASPA recognise deputies on project licences. The PPLh should be the most suitable person in the research group or department to manage the project and have the appropriate level of authority to do so. It is not essential that a PPLh is also a personal licence holder.

The PPLh may appoint individuals with whom they agree local arrangements to assist them in their duties as a PPLh, for example if the project is being performed on more than one site within the same establishment, or if the PPLh is absent from time to time. However, this does not take away from the PPLh their legal responsibility for compliance with their licence and conditions at all times.

For the role and responsibilities of the PPLh see the Home Office Guidance to ASPA Sections 5.7.6 and 5.23.

Personal Licence Holder [PILh]
Under ASPA, a PILh is not allowed to apply a regulated procedure to an animal unless all three of the following requirements are met:

a. they hold a personal licence authorising them to apply a procedure of that description to an animal of that type;

b. the procedure is applied as part of an authorised programme of work specified in a project licence; and

c. the place where the procedure is carried out is specified in that project licence.

Each personal licence shows that the Home Office has authorised the PILh to carry out specified categories of regulated procedures, under supervision if necessary.

For the role of the PILh see the Home Office Guidance to ASPA Section 4.13.

7. Home Office Animal Science Regulatory Unit [ASRU]

ASRU is the unit of the Home Office responsible for implementing ASPA and comprises inspectors, licensing officers and those responsible for policy. These officials operate the licensing system and provide policy advice to Ministers.
Animals (Scientific Procedures) Inspectorate [ASRUI]

Home Office inspectors are responsible for:

a. Providing advice to the SoS on applications for ASPA licences, and on requests for their variation or revocation;
b. Advise on the periodic review of licences, including retrospective assessments;
c. Visiting licensed breeding, supply and user establishments, and other places where work under ASPA is carried out (POLEs) to monitor standards and practices and compliance with ASPA and the conditions of any licences;
d. Report all non-compliance and recommend the action to be taken; and
e. Encourage good practice.

Inspectors have no powers to grant, refuse, vary or revoke licences. They provide this advice to the SoS. Granting and amending licences, and other actions, are carried out by administrative staff acting on behalf of the SoS.


It is a Government requirement that all establishments designated under ASPA should have an AWERB that is acceptable to the Home Office. It is the responsibility of the holder of a section 2C (establishment) licence under ASPA [PELh] to present the Home Office with a description of an AWERB suitable for the establishment. The requirements for a suitable process were initially described to PELh in the Home Office letter of 1 April 1998.

ASPA Schedule 2C, Part 1, paragraph 6 requires that there is a standard condition on the establishment licence which stipulates that the PELh must establish and maintain a body known as the AWERB. The minimum composition of the AWERB and the tasks which must be carried out, as specified in Article 27 of the European Directive 2010/63/EU as follows:

a) Advise staff dealing with animals in the licensed establishment on matters related to the welfare of the animals, in relation to their acquisition, accommodation, care and use;
b) Advise on the application of the 3Rs, and keep it informed of relevant technical and scientific developments;
c) Establish and review management and operational processes for monitoring, reporting and follow-up in relation to the welfare of animals housed or used in the licensed establishment;
d) Follow the development and outcome (retrospective review) of projects carried out in the establishment, taking into account the effect on the animals used; and to identify and advise on elements that could further contribute to the 3Rs; and
e) Advise on re-homing schemes, including the appropriate socialisation of the animals to be re-homed.

Additionally Section 10.5 of the Home Office Guidance sets out the following AWERB tasks:

a) Advise the PELh whether to support project proposals, primarily considering such proposals from a local perspective and bringing local knowledge and local expertise to bear;
b) Assist with the retrospective assessment of relevant projects carried out at their establishment; and
c) Respond to enquiries, and consider advice received from the Animals in Science Committee [ASC].

More generally Section 10.5 of the Home Office Guidance requires AWERBs to:
a) Promote awareness of animal welfare and the 3Rs;
b) Provide a forum for discussion and development of ethical advice to the PELh on all matters relating to animal welfare, care and use at their establishment;
c) Support named persons, and other staff dealing with animals, on animal welfare, ethical issues and provision of appropriate training;
d) Help to promote a ‘culture of care’ within the establishment and, as appropriate, in the wider community.

9. The University Biomedical Services [UBS] Committee Structure

The University of Cambridge AWERB process evolved further following the 2015 reorganization of the animal facilities management structure within the University which required a review of the University AWERB process in order to align this with the revised management structure, and to improve its overall effectiveness and efficiency. Further information about the University policy and terms of reference for the AWERB committees detailed below can be found in the University Biomedical Services Policy and Terms of Reference documents on the University Biomedical Services website and the UBS committee structure is shown on the next page.

The revised AWERB Process ensures that the University continues to consider the use of animals in or destined for use in Scientific Procedures.

1. Biomedical Services Governance and Strategy Committee
   This committee has overall responsibility for setting the strategic direction of the Biomedical Services Division and ensuring governance systems, which include the AWERB process, are legally compliant and fit for purpose.

2. AWERB Standing Committee
   This committee is the principal body that reviews all research work and reports to the PELh. It comprises internal and external members with an external Chairperson independent of the University. Whilst protecting confidentiality, it may be appropriate to share some of the outputs from the AWERB with colleagues in the establishment, and the wider community, to promote awareness of the AWERB’s activities. The AWERB Standing committee encompasses two other committees: the AWERB Sub- and AWERB Licence Amendment committees.

3. AWERB 3Rs Committee
   This committee reports to AWERB Standing Committee and draws together and makes available information relating to the 3Rs and provides advice and support to the AWERB Standing, Named Persons Committees and to the training school as appropriate. This committee responds to requests from the AWERB Standing Committee to consider the 3Rs sections of some new project licence applications and amendments. In addition the 3Rs committee considers all Retrospective Review and Assessments of project licence from a 3Rs perspective.

4. AWERB Named Persons Committee
   This committee is responsible for the welfare of the animals under the care of the University. It provides a forum for examining the standards of accommodation, husbandry and welfare, and monitors the research procedures to ensure full implementation of the AWERB’s recommendations. It serves as an operational management and monitoring body, reporting to the PELh and the AWERB Standing Committee.
addition this committee has the purpose of ensuring that all staff involved in the use of live animals are fully aware of their legal and ethical responsibilities under the Act sharing information, promotion of good practice, care and welfare.

5. **Project Licence Teams**
Each Project licence holder [PPLh] will be expected to form a Project Licence Team. The aim of these teams is to support each PPLh with all aspects of project licence management; for example: writing new applications, amendment and presentation to the AWERP Standing Committee.

6. **Facilities Operations and Management Committee**
This committee oversees the activities of the Users Committees and reports to the Biomedical Services Governance and Strategy Committee.

7. **Users Committees**
There are currently 11 users committees. These committees consider, at the local animal facility level, staff requirements, animal occupancy, equipment requirements, health, safety and security matters and receives reports from the Named Persons and other AWERP committees. These committees identify where new or revisions are necessary to Standard Operating Procedures [SOPs] and implement University agreed policy and SOPs.
BIOMEDICAL SERVICES
COMMITTEE STRUCTURE

Facilities Operations & Management Committee

User Committees

Biomedical Services Governance and Strategy Committee

Animal Welfare, Ethical Review Body Standing Committee

3Rs Committee

Named Persons Committee

OPERATIONS

Animal Welfare & Ethical Review
10. Project Licence – University of Cambridge Application Process

The table below details the Process Timeline for a new project licence. This process has been mapped onto a PPL Tracker (see page 17) which records the movement of all new applications from the time they are identified as required until they are granted by the Home Office. The people responsible for the Actions are detailed below the table with the exception of the Named Veterinary Surgeons.

<table>
<thead>
<tr>
<th>Task</th>
<th>Action</th>
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<tbody>
<tr>
<td>1. Either:</td>
<td>UBSCO</td>
</tr>
<tr>
<td>i. UBS Central Office (UBSCO) will notify the Deputy Director (DD) of the name of each Project Licence Holder (PPLh) 15 months’ ahead of the Project Licence (PPL) expire date. This will occur when UBS send the PPL 15 month reminder letter and tailored Retrospective Review (RR) document, OR</td>
<td>PI</td>
</tr>
<tr>
<td>ii. DD is contacted by new Principal Investigator (PI) requesting to become a PPLh</td>
<td>DD</td>
</tr>
<tr>
<td>If i. DD to confirm with PPLh whether a new licence is required, update the PPL Tracker and notify UBSCO.</td>
<td>DD</td>
</tr>
<tr>
<td>If ii. DD will update the PPL Tracker and notify UBSCO.</td>
<td></td>
</tr>
<tr>
<td>2. a) DD either meets or corresponds by e-mail with PPLh providing booklets (writing guidance, AWERB Handbook ATunes and PPL team meeting template), explaining the next steps (e.g. set up PPL Team, complete RR) and flags any other units they will be working in. b) DD enters the details of the meeting onto the PPL Tracker and sends the applicant the template of information needed for the PPL Team meeting. c) DD will notify UBSCO of the PPLs name, Department and PPL title (if available) to enable UBSCO to start setup administrative processes. d) PPLh sets up PPL Team and organises date for the first meeting and is responsible for notifying members of their PPL Team.</td>
<td>DD</td>
</tr>
<tr>
<td>3. The meeting template must be returned to PPL Team at least 1 week before meeting. If the licence is to continue work the PPLh must also return the completed RR to the PPL Team.</td>
<td>PPLh</td>
</tr>
<tr>
<td>4. a) PPLH calls group meeting – with the use of the template (and RR) talks through work. b) If work is to be undertaken in more than one Biofacility the DD for core Biofacility will take the lead on the process. c) Completed and agreed RRs will be sent to UBSCO by DD to forward to AWERB 3Rs committee. If not completed satisfactorily, DD and NVS will address issues with PPLh d) The DD will update the PPL Tracker with the date of this meeting</td>
<td>PPLh</td>
</tr>
<tr>
<td>5. a) After meeting, if ASPeL is used the DD sends the most up to date ASPeL application to PPLH and asks UBSCO to arrange ASPeL access.</td>
<td>DD &amp; UBSCO</td>
</tr>
<tr>
<td>b) If paper copy is used the DD will provide the PPLh with a link to the HO ASPeL one provided</td>
<td>DD</td>
</tr>
<tr>
<td>6. a) Draft 1 sent out by the PPLh to the DD and NVS. b) DD and NVS will quickly check Draft 1 to see if it is suitable, they will forward the draft to the PPL Team for their comments on the application only if the application is considered suitable. c) If Draft 1 is poor, only high level comments will be provided by the DD and NVS and the PPLh asked to re-read the PPL Writing Guidance and redraft their application.</td>
<td>PPLh</td>
</tr>
<tr>
<td></td>
<td>DD &amp; NVS</td>
</tr>
<tr>
<td></td>
<td>DD &amp; NVS</td>
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</tr>
<tr>
<td>d)</td>
<td>DD will enter received and response dates into the PPL Tracker and add a comment about the level of advice provided (e.g. high level advice only/detailed advice).</td>
</tr>
<tr>
<td></td>
<td><em>(after the first draft has been received and comments provided the PPLh has the opportunity to submit one further draft)</em>.</td>
</tr>
<tr>
<td>e)</td>
<td>When an acceptable draft is submitted, it will be reviewed by the whole of the PPL team and comments returned to the PPLh. PPLhs should not expect their PPL Team to comment on more than 2 drafts. At this point the Welfare Director (WD) will agree with the DD and NVS who should be the Single Point of Contact (SPC) for the licence and notify UBSCO. <strong>The SPC will be the nominated person with whom the PPLh will liaise after the application has been heard by the AWERB Committee and up to the point the application is considered ready for submission to the Home Office (HO).</strong></td>
</tr>
<tr>
<td>7.</td>
<td>a) DD and NVS to decide when the PPL is considered suitable to go to Home Office Inspector (HOI) for comment (via ASPeL or cjsm).</td>
</tr>
<tr>
<td></td>
<td>b) Either the DD will advise PLH to upload the application to ASPeL and ask the PPLh to notify when this has happened OR</td>
</tr>
<tr>
<td></td>
<td>c) If submitted ultimately as a paper copy the PPLh will provide the DD with an electronic copy of the application to send to the HOI by cjsm.</td>
</tr>
<tr>
<td></td>
<td>d) DD will update the PPL Tracker.</td>
</tr>
<tr>
<td>8.</td>
<td>a) When the draft is returned from HOI, the DD will update the PPL Tracker and advise the PPLh to update their application to incorporate HOI comments and return the next version to DD and NVS.</td>
</tr>
<tr>
<td></td>
<td>b) If using ASPeL, the PPLh will circulate the HOI’s comments to the members of their PPL Team so the PPL Team can learn from the HOI comments.</td>
</tr>
<tr>
<td>9.</td>
<td>Once the DD, NACWO and NVS have agreed, the updated PPL will be submitted to UBSCO electronically by the DD. In the covering e-mail the DD will clearly state the application is ready to go to the next available AWERB. Each application should be accompanied by: - an electronic copy of the NACWO approval form and - a copy of the HOI comments for the AWERB Committee.</td>
</tr>
<tr>
<td></td>
<td>UBSCO will update the PPL Tracker.</td>
</tr>
<tr>
<td>10.</td>
<td>a) UBSCO will keep the AWERB booking sheet up to date on the K:drive so DDs will check AWERB meeting availability. The same folder will contain the latest version of the AWERB Committee dates and when papers are due.</td>
</tr>
<tr>
<td></td>
<td>b) UBSCO will confirm allocated AWERB Committee meeting and submission dates with the DD and NVS.</td>
</tr>
<tr>
<td></td>
<td>c) UBSCO will arrange and confirm AWERB agenda with the WD and Chair, and invitations to applicants with copy to the NVS and DD.</td>
</tr>
<tr>
<td></td>
<td>d) UBSCO will confirm with the DD the PPL version to be sent to AWERB members.</td>
</tr>
<tr>
<td></td>
<td>e) UBSCO will confirm availability of NACWO attending full meeting with the NACWO according to the rota.</td>
</tr>
<tr>
<td></td>
<td>f) DD to organise the unit NACWO to attend AWERB to cover their licences.</td>
</tr>
<tr>
<td></td>
<td>g) WD to organise a scientist to review PPL and UBSCO will send invitation letter to scientist with sample questions and paperwork.</td>
</tr>
<tr>
<td></td>
<td>h) UBSCO will send the AWERB Committee members a copy of the Agenda and Papers and update the PPL Tracker.</td>
</tr>
</tbody>
</table>
11. Following the AWERB Committee meeting the AWERB comments and minutes will be compiled by UBSCO in conjunction with NVS. Minutes and comments will be agreed with the WD.

12. UBSCO will compile a letter containing AWERB comments and send this letter to PPLh, NVS, DD and HOI and will notify the PPLh who their SPC is and update the PPL Tracker.

13. a) PPLh will update their licence and return their application to the nominated SPC.
   b) The SPC will check the licence against AWERB comments and either agrees no further changes are required or will ask the PPLh to attend to matters that they have overlooked. SPC will update the PPL Tracker.
   c) When considered complete the SPC (if not the DD) will forward the electronic copy of the application to the DD.
   d) The DD will prepare the final package, and submit the application electronically to UBS and update the PPL Tracker.

14. a) If the application is to be submitted via ASPeL, the PPLH will notify the DD, NVS and UBSCO when they submit their application.
   b) The DD will update the PPL Tracker.
   c) If the application is to be submitted by post UBSCO will notify the PPLh, DD and NVS when the application is posted. A fair faced (and if appropriate a highlighted copy) of the application will be submitted to the HO.
   d) In both cases UBSCO will ask MV to sign off the application.
   e) UBSCO will update the DD and PPL Tracker.

15. a) When the 'Red Seal' is returned by the HO:
   i. Via ASPeL, UBSCO will be notified by the HO. UBSCO will notify PPLh, DD and NVS. A paper copy will be sent to DD.
   ii. By post, UBSCO will send the original to the PPLh after taking a copy for the UBSCO files and a copy for the DD.
   b) UBSCO to upload to the UBS website and update the PPL Tracker.
   c) PPLh must make sure everyone who needs access to a copy of the licence has access.

Notes:
1. To be reviewed when ASPeL goes live.

DD's:
Alan Graham: Sub-Department of Animal Behaviour, Barcroft Centre, Innes Building, Anatomy, Combined Facility rodent and fish.
Sam Jameson: Gurdon Institute, Stem Cell Institute, Pathology
Maggie Gentry: CBS, Phenomics, Hutchison Frogs and Brain Repair Centre

UBSCOs:
Primary contact – Laura Elmer
Secondary contact – Zara Preston
Application Process

The flow diagrams on the following two pages illustrate the process for obtaining a Project Licence. A Project Licence writing course, run by the Training School, is mandatory for new applicants and strongly advised for those writing licences to continue their programme of work when their current licence expires. As explained above the onus is on the applicant to generate a first draft which can be usefully critiqued by the members of your Project Team.

For further information please contact the Licence and Training Support Team in UBS (UBSSHOLicencing@admin.cam.ac.uk; UBSS.Office@admin.cam.ac.uk).
Timeline to a new Project Licence for new licence holders

### Timeline

**9 to 5 months**

1. **University Biomedical Services (UBS)**
   - Contact UBS and Deputy Director.
   - Organise Project Team meeting.

2. **PPL Holder**
   - Attend Home Office PPL course, if required. Obtain certificate.
   - Provide current form and advice as required.

3. **Project Team**
   - Write 1st PPL draft. Internal error check.
   - Consult and comment on PPL 1st draft (2 weeks).

4. **AWERB**
   - Write 2nd draft of new PPL (Send to Home Office).

5. **Project Team**
   - Consult and comment on PPL 2nd draft (2 weeks).

6. **AWERB**
   - Comments received from Home Office. Amend and write 3rd draft of new PPL.

7. **Project Team**
   - Consult and comment on PPL final draft (2 weeks).

8. **Home Office**
   - Draft submitted to Home Office inspector for comment.

9. **AWERB**
   - Draft submitted to Home Office.

10. **Project Team**
    - Consult and comment on PPL final draft (2 weeks).

11. **Home Office**
    - Review PPL application. Provide feedback to PPL holder.

12. **AWERB**
    - Submit final version of new PPL to UBS.

13. **Project Team**
    - Address any AWERB comments. Submit signed PPL to UBS.

14. **Home Office**
    - Submit new PPL to Home Office.

15. **AWERB**
    - Home Office issues new PPL.

16. **Project Team**
    - Attend AWERB Standing Committee.

17. **Home Office**
    - Receive PPL and book into AWERB Standing Committee and notify PPL holder.

18. **Project Team**
    - Submit final revised PPL to UBS.

19. **AWERB**
    - Home Office forwards granted PPL to PPL holder.

20. **Home Office**
    - UBS check application and PEL signs.

21. **AWERB**
    - Submit new PPL to Home Office.

22. **Project Team**
    - Attend AWERB Standing Committee.

23. **Home Office**
    - Receive PPL and book into AWERB Standing Committee and notify PPL holder.

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Steps 1 to 23 will be tracked on the UBS PPL Tracker.

... → Steps 3, 10-13 should not be necessary.
Timeline to a new Project Licence for existing licence holders

**Timeline 15 months**

1. Remind PPL is expiring and retrospective review due. Request confirmation of receipt.
2. Acknowledge UBS communication. Set up/Contact Project Team.
3. Provide current form and advice/review as required.
4. Complex licence reviews referred to AWERB Standing Committee.
5. Send licence review to UBS and Project Team.
6. Remind PPL is expiring. Offer PPL writing course, provide preliminary advice. Request confirmation of receipt.
7. Organise Project Team meeting.
8. Provide current form and advice as required.
9. Write 1st draft of new PPL. Send to Project Team for comment.
10. Consult and comment on PPL 1st draft. (2 weeks)
11. Write 2nd draft of new PPL. [Send to Home Office Inspector]
13. Comments received from Home Office. Amend and write 3rd draft of new PPL if needed.
14. Consult and comment on PPL 3rd draft. (2 weeks)
15/17. Comments received from Home Office. Amend and write final draft of new PPL if needed.
17. Submit final version of new PPL to UBS.
18. Consult and comment on PPL final draft. (2 weeks)
19. Attend AWERB Standing Committee.
20. Receive PPL and book into AWERB Standing Committee and notify PPLh.
22. Review PPL application. Provide feedback to PPLh.
23. Address any AWERB comments. Submit signed PPL to UBS.
24. UBS check application and PELh signs.
26. Home Office issues new PPL.

**Project Team**

- Write 1st draft of new PPL.
- Send to Project Team for comment.
- Comments received from Home Office.
- Amend and write final draft of new PPL (if needed)
- Consult and comment on PPL final draft. (2 weeks)
- 3rd draft of new PPL (if needed)
- Submit final version of new PPL to UBS.
- Attend AWERB Standing Committee.
- Address any AWERB comments.
- Submit signed PPL to UBS.

**PPL Holder**

- Acknowledge UBS communication. Set up/Contact Project Team.
- Send licence review to UBS and Project Team.
- Organise Project Team meeting.
- Write 1st draft of new PPL. Send to Project Team for comment.
- Provide current form and advice as required.
- Consult and comment on PPL 1st draft. (2 weeks)
- Provide current form and advice as required.
- Consult and comment on PPL final draft. (2 weeks)

**UBS**

- Remind PPL is expiring and retrospective review due. Request confirmation of receipt.
- Attend PPL writing course.
- Steps 1 to 27 will be tracked on the UBS PPL Tracker.
- Steps 14 -18 should not be necessary.
- Receive PPL and book into AWERB Standing Committee.
- Submit final version of new PPL to UBS.

**Home Office**

- Home Office issues new PPL.
- Complex licence reviews referred to AWERB Standing Committee.
- Provide current form and advice as required.
- Consult and comment on PPL 3rd draft. (2 weeks)
- Review PPL application. Provide feedback to PPLh.

**Timeline**

- 15 months
- 12 to 9 months
- 9 to 5 months
- 4 months
- 3 months
11. Project Licence Retrospective Review

The Home Office Guidance to the Act Section 10.4 requires the AWERB to complete the following task:

- Follow the development and outcome (Retrospective Review) of projects carried out in the establishment, taking into account the effect on the animals used, and to identify and advise on elements that could further contribute to the 3Rs.

Retrospective Reviews of projects at the University normally take place approximately 12 to 15 months before the licence expires (see pages 14 and 19). However at the University of Cambridge one (or possibly more) of the following will determine when a licence will be requested for review:

a. 6 to 12 months before the existing licence is due to expire if the PPLh has no plans to write a new licence;
b. 12 to 15 months before the existing licence is due to expire if the PPLh plans to write a new project licence;
c. 3 months before the termination of the licence if the PPLh intends to revoke their licence before its due expiry date;
d. When there is a change of project licence holder (in this case the person currently holding the licence should complete the retrospective review before the amendment is made to change the project licence holder);
e. As determined by the AWERB Standing Committee. The AWERB Standing Committee may decide a licence should be reviewed at a specified time or times based for example on the severity of the work, novelty of the models etc..

The Project Team will be able to provide advice if required before a PPLh begins to prepare this report. The University has a Retrospective Review template which will be tailored to the PPL requirements and sent to the PPLh by UBS HO Licensing staff. This template should be used to capture all the information the University feels it requires in order to comply with ASPA. In the case of non-complex licences it may be possible for the Project Team to review the licence and a summary report submitted to the AWERB Sub-committee to note. The 3Rs section of all Retrospective Reviews will be considered by the AWERB 3Rs committee and in the case of more complex licences the PPLh may be asked to attend the AWERB Sub-committee in person.

12. Project Licence Retrospective Assessment

Although many aspects of a Retrospective Assessment will be similar to the Retrospective Review it will be the Home Office inspector who determines which licences require a Retrospective Assessment. The requirement for the AWERB to be involved is stipulated in the Home Office Guidance Section 10.5 which states:

- Assist with the retrospective assessment of relevant projects carried out at their establishment.

The licences which will require retrospective assessment will be those authorising the use of:

- non-human primates,
- cats,
- dogs and
- equidae and
- those involving procedures classified as severe.
In addition, the Home Office will require Retrospective Assessments of all project licences for education and training and those authorising the use of endangered animals.

Finally the Home Office reserves the right to consider whether other projects should be assessed retrospectively and, if so, when on a case-by-case basis. In this case the decision is made when the inspector assesses the application.

All PPLhs will be informed when their project licence is granted or amended whether a Retrospective Assessment is required.

When considering whether a Retrospective Assessment is required the Home office will take account of:

- the number and type of procedures to be used;
- the number and species of animals to be used;
- the nature of the programme of work and its objectives; and
- whether the project raises any important animal welfare or ethical concerns, novel or contentious issues, or societal concerns.

PPLhs can check whether their licence requires a Retrospective Assessment by looking at the covering letter that accompanied their licence when it was granted and every time it is amended. If the licence requires a Retrospective Assessment the Home Office expects the PPLh to provide information to the University AWERB Standing Committee by the date in the covering letter. The information that is required must include an updated non-technical summary (NTS) and sufficient information to enable the University AWERB Standing Committee to consider:

- whether the programme of work has been carried out;
- whether the objectives of the programme of work have been achieved;
- the amount of harm caused to animals by the carrying out of the programme of work (including the number of animals subjected to regulated procedures as part of the programme of work, the species of animals subjected to those procedures and the severity of those procedures); and
- whether any lessons can be learnt from the programme of work which may contribute to the further implementation of the principles of replacement, reduction and refinement.

UBS has produced a Retrospective Assessment template which will be sent to the PPLh, tailored to the licence. UBS maintains record of those licences requiring Retrospective Assessment however responsibility still remains with the PPLh to check if and when such Assessment is required.

The University AWERB Standing Committee will retrospectively assess your project also taking into account the harms and benefits. When the AWERB Standing Committee has completed its Retrospective Assessment, which will normally be within three months of the date on the covering letter from the Home Office, they will respond to you.

PPLhs are required to submit the University AWERB Standing Committee’s conclusions, together with their updated non-technical summary as agreed with the University AWERB Standing Committee to the Home Office so that an inspector can complete the assessment on behalf of the Secretary of State. UBS will help with this process. This is explained in the correspondence the PPLh receives following the committee’s consideration of your Retrospective Assessment.
13. Project licence amendment

A project licence should be viewed as a living document and therefore is likely to require amended as research progresses during the tenure for which the licence has been granted (normally 5 years). Project Team members will be able to provide PPLhs with advice or put PPLhs in contact with their inspector.

As a basic rule if a PPLh needs to amend their licence their inspector will expect to see an explanation as to why the licence is being amended and how the new work will be undertaken – this justification should appear in the Part D Project Plan. This will also apply if the amendment includes the addition or changes to a protocol(s).

Project licence amendments will be handled by a virtual AWERB Licence Amendment committee when the amendment is straightforward and does not fall into any of the categories listed below. If the amendment needs to go to an AWERB Sub-committee the PPLh will be invited to attend, although this is not mandatory. It is unlikely that PPLhs will be asked to give a presentation.

The following amendments will be considered by the AWERB Sub-committee and NOT the virtual AWERB Licence Amendment committee when:

a) The amendment is complex and the NVS, NACWO or scientist flag that the amendment should be tabled at an AWERB Sub-committee meeting.

b) The amendment is ambiguous or unclear and the issue cannot be resolved by the virtual AWERB Licence Amendment committee process.

c) The amendment raises ethical, societal or welfare concerns.

d) The amendment involves special species.

e) The amendment requests a significant increase in the numbers of animals used on moderate or severe severity protocols.

f) The amendment requests the severity classification of a protocol to be increased and/or the addition of one or more severe severity protocols.

As with all new project licences the progress of all amendments are all tracked using the UBS PPL Amendment Tracker.

14. Project Licence – University of Cambridge Amendment Process

The table below details the Process Timeline for an amendment to an existing project licence. This process has been mapped onto a PPL Tracker (similar to the new Project licence tracker illustrated on page 17) which records the movement of all new applications from the time they are identified as requiring amendment until the amendment is granted by the Home Office. The people responsible for the Actions are detailed below the table with the exception of the Named Veterinary Surgeons.

<table>
<thead>
<tr>
<th>Task</th>
<th>Action</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Amendment identified by PPLh, UBS staff or requested by HOI: If necessary the PPLh arranges to meet with NVS, DD and NACWO. The amendment may be discussed either electronically or in person. NVS, DD and NACWO will advise on technical and welfare aspects of writing the amendment, if necessary. The DD will advise the PPLh what paperwork is required, if necessary and update the PPL Amendment Tracker</td>
<td>PPLh, NVS, DD, NACWO, DD</td>
</tr>
<tr>
<td></td>
<td>If the NVS, DD or NACWO deem the amendment requires HOI involvement the PPLh will be advised to contact their local HOI directly before progressing further. When requested, the DD will contact the HOI on behalf of the PPLh. The DD will update the PPL Amendment Tracker.</td>
</tr>
<tr>
<td>---</td>
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</tr>
<tr>
<td>3.</td>
<td>PPLh will draft the PPL amendment and pass the amendment to DD, NVS and NACWO and the DD will update the PPL tracker.</td>
</tr>
<tr>
<td>4.</td>
<td>NVS, DD and NACWO respond with comments, if necessary, to the PPLh directly or as a combined single response, copied to or sent from the DD. The DD will update the PPL Amendment Tracker.</td>
</tr>
<tr>
<td>5.</td>
<td>PPLh makes any necessary changes and sends copy to the NVS, DD and NACWO.</td>
</tr>
<tr>
<td>6.</td>
<td>If the amendment requires further attention by the PPLh the NVS, NACWO and DD will decide if the PPLh requires a) minimal additional support to prepare the amendment for AWERB in which case they will work with the PPLh; or b) where significant additional support is deemed necessary will advise the PPLh contacts their local HOI. The DD will update the PPL Amendment Tracker.</td>
</tr>
<tr>
<td>7.</td>
<td>When NVS, DD and NACWO consider that the amendment is suitable for AWERB, the DD will advise the PPLh how to submit the amendment to the UBSCO. The DD will also advise the UBSCO whether the amendment should be consideration by the virtual AWERB Licence Amendment Committee or whether it should be submitted to the AWERB Standing Sub-committee (see below).</td>
</tr>
<tr>
<td>8.</td>
<td>UBSCO logs receipt of amendment on the PPL Amendment Tracker and sends draft amendment to either the virtual AWERB Licence Amendment Committee members who have 2 weeks in which to respond or books the amendment into the next available AWERB Subcommittee meeting, circulating papers to the committee members ahead of the meeting.</td>
</tr>
<tr>
<td>9.</td>
<td>Either: a) The virtual AWERB Licence Amendment Committee members return comments to the UBSCO who will collect comments in a folder. UBSCO (by adding a comment to the relevant cell) will record on the PPL Amendment Tracker when each virtual AWERB Licence Amendment Committee member responds and the date when all comments were received. When all committee members have responded the UBSCO will forward the comments to the NVS and DD. The NVS and/or DD will consider all the responses received from the members of the virtual committee and draft a collated response which will be forward to the UBSCO. The DD will update the PPL Tracker, or b) After the committee meeting the SPC will collate the AWERB Subcommittee comments and send the comments to the UBSCO. The UBSCO will update the PPL Amendment Tracker.</td>
</tr>
<tr>
<td>10.</td>
<td>The UBSCO will forward the collated response to the PPLh and will either: a) copy the same to all the virtual AWERB Licence Amendment committee members and DD and HOI or</td>
</tr>
</tbody>
</table>

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23
b) forward the SPCs comments to the PPLh, with copies to the DD and HOI. The USBCO will update the PPL Amendment Tracker.

11. The PPLh will address the points raised and send the changed amendment to UBSCO. UBSCO will either:
   a) In the case of the virtual AWERB Licence Amendment committee, send the response to the NVS, DD, NACWO and scientist to check, or
   b) In the case of the AWERB Sub-committee send the response back to the SPC to check.

12. (Optional step) If the NVS, NACWO, scientist in the case of the virtual committee route or SPC in the case of the AWERB Sub-committee will check that the PPLh has made the changes requested. If further changes are required or they believe that the PPLh has not adequately addressed the issues raised they will notify UBSCO who will work with the DD or SPC to communicate the response back to the PPLh. The UBSCO will record the process using the PPL Amendment Tracker.

13. When any one of the following: NVS, NACWO, scientist or the SPC, indicate to the UBSCO that the amendment is considered suitable to send to the HO the UBSCO will notify the DD who will advise the PPLh what to do next. Either:
   a) where ASPeL is used DD will advise the PPLh to submit their application and provide assistance if required. The DD will update the PPL Amendment Tracker. or
   b) If the amendment is submitted on paper the PPLh will forward the papers to the DD to submit to UBSCO for onward submission to the HO. The DD will update the PPL Amendment Tracker when the paperwork is submitted to UBS. The UBSCO will update the PPL Amendment Tracker when the paperwork is submitted to the HO.

* Indicates where the amendment may be sent in draft form to the HOI for comment or to alert them that a draft is in progress.

The following criteria will be used to decide which amendments need to be considered by the AWERB Sub-committee and not a virtual AWERB Licence Amendment Committee:

- g) the amendment is complex and the NVS, DD, NACWO or scientist flag that the amendment should be tabled at an AWERB Sub-committee meeting;
- h) the amendment is ambiguous or unclear and the issue cannot be resolved by the virtual AWERB Licence Amendment Committee process;
- i) the amendment raises ethical, societal or welfare concerns;
- j) the amendment involves special species;
- k) the amendment requests a significant increase in the numbers of animals used on moderate or severe severity protocols;
- l) the amendment requires the severity classification of a protocol to be increased and/or the addition of one or more severe severity protocols.
### Biofacility DD’s:

- **Alan Graham:** Combined facilities, Anatomy, Madingley, Innes Building, Barcroft Centre
- **Sam Jameson:** Gurdon Institute, Stem Cell and Pathology
- **Maggie Gentry:** Central Biomedical Services, Phenomics, Hutchison, [Brain Repair Centre]

### SPC:
A person nominated by the AWERB Standing Sub-committee and is likely to be the Welfare Director, NVS or Biofacility DD.

### UBSCOs:
Primary contact – Laura Elmer
Secondary contact – Zara Preston

### Biofacility Vets:

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<tr>
<th>Unit</th>
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<tr>
<td>Barcroft Centre</td>
<td>Jo Keeley and Amelia Phillips</td>
<td>Innes</td>
<td>Jo Keeley</td>
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<td>Madingley</td>
<td>Jo Keeley</td>
<td>Combined rats</td>
<td>Chris Handley and Amelia Phillips</td>
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<td>Anatomy rodents</td>
<td>Chris Handley and Amelia Phillips</td>
<td>Combined mice</td>
<td>Wairimu Gatome</td>
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<td>Anatomy primates</td>
<td>Wairimu Gatome</td>
<td>Combined fish</td>
<td>Chris Handley and Amelia Phillips</td>
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<td>Pathology</td>
<td>Chris Handley and Amelia Phillips</td>
<td>Gurdon Institute</td>
<td>Wairimu Gatome</td>
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<td>CBS</td>
<td>Jo Keeley</td>
<td>Stem Cell</td>
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<td>Phenomics</td>
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<td>Hutchison Frogs</td>
<td>Wairimu Gatome</td>
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### 15. Referral of project licences to the Animals in Science Committee [ASC]

Under **ASPA section 9(1)**, the SoS may refer project licence applications to the ASC for advice. In particular they will seek specific or general advice, as appropriate, on applications involving:

- The use of wild-caught non-human primates;
- The use of cats, dogs, equidae or non-human primates in severe procedures;
- Use of endangered species;
- Projects with major animal welfare or ethical implications;
- Projects involving the use of admixed embryos falling into category 3 of the Academy of Medical Sciences (AMS) report on Animals Containing Human Material (ACHM) and category where the predominance of an admixed embryo is unclear or uncertain;
- Projects which may invoke any of the ‘safeguard clauses’ in the Directive with respect to the purpose of primate use, proposals for the use of a great ape, or proposals to cause long-lasting pain, suffering or distress that cannot be ameliorated; or
- Projects of any kind raising novel or contentious issues, or giving rise to serious societal concerns.

If a PPL falls into any of these categories then the Home Office reserves the right to extend the time required to consider the application from 40 working days to 55 working days.
16. If Something Goes Wrong

What can you do?

The PILh holds primary responsibility for the welfare of animals to which they have applied regulated procedures. If adverse effects occur or the severity category for the protocol is exceeded then the PILh is required to notify the PPLh (PIL Standard Condition 13).

However if a PILh has any concerns about the welfare of any of their animals they should in the first instance contact the unit NACWO and/or NVS.

It is the responsibility of the PPLh to ensure adherence to the severity categories as specified in the project licence protocols and observance of any other controls described in the protocol adverse effects sections. If these constraints appear to have been, or are likely to be, breached, the PPLh should ensure that the Secretary of State is notified as soon as possible (PPL Standard Condition 18).

Staff concerns or objections and the University of Cambridge Whistleblowing procedure

In the event that any member of staff genuinely believes that ethical or animal welfare concerns relating to any research animal are not being properly observed or implemented, that staff member should be encouraged to raise the concern in accordance with this procedure or the University of Cambridge Whistleblowing procedure.

In the first instance, the staff member should raise the issue with their Group leader, Line Manager or the appropriate unit NACWO or with the NVS. If the staff member is not satisfied with the response, a formal submission in writing should be made to the PELh outlining the nature of the concern.

If the staff member believes that the issue is of such significance, or that the response from the PELh is inadequate, a submission in writing should be made to an independent member of the AWERB Standing Committee addressed to the Chairman marked “Private and Confidential”.

With approval of the staff member, the PELh or the Chairman may refer the matter for consideration by the Committee and if appropriate calling a closed meeting of the external members. Unless agreed otherwise by the staff member, the identity of the staff member will at all times be treated as confidential.

In the event that these lines of communication fail, or are perceived to have failed, or where the staff member is unable or unwilling to go to the appropriate unit NACWO or NVS, a whistle blowing procedure will allow the staff member to go direct to an independent member or the AWERB Standing Committee Chairman.

If any staff member or licensee has any problems communicating themselves or have concerns that procedures are not being implemented correctly they should telephone the confidential helpline: 07442 821708 and leave a message, which will be considered anonymous. The helpline is monitored by the University Named Information and Compliance Support Officer.

If any staff member or licensee feels the need to speak to someone outside the University they can contact the Home Office by phone on 0207 035 0477 or by writing to Home Office Animals in Science Regulation Unit, 1st floor Peel Building, North East Quarter, 2 Marsham Street, London. SW1P 4DF.
17. Record Keeping

Information gathered through the AWERB process will be retained for a period of 3 years.

All information is considered confidential and may only be released in agreement with the University Freedom of Information Officer, and the individuals involved.
Appendix A: Suggested members for you Project Team and other useful contacts

Project Licence holder: Yourself

Members of the research team: Could be personal licence holders and researchers involved with your work. You can also involve members of the animal care staff in the unit if you work closely with them.

Deputy Directors/Named Training and Competence Officer (NTCO):

Named Veterinary Surgeon (NVS):
Veterinary Surgeon (VS)

Named Animal Care and Welfare Officer (NACWO):

Named Information Officer and Compliance Support Officer (NIO)

Bio-Statistician

Training School Manager:
Appendix B: Links

University of Cambridge Animal research:
http://www.cam.ac.uk/research/research-at-cambridge/animal-research

Home Office:
https://www.gov.uk/guidance/research-and-testing-using-animals

Freedom of Information:
http://www.admin.cam.ac.uk/univ/information/foi

http://www.opsi.gov.uk/Acts/acts2000/ukpga_20000036_en_1

NC3R’s:
http://www.nc3rs.org.uk

Laboratory Animal Science Association:
www.lasa.co.uk

RSPCA:
http://www.rspca.org.uk/sciencegroup/researchanimals

Institute of Animal Technology:
www.iat.org.uk

Concordat on openness:
http://www.understandinganimalresearch.org.uk/policy/concordat-openness-animal-research