Advice based on Animals (Scientific Procedures) Act 1986
As reviewed and transposed 1 January 2012 and Amended 1 January 2013

UNIVERSITY OF CAMBRIDGE

University Biomedical Services

University of Cambridge Animal Welfare and Ethical Body [AWERB] Handbook

Version 6.6

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 the Director or Deputy Director for Governance and Welfare/Named Training and Competence Officer or the UBS Website to make sure they have the most up to date version.

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 fundamental understanding of the biological sciences, and the treatment and cure of 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. These non-animal models are designed to effectively reproduce in part or fully the complex biological characteristics of man and animals. When validated these non-animal models remove the need for animal use and allow us to move towards our goal of eventually ending the use of animals in fundamental, medical and veterinary research.

In the UK, research with animals is governed by a range of legislation, including Animals (Scientific Procedures) Act [ASPA][1.] and, in the case of teaching 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 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 licensed by the Home Office. All animal research project licences are subject to robust scrutiny by the University Animal Welfare Ethical Review Body [AWERB] process. The AWERB committees tasked with the review of project licences have memberships consisting of lay-members, veterinary surgeons, animal welfarists/animal care staff and academic staff. On many of the committees members are drawn from

both outside the animal research field (lay members) and when required from other research establishments (specialist scientists). Only where a programme of animal research is necessary and considered justified by AWERB 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 on Openness[2].

Where wild animals need to be observed and studied in their natural habitat, our responsibilities will 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 require researchers to adopt the same high standards of care and humane treatment of their animals and adherence with all relevant laws and guidelines. Wherever possible and feasible, rehoming laboratory animals is investigated and supported. The University expects everyone involved in animal research to follow the Laboratory Animal Science Association [LASA] guiding principles[3] as set out in their published documents , apply the use of analgesia and anaesthetic regimes together with applying a robust welfare ethos and strongly discourage aversive training and testing regimes. All experiments using animals should be carefully designed and conducted in line with the principles set out in the PERPARE guidelines and data published in accordance with the ARRIVE guidelines[4]. Wherever possible negative data should be published (for example in F1000) thereby reducing the risk of experiments being repeated unnecessarily by others.

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 used 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 the 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 privilege 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.

1. https://www.gov.uk/guidance/research-and-testing-using-animals#animals-scientific-procedures-act-1986
2. http://www.understandinganimalresearch.org.uk/policy/concordat-openness-animal-research
3. www.lasa.co.uk
4. https://www.nc3rs.org.uk/results-search/all/Arrive%20Guidelines

3. Glossary of Terms

2C Licence	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
3R's	The principles of replacement, reduction and refinement
Actual severity	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. The actual severity recorded for each animal on a protocol can differ and can be different from the Prospective Protocol Severity Classification/Category. The Classification/Category may be sub-threshold, mild, moderate, severe or non-recovery
ASC	The Animals in Science Committee – the independent, non-departmental public body set up under ASPA sections 19 and 20
ASPA	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
ASRU	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
AWERB	Animal Welfare and Ethical Review Body
Cumulative effect	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
DD	UBS Deputy Director
DDGW	UBS Deputy Director for Governance and Welfare
D/DDGW	UBS Director or Deputy Director for Governance and Welfare
DGW	UBS Director for Governance and Welfare
Harm–benefit analysis	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
HOI	Home Office Inspector
HOLC	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
Humane end-point	Clear, predictable and irreversible criteria that allow early termination of a procedure before an animal experiences harm that is not authorised or scientifically justified
IAT	Institute of Animal Technology
LASA	Laboratory Animal Science Association
NACWO	Named Animal Care and Welfare Officer
NC3Rs	National Centre for Replacement, Refinement and Reduction of Animals in Research
NIO	Named Information Officer

NPRC	Named Person Responsible for Compliance
NTCO	Named Training and Competency Officer
NVS	Named Veterinary Surgeon
PELh	The holder of a section 2C (establishment) licence under ASPA
PILh	The holder of a personal licence under ASPA
POLE	Place other than a licensed establishment (formerly known as a 'PODE')
PPLh	The holder of a project licence under ASPA
Procedure	An act of commission, deliberate omission or permission applied to, or having any effect on, an animal
Prospective Protocol Severity Classification/ Category	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. A severity Classification/Category is applied to every protocol on a licence before the licence is granted and may be mild, moderate, severe or non-recovery
Protocol	A procedure or series of procedures carried out for a particular purpose as part of an authorised project
Regulated Procedure	A procedure which is regulated under ASPA. The threshold at which the level of pain, suffering, distress and lasting harm for a procedure to qualify is set as equivalent to, or higher than, that caused by the introduction of a needle in accordance with good veterinary practice
Retrospective assessment	The formal assessment required in ASPA section 5(B)(7) and 5F and HO Guidance sections 5.17 and 10.5 for 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
Retrospective review	One of the tasks set out in HO Guidance Glossary and section 10.4 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
RSPCA	Royal Society for the Prevention of Cruelty to Animals
SPC	Single Point of Contact
Technique	A single action carried out on an animal as part of a procedure or series of procedures
The Act	The Animals (Scientific Procedures) Act1986 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.
UBS	University Biomedical Services
UBSCO	University Biomedical Services Contact Officer

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 fetal 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 fetal, 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 a person occupying a position of relevant authority at the establishment. 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.

The establishment licence must specify named individuals who are responsible for the following activities:

a. **Named Person Responsible for Compliance [NPRC]** - Ensuring that the requirements of ASPA and the conditions of the establishment licence are complied with. At the University this role is undertaken by the establishment licence holder;
b. **Named Veterinary Surgeon [NVS]** with expertise in laboratory animal medicine - Advising on the health, welfare and treatment of the animals. 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. **Named Animal Care and Welfare Officer [NACWO]** - Overseeing the welfare and care of the animals;
d. **Named Training and Competency officer [NTCO]** - 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; and
e. **Named Information Officer [NIO]** - Ensuring that those dealing with animals have access to information they need about the species they are using.

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.

8. Animal Welfare and Ethical Review Body [AWERB]

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 **Section 10.4 of the Home Office Guidance** 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.

<u>Additionally Section 10.5 of the Home Office Guidance sets out the following AWERB tasks:</u>

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].

<u>More generally Section 10.5 of the Home Office Guidance requires AWERBs to:</u>

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 three committees: the AWERB Standing, AWERB Sub-Standing and AWERB Virtual Licence Amendment committee.

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, AWERB Operations 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 licences from a 3Rs perspective.

4. AWERB Operations Committee

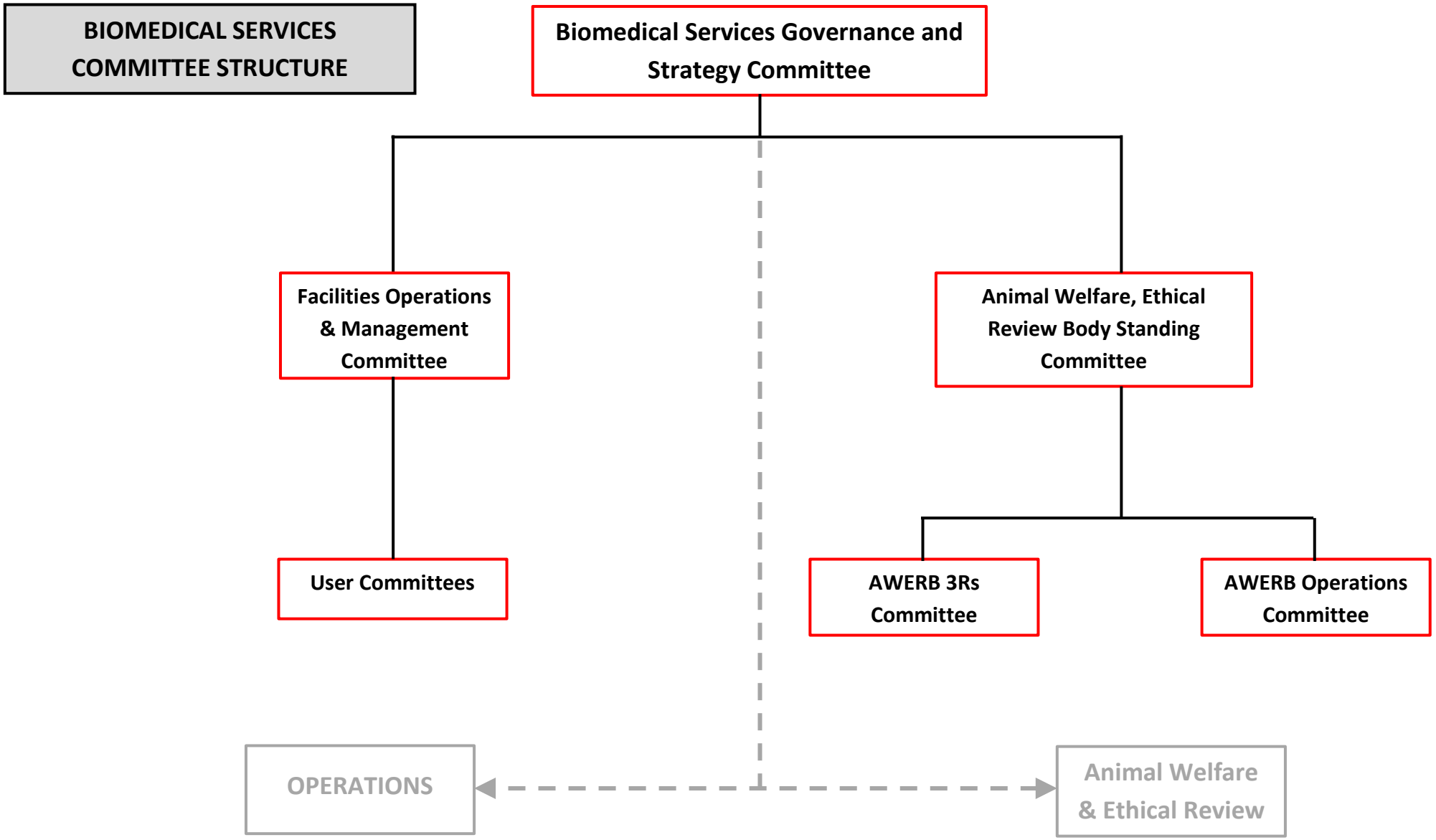
This committee is responsible for the welfare of the animals under the care of the University. It provides a forum for examining the standards of accommodation, husbandry and welfare, and monitors the research procedures to ensure full implementation of the AWERB's recommendations. It serves as an operational management and monitoring body, reporting to the PELh and the AWERB Standing Committee. In 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. Facilities Operations and Management Committee

This committee oversees the activities of the Users Committees and reports to the Biomedical Services Governance and Strategy Committee.

6. 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 AWERB 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
Biomedical Services Governance and Strategy Committee
Facilities Operations & Management Committee
Animal Welfare, Ethical Review Body Standing Committee
User Committees
AWERB 3Rs Committee
AWERB Operations 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 spreadsheet which will which records the movement of all your application transactions from the time you have been identified as requiring a project licence until when it is granted by the Home Office. The people responsible for the Actions are detailed below the table.

	Time (working days)	Timing comments	Task	Comments
A.			a) <u>For existing UofC project licence holders</u>: UBS sends 15 month reminder letter and RR template to applicant, copies in D/DDGW **OR** b) <u>For UofC researchers applying for a project licence</u>: Applicant contacts ALL Directors and Deputy Directors to inform them of work the applicant wants to undertake and space needed. DofO informs D/DDGW and DD of unit where work will be based. DD to say applicant can expect to be contacted by the D/DDGW	Provide D/DDGW with name, e-mail and phone number of applicant and D/DDGW sets up the Project workflow spreadsheet and enters date in Round 1 cell B7: a) UBS staff notify b) DD notifies D/DDGW and will also provide UBS with applicants name and contact details
B.	5 days		D/DDGW arranges visit to meet with applicant and arranges access for the PPL applicant to the UBS website if not already in place	D/DDGW enters date cell C7
C.			D/DDGW meets with applicant and explains the processes and agrees time lines (use UBS Project Application Process: C document which is signed at the meeting and uploaded to K:drive after the meeting) D/DDGW provides applicant with a copy of the Project meeting template and if necessary, instructions on how to complete it.	Timing will depends on availability of D/DDGW and applicant. D/DDGW enters date of the meeting in cell E7 and encourages the applicant to provide working day targets in cells I6, K6, M6, O6, Q6, S6, U6, Y6, AG6, AQ6. D/DDGW gives copy of spreadsheet to UBS Admin (Fiona) to upload a copy on the UBS secure website area
D.		Date when letter is sent will be agreed between D/DDGW and	MV letter to applicant	UBS Admin enters date when MV's letter is sent (with read receipt flag) in cell G7

		applicant (see C. above)		
E.	5 days		Applicant completes on-line module training (currently under construction)	UBS Admin enters date in cell I7
F.	Next available date		Applicant books and attends PPL writing workshop	Currently workshops are held throughout the year with maximum of 6 people attending each workshop. Dates are on the website and places can be booked via the UBS Training Centre (ubsts@admin.cam.ac.uk) Training Centre notifies UBS Admin when applicants book and attend the PPL workshop and UBS Admin enters dates in cells K7 and M7
G.	As soon after attending F as possible.		Applicant sets up Project Support group and organises meeting	UBS Project Support staff should endeavour to attend a Project Support group meeting when asked. However applicants should be aware it can take up to 20 working days to arrange a mutually convenient time and date. As a minimum the D/DDGW, NVS and NACWO should attend. D/DDGW advises applicant to set up PPL Support group meeting and provide UBS Admin with the date when this is done. D/DDGW will also advise UBS Admin of the date when the meeting takes place. UBS Admin will enter dates in cell Q8 and S8 respectively. (There may need to be overlap with A above)
H.			Project Support group and applicant meet (use UBS Project Application Process: H document which is signed at the meeting and uploaded to K:drive after the meeting)	
I.	20 days		Applicant prepares draft 1 and submits to Project Support group	D/DDGW informs UBS Admin of the date draft 1 is received. UBS Admin enters this date in cell U8
J.	10 days			

	(15 working days for application over 200 pages [Word version]		Project Support group review draft 1 and decide: a) Good quality draft →	Application progresses to K and D/DDGW notifies UBS Admin so date can be added to cell W8 adding comment whether draft falls into option a), b) or c) If a) UBS Admin are advised to update in cell AC8.
	20 days plus applicants response times		b) Intermediate quality draft →	Application undergoes further iteration with the Project Support group and D/DDGW notifies UBS Admin so cells Y8 and AA8 can be completed after which the third draft will be sent to DGW to review ahead of AWERB and UBS Admin is notified of the date when this is done so UBS Admin can insert the date in cell AC8.
			c) Poor quality draft →	PPL Support group sends draft to D/DDGW with reason for referral and notifies UBS Admin of the date so UBS Admin can complete cell AC8. DGW reviews application and will i) either provide electronic comments or ii) may arrange to meet with the applicant in which case the advice is likely to be: a) changes that are required to the application before submission to AWERB and DGW provides UBS Admin with the date when advice is provided to enter in cell AE7 or b) reattend PPL writing workshop in which case the DGW will recommend the applicant books onto next appropriate PPL writing workshop and asks UBS Admin to enter the date when this booking is made is provided in cell K14. The applicant therefore enters Round 2 of the process by returning to F. above.

			d) Poor quality draft after re-attendance at PPL writing workshop and reaches third draft in Round 2 without producing a good quality draft	MV will write to the applicant
K.	(15 working days for application over 200 pages [Word version]		D/DDGW reviews either draft 1 or 2 (see J. above) a) Good quality draft →	See L. below and D/DDGW completes cell AE8 and lets applicant know that the draft should be submitted to UBS Admin for AWERB
	10 days + applicants response time		b) Intermediate quality draft →	D/DDGW provides comment and provides UBS Admin with date when comment is provided and the date is entered into cell AE8 (AE15 or AE22) and applicant is advised to attend to the comments prior to resubmitting their application to UBS for AWERB and UBS Admin puts the date when they receive the AWERB ready application in cell AG8 (AG15 or AG22)
L.			1. Application does <u>not</u> contain: a. severe severity protocols, special species or societal concerns	UBS Admin books into next AWERB Standing meeting and enters date when this is done into cell AI8 [AI15 or AI22] AWERB Standing committee meets once a month at the end of the month. Drafts needs to be with UBS Admin 3 weeks before the meeting
			2. Application contains: a. severe severity protocols, b. special species or societal concerns	UBS Admin books application into AWERB 3Rs meeting and at the same time books the application into the next available AWERB Standing meeting thereafter. AWERB 3Rs meetings take place during the first week of every month and draft applications are required 3 weeks before the meeting date.
M.			AWERB 3Rs meeting	UBS Admin enters date of meeting into cell AK8 (AK15 or AK22) and updates the AWERB booking spreadsheet.
N.			AWERB Standing meeting	UBS Admin enters date of meeting into cell AM8 (AM15 or

				AM22) and updates the AWERB booking spreadsheet.
O.	5 days		AWERB recommendations sent to applicant DDGW to arrange for a blank PPL application to be ready in the applicants ASPeL account	UBS Admin enters dated into cell AO8 (AO15 or AO22). For applications sent to both committees one set of combined recommendations will be sent to the applicant within 5 working days of the AWERB Standing committee meeting. D/DDGW copied in.
P.	10 days		Applicant prepares draft application to submit to the HOI via ASPeL and will send a copy to UBS for proof reading	Applicant sends draft to HOI and sends the exported word version by e-mail to the D/DDGW and UBS Admin. UBS Admin enters date when the draft application is sent to the inspector into cell AQ9 (AQ16 or AQ23)
Q.	Could take up to 80 days		UBS proof read	
			HOI returns comments to the applicant via ASPeL	When HOI comments are received by the applicant, they will export and send a copy of the track changed application and any additional inspector comments by e-mail to the D/DDGW and to UBS Admin. UBS Admin enters date when the applicant receives comment from the HOI into cell AS9, (AS16 or AS23).
R.			UBS Admin comments sent to applicant and D/DDGW	UBS Admin will send any typographical and/or grammatical recommendations to the applicant as track changes on the exported word version of the application, copied to the D/DDGW.
S.	10 days		Applicant is advised to prepare final complete and correct version of their application and submit via ASPeL for ELH signature. Applicant to tell D/DDGW and UBS Admin when they have submitted the final version of their application via ASPeL	The D/DDGW will also advise the applicant how to return amended draft (now the complete and correct version) promptly, taking care to ensure that all the inspectors' comments and any typographical/grammatical changes have been addressed. Track changes should be removed before a final copy is sent to the HOI. When notified of the submission date, by the PPL applicant to the D/DDGW, UBS Admin will enter the

				submission date into cell AU9 (AU16 or AU23), complete the UBS/ELH spreadsheet and notify MV/SB the application is waiting.
T.			ELH "signs" and submits application to the Home Office	ELH notifies UBS Admin the application has been submitted and UBS Admin enters the date when signed in cell AW9 (AW16 or AW23) and sends e-mail to update the D/DDGW
U.	40 days + 15 days more if referred to ASC		Response received from the HO via ASPeL UBS notify D/DDGW	Could take up to 40 working days for straightforward applications. Applications that need to be referred by the HO to ASC may take an additional 15 working days. When application has been granted UBS Admin will enter date into cell AY9 (AY16 or AY23) and will notify the D/DDGW, applicant and DD.
V.		To be arranged as soon as possible after application has been granted	D/DDGW contacts the applicant to arrange a meeting (use UBS Project Application Process: V document which is signed at the meeting and uploaded to K:drive after the meeting)	Wash up meeting to discuss lessons learnt. Date of meeting to be entered into cell BD10 (BD17 or BD23) by UBS Admin after date is provided by the D/DDGW.

Screenshot of a blank project applicant's spreadsheet

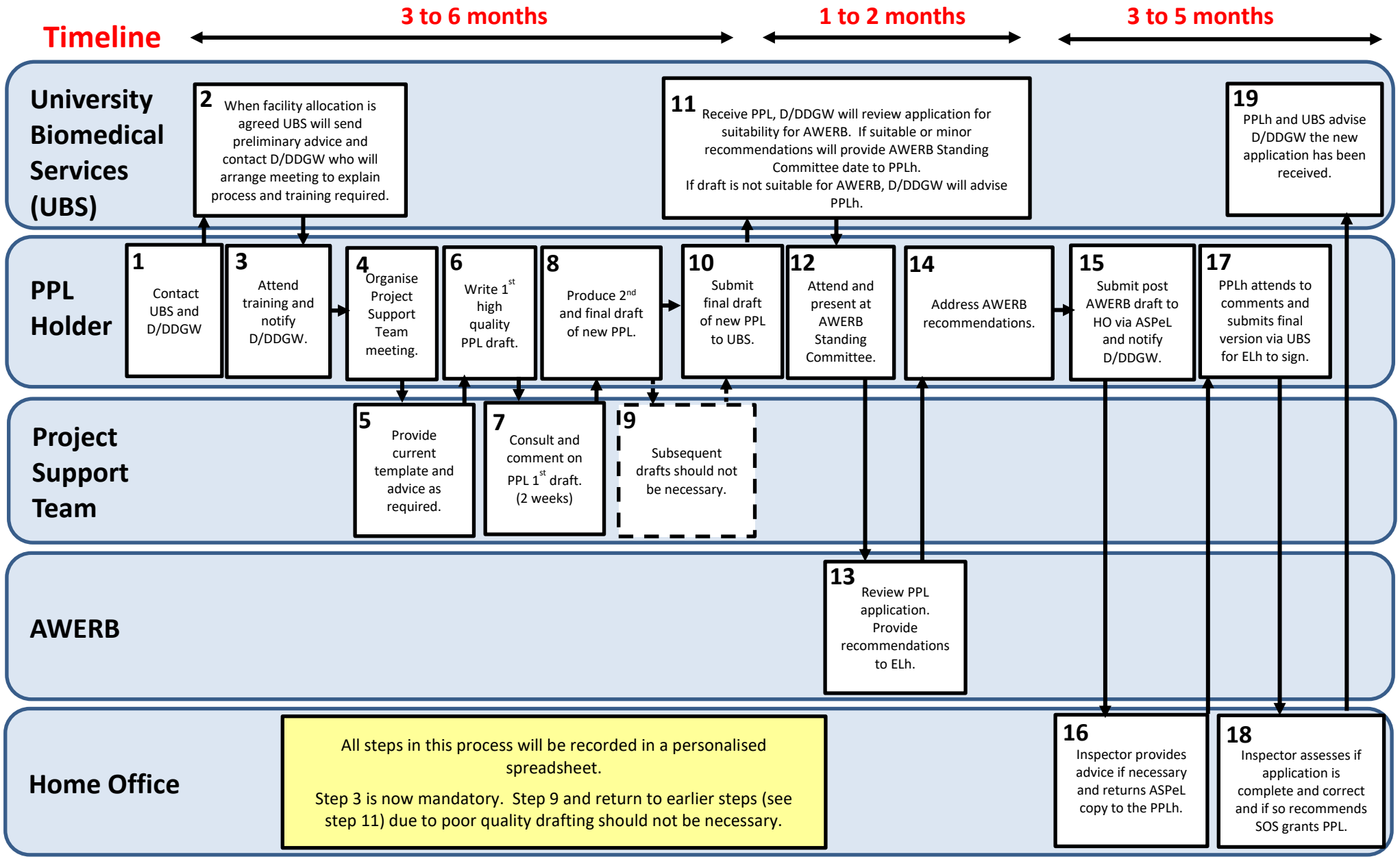
	Date sent	Date	days	Date	days	Date	days	Date	days	Date	days	Date	days	Date	days	Date	days	Date	days	Date	days	Date	days
Task	15 mth reminder/ Project template sent	AMF makes contact		Meeting with AMF		ELh letter sent by UBS		Applicant completes PPL module on line		Applicant books PPL writing workshop		Applicant attends PPL writing workshop		Completed RR received by DD		starts to arrange Project Support group meeting		Date of Project Support group meeting		Applicant sends Support group draft 1		Support group responds with comments	
Round 1																							
Target days			5				3												20				10
Actual time stage 1			0		0		0		0		0		0		0								
Actual time stage 2																	0		0		0		0
Actual time stage 3																							
Actual totay days																							
Round 2																							
Target days																			20				10
Actual time stage 1											0		0										
Actual time stage 2																	0		0		0		0
Actual time stage 3																							
Round 3																							
Target days																			20				10
Actual time stage 1			0		0		0		0		0		0										
Actual time stage 2																	0		0		0		0
Actual time stage 3																							

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 all applicants writing licences. 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 Support Team.

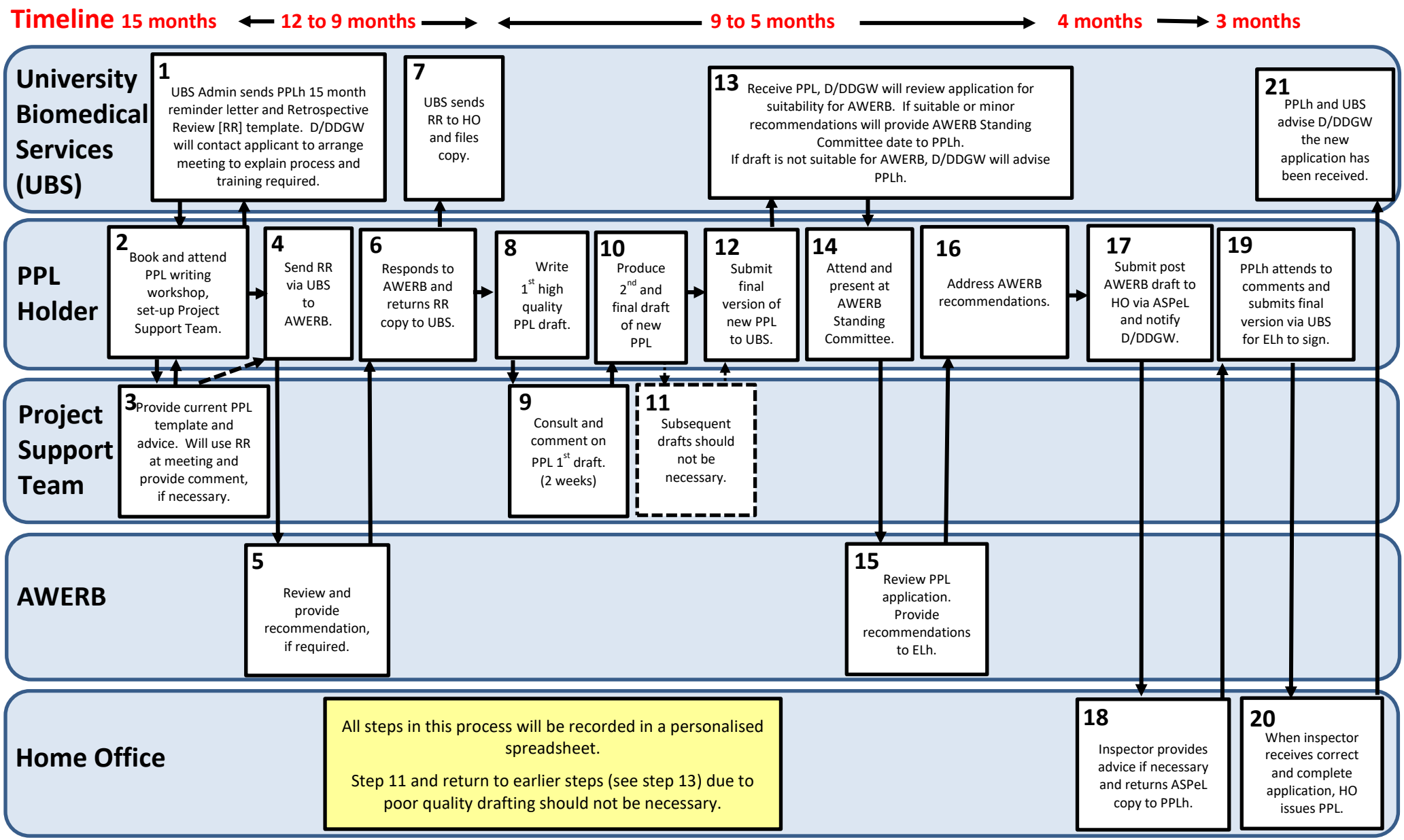
For further information please contact the Licence and Training Support Team in UBS (UBSSHOLicencing@admin.cam.ac.uk; UBSS.Office@admin.cam.ac.uk).

Timeline to a new Project Licence for new licence holders



Timeline to a new Project Licence for existing licence holders

13



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 Support 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 Support 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

Many aspects of a Retrospective Assessment are similar to the Retrospective Review and for this reason UBS has decided to use one template to capture all the information required for both reviews. The Home Office have decided that Retrospective Assessments need to be completed and submitted to the Home Office within 3 months of licence expiry. UBS recommends that licensees complete the UBS Retrospective Review template and then update information once their licence expires. The updated information can be copied and pasted into the Home Office Retrospective Assessment template prior to submission to the Home Office. 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.

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.

It is the PPLhs responsibility to check whether their licence requires a Retrospective Assessment. This can be done 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 in time for the committee to consider the information prior to forward submission to the Home Office within 3 months of licence expiry. The information submitted on the Home Office Retrospective Assessment template will be used as the updated non-technical summary (NTS) and placed on the Home Office website adjacent to the original NTS.

13. Project licence amendment

A project licence should be viewed as a living document and therefore is likely to require amendment as the 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 any of the protocols.

Project licence amendments will be handled by a virtual AWERB Licence Amendment committee when the amendment is straight forward 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, although UBS has a presentation template licensees are invited to use should they wish 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 (spreadsheet) which records the movement of all amendments from the time they are identified to when the amendment is granted by the Home Office. The people responsible for the Actions are detailed below the table.

	Task	Action
1.	Amendment identified by PPLh, UBS staff or requested by HOI: If necessary, the PPLh arranges to meet with NVS and NACWO. The amendment may be discussed either electronically or in person. D/DDGW, NVS and NACWO will advise on technical and welfare aspects of writing the amendment, if necessary. The D/DDGW will advise the PPLh what paperwork is required, if necessary and update the PPL Amendment Tracker	**PPLh** **NVS, NACWO D/DDGW** **D/DDGW**

2.*	If the D/DDGW, NVS 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 D/DDGW will contact the HOI on behalf of the PPLh. The D/DDGW will update the PPL Amendment Tracker.	**PPLh** **D/DDGW** **D/DDGW**
3.	PPLh will draft the PPL amendment and pass the amendment to D/DDGW, NVS and NACWO and the D/DDGW will update the PPL tracker.	**PPLh** **D/DDGW**
4.	D/DDGW, NVS and NACWO respond with comments, if necessary, to the PPLh directly or as a combined single response, copied to or sent from the D/DDGW. The D/DDGW will update the PPL Amendment Tracker.	**D/DDGW, NVS, NACWO** **D/DDGW**
5.	PPLh makes any necessary changes and sends copy to the D/DDGW, NVS and NACWO.	**PPLh**
6.*	If the amendment requires further attention by the PPLh the D/DDGW NVS and NACWO 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 D/DDGW will update the PPL Amendment Tracker.	**NVS, NACWO** **D/DDGW** **NVS, NACWO** **D/DDGW, D/DDGW**
7.*	When D/DDGW, NVS and NACWO consider that the amendment is suitable for AWERB, the D/DDGW will advise the PPLh how to submit the amendment to the UBSCO. The D/DDGW 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).	**NVS, NACWO, D/DDGW** **D/DDGW**
8.	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 Sub-committee meeting, circulating papers to the committee members ahead of the meeting.	**UBSCO**
9.	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 D/DDGW. The NVS and/or D/DDGW 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 D/DDGW will update the PPL Tracker, or b) After the committee meeting the SPC will collate the AWERB Sub-committee comments and send the comments to the UBSCO. The UBSCO will update the PPL Amendment Tracker.	**UBSCO** **UBSCO** **NVS or D/DDGW** **D/DDGW** **SPC** **UBSCO**
10.	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 D/DDGW and HOI or	

	b) forward the SPCs comments to the PPLh, with copies to the D/DDGW and HOI. The USBCO will update the PPL Amendment Tracker.	**UBSCO**
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 D/DDGW, NVS, NACWO and scientist to check, or b) In the case of the AWERB Sub-committee send the response back to the SPC to check.	**PPLh** **UBSCO**
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. I 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 either the D/DDGW or SPC to communicate the response back to the PPLh. The UBSCO will record the process using the PPL Amendment Tracker.	**NVS, NACWO, Scientist SPC** **D/DDGW or SPC** **UBSCO**
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 D/DDGW who will advise the PPLh what to do next. Either: a) where ASPeL is used D/DDGW will advise the PPLh to submit their application and provide assistance if required, The D/DDGW will update the PPL Amendment Tracker. or b) If the amendment is submitted on paper the PPLh will forward the papers to the D/DDGW to submit to UBSCO for onward submission to the HO. The D/DDGW 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.	**UBSCO** **PPLh, D/DDGW** **D/DDGW** **PPLh, DD** **D/DDGW** **UBSCO**

*. 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, 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.

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 and the severity classification/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 classification/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 is 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 one of the NVSs. 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".

The PELh or the AWERB Chairman may refer the matter for consideration by the AWERB Committee and, if appropriate, call a closed meeting of the external members.

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 a senior UBS staff member, an independent AWERB member or the AWERB Standing Committee Chairman.

If any staff member or licensee has any problem raising their issue themselves or have concerns that procedures are not being implemented correctly they should telephone the confidential helpline: **07595 436486** and leave a message. The helpline is monitored by the University Named Information and Compliance Support Officer. Anonymity cannot be assured where cases need to be referred to the Home Office or where illegal activities are suspected the incident needs to be reported to the police.

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 4469 or by writing to Home Office Animals in Science Regulation Unit, ASRU, Home Office, 14th Floor, Lunar House, 40 Wellesley Road, Croydon CR9 2BY.

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. Redacted copies of all AWERB committee minutes are published on the UBS website and can be viewed by the general public.

Appendix A: UBS Roles and Contact details

Establishment Licence holder:

Director for Governance and Welfare:

Facilities Director:
Operations Director
Deputy Director for Governance and Welfare/Named Training and Competence Officer (NTCO) (contact for advice on Project Applications and Amendments)
Project Support:

Deputy Directors Operations and Facilities:

Named Veterinary Surgeon (NVS):

Named Animal Care and Welfare Officer (NACWO):

Named Information Officer and Compliance Support Officer (NIO)

Training School Manager and Named Training and Competence Officer (NTCO):

UBS HO Licencing staff/University Biomedical Services Contact Officers (UBSCO):

Appendix B: Links

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

UBS Website and 3Rs Search Tool
https://www.ubs.admin.cam.ac.uk/
https://www.ubs.admin.cam.ac.uk/3rs/3rs-search-tool

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