

# University Biomedical Services

Animal Welfare and Ethical Review (AWERB) Handbook

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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 AWERB Process has been set up with the strictest possible ethos to fulfil this particular emphasis of ethical review of animals in research. The AWERB committee (s) are formed to advise the Establishment Licence Holder (ELH) on all animal welfare and ethical issues relating to the use of animals in research at the University under the Animals (Scientific Procedures) Act 1986.

The AWERB will serve as a learning process by exposing research staff to 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, Research Assistants, Animal Technicians and Care Personnel to processes on the use of animals in research at the University of Cambridge, set locally and within UK Legislation.

Contained within this document is information on the Animals (Scientific Procedures) Act 1986, the AWERB, Project Licence Writing Process and information on Key Personnel at the University who can help you or have legal responsibilities under A(SP)A 1986. A step by step guide to the whole process is also provided including links.

## **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 disease. We realise that we must not be complacent and therefore will actively promote, investigate and use new methods of medical 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 research.

In the UK, research with animals is governed by a range of legislation, including the Animals (Scientific Procedures) Act, 1986 and, in the case of teaching to veterinary students, the Veterinary Surgeons Act 1966. Compliance of our research covered by this legislation is monitored by University staff, including the Named Veterinary Surgeons and by the Home Office through its Inspectors. All members of the University carrying out procedures regulated under the Act must by law have prior training, relevant experience, assessment of competence and licence authority from the Home Office. All animal research project licences are subject to robust assessment and consideration by the University Animal Welfare and Ethical Review Body 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 justifiable by this body and with due consideration to the 3R's 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 reduction, refinement and replacement of animals

in research (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 our use of animals in research and will make every opportunity to deliver on our registration to the Concordat.

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 to 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) principles and guidelines 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, in order to eliminate the need for animals in research.
- d) Animals are transported, housed and cared for by dedicated and trained staff under professional supervision in a manner designed to maximise health and wellbeing of the animal, 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 commitment to achieving the highest standards of animal welfare and an ongoing commitment to replacement, reduction and refinement.

### 3. Glossary of Terms

<b>3R's</b>	The principles of replacement, reduction and refinement
<b>Actual severity</b>	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
<b>ASC</b>	The Animals in Science Committee – the independent, non-departmental public body set up under ASPA sections 19 and 20
<b>ASRU</b>	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
<b>ASPA</b>	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
<b>AWERB</b>	Animal Welfare and Ethical Review Body
<b>Cumulative effect</b>	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
<b>FOI</b>	Freedom of Information Act
<b>Harm–benefit analysis</b>	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
<b>HOI</b>	Home Office Inspector
<b>HOLC</b>	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
<b>Humane end-point</b>	Clear, predictable and irreversible criteria that allow early termination of a procedure before an animal experiences harm that is not authorised or scientifically justified
<b>IAT</b>	Institute of Animal Technology
<b>LASA</b>	Laboratory Animal Science Association
<b>NACWO</b>	Named Animal Care and Welfare Officer
<b>NC3R's</b>	National Centre for Replacement, Refinement, Reduction
<b>NCO NPRC</b>	Named Compliance Officer – a term sometimes used for the Named Person Responsible for Compliance or Named Person Responsible for Compliance (the preferred term, also sometimes referred to as a Named Compliance Officer)
<b>NIO</b>	Named Information Officer
<b>NTCO</b>	Named Training and Competency Officer
<b>NVS</b>	Named Veterinary Surgeon
<b>PEL holder</b>	The holder of a section 2C (establishment) licence under ASPA
<b>POLE</b>	Place other than a licensed establishment (formerly known as a 'PODE')
<b>PIL holder</b>	The holder of a personal licence under ASPA
<b>PPL holder</b>	The holder of a project licence under ASPA
<b>Procedure</b>	An act of commission, deliberate omission or permission applied to, or having any effect on, an animal
<b>Prospective Severity</b>	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
<b>Protocol</b>	A procedure or series of procedures carried out for a particular purpose as part of an authorised project
<b>Regulated Procedure</b>	A procedure or series of procedures carried out for a particular purpose as part of an authorised project

<b>Retrospective assessment</b>	The formal assessment required in the Directive (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
<b>Retrospective review</b>	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
<b>RSPCA</b>	Royal Society for the Protection of Cruelty to Animals
<b>Severity</b>	The intensity of the pain, suffering, distress or lasting harm experienced by an animal during a procedure
<b>Severity classification</b>	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
<b>Severity limit</b>	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
<b>Technique</b>	A single action carried out on an animal as part of a procedure or series of procedures

#### 4. Animal Welfare and Ethical Review Body (AWERB)

It is a Government requirement that all establishments designated under the Animals (Scientific Procedures) Act 1986 (ASPA) should have an *Animal Welfare and Ethical Review Body* (AWERB) that is acceptable to the Home Office. It is the responsibility of the The holder of a section 2C (establishment) licence under ASPA (PEL Holder) to present the Home Office with a description of an AWERB suitable for the establishment. The requirements for a suitable process were described to PEL Holders in the Home Office letter of 1 April 1998.

The AWERB Process ensures that the University continues to consider the use of animals used or destined for use in Scientific Procedures, and to regularly review the points set out in section **10. Animal Welfare and Ethical Review bodies (AWERBs)** of the Guidance on the Operation of the Animals (Scientific Procedures) Act 1986 Amendment Regulations.

The key objectives of AWERB (**ASPA Schedule 2C, Part 1, paragraph 6(1)**) stipulates that the Establishment Licence Holder must establish and maintain a body known as the AWERB and the minimum composition and which must carry out the tasks set out in **Article 27** of the Directive) are:

- 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 rehomed.

Additionally Section 10 of the HO Guidance sets out the following tasks:

- a) Advise the Establishment Licence Holder 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 to carried out at their establishment; and
- c) Respond to enquiries, and consider advice received from the Animals in Science Committee (ASC).

More generally AWERBs should:

- a) Promote awareness of animal welfare and the 3Rs;
- b) Provide a forum for discussion and development of ethical advice to the Establishment Licence Holder 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.

The aims of the AWERB are:

- a) To provide independent ethical advice to the Establishment Licence Holder, particularly with respect to project licence applications and standards of animal care;
- b) To provide support to named people and advice to licensees regarding animal welfare and ethical issues arising from their work;
- c) To promote the use of ethical analysis to increase awareness of animal welfare issues and to develop initiatives leading to the widest possible application of the 3Rs (see AWERB Terms of Reference in this booklet).

#### 1. AWERB Standing Committee

This will be the principle body that reviews all research work and reports to the Establishment Licence Holder (the PEL Holder). It comprises internal and external members with an external Chairman 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. Terms of Reference are given in Section 13.

#### 2. 3Rs Sub-Committee

This committee reports to AWERB. It scrutinises proposals to ensure that the principles of the 3Rs (Reduction, Refinement, Replacement) of animals used in research have been thoroughly incorporated and that the cost benefit analysis and scientific validity have been adequately addressed.

#### 3. NPC Sub-Committee

This 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 PEL Holder and the AWERB. In addition this 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.

#### 4. Retrospective Review-Licence Review Committee

A Review of Project licences is carried out on all live licences towards the end of the term of the licence.

The Licence Review Committee will act as a forum for discussing issues such as:

- a) Good practice;
- b) 3Rs;
- c) Training, education, legislation;
- d) Role-Examining harms and benefits and informing future work, by:
  - i. Providing feedback to the AWERB on progress with the project, its achievements, the impact of any amendments, and any problems or difficulties;



- ii. Comparing the actual harms and benefits of the work with those predicted at the application stage, in order to inform future judgements;
- e) Enhancing implementation of the 3Rs, by:
- f) Identifying any 3Rs advances made during the project, and helping to ensure that they are implemented in the institution wherever possible and publicised more widely;
- g) Bringing together a range of expertise to provide advice and assistance to research teams, to help in:
  - i. Addressing any technical or scientific difficulties not yet resolved;
  - ii. Raising awareness of any steps that can be taken to implement the 3Rs more fully.

And for optimising project management by:

- a) Identifying and addressing any concerns about project or animal facility management, including resources, staffing, training requirements, communication and dissemination of information;
- b) Planning ahead, e.g. for authorisation of future work and/or amendments to on-going work.

Assisting with collection and reporting of data on the actual severity of adverse effects and:

- a) Using these data to help identify priority areas for further application of the 3Rs.

#### 5. Retrospective Assessment of Project Licenses

In relation to projects authorised after 1 January 2013, all those using **non-human primates, cats, dogs and equidae** and all those involving **procedures classified as severe**, must be assessed retrospectively. In addition, it is ASPA policy that all project licences for education and training **and those authorising the use of endangered animals** will normally be assessed retrospectively.

- a) The number and type of procedures to be used;
- b) The number and species of animals to be used;
- c) The nature of the programme of work and its objectives;
- d) Whether the project raises any important animal welfare or ethical concerns, novel or contentious issues, or societal concerns;
- e) Whether the programme of work has been carried out;
- f) Whether the objectives of the programme of work have been achieved;
- g) 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.

Membership:

- AWERB Committee

Output:

- a) Advise PPL holder on non-technical summary
- b) Advise Establishment Licence Holder
- c) Biomedical Services Governance and Strategy Committee (for information and action if required)
- d) Home Office Inspectorate - As soon as AWERB has completed its retrospective assessment which will include the harms and benefits (normally within three months of the due date), the HO

requires the Project Licence holder to submit the AWERB's conclusions, together with the updated non-technical summary agreed with the AWERB, in order that an Inspector can complete the assessment on behalf of the Secretary of State.

## **5. Animals (Scientific Procedures) Act 1986**

The use of animals in scientific procedures is regulated by the Animals (Scientific Procedures) Act 1986, which is widely viewed as the most rigorous piece of legislation of its type in the world. It puts into effect, and in some ways exceeds, European Union Directive 86/609/EEC (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 Licences do you require to use animals in research?**

Under the 1986 Act, both personal and project licences are required. These ensure that those doing the work are qualified and suitable; 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 have been weighed against the potential benefits (to humans or animals). Special conditions control and minimise any pain or suffering. In addition, work can only be carried out at establishments which meet high standards and which have suitable veterinary and animal welfare personnel.

### **2. 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:

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

### **3. A Protected Animal**

All living vertebrates, other than a human, including certain immature forms, and any living cephalopod

## **6. Home Office Inspectorate**

### **Animals (Scientific Procedures) Inspectorate**

The Animals (Scientific Procedures) Inspectorate provides scientific advice to the Home Secretary and to the 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 officials who operate the licensing system and provide policy advice to Ministers.

Home Office Inspectors are responsible for policy on the use of living animals in scientific procedures and for the operation of the Animals (Scientific Procedures) Act 1986 Act in England. They aim to maintain the balance required by the 1986 Act between the interests of science and industry and animal welfare. The Home Office Inspectorate is responsible for:

- Processing applications for new licences and certificates
- Amending existing authorities
- Revoking licences when necessary

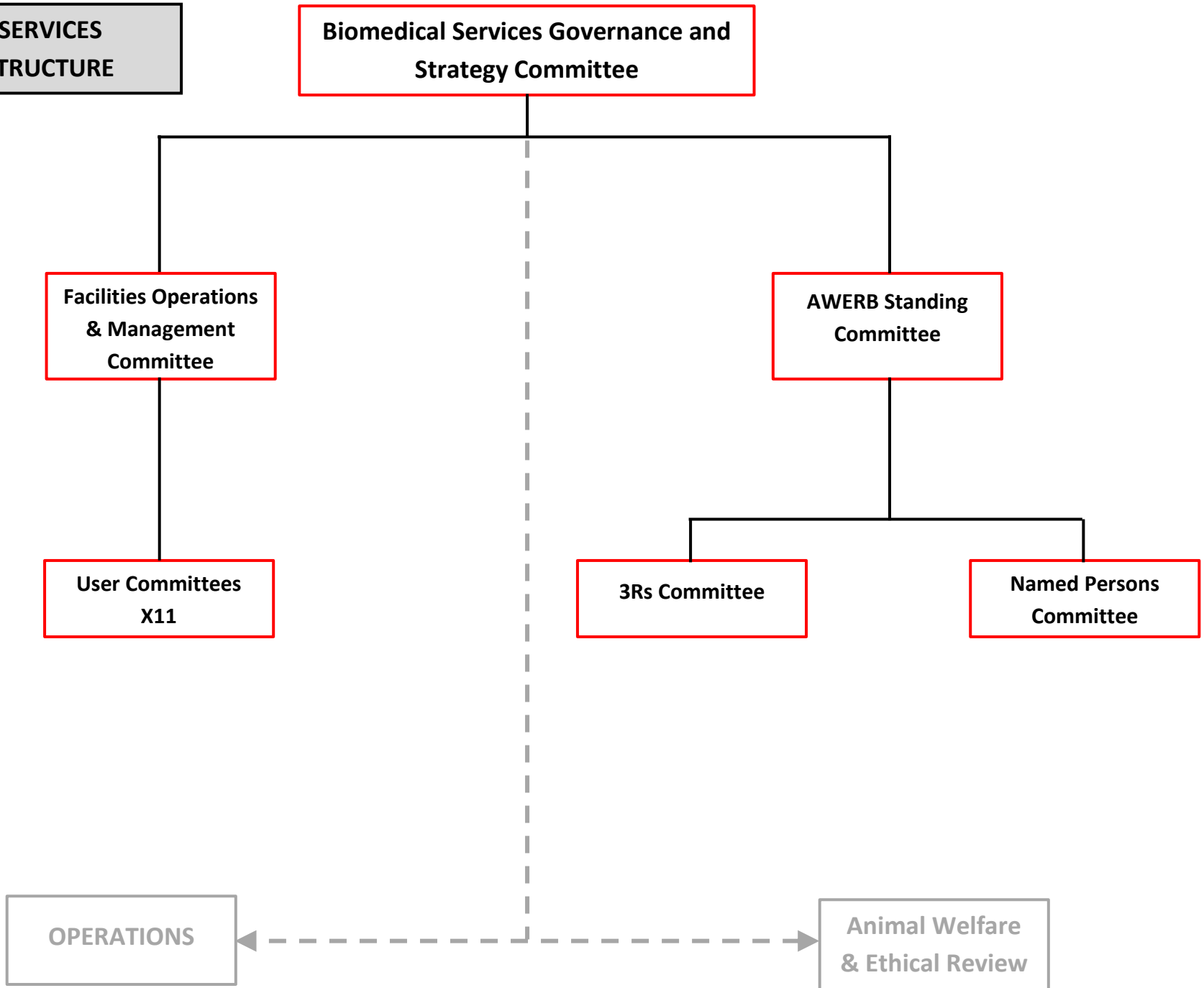
The Local Home Office Inspector is responsible for:

- Inspecting premises
- Assisting with Project Licence Applications

## **7. Biomedical Services Committee Structure**

The Biomedical Services committee structure is shown on the following page. Terms of Reference for all Biomedical Services committees can be found on the Biomedical Services website.

**BIOMEDICAL SERVICES  
COMMITTEE STRUCTURE**



## **8. Named Persons and Responsibilities**

### **Establishment Licence Holder (ELH)**

Establishment Licences (PEL) are issued to persons occupying positions of authority at the establishments. Communication with those holding responsibilities under the Act and co-ordination of their activities are key functions for the PEL. They must implement and maintain local AWERB processes acceptable to the Secretary of State.

Establishment Licence Holders must nominate one or more persons responsible for the day-to-day care of the animals, known as Named Animal Care & Welfare Officers, one or more Named Veterinary Surgeons - or, exceptionally, other suitably qualified experts - to provide advice on animal health and welfare.

### **Named Animal Care & Welfare Officers and Named Veterinary Surgeons (NACWO and NVS)**

NACWO and NVS are actively involved, on a day-to-day basis, in safeguarding the welfare of the protected animals which are bred, kept and used at licenced establishments. They need to be entrusted with the necessary management authorities and their advice on the welfare of animals should be sought and taken by project and personal licence holders, of whatever seniority, both at the planning stage and whilst work is in progress on Licences, and in preparation for animal studies or AWERB.

To discharge their responsibilities, Named Veterinary Surgeons and NACWOs should have access to licences and other relevant documentation relating to the production, care and use of animals within the licenced establishment. They should play a central role in the local AWERB process.

Direct lines of communication between named persons and the Establishment Licence Holder should be provided and used effectively.

### **Named Training and Competency Officers**

Ensure everyone planning to work with animals under ASPA (including non-licensed people such as people undertaking Schedule 1 killing and those caring for animals) at the establishment is made known to them in order to discuss their training needs.. They should:

- Be familiar with the main provisions of ASPA;
- Provide relevant training courses available either in-house or commercially;
- Advise individuals on the training they will need to have completed in order to be issued with the licence(s) they seek and on any practical training and supervision they will need after they have received their licence;
- Advise individuals how supervision and assessment of competence is managed in the establishment;
- Ensure provision is made for appropriate supervision to support formal training as a means to achieve competence;
- Identify trainers for specialist procedures or techniques;
- Ensure assessment of competence is conscientiously performed and properly recorded;
- Ensure records, including certification, are maintained of training provided and competence assessments for all individuals working with animals under ASPA;
- Set local standards for training, supervision, competence and continuing professional development for those carrying out procedures, designing projects and studies, taking care of and killing animals in line with national expectations;
- Communicate local requirements and expectations to all relevant staff;
- Endorse personal licence applications and applications for amendment to a personal licence;

- Ensure that individuals working with animals under ASPA participate in appropriate continuous training to supplement their basic training; and that this is recorded as evidence that their competence is maintained;
- Be familiar with the species used and types of research performed at the establishment so that you can recommend appropriate basic and further training courses and identify appropriate supervisors;
- Develop local training and assessment records and ensure that they are kept up to date;
- Ensure that competence is maintained and establish mechanisms to identify refresher training requirements;
- Be actively involved with, and provide advice to, the AWERB on matters related to education and training.

### **Named Information and Officer**

The Named Information Officer (NIO) ensures that everyone dealing with animals at the establishment has access to the information they need about the species concerned as well as about replacement, reduction and refinement (the 3Rs).

They ensure that current information of appropriate quality is readily available. The information may be in hard copy format or electronically available.

They should:

- Be familiar with the main provisions of ASPA; be familiar with the species used and the types of research performed to ensure the information available is relevant;
- Have up-to-date information about accessing information sources, including sources of information on implementing replacement, reduction and refinement (the 3Rs);
- Provide advice to the AWERB on the state of information access for all those dealing with animals.

## **9. Home Office Licensed Personnel**

### **Project Licence Holders**

Project Licence holders are responsible for the proper design and conduct of programmes of work.

They must ensure that they are kept informed about progress being made and problems encountered whilst licensed work is in progress; and that there is compliance with the authorities, severity limits and conditions of issue on the relevant project licence. They must ensure that personal licensees working under their control are aware of the nature and limitations of the project licence authorities, are adequately supervised and trained; and that the regulated procedures are competently performed in accordance with the project licence authorities.

The Secretary of State requires that the project licence applicant seeks advice from the appropriate Named Veterinary Surgeon and Named Animal Care & Welfare Officer during preparation of the application. The licence holder should continue to liaise with them as work progresses. These named persons can provide invaluable advice on the care and welfare of animals.

AWERB personnel provide project licence applicants and holders with additional opportunities and resources to improve their proposals and methodology.

### **Personal Licence Holders**

Personal licence holders assume primary responsibility for the welfare of animals on which they perform regulated procedures. They are accountable to the Home Office for compliance with the terms and conditions of issue on their personal licence. They must ensure that they understand, and abide by,

these authorities. It is essential that personal licence holders also understand the tasks delegated to them by project licence holders and the authorities granted by the project licence, including the endpoints to be implemented.

## **10. Project Licence – Ethical Review and Application Process**

### **Ethical Review**

The University of Cambridge AWERB process has now evolved due to a 2015 reorganization of the management structure within the University Animal Facilities leading to 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. Terms of Reference for the AWERB Standing Committee can be found in Section 13 of this document and for all AWERB Committees in the Biomedical Services AWERB Policy Handbook.

The revised (AWERB Process) ensures that the University continues to consider the use of animals used for or destined for use in Scientific Procedures, and to regularly review the points set out in section 10-Animal Welfare and Ethical Review bodies (AWERBs) of the Guidance on the Operation of the Animals (Scientific Procedures) Act 1986 Amendment Regulations. The key objectives of AWERB (ASPA Schedule 2C, Part 1, paragraph 6(1) stipulates that the establishment licence holder must establish and maintain a body known as the AWERB and the minimum composition and which must carry out the tasks set out in Article 27 of the Directive) to achieve these objectives, AWERB will carry out tasks in these main areas:

Ethical review of project licence applications and amendments involving the use of protected animals undergoing regulated procedures within the establishment.

Retrospective assessment of relevant projects carried out at the establishment

#### **Through the AWERB Standing Committee**

Awareness raising activities to provide information and advice to assist members of the University in addressing welfare concerns, and other ethical issues arising in the course of their work including wider examination of standards of animal care and use within the establishment. Help to promote a 'culture of care' within the establishment and, as appropriate, in the wider community.

#### **Through the Named Persons Committee**

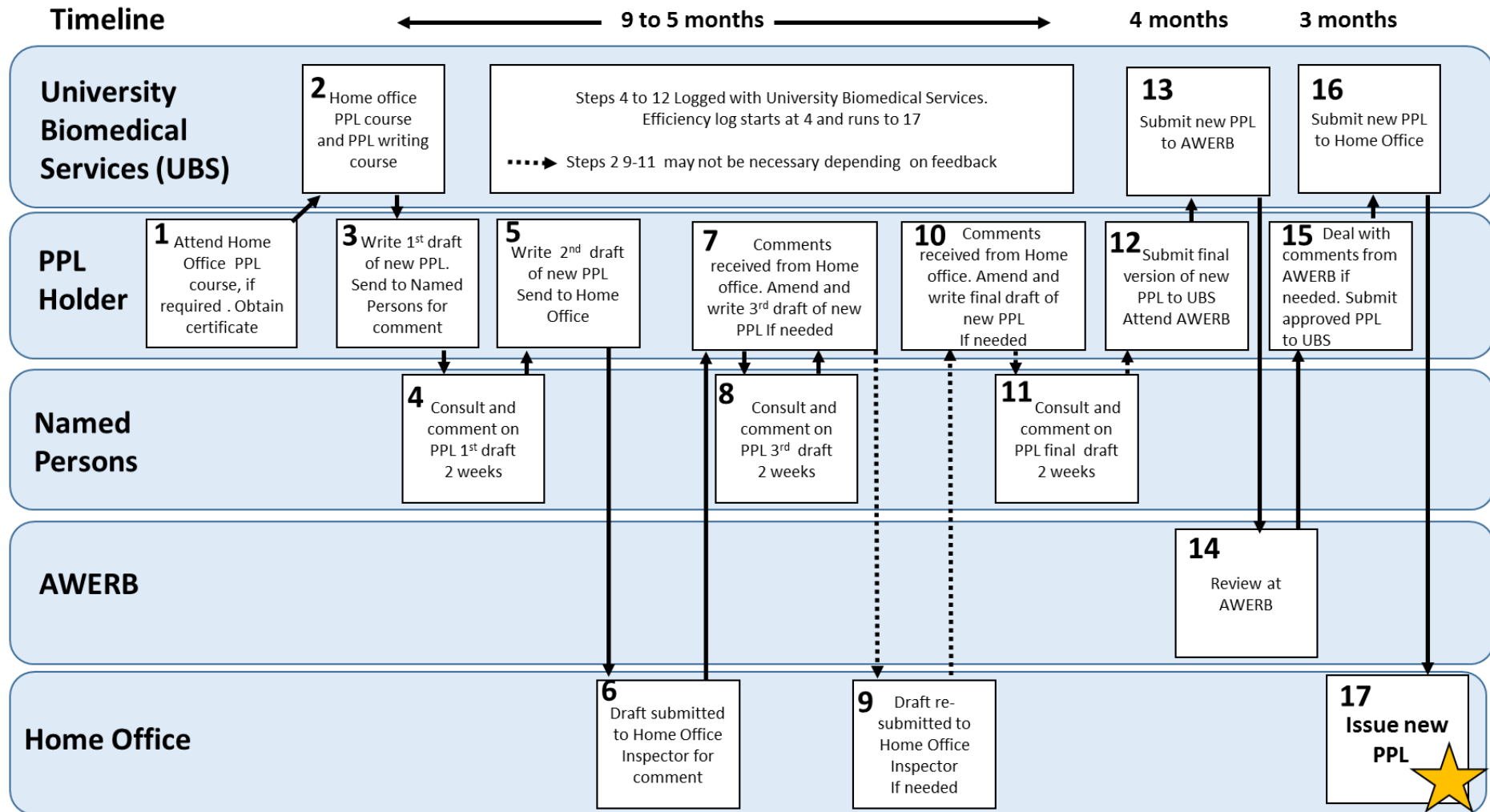
To scrutinize research projects and procedures involving the use of live animals to ensure that the 3Rs have been adequately applied. To carry out a full examination of the harms/benefits and scientific justification for proposals and ensure this information is presented in a suitable format for consideration by AWERB. Finally, to promote and encourage the development of the 3Rs throughout the University by disseminating information.

#### **Through AWERB, 3Rs, and Named Persons Committees**

### **Application Process**

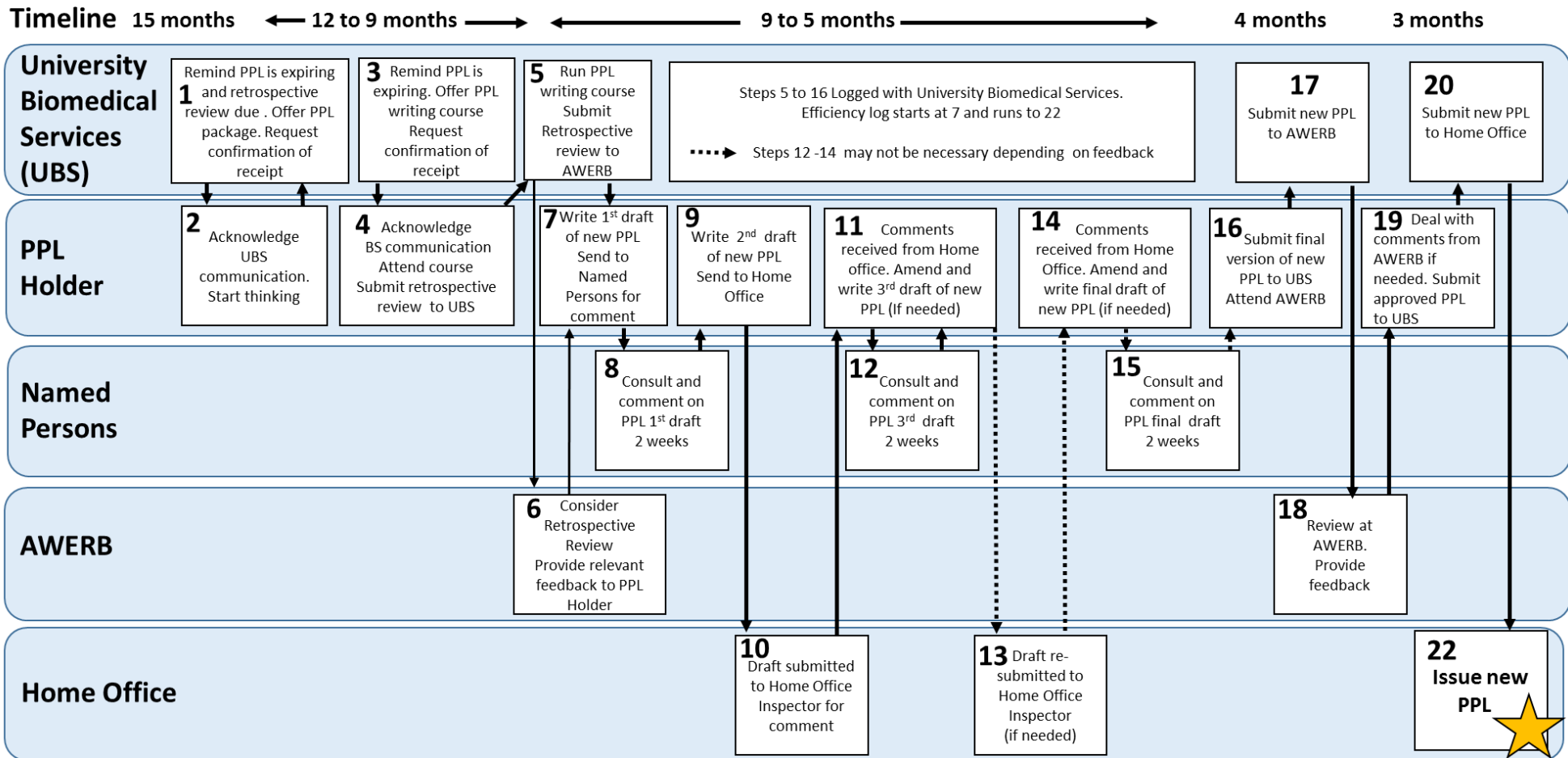
The flow diagrams on the following two pages illustrate the process for obtaining a Project Licence. A Project Licence writing course run by the Training School is mandatory for new applicants and strongly advised for those renewing. The onus is on the applicant to generate a first draft which can be usefully critiqued by the Named Persons. For further information please contact the Licence and Training Support Team in Biomedical Services ([UBSSHOLicensing@admin.cam.ac.uk](mailto:UBSSHOLicensing@admin.cam.ac.uk); [UBSS.Office@admin.cam.ac.uk](mailto: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



## 11.If Something Goes Wrong

### What can you do?

The Personal Licence Holder holds **Primary responsibility for the welfare** of animals to which they have applied regulated procedures. For any concerns of animal welfare contact the NACWO and/or NVS.

It is the responsibility of the project licence holder to ensure adherence to the severity limits as shown in the listing of procedures/protocols and observance of any other controls described in the procedure/protocol sheets. If these constraints appear to have been, or are likely to be, breached, the Project Licence Holder shall ensure that the Secretary of State is notified as soon as possible.

### Staff concerns or objections

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.

In the first case, the staff member should raise the issue with their Group leader, Line Manager or the appropriate 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 Establishment Licence Holder outlining the nature of the concern.

If the staff member believes that the issue is of such significance, or that the response from the Establishment Licence Holder is inadequate, a submission in writing should be made to an independent member of the AWERB committee addressed to the Chairman of AWERB marked "Private and Confidential".

With approval of the staff member, the ELH 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 NACWO or NVS, a whistle blowing procedure will allow the staff member to go direct to an independent member or the Chairman of the Committee.

If you have any problems communicating yourself or concerns procedures are not being implemented correctly please telephone the confidential helpline: **07442 821708** to leave a message which will be considered anonymous.

## 12. 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.

Engagement with the Animals in Science Committee (ASC): Under **ASPA section 9(1)**, the Secretary of State may refer project licence applications to the Animals in Science Committee 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.

## 13.AWERB Standing Committee Terms of Reference

### Constitution

#### A. Membership

- a. Chairperson (External to the University; 3 Year Term of Office)
- b. Establishment Licence Holder
- c. Welfare Director (Secretary)
- d. Named Veterinary Surgeon (one or more)
- e. Principal NACWOs (one or more)
- f. Named Information and Compliance Support Officer
- g. Named Training and Competency Officer
- h. Scientist (Project Licence Holder, Primary Investigator one or more)
- i. 3Rs Member (with expert knowledge of replacement alternatives)
- j. Scientific Lay Member (Internal with biomedical research and testing knowledge)
- k. Non-scientific Lay Members (External)

*(Minimum attendance for a quorum is the Chairperson (or deputy) and at least three other members)*

#### B. In Attendance

- a. Operations Director (Biomedical Services)
- b. Facilities Director (Biomedical Services)

#### C. Invited

- a. Home Office Inspector(s)

### Terms of Reference

#### A. Role (under ASPA)

- a. To examine a range of specified project licence applications and amendments to project licences, for example, new applications and amendments to those licences authorising the use of equidae and non-human primates, and those with severe procedures, as determined by the Establishment Licence Holder or his/her nominee;
- b. To consider from a local perspective the nature, likelihood and intensity of adverse effects, compliance and endorsement of policy and to undertake a harm/benefit assessment based on additional information provided in a standardised format. Assure a **harm–benefit analysis** of the project, to assess whether the harm to the animals in terms of suffering, pain and distress is justified by the expected outcome taking into account **ethical considerations**, and may ultimately benefit human beings, animals or the environment has been completed by the applicant;
- c. To interact with information and advice provided by the 3Rs Committee and Named Persons Committee;
- d. Advise the Establishment Licence Holder whether to support project proposals, primarily considering such proposals from a local perspective and bringing local knowledge and local expertise to bear;
- e. Provide a forum for discussion and development of ethical advice to the Establishment Licence Holder on all matters relating to animal welfare, care and use at the establishment;

- f. Support Named Persons, and other staff dealing with animals, on animal welfare, ethical issues and provision of appropriate training;
- g. Help to promote a 'culture of care' within the establishment and, as appropriate, in the wider community;
- h. Consider Retrospective Assessments prior to submission to the Home Office.

### **Retrospective Assessment Role**

In relation to projects authorised after 1 January 2013, all those using **non-human primates, cats, dogs and equidae** and all those involving **procedures classified as severe**, must be assessed retrospectively. In addition, it is ASPA policy that all project licences for education and training **and those authorising the use of endangered animals** will normally be assessed retrospectively regarding:

- a. The number and type of procedures to be used;
- b. The number and species of animals to be used;
- c. The nature of the programme of work and its objectives; and
- d. Whether the project raises any important animal welfare or ethical concerns, novel or contentious issues, or societal concerns;
- e. Whether the programme of work has been carried out;
- f. Whether the objectives of the programme of work have been achieved;
- g. 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.

### **B. Standing Agenda Items – For Discussion (Monthly)**

- a. AWERB Report [given by the Chair of the AWERB Standing Committee; prepared by the Welfare Director – would include information on numbers of applications and processing times, key issues arising from the 3Rs and Named Persons Committees, governance issues arising from Ethical Review requiring discussion and decision];
- b. Project Licence Applications (for Ethical Review);
- c. Establishment Licence Holder Report.

### **Retrospective Assessment**

- a. Project Licence Report [given by the Licence Holder – would include information on a-f above, key issues regarding to the 3Rs requiring discussion and decision];
- b. Project Licence Applications (for Retrospective Assessment Review);
- c. Establishment Licence Holder Report (Advise PPL holder on Non-technical summary);
- d. University Biomedical Services Governance and Strategy Committee (for information and action if required).

### **C. Standing Agenda Items – For Discussion (Termly and Annually)**

- a. Termly Report from the AWERB Standing Committee to the Biomedical Services Governance and Strategy Committee;
- b. Retrospective Review and Assessment (Termly);
- c. Review Terms of Reference and Membership (Annually).

**Retrospective Assessment**

- a. Annual Report from the AWERB Standing Committee to the Biomedical Services Governance and Strategy Committee;
- b. Retrospective Review and Assessment;
- c. Review Terms of Reference and Membership.

**D. Standing Agenda Items – For Report**

- a. Minutes of the 3Rs Committee;
- b. Minutes of the Named Persons Committee.

**Retrospective Assessment**

- a. Home Office Inspectorate – As soon as AWERB has completed its retrospective assessment which will include the harms and benefits (normally within three months of the due date), the HO requires the Project Licence holder to submit the AWERB's conclusions, together with the updated non-technical summary agreed with the AWERB, in order that an Inspector can complete the assessment on behalf of the Secretary of State.

**E. Frequency of Meetings**

- a. Once per month

**Retrospective Assessment**

- a. As required

**F. Reporting Lines**

- a. Formally to the Biomedical Services Governance and Strategy Committee;
- b. Minutes to be available online (Cam-only).

**Retrospective Assessment**

- a. Home Office Inspectorate – as soon as AWERB has completed its retrospective assessment

## 14. Links

### University of Cambridge Biomedical Services

<http://www.biomedicalservices.cam.ac.uk>

### University of Cambridge Animal research:

<http://www.cam.ac.uk/research/research-at-cambridge/animal-research>

### Home Office:

<http://scienceandresearch.homeoffice.gov.uk/animal-research/legislation/>

### Project Licence Application:

<http://scienceandresearch.homeoffice.gov.uk/animal-research/application-forms/project/index.html>

### Personal Licence Application:

<http://scienceandresearch.homeoffice.gov.uk/animal-research/application-forms/personalapps/index.html>

### NC3R's:

<http://www.nc3rs.org.uk/landing.asp?id=38>

### Home Office Guidance on handling Infringements:

<http://scienceandresearch.homeoffice.gov.uk/animal-research/publications-andreference/publications/guidance/handling-of-infringementsa8cf.html?view=Html>

### Laboratory Animal Science Association:

[www.lasa.co.uk](http://www.lasa.co.uk)

### RSPCA:

<http://www.rspca.org.uk/sciencegroup/researchanimals>

### Freedom of Information:

<http://www.admin.cam.ac.uk/univ/information/foi/>

[http://www.opsi.gov.uk/Acts/acts2000/ukpga\\_20000036\\_en\\_1](http://www.opsi.gov.uk/Acts/acts2000/ukpga_20000036_en_1)

<http://www.whatdotheyknow.com/search/scientific%20procedures%20animals/bodies>