

# **Guiding principles on good practice for Animal Welfare and Ethical Review Bodies**

4th edition - January 2026

# Authors

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# Foreword

These Guiding Principles help to interpret the requirements for UK local Animal Welfare and Ethical Review Bodies (AWERBs) and to share good practices. They are recommended as an AWERB information source in the Home Office Animals in Science Regulation Unit (ASRU) Guidance on the Operation of the Animals (Scientific Procedures) Act 1986 (ASPA).

This document will assist AWERBs in:

- complying with the legal requirements of the ASPA, which is administered by ASRU;
- developing their role in improving animal welfare and the quality of science;
- developing their role in the identification and wider understanding of ethical issues and how these can be addressed;
- furthering the application of all 3Rs [1]; and
- promoting a Culture of Care at all establishments where animals are bred, supplied or used for research.

It will also be helpful to all those working under the ASPA, as well as people working closely with the AWERB itself.

To produce this 4th edition of the Guidelines, the Royal Society for the Prevention of Cruelty to Animals (RSPCA) and the Laboratory Animal Science Association (LASA) asked contributors with a range of expertise, whose names are listed opposite, to revise and update the 3rd edition. The Guidelines are also based on relevant guidance from ASRU [e.g. 2, 3, 4, 5, 6].

Additional material developed by a European Commission (EC) expert working group as guidance for the Animal Welfare Bodies (AWBs) required across Member States is also incorporated [7]. **The document therefore also applies beyond the UK and should prove useful for similar bodies internationally, such as AWBs, Institutional Animal Care and Use Committees and Animal Ethics Committees.**

## How to use these guiding principles

There is a great deal of information in this document – too much to take in, in one go! Each section stands alone and can be read separately. We suggest readers begin with the regulatory requirements, if not already familiar with these, and then move on to the ten top tips for an effective AWERB. After that you can work through the individual sections in any order, depending on which are most relevant, where your AWERB might need 'help', or what you would most like your AWERB to achieve.

Please send any comments or ideas for improving the content or clarity of this document to the LASA secretariat at: [info@lasa.co.uk](mailto:info@lasa.co.uk)

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# 1. Regulatory requirements

## AWERB aims, tasks and membership

The requirement for each breeding, supplying and user establishment to set up an AWERB is explained in section 10 of the [Guidance on the operation of the Animals \(Scientific Procedures\) Act 1986](#) [2] and set out in establishment licence standard condition 6<sup>1</sup>.

This section **summarises the minimum requirements** set out in the legislation and accompanying documents.

## AWERB definition

**The AWERB is a local framework acting to ensure that all use of animals in the establishment is carefully considered and justified; that proper account is taken of all possibilities for replacement, reduction and refinement (the 3Rs); and that high standards of accommodation and care are achieved.**

Details of the AWERB's role, tasks and membership from the Guidance on the operation of the ASPA [2] are summarised below. Further details on all these aspects, and how to interpret them, are provided in subsequent sections of this document.

### In general AWERBs should:

- **promote awareness** of animal welfare and the 3Rs;
- **provide a forum for discussion and development of ethical advice** to the establishment licence holder on all matters related to animal welfare, care and use at their establishment;
- **support named persons** and other staff dealing with animals, on animal welfare, ethical issues and provision of appropriate training; and
- help to **promote a 'Culture of Care'** and, as appropriate, in the wider community.

This is achieved through the following tasks.

### The minimum tasks of the AWERB are to:

- 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;
- advise on the application of the 3Rs, and keep staff informed of relevant technical and scientific developments;
- 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;

<sup>1</sup> All establishment, project and personal licences are granted subject to standard conditions. These are minimum legal requirements for systems within the establishment, the 3Rs and animal care and use. This is covered in more detail in Section 10.

- 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
- advise on re-homing schemes, including the appropriate socialisation of the animals to be re-homed.

## **In addition, AWERBs have the following advisory and reviewing tasks; to:**

- advise the establishment licence holder whether to support project proposals, primarily considering such proposals from a local perspective and bringing to bear local knowledge and local expertise;
- assist with the retrospective assessment of relevant projects carried out at the establishment; and
- respond to enquiries, and consider advice received, from the Animals in Science Committee (ASC).

## **Membership of the AWERB**

### **The minimum membership must include at least the:**

- **Named Animal Care and Welfare Officer(s) (NACWO);**
- **Named Veterinary Surgeon(s) (NVS); plus**
- **A scientific member (if the establishment is a user establishment)**

Given the nature of the AWERB's responsibilities and tasks, it is a significant advantage to include the Named Information Officer(s) (NIO) and Named Training and Competency Officer(s) (NTCO) as members.

**Also, in order to ensure the integrity of the process, ASRU expects the establishment licence holder to ensure that the AWERB seeks a wider membership, taking into account the views of people who do not have direct responsibilities under ASPA, as well as one or more persons who are independent of the establishment.**

All AWERBs should therefore include one or more lay, or independent, members. These may be internal or external, but they should be completely independent of the science at the establishment (see Section 2 for further advice on membership).

ASRU Inspectors are not members of the AWERB, and will not be involved in any decisions that it makes.

## Record keeping

The establishment licence holder has to ensure that a record is kept of advice given by the AWERB and any decision taken as a consequence. These records must be held for at least three years and be made available for an ASRU Inspector, or the Secretary of State, on request.

## ASRU audits, inspections and the AWERB

### Great Britain

The Animals in Science Regulation Unit has been undergoing changes since 2021 to focus on strengthening its role as an effective regulator. This has included moving away from assigning local Inspectors to establishments, replacing this with a system of audits. The purpose of the audit is primarily supportive; it aims to recognise areas where systems are strong, to maintain compliance, and to identify areas where improvements could be made. With this change has come much more focus on self-governance at the establishment level. These changes have reinforced the AWERB's critical role in oversight of animal research at the establishment, ensuring that systems and processes are appropriate to promote: high standards of welfare; implementation of the 3Rs; a good Culture of Care; rigorous training and competence assessment; and facilitation of compliance.

### Northern Ireland

The purpose of AWERB inspection in Northern Ireland is also primarily supportive, aiming to recognise areas where there is compliance, as well as identifying areas where improvements could be made, or where non-compliance is identified which must be rectified (e.g. in relation to AWERB membership, tasks or record keeping).

The AWERB also has an important role in oversight of animal research at the establishment in Northern Ireland. It should facilitate compliance of all staff by:

- developing and ensuring use of systems and processes to promote high standards of animal welfare and use (including each of the 3Rs),
- ensuring training and competence assessment of all staff involved in animal use is consistently of high quality across the establishment and recorded appropriately, and
- promoting a good Culture of Care (including by sharing relevant information).

## AWERBs and the Animals in Science Committee

'The Animals in Science Committee is responsible for providing independent impartial, balanced and objective advice to the Home Office, and to the Northern Ireland Department of Health, on issues relating to the ASPA and the regulator's functions under it. The ASC is also responsible for advising, promoting and sharing good practice with, and between, AWERBs in the UK' [8].

In its considerations, the ASC must have regard to both the legitimate requirements of science and industry and to the protection of animals against avoidable suffering and unnecessary use in scientific procedures. Members of the ASC are expected to work in the public interest, in accordance with the seven principles of public life ([The Seven Principles of Public Life - GOV.UK](#)).

Certain categories of project must be referred to the ASC for review (see Box below).

### Project applications including the following will be referred to the ASC:

- 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;
- some categories of Animals Containing Human Material (ACHM, see [acmedsci.ac.uk/policy/policy-projects/animals-containing-human-material](http://acmedsci.ac.uk/policy/policy-projects/animals-containing-human-material));
- projects which may invoke the 'safeguard clause' in European Union Directive 2010/63/EU<sup>2</sup> [9] with respect to some purposes of primate use, or proposals to cause long-lasting pain, suffering or distress that cannot be ameliorated; and
- projects of any kind raising novel or contentious issues, or giving rise to serious societal concerns.

<sup>2</sup> Although the UK is no longer in the EU, we have retained the 'safeguard clause' from Directive 2010/63/EU; this Directive was previously implemented as the ASPA. The 'safeguard clause' allows a member state to temporarily use an otherwise banned procedure, like one causing long-lasting, severe suffering that cannot be ameliorated. This requires exceptional scientific justification and must be reviewed by the European Commission, which can approve or reject the request. At the time of writing, the authors are not aware of the 'safeguard clause' ever having been invoked.

## The ASC AWERB Subgroup and Hub Network

The Animals in Science Committee has a standing AWERB Subgroup, as a key part of fulfilling its role of 'advising, promoting and sharing good practice with, and between, AWERBs in the UK'. The ASC promotes the UK AWERB Hub network and maintains the key mechanisms for communications. These include the Hub chairs' support note, the AWERB Knowledge Hub (an online discussion forum) and AWERB Hub workshops: see the AWERB Hub support note for further information [\[10\]](#). If you are an AWERB member, you should be signed up, as an individual, to the Knowledge Hub, which you can join by contacting the ASC secretariat at [asc.secretariat@homeoffice.gov.uk](mailto:asc.secretariat@homeoffice.gov.uk)

AWERB Hubs were set up on a regional basis and have been successful in bringing together AWERBs across academia and industry, working in different research with different species, to compare and share good practice around running an effective AWERB. It is to the AWERB's advantage to be alert to ASC activities and engage with these. This will not only help to share good practice throughout the Hub, but also enable AWERBs to identify good practices to emulate. AWERB chairs can find information regarding their individual Hub's activities by emailing the ASC secretariat at the above address.

While the ASC facilitated the development of the Hub network in its initial phases, the goal was that it should be self-sustaining. The Committee expects to progress towards an oversight role, providing appropriate guidance and information as necessary.

## Leading practice

At the time of writing, the ASC is reviewing how the animals in science sector currently develops, shares and uses leading practice for the 3Rs, and collecting evidence to inform recommendations on how this culture might be improved. For further information and updates, see the ASC website [\[8\]](#).



## 2. General principles

### Principles of good practice

The AWERB's aims formalise what any establishment licensed under the Animals (Scientific Procedures) Act (ASPA) should be doing to: promote high standards of animal welfare; implement the 3Rs; enhance scientific achievements; stimulate discussion of ethics; and generate a good Culture of Care. This section presents a set of principles which are key to achieving these aims.

The AWERB can help define, develop and foster a Culture of Care that underpins good practice and ensures caring and respectful attitudes and behaviours towards animals, encouraging acceptance of responsibility and accountability in all aspects of animal care and use. It provides a framework to promote dialogue between named persons, personal and project licence holders and other staff, to ensure that local knowledge and expertise informs the planning and management of animal breeding, sourcing, care and use. A well-running AWERB is therefore a valuable resource that should benefit all staff. As a high level body advising the establishment licence holder, it should be well placed to provide a focal point to drive improvements and to help identify and prioritise the need for resources such as new animal facilities, equipment or staff.

However, there is no 'one size AWERB to fit all'. It is an establishment's responsibility to decide how its AWERB should be organised and managed - though this must be in accordance with the principles in Section 10 of the Guidance on the Operation of the ASPA [2]. The AWERB needs to be designed to best fit the requirements, practices and resources of the individual establishment: i.e. it needs to accommodate and reflect local needs and perspectives and it must have sufficient time and resource to carry out all its functions effectively.

#### Ten top tips for a successful AWERB

1. Ensure that senior management understands, and is committed to, the AWERB and provides leadership, support and sufficient resources
2. Ensure that the aims and intended outcomes of the AWERB are well thought through and clear
3. Make sure that, in discharging its functions, the AWERB 'adds value' over and above the work of other external or internal bodies
4. Make sure all the AWERB's functions are fully addressed
5. Think carefully about the selection of participants, including the Chair, and provide adequate induction, training and Continuing Professional Development (CPD)
6. Make sure the process is organised efficiently
7. Ensure that there is effective communication between all parts of the AWERB and any other relevant bodies in the establishment: all staff should know what the AWERB is for, why it is important, who is involved, how it affects them and how it works
8. Be reactive and responsive to the needs of AWERB 'users'
9. At intervals, carry out a self assessment process to evaluate the AWERB's aims and outcomes and whether its operation is efficient and appropriate
10. Interact, and share ideas for good practice with, participants in other establishment's AWERBs and the Animals in Science Committee (ASC), particularly its AWERB Subgroup and Hub network

## Ten top tips for a successful AWERB

### 1) Ensure that senior management understands and is committed to the AWERB and provides leadership, support and sufficient resources

The AWERB needs to be recognised as an important body with stature that senior management, including the establishment licence holder, *demonstrably* supports and listens to. Senior management (e.g. Vice Chancellors, Directors, budget holders) needs to understand the AWERB's contribution to research integrity and minimising reputational risk, as well as to science, ethics and animal welfare, and recognise that the process must have an appropriate budget. They should also recognise that an effective AWERB requires staff time, so members' AWERB roles should be included in their job descriptions. Their contributions should be professionally recognised as an integral part of their individual work programmes and objectives, and be included in performance appraisals.

### 2) Ensure that the aims and intended outcomes of the AWERB are well thought through and clear

The aims and intended outcomes for each of the AWERB's functions need to be defined in the context of the individual establishment. Bear in mind that there will be overlap between some of the functions and in how they can be implemented. For example, the requirement to: 'advise staff dealing with animals in the licensed establishment on matters relating to the welfare of the animals, in relation to their acquisition, accommodation, care and use' is relevant to almost all of the other functions. Grouping similar functions together (such as retrospective review with retrospective assessment) may simplify matters and help to avoid any unnecessary duplication. It is good practice for the AWERB to set out annual objectives relating to each task, which can be led by the Chair.

### 3) Make sure that, in discharging its functions, the AWERB 'adds value' over and above the work of other external or internal bodies such as Research Ethics or Governance Committees

This is particularly important with respect to consideration of project licences. The AWERB's role is 'to 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'. Serious thought needs to be given to how this is done so that the process does not just duplicate or try to 'second guess' the Animals in Science Regulation Unit (ASRU) Inspector's views. The ASRU review of licences is carried out within a national legal and policy framework which takes account of issues beyond the scope of the local establishment.

### 4) Make sure all the AWERB's functions are fully addressed

Project review should not be the only focus. The other functions are important too, and if they are dealt with well, projects will be better prepared and review will be quicker and easier. At formal AWERB meetings, it is helpful to have a standing agenda item for each function with sufficient time allocated to discuss any points raised.

ASRU carries out audits of AWERBs [11] and these require evidence that all the functions are 'adequately addressed' and included in the AWERB's Terms of Reference.

## **5) Think carefully about the selection of participants, including the Chair, and provide adequate induction, training and CPD**

A minimum core list of participants is set out in section 10 of the ASPA (see page 6), but, given the breadth of the AWERB's functions, it is recognised good practice to include people with a range of relevant knowledge, skills, perspectives and seniority. It is helpful to identify key personnel who will provide the drivers to achieve the AWERB's aims and functions and to communicate its activities and outcomes. Identifying an effective Chair is also critical to establishing an effective process (see box on page 16).

Induction, training and CPD for members is frequently identified as an issue that affects the AWERB's effectiveness. Although some AWERBs provide a good programme, a 2024 survey of members by the RSPCA reported that 14% of respondents received no induction or training at all. This topic is addressed in section 8.

## **6) Make sure the process is organised efficiently**

Efficient organisation is essential in order to minimise the resources (both financial and with respect to staff time) needed by the AWERB and to help achieve its benefits effectively. For example:

- Do not feel that every function needs a dedicated sub-committee; there may be better ways of dealing with the relevant issues, so wherever possible use existing systems that are working well. For example, if there are groups for NACWOs (Named Animal Care and Welfare Officers) or NVSs (Named Veterinary Surgeons) that have responsibility for health, husbandry and care, and the composition and remit of these is appropriate, they can report to the main AWERB rather than setting up an additional committee to deal with the functions pertaining to housing and care.
- Do not rely solely on formal and/or in-person meetings to progress issues. Ad hoc meetings, email discussions and online meetings are all useful tools.
- Do not over-complicate the process and over-burden everyone with paperwork. For example, some interim reviews of projects may be best addressed by the project licence holder attending the AWERB and presenting feedback on progress rather than asking for this through detailed forms. Either way, try to decide what information the AWERB actually needs and trial any forms, templates or guidance to licensees to ensure they are user friendly and achieve what is required.
- Try to set meetings for dealing with project licence applications in advance throughout the year, with full details and a timetable of the process so people know what to expect and what

they have to do. If there are any delays, or potentially contentious issues within a licence which are likely to require discussion, notify the project licence applicant as soon as possible.

- Do have a fast track system, for example, for non-contentious licence amendments that will not significantly affect animal numbers or severity.
- Do ensure sufficient administrative support is available to prepare papers for meetings and to co-ordinate and support other activities.

**7) Ensure that there is effective communication between all parts of the AWERB and any other relevant bodies in the establishment: all staff should know what the AWERB is for, why it is important, who is involved, how it affects them and how it works**

The AWERB should be able to liaise effectively with all other relevant bodies within the establishment, such as committees dealing with Research Governance or Research Integrity. An easy way to achieve this is for one or more members to sit on other relevant committees, e.g. a member of the AWERB could sit on the Research Integrity Committee and vice versa, ensuring that there is effective liaison.

The AWERB should also explain to all staff what its benefits are in terms of animal welfare, good science, regulatory compliance, maintenance of a constructive, caring culture, and transparency with the public. Publish this information internally - perhaps designing a 'know your AWERB' poster or intranet site - and consider publishing it externally as part of the establishment's position statement and contribution to openness on animal use. Encourage staff to view the process positively.

Include information about the local AWERB as part of the induction and training package for all staff and invite them to bring matters to its attention. Participation in the AWERB should be considered one of the responsibilities of all relevant staff (not just named people) and should be included in their personal development goals and appraisals.

**8) Be reactive and responsive to the needs of AWERB 'users'**

The AWERB needs to be accessible to all staff and particularly to engage with those whose activities it affects (including personal and project licensees and the establishment licence holder) to encourage their input and support, identify any concerns and resolve these. There should be a mechanism for any member of staff to provide input and feedback to the AWERB about its role and activities and how it affects them and their work. The AWERB should likewise provide regular feedback to staff on its activities and ensure that it is transparent by publishing agendas, minutes and reports.

## **9) At intervals, carry out a self assessment process to evaluate the AWERB's aims and outcomes and whether its operation is efficient and appropriate**

Every AWERB needs a system for evaluating its effectiveness and making sure its resources are directed where they are most needed and can make the most difference. These 'ten top tips', along with the rest of the material contained within this document, can be used to help develop an evaluation process. Ensure the views of AWERB participants and staff as a whole are sought.

## **10) Interact, and share ideas for good practice with, participants in other establishments' AWERBs and the ASC, particularly its AWERB Subgroup and Hub network**

There are a number of opportunities for AWERB participants to get together both formally and informally. The ASC has a standing AWERB subgroup and a role in 'sharing best practice' with AWERBs, so good channels of communication between local AWERBs and the ASC are needed. The ASC's AWERB Hub network organises workshops and maintains an online AWERB Knowledge Hub (see page 9).

Both the Laboratory Science Association (LASA) and the Establishment Licence Holders' Forum (ELHF) hold AWERB-related workshops. The RSPCA runs an annual Forum for Lay Members, which other AWERB participants also attend. AWERB-UK, organised jointly by the RSPCA, the Institute of Animal Technology (IAT), LASA and the Laboratory Animals Veterinary Association (LAVA) also organises occasional AWERB-themed meetings.

In addition, assuming there are no insoluble commercial (or other) confidentiality issues, AWERB participants from different establishments can be encouraged to attend each others' meetings occasionally, to experience different approaches and views on good practice.

## **Achieving the right mix of participants**

**Getting the 'right' people involved in the AWERB is integral to its success.** The membership needs to comprise a balance of different levels of seniority, roles and expertise, and include staff from different parts of the organisation. For example, involving personal licensees at an early stage in their career, and assigning value to their input, benefits their long-term development as future project licence holders, as well as enabling them to contribute to the Culture of Care.

The requirements for **minimum membership** and the **key roles** that should be represented are shown on page 6. However, given the AWERB's many different tasks and the expertise needed to address these properly, a broader membership is required. The **key competencies** that contribute to an effective AWERB must therefore also be taken into account. These are listed in the box on page 16 together with the **personal qualities** that are desirable. Membership can be flexible and it may be that not all of the competencies are required all of the time. In some cases, having access to people with appropriate expertise (e.g. in biostatistics) will work better than having additional members of the AWERB.

**Support from senior management** is essential and is best demonstrated by senior staff sitting on the AWERB, showing an interest in and participating in discussions, ensuring that all necessary resources are devoted to its work and demonstrating commitment to implementing its recommendations.

**Good chairing** is also essential to ensure the focus is on outcomes, the process is efficient, that everyone has the opportunity to contribute and express opinions, and to set the right tone. The Chair needs to create a supportive, inclusive environment where everyone is listened to and in which open and forthright discussion is encouraged.

**Lay and/or independent members** have proved very useful as participants in UK AWERBs and in equivalent bodies around the world. They can ask the kind of insightful questions that people directly involved with the science may not consider asking, and can bring a fresh eye, questioning established practice and challenging accepted norms. This can help to stimulate new or different ways of thinking about the ethical, animal welfare and scientific issues.

The Guidance to the ASPA does not explicitly mention lay members, but says that ASRU 'expect[s] establishment licence holders to arrange for their AWERBs to actively seek a wider membership, taking into account, in a transparent manner, the views of people who do not have responsibilities under ASPA, as well as one or more persons who are independent of the establishment'.

In practice, people from diverse disciplines may be regarded as lay, and may be recruited either from within the establishment or be entirely independent from it. It is possible to have a 'lay' member who works at the establishment, but is not involved in the science (e.g. an administrator). It could be argued that such a member is not truly independent, but the right person can still bring a valuable lay perspective. It is also possible to have a completely independent member, who is not connected to the establishment in any way, but who has a scientific or animal welfare background so is not really 'lay'. Both lay, and independent, viewpoints are important, and careful member selection should enable an AWERB to benefit from the two aspects.

**A Home Office Liaison Contact (HOLC)** is employed by many establishments to help administer, contribute to, and disseminate information about the AWERB. This is considered to contribute significantly to its success and efficient operation.

**The Named Information Officer (NIO)** plays an important role within the AWERB. The NIO can help in obtaining advice on specific issues, e.g. species that are new to the establishment, or new refinements, techniques or sources of information such as newsletters. They also advise on where and how to search for information on all 3Rs, and assist project and personal licensees with specific information requests. It is good practice to include the NIO as an active participant in the AWERB.

Training and competence are critical factors in maintaining high standards of animal care and welfare and of scientific quality. This is directly relevant to the work of the AWERB. **The Named Training and Competence Officer (NTCO)** has a key role in assuring such standards are met, so the engagement of the NTCO in AWERB discussions is strongly recommended. They should also be able to advise on induction and training for AWERB members.

### Key competencies

Knowledge, understanding & expertise in:

- animal husbandry, care and welfare
- each of the 3Rs
- education and training
- ethical issues
- scientific techniques
- public opinion and perspectives
- relevant scientific fields
- statistics and experimental design
- welfare assessment
- humane end-points

**Note, no individual is expected to have all of these!**

### Personal qualities

- open-minded, fair and impartial
- prepared to listen and respond to differing views and not be unnecessarily defensive
- prepared to 'think outside the box' and have the confidence to question the status quo
- realistic expectations of what can be achieved
- time and commitment to make an active and informed contribution and do the role justice

### Recruiting a good Chair

The role of the Chair is critical to the effective management and functioning of the AWERB. They need to have the time and personality to:

- have a 'vision' for the AWERB
- initiate, and help set, annual objectives and ensure the focus is on outcomes
- ensure that all AWERB functions are properly addressed, that the AWERB processes are efficient and that meeting agendas run to time
- summarise agreed actions and ensure these are followed up
- set the right tone, creating a supportive, inclusive environment where everyone has the opportunity to contribute, express opinions and be listened to and in which open and forthright discussion is encouraged
- be able to exert control and moderate if discussions become emotional
- set out the skills and personal qualities needed for the AWERB to be effective; assess the existing skills of members and help them access training whenever necessary; identify topics for CPD for the whole AWERB
- organise annual self assessment of the AWERB's work

# 3. Culture of Care

***"Help to promote a Culture of Care within the establishment and, as appropriate, the wider community"***

## Why a Culture of Care is Important

The use of animals in research and testing is an area where there are polarised views within society. It is an emotive topic, and an emotional burden, for all staff who work with animals. A positive Culture of Care leads not only to better animal care and welfare but also to enhanced scientific quality from the animal research conducted, and to staff who feel supported, engaged, and respected for their contributions. This further encourages them to challenge the status quo and strive for improvement in the care and use of the animals. Within a positive Culture of Care, including a good level of openness and transparency with the general public, the risk of non-compliance should also be reduced.

## The role of the AWERB

The AWERB is not solely responsible for an establishment's culture - but it is in an ideal position to drive the Culture of Care, and should, along with senior management (e.g. Chief Executive Officers, Directors, budget holders), demonstrate effective leadership in this area. This goes beyond simply assuming that, because other AWERB tasks are addressed, the Culture of Care will be good. Active focus is required to define, develop and maintain a high quality, local culture.

The Culture of Care should permeate throughout the establishment, but it is essential that senior management visibly demonstrates commitment to, and support for, generating and maintaining such a culture. The AWERB provides a good channel of communication to and from senior management because it advises the establishment licence holder, who is usually a senior manager. Other members of senior management also ought to be aware of the AWERB and the Culture of Care.

With respect to the wider community, the AWERB can play a role in ensuring that the establishment's communications about its animal use are accurate, specific, and include the benefits, harms and limitations of animal use, as set out in the [Concordat on Openness on Animal Research](#). The AWERB can also engage with the public about its specific role and functions, including its oversight of the science done at the establishment, animal welfare and ethical issues, and it can educate people about the Culture of Care. Note that promoting the benefits of the establishment's animal use is not the responsibility of the AWERB, and is not the same as 'promoting a Culture of Care'. However, AWERB members as individuals may wish to talk about the benefits of research, separately from the AWERB itself.

## Defining the Culture of Care

All establishments should ensure that they have a clear vision of what a Culture of Care means for them. The culture of an organisation relates to the beliefs, values and attitudes of its staff and the development of processes that determine how they behave and work together. The 'Culture of Care' describes an establishment-wide, demonstrable commitment to improving animal welfare, scientific quality, care of staff, and transparency for all stakeholders, including the public.

Every designated establishment should have a culture that demonstrates caring and respectful attitudes and behaviour towards animals and encourages acceptance of responsibility and accountability in all aspects of animal care and use. This should go beyond simply having animal facilities and resources that meet the minimum requirements of the legislation. Every establishment should strive for improved animal (and staff) welfare and enhanced scientific outcomes.

Increased awareness of the potential for compassion fatigue, or emotional labour, among personnel, has led to more emphasis on the 'caring for staff' element of the Culture of Care. All roles can be affected, so clearly signposted, tailored assistance should be available in case anyone experiences emotional distress. The 3Rs Collaborative has very helpful, free resources on compassion fatigue at [3rc.org/compassion-fatigue](http://3rc.org/compassion-fatigue) and the [Institute of Animal Technology](http://instituteofanimaltechnology.org) also has a mental health first aid service.

## Assessing the Culture of Care

A healthy Culture of Care requires a shift away from merely responding to externally imposed standards, to one in which leaders and frontline staff are actively committed to working together to improve the 3Rs, animal welfare and the quality of the science. Assessing the Culture of Care is a good way to monitor progress and some establishments have begun to do this, using a survey and information-gathering approach. This requires a manageable number of indicators that are subjective (e.g. survey questions asking 'what do you believe a Culture of Care is?' or asking participants to rate statements like 'I feel accountable for animal welfare', or 'I feel there is open discussion across all teams'); objective (such as whether there are sufficient veterinary and other resources); and animal-centred (e.g. information on enrichment or the fates of animals) [12, 13, 14].

Some factors shown to foster an appropriate culture within an establishment are listed below.

## Features of a Culture of Care

The three boxes below set out structural and behavioural elements of the Culture of Care, with some examples of activities that can help to further develop the culture. The structural elements, when properly developed and implemented, should drive behavioural and cultural aspects. This is a sustainable approach, because it is less reliant on individuals than simply having designated leaders or 'champions'. 18

## Structural elements

### General principles

- An establishment expectation of high standards in legal, ethical, animal welfare, 3Rs and scientific aspects of the care and use of animals. All of these should extend beyond the legal minimum, and be endorsed and implemented at all levels throughout the establishment
- An effective AWERB supporting ethical review of scientific work undertaken with a thoughtful and rational approach
- An effective operational structure with clear roles, responsibilities and tasks in which animal technologists and care staff, named persons (NVS, NACWO, NIO, NTCO)<sup>1</sup>, trainers and assessors are listened to and their work supported throughout the establishment
- Mechanisms to ensure that standards at animal suppliers, contracted organisations, and research partners overseas are at least consistent with the good practice that is implemented in-house

### Communication

- Good establishment-wide communication processes regarding animal welfare, care and use issues and the relation of these to good science. Effective and respectful communication between researchers, named persons and animal technologists and care staff
- A common set of values and standards which are communicated, understood and implemented across all parts of the establishment, with respect for differing ethical perspectives on animal use

### Training elements

- A robust framework for training and assessment of competence, together with recognition of the importance of continuing professional development (CPD) for all staff, and AWERB members, with adequate opportunities and resources provided
- Dedication to effectively achieving learning outcome 6 of the Local Module: '*discuss the importance of proactive approach to, and mechanisms of communication, as a tool to promote the Three Rs and the Culture of Care*' (the Local Module is part of the accredited training programme for those working under ASPA; it sets out the management structure, key personnel, and AWERB processes that promote animal welfare, good-quality science and a Culture of Care)

### Revision and review

- Promotion of a 'learning culture' so that mistakes, including non compliances, are openly shared, discussed and learned from
- Dedication to a cycle of review and improvement of policies and processes, to strive towards higher standards of animal welfare and all other aspects of the Culture of Care

**Plus a commitment to provide sufficient resources to achieve all of the above**

<sup>1</sup> Named Veterinary Surgeon, Named Animal Care and Welfare Officer, Named Information Officer, Named Training and Competency Officer

## Values and behaviours

- Strong commitment, support and leadership from senior management, which provides the resources to deliver the values of the institution
- Demonstrable respect for animals and recognition of their intrinsic worth, e.g. encouraging staff to empathise with animals, enabling them to express their feelings around harms to animals in science, facilitating rehoming wherever possible
- A proactive attitude and approach to improving standards of animal care and use and related organisational and management practices, rather than merely reacting to problems as they arise
- Staff having the appropriate attitude, demonstrating empathy for colleagues and animals and embracing good practice guidelines
- Acceptance of individual responsibility and accountability for animal use, from staff who are willing to take the initiative to resolve problems should any arise, with collective responsibility where appropriate
- An open culture where all have the ability to challenge the status quo, to speak out without fear and to support those that do; where staff are confident to report problems and raise any concerns, knowing these will be listened to, discussed and resolved in a positive way
- Commitment to openness and honesty about animal use - its benefits, harms and limitations - both internally and in the public domain

## Activities that can help in developing the culture

### Defining and developing the Culture of Care

- Developing an organisational vision and mission statement regarding the Culture of Care, for example by holding an interactive workshop for staff with a range of different roles
- Including consideration of animal usage outside that governed by ASPA regulations e.g. invertebrates (other than cephalopods, which are in scope), or use of animals for non-regulated purposes such as below-threshold behavioural studies

## Encouraging engagement and collaboration within the establishment

- Inviting animal technologists and care staff to research-group or laboratory meetings and including animal welfare, husbandry and care as standing agenda items at these
- Engaging project licence holders, personal licensees and animal technologists to sit on the AWERB, e.g. with rotation of membership
- Communicating effectively with the establishment licence holder about expectations regarding their accessibility and engagement with the AWERB; inviting them to visit the animal facilities on a regular basis; providing constructive feedback on how they listen to and action AWERB advice and recommendations
- Encouraging a collaborative approach to publication of research findings, scientific posters and presentations between animal care staff and researchers, ensuring that animal welfare and 3Rs-related material is included

## Training and staff wellbeing

- Including the Culture of Care with respect to animal use in an establishment as a core element of induction/training materials for all staff. The training resource Care-full Stories can help with this [\[15\]](#)
- Setting up a process for regularly checking-in with all staff to see whether there are issues with compassion fatigue or emotional labour, e.g. workshops, including the issue in 1-2-1s and making sure people know where to go with concerns about themselves or others

## Communicating about the Culture of Care

- Producing regular newsletters on issues relating to ethics, animal and staff welfare, 3Rs, scientific and other 'cultural' issues
- Having input into public engagement outside the establishment at schools, institutions of higher education and community groups, ensuring that animal use is appropriately represented and the Culture of Care is properly interpreted
- Joining the International Culture of Care Network - see [norecpa.no/coc](http://norecpa.no/coc)
- For other suggestions, see the poster overleaf, which was produced by the Culture of Care Network and can be downloaded at [tinyurl.com/y93s37zm](http://tinyurl.com/y93s37zm)

## Events

- Establishing 3Rs awards with recognition around the establishment, promoting these through attending meetings and via publications
- Taking part in open days e.g. for family of staff, students and the general public, and explaining the role of the AWERB and the meaning of the Culture of Care
- Presenting Culture of Care Recognition awards, including recognition of 'above and beyond' care towards the animals and/or colleagues

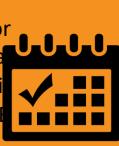
## Communication and the Culture of Care

Penny Hawkins, RSPCA Research Animals Department  
on behalf of the International Culture of Care Network\*

Effective two-way communication between scientists and animal technologists is essential for a good Culture of Care  
The European Commission suggests the 'development of formal and informal communication channels, for mutual benefit with respect to science and animal welfare'  
Here are some examples from International Culture of Care network members

### Regular meetings

Scheduled meetings for scientists, animal technologists, vets, unit managers and AWERB members



Regular refresher/update meetings for all organised by NTCO

### Special events

Duo-talks: researcher talks about their science, and animal technologists talk about techniques and animal care within the project



ELH organises an informal meeting for all, in which anyone can raise welfare issues



### Building communication into existing processes

Each study has a pre-start and wash-up meeting involving everybody



Three Rs improvements reported to AWERB & shared at external user meetings



### Other ideas

A 'boxless' event: anyone can submit 'out of the box' ideas to improve practice



A staff survey for all e.g. how much do you agree with statements such as 'in our group we listen to each others' ideas about animal welfare'



\*norecopa.no/culture-of-care

# 4. Application of the 3Rs

***"Advise on the application of the 3Rs and keep staff informed of any relevant technical and scientific developments"***

## What to aim for...

The AWERB can implement this task in a number of ways. For example, it can:

- Develop and implement an establishment-wide 3Rs strategy to clearly demonstrate the value the establishment places on the 3Rs, making them integral to its work (see 'Developing and implementing an institutional 3Rs strategy' by the NC3Rs [16])
- Work closely with, and support, the Named Information Officer (NIO) to provide a 'hub' for 3Rs knowledge and advice, capturing innovations and proactively disseminating information such as institutional policy decisions concerning local good practice
- When reviewing project licences, ensure the project licence applicant has adequately addressed the 3Rs, including the choice of model and experimental design
- Provide a mechanism to encourage and facilitate wide staff involvement in the 3Rs, motivating people to:
  - be proactive as well as reactive, actively searching for alternatives to animal use and selecting the most appropriate (and refined) model
  - regularly check out information from 3Rs organisations (you can find a list of these at [eusaa.eu](http://eusaa.eu))
  - think about and implement existing 3Rs opportunities
  - develop new 3Rs initiatives and activities
  - disseminate 3Rs information as widely as possible

It is important for AWERBs to approach 3Rs-related advice, and activities, both in the review of individual project licence applications and more generally within the establishment.

**Another key issue is that opportunities for each R must be explored – too often, only Refinement and Reduction are considered and Replacement is not adequately addressed**



## Examples of successful organisational approaches...

### ...within project review

**Set up one or more 'panels' to review 3Rs aspects of licence applications prior to these being discussed at a full AWERB meeting.**

Application of the 3Rs principles is essential in order to deliver high quality science as well as benefitting animal welfare. As a consequence, project applicants need to be encouraged to think about how they can apply each of the 3Rs as an integral part of their program of work. The questions on the project licence application form itself should help in this respect, but some AWERBs also develop their own set of questions to stimulate wider thought around each 'R'. Replacing Animal Research has developed a useful checklist specifically for Replacement which can be used both to stimulate thought about potential alternatives and to assess how well searches for alternatives have been carried out [17]. The RSPCA has also produced a sheet of 'questions to ask' when discussing replacement, aimed specifically at AWERB members [18].

Early sight of project proposals will enable 3Rs and experimental design issues to be explored and worked through with the project licence applicant. This engages licensees with the process in good time and can accelerate project processing considerably. The use of study plans such as PREPARE [19] and the ARRIVE Study Plan [20] and the Experimental Design Assistant (EDA)[21] can also help with proper assessment of experimental design.

Some establishments find it helpful to consider the 3Rs on a study by study basis. For example, in contract research organisations (CROs) the nature of the compound to be tested, and hence any associated scientific, welfare, ethical or management issues, may not be known until the start of a study notwithstanding the fact that the licence has already been authorised. In these circumstances, examining the potential to apply the 3Rs prior to each individual study makes good sense.

### ...for advising on the 3Rs outside project application review

**Assign responsibility to particular staff to interact with and feedback to the AWERB on specific 3Rs opportunities and issues e.g. refinement of housing, or specific procedures, or models.**

In establishments with few project licences covering a limited number of procedures on only a few species, it may be appropriate to assign responsibility for driving 3Rs activities to a nominated person, a central point of contact or facilitator. Some obvious focal points for this is the NIO, institutional research managers or 3Rs 'champions' or committees.

In establishments with more, and varied, licences, no one person will have all the expertise required, nor is it reasonable to expect them to have sole responsibility for all potential 3Rs activities. In such cases it will be necessary to draw on a wider range of expertise and perspectives. Responsibilities and workloads can be spread within one or more groups or sub-committees which can provide advice and feedback to the main AWERB. Involving one or more core groups of interested people provides a stimulus to think creatively, to generate useful ideas and to promote discussion.

**Such groups need a strong Chair or 'Champion' to drive the process, and to include people with specific expertise in each 'R'.** For example, a Named Animal Care and Welfare Officer (NACWO) could organise refinement activities around housing and care; an Named Veterinary Surgeon (NVS) could take responsibility for refining surgery; someone with statistical expertise could advise on opportunities for reduction; a researcher could take responsibility for refining a specific animal model or thoroughly reviewing the opportunities for Non-Animal Methods to replace all or some animal use.

In all cases, even if a single person acts as the organiser, it is important to harness a wider range of expertise and perspectives. As well as encompassing veterinary, animal care and scientific staff this could also include researchers who are working on replacements or partial replacements either at the establishment or wider, encouraging information sharing. The NIO can help by putting people with common interests in touch with each other.

**Implementing leading practice with respect to advising on the 3Rs - within and outside project review - is a significant task and it is essential that adequate resources are devoted to this. In particular, the NIO should have the time and resources to actively perform their role.**

## Examples of 3Rs activities

**The following lists of potential activities are intended as *ideas for what can be done*. Clearly, not all the activities will be relevant to all establishments.**

### General 3Rs

- Bring together project groups who share interests in similar mechanisms of physiological systems to consider all aspects of animal use within a specific research area. Knowledge could be shared on replacement technologies, e.g. the use of in vitro systems to assess effects on QT interval, an important measure of cardiac safety which has resulted in dramatically reduced reliance on animal models; or to review the validity and usefulness of the different models and protocols used for similar projects.

- Request feedback when novel techniques or pilot studies have been performed (successfully or unsuccessfully) so that information can be disseminated and applied in future studies.
- For establishments that are part of multinational companies or research programmes, contribute to the development of international initiatives and oversight mechanisms for the 3Rs (e.g. see box on page 29: The Marseille Declaration).
- Arrange workshop sessions to discuss more radical 3Rs approaches (e.g. eliminating procedures that cause severe suffering, performing 'gap analysis' with regard to replacing animal use in a given project or challenging the value of a regulatory toxicity study).
- Use mid-term/retrospective project licence reviews to identify and disseminate 3Rs approaches that may benefit others.

## Refinement

- Develop species-specific welfare assessment protocols/Standard Operating Procedures (SOPs) and score sheets for commonly used procedures/models and establish a mechanism for their regular review.
- Periodically consider individual topics focusing on species-specific welfare issues (e.g. housing and procedures involving rats) or broader issues, such as reviewing the provision of environmental enrichment and how this could be improved.
- Initiate internal reviews of procedures (e.g. blood sampling, telemetry, biopsy methods, use of metabolism cages, restraint, or aseptic techniques [22]), with a view to refining these and/or writing refined protocols/internal guidelines for the establishment. The latter can then be used as a consistent establishment standard and applied to work done under all relevant project licences. All such documents should be version dated and reviewed on a regular basis.
- Focus on identifying severe procedures and developing ways of refining and eliminating these (see [focusonseveresuffering.co.uk](http://focusonseveresuffering.co.uk)). If there are no severe procedures, apply the same process to other levels of severity.
- Encourage focused evidence-based studies to challenge preconceptions about the way procedures 'have always been done'.

## Reduction

- Facilitate access to expert biostatistical advice to ensure that the minimum number of animals is used whilst still achieving the scientific objectives.

- Review whether there is any over-breeding and/or wastage of animals e.g. whether animals are requested, but not used, or why only one sex is required (see the Sex Inclusive Research Framework [\[23\]](#)). Discuss and agree ways of reducing this, for example, by improving communication with the supplier or raising awareness of the issue with the project licence holder.
- Set up a co-ordinated process for tissue sharing within or between establishments.

## Replacement

- Start a dialogue with the Research Office or Research Integrity Departments (or equivalent), to help them in guiding researchers to think about replacement earlier in the research design process when they are applying for funding.
- Encourage researchers to actively engage with relevant organisations including the UK NC3Rs (more 3Rs centres are listed at [eusaa.eu](#)), [Replacing Animal Research](#) or [Norecopa](#), to assist them with searching for and identifying replacements.
- Where possible facilitate links and collaboration between researchers using different approaches such as in vitro or in silico methods, to encourage discussion and idea sharing around replacement in early project planning stages.
- Consider recruiting a non-animal methods expert to your AWERB and/or setting up a replacement network to bring together those working on replacement technologies with those looking to use them, e.g. see the GW4 Animal Replacement Network ([gw4.ac.uk/gw4-animal-replacement-network](#)).
- Ensure that all points within the 2024 Home Office Guidance Notes for Project Licence Applications [\[3\]](#) have been addressed, including providing evidence of rigorous exploration of alternatives and selection of the best/most appropriate model and species, with references. Ask if the AWERB can share good examples.
- Set up in-house ‘clinics’ with the help of librarians (or those with equivalent expertise in finding information) to support individuals exploring opportunities to replace animals in part, or all, of their research programme.

## Disseminating 3Rs information

The AWERB needs to build a local culture that facilitates communication of, and engagement with, the 3Rs (see also section 3 on the Culture of Care). This requires mechanisms for disseminating information, bringing relevant issues (e.g. legislation, meetings and publications) to the relevant people’s notice and fostering interest more widely.

This has proved easier in establishments where the 3Rs are dealt with by one or more dedicated 3Rs groups. Relying on disseminating all information to all staff, regardless of its relevance or their interest (a scattergun approach), is unlikely to be effective since it does not involve and engage people. **Targeting individuals with information relevant to them, preferably through personal interactions, is more effective.** For example, taking the time to explain how a specific refinement relates to a particular piece of work, and how it is likely to improve scientific outcomes, is more likely to persuade a licence holder to implement a change than merely including such information in a standard newsletter or email. Although this may be more time-consuming, it has the long-term advantage of achieving better 'buy in' to what the AWERB is trying to achieve.

## Examples of useful communication activities

- Provide access to on-line information sources: for example, a central local intranet, external websites and on-line discussion groups.
- Provide a 3Rs staff newsletter or email alerts with information on 3Rs publications, grant availability, meetings, courses or other activities.
- Ask the NACWO, NVS, or Home Office Liaison Contact (HOLC) to assist the NIO in assimilating 3Rs information and sharing it with each other and those who need to consider it. Staff in the named person roles often have a good national communications network through which to gather and disseminate information both locally and externally.
- Encourage project licence holders to keep the NIO informed about any developments in the 3Rs so that this information can be shared widely across the institution.
- Ask project licence holders to summarise any 3Rs developments for the AWERB either annually, or at retrospective review. At some establishments this has been linked successfully to an internal 3Rs symposium, poster or prize day.
- Showcase individuals who have managed to replace animals in part, or all, of their research programme.
- Invite speakers from 3Rs (e.g. NC3Rs) or individual R (e.g. RAR) organisations to give talks/webinars/workshops.
- Encourage all staff to disseminate information on 3Rs innovations externally through publications, posters and conferences.
- Convey information through animal user group (and other similar) meetings.
- Encourage staff to visit other establishments to observe different working practices or 3Rs initiatives.
- Provide training opportunities in the 3Rs, either online or face to face.

## The Marseille Declaration

In 2022, eleven pharmaceutical companies signed the 'Marseille Declaration', a joint agreement to uphold high global standards for the welfare of laboratory animals and oversight of their use. The declaration states a commitment to the 3Rs, ensuring that high and consistent standards are applied in all their research and production activities, including those conducted by external partners.

This is helping to establish shared values and expectations for animal use, and the Culture of Care, across the pharmaceutical industry. See: [merckgroup.com/en/sustainability/business-ethics/marseille-declaration.html](https://merckgroup.com/en/sustainability/business-ethics/marseille-declaration.html)



# 5. Project Review

***"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"***

## What to aim for...

The AWERB needs to define clearly what it wishes to achieve by considering project licence applications and amendments. The task needs to be seen in the context of some of the other functions of the AWERB, including providing a forum for discussion and development of ethical advice to the establishment licence holder (see section 9). Ethical aspects of project licences should therefore be considered as well as harm/benefit issues and the 3Rs. Since the AWERB has a role in supporting named persons, it should allow any of their concerns about a licence application to be considered and acted upon where needed.

Many of the general principles on pages 10 to 16 of this document are relevant to achieving good practice for project review. In particular, there is a need to ensure that project licence applications are dealt with in a timely and effective manner and that there is not a disproportionate focus on this aspect of the AWERB's work, to the detriment of other tasks.

**A key issue is to decide where and how the AWERB can add value over and above any other sources of input to the licence.** For example, the scientific aspects of some project proposals, including the scientific merits of the work, may have been considered by the research funders or the establishment or company concerned, and the project licence application will be reviewed by the Home Office Animals in Science Regulation Unit (ASRU) Inspectorate. The AWERB should aim to complement these reviews, because its benefit comes from looking at projects from a **local perspective**, bringing **local knowledge** and **local expertise** to bear. As an example, the **Appendix** on page 70 illustrates how blood sampling procedures would be dealt with by the different review bodies.

## Where the AWERB adds value...

### For the establishment as a whole, the AWERB:

- Ensures that *local* knowledge, expertise and perspectives are brought to bear on the project with respect to:
  - the establishment's policies, procedures and culture;
  - the acceptability of the work to the establishment, both in general and with respect to the scientific, animal welfare and ethical aspects of the project;
  - the availability of suitable facilities, resources and appropriate expertise in house or at an alternative establishment;

- the provision of a forum for constructive discussion between people with relevant but diverse expertise and perspectives;
- ensuring that 'leading practice' is implemented within the project and that there is consistency of preparation, examination and submission of individual project licence applications;
- provision of wide 'ownership' of the project, helping to ensure that there is appropriate supervision of, and support for, licensees, together with appropriate dissemination of information; and
- ensuring that the project is conducted in accordance with the Culture of Care.

**For the establishment licence holder, the AWERB:**

- provides high quality independent advice with regard to animal work carried out at the establishment, which is ultimately his or her legal responsibility as establishment licence holder;
- provides assurance that licence applications submitted to the ASRU are well prepared, the potential benefits and likely harms have been identified and assessed, the 3Rs have been applied and the harm/benefit assessment is considered appropriate.

**For the named persons, the AWERB ensures that:**

- the expertise and perspectives of local Named Animal Care and Welfare Officers (NACWOs), Named Veterinary Surgeons (NVSs) and animal technologists and care staff are acknowledged, understood, supported and brought to bear;
- the Named Information Officer (NIO) has a channel for provision of information and advice; and
- the Named Training and Competency Officer (NTCO) can provide comments and advice about any training and competency issues that are likely to arise.

**For the project licence holder, the AWERB:**

- can help the prospective project licence holder to produce well structured, well considered project licence applications for submission to ASRU, in which the harms, benefits and opportunities to apply the 3Rs are clearly described, and any problems/issues have been addressed at an early stage;
- can provide helpful feedback from the lay member/s on the non-technical summary and whether this would enable the science to be understood by the public; and
- demonstrates the establishment's confidence in, and support for the project.

**Some useful approaches...**

AWERBs vary in the stage at which they get involved in preparing and/or reviewing a project licence application and in how they go about this. There are two aspects to consider:

- whether, and how far, the AWERB wants to be involved in assisting with the *preparation* of a licence application; and
- how the AWERB interprets its task of *considering project licence proposals* and amendments.

There are no hard and fast rules. Each establishment needs to decide how it wants the AWERB to deal with these two aspects, what it plans to achieve with respect to both, and the best approach for its individual circumstances. This will depend on factors such as the nature and number of licence applications the establishment processes each year and the time constraints that this imposes.

## Assisting with the preparation of the licence

Drafting a licence is the responsibility of the prospective project licence holder - and the AWERB should not write it for them. However, AWERB input at the project planning and application stage can provide opportunities to improve the quality of applications, promote application of the 3Rs, ensure ethical issues are identified and determine whether there are suitable facilities and expertise for the work within the establishment. It also helps ensure that local policies, 'rules' or standards have been considered.

It is good practice for project licence applicants to consult with the named persons; the NACWO, NVS, NIO, NTCO, Home Office Liaison Contact (HOLC) and any other staff likely to be involved, early on in the planning of a project and to document the outcome of such discussions. Since many named persons are participants in the AWERB, this early input could be considered as a part of the overall AWERB process. Named persons may be consulted individually or within small groups that advise on what the licence should contain and help the project licence applicant, specifically, to address the practical issues in the licence. This enables any factual and/or technical issues to be sorted out before the licence application goes for formal AWERB review, thus facilitating the process.

If the licence application is well prepared and well written, its consideration by the AWERB and formal review by the ASRU will be faster and easier, since there will be less need for a to and fro of questions or advice. A key issue for the project licence holder, therefore, is how to ensure that the licence application is submitted for formal AWERB consideration in good form with:

- clear and achievable objectives;
- a clear project plan which explains the experimental design and how the protocols will be used to address the objectives as well as how they will be carried out;
- all proposed likely benefits clearly described and achievable;
- an explanation of how each of the 3Rs will be applied, together with a description of how they have searched for Replacement opportunities and non-animal methods;
- all likely welfare issues (harms including cumulative severity) identified and clearly described and categorised, with a detailed plan as to how they will be ameliorated;
- humane endpoints clearly defined;
- any resource issues identified;
- staff training, supervision and competency requirements appropriately addressed.

Whatever the process for licence preparation, the AWERB needs to communicate clearly what their consideration of the licence involves and what information the AWERB needs to see. These issues should also be explained in licensee training and in-house Continuing Professional Development (CPD).

## Considering the licence application

Proposed objectives for AWERBs when formally considering a project licence application are to:

- ensure that the project licence application has been prepared to a satisfactory standard, consistent with local requirements relating to good practice in science, experimental design, animal welfare and the 3Rs (see the box overleaf), and advise the establishment licence holder on whether to approve submission to the ASRU;
- ensure that there is a satisfactory non-technical summary written in appropriate language for a lay person to understand;
- identify the ethical and welfare issues and consider the harm-benefit balance from the local perspective;
- identify any concerns/issues likely to apply to other projects and consider development of establishment-wide good practice guidance and SOPs if this would be helpful, thereby acting as a mechanism for driving improvements and consistency;
- propose time points for mid-term or retrospective review.

The AWERB may not need to *review the detail* on all of the above points. For example, if there is a statistician who has already reviewed the statistical design this should be sufficient.

However, AWERB participants will need to feel comfortable that *all* the issues in the box overleaf have been satisfactorily addressed and that there has been sufficient opportunity for discussion and resolution of any concerns.

When reviewing a project licence, some discussions may take place in order to identify edits to the application before it goes to ASRU, for example to define a maximum percentage of body weight loss as a humane endpoint. Other discussions may be solely to reassure the AWERB that things will be done according to good (or leading) practice, such as using a particular formulation of analgesic jelly for rodents to self-administer post-surgery. While records may be kept of these types of discussion, it is not always appropriate (and is sometimes unhelpful) to add this level of detail to the project licence. Named persons can advise about this.

## The AWERB needs to seek reassurance that:

- the **benefits and quality of the science have been considered** (e.g. with respect to the appropriateness of the animal model) and that the scientific approach is fully justified
- there is a **realistic appraisal of what can be achieved from the animal work**, within the timeframe for which the licence will be granted and how the benefits will be realised (e.g. feeding into collaborative research projects, contributing to clinical trial proposals)
- there has been a **robust analysis of the methodology** including all relevant aspects of experimental design (e.g. randomisation and blinding) and sex selection [23], ensuring that, where necessary, expert biostatistical advice has been sought
- all the **potential harms have been identified** (encompassing the animals' cumulative lifetime experiences), clearly described, understood, assessed, and alleviated throughout the life of the project
- there is **evidence that each of the 3Rs has been fully and separately considered**, and implemented as far as possible, and that staff with relevant expertise (NIO, NACWO and NVS in particular) have had the opportunity to contribute in this respect
- **local policies and leading practice procedures will be implemented**, e.g. on issues such as genotyping, pain management, administration of substances, welfare assessment
- the project licence **applicant is appropriately qualified and has the necessary skills** to manage the project within the establishment and any training/supervision/competency needs of the staff who will work under the licence are being addressed
- suitable **funding, facilities and equipment are available**, and there are enough staff with the necessary expertise to carry out all work associated with the project within the time frame outlined in the project licence application
- there is a **clear and transparent non-technical summary** which adequately covers possible animal welfare issues as well as the justification for, and benefits likely to arise from, the work
- ethical concerns have been identified and the balance of harms and benefits has been thoughtfully weighed, with **sufficient justification provided for the specified animal use**

## Reviewing the science

A common question is whether the AWERB should have a role in reviewing the science if this has already been peer-reviewed by a funding body or industry scientific review panel. These bodies are likely to have different priorities and perspectives from the AWERB when reviewing the science. For example, they may review the overall strategic approach to a problem; whether the science is novel; whether the 'right' scientific questions are being asked; and whether the experimental approach allows the scientific questions to be answered.

The AWERB has a responsibility to ensure these issues have been dealt with either externally or in-house and will need to consider the science and its benefits alongside the harms in order to assess the justification for the research taking into account local factors, priorities and perspectives. For example, the establishment may have decided not to carry out particular regulatory tests, nor to carry out procedures that cause severe suffering, or there may be insufficient technical expertise and equipment available. The potential for further review of the science depends on whether there is specific local expertise in the field that can provide a useful additional contribution.

It is not possible to properly consider the benefits alongside the harms and therefore address the ethics in ethical review, without knowing whether the benefits are clearly set out, significant, likely to be achieved and have not already been addressed elsewhere.

*Whatever the approach, the science needs to be explained so AWERB members can make an informed judgement on its possible benefits in relation to the likely harms to animals.*

## Developing an efficient, helpful, enabling process...

Project evaluation by the AWERB should be positive, constructive and efficient. If the process is organised, or performed, poorly it can be frustrating to both AWERB members and project licence applicants. Potential project licensees need to see the AWERB process as enabling, so it is good practice to involve as many of them as possible as participants, perhaps on a rotational basis, during their time at the establishment. Then they can see first-hand how the process works and how they can contribute. The RSPCA has produced a pack to develop and maintain good AWERB-scientist relations, available at [tinyurl.com/AWERBengagement](http://tinyurl.com/AWERBengagement).

Ideally, the full AWERB should meet to consider project licence applications. This ensures that all members can raise and resolve questions easily and gain a good understanding of the work in order to advise the establishment licence holder. However, some AWERBs find it helpful for preliminary issues to be considered by a core subgroup of AWERB members before the licence is discussed by the AWERB as a whole. Others have set up project review subgroups that review applications and report back to the main AWERB.

Face to face consideration of new applications provides a valuable learning opportunity for both the licensee and AWERB members, because of the inclusive and discursive nature of meetings. It also helps engage the project licence applicant and familiarises them with the AWERB's work. 'Virtual' meetings can be useful in certain circumstances but these should not completely replace 'in-person' meetings which have the advantages described above. The circumstances under which virtual meetings and email discussion could be considered need to be agreed by the full AWERB.

The following boxes provide examples of **AWERB Dos and Don'ts** which, together with the **ten top tips** on page 10, should help to ensure that the process is both effective and painless.

### Summary Dos

- Decide what you want to achieve from the review and what the outputs should be
- Start the process early and work to defined time-frames to help manage applicant expectations
- Be clear about the information the AWERB needs, when and why, and streamline any paperwork
- Consider developing good practice Standard Operating Procedures (SOPs) for common procedures so that there are defined local standards, which can be applied to all projects
- Identify key questions and points for discussion in advance of AWERB meetings
- Ensure the process is transparent and that project licence applicants know what (and who) the process involves and what input is expected of them personally. Include this information in the AWERB's Terms of Reference (ToR)
- Conduct meetings in an environment that is conducive to constructive discussion
- Offer project licence applicants the opportunity to meet and discuss points in person: i.e. *involve them in the process*
- Decide on a policy/procedure for fast tracking minor amendments and set clear criteria for decisions on which amendments can follow this route
- Keep a record to track applications to show where and why any delays occur and who bears the responsibility for these
- Build in a mechanism for licensees to feedback the Inspector's comments on the licence to the AWERB to help inform future reviews
- During ASRU audits, ask for feedback from ASRU on the quality of licence applications in general, as well as on the operation and effectiveness of the AWERB
- Regularly review how well the system is working, making sure AWERB members and licensees are consulted

## Summary Don'ts

- Over complicate the process; create excessive paperwork or duplicate anything required for other purposes
- Dictate the style of writing, try to rewrite the application, or write it for the applicant
- Insist on inclusion of levels of detail that are not actually required by ASRU
- Conduct the review without the full AWERB having the opportunity to input
- Make the review process confrontational for the project licence applicant, or allow them or AWERB members to feel intimidated in meetings
- Insist on formally reviewing minor changes with no harm/benefit implications, or that would lead to an animal welfare improvement

## Dealing with amendments

Amendments to existing project licences can be vastly different in scope, varying from minor editorial clarifications to the addition of major new procedures with the potential to have an appreciable effect on animal welfare. The approach of the AWERB to amendments should be proportionate to the level of change requested. As for new applications, the AWERB can decide whether virtual meetings or email discussions may be appropriate.

Major changes should receive similar scrutiny to that devoted to a new application because they may affect the overall harm-benefit analysis for the project. Examples of major changes include:

- extending the scope of research within the stated purpose of the project;
- an increase in the severity category of one or more protocol(s), which is likely to affect the harm-benefit assessment;
- addition of new protocols;
- a significant increase in animal numbers;
- the use of an additional animal species or life stage; or
- the use of a new strain with an adverse phenotype (an animal whose genetic makeup, or genotype, has resulted in them developing harmful physical characteristics).

For minor amendments where there are negligible adverse animal welfare or harm-benefit implications, there is a clear benefit to having a fast track processing system. For example, consideration of the amendment could be delegated to a small group of key AWERB members including both the NACWO and NVS.

### **Examples of minor amendments include:**

- refinement of an existing technique with an animal welfare benefit;
- addition of an alternative, equally or less harmful, route or site of administration;
- replacement of a behavioural test with a new one of equal or lower severity;
- clarification of wording within existing protocols, e.g. improved description of adverse effects;
- acquisition of additional scientific data/additional techniques performed under terminal anaesthesia at the end of a study e.g. some imaging procedures or intra vital microscopy; or
- changes in personnel with equivalent expertise.

The AWERB as a whole needs to develop criteria for deciding which amendments can be 'fast tracked'. The criteria need to be clearly stated in its Terms of Reference and be easily accessible to staff so that they know what to expect and what they need to do. The AWERB also needs to set time-lines and agree these with the establishment licence holder. If the criteria are clear, then someone from the AWERB (e.g. the HOLC) can be appointed to organise and administer the fast-tracking process.

It also needs to be clear when involvement of a wider set of AWERB members is required, and members should always have the option of asking to see licence amendments that have been submitted for fast tracking. If there is any disagreement or doubt with regard to a particular amendment, the AWERB chair can make the final judgement on how to proceed. Regular feedback to the AWERB on fast-tracks should provide reassurance that contentious issues are not missed or handled inappropriately.

### **Dealing with additional (or 'secondary') availability**

The project licence applicant must specify the place where the work will be done, which is usually a licensed establishment. This is the 'primary availability'. If the licence names other licensed establishments where the work can take place, these are called 'additional availabilities'.

The establishment licence holder of an establishment providing additional availability is required to endorse the work before the project licence can be sent to ASRU for authorisation. The AWERBs at both the main and the additional availability establishments have to consider the application, and licensees need to be made aware of this requirement in internal guidance documents so that they can familiarise themselves with the details of the processes at both establishments.

Also, each individual establishment will need to decide what review criteria and standards to apply to a) projects for which it has agreed to provide additional availability; and b) its own projects when additional availability is being sought elsewhere. In both cases, the key consideration for the AWERB is to decide on how important it feels it is to ensure the work is assessed, justified and carried out to its own standards.

There is a need for AWERBs to remain flexible where institutional requirements differ although without compromising their own position. Early discussion of such issues is recommended, together with identification of a suitable contact person (e.g. the HOLC) at the additional availability establishment, who can guide the application through its review process and feedback any comments quickly.

Consideration of the project licence by the AWERB at the additional availability establishment is advantageous because it provides a mechanism for exchanging ideas and disseminating information on good practice. It is important to ensure that the process, and expectations, are well managed, because of the time this can take and the potential for different AWERBs to reach different decisions. For establishments that have many different availabilities (for example arising from collaborative projects), it may be worth considering setting up joint AWERB meetings to consider the licence applications concerned.

## **Reviewing projects with animals or work that is not regulated under ASPA**

Some AWERBs now consider all work on animals carried out within an establishment, i.e. non-ASPA regulated (NASPA) work as well as regulated procedures. This ensures that the AWERB has oversight of all animal work and that ethical considerations and standards of supply, accommodation, care and humane killing are applied and consistent across *all* studies. NASPA review also allows for exchange of information between different fields. NASPA procedures include studies on invertebrates (apart from cephalopod molluscs, which are already in the scope of ASPA) animals killed for their tissues without undergoing any regulated procedures, non-invasive companion animal studies, projects using immature forms of 'protected' species (e.g. zebrafish larvae 4 days after fertilisation), work done overseas, or noninvasive field work on farm or wild animals.

As well as the oversight of all animal work, the benefits include greater transparency regarding animal use and better understanding and management of any potential reputational issues that may arise. For example, a researcher may not be aware that their procedures could be approaching the threshold for regulation, especially if there are cumulative effects. As another example, invasive overseas work done in countries with standards below that of the NASPA is fraught with reputational risk.

There are a number of different approaches that AWERBs can take, including an in-house form asking about the application of the 3Rs, harms and benefits and how any animal welfare risks will be identified and mitigated. This could be reviewed by the AWERB or a NASPA subgroup. Alternatively, applications can be triaged by NVS/NACWO with only contentious projects going before the NASPA committee. Whatever the approach, the proposed research, or other use of animals, should always align with the local Culture of Care at the establishment.

# 6. Retrospective Review and Assessment

***“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 “assist with the retrospective assessment of relevant projects carried out at their establishment”***

**There are two AWERB tasks related to reviewing projects once they have been authorised:**

- following the development and outcome (retrospective review) of all projects, taking into account the effect on the animals used; identifying and advising on elements that could further contribute to the 3Rs; and
- the retrospective assessment of selected projects (e.g. those involving severe procedures), where the AWERB is asked to undertake assessments and submit these to the Home Office Animals in Science Regulation Unit (ASRU)

**Retrospective reviews (for all projects) and retrospective assessments (for selected projects)** both employ similar processes. One key difference is that retrospective reviews can be done at various stages within the project (e.g. mid-term) as well as at the end, whereas retrospective assessment focuses solely on evaluating the final outcomes of a project. Both are considered extremely powerful tools to facilitate critical review of the use of animals in scientific procedures, to identify future 3Rs improvements and, if published, to inform future studies and to enhance transparency to the public.

## Retrospective review

A key overall purpose of retrospective review in the general sense of ‘*following the development and outcome of projects*’ is, wherever possible, to reduce the harms and increase the benefits of every project at an establishment. Other aims include improving animal welfare, the application of the 3Rs and the quality of the science, and helping to inform future decisions around these issues. Gathering metrics, for example on how many animals were bred but not used, or how many animals experienced severe suffering each year, is also a powerful tool in promoting good practice.

The LASA Education, Training and Ethics Section (ETES) has developed this overall purpose into a set of three activities shown in the boxes on pages 41 to 44. Not all of the points listed in the boxes will be relevant to all projects, but they provide an indicator of questions the AWERB can consider. Information requirements for retrospective review are similar to those outlined on page 47 for retrospective assessments.

## Some common approaches are ...

- to carry out a retrospective review of **projects on their completion**;
- to review the work **at a single interval during the life of the project**, for example: a single mid-term review; or a review one year before the project ends. The latter is advantageous as it helps to prepare for any future project licence application;
- to review the work **at a designated point during the project** (e.g. when pilot studies have been completed) in order to address any concerns raised by named persons or the AWERB during project evaluation (e.g. if the work is novel or raises specific welfare concerns such as severe procedures);
- to **carry out reviews annually** during the course of a 5 year project;
- to **carry out study by study review**; this enables improvements to be rapidly incorporated.

The latter four approaches are usually described as **interim reviews**. Where research is considered on a study by study basis, flexibility is essential even within a single establishment, since it is unlikely that all licensed work will require the same review schedule.

## Aims of retrospective review

**(i) To determine whether the actual harms and benefits are in line with those anticipated, and ensure information and experience gained during the course of the review period is applied to future assessments**

Defined time points for review provide a 'time-out reminder' for all relevant staff to raise any concerns they may have regarding the project and to determine how to resolve them. They also provide opportunities to report things that are going well and which could influence future directions and/or funding decisions for current and future projects. Issues to consider include:

- whether the science is on-track and the results are as expected
- the actual adverse effects experienced by the animals, including those that were both predicted and unpredicted

- the actual severity compared with predicted severity
- whether any problems have been identified and addressed
- whether any Standard Condition 18 reports were generated
- whether there are any recent developments in science or technology (including opportunities for complete or partial replacement) which influence the direction or conduct of the study or affect its value
- whether anything has changed which might alter the original harm-benefit analysis

**(ii) To identify, develop and promote good practice and improvements in the 3Rs during the course of a project**

Issues to consider include whether:

- there have been any new opportunities to partly, or completely, replace animal use with non-animal methods since the project began
- the licence holder has developed any non-animal methods themselves
- there have been further opportunities to reduce, or optimise, numbers since beginning the project
- the experimental design has been improved, to answer the scientific question(s) more effectively
- new refinements have been made to procedures (e.g. restraint, administration of substances, sampling, analgesic regimes, surgical techniques) and/or humane endpoints
- welfare assessment sheets and monitoring procedures are working well and there have been opportunities to improve, and tailor, these
- practice has been optimised to minimise any adverse effects associated with supply and transport, and/or housing, husbandry and care
- measures have been taken to improve the quality of life of animals on long-term studies, to help them cope and minimise the risks of physical or behavioural problems (e.g. age-related diseases or stereotypic behaviours)
- any special housing and care needs have been effectively catered for (e.g. refinements to ensure that cages do not become soaked with urine when housing diabetic animals)
- humane killing methods have been reviewed and refined
- the risk of animal wastage has been avoided and minimised
- opportunities for release or re-homing of animals have arisen, and how well this has been handled in practice
- the licence holder has shared, and/or plans to share, 3Rs improvements with colleagues within and outside the establishment

### (iii) To facilitate project management

Issues to consider include whether:

- any amendments are likely to be needed in the near future, perhaps due to unexpected harms or new discoveries as highlighted in aim (i)
- there are any flawed data, or unforeseen results, and what caused these
- the facilities are still appropriate, or if there is anything that the project licence holder should be made aware of (e.g. facility refurbishment, new equipment, new guidelines or Standard Operating Procedures [SOPs])
- there are any human resource issues (e.g. staff shortages) that affect the project
- any training needs have been identified and have been discussed with the Named Training and Competency Officer (NTCO)
- there is satisfactory communication within and/or between research team(s)
- animal care staff, or the veterinarian(s), have any concerns about the work; their roles and opinions are being well supported by the establishment; and whether there are any conflicts with the project licence holder
- there are any problems with sourcing animals or change in health status, e.g. a disease outbreak which delayed the project
- the project licence holder feels the project is well supported by the establishment
- there is any new, relevant information on the 3Rs that could be disseminated within and/or between research groups and establishments
- there have been any difficulties in managing the licence, including potential for non-compliance incidents (e.g. those requiring reporting under Standard Condition 18 may be non-compliant); if so, what lessons were learnt
- there are any commendations for any of the project team

## Developing an effective process

The general principles set out on pages 10 to 16 and many of the points on prospective project review (previous section) also apply to retrospective review. The process needs to be positive and constructive, with objectives clearly defined, so that licence holders know what is expected of them and can see how it benefits them, their science and animal welfare.

Information on the process should therefore be included in local training, inductions and AWERB licensee information packs. There may also be a benefit in organising a local workshop to consider how retrospective reviews should be performed at the establishment and to enable animal care and scientific staff to contribute to the development of the local process.

If the local culture supports the view that an ongoing review is good practice, then it can become an integral part of normal project management and team meetings, with feedback from these going to the main AWERB. The box below provides examples of beneficial outcomes of retrospective review reported by contributors to this document.

## Example outcomes from retrospective reviews

### Replacement

- An increase in the amount of work within a project which was able to be undertaken in vitro
- Sharing of equipment or expertise and training between groups

### Reduction

- Reduction in mouse usage and development of more humane endpoints by the application of novel imaging techniques
- Identification of new genetically altered (GA) models that benefited other projects, reduced the need for other reporter lines, avoided duplication of similar lines, refined the protocol, and allowed for the dissemination of this information to others in a timely fashion
- Sharing of expertise and training between groups

### Refinement

- Development of a planned programme of back-up studies so that animals from a cancelled study were not wasted
- Implementation of positive reinforcement training programmes that reduced the need for restraint of animals
- Updated mouse passports with details about optimal breeding practices, husbandry needs, litter sizes, reproductive life details (useful for facilitating the movement of animals within and between establishments)
- Development of new score sheets for animal welfare monitoring based on previous observation of clinical signs
- Better description of welfare indicators used to define humane end points for species not previously widely studied e.g. mole rats, grasshopper mice, tadpoles, newts
- In contact (in cage) transmission of infectious agents such as gastrointestinal bacteria to cohorts of animals, thereby mimicking human disease better and avoiding the need for more invasive administration techniques e.g. oral gavage
- Removal of requirement to food restrict/deprive rodents for periods of time on certain metabolic/behavioural studies
- The reduction of adverse effects associated with the use of Complete Freund's Adjuvant (CFA, which can have significant adverse effects) through the dissemination of good practice
- The reduction in the use of foot pad inoculations to stimulate immune responses by demonstrating the efficacy of an alternative, less painful route of administration

## Timing

**It is helpful that the AWERB identifies provisional dates for interim or retrospective review of each project licence and advises the establishment licence holder of these when the application is submitted to them for signing. In the case of projects where a retrospective assessment is required, the Home Office will advise on the timing when the licence is granted or amended.**

The timing of retrospective review(s) may vary with each licence, and the nature, novelty and severity of the procedures involved. For example, a simple pharmacokinetic study to measure drug concentration in blood, which requires a single oral dose followed by collection of serial blood samples of small volume from superficial blood vessels, is unlikely to require frequent review.

For more complex projects it might be more appropriate to carry out a review on a regular (annual, or possibly experiment by experiment) basis. For example the development of a new animal model, or the provision of a drug metabolism service to a number of drug discovery projects, using a variety of different dosing routes and different types of compound, will benefit from regular reviews.

Reviews should be frequent enough to take account of the rapidly accumulating body of knowledge on issues such as husbandry and care, animal behaviour, refinements in procedures and alternative approaches. In circumstances where a large number of projects are running concurrently, reviews may need to be prioritised according to whether there are any particular concerns (such as large numbers of animals, models or species that are new to the establishment, or where there are concerns regarding severity).

Some establishments use the submission of a licence amendment as a trigger to carry out retrospective review. The benefits of this process needs to be balanced against the irregularity (or in some cases the frequency and regularity) with which amendments may be submitted, and the administration this will require from the project licence holder and AWERB.

## Documentation

**The most productive retrospective reviews focus on outputs, and how to take things forward, and involve face to face discussion rather than filling in forms. In most cases they are best achieved by inviting project licence holders to attend and present the key issues to the AWERB.**

Some establishments have developed structured proforma or templates to help the project licence holder assemble the information required. If these are used, it is important to check they are easy to complete and that they deliver information that is actually helpful and usable. It needs to be clear what is required as *input* into the retrospective review (i.e. when and what information is needed, from whom and in what form) and what records will be maintained to record the *outcome*. It is important to keep the overall aim of the review in sight and not to over-document either aspect.

## Providing feedback

**The outcomes of the review need to be fed back to the research team. Concerns about the project or the process, if any, need to be resolved (i.e. action must be taken) otherwise the review will be a waste of time.**

It may be that general issues - or improvements - are identified which apply to a number of projects, or are likely to apply to future work. If so, it may be helpful to develop a 'standard' solution and communicate this to relevant staff. Setting up an in-house database of projects would allow the solution to be applied to them all more easily and without delay, rather than waiting for the formal review of each one.

## Retrospective assessment

Retrospective assessment must be performed for all projects using non-human primates, cats, dogs or equidae, and all severe procedures using any species. The Home Office states that licences for education and training and those authorising the use of endangered animals will also 'normally be assessed retrospectively'.

The Home Office may also determine that some other projects require retrospective assessment, on a case-by-case basis. This could be decided when the ASRU Inspector reviews the initial licence application, or an amendment might trigger this requirement. The Home Office take into account the following points when considering whether a licence will require retrospective assessment:

- 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 other important animal welfare or ethical concerns, novel or contentious issues, or societal concerns.

The AWERB's role is to carry out the retrospective assessment (including an agreement on an updated non-technical summary) within three months of the due date set by ASRU. The project licence holder then submits the AWERB's conclusions to ASRU to enable an Inspector to complete the assessment on behalf of the Secretary of State.

## Information requirements

ASRU requires the project licence holder to provide information to the AWERB at the time the retrospective assessment is carried out. This must include information to update the non-technical summary, and which should enable the AWERB to consider:

- whether the programme of work has been carried out;
- whether the objectives of the programme of work have been achieved;
- the amount of harm caused to animals by carrying out the programme of work (including the number and species of animals subjected to regulated 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.

With respect to the last point above, the AWERB should encourage the project licence holder to share all useful 3Rs learnings with colleagues, for example by including them in papers, posters and presentations. The same applies to retrospective reviews.

For retrospective assessments, the non-technical summaries and their updates are a good way of sharing 3Rs innovations more widely, because they are publicly available. The AWERB can help to ensure that the updates set out clear information that will be easy for others to find and implement.

Although the UK is no longer in the European Union, the European Commission has published a very helpful document on Retrospective Assessment Results [\[24\]](#). This includes guidance, a template and some examples of good practice, which are also useful for retrospective reviews.



# 7. Acquisition, accommodation, care & use, and rehoming

***"Advise staff dealing with animals in the licensed establishment on:***

- matters relating to the welfare of animals, in relation to their acquisition, accommodation, care and use; [...] and]***
- re-homing schemes, including the appropriate socialisation of the animals to be re-homed"***

Many of the other AWERB tasks link to, or overlap with, providing guidance on acquisition, accommodation and care and use of animals, so this task should not be seen in isolation. The task to advise on re-homing schemes for example is encompassed by the 'advising staff' task and so the two aspects are included together in this section.

## What to aim for...

**The AWERB should aim to provide a central focus point where:**

- any matter relating to animal accommodation, care and use, humane killing and re-homing, re-use and release can be discussed
- establishment policies/Standard Operating Procedures (SOPs) on such issues can be initiated, developed, endorsed and enforced with particular reference to the 3Rs and animal welfare
- any problems can be identified and resolved
- support for new initiatives can be provided
- feedback from named persons meetings can be received and actioned
- feedback from staff and/or the Home Office Animals in Science Regulation Unit (ASRU) Inspectorate can be received and actioned

## Some common approaches that work well include...

- Setting up one or more sub-committees or groups to deal with the topics listed opposite and report to the main AWERB. For example, there could be one or more groups set up to focus on: environmental enrichment, housing for particular species (e.g. a dog, mouse or fish group), housing, husbandry and care for animals with special needs (e.g. some disease models, or aged animals), or animals used in severe protocols.

- Establishing standing agenda items to receive written and/or verbal reports from animal care and veterinary staff on accommodation, animal care, welfare and health, or related ethical issues. This has the advantage of giving the named persons a defined voice on the AWERB as well as identifying health and welfare issues for consideration.
- Commissioning reports at AWERB meetings on specific issues. Examples include: trends in the establishment's use of animals; humane killing; management of genetically altered (GA) animal breeding; new refinements from the literature, meetings or unit visits that the establishment could try; updates on in-house projects to evaluate enrichment; efforts made to minimise transport stress when acquiring or moving animals.

## In addition:

- Licence reviews, both prospective and retrospective, may raise accommodation and care questions, which the AWERB can then ask specific individuals or groups to pursue.
- During an audit or visit, the attending ASRU inspector may suggest topics the AWERB needs to address in relation to accommodation and care and humane killing.

**Whatever approach is used, AWERB members who are not familiar with the work in the animal units must visit these to develop their understanding of the facilities, the procedures carried out and the animal welfare issues. This also provides the opportunity to ask those working within the facility if there is any advice from the AWERB that staff would find helpful.**

The RSPCA has produced an information sheet that will help you to prepare for a visit to the animal unit ([tinyurl.com/visitaunit](http://tinyurl.com/visitaunit)).

## Some useful issues to address...

### Standards of accommodation and care

The AWERB has a leading role in setting the standard of accommodation and care that individual establishments should aspire to. It can also help to ensure consistency of standards and operations across multi-site establishments and within multi-national companies. For example, the Home Office Code of Practice on Accommodation and Care [25] sets out the statutory *minimum* requirements for animal accommodation and environmental enrichment, but many establishments choose to implement leading practice by using larger, more enriched accommodation and being proactive in implementing refinements to the lifetime experience of their animals. The AWERB can take a leading role in defining, driving and ensuring the delivery of such improvements.

The AWERB may also consider any exceptions to standard practices requested (e.g. any requirement for single housing of social animals) and develop guidance on how these should be handled and monitored to assess the impact on animals.

## Source and supply of animals and the sharing of tissues

The AWERB can:

- develop policies (or ensure that such policies are in place and up to date) on the sourcing of animals, such that animals are obtained only from breeders with a good record of animal welfare that are at least in accordance with the establishment's own standards. For example, an AWERB could decide not to use a supplier that tail tips mice for genotyping when its own establishment uses more refined methods. Explaining this to the supplier would hopefully promote better practice;
- ensure that transport stress is minimised, primarily by reducing journey times and minimising or, ideally avoiding, transfers. This could also include identifying UK suppliers to minimise the transport of animals from overseas;
- advise that enough time is allowed for animals to acclimatise to the new accommodation and care routines prior to their use;
- periodically review the match between supply and demand and whether there is any unnecessary wastage of animals, making sure that there are no historical demands (e.g. for a single sex) that are not scientifically justified [23]; and
- maintain an overview of work throughout the establishment to identify potential opportunities for collaboration between individuals, or groups, with respect to tissue sharing, use of surplus animals, or other 3Rs opportunities.

Some AWERBs will have oversight of (and may choose to inspect) conditions and/or studies carried out externally. These may be under additional availability of the licence (see section 5 on project review), or as part of collaborative studies in the UK or overseas. If a researcher applies to use animals abroad, the AWERB should ensure that checks have been made to confirm that the standards of housing, husbandry and care are at least equal to those required in the UK, and that experimental facilities and support are adequate.

If the proposal is to send animals overseas, AWERBs should be assured that transport conditions and the receiving establishment are appropriate and meet the standards they set. Some establishments extend this to places from which animal derived reagents, such as antibodies and cell growth media, are sourced and hold a list of approved suppliers. This is recommended as good practice.

## Re-homing and release

The purpose of rehoming and release is to offer an animal a 'good life' beyond their use as a research animal [26]. This may not be appropriate or possible for all animals, but where it is appropriate, the AWERB can ensure that the establishment has a process in place to do this successfully, and that the interests of the individual animals concerned, as well as all legal requirements, are taken into account.

## Re-homing

Rehoming programmes have traditionally tended to focus on dogs, but an increasing number of schemes now rehome other species including rodents, fishes and horses. Although relatively few animals are rehomed, this is a good way of recognising the intrinsic worth of animals as individuals and is also very good for staff morale and the Culture of Care. The AWERB can ensure there is guidance that sets out the establishment's policy on re-homing animals and the conditions that need to be met for this to be successful. The guidance should include the following information.

- The circumstances under which an animal might be re-homed, e.g. the availability and suitability of potential owners to provide for the needs of the animal and the home environment (including both the physical environment and the presence of other animals)
- How the animal has been identified as a candidate for re-homing and how the animal's welfare will be maintained/enhanced by inclusion in a re-homing programme
- The pre rehoming veterinary input necessary to the process. Once the animals are released all care, including veterinary care, is the responsibility of the new owner
- If applicable, details of health/use/preventive medicine programme/potential allergens as necessary
- Details of the proposed socialisation programme, for social animals (to be agreed with suitably qualified experts)
- The criteria on which to assess the suitability of a new owner/environment. Some establishments provide the option for new owners to visit the establishment to discuss handling and care. This can also help assess the suitability of the home and the new owner
- Defined responsibilities and related declaration templates for new owners
- Agreed documentation to accompany the animal
- Details of any post rehoming follow-up required
- How to maintain effective communication with the new owners (e.g. through a named contact person). For example, it can help to obtain a commitment from the new owner to send photos of the animal in the new home set up within a week of ownership
- Identification of potential new owners. This could be through adverts to specific groups within the establishment or via an internal newsletter. In some countries, collaboration with animal charities, with expertise in re-homing schemes, has proved successful in enabling animals to be rehomed to the wider community. One example is GRAAL, in France, which collaborates with partner laboratories to rehome a range of laboratory species ([graal-defenseanimale.org/english/](http://graal-defenseanimale.org/english/))
- For further information, see ASRU guidance on rehoming [5]

## Re-use

Re-use must in all cases be authorised in the project licence by ASRU and the AWERB can ensure that there is an establishment-wide understanding of ASRU policy. However, the establishment may also want to set its own criteria for allowing re-use. The associated ethical and welfare issues need to be thoughtfully addressed and the AWERB provides a useful forum where such issues can be discussed.

Considerations include how to balance reducing the number of animals used against the increased welfare burden for each individual re-used animal, and the ethical and animal welfare issues associated with re-using animals, against bringing in naïve animals.

## Problem solving

The AWERB provides a central point for reporting welfare issues (both positive, such as improved types of housing, and negative, such as outbreaks of disease or stereotypic behaviour) which may affect both welfare and science. The AWERB can then ensure there is a mechanism for communication to all relevant parties, including project and personal licence holders, and where necessary, the establishment licence holder and ASRU. If the issue is likely to impact on the timeline of the research, then the funding body may also need to be informed.

## Humane killing

The AWERB can ensure there is a system in place for:

- review establishments SOPs for Schedule 1<sup>1</sup> at appropriate intervals, including how techniques are chosen and refined;
- incorporating new knowledge about the welfare concerns of techniques such as carbon dioxide inhalation;
- assessing the justification for, and refinement of, non-Schedule 1 methods;
- ensuring all staff required to kill animals are appropriately trained and competent;
- ensuring support for the emotional wellbeing of staff who have to kill animals (this is included in section 3 on the Culture of Care).

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<sup>1</sup> Schedule 1 to the Animals (Scientific Procedures) Act (ASPA) lists approved methods for humanely killing animals. There may be a scientific requirement to use an alternative killing method, which will have to be justified and added to the project licence.

## Resources

The AWERB should highlight any resource issues and necessary upgrading of facilities to senior management and help to get these resolved. Concerns, ideas and achievements of animal care staff should be reported to the AWERB, which will encourage the spread of knowledge about animal accommodation and care and related issues in order to improve animal welfare. Staff achievements should also be celebrated.

### Examples of activities recently initiated, developed, supported and/or promoted by individual AWERBs

#### General points

- Review of local procedures in response to external guidelines, e.g. LASA guidance on record keeping [27]

#### Breeding

- Review of trends in figures for supply and demand, to identify any problems such as over breeding
- Use of frozen sperm as a way to archive GA animals without requiring specialist equipment
- Instigation of cryopreservation and archiving to reduce numbers of GA animals maintained

#### Housing and care

- Change in rabbit housing from cages to floor pens
- Change in poultry housing from cages to raised floor pens
- Increased out-of-pen exercise opportunities for dogs
- Review of source, nature and noise levels in animal facilities, to reduce injurious noise (including loud or repetitive ultrasound, for species that can hear this)
- Review of potential to group-house instrumented animals e.g. primates and rodents
- Review of species-specific enrichment items, and whether to rotate these for animals that will benefit from this
- Review of acclimatisation periods following transport for animals entering the facilities, to ensure these are long enough
- Instigation of Positive Reward Training of animals to reduce stress during routine husbandry or experimental procedures
- Input into the development of welfare assessment score sheets providing information on potential behaviour-related welfare indicators linked to husbandry

## **Identification**

- Review of methods of identification for all species to ensure the least invasive are used, including natural markings under some circumstances
- Change of method of identification for poultry from wing to leg banding

## **Surgery**

- Promotion of newer gaseous anaesthetic agents which are less aversive, minimally metabolised and provide a more rapid recovery
- Application of LASA guidelines on good standards of aseptic surgery throughout the establishment
- Review of standards of post-operative care and checking regimes; instigation of local policies to ensure that recovery surgery is not performed on Fridays, after a certain time of day, or at weekends

# 8. Supporting staff and training

***“Support named persons, and other staff dealing with animals, on animal welfare, ethical issues and provision of appropriate training”***

## What to aim for...

Ensuring that staff are supported is a key element of the AWERB's work and a defining feature of a Culture of Care. Named persons<sup>1</sup> in particular need support from the establishment licence holder and a productive relationship with both personal and project licence holders, especially if they have multiple named person roles. The AWERB can aim to develop and deliver such relationships. It should also make sure its own members are supported, since membership can be time-consuming and take staff away from their normal duties.

## Providing support

Many of the elements necessary to implement this task are set out in the section on Culture of Care and elsewhere in this document, but some additional points relating specifically to the way the AWERB can provide support are given below.

### Ways of supporting AWERB participants and increasing their confidence

- Establish an induction process for all members - see the example opposite and the RSPCA/LASA document on Induction for AWERB members [28] for ideas on what this should involve. Members need to be aware of the role, tasks, aims and values of the AWERB, what is expected of them as members and the likely timelines
- Review your induction, training and continuing professional development (CPD) for AWERB members, using the RSPCA AWERB training survey as a guide
- Suggest that members take some of the ETPLAS Training Modules ([etplas.eu/en/eu-modulescourses](http://etplas.eu/en/eu-modulescourses))
- Create a skills matrix for optimal AWERB function, in order to ascertain members' individual training needs and to focus relevant training for them
- Select a good AWERB Chair (see section 2 on general principles) who will ensure that everyone in the AWERB feels included and who will help less confident members to contribute
- Provide training on effective communication, committee skills and conflict resolution to ensure all viewpoints are heard and considered

<sup>1</sup> Named Animal Care and Welfare Officers (NACWOs), Named Information Officers (NIOs), Named Training and Competency Officers (NTCOs) and Named Veterinary Surgeons (NVSS)

- Encourage those who have difficulty contributing in meetings to provide written comments in advance to the Chair or named persons
- Ensure AWERB meetings are a positive experience for all those involved – including any prospective project licence applicants; and extend this outside of meetings for example by AWERB members actively seeking to meet licence holders and visit animal facilities
- Encourage named persons to work together to formulate ideas and take them to the AWERB
- Encourage scientists and named persons to work together to bring issues and ideas/initiatives to the AWERB
- Provide a 'safe opportunity' for junior staff members to propose suggestions for 3Rs or to raise matters of concern
- Provide training on transparency and accountability in reporting committee decisions and research outcomes; similarly, on recognising and mitigating biases in decision-making, including implicit biases about the value of animal models versus alternative methods
- Organise additional establishment focused workshops e.g. workshops on balancing scientific benefit and animal welfare in complex scenarios; or on assessing the feasibility of replacement strategies in research proposals

### An example of a basic AWERB member induction programme

- An introductory meeting with the AWERB Chair, an experienced member, to work through and discuss the self-assessment tables in the RSPCA/LASA Guidance on AWERB induction (allow 1-1½ hours)
- Be assigned an AWERB 'buddy' to attend meetings with and have pre- and post-meeting discussions and debriefs
- Use **The AWERB Dictionary** ([tinyurl.com/AWERBterms](http://tinyurl.com/AWERBterms))
- Read **Being an effective lay member of an AWERB** infographic – much of this applies to all members ([tinyurl.com/LMInfographic](http://tinyurl.com/LMInfographic))
- Read the local AWERB Terms of Reference
- Take a tour of the animal unit
- Attend the Home Office Local Module
- Follow-up discussion and feedback (e.g. with the same person as in the introductory meeting) after an appropriate period of time

## Providing operational support

- Senior management (e.g. Chief Executive Officers, Directors, budget holders) need to recognise the importance of the AWERB's role and ensure it is adequately resourced so that all its responsibilities can be discharged properly. There should be a well-resourced secretariat, with time to organise and run AWERB business efficiently
- There needs to be a strict timetable enforced for submission of papers/reports, so that members have time to consider them in advance of the meeting. It is not fair to expect busy people to carefully review large documents only a day or so before a meeting. There needs to be sufficient time for adequate time to review and discuss all issue
- Agendas should be structured so that the work of all of the named persons is addressed in a timely fashion; maybe having themed meetings where common issues are discussed and more staff can attend
- The AWERB needs to be seen as enabling, not obstructive
- When things go wrong they should be dealt with quickly and lessons learnt for the future
- Policies should be branded as belonging to the AWERB, so that they are not seen as just coming from the named persons or animal facilities



## Supporting named persons

Named persons often have multiple roles and can be overladen with tasks if they are not properly supported. An RSPCA workshop on the topic ([tinyurl.com/suppNP](https://tinyurl.com/suppNP)) came up with these example approaches for the AWERB to better support named persons:

- The AWERB creating an annual plan, with tasks allocated to individuals with specific roles, to identify whether people are overloaded (and address it if they are)
- The AWERB promoting the importance of the named persons to the wider establishment, especially those in senior management, and help to create a business case to ask for more resource for these roles
- Named persons asking for tasks to be shared, or saying 'no' to tasks, or the role itself, if they do not have capacity - and the AWERB to support them in this
- Named persons networking with other named persons, to see how they are supported, including AWERB exchanges (if the named person sits on an AWERB)
- The AWERB engaging with the requirement to support named persons, benchmarking this and setting itself targets

## Training and competency

ASPA recognises the importance of training, competency and CPD and this is the focus of a separate ASRU report on the governance framework for these requirements with associated learning outcomes, published in 2023 [\[29\]](#).

Given the acknowledged importance to scientific quality, animal welfare and compliance of having sufficient appropriately trained and competent staff, the AWERB needs to be confident that the establishment has in place a good system of education, training and assessment of competence for all staff who need it - including AWERB members.

The Named Training and Competency Officer is therefore a very important member of the AWERB in dealing with all of these issues.



## Useful approaches ...

At most establishments, the AWERB is unlikely to have a direct role in staff training, although it does have an educational role in explaining its own roles and responsibilities to relevant departments across an establishment. The way this task is approached therefore depends on how training is organised and managed within the establishment. If there is already a structured training unit, team or training officer(s) as well as the NTCO, then the AWERB may only need to receive and review regular reports from these. Provided there is good communication between the AWERB and staff responsible for training, then any issues relating to training, supervision, competence and CPD that arise from other AWERB work can be directed to the training staff for discussion and action if required.

In the absence of a dedicated training 'body', the AWERB should ensure the NTCO is adequately supported and resourced and require them to report any current or future training needs.

Key points for the establishment, and therefore for the AWERB to consider with respect to any of these issues, are listed in the box below.

### **The establishment should ensure that:**

#### **Training and CPD needs are regularly identified and reviewed**

- All training needs (with respect to knowledge, skills and attitude) for individuals and the establishment as a whole are identified and reviewed at appropriate intervals
- Appropriate training is provided, including Home Office modules, 'on the job' training and CPD, with refresher training for personal and project licensees. The suitability of this should be reviewed at regular intervals, in consultation with trainees
- There is a reliable system for recording staff training, competence and CPD
- The Local Module component of accredited training for those working under ASPA includes the roles, functions, membership and operation of the AWERB and why it is important for all staff to engage with the process
- There are sufficient qualified and competent trainers, assessors and supervisors available
- Staff know who to go to with questions regarding any training issue

#### **Systems are in place to ensure ongoing competence**

- Members stay up to date with regulatory requirements and compliance management – specifically any opportunities for refresher training or improvements in system managements are reviewed by the AWERB

- Account is taken of career gaps and 'skills fade' when maintaining competence over time. There needs to be a robust system for assessing the continued competence of all relevant staff and for advising staff when they do not meet the required standards. The difficulties in doing this need to be acknowledged and overcome
- There is a system for providing training and assessment of more refined methods, when these replace practices already in use

#### Adequate supervision is in place

- Supervisory requirements for personal licensees are clearly defined and fulfilled and everyone knows their responsibilities in this respect [30]

#### Training is provided for specific roles

- The **establishment licence holder** has access to training relevant to their role, e.g. Home Office modules and establishment licence holder training days. There may be topics specific to establishment licence holders that need to be included in training, such as issues arising from Standard Condition 18 reports
- Any specific training requirements for **lay or independent AWERB members** are identified and addressed; likewise any specific training needs for named persons
- Any specific training requirements for **individuals engaged in specific projects** are identified and addressed at an early stage, and reviewed as necessary during the life of the project
- **Personal licensees** are familiarised early on with issues of project design and management, and understand the role of the project licence holder as well as their own role



## 9. Providing a forum for discussion

***"Provide a forum for discussion and development of ethical advice to the establishment licence holder on all matters related to animal welfare, care and use at the establishment"***

Providing the opportunity to raise and discuss ethical issues is not only an essential AWERB task in its own right, but should also run throughout all of the AWERB's other tasks. For example, points of general concern or interest may arise during prospective or retrospective review of specific projects, or aspects of severity assessment identified during retrospective reporting. Fundamental to all of this is a good working concept of what is meant by 'ethics'.

A common belief within AWERBs is that 'doing ethics' just means applying the 3Rs and improving animal welfare, with advice to the establishment licence holder confined to comments on these issues during project review. But ethics encompasses much deeper considerations about what it is, or is not, justifiable to do to animals in the name of science. Recognising and discussing these are essential in developing a more reflective approach to animal use, so that people are more able and willing to question, and challenge, the status quo (see [tinyurl.com/E4ethics](http://tinyurl.com/E4ethics)).

Many AWERB members say that they do not find identifying and considering ethical issues easy. Unlike the 3Rs, which are practical and usually based on factual information, the definition of an 'ethical issue' can be subjective and there may be reluctance to tackle issues that are viewed as not directly relevant to current practices. It can also be difficult to introduce ethical considerations during project licence review, which is why creating separate forums helps to ensure deeper reflection on ethical and societal issues.

For example, when is it right to seek new medicines for conditions that can be treated using non-medical interventions such as social prescribing or social policy measures; do research groups liaise enough with clinicians and patient groups to check whether the outcomes of projects are wanted and needed? Are all species valued, and treated, the same within the establishment? What is in place to support staff who may be experiencing compassion fatigue or emotional labour? The RSPCA has produced a 'thought starter' to help reflect on and identify ethical issues, available at [tinyurl.com/ethicsTS](http://tinyurl.com/ethicsTS).

The AWERB should aim to be alert to these wider ethical issues arising from the use of animals, both within the establishment and beyond. It should also encourage staff to be aware of these issues and consider the implications for their own work. The wider resulting engagement should benefit staff development and should help promote better understanding of the role and value of the AWERB.

## Approaches to providing a 'forum'

The nature of the 'forum for discussion' is not defined. An AWERB can be considered a forum for dialogue and discussion in itself, albeit largely between people directly involved in the process. It is possible to go beyond this by encouraging other staff to contribute topics that they think would be helpful for the AWERB to discuss, and by inviting a wider group of people to engage.

The AWERB administrator could for example:

- advertise upcoming AWERB meetings widely within the establishment to give staff the opportunity to bring matters to its attention; and
- set up a physical or online suggestions box (which could also provide a confidential mechanism for raising any issues of concern).

The AWERB could also establish a **wider discussion forum within the establishment** and encourage all staff to contribute [31]. This would help disseminate information outside the AWERB's immediate membership, and could also help engage people with topics that can be difficult or controversial.



For example, the AWERB could organise (online or in-person) seminars or one-day events to challenge existing thinking and practices. These could either use outside speakers on animal welfare and ethics, or people from specialist disciplines, student groups or other interest groups from within or outside the establishment. This legitimises such discussions and demonstrates that it is acceptable to hear and encompass a range of views. Of course, a forum does not need to be confined to meetings – interactive intranet sites and regular newsletters also play useful roles.

## **Examples of topics that could be discussed within the AWERB or more widely**

### **Whether there should be establishment-wide policies on particular issues, for example:**

- whether the establishment wants to rule out certain types of work, or use of certain species or techniques
- whether the AWERB should review work on species that are not covered by ASPA, e.g. invertebrates (apart from cephalopods which are already in the scope of ASPA)
- how the establishment could reduce and avoid severe procedures
- how the establishment should interact with the public; including ensuring openness and transparency around the harms, benefits and limitations of animal research
- defining principles and criteria for outsourcing work and collaborations both within and outside the UK, and associated welfare audits and assurances
- developing structures and policies to ensure concerns can be raised by any member of staff, acknowledged and acted on
- ensuring good engagement and communication between the AWERB and bodies concerned with Research Governance and Research Integrity at the establishment, e.g. by inviting members of these bodies to attend AWERB meetings
- ensuring adequate support is in place to support staff who may be experiencing compassion fatigue/emotional labour

### **General discussion that may cover difficult or controversial issues:**

- whether 'special' species (primates, cats, dogs, equidae) are truly special, and why/why not
- whether there are any harms that it is believed ought not to be caused at the establishment (regardless of whether these may be permissible under the ASPA)
- reviewing the clinical relevance of disease models used at the establishment
- debating the impact of a hypothetical legislative ban on an aspect of, or all of, animal research in order to stimulate more challenging thought on alternative approaches to animal use
- discussing whether novel or contentious issues, and societal concerns are being identified and dealt with appropriately (e.g. by referring to the Animals in Science Committee)
- policies regarding non-research animals, e.g. procurement of animal-based foods, use of animal tissues or products, consideration for wild animals including dealing with 'pests'

Identifying and discussing ethical issues is worthwhile in itself, as a means of improving the Culture of Care and boosting staff morale, but it should also lead to positive outcomes, and impacts, particularly for animals. The diagram below lists examples of potential outcomes of ethical discussions. All of the outcomes are possible in theory and they range from least likely on the left, to most likely on the right ('technique', in the green box, means a 'technical act' such as the Forced Swim Test when used as a model for depression or retro-orbital bleeding<sup>1</sup>).

An entire research field should not be pursued  
or  
A project should not be done

In vivo scientists increase liaison with clinicians, to better ensure their results will be of benefit  
or  
A protocol should not be done

New refinements are implemented  
or  
Constructive discussion better mutual understanding  
or  
A technique should not be done

The AWERB, as a body, should be clear about what it might expect to happen as outcomes of the ethical review of projects, and ethical discussions in general. The Chair should also ensure that a 'safe space' is provided for ethical discussions, so that all voices can be heard, and should aim to identify actions that will lead to positive outcomes and impacts wherever possible.



<sup>1</sup> Both of these raise special animal welfare and ethical concerns and some establishments may choose not to use them. Retro-orbital bleeding is blood sampling from behind the eye in mice; it is possible to use other, less harmful routes, and an establishment may decide to permit this only under terminal anesthesia, or not at all.

# 10. Managerial systems

***"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"***

## Interpreting the task...

The AWERB is ideally placed to provide oversight and advice on the establishment's processes and systems that enable high quality animal welfare and care, good science, consideration of ethical issues and regulatory compliance. It can also help maintain an overview of how diverse processes interact and how resilient they are when staff, requirements or resources change.

The task can be wide-ranging, so it is important for the AWERB to assess the areas where its efforts should be prioritised, perhaps through setting annual goals. One approach is to view it as providing advice to the establishment licence holder (ELH) on processes and systems that enable them to readily meet their Standard Licence Conditions. These 25 conditions are attached to all establishment licences and encompass a range of criteria including ensuring that the 3Rs are implemented, staffing levels are adequate, proper records are kept and there is an AWERB (see table below and [32]). Project and personal licences also have specific standard conditions attached to them so the AWERB may also advise on processes that support project or personal licence holders in remaining compliant.

**Suggestions for AWERB activities linked to some of the Standard Conditions in the establishment licence are set out in the table below.**

Standard Condition	Suggested issues to consider
<b>Condition 1</b>  Regulated activities are carried out in a manner that is consistent with the principles of replacement, reduction and refinement.  <i>Aligns with AWERB task on 3Rs (see section 4).</i>	The AWERB can review how the ELH demonstrates this condition by considering: <ul style="list-style-type: none"><li>the establishment wide processes in place to ensure regulated activities are consistent with the 3Rs and how the ELH demonstrates this;</li><li>the support and resources the ELH provides;</li><li>how the ELH supports the AWERB in delivering its task of promoting implementation of the 3Rs;</li><li>carrying out periodic reviews of 3Rs-related practices such as minimising surplus from breeding, or training and assessment policies.</li></ul>

<p><b>Condition 2</b></p> <p>The ELH must ensure that:</p> <ol style="list-style-type: none"> <li>1. A register is maintained of those who are competent (adequately educated and trained) to kill protected animals.</li> <li>2. The register must specify the descriptions of animals that the person is competent to kill and the methods of killing.</li> <li>3. Each person should be supervised when killing animals until he or she has demonstrated competence.</li> <li>4. The number of persons who are registered and are present at the establishment is sufficient to enable any protected animal that needs to be killed to be killed expeditiously.</li> </ol> <p><i>This aligns with AWERB tasks on accommodation and care and staff training (see sections 7 and 8).</i></p>	<p>The AWERB needs to make sure it is aware of:</p> <ul style="list-style-type: none"> <li>• how the register is maintained, where it is held, how it can be accessed and who maintains the register on behalf of the ELH;</li> <li>• how often the AWERB should review the Competency to Kill Register;</li> <li>• the process for assessing maintenance of competence and how regularly staff should be reassessed;</li> <li>• whether there is a process for removing staff from the register who have not performed the methods for a set period of time and how that is determined;</li> <li>• whether the register can be easily accessed for audits.</li> </ul>
<p><b>Condition 4</b></p> <p>This condition is one that covers the facility, housing and husbandry procedures, enrichment, food and water, daily checks and transport.</p> <ol style="list-style-type: none"> <li>1. All protected animals must be provided with adequate care and accommodation appropriate to their type or species.</li> </ol>	<p>According to ASRU annual reports [33] the top non-compliance events reported are failure to provide adequate care and failure to provide food and/or water.</p> <p>The AWERB can advise the ELH on:</p> <ul style="list-style-type: none"> <li>• the appropriateness of daily health checks, including taking every step to ensure that food and water are checked.</li> </ul> <p>The AWERB can ask:</p> <ul style="list-style-type: none"> <li>• to observe the daily health check process and review SOPs and training in relation to this critical task;</li> </ul>

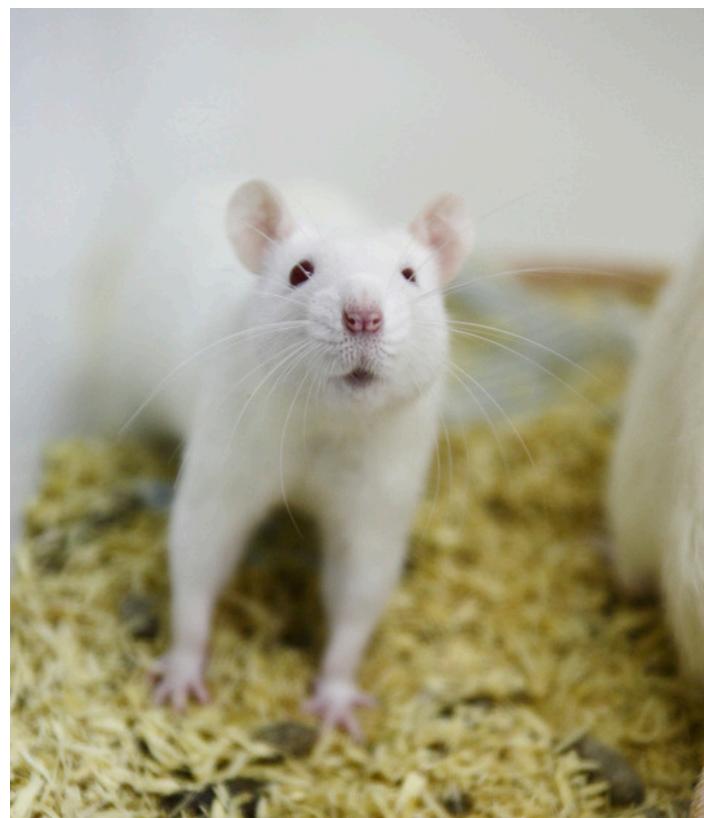
<p>2. Any restrictions on the extent to which such an animal can satisfy its physiological and ethological needs shall be kept to the absolute minimum.</p> <p>3. Unless otherwise authorised by the Secretary of State an environment, housing, freedom of movement, food and water appropriate for the health and well-being of each protected animal shall be provided.</p> <p>4. The health and well-being of protected animals, and the environmental conditions shall be checked at least once daily by competent persons and that any pain, suffering, distress or lasting harm are eliminated as soon as possible.</p> <p>5. The holder shall ensure that the conditions under which any protected animal is transported are appropriate for the animal's health and well-being.</p> <p><i>This aligns with the AWERB task on accommodation and care (see section 7).</i></p>	<ul style="list-style-type: none"> <li>• how the environmental conditions are monitored and responded to;</li> <li>• how resources are calculated and how the establishment ensures that there are always adequate resources to cover, as a minimum, a daily check 365 days a year.</li> </ul>
<p><b>Condition 15</b></p> <p>The licence holder shall nominate and be responsible for the performance of named persons.</p> <p><i>This aligns with the AWERB task of supporting the named persons (see section 8).</i></p>	<p>The AWERB should receive regular reports from the named persons, and from those responsible for managing facilities, and provide feedback to them.</p> <p>The AWERB should ensure that any issues or actions are followed up on and that outcomes are documented.</p>

**Condition 20**

All reasonable steps should be taken to prevent the performance of unauthorised procedures in the establishment.

The conduct of unauthorised procedures is another common non-compliance reported in the ASRU annual reports [33].

The AWERB can review processes at the establishment to prevent the performance of unauthorised procedures and other forms of non-compliance. For example, it could check what processes are in place before regulated procedures are performed, to ensure there is appropriate licence authority. There should be a focus on learning from any such events.



## Some related operational and management processes that AWERBs may discuss ...

- Are we aware of the processes for dealing with Project Licence Standard Condition 18\* (SC18) reports and have we developed processes for ensuring actions are completed and, where appropriate, learning is shared more widely? The AWERB should also ensure there is a process for tracking and reporting on any trends in SC18 reports across the establishment, assigning this role to an appropriate individual
- Have we ensured there are internal mechanisms to enable anyone to raise animal welfare concerns either openly or confidentially (and without fear of negative consequences)?
- Could we consider using external experts to peer review internal systems and/or animal facilities? This might be through formal processes such as AAALAC<sup>1</sup> , or visits by clients, or through less formalised visits by colleagues from other institutions

\*Project licence SC18 says:

*The [project] licence holder shall ensure adherence to the severity limits as specified in the project licence and observance of any other controls described in the licence. If these constraints appear to have been, or are likely to be, breached, the holder shall ensure that the Secretary of State is notified as soon as possible.*

For example, if a protocol had a mild severity limit, but an animal experienced moderate severity, SC18 would be breached and this would have to be reported to the Home Office. The same generally applies if animals are found dead, in which case severity is assumed to be 'severe' unless there is evidence otherwise. It is important to keep track of, and analyse, SC18s on both animal welfare and scientific grounds, and to maintain the Culture of Care.

<sup>1</sup> The AAALAC (Association for Assessment and Accreditation of Laboratory Animal Care) International accreditation program evaluates organisations that use animals in research, teaching or testing. Those that meet or exceed AAALAC standards are awarded accreditation. See: [aaalac.org/accreditation-program/what-is-aaalac-accreditation/](http://aaalac.org/accreditation-program/what-is-aaalac-accreditation/)

# Appendix

## The roles of different review bodies with regard to blood sampling protocols in a research project

Body funding the research (e.g. funding body or institution)	AWERB	Home Office Animals in Science Regulation Unit (ASRU)
<p>Reviews the grant (not project) application at a high level, asking questions about the validity and value of the science.</p> <p>Unlikely to require, or consider, the detail of individual procedures such as blood sampling.</p>	<p>Uses local expertise to define in-house protocols for the most refined methods to be used throughout the establishment. For example, the AWERB could develop a Standard Operating Procedure (SOP) for preparation, sampling route, method and volume, and for animal monitoring after sampling.</p> <p>Ensures each project licence takes account of local good practice, but does not insist on including details of methods in the actual licence applications unless required to do so by ASRU.</p> <p>Includes the animal's experience of blood sampling in the overall assessment of cumulative severity, harms and benefits of the work.</p> <p>In mid-term or retrospective reviews of projects, considers any practical or animal welfare problems that have occurred and whether any changes need to be made to the blood sampling procedure.</p>	<p>Checks compliance with the Animals (Scientific Procedures) Act 1986 (ASPA).</p> <p>Determines that all relevant and necessary information is in the licence application.</p> <p>Assesses proposed sampling procedures against good practice guidelines and considers the justification for any deviation from these.</p> <p>Advises on any further possibilities for refinement within the sampling protocol.</p> <p>Reviews protocol severity classifications.</p> <p>Weighs the likely harms and potential benefits of the project on behalf of the Secretary of State.</p>

# Glossary

<b>3Rs</b>	The principle of Replacement, Reduction and Refinement
<b>ASC</b>	Animals in Science Committee
<b>ASPA</b>	Animals (Scientific Procedures) Act 1986
<b>ASPeL</b>	Animals (Scientific Procedures) e-Licensing system
<b>ASRU</b>	Animals in Science Regulation Unit
<b>AWERB</b>	Animal Welfare and Ethical Review Body
<b>ELH</b>	Establishment Licence Holder
<b>HBA</b>	Harm-Benefit Analysis
<b>HOI</b>	Home Office Inspector
<b>HOLC</b>	Home Office Liaison Contact
<b>HOLTIF</b>	Home Office Liaison, Training and Information Forum
<b>IAT</b>	Institute of Animal Technology
<b>LASA</b>	Laboratory Animal Science Association
<b>LAVA</b>	Laboratory Animals Veterinary Association
<b>NACWO</b>	Named Animal Care and Welfare Officer
<b>NIO</b>	Named Information Officer
<b>NPRC</b>	Named Person Responsible for Compliance
<b>NTCO</b>	Named Training and Competency Officer
<b>NTS</b>	Non-Technical Summary
<b>NVS</b>	Named Veterinary Surgeon
<b>PEL</b>	Establishment Licence
<b>PIL</b>	Personal Licence
<b>POLE</b>	Place Other than a Licensed Establishment
<b>PPL</b>	Project Licence
<b>SC18</b>	Standard condition 18
<b>Sch1</b>	Schedule 1 to the ASPA, a list of approved humane killing techniques

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## Notes

# Further resources for AWERB members

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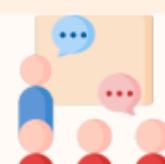
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