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

3rd Edition – September 2015

These ‘Guiding Principles’ are intended to help interpret the requirements for UK local Animal Welfare and Ethical Review Bodies (AWERBs) and share good practices. They should help AWERBs to continue to: develop their role in improving animal welfare and the quality of science; further the application of all 3Rs [1]; and promote a ‘culture of care’ at all establishments where animals are bred, supplied or used for research. Since the document explains the AWERB’s role and functions, it should be helpful to all people working under the Animals (Scientific Procedures) Act 1986 (ASPA) as well as those working closely within the AWERB itself.

The document updates the 2010 version [2] produced for the Local Ethical Review Processes (ERPs) in existence in the UK at that time. Like that edition, it is based on the output from UK workshops organised by the Royal Society for the Prevention of Cruelty to Animals (RSPCA) and Laboratory Animal Science Association (LASA) with input from the Institute of Animal Technology (IAT) and Laboratory Animal Veterinary Association (LAVA), together with key points from previous Home Office reports, and guidance from the Animal Procedures Committee (now the Animals in Science Committee) (ASC) [3,4,5,6]. This edition also incorporates additional material developed by an EU expert working group as guidance on the Animal Welfare Bodies required across Member States [7] as well as current Home Office Guidance [8].

These Guiding Principles are intended to be a ‘dynamic document’ that will be updated as AWERB processes evolve and as experience of good practice develops. Please send any comments or ideas for improving the content or clarity of the document to the LASA secretariat at: info@lasa.co.uk.

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Home Office requirements

AWERB aims, tasks and membership

The requirement for each breeding, supplying and user establishment to set up an AWERB is stated in Schedule 2C, Part 2, paragraph 6 of the [Animals \(Scientific Procedures\) Act 1986 as amended in 2012](#) (ASPA), and in the [Home Office Guidance on the Operation of the ASPA](#) (see Appendix A, standard condition 6 for Establishment Licences) [8].

The Home Office emphasises that AWERBs ***“should in most respects continue and develop the work of the local Ethical Review Processes (ERPs) they replaced on 1 January 2013.”*** The original definition of the ERP can therefore usefully be applied to the AWERB and is summarised below.

The ERP or 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 reduction, refinement and replacement (the 3Rs); and that high standards of accommodation and care are achieved

The role, tasks and membership of the AWERB devolve from Articles 26 and 27 of Directive 2010/63 [9] and are described in the [‘Guidance on the Operation of the ASPA’](#) [8]. These requirements are summarised below.

In general AWERBs should:

- **promote awareness** of animal welfare and the 3Rs [1];
- **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’** within the establishment and, as appropriate, in the wider community.

This is achieved through the following tasks.

The minimum tasks of the AWERB are to:

- a) advise staff dealing with animals in the licensed establishment on matters related to the welfare of the animals, in relation to their acquisition, accommodation, care and use;
- b) advise on the application of the 3Rs, and keep the AWERB informed of relevant technical and scientific developments;

- c) establish and review management and operational processes for monitoring, reporting and follow-up in relation to the welfare of animals housed or used in the licensed establishment;
- d) follow the development and outcome (retrospective review) of projects carried out in the establishment, taking into account the effect on the animals used; and to identify and advise on elements that could further contribute to the 3Rs; and
- e) advise on re-homing schemes, including the appropriate socialisation of the animals to be re-homed.

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

- a) 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;
- b) assist with the retrospective assessment of relevant projects carried out at the establishment; and
- c) 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 one* of the establishment's

- Named Animal Care and Welfare Officer(s) (NACWO)
- Named Veterinary Surgeon(s) (NVS)

plus

- A scientific member (if the establishment is a user establishment)

In addition

The Named Information Officer(s) (NIO) and Named Training and Competence Officer(s) (NTO) should also be "*actively engaged with the AWERB given the breadth of its tasks*"

In order to ensure the integrity of the process, the establishment licence holder is expected "*to arrange for their AWERBs **actively to 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*"

Home Office inspectors may also attend meetings from time to time as part of their responsibilities for monitoring compliance with the legislation

Record keeping

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

AWERBs and the Animals in Science Committee

The national [Animals in Science Committee](#) (ASC) [10] has a specific role in relation to AWERBs in that, in accordance with EU Directive Article 49, it is convened to:

- provide advice to Ministers, Animal Welfare and Ethical Review Bodies and to share best practice on matters relating to the acquisition, breeding, accommodation, care and use of protected animals; and
- share information with national committees in other EU Member States on the evaluation of project licences and on the operation of Animal Welfare and Ethical Review Bodies.

The ASC, in its considerations, 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.

At the time of writing, the ASC has set up a sub-committee specifically to develop its work on AWERBs.

Impact of the ASC on the AWERB

Certain categories of project will need to be referred to the ASC for review, and although referral is done by the Home Office, AWERBs need to be aware of the likely implications in terms of timing and issues to be considered.

Ideally, the AWERB should have a defined contact person for two way communication and information exchange with the ASC. AWERBs need to be alert to ASC activities and engage with these. They need to take the initiative to provide examples of good practice for the ASC to disseminate more widely, both at a national level and between national committees across the EU.

General principles of good practice

Principles of good practice

The AWERB's aims formalise what any establishment licensed under the ASPA should be doing to promote high standards of animal welfare, implement the 3Rs [1], enhance scientific achievements and generate a 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 production, care and use. A well-designed AWERB is therefore a valuable resource that should benefit all staff. As a high level body advising the establishment licence holder, it is 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 and staff.

However, there is no 'one size AWERB to fit all'. It is an establishment's responsibility to decide how the AWERB should be organised and managed - though this should be in accordance with the principles in Section 10 of the revised Guidance on the Operation of the ASPA [8]. 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.

Ten top tips for a successful AWERB

- 1) Ensure that senior management understands and is committed to the AWERB and provides leadership and support
- 2) Ensure that the aims and expected 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 functions are addressed in some way
- 5) Think carefully about the selection of participants and particularly the Chair
- 6) Make sure the process is organised efficiently
- 7) Ensure that there is effective communication between all parts of the AWERB and any other bodies that affect its work: ensure that all staff know what the AWERB is for, why it is important, who is involved and how it affects them.
- 8) Be reactive and responsive to the needs of AWERB 'users'
- 9) At intervals, re-evaluate the AWERB's aims and outcomes and whether its operation is efficient and appropriate
- 10) Try to interact with and share ideas for good practice with participants in other AWERBs and the ASC

Ten top tips for a successful AWERB

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

The AWERB needs to be recognised as a body with stature that senior management supports and listens to. Thus, there needs to be *demonstrable* support from senior management, including the establishment licence holder, and recognition by them that the process must have an appropriate budget. They should also recognise staff contributions to the AWERB as an integral part of their individual goals and performance appraisals.

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

The aims and expected 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” (Para 10.4a in the HO Guidance [8]) is relevant to almost all of the other functions. Grouping similar functions together (such as retrospective assessment with retrospective review) may simplify matters and help to avoid any unnecessary duplication.

3) Make sure that in discharging its functions your AWERB adds value over and above the work of other external or internal bodies

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 Home Office Inspector's views. The Home Office review of licences is carried out within the national legal and policy framework which takes account of issues beyond the scope of the local establishment.

4) Make sure *all* the AWERB functions are addressed in some way

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 allowed to discuss any points raised.

5) Think carefully about the choice of participants and particularly the Chair

A minimum core list of participants is required by the Home Office but, given the breadth of the AWERB's functions, it is widely accepted as 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 page 13).

6) Make sure the process is organised efficiently

Efficient organisation is essential in order to minimise the costs of the AWERB (both financial and with respect to staff time) and 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 NACWO/NVS groups 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 set meetings to progress issues. *Ad hoc* meetings, email discussions and teleconferences are all useful tools.
- Do not over-complicate the process and over-burden everyone with paperwork. For example, interim review of projects may be best addressed by the project licence holder coming 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 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.
- 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 bodies that affect its work: ensure that all staff know what the AWERB is for, why it is important, who is involved, how it affects them.**

Explain to all staff within the establishment what the benefits of the AWERB are in terms of animal welfare, good science, regulatory compliance, maintenance of a constructive, caring culture, and public opinion. Encourage them to view the process positively.

Publish this information internally - perhaps designing a '*know your AWERB*' poster or website and consider publishing it externally as part of the establishment's position statement and contribution to openness on animal use.

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 could 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 (e.g. 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, re-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 most difference. These 'top ten tips', along with the rest of the material contained within this document, can be used to formulate an evaluation process. Ensure the views of AWERB participants and staff, as a whole, are sought. Consulting the local Home Office Inspector for his or her view on such matters is also valuable.

- 10. Try to interact with and share good practice ideas with participants in other AWERBs and the Animals in Science Committee**

Although there is not currently a national AWERB '*forum*', there are a number of opportunities for AWERB participants to get together informally. Both 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.

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

The ASC now has a role in “*sharing best practice*” with AWERBs, so good channels of communication between the AWERB and the ASC will be needed.¹

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 has a long-term benefit in their development as future project licence holders, as well as developing the contribution they can make to the overall culture of care.

The Home Office requirements for **minimum membership** (which differ slightly from EU Directive Article 26 minimum requirements) and the **key roles** that should be represented are shown on page 6. However, it is recognised both by the Home Office and the European Commission [7,8] that a broader membership is required given the nature of the AWERB's tasks and the expertise needed to address these properly. Therefore it is also important to consider the **key competencies** that contribute to an effective AWERB. These are listed in the box on page 14, together with the **personal qualities** that are desirable. However, 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 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 resources are devoted to its work and demonstrating commitment to implementing its recommendations.

Good chairmanship 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 members² have proved very useful as participants in AWERBs in the UK 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,

¹ At the time of writing in 2015 this ASC function is in development.

² A wide diversity of people from a variety of disciplines may be regarded as lay participants. An interpretation of their role is set out in a [Resource book for lay members of ethical review and similar bodies worldwide](#) [11]

questioning established practice and challenging accepted norms. This in turn can help to stimulate new or different ways of thinking about the ethical, animal welfare or scientific issues. People from diverse disciplines may be regarded as lay and may be recruited either from within the establishment or be entirely independent from it.

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. unusual species or new techniques/models) or information on other relevant legislation (e.g. on transport, the Animal Welfare Act, or regulations on Genetically Modified animals). Many establishments will therefore include the NIO as an active participant in their 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.

Key competencies

Knowledge, understanding and expertise in:

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

Personal qualities

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

Application of the 3Rs

"Advise on the application of the 3Rs and keep it 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:

- Clearly demonstrate the value the establishment places on the 3Rs, making them integral to its work
- 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
- Provide a mechanism to encourage and facilitate wide staff involvement in the 3Rs, motivating people to:
 - be proactive as well as reactive
 - think about and implement existing 3Rs opportunities
 - develop new 3Rs initiatives and activities
 - disseminate 3Rs information as widely as possible

3Rs related activities can be approached both in the review of individual project licence applications and more generally within the establishment.

What works well: examples of successful organisational approaches...

For 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.

It is widely acknowledged that 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 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. However, some AWERBs also develop their own set of questions to stimulate wider thought around each 'R'.

Early sight of project proposals to enable 3Rs and experimental design issues to be identified and worked through with the project licence applicant can accelerate project processing considerably and engages licensees with the process in good time.

Some establishments also 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 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 the individual study makes good sense.

For more general 3Rs application

Assign responsibility to particular staff to interact with and feedback to the AWERB on specific 3Rs issues e.g. refinement of housing, or specific procedures, or models (e.g. myocardial infarction, rheumatoid arthritis or stroke).

In a small establishment, with few project licenses 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. The obvious focal point for this is the NIO.

However, in larger establishments, no one person will have all the expertise required neither is it reasonable to expect them to have sole responsibility for all potential 3Rs activities. In such cases it will still be necessary to draw on a wider range of expertise and perspectives and to spread responsibilities and workloads within one or more groups/sub-committees which can provide advice and feedback on these 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.

The groups need a strong Chair or 'champion' to drive the process, and to include people with specific expertise in the relevant 'R'. For example, a NACWO could organise refinement activities around housing and care; an NVS could take responsibility for refining surgery; a researcher could take responsibility for refining a specific animal model.

In all cases, even if a single person acts as the organiser, it is important to harness a wider range of expertise and perspectives and to encompass veterinary, animal care and scientific staff. The NIO can help by putting people with common interests in touch with each other locally and more widely.

Examples of 3Rs activities

- Develop species-specific **welfare assessment protocols** and score sheets for commonly used procedures/models and establish a mechanism for their regularly review
- Periodically **consider individual topics** focussing on species-specific welfare issues (e.g. housing and procedures involving dogs) or broader issues, such as reviewing the use of environmental enrichment and how this could be improved
- 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** used for similar projects.
- Initiate **internal reviews of procedures** (e.g. blood sampling, telemetry, biopsy methods, use of metabolism cages, restraint, or aseptic techniques [12]), 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 these [13]
- 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
- **Challenge preconceptions** about the way procedures 'have always been done' by encouraging focussed evidence-based studies
- 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) and discuss and agree ways of reducing this: for example, by raising awareness of the issue with the project licence holder or improving communication with the supplier. Question the keeping of homozygous colonies to minimize animal numbers
- Set up a **co-ordinated process for tissue sharing** within or between establishments
- For establishments that are part of multinational companies or research programmes, contribute to the development of **international initiatives and oversight mechanisms** for the 3Rs
- **Facilitate access to statistical advice** to ensure that the minimum number of animals are used whilst still achieving the scientific objectives
- 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)

Disseminating 3Rs information

The AWERB needs to build a culture that facilitates communication of, and engagement with, the 3Rs (see culture of care section on page 55). This requires mechanisms for disseminating information, bringing relevant issues (legislation, meetings, and reports) 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 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 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 prize or poster day
- Convey information through animal user group (and other similar) meetings
- Encourage all staff to disseminate information on 3Rs innovations externally through publications, posters and conferences
- Encourage staff to visit other establishments to observe different working practices or 3Rs initiatives; bursaries are available for such exchanges from organisations such as [LASA](#), [Laboratory animals Limited \(LAL\)](#) and [Animals in Science Education Trust \(ASET\)](#)

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...

When considering project licence applications, it is particularly important to define clearly what the establishment believes should be achieved by the process. AWERB input at the project planning and application stage can provide opportunities to improve the quality of applications, ensure that the 3Rs will be implemented 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. The task needs to be seen in the context of the other functions of the AWERB, which include providing a forum for discussion and development of ethical advice to the establishment licence holder. Ethical aspects of project licences should therefore also be considered. 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 resolved³.

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 Inspectorate. The AWERB should aim to complement these reviews, its benefit being to look at projects from a **local perspective**, bringing **local knowledge and local expertise** to bear. The appendix on page 62 at the end of this guidance illustrates how blood sampling procedures, for example, would be dealt with by the different review bodies.

Many of the general principles on pages 8 to 14 of this document are highly 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 to avoid a disproportionate focus on this aspect of the AWERB’s work.

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, ‘rules’ and culture;

³ Additional task under ASPA Guidance Para 10.5

- the acceptability of the work to the establishment, both in general and with respect to the harm/benefit assessment of the specific project;
- the availability of suitable facilities, resources and appropriate expertise;
- establishing a plan of action when facilities, resources and expertise are not available locally; this may involve recommending that the work may be better suited to an alternative establishment;
- providing a forum for constructive discussion between people with relevant but diverse expertise and perspectives;
- ensuring that good practice is implemented within the project and that there is consistency of preparation, examination and submission of individual project licence applications; and
- providing wide 'ownership' of the project, and helping to ensure that there is appropriate supervision of, and support for, licensees, together with better dissemination of information.

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 personal legal responsibility;
- provides assurance that licence applications submitted to the Home Office are well prepared;
- Contributes significantly to the culture of care.

For the named persons, the AWERB ensures that:

- the expertise and perspectives of local NACWOs, NVSs and animal care staff are acknowledged, understood, supported and brought to bear;
- the NIO has a channel for provision of information and advice; and
- the NTCO can provide comments 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 the Home Office, in which the harms, benefits and 3Rs issues are clearly laid out, and any problems/issues have been addressed at an early stage; and

- demonstrates the establishment's confidence in, and support for the project, and ensures appropriate backing from the establishment and its staff.

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:

- (i) whether, and how far, the AWERB wants to be involved in assisting with the *preparation of a licence* application; and
- (ii) 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. If the licence application is well prepared and well written, its consideration by the AWERB and formal review by the Home Office will be faster and easier, since there will be less need for a to and fro of questions or advice. Therefore, a key issue for the project licence holder is how to ensure that the licence application is submitted for formal AWERB consideration stage 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 the 3Rs will be applied;
- all welfare issues (harms) identified and clearly described, with a detailed plan as to how they will be ameliorated;
- any resource issues identified;
- staff training, supervision and competency requirements appropriately addressed.

It is good practice for project licence applicants to consult with the NACWO, NVS, NIO, NTCO, 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. This may be done 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 review, thus facilitating the process. Since named persons are participants in the AWERB establishments should consider this early input as a part of the overall AWERB process. Early consultation with the local Home Office Inspector is, of course, also helpful.

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 Continuous Professional Development (CPD) and licensee information packs.

Considering the licence application

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

- (i) 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 on the opposite page), and advise the establishment licence holder on whether to approve submission to the Home Office;
- (ii) identify the ethical and welfare issues and consider the harm-benefit balance from the local perspective;
- (iii) identify any concerns/issues likely to apply to other projects and consider development of establishment-wide good practice guidance if this would be helpful, thereby acting as a mechanism for driving improvements and consistency;
- (iv) 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 opposite have been satisfactorily addressed and that there has been sufficient opportunity for discussion and resolution of any concerns.

The AWERB needs to seek reassurance that:

- there has been a **robust analysis of the methodology** including experimental design, ensuring that, where necessary, statistical advice has been sought
- all the **potential harms have been identified** (encompassing the animals' cumulative lifetime experience), clearly described and understood, and that these will be either avoided or effectively recognised, assessed, and alleviated throughout the life of the project
- there is evidence that **the 3Rs have been fully 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 good practice procedures will be implemented** (e.g. on issues such as tail tipping, use of analgesics, injection volumes, score sheets)
- **the benefits and quality of 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
- 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
- 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**
- 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

One question that has been debated is whether the AWERB has a role in reviewing the science when this has already been peer-reviewed by a funding body or industry scientific review panel. These different bodies may 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 depending on local expertise. However, it will also want to consider the science and its benefits alongside the harms and consider 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.

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

Developing an efficient, helpful, enabling process...

Project evaluation by the AWERB should be positive, constructive and efficient. If the process is performed or organised poorly it can be frustrating to both AWERB members and project licence applicants. Potential project licensees need to see the AWERB process as enabling and 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.

Ideally, the full AWERB should meet to consider project licence applications. This ensures that members can raise and resolve questions easily and gain a good understanding of the work in order to advise the establishment licence holder. The face to face consideration of new applications provides a valuable learning opportunity for both the licensee and AWERB membership because of the inclusive and discursive nature of meetings. It also helps engage the project licence applicant and familiarise them with the AWERB's work.

However, it may be useful in certain circumstances to allow for email 'discussion' *provided* that any member can request discussion 'around the table' in a full meeting should they feel this is necessary. As in the case of amendments (see below), the circumstances under which email discussion could be considered need to be agreed by the full AWERB.

The boxes, opposite, provide examples of AWERB **Dos and Don'ts** which, together with the **Ten Top Tips** on page 9, 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 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
- 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
- Ask for feedback from the Home Office Inspector 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 any required for other purposes
- Dictate the style of writing, try to rewrite the application, or insist on inclusion of detail that is not required by the Home Office
- Conduct the review solely by virtual means
- Make the review process confrontational for the project licence applicant
- Allow AWERB members or licence applicants to feel intimidated in meetings
- Insist on formally reviewing minor changes with no harm/benefit implications, or implementation of 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 influence (or effect) on animal welfare. The approach of the AWERB to amendments should be proportionate to the level of change requested.

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;
- an increase in animal numbers;
- the use of an additional animal species;
- the use of a new strain with an adverse phenotype.

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, less harmful, route or site of administration;
- replacement of a behavioural test with a new one of 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.

The AWERB as a whole needs to develop criteria for deciding which amendments can be 'fast tracked'. These need to be clearly stated in the 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 availability

The establishment licence holder of an establishment providing secondary availability is required to endorse the work before the project licence can be sent to the Home Office for authorisation. Moreover, the AWERBs at both the main and the additional availability establishments have to consider the application. Licensees need to be made aware of this requirement. Then they can make sure that they have early sight of the details of the processes at both establishments so these need to be clearly described in the AWERB 'information package' and included within in-house training.

In addition, 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.

When considering work that will be carried out in another establishment, either in the UK or abroad, the AWERB may impose its own minimum standards, but there is a need to remain flexible where institutional requirements differ. 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 feed back 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. The disadvantage is the time this can take and the potential for inconsistent decisions and unrealistic expectations, so it is important to ensure that the process is well managed. 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.

Retrospective assessment & review



6. Retrospective assessment and retrospective review

Formal “retrospective assessment of relevant projects carried out at the establishment” and “following the development and outcome (retrospective review) of projects carried out in the establishment”

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

- the formal **retrospective assessment** of selected projects where the AWERB will be asked to undertake assessments and submit these to the Home Office;
- the requirement to follow the development and outcome (**retrospective review**) of *all* projects taking into account the effect on the animals used; and to identify and advise on elements that could further contribute to the 3Rs

Retrospective assessment and retrospective review are both, as stated by the [European Commission](#) [14], “**considered an extremely powerful tool 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 assessment

All projects using non-human primates, cats, dogs or equidae, and those involving severe procedures, must be assessed retrospectively. The Home Office state that licences for **education and training** and those authorising the use of **endangered animals** will also “normally be assessed retrospectively”. In addition, a formal retrospective assessment may be required for some other projects. This is decided when the Home Office Inspector reviews the licence application before recommending whether, and on what terms, it should be granted. There might be a recommendation for another review, during the lifetime of the project, for example if an amendment request triggers the requirement.

The following points are taken into account by the Home Office when considering whether a licence will require formal 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;
- whether the project raises any important animal welfare or ethical concerns, novel or contentious issues, or societal concerns.

6. Retrospective assessment and retrospective review

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

Information requirements

The Home Office requires the project licence holder to provide information to the AWERB at the time the retrospective assessment is carried out. This must include an updated non-technical summary and sufficient information to 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 of animals subjected to regulated procedures as part of the programme of work, the species of animals subjected to those procedures and the severity of those procedures); and
- whether any lessons can be learnt from the programme of work, which may contribute to the further implementation of the principles of the 3Rs.

The approaches and processes for formal retrospective assessment are similar to those for more general retrospective review discussed below.

Retrospective Review

The 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. The aim is to improve both animal welfare and the quality of science and to help inform future debate on these issues. LASA [15, 16] developed this overall purpose into a set of three activities shown in the boxes on pages 33 to 35. 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 are similar to those outlined above for retrospective assessments.

6. Retrospective assessment and retrospective review

Some common approaches are ...

- (i) to carry out a retrospective review of **projects on their completion**;
- (ii) 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 helps to prepare for any future project licence application;
- (iii) 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);
- (iv) to **carry out reviews annually** during the course of a 5 year project;
- (v) 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 costs 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**

A defined review point provides 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. It also provides the opportunity to report things that are going well and which could influence future directions and/or funding decisions for this and other projects. Issues to consider include:

- whether the science is on-track and the results are as expected
- how the actual adverse effects and severity compare with those predicted
- whether any problems have been identified and addressed
- whether there are any recent developments in science or technology which influence the direction or conduct of the study or affect its value
- whether anything has changed which might alter the original harm-benefit judgement

6. Retrospective assessment and retrospective review

(ii) To identify, build on, enhance and promulgate good practice and improvements in the 3Rs during the course of a project

Issues to consider include whether:

- any new alternative methods/models (including new *in vitro* techniques) have become available that would involve less suffering
- given current progress, the experimental design could be improved to answer the scientific questions more effectively
- in the light of results to date, the numbers of animals are statistically appropriate (neither too few nor too many)
- procedures (e.g. restraint, administration, sampling, analgesic regimes, surgical techniques) and/or humane endpoints could be further refined
- welfare assessment sheets and monitoring procedures are working well and are effective and/or whether these could be improved
- there are any adverse effects associated with supply and transport, or housing and care which could be reduced by changing current practice
- animals on long-term studies are coping and whether they show any physical or behavioural problems (e.g. age-related disease and stereotypic behaviours)
- special housing and care needs have arisen
- euthanasia methods are the most appropriate or could be further refined
- there has been any wastage of animals, the reasons for this and how it could be avoided in future
- opportunities for release or re-homing of animals have arisen and how well this has been handled in practice

6. Retrospective assessment and retrospective review

(iii) To facilitate project licence 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 erroneous or strange results and what the causes of these were
- 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 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 NTCO
- there is satisfactory communication within and/or between research team(s)
- animal care staff or the veterinarians have any concerns about the work; their roles and opinions are being well supported by the establishment and there are no 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 developing 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 (Standard Condition 18 of PPL) and lessons learnt
- there are any commendations for any of the project team

Developing an effective process

The general principles set out on pages 8 to 14 and many of the points on prospective project review (pages 20 to 29) 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 review should be performed at the establishment and to allow animal care and scientific staff to contribute to the development of the local process.

6. Retrospective assessment and retrospective review

If the local culture supports the view that 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

- Development of a planned programme of back-up studies so that animals from a cancelled study were not wasted
- Implementation of positive re-enforcement training programmes that reduced the need for restraint of animals
- An increase in the amount of work within a project which was able to be undertaken *in vitro*
- Reduction in mouse usage and development of more humane endpoints by the application of novel imaging techniques
- Identification of new 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
- 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 etc
- In contact (in cage) transmission of infectious agents such as gastrointestinal bacteria to cohorts of animals therefore 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) through the dissemination of good practice
- The reduction in the use of foot pad inoculations to stimulate immune responses in the popliteal lymph node by demonstrating the efficacy of an alternative, less painful route of administration
- Sharing of equipment or expertise and training between groups

6. Retrospective assessment and retrospective review

Timing

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

For in-house retrospective review, the timing 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 an experiment by experiment) basis. For example, where a new animal model is developed, or a drug metabolism service is provided to a number of drug discovery projects, using a variety of different dosing routes and different types of compound,

The review 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 questions about severity).

Some establishments use the submission of a licence amendment as the trigger to carry out a review of a project. The benefits of this needs to be balanced against the irregularity (or in some cases the frequency and regularity) with which amendments may be required, and the additional administrative burden this may impose on the project licence holder and those involved in the 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 come 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 useable, so it needs to be clear what is required as *input* into the retrospective review (i.e.

6. Retrospective assessment and retrospective review

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 is a waste of time.

It may be that general problems - 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 a 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.

**Acquisition,
accommodation, care,
use & rehoming**

7. Acquisition, accommodation, care & use, re-homing

“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 clearly 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 humane killing and re-homing (or re-use and release) can be discussed
- establishment policies/SOPs on such issues can be initiated, developed, endorsed and enforced
- 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 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 kind of issues 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 individual species (e.g. a dog or mouse group), welfare issues in particular types of project such as how to support aged animals, or animals in models of degenerative conditions, or severe severity protocols.
- Establishing standing agenda items to receive written and verbal reports on accommodation, care and health issues from animal care and veterinary staff. 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.

7. Acquisition, accommodation, care & use, re-homing

- Commissioning reports on specific issues such as trends in the establishment's use of animals, CO₂ euthanasia or management of genetically altered (GA) animal breeding at AWERB meetings.

In addition:

- Licence reviews, both prospective and retrospective, may raise accommodation and care questions, which the AWERB then asks specific individuals or groups to pursue.
- The **Home Office Inspector** may suggest topics the AWERB needs to address in relation to accommodation and care and humane killing.

Whatever approach is used, AWERB members should also visit animal units to develop their understanding of the facilities, the procedures carried out, the animal welfare issues and the nature of the advice that staff would find helpful.

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, and in helping 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 [17] sets out the statutory minimum requirements for cage sizes and environmental enrichment, but the establishment may choose to use larger, more enriched cages and be more proactive in implementing refinements to the lifetime experience of its animals. The AWERB can take a leading role in driving, defining 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 species) 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;
- ensure that transport stress is minimised, and enough time is allowed for animals to acclimatise to the new accommodation and care routines;

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- 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;
- maintain an overview of work throughout the establishment to identify potential opportunities for collaboration between individuals, or groups, with respect to tissue sharing or use of surplus animals.

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 or as part of collaborative studies in the UK, or overseas. AWERBs should discuss proposals to send animals overseas to ensure 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 are sourced and hold a list of approved suppliers.

Re-homing and release

If animals are released or re-homed the AWERB can ensure that the establishment has a process in place to do this successfully, and that this fully takes into account the interests of the individual animals concerned, as well as all legal requirements.

Re-homing

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 information on:

- The circumstances under which an animal might be re-homed
- 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 veterinary input necessary to the process and any follow up required
- Details of health/use/preventive medicine programme as necessary
- Details of the proposed socialization programme (to be agreed with suitable experts)
- The criteria on which to assess the suitability of a new owner/environment
- Defined responsibilities and related declaration templates for new owners
- Agreed documentation to accompany the animal
- Details of any follow-up programme
- How to maintain effective communication with the new owners (e.g. through a named contact person)
- Identification of potential new owners (N.B. collaboration with animal charities, with expertise in re-homing schemes, has proved successful in some countries)
- (See also: LASA 2004 report on the re-homing of dogs [18] and Home Office guidance [19])

7. Acquisition, accommodation, care & use, re-homing

Re-use

Re-use must in all cases be authorised in the project licence by the Home Office and the AWERB can ensure that there is establishment-wide understanding of Home Office policy. However, the establishment may want to set its own criteria for allowing re-use in addition to those of the Home Office. 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: any scientific value achieved through making repeated measurements in the same animal; the balance between reducing the number of animals used against the increased welfare burden for the individual re-used animal; and the consequences of bringing more naive animals into the laboratory environment.

Euthanasia

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

- review of site procedures for Schedule 1 euthanasia at appropriate intervals;
- incorporation of new knowledge about techniques such as the use of CO₂;
- assessing the justification for and refinement of non Schedule 1 methods;
- ensuring support for the emotional wellbeing of staff who have to kill 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 disease outbreaks) which may have an establishment-wide effect on welfare and/or science. The AWERB can then ensure these are communicated to all relevant parties including project and personal licence holders, and where necessary, the establishment licence holder and the Home Office. If the issue is likely to impact on the timeline of the research, then the funding body may also need to be informed.

Resources

The AWERB can hear about, and then highlight resource issues to senior management and help to get these resolved. It can receive reports on, and support the need for, larger scale upgrading of facilities. It can hear the concerns, ideas and achievements of animal care staff, and encourage the spread of knowledge about animal accommodation and care and related issues in order to improve animal welfare.

7. Acquisition, accommodation, care & use, re-homing

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

- Review of trends in figures for supply and demand to identify any problems such as over breeding
- Change in rabbit housing from cages to floor pens
- Review of exercise possibilities for dogs
- Review of source, nature and noise levels in animal facilities
- Review of methods of identification for amphibians to ensure the least invasive are used
- Review of potential to group-house instrumented primates and rodents
- Instigation of cryopreservation and archiving to reduce numbers of genetically altered animals maintained
- Instigation of Positive Reward Training of animals to assist with routine husbandry or experimental procedures
- Promotion of newer gaseous anaesthetic agents which are minimally metabolised and provide a more rapid recovery
- Review of acclimatisation periods following transport for animals entering the facilities
- Application of LASA guidelines on good standards of aseptic surgery throughout the establishment [12]
- 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
- Input into the development of welfare assessment score sheets providing information on potential behaviour-related welfare indicators linked to husbandry
- Review of local procedures in response to publication of new guidelines, e.g. LASA guidance on record keeping [20]
- Use of frozen sperm as a way to archive GA animals without requiring specialist equipment
- Adopting the principles set out in the ARRIVE Guidelines [21]

Non-regulated animals/non licensed procedures

An AWERB may choose to ensure that non-regulated work is carried out to a standard consistent with that of regulated work, so may choose to consider accommodation and care as well as euthanasia issues for all animals (e.g. invertebrates) and all procedures (e.g. use of animals solely for supply of tissues), not just those licensed under ASPA.

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 in particular need support from the establishment licence holder and a productive relationship with both personal and project licence holders. The AWERB can aim to develop and deliver this. Many of the elements necessary 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.

Supporting AWERB participants and increasing their confidence

- Choose a good Chair who will ensure that everyone in the AWERB is properly involved and will direct questions appropriately to less confident members
- Provide an induction pack for all participants with written information about who is involved, what to expect from the process and also what is expected from them, including likely timelines, to help with planning
- Encourage those who have difficulty contributing in meetings to provide written comments in advance
- 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
- Ensure AWERB meetings are a positive experience for all those involved – including any prospective project licence applicants; and extend this outside meetings for example by AWERB members actively seeking to meet licence holders and visit animal facilities
- Provide participants with training in ‘soft skills’ such as communication and committee skills, and ensure that they are aware of the aims and values of the AWERB
- Provide a safe opportunity for junior staff members to propose suggestions for 3Rs or raise matters of concern

Providing operational support

- Structure the agenda 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
- Make sure the AWERB is enabling not obstructive
- Ensure that when things go wrong they are dealt with quickly and lessons are learnt
- Rebrand policies as belonging to the AWERB, so that they are not seen as just coming from the named persons or animal facilities
- Support the need for resources to ensure that all roles and responsibilities can be discharged properly
- Have a well resourced secretariat who has time to organise and run AWERB business efficiently

Training and competency

There is now greater focus on training and competency in the EU Directive [22] and ASPA [8]. Given the acknowledged importance to science, 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 and training and assessment of competence for all staff who need it - including AWERB members. This should be easier to deal with now there is a requirement for a Named Training and Competency Officer (NTCO) who must be “*actively engaged*” in the AWERB.

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. 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 department or training officer/s as well as the NTCO, then the AWERB may only need to receive regular reports from these. Provided there is good communication between the AWERB and staff responsible for training, then any issues relating to training, supervision and competence 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 could 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 training and competence, are listed in the box below.

The establishment should ensure that:

- 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 (Home Office modules, 'on the job' and CPD) is provided (including refresher training for personal and project licensees), and the suitability of this is reviewed at regular intervals in consultation with trainees
- Supervisory requirements for personal licensees are clearly defined and fulfilled and everyone knows their responsibilities in this respect [22,23]
- There is a robust system for assessing the 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 reliable system for recording staff training and competence
- The establishment licence holder has access to training relevant to his/her role (e.g. Home Office modules, the establishment licence holder training days)
- 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
- Training 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

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”

Aims ...

Providing the opportunity to raise and discuss ethical issues is integral to the AWERB’s role in promoting a culture of care. The AWERB should aim to be alert to the wider ethical and legal issues arising from the use of animals, both within the establishment and beyond. It should 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.

....and approaches

The nature of the *“forum for discussion”* is not defined and this could take different forms depending on the establishment. An AWERB, by virtue of holding meetings, *in itself* provides a forum for dialogue and discussion, albeit largely between people directly involved in the process.

However, it is beneficial to go beyond this and encourage other staff to contribute topics that, in their view, would be helpful for the AWERB to be aware of and discuss and invite 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;
- set up a physical or online suggestions box (which could also provide a confidential mechanism for raising any issues of concern).

The AWERB could, in addition, establish a **wider discussion forum within the establishment** for points of general and specific interest, and encourage *all* staff to contribute. This would help disseminate information outside the AWERB’s immediate membership, and could also help engage people with topics that can be difficult and controversial. For example, the AWERB could organise 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 a useful role.

There is interplay between this task and many other aspects of the AWERB’s work. The AWERB needs to be aware of issues arising from these that would benefit from further discussion. Examples include points of general concern or interest that arise during prospective or retrospective review of specific projects, or aspects of severity assessment identified during retrospective reporting.

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 to consider work on species (i.e. most invertebrates) that are not covered by ASPA
 - how the establishment deals with severe procedures
 - whether and how the establishment should interact with the public; how its research is presented and publicised - the language and tone of such communications; how to support and implement the Concordat for Openness [24]
 - how to manage additional availability
 - defining principles and criteria for outsourcing work and associated welfare audits
 - internal guidance on collaborations outside the UK (e.g. see: 'Responsibility in the use of animals in bioscience research: Expectations of the research councils and charitable funding bodies' [25])
 - developing structures and policies to ensure concerns can be raised by any member of staff, heard and acted on
 - exploration of how research integrity issues relate to animal use

- **Changes in legislation, or in administration of the ASPA, for example:**
 - changes in the project licence application process or other administrative procedures
 - new Home Office Codes of Practice, advice notes and guidance
 - Home Office newsletters
 - feedback from Named Persons' meetings

- **General discussion that may cover difficult or controversial issues**
 - the emotional well-being of staff involved in the killing of animals
 - issues related to the use of 'sensitive' species (e.g. cats, dogs, primates)
 - response to infiltrations and subsequent reports which appear in the media
 - reviewing the clinical relevance of disease models
 - 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
 - debating the pros and cons of using CCTV in all/some procedure and/or holding rooms
 - exploration of the question: 'are our lay members 'lay' enough' and if so do they have sufficient support

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...

This task can be seen as helping the establishment licence holder to meet his or her wider responsibilities by providing an overview of how management processes combine to ensure high quality animal care and use, perhaps also considering how processes interact and how resilient they are when staff change.

These issues are usually addressed through internal management systems and procedures that support animal welfare, quality science and regulatory compliance. The mechanisms adopted will vary depending on the size of the establishment and the nature, and complexity of the work being carried out and species used. However, all breeders, suppliers and users should have quality control procedures defined and recorded.

The AWERB should receive regular reports from those responsible for managing facilities and provide feedback to them.

Some issues that AWERBs may discuss ...

The following suggestions are for mechanisms that will help in establishing and reviewing management and operational processes. These have already worked successfully in some establishments, but their applicability will depend on the nature of the establishment and no one establishment is likely to have or need all of them in place. Most of the issues relate to the establishment licence holder's responsibilities or form part of other AWERB tasks.

Mechanisms that will help in establishing and reviewing management and operational processes

- Formal or informal audits of projects or procedures. This may involve AWERB members or others observing procedures. It is important that any audit findings are recorded and remedial actions tracked
- Use of external experts to review internal systems and/or animal facilities. This might be through formal processes such as AAALAC, or visits by clients, or through less formalised visits by colleagues from other institutions
- A standard process for dealing with non-compliance or welfare concerns, e.g.:
 - procedures to track issues and ensure they have been followed up and resolved
 - monitoring of trends/recurrence of issues
 - identification of a specific individual as responsible for tracking and monitoring issues
 - an internal mechanism to enable anyone to report animal welfare concerns confidentially and without fear (i.e. a 'whistle blowing' process)
 - mechanisms to raise concerns with senior management
- Periodic internal reviews of specific issues, e.g.: minimising animal surplus; ensuring that the correct authorities are in place for the ordering and issuing of animals and that these are maintained when staff change; reviewing anticipated versus actual severity and how often humane endpoints are reached
- Systems in place to ensure overall compliance with ASPA e.g.: to prevent unauthorised use or re-use of animals; and that all the associated Home Office Codes of Practice and Advice Notes are implemented
- AWERB animal housing facility reviews with input and feedback to scientific and care staff
- Review of proposals for any new facilities or refurbishments or repairs, or acquisition of newer types of accommodation
- Reviews to ensure: that staffing levels are appropriate; that the systems in place to monitor animals are adequate to optimise welfare (e.g. the day-to-day cage-side, observations and recording of behaviour and clinical signs)
- A 'team approach' to setting out and implementing a welfare assessment protocol for each study. The EU Guidance Document on a Severity Assessment Framework [26] recognises that this is good practice. It also recommends that AWERBs play a role in defining protocols for actual severity assessment, to help ensure consistency. A verification process, in which judgements made by different people are compared, is also cited as helping to promote consistent use of the system
- System for internal follow-up of formal Home Office inspections
- A check that the AWERB's own procedures are effective and not overly burdensome

Promoting a culture of care

“Help to promote a culture of care within the establishment and, as appropriate, the wider community”

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, demonstrate effective leadership in this area.

The culture of care should permeate throughout the establishment, but it is essential that senior management understands the issues and 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 since it advises the establishment licence holder, who is a senior manager. Many of the ideas for AWERB activities throughout the other sections of this document contribute to achieving a good culture and so these will not be discussed again here.

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. Every establishment that uses animals for a scientific purpose 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 enhance scientific outcomes.

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 improving 3Rs, animal welfare and research and working together to do so. Some factors shown to foster an appropriate culture within an establishment are listed opposite.

Features of a culture of care

Structural elements

- A **corporate expectation of high standards** in legal, ethical, animal welfare, 3Rs and scientific aspects of the use of animals that extends **above and beyond the legal minimum**, and which are endorsed and implemented at all levels throughout the establishment
- An effective operational structure with **clear roles, responsibilities and tasks** in which animal technologists and care staff, named persons [NVS, NACWO, NIO, NTCO], trainers and assessors are listened to and their work supported throughout the establishment
- Effective and well supported **ethical review** of scientific work undertaken with a thoughtful and rational approach
- A robust framework for **training and assessment of competence**, together with recognition of the importance of continuing professional development (CPD) for all staff, and with adequate opportunities and resources provided
- Good establishment-wide **communication processes** regarding animal welfare, care and use issues and the relation of these to good science, with good communication between researchers and animal technologists and care staff
- Mechanisms to ensure that **standards** at animal suppliers, contracted organisations, and research partners overseas **are consistent** with the good practice that is implemented in-house
- Commitment to provide **sufficient resources** to achieve all of the above

Behavioural elements

- Strong commitment, support and **leadership from senior management** which provides the resources to deliver the values of the institution
- Demonstrable **respect for animals and for differing ethical perspectives** on animal use
- A **common set of values and standards** which are communicated, understood and implemented across all parts of the establishment
- 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 working within ethical and welfare frameworks, such as 3Rs and LASA good practice and guiding principles documents
- 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
- Willingness to **challenge the status quo**, to speak out without fear and to support those that do; internally, an open culture where staff are confident to report problems and raise any concerns, and where these are listened to, discussed and resolved in a positive way
- Commitment to **openness and honesty** about animal use both internally and in the public domain
- Dedication to a cycle of **review and improvement** of policies and processes to strive towards higher standards of animal welfare

Activities that can help in developing the culture

- Inviting animal technologists and care staff to research-group or laboratory meetings and including animal welfare, husbandry and care as standing agenda items
- Engaging project licence holders and personal licensees on the AWERB e.g. with rotation of membership
- Including the culture of care with respect to animal use in an establishment as a core element of induction/training materials for all staff
- Establishing a good relationship with the Home Office Inspectorate and organising Inspector-led meetings and surgeries
- Developing an organisational mission statement regarding animal use
- Producing regular newsletters on issues relating to ethics, animal and staff welfare, 3Rs, scientific and other 'cultural' issues
- Inclusive consideration of animal usage outside that governed by ASPA regulations e.g. invertebrates, use of animals for non-regulated purposes
- Appointing an establishment licence holder who is accessible and engaged; who is prepared to visit the animal facilities on a regular basis; and who listens to and actions 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
- Establishing 3Rs awards with recognition around the establishment, promoting these through attending meetings and via publications
- Considering open days e.g. for, family of staff, students and the general public, and asking them for feedback
- Encouraging public engagement outside the establishment at schools, institutions of higher education and community groups

Glossary

APC	Animals Procedures Committee
ASC	Animals in Science Committee
ASPA	Animals (Scientific Procedures) Act 1986
AWERB	Animal Welfare and Ethical Review Body
CO₂	Carbon Dioxide
COP	Code of Practice
CPD	Continued professional development
CRO	Contract research organisation
EC	European Commission
ERP	Ethical Review Process
GA	Genetically Altered [animal]
HO	Home Office
HOLC	Home Office Liaison Contact
IAT	Institute of Animal Technology
LASA	Laboratory Animal Science Association
LAVA	Laboratory Animal Veterinary Association
NACWO	Named Animal Care and Welfare Officer
NIO	Named Information Officer
NTCO	Named Training and Competency Officer
NVS	Named Veterinary Surgeon
RSPCA	Royal Society for the Prevention of Cruelty to Animals
3Rs	Reduction, Refinement and Replacement of animal use
SOP	Standard Operating Procedure

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**The role of different review bodies with regard to blood sampling protocols
in a research project**

Funder/ Organisation	AWERB	Home Office Inspectorate
<p>Reviews grant application at a high level, asking questions about validity and value of science; are unlikely to require or consider the detail of individual procedures such as blood sampling</p>	<p>Uses local expertise to define local protocols for the most refined methods to be used throughout the establishment; e.g. the AWERB could develop an SOP for preparation, sampling route, method and volume, and for animal monitoring</p> <p>Ensures individual project licences take account of local good practice, but does not insist on including detail of methods in the actual licence applications unless required to do so by the Home Office</p> <p>Includes consideration of potential adverse effects in the AWERB's overall assessment of harms and benefits of the work</p> <p>Considers any problems that have been reported during the studies and whether any changes in procedures need to be made</p>	<p>Determines that all relevant and necessary information is in the licence</p> <p>Assesses proposed sampling procedures against national policy and considers the justification for any deviation from these</p> <p>Advises on any further possibilities for reduction and refinement within the sampling protocol</p> <p>Reviews protocol severity classifications/categories</p> <p>Checks compliance with legal requirements</p> <p>Weighs the potential harms and benefits on behalf of the Secretary of State</p>



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Royal Society for the Prevention of Cruelty
to Animals

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