

Guiding principles on good practice for Ethical Review Processes

1st Edition - May 2010

This document is intended to help interpret the requirements for UK local Ethical Review Processes (ERPs) and, by sharing good practices, to develop more efficient and effective processes. It has been produced in response to comments that there is “scope for improvement in this area” made by the Home Office, the Animal Procedures Committee (APC) and others working within the ‘Better Regulation’ agenda.

The document is based on the output of two workshops held in 2008, which brought together ERP participants from over 50 UK establishments to discuss the ERP’s aims and functions and provide examples of good practice in implementing these. It also incorporates key points from previous Home Office and APC guidance, LASA workshops and RSPCA Lay Members’ Forums. Since it explains the ERPs role and functions, the ‘Guidance’ should be helpful for all people working under the Animals (Scientific Procedures) Act 1986 (ASPA) as well as those working closely within the ERP itself.

The Guidance is intended as a ‘dynamic document’ to be updated as the ERP evolves and experience of good practice develops. This will be particularly important as the revised EU Directive regulating animal experiments is translated into UK law. Please send any comments or ideas for improving the content or clarity of the document to any of the authors below.

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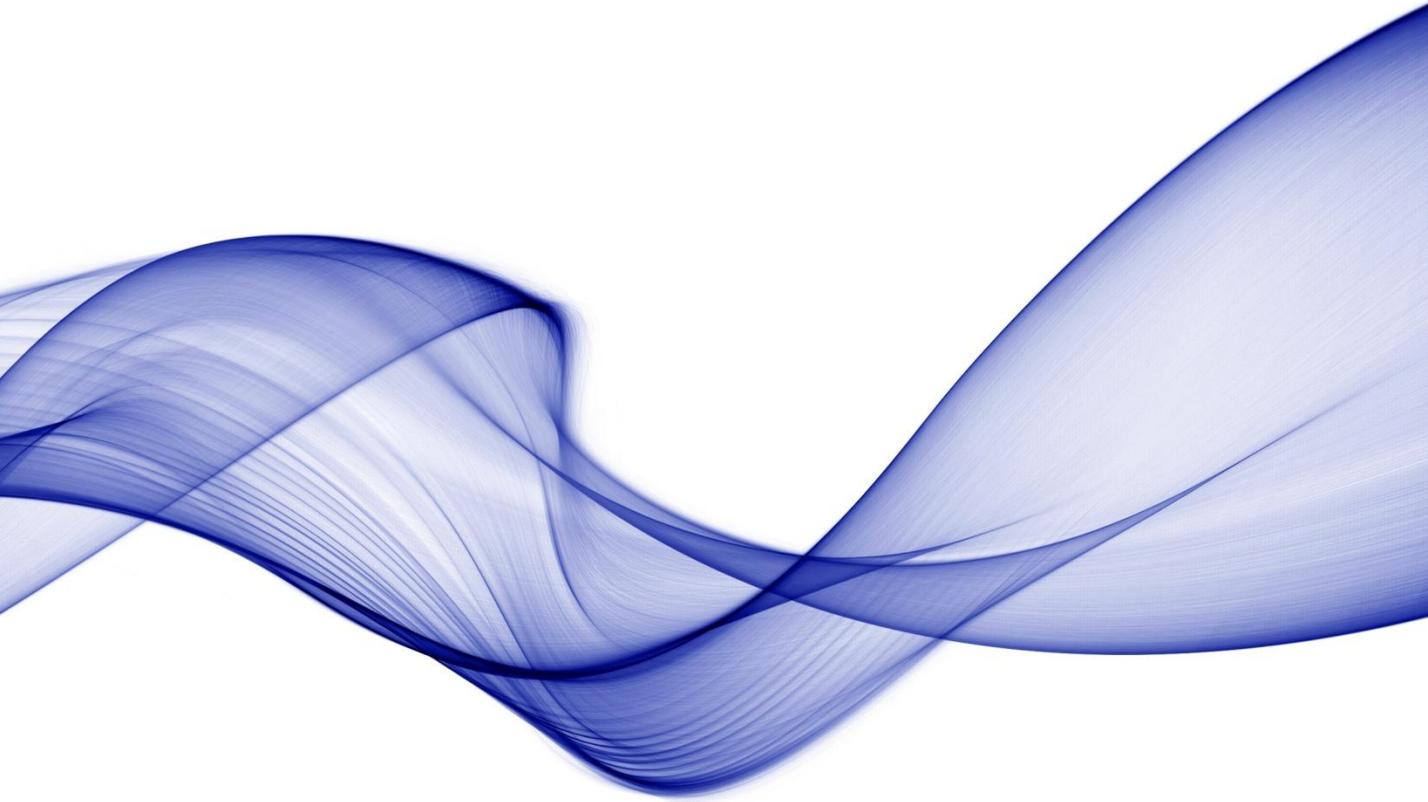
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Home Office requirements



ERP aims, functions and membership

The aims, functions and membership of the local ERP are set out in [Appendix J](#) to the Home Office 'Guidance on the Operation of the Animals (Scientific Procedures) Act 1986'¹ and the main sections of text are reproduced below. The over-arching aim described by the Home office is shown in the box. This is then broken down into three more specific aims which can be achieved by implementing the seven functions.

"... a local framework acting to ensure that all use of animals in the establishment, as regulated by the Animals (Scientific Procedures) Act 1986, 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 aims of the ERP

- To **provide independent ethical advice to the Certificate Holder**, particularly with respect to project licence applications and standards of care and welfare.
- To **provide support to Named persons** and **advice to licence holders** regarding animal welfare and ethical issues arising from their work.
- To **promote the use of ethical analysis to increase awareness of animal welfare issues** and develop initiatives leading to the widest possible application of the 3Rs².

The seven functions of the ERP

1. Promoting the development and uptake of reduction, replacement and refinement alternatives (the 3Rs) in animal use, where they exist, and ensuring the availability of relevant sources of information.
2. Examining proposed applications for new project licences and amendments to existing licences, with reference to the likely costs to the animals, the expected benefits of the work and how these considerations balance.
3. Providing a forum for discussion of issues relating to the use of animals and considering how staff can be kept up to date with relevant ethical advice, best practice, and relevant legislation.
4. Undertaking retrospective project reviews and continuing to apply the 3Rs to all projects, throughout their duration.
5. Considering the care and accommodation standards applied to all animals in the establishment, including breeding stock, and the humane killing of protected animals.

Home Office requirements

6. Regularly reviewing the establishment's managerial systems, procedures and protocols where these bear on the proper use of animals.
7. Advising on how all staff involved with the animals can be appropriately trained and how competence can be ensured.

In addition, the Home office states: "Commonly, there should be a promotional role, seeking to educate users (in applying the 3Rs) and non-users (by explaining why and how animals are used), as appropriate".

Membership of the ERP

Participants *required*

- A Named Veterinary Surgeon
- Named Animal Care and Welfare Officer(s)
- Project licence holder(s)
- Personal licence holder(s)

Participants *suggested*

- Where possible, the views of those who have no responsibilities under the Act should be taken into account.
- One or more lay persons^a, independent of the establishment should be considered^b.

In addition:

The Certificate Holder "should ensure as wide an involvement of establishment staff as possible" in the ERP.

Home Office inspectors have the right to attend any meetings and to have access to the records of the ERP.

Additional guidance

Further Home Office guidance can be found in a [supplementary note by the Chief Inspector \(2000\)](#)⁵ and the reports of two reviews carried out by the Home Office Inspectorate in [2001](#)⁶ and [2006](#)⁷.

The APC published advice on good practice prepared in the context of Better Regulation in [2008](#)⁸.

^a A wide diversity of people from a variety of disciplines and fields of work may be regarded as lay participants. An interpretation of their role can be found in the [Resource book for lay members of Ethical Review Processes published by the RSPCA](#)³.

^b [The House of Lords, in their 2002 report](#),⁴ recommended that an external lay member should be required.

General principles



Principles of good practice

This section presents a set of principles (summarised below and in the ‘Ten top tips’ box and expanded in subsequent pages), which in the experience of contributors to this document are key to achieving the ERP’s aims.

The ERP aims and functions formalise what any establishment should be doing to promote high standards of animal welfare, enhance scientific achievements and generate a good culture of care.

There is no ‘one size ERP to fit all’. It is an establishment’s own responsibility to decide how the ERP should be organised and managed, though this should be in accordance with the principles in [Appendix J](#) to the Guidance on the Operation of the ASPA¹. The ERP 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. It does not have to be set up as a formal committee, although most places do employ some form of central body to facilitate the work.

A well-designed ERP is a valuable resource because it draws on and makes available local expertise, and so should benefit all staff. As a high level ‘body’ advising the Certificate Holder, it is well placed to help identify and prioritise the need for resources such as new buildings, staff and equipment.

The ERP provides a framework to promote dialogue between Named persons and other staff, to ensure their expert advice informs the planning and management of animal production, care and use.

Ten top tips for a successful ERP

1. Have a clear concept of what the outcomes of your ERP should be
2. Make sure that in discharging its functions your ERP ‘adds value’ over and above the work of other external or internal bodies
3. Make sure *all* the ERP functions are addressed in some way
4. Think carefully about the selection of participants and particularly the Chair
5. Make sure the process is organised efficiently
6. Ensure that all staff know what the ERP is for, why it is important, who is involved and how it affects them
7. Ensure effective communication within and between all parts of the ERP and any other bodies that impact on its work
8. Be reactive and responsive to the needs of ERP ‘users’
9. At intervals, re-evaluate whether the ERP’s aims are being achieved and whether its operation is efficient and appropriate, making sure its resources are directed where they are most needed and can make most difference
10. Try to interact with and share good practice ideas with participants in other ERPs

Ten top tips for a successful ERP ...

1. Have a clear concept of what the outcomes of your ERP should be

Think through each of the seven functions and decide on what you want each to achieve and the outcomes you expect *for your establishment*. Bear in mind that there is overlap between some of the functions and in how they can be implemented. For example, function 1, to promote the 3Rs and ensure the availability of 3Rs information (p 13), also contributes to function 3, to consider how staff can be kept up to date with best practice (p27) and function 5, to consider standards of accommodation (p 37).

2. Make sure that in discharging its functions your ERP adds value over and above the work of other bodies

This is particularly important with respect to function 2 “examining proposed applications for new project licences”. The Home Office conducts an ethical review within the National legal and policy framework. This takes account of issues beyond the scope of the local establishment. Research funders review grant proposals for quality of science and value for money. The local ERP considers *local* ethical and animal care and use issues from a *local* perspective in the light of *local* expertise, opinions and facilities (see p 18 for further explanation).

3. Make sure *all* the ERP functions are addressed in some way

Do not focus only on function 2. The other functions are important too, and if they are dealt with well, project review will be quicker and easier. Where establishments have an overarching ERP committee, it is helpful as a reminder to have a standing agenda item for each function with sufficient time allowed to discuss any points raised.

4. Think carefully about the choice of participants and particularly the Chair

A minimum core list of participants is required by the Home Office, but it is accepted as good practice to include people with a wide range of relevant knowledge, skills and perspectives as well as staff at different levels of seniority. It is helpful to identify key personnel who will provide the drive to achieve the ERP’s aims and functions and to communicate its activities. Identifying an effective chair is also critical to establishing an effective process (see p 12).

5. Make sure the process is organised efficiently

Efficient organisation is essential in order to minimise the costs of the ERP (both financial and with respect to staff time) and help achieve its benefits effectively, so, 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 ERP rather than setting up an additional committee to deal with function 6.

- Do not over-complicate the process and over-burden everyone with paperwork. For example, if the ERP asks for a lay abstract for project licences, the abstract produced for the Home Office could be used to avoid further paperwork provided the abstract is well written and covers the necessary points.
- Do decide what information the ERP actually *needs* and trial any forms to ensure they are user friendly.
- Do not rely solely on formal set meetings to progress issues. *Ad hoc* meetings, email discussions and teleconferences are all useful tools.
- Do ensure sufficient administrative support is available to prepare papers for meetings and to co-ordinate and support other activities.
- Do 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 aim for. If there are any delays, or potentially contentious issues within a licence which are likely to require further discussion, notify the project licence applicant as soon as possible.
- Do have a fast track system, for example, for non-contentious licence amendments.

6. Ensure effective communication within and between all parts of the ERP and any other bodies that impact on its work.

7. Ensure that all staff know what the ERP is for, why it is important, who is involved and how it affects them.

Explain what the benefits of the ERP are to the establishment as a whole and to staff as individuals. Be clear about the benefits in terms of animal welfare, science, regulatory compliance, a constructive culture and public opinion, and encourage staff to view the process positively. Publish this information internally - perhaps designing a 'know your ERP' poster or website - and consider publishing this information externally as part of the establishment's position statement on animal use.

Include information about the local ERP as part of the induction and training package for all staff and invite them to bring matters to its attention. The ERP should be recognised as a body accorded stature that senior management listens to.

Participation in the ERP should be considered part of the responsibilities for 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 ERP 'users'.

The ERP needs to be accessible to all staff who should be encouraged to bring issues to its attention.

It needs to consult the staff whose activities it affects (e.g. personal and project licensees) to identify and solve concerns and capitalise on achievements.

It should provide regular feedback to staff on the ERP's work and ensure that it is transparent by publishing agendas, minutes and reports.

9. At intervals, re-evaluate whether the ERP's aims are being achieved and whether its operation is efficient and appropriate.

Make sure the resources of the ERP are directed where they are most needed and can make most difference.

Ensure the views of ERP 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 ideas with participants in other ERPs

Although there is not currently a national ERP 'forum', there are a number of opportunities for ERP participants to get together informally. Both [LASA](#) and the [Certificate Holders' Forum \(CHF\)](#) hold ERP-related workshops. The [RSPCA](#) runs an annual Forum for Lay Members, which other ERP participants also attend.

In addition, assuming there are no irresolvable confidentiality issues, individual establishments could encourage guest visitors from other establishments to attend their ERPs in order that information is shared and disseminated; equally your participants can be encouraged to visit other establishments to experience different approaches and views on good practice.

Achieving the right mix of participants

Getting the 'right' people involved in the ERP 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 developing them 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 the **key roles** that should be represented are shown on page 6, but it is also important to consider the **key competencies** which contribute to making the ERP effective. These are listed in the box over page, together with the **personal qualities** that are desirable as well.

The ability to obtain additional advice on specific issues (e.g. unusual species or new techniques/models) is necessary and it is also useful to have easy access to someone who understands other relevant legislation (e.g. on transport, the Animal Welfare Act, regulations on Genetically Modified animals).

Good chairmanship is 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'. This should create a supportive, inclusive environment that will encourage open and forthright discussion.

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

A Home Office Liaison Officer (HOLO) is employed by many establishments to help administer, contribute to, and disseminate information about the ERP. This is considered to contribute significantly to the success and efficient operation of the ERP.

Key competencies

Knowledge, understanding and expertise in:

- animal husbandry, care and welfare
- each of the 3Rs
- education and training
- ethical issues and discussion
- individual techniques
- public opinion and perspectives
- relevant scientific fields
- statistics
- 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 challenge the status quo
- having realistic expectations of what can be achieved
- having the time and commitment to take an active role and do the role justice

Promoting the 3Rs



Function 1 – Promoting the 3Rs

Promoting the development and uptake of reduction, replacement and refinement alternatives (the 3Rs) in animal use, where they exist, and ensuring the availability of relevant sources of information.

What to aim for ...

The ERP can implement this function in a number of ways. For example it can:

Show recognition of the value of the 3Rs and support for 3Rs initiatives, making them integral to the work of the establishment

Provide a focal point for advice on the 3Rs

Provide a mechanism to encourage and facilitate wider staff involvement in the 3Rs, acting as a driver and motivator to get people to:

- think about and implement existing 3Rs opportunities
- develop new 3Rs initiatives and activities
- disseminate 3Rs information as widely as possible

These activities can be approached both in the **review of individual project licence applications** and **more generally within the establishment**.

What works well...

Two successful organisational approaches are:

- **Assign responsibility for specific 3Rs issues to one or more groups/sub-committees of staff who provide advice and feedback on these to the main ERP.**

This has the advantage that involving a core group 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 them, and to include people with specific expertise in each of the 3Rs (including experimental design and statistics). However, it is also helpful to harness a wider range of expertise and perspectives and encompass animal care staff and personal licensees.

- **Assign responsibility for driving this function to a nominated person – a central point of contact or 'facilitator' – who could be a NACWO, NVS, or HOLO.**

This approach may be more appropriate in a smaller establishment with few projects covering a limited number of procedures on only a few species. However, no one person will have all the expertise required and so it will still be necessary to draw on a wider range of expertise and perspectives and to spread responsibilities and workloads.

Examples of 3Rs activities

- Have early sight of project proposals to identify 3Rs and experimental design issues, advise the project licence applicant on how to deal with these and feedback to the main ERP – some establishments find it helpful to do this on a study by study basis
- Develop welfare assessment protocols and score sheets for commonly used procedures/models
- Periodically consider individual topics such as ‘housing and environmental enrichment’, reviewing how this could be improved
- Organise species related activities, for example to consider all housing and procedures on dogs and how these could be refined
- Organise project based groups to consider all aspects of animal use within a specific project or work programme (e.g. how the 3Rs could be applied to cancer models)
- Periodically review the continuing validity and usefulness of different models used for similar projects (e.g. the comparative validity of different GA models), and of similar models used across a range of different projects
- Initiate internal reviews of procedures (e.g. blood sampling, telemetry, biopsy methods, use of metabolism cages or restraint chairs, [aseptic techniques⁹](#)) with a view to refining these and/or writing refined establishment protocols/internal guidelines. The latter can then be used as a consistent establishment standard and applied to work done under all relevant project licences
- 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 wastage of animals (e.g. whether animals are requested and 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
- Set up a co-ordinated process for tissue sharing within or between establishments
- For establishments that are part of multinational companies or research programmes, develop global initiatives and oversight mechanisms for the 3Rs

Function 1 – Promoting the 3Rs

Disseminating 3Rs information

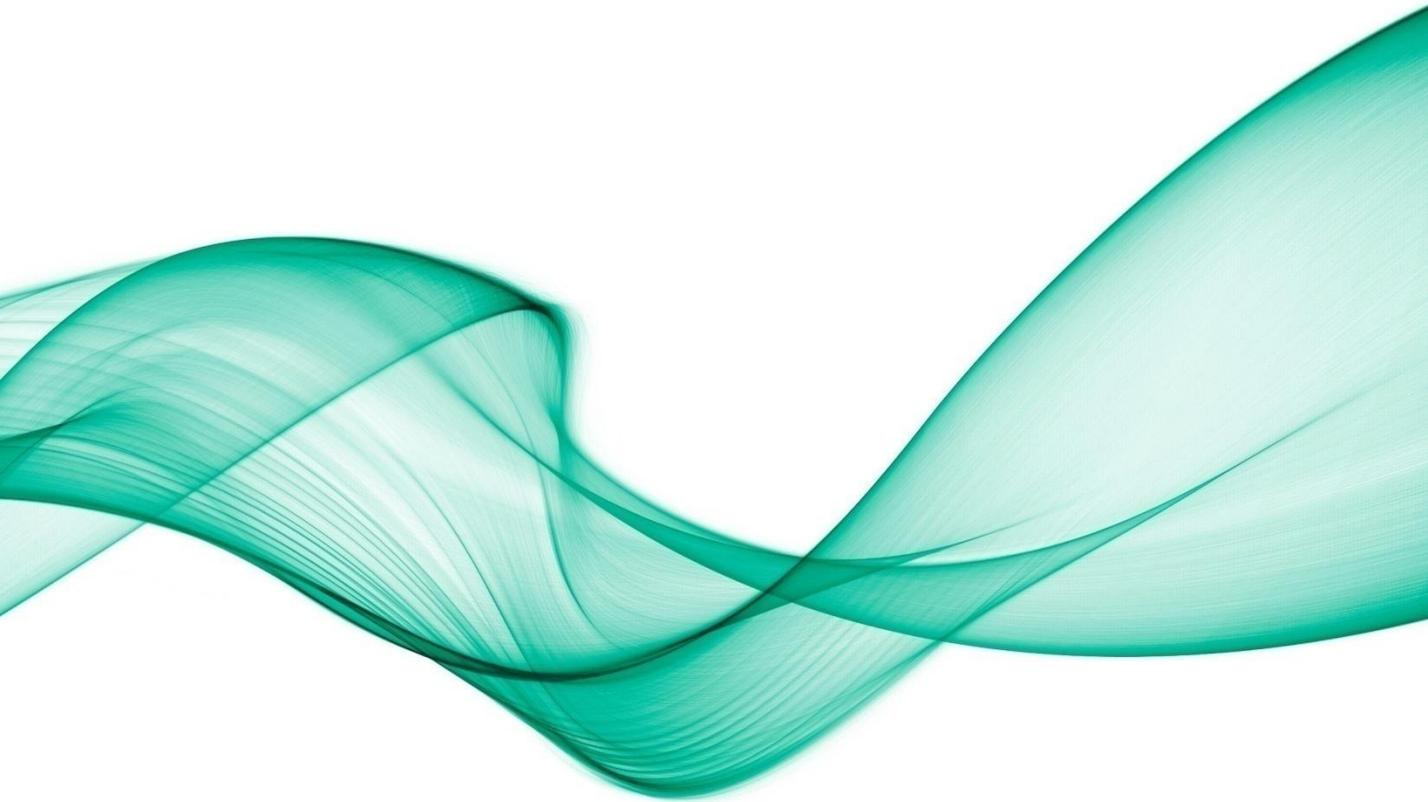
The ERP needs to build a culture that facilitates communication, however the 3Rs activities are approached. This requires mechanisms for disseminating information, bringing relevant issues (legislation, meetings, reports) to the relevant people's notice and fostering interest more widely. This has proved 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 *relevant* information, 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 get a licence holder to implement a change than just including such information in a standard newsletter or email. Although this may seem more time-consuming, it has the long term advantage of achieving better 'buy in' to what the ERP 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 newsletter that goes to all staff or email alerts with information on 3Rs publications, grant availability, meetings, courses or other activities
- Ask the NACWO, NVS or HOLO to get relevant 3Rs information together and pass on to the people who need to consider it. Staff in these roles often have a good national communications network through which to gather and disseminate information both locally and externally
- Convey information through animal user group (and other similar) meetings
- Ask project licence holders to summarise any 3Rs developments for the ERP annually or at retrospective review. At some establishments this has been successfully linked to an internal 3Rs prize or poster day
- Encourage staff to disseminate information on 3Rs work externally through posters and papers
- Encourage staff to visit other establishments to observe different working practices or 3Rs initiatives; [LASA bursaries](#) are available for such exchanges

Examining costs and benefits



Function 2 – Examining costs and benefits

Examining proposed applications for new project licences and amendments to existing licences, with reference to the likely costs^c to animals, the expected benefits of the work and how these considerations balance

What to aim for ...

In implementing function 2, it is particularly important to clearly define what, *as an establishment*, you want to achieve in ‘examining proposed applications...’ to avoid disproportionate focus on this aspect of the ERP’s work, and to ensure project licence applications are dealt with in a timely and effective manner. Many of the general principles on pages 8 to 12 are particularly relevant to achieving good practice for this function.

The key issue is to decide where the local ERP can add value. The scientific aspects of some project proposals, including the scientific value of the work, will 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 ERP should aim to complement these reviews; its benefit being that it looks at projects from a **local perspective**, bringing **local knowledge** and **local expertise** to bear. The box on page 26 illustrates how blood sampling procedures, for example, would be dealt with by the different review bodies.

Function 2 should be developed in this context and with the overall aims of the ERP (see p 5) in mind (i.e. to provide independent ethical advice to the Certificate Holder; support to Named persons and advice to licence holders; and to promote the use of ethical analysis).

Where the ERP can add value ...

For the establishment as a whole, the ERP:

- Ensures that *local* knowledge, expertise and perspectives are brought to bear on the project with respect to:
 - the establishment’s policies, ‘rules’ and culture;
 - 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 and resources, and appropriate expertise.

^c ‘Harms’ is used in place of ‘costs’ throughout, except where the text is a direct quote from Home Office documents

Function 2 – Examining costs and benefits

- Provides a forum for constructive discussion between people with relevant but diverse expertise and perspectives
- Ensures that good practice is implemented within the project and that there is consistency of preparation, examination and submission of individual project licence applications.
- Provides for wide ‘ownership’ of the project, and helps ensure there is appropriate supervision of and support for licensees, together with better dissemination of information.

For the Certificate Holder, the ERP:

- Provides consistent 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.

For the Named persons, the ERP:

- Ensures that the expertise and perspectives of local NACWOs, NVSs and animal care staff are acknowledged, understood, supported and brought to bear.

For the project licence holder, the ERP:

- Helps 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.
- Demonstrates the establishment’s confidence in, and support for, the project, and ensures appropriate back up from the establishment and its staff.

Some useful approaches ...

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

- whether, and how far, the ERP wants to be involved in assisting with the preparation of a licence application; and
- how the ERP sees its function in examining new and existing applications and amendments.

Function 2 – Examining costs and benefits

There are no hard and fast rules and each establishment needs to decide how it wants the ERP to deal with these two aspects, i.e. 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 number of licence applications the establishment processes each year and the time constraints involved.

Assisting with the preparation of the licence

Drafting a licence is the responsibility of the prospective project licence holder not the ERP. If the licence application is well prepared and well written, the formal consideration process by the ERP and the Home Office will be quicker and easier, since there will be less need for a ‘to and fro’ of questions or advice. A key issue for the project licence holder, therefore, is how to get the licence application to the formal ERP consideration stage (and to the Home Office) in good form with all the harms and benefits clearly described and with issues such as experimental design, application of the 3Rs, resource issues, staff training and supervision requirements appropriately addressed.

Attention to these issues at the project planning stage will ensure better quality licence applications coming to review and thus save time. Reports from ERPs support the view that any review that only starts once an application has been submitted for formal consideration is unlikely to work well since the applicant will already be committed to the strategies in the licence and questions from the ERP will be perceived as additional bureaucratic delay.

Each establishment may approach the process for drafting licences differently, and may or may not label it as part of the ERP. For example, it is good practice for project licence applicants to consult with the NACWO, NVS, HOLO (if there is one) and any other relevant staff early on in the planning of a project regarding the issues above. (Early consultation with the local Home Office Inspector is also helpful.) Since these people are participants in the ERP, some establishments consider this early input as an extremely helpful part of the overall ERP process. Indeed, because the ERP is a process not a committee, and is intended to help facilitate both good welfare and good science, all of these activities do come under the ERP umbrella and re-enforce its role as an enabling process, helping to deliver a good licence application in a timely manner.

Some establishments have small committees or groups that help the project licence applicant specifically to address the practical issues in the licence, together with a HOLO who has the expertise to advise on what the licence should contain. This enables any factual and/or technical issues to be sorted out *before* the licence application goes for formal review, thus facilitating the process. Again, these activities may be labelled as part of the overall ERP.

In all cases, the ERP needs to communicate clearly to those preparing, and helping to prepare, the licence application regarding what the formal licence consideration involves

Function 2 – Examining costs and benefits

and what information the ERP needs to see. These issues should also be covered in licensee and in-house Continuous Professional Development (CPD) training.

Examining the licence application

Some ERPs consider all licence applications, some only look at those identified (e.g. by the named persons or HOLO) as being particularly contentious, while others review individual studies planned within an overall project licence, rather than the licence itself. As stated earlier, in selecting the best approach, the critical factor is to decide what *your establishment* wants to achieve in the light of the overall aims of the ERP and the added value of ERP input. Participants in the RSPCA/LASA ERP workshops proposed the following objectives:

- to ensure that the project licence application has been prepared to a satisfactory standard, consistent with local requirements relating to good practice in science, animal welfare and the 3Rs, and is ready for submission to the Home Office;
- to identify the ethical issues and consider the harm-benefit balance from the *local perspective* so as to advise the Certificate Holder whether the establishment should support the work;
- to identify any concerns/issues likely to relate to other projects and consider development of establishment-wide good practice guidance if this would be helpful, thus acting as a mechanism for driving change;
- to propose time points for retrospective review.

To achieve these objectives, ERP participants will want to feel comfortable that all the issues in the box over page have been satisfactorily addressed and that there has been sufficient opportunity for discussion of any issues of concern. The ERP itself may not need to review the detail on many of these issues. For example, if there is an on-site statistician who has already reviewed the statistical design this should be sufficient; if there has been a robust review of the science by the funding body then the scientific value need not be reviewed again, unless there is specific local expertise in the field that can provide a useful contribution. At establishments where there is study by study review, some of the issues may be addressed more efficiently at that stage.

Function 2 – Examining costs and benefits

The ERP will need to seek reassurance that the following issues have been satisfactorily addressed:

- there has been a robust analysis of the methodology including experimental design, ensuring that the project has a good statistical basis (where relevant)
- all the potential harms (encompassing the animals' cumulative lifetime experience) have been identified and understood, and that these will be effectively avoided or recognised, assessed, and alleviated throughout the life of the project
- there is evidence that the 3Rs have been implemented as far as possible (e.g. where appropriate, evidence of literature searches including recent publications; requirement for pilot studies where high levels of suffering/large numbers of animals/new techniques are concerned) and that staff with relevant expertise have had the opportunity to contribute ideas in this respect
- local policies and procedures (e.g. on issues such as tail tipping, use of analgesics, injection volumes, score sheets) will be implemented
- the benefits and quality of science issues have been considered (e.g. with respect to the appropriateness of an animal model) and that the science is demonstrably robust
- ethical concerns have been identified and the harms and benefits have been thoughtfully weighed, with sufficient justification provided for animal use, both in general and for the particular species concerned
- there is a realistic appraisal of what can be achieved from the animal work, and within the timeframe
- the project licence applicant is appropriately qualified 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 facilities and equipment are available, and there are enough staff and expertise to carry out all work associated with the project

Developing an efficient , helpful, enabling process ...

The consideration of project licence applications needs to be done efficiently, taking into account the principles of [better regulation](#)¹⁰. To date, most of the concerns with the work of ERPs relate to how this function is carried out. Common problems are: the time taken to review licence applications can seem excessive, as can the amount of paperwork

Function 2 – Examining costs and benefits

required; and the review process may be set up in an overly formal, intimidating and judgemental way with poor communication between the ERP and project licence applicants as to what is required.

A particular problem is that some ERPs may insist on adding detail into the licence application that is not required by the Home Office. It is important to clarify with the local Inspector the level of information required and what can be dealt with by reference and adherence to local guidelines. Employing a HOLO to advise on such matters helps a great deal. Having a mechanism for the licensee to feed back to the ERP the Inspector's comments will also help identify any problems in this respect.

Implementing the **Ten Top Tips** on page 8 of this document should also help, as should attention to the **Summary of Do's and Don'ts** in the table below.

Summary Do's

- Decide what you want to achieve from the review and what the outputs should be
- Have a clear view of the information the ERP needs and why, and streamline any paperwork
- Consider developing good practice SOPs for common procedures so that there are defined local standards which apply to all projects
- Identify key questions and points for discussion
- Use efficient methods of communication
- Ensure project licence applicants know what (and who) the process involves and what is expected of them
- 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 applications and amendments and set clear criteria for decisions on which can follow this route
- Keep a record to track and time applications to help show why and where any delays occur and who bears the responsibility for these
- Ask for feedback from the Home Office Inspector on the quality of licence applications as well as on the operation and effectiveness of the ERP
- Regularly review how well the system is working, making sure both ERP members and licensees are consulted

Function 2 – Examining costs and benefits

Summary Don'ts

- Over complicate the process
- Create excessive paperwork or duplicate that 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
- Do a line by line consideration, looking at every word in the project
- Conduct the review solely by virtual committee
- Make the review process confrontational for the project licence applicant
- Allow ERP 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 are likely to be vastly different in scope, varying from very minor amendments to the addition of major new procedures with the potential to impact significantly on animal welfare. The approach of the ERP to consideration of these should be proportionate to the level of change requested.

Major changes should receive similar scrutiny to a new application since in some cases they may affect the overall harm-benefit analysis for the project. Examples include:

- extending the scope of research within the stated purpose of the project;
- an increase in the overall severity band of the licence or protocol severity limit;
- addition of new protocols;
- a significant increase in animal numbers;
- the use of an additional animal species or strain.

Where a minor amendment to a project licence is sought and, in the opinion of key experienced members of the ERP (including both the NACWO and NVS) no statistical input, peer review or lay person involvement is necessary, they may recommend to the Certificate Holder that the amendment be forwarded directly to the Home Office. Examples of minor amendments include refinement of an existing technique, addition of an alternative, less harmful, route or site of administration, or personnel changes. Alternatively, the Named persons may feel that wider scrutiny is required, but recommend a fast track procedure (see below).

Function 2 – Examining costs and benefits

Setting up fast track procedures

There is clear benefit to having fast track systems for some project licence applications and for amendments where there is little or no likely adverse animal welfare or harm-benefit implications, for example an amendment replacing a behavioural test with a new one of mild severity.

The ERP as a whole needs to develop criteria for deciding which applications or amendments can be fast tracked, set time-lines and agree these with the Certificate Holder. If the criteria are clear, then someone from the ERP (e.g. the HOLO) can be appointed to organise and administer the fast-tracking process.

Fast tracking can often be delegated to a small group of people, using 2 or 3 key reviewers (e.g. the NACWO, NVS) who may carry out the review by email rather than arranging a meeting. However, as in the case of amendments, it needs to be clear when involvement of a wider set of ERP members is required. If there is any disagreement or doubt with regard to a particular application or amendment, the ERP chair can make the final judgement on how to proceed. Regular feedback to the ERP on 'fast-tracks' should provide reassurance that contentious issues are not being missed.

The criteria (and principles) for fast-tracking need to be clearly stated in the ERP's terms of reference and made available to relevant staff so that they know what they need to do.

Dealing with additional availability

It is up to the individual establishment to decide how to deal with projects for which it has agreed to provide [secondary availability](#)^{1a} and for its own projects when additional availability is sought elsewhere. In the former case, the Certificate Holder has a responsibility to know what work is being done in his/her establishment so advice from the ERP is important in this respect. In both cases, the key consideration for the ERP is how important the establishment feels it is to ensure work with which it is associated (but over which it has no direct control) is done to its own standards.

When 'hosting' work from an external collaborator, the ERP may either carry out a review of the project licence application as if it were a new local project, or only review the parts of the project that will be carried out at the establishment. The timing of a request, which may come either before or after the project licence has been granted by the Home Office, may affect the decision as to how to proceed.

It is also essential that licensees know that, if they are carrying out work at an establishment where they have secondary availability, the host ERP as well as their own will need to consider the work. They can then make sure in good time that they have details of the procedures they need to go through at both establishments. The process therefore needs to be clearly described in the ERP 'information package' and included within in-house training so that licensees are forewarned.

Function 2 – Examining costs and benefits

When considering work which will take place outside the establishment, the ERP 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 at the secondary availability establishment, who can guide the application through its review process and feed back any comments quickly.

For establishments that have many secondary or multiple availabilities (for example arising from collaborative projects), it may be worth considering setting up joint ERP meetings to consider the licence applications concerned.

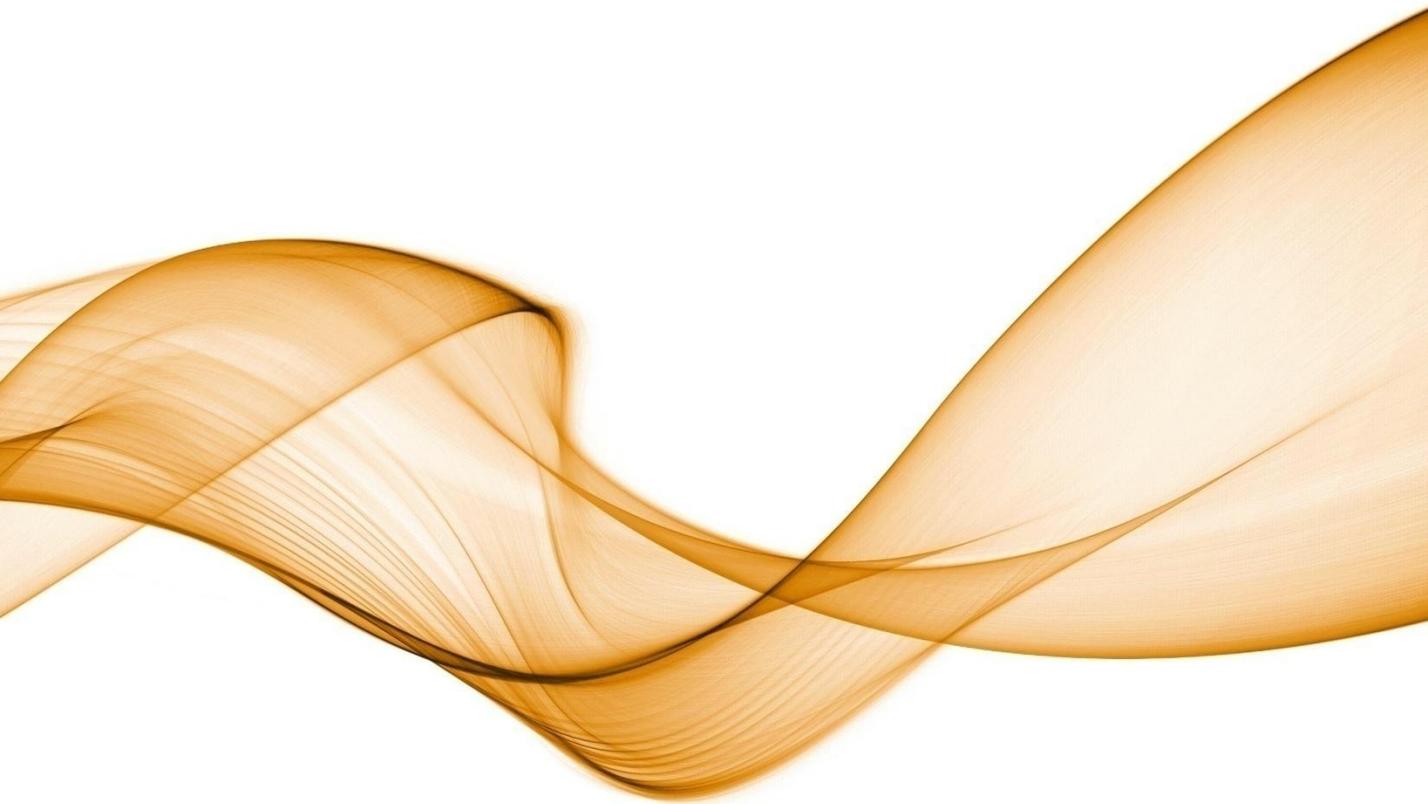
Consideration of the licence application, or parts of it, by the ERP at the secondary availability establishment is advantageous because it provides a mechanism for exchanging ideas and disseminating information on good practice. The down side is the time this can take and the potential for inconsistent decisions and unrealistic expectations, so it is important to ensure that the process is well managed.

Appendix ...

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

Funder/organisation	ERP	Home Office Inspectorate
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>Under function 1, uses local expertise to define local protocols for the most refined methods to be used throughout the establishment; e.g. the ERP could develop a SOP for preparation, sampling route, method and volume, and for animal monitoring.</p> <p>Under function 2, ensures an individual project licence <i>takes account of</i> local procedures for the most refined methods as above, but <i>does not insist on the detail</i> of the methods in the licence application unless required to do so by the Home Office.</p> <p>Includes consideration of potential adverse effects in the ERP's overall assessment of harms and benefits of the work.</p> <p>Under function 4, 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 schedule (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 limits (and assigns severity band to the project as a whole).</p> <p>Checks compliance with legal requirements.</p> <p>Weighs the potential harms and benefits on behalf of the Secretary of State.</p>

Forum for discussion



Function 3 – Forum for discussion

Providing a forum for discussion of issues relating to the use of animals and considering how staff can be kept up to date with relevant ethical advice, best practice, and relevant legislation.

Aims ...

The emphasis of this function is on the provision of a forum for discussion of topics relating to the use of animals (for examples see box overleaf). The ERP should aim to be alert to the wider ethical and legal issues arising in the use of animals, both within the establishment and beyond, and to encourage staff to be more aware of these and consider the implications for their own work. The wider engagement this encourages should benefit staff development and, with that, the establishment's culture of care. It should also help promote better understanding of the role and value of the ERP.

... and approaches

The nature of the 'forum for discussion' is not defined and this can take different forms depending on the nature of the establishment. An ERP committee *in itself* provides a forum for dialogue and discussion, albeit this is largely between people directly involved in the process and/or who attend any formal ERP meetings. It is also beneficial to extend the process beyond this and to encourage other staff to contribute topics they feel it would be helpful for the ERP to be aware of and discuss. The ERP administrator could email all staff prior to ERP meetings to see if they have anything they would like raised; or there could be a physical or online suggestions box. This could also provide for a confidential mechanism for raising any more serious issues of concern.

The ERP could, in addition, establish a *wider discussion forum* for issues of general and specific interest, and encourage all relevant staff to contribute. This would help disseminate information outside the ERP's immediate membership, and could also help engage people with topics that can be difficult and controversial. For example, the ERP could organise seminars or one-day events with outside speakers on animal welfare and ethics, bringing people in from specialist disciplines, or interest groups from within or outside the establishment, to introduce challenges to existing thinking and practices. 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.

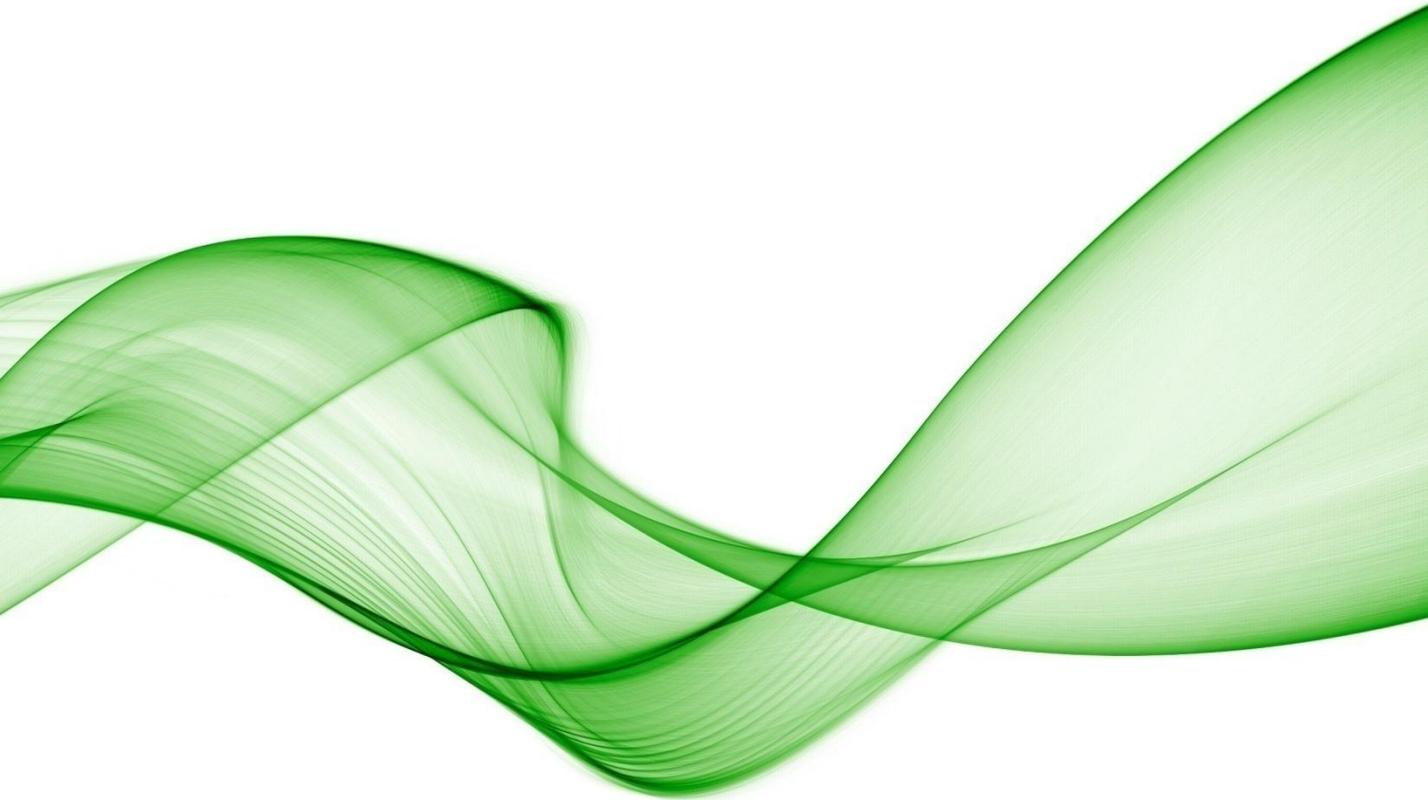
Function 3 – Forum for discussion

Bear in mind that there is interplay between function 3 and other aspects of the ERP's work, and the ERP needs to be alert to issues arising from these that would benefit from further deliberation. Examples include points of general concern or interest arising during review of specific projects (functions 2 and 4), or matters relevant to dissemination of information on the 3Rs (function 1), accommodation and care (function 5) or training (function 7).

Examples of the kind of topics that might be raised and discussed either within the ERP or more widely

- Whether there should be an establishment-wide policy on particular topics for example:
 - contracting work out and associated welfare audits
 - how to deal with additional availability
 - collaborations outside the UK (e.g. see: ['Responsibility in the use of animals in bioscience research: Expectations of the major research council and charitable funding bodies'](#)¹¹)
 - whether the establishment wants to engage in certain types of work, or use certain species
 - whether and how the establishment should interact with the public
- Changes in legislation, or in administration of the ASPA, for example:
 - the new European directive and what this means for the establishment
 - changes in project licence applications or other administrative procedures
 - compliance with the principles of efficient regulation
- What constitutes the “relevant ethical advice” that staff “can be kept up to date with” and where this could be obtained from
- Issues that impact on science as well as animal welfare such as:
 - choice of the most appropriate animal model and how this is assessed
 - opportunities for interdisciplinary collaborations (such as sharing of imaging facilities, incorporation of novel *in vitro* techniques)
 - health status of animals and the effect on research
 - effect of subclinical infections and pathogens on research
 - preferred methods of tissue sampling for genotyping transgenic rodents
 - import/export/transport and acclimatisation of animals
- News of local 3Rs initiatives
- Emotional well-being of staff who have to kill animals

Retrospective review



Function 4 – Retrospective review

Undertaking retrospective project reviews and continuing to apply the 3Rs to all projects, throughout their duration

What to aim for ...

When the Home Office reviewed the operation of the ERP in 2001 it explained the purpose of retrospective review as being to:

“.. look back on the animal welfare costs encountered and benefits realised. This permits assessment of the extent to which the original assumptions, including the severity limit of protocols, were correct when the request for authority was originally considered, and to consider if additional 3Rs strategies can be identified and incorporated. This information is of value to licensees and the ERP in planning future work and, as ERP records are available to the Inspectorate, it may also influence future Home Office assessments.”

Put simply , this means that ...

... the overall purpose of retrospective review is to reduce the harms and increase the benefits of a project, aiming to improve both animal welfare and the quality of science, and to help inform future debate on these issues.

LASA subsequently developed this overall purpose (see: [2004 report](#)¹² and [2005 poster](#)¹³) into a set of three activities shown in the boxes on pages 32 to 33. Not all of the points listed in the boxes will be relevant to all projects, but they provide an indicator of how retrospective review can be approached.

Most of what has been written about retrospective review focuses on the review of individual project licences. However, there is some overlap with other functions with regard to *“..continuing to apply the 3Rs throughout their[the project’s] duration”*. The list of 3Rs activities on page 15 and the issues described for function 5, accommodation and care, all contribute to a more general retrospective review.

Some common approaches...

The original Home Office process statement in 1998 provides ERPs with considerable flexibility in deciding when and how projects should be reviewed. The three most common approaches are: to carry out a retrospective review of projects on their completion - generally termed **end of term review**; to review the work being carried out under a project at intervals during the life of the licence, for example at one, two and four years in the course of a five year project – generally described as **interim review**; or, as a variation on the latter, to review the licence one year before it expires. Where research is considered on a study by study basis, interim review enables improvements to be rapidly

Function 4 – Retrospective review

incorporated. Flexibility is essential even within a single establishment, since it is unlikely that all licensed work will require, or fit, into the same 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 work out how to resolve them. It also provides the opportunity to report things that are going well and which may influence future directions and/or funding decisions. Issues to consider include:

- how the actual adverse effects and severity levels compare with those predicted and identify and address any problems
- whether the science is on-track and the results are as expected
- 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

(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
- whether, given current progress, the experimental design could be improved to answer the scientific questions more effectively
- whether, in the light of results to date, the numbers of animals are statistically appropriate (neither too few nor too many)
- whether procedures (e.g. restraint, administration, sampling, analgesic regimes, surgery) and/or humane endpoints could be further refined
- whether score sheets and monitoring procedures are working well, and whether monitoring procedures could be improved
- whether there are any adverse effects associated with supply and transport, or housing and care which could be reduced by changing current practice

Function 4 – Retrospective review

- how animals on long term studies are coping and whether they show any physical or behavioural problems
- whether special housing and care needs have arisen
- whether it is possible to refine methods of euthanasia
- whether there has been any wastage of animals and the reasons for this
- whether opportunities for release or rehoming of animals have arisen and are in their best interests

(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)
- whether 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)
- whether there are any human resource issues (e.g. staff shortages) that affect the project
- whether any training needs have been identified
- whether there is satisfactory communication within and/or between research team(s)
- whether animal care staff or the veterinarians have any concerns about the work
- whether their roles and opinions are being well supported by the establishment and there are no conflicts with the project licence holder
- whether the project licence holder feels the project is well supported
- whether there is any developing information on the 3Rs that could be disseminated within and/or between establishments
- whether there have been any difficulties in managing the licence including potential for infringements
- whether any commendations are possible for any of the project team

Developing an effective process ...

The general principles set out on pages 8 to 12 of this document, and many of the points in the section on function 2, also apply to retrospective review. The process needs to be positive and constructive with objectives clearly defined, so that staff 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. There can also be benefit in organising an awareness-raising event or local workshop to consider how retrospective reviews might best be performed within individual establishments and to enable staff to contribute to the development of the process.

Timing

It is helpful for the ERP to identify provisional dates for interim/retrospective review of each project licence and to advise the Certificate Holder of these when the application is submitted to him/her for signing. The timing may vary with each plan of work, 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. More complex projects, 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, may more appropriately be reviewed on a regular (annual) basis.

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 any particular concerns. For example, priority could be given to projects involving:

- models and/or species that are new to the laboratory;
- a particular species (e.g. dogs, cats, primates or equidae);
- procedures of substantial severity;
- procedures where there is a concern arising from their nature and/or novelty;
- large numbers of animals.

Function 4 – Retrospective review

Some establishments use the submission of a licence amendment as the trigger to carry out a review of a project. The benefits of this need 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 ERP.

Documentation

The most productive retrospective reviews focus on face to face discussion and outputs and how to take things forward, not the filling in of forms! In most cases they are best achieved by inviting project licence holders to present the key issues to the ERP in person.

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, so be clear about what is required as *input* into the retrospective review (i.e. what information is needed and when, who from and in what form) and what records will be maintained to record the *outcome*. It is important not to over-document either aspect and to keep the overall aim of the review in sight.

Providing feedback

Feedback on the outcomes of the review needs to be provided and explained to the research team, and if there are any concerns about the project or the process these need to be resolved (i.e. action must be taken) otherwise the review is a waste of time. It may also be that general problems are identified which apply to a number of projects, or are likely to apply to future work, in which case 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 more easily applied to them all straight away, rather than waiting for the formal review of each one.

Resource issues

The process may not need the input of the whole ERP committee and need not be overly formal. For example, retrospective review could be made an integral part of normal project management and team meetings, with feedback from these going to the main ERP. However, as a minimum, the process requires input from project and personal licensees, the NVS and the NACWO. Efficiency can be enhanced by combining retrospective review with other activities such as submission of amendments, feedback to the grant-awarding body, preparation of presentations, or papers for publication.

Function 4 – Retrospective review

The box below provides examples of beneficial outcomes 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
- study of receptor profiles in various species leading to replacement of poor models
- implementation of positive re-enforcement training programmes to reduce the need for restraint
- 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
- instigation of an annual prize for the best contribution to the 3Rs in the year – the initial winner introduced a less severe animal model; the runners-up had improved experimental design during the project to involve fewer animals and with improved quality of data
- 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

Care and accommodation



Function 5 - Care and accommodation

Considering the care and accommodation standards applied to all animals in the establishment, including breeding stock, and the humane killing of protected animals.

What to aim for ...

The ERP provides:

A central focus point where any matter relating to animal accommodation, care and humane killing can be discussed and for example:

- establishment policies/SOPs on such issues can be developed
- any problems can be resolved
- support for new initiatives can be provided
- feedback from staff and/or the Home Office Inspectorate can be received

Many of the other functions will link to, or overlap with, this one, in particular functions 1 and 3 (e.g. with respect to setting local standards of housing and care, discussing and developing policies on environmental enrichment, euthanasia, rehoming and release of animals) and function 7, training (e.g. with respect to animal handling and methods of euthanasia).

Some common approaches...

Approaches that have been shown to work well include:

- One or more sub-committee or group which deal with the kind of issues described below and report into the main ERP. For example, there could be one or more group focussing on environmental enrichment, housing for individual species (e.g. a dog or mouse group) or particular types of project.
- Reports to the main ERP from the NACWO and/or NVS on the type of accommodation and care issues described below, together with presentations on specific issues such as trends in the establishment's use of animals and CO₂ euthanasia.
- ERP members also need to visit animal units to develop their understanding of the facilities and procedures carried out.

In addition:

Licence review, both prospective and retrospective, may raise questions, which the ERP then asks specific individuals or groups to pursue.

Function 5 - Care and accommodation

The Home Office Inspector may suggest topics the ERP needs to address in relation to accommodation and care and humane killing.

Issues that ERPs report it useful to address

Standards of accommodation and care

The ERP has a leading role in setting the standard of accommodation and care that the individual establishment 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 Codes of Practice on accommodation and care set out minimum requirements for cage sizes and environmental enrichment, but the establishment may choose to use larger more enriched cages and opt for additional quality control systems.

Source and supply of animals and the sharing of tissues

The ERP can:

- develop policies (or ensure that such policies are in place and up to date) on the sourcing of animals, ensuring these are obtained from breeders with a good record of animal welfare, that transport stress is minimised, and enough time is allowed for animals to acclimatise to the new accommodation and care routines;
- 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;
- make sure there is a mechanism for auditing of stock, including animals in use by a third party, and of auditing conditions of accommodation and care where animals are sent elsewhere, for example, in the case of projects that have additional availability.

Re-homing, release and re-use

If animals are released or re-homed the ERP can ensure that the establishment has a mechanism in place to do this successfully, and that this fully takes into account the interests of the individual animals concerned as well as the legal requirements (see: [LASA 2004 report](#)¹⁴).

It can ensure that there is establishment-wide understanding of [Home Office policy on continued use and re-use](#)¹⁵ and of the difference between these, that the legal requirements of re-use and continued use are met and that the associated ethical and welfare issues are thoughtfully addressed.

Function 5 - Care and accommodation

Euthanasia

The ERP can ensure there is a system in place:

- for the review of site procedures for Schedule 1 euthanasia at appropriate intervals;
- for incorporation of new knowledge about techniques such as the use of CO₂;
- for assessing the justification for and refinement of non Schedule 1 methods; and
- to ensure that all staff are aware of these kinds of issue.

The ERP can also ensure that the Schedule 1 staff register is appropriate and that the emotional wellbeing of staff who have to kill animals is supported.

Problem solving

The ERP 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 ERP can then ensure these are communicated to all relevant parties including project licence holders, for example, through internal 'news alerts'.

Resources

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

Non-regulated animals/procedures

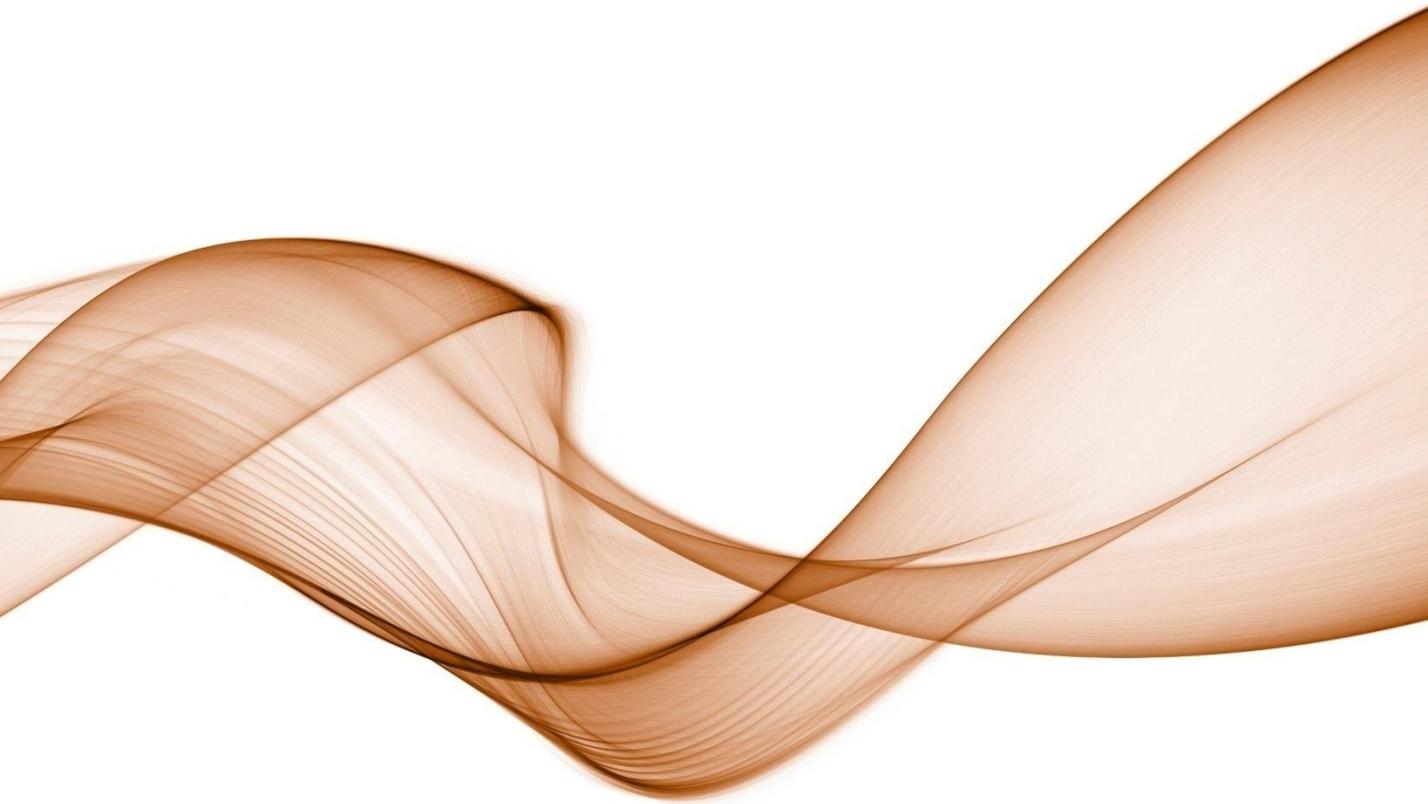
It is within the ERP's remit to ensure that non-regulated work is carried out to a standard consistent with that of regulated work, so it can choose to cover accommodation and care and euthanasia issues for all animals (e.g. invertebrates) and all procedures (e.g. use of animals solely for supply of tissues), not just those regulated under ASPA.

Function 5 - Care and accommodation

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

- Review of trends in figures for supply and demand to identify any problems
- Change in rabbit housing from cages to floor pens
- Review of exercise possibilities for dogs
- Review of 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
- Review of minimum 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 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](#)¹⁶

Managerial systems



Function 6 – Managerial systems

Regularly reviewing the establishment’s managerial systems, procedures and protocols where these bear on the proper use of animals

Interpreting the function...

In some ways, Function 6 can be seen as an overarching function for all other ERP activities taking account of the fact that the first of the three aims of the ERP is “*to provide independent advice to the Certificate Holder*” and that s/he has *overall responsibility to the Home Office for the work done under the ASPA* at the establishment.

The [Certificate Holder’s](#)^{1b} responsibilities are many and various. In the Home Office Guidance on the Operation of the ASPA, they are grouped under eight headings: the ERP; prevention of unauthorised procedures; animal care and accommodation; staffing; identification of animals; records; source; and disposal of animals. These issues are normally addressed through appropriate internal management systems and procedures that support animal welfare, quality science and regulatory compliance.

The Home Office view of the purpose of function 6 is that it invites the ERP to advise on how these systems and procedures operate in practice. The ERP can test the systems from time to time to check that they do what they are intended to do, and that there is no ‘drift’ stemming from changes in staff, research directions, reorganisations or resources for example. It also provides the ERP with an additional incentive to check that its own procedures are effective and not overly burdensome.

The regularity of the reviews required by the function’s title depends on the needs of the individual establishment and Certificate Holder, and on any other quality systems and inspections, so this can be determined locally.

Some issues to cover ...

Most of the issues above should already be dealt with if the other six ERP functions are addressed properly. For example, the Certificate Holder has overall responsibility for ensuring that staff are appropriately trained, supervised and competent. S/he is unlikely to be personally involved in delivering training, but will need to ensure that the establishment has appropriate training systems in place, for example, that personal licensees are adequately supervised until deemed competent. Such matters should be dealt with through the training function (function 7), but with function 6 taking more of an overview, perhaps considering how training and supervision systems are affected when staff change, or how they fit with other internal processes.

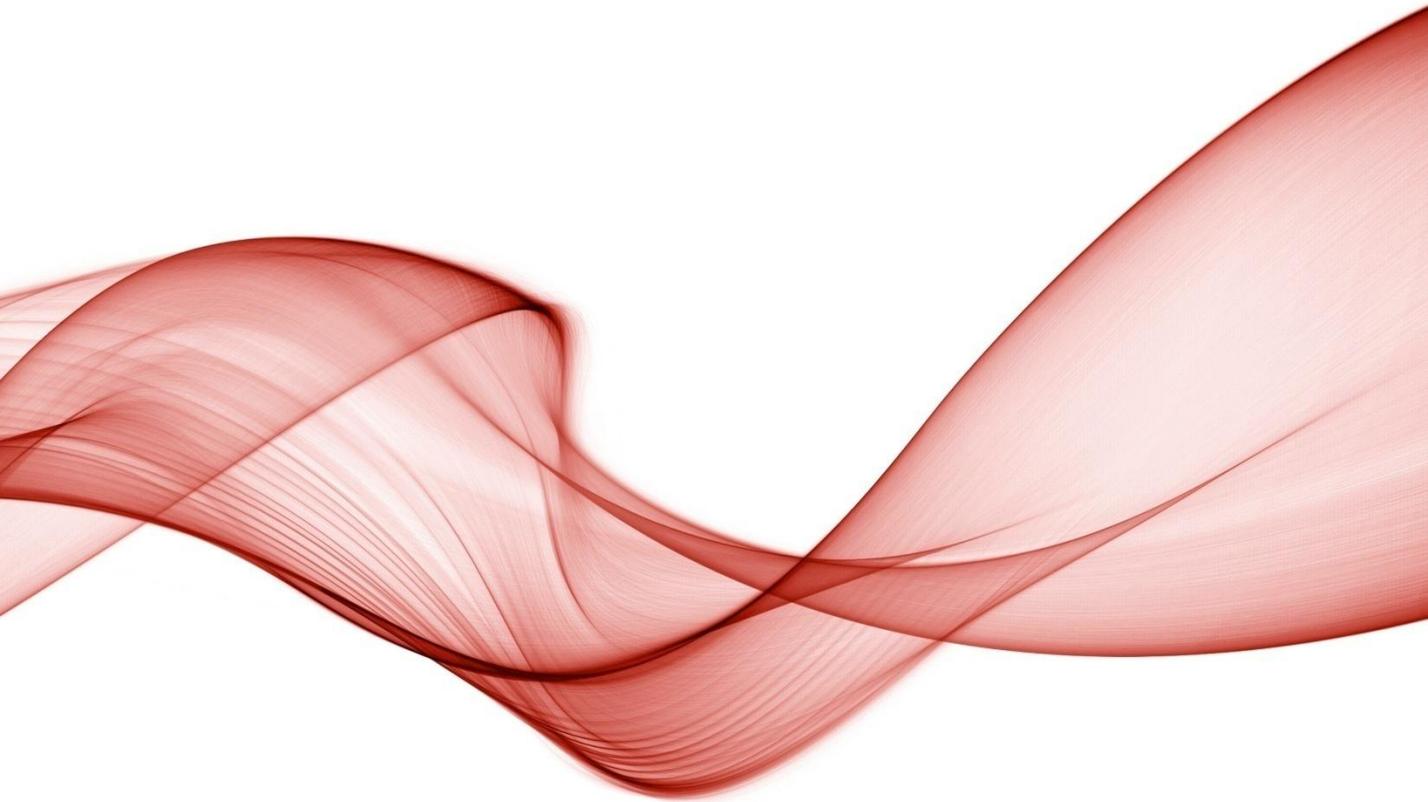
Function 6 – Managerial systems

There are additional areas of Certificate Holder responsibility that may not obviously be covered by other ERP functions and for which function 6 can ensure correct oversight. For example ensuring that:

- all the correct authorities are in place for the ordering and issuing of animals and that these are maintained when staff change;
- there are systems in place to prevent unauthorised use, continued use or re-use of animals;
- overall compliance with ASPA and all the associated Codes of Practice is maintained and that there is a system in place to prevent infringements;
- staffing levels are appropriate in relation to animal numbers, the time needed to perform husbandry procedures, and organisation of an adequate daily checking regime that ensures optimum animal welfare;
- any new facilities or refurbishments or repairs, or acquisition of newer cage types or designs to comply with new legislation are actioned;
- there is an internal mechanism for staff to express, in confidence, any concerns they may have about animal work within the establishment.

There may be additional matters on which the Certificate Holder would welcome the ERP's advice and/or where there should be an interface with senior management through the Certificate Holder. For example, when appointing new staff whose research involves using animals, an ERP interface can help to avoid downstream problems ensuring that there are facilities and support on site for any new work. Similarly, an interface with the establishment's financial planning helps ensure the feasibility and acceptability of research within the existing budget, and that the need for any capital outlay associated with new posts or areas of research is taken into account.

Training



Advising on how all staff involved with the animals can be appropriately trained and how competence can be ensured

What to aim for ...

Given the importance to both science and animal welfare of having sufficient appropriately trained and competent staff, the ERP needs to be confident that the establishment has a good system of education and training in place for all relevant staff - including ERP members.

Advice to the Certificate Holder on this issue should be a particularly useful contribution since ensuring appropriate education and training of staff in the establishment is ultimately his or her responsibility.

Key points for the ERP to consider are listed in the box on page 47.

Useful approaches ...

At most establishments, the ERP is unlikely to have a *direct* role in staff training, although it does have an *educational* role in explaining its own roles and responsibilities, and according to the original process statement, “a promotional role seeking to educate users (in applying the 3Rs) and non-users (by explaining why and how animals are used), as appropriate”. The way this function 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, then the ERP may only need to receive regular reports from these. Provided there is good communication between the ERP and staff responsible for training, then any issues relating to training, supervision and competence that arise from other ERP work can be directed to them for discussion and action if required.

In the absence of a dedicated training ‘body’, the ERP could set up a training group or, in smaller establishments designate an individual, with a remit to ensure training issues are addressed, reporting back to the main ERP as appropriate.

Other ERP functions also have a bearing on training/CPD, particularly function 1 (disseminating information – and understanding – of the 3Rs), function 3 (providing a forum for discussion) and function 5 (housing and care).

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 fulfilled and everyone knows their responsibilities in this respect (see: [LASA 2007](#)¹⁷)
- There is a robust system for assessing competence of all relevant staff
- The Certificate Holder has access to training relevant to his/her role (e.g. module 1, the [Certificate Holders' Forum](#) training days)
- There is a reliable system for recording staff training and competence
- Any specific training requirements for individual 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 the issues of project design and management that they will need to deal with should they become project licence holders
- Training includes the roles, functions, membership and operation of the ERP
- There are sufficient qualified and competent trainers and supervisors available
- Staff know who to go to with questions regarding any training issue



Glossary

APC – Animals Procedures Committee

ASPA – Animals (Scientific Procedures) Act 1986

CHF – Certificate Holders' Forum

CO₂ – Carbon Dioxide

CPD – Continued Professional Development

ERP – Ethical Review Process

GA – Genetically Altered [animal]

HO – Home Office

HOLO – Home Office Liaison Officer

LASA – Laboratory Animal Science Association

NACWO – Named Animal Care and Welfare Officer

NVS – Named Veterinary Surgeon

RSPCA – Royal Society for the Prevention of Cruelty to Animals

SOP – Standard Operating Procedure

3Rs – Reduction, Refinement and Replacement of animal use²

References

1. Home Office (2000). *Guidance on the operation of the Animals (Scientific Procedures) Act 1986*. HC 321. TSO: London. [Appendix J](#): The ethical review process, pp. 99-100; 1a: Primary and secondary availability p27; 1b: Certificate holder's responsibilities pp. 17-26
2. Russell, W.M.S. & Burch, R.L. (1959). *The principles of humane experimental technique*. UFAW: Potters Bar, UK.
3. Smith, J.A. and Jennings, M. (2009). [A resource book for lay members of Ethical Review Processes](#). 2nd edition. RSPCA: Horsham, UK.
4. House of Lords (2002). [Select Committee on Animals in Scientific Procedures, Volume 1 - Report](#). The House of Lords. TSO: London.
5. Home Office (2000). [The local ethical review process: supplementary note by the Chief Inspector](#). Home Office: London.

6. Home Office (2001). [*Animals \(Scientific Procedures\) Inspectorate review of the 'Ethical Review Process' in establishments designated under the Animals \(Scientific Procedures\) Act 1986.*](#) Home Office: London.
7. Home Office (2007). Surveying the ethical review process, pp. 17-24, in: [*Animals \(Scientific Procedures\) Inspectorate Report 2006.*](#) Home Office: London
8. Animal Procedures Committee (2008). [*Summary report of the APC working group on the Ethical Review Process.*](#) Home Office: London.
9. LASA (2010). [*Guiding principles for preparing for and undertaking aseptic surgery.*](#) A report by the LASA Education, Training and Ethics section. (M. Jennings and M. Berdoy eds.). LASA: Tamworth.
10. Home Office website page on: [*Better Regulation*](#)
11. BBSRC, DEFRA, MRC, NC3Rs, NERC & Wellcome Trust (2008). [*Responsibility in the use of animals in bioscience research: Expectations of the major research council and charitable funding bodies.*](#) NC3Rs, London.
12. LASA (2004). [*Guidance notes on retrospective review.*](#) A discussion document prepared by the LASA Ethics and Training Group (M. Jennings and B.Howard eds.) LASA: Tamworth.
13. LASA (2007). [*The value of looking back: improving science and welfare through retrospective review.*](#) Poster prepared for the LASA ethics and Training Group by M. Jennings (RSPCA), B. Howard (LASA) & M. Berdoy (Oxford University) . LASA: Tamworth.
14. LASA (2004). [*Guidance on the Rehoming of Laboratory Dogs.*](#) A report based on a LASA working party and LASA meeting on rehoming laboratory animals. (M. Jennings and B.Howard eds.) LASA: Tamworth.
15. Home Office (2008). Guidance on: [*Use, continued use and reuse.*](#) Home Office: London.
16. LASA (2009). [*Guiding Principles on Record Keeping for Personal Licence Holders.*](#) A report by the LASA Education, Training and Ethics section. (M. Jennings and M. Berdoy eds.) LASA: Tamworth.
17. LASA (2007). [*Guiding Principles on the Supervision Requirements for Personal Licensees.*](#) A report by the LASA Education, Training and Ethics section. (M. Jennings and M. Berdoy eds.) LASA: Tamworth.



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