

Notes from a **Lay Members' Forum - an inaugural meeting**

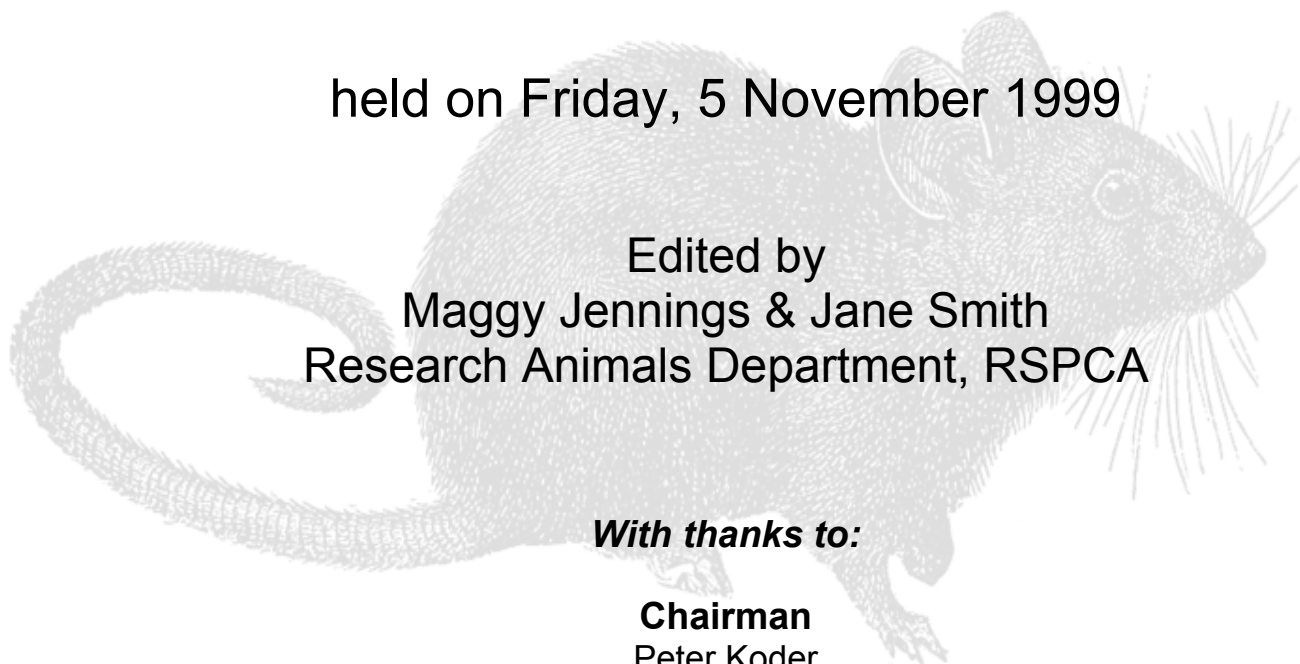
held on Friday, 5 November 1999

Edited by
Maggy Jennings & Jane Smith
Research Animals Department, RSPCA

With thanks to:

Chairman
Peter Koder

Speakers
Mary-Ann Elston, Robert Hubrecht, Beverley Marczycha,
Jon Richmond, Jim Wallace



CONTENTS

| | <i>Page</i> |
|--|-------------|
| 1. Lay members' early experience of the ERP | 1 |
| 2. Practical approach to ethical review of projects | 4 |
| 2.1 Assessing costs and benefits | 4 |
| 2.2 Obtaining information for review of licence applications | 7 |
| 3. Consideration of animal welfare and the 3Rs | 9 |
| 4. Visiting animal houses | 10 |
| 5. Other points | 12 |
| 5.1 Measuring the success of the ERP | 12 |
| 5.2 Further issues for discussion, both locally and at future Forums | 13 |
| Conclusions and list of proposals | 13 |
| References | 15 |
| Appendix I: List of speakers and titles of talks | 16 |
| Appendix II: Questions from discussion periods | 17 |

Notes from a

Lay Members' Forum – an inaugural meeting

Organised by the RSPCA in conjunction with Imperial College, London
on 5 November 1999

Guy Fawkes' day marked the date of an initial meeting to establish a forum for 'lay members' of ethical review processes (ERPs). The meeting was held in the resplendent Council Room, Queens Gate, Imperial College. We had underestimated the keenness of people to participate, and, with over 60 delegates, the room was rather crowded, but this was made up for by the enthusiasm of the discussion generated throughout the day! There was wide variation in the type of ERP represented, the approaches to the tasks required of them, and the backgrounds and experiences of lay members present. This enabled the meeting to gain a broad appreciation of the main issues.

The programme involved a mixture of group discussions and feedback on questions suggested by participants, interspersed with talks from lay members and others with particularly relevant expertise. This format seemed to work well, providing an opportunity to share experiences, gain information and generate useful ideas.

These notes provide a summary of the points that were discussed, and highlight plans for developing the kinds of resources proposed during the meeting. A programme together with a list of the questions raised and discussed by participants is included at the end of the report. Some of the issues were explored in detail at a Lay Members' Workshop held in 1998 (Jennings, 1999) and are not repeated here.

1. Lay members' early experience of the ERP

An introductory discussion period was devoted to consideration of early experiences of the ERP. Participants discussed:

- their own roles within the ERP;
- how fully involved in the process they felt;
- whether, in addition to review of licence applications, they played a part in wider functions of the ERP (see Box 1);
- the time and other resources they needed;
- any specific concerns.

BOX 1: Wider roles of the ERP

The success of local ERPs will not simply be assessed in terms of their effectiveness in project review, but also by how well they encourage establishments to address wider issues impacting on the use of animals. These broader 'criteria for success' or 'outcomes' include:

- widespread awareness and understanding of the role, purpose and function of the ERP within the establishment
- support for named persons and their roles within the establishment
- high standards of animal accommodation and care, including appropriate environmental enrichment
- provision of suitable initial and continuing training for staff, promoting competence in all aspects of use of animals
- promotion and implementation of the 3Rs throughout the establishment; availability and dissemination of information on these

Some of the issues raised were:

i) Roles of lay members

Some people felt very comfortable in their roles, others were less certain, and asked questions about the nature of the contribution lay members can make (see also 1998 Workshop report).

It was suggested that lay members are there at least to ensure the integrity of the process of review (a role rather like that of a non-executive director). In this context they should be able to satisfy themselves that the 'other' members have all played their proper part. In addition, they can bring a fresh eye to the issues - questioning custom and practice, challenging accepted norms, or playing Devil's advocate; and, from a naïve position, can ask more probing questions than scientists would necessarily ask each other.

To do all this, lay members require considerable confidence and should feel able to put items for discussion on the ERP agenda. Participants at the Forum said that they particularly value the support of an active, challenging Chair of the ERP and that this support can be enhanced when that Chair is also a lay person. It was suggested that, without such support within the ERP, lay people might be seen as simply 'sanitising', or 'validating', procedures on animals.

Later in the Forum, it was pointed out that in other regulatory systems there is no single definition of a lay person² and that everyone is a lay person outside their own particular area of expertise. Thus, there is no strict dichotomy between 'lay' and 'expert' within the ERP, and lay members need not feel apologetic about a lack of expertise - since, depending on the issue under discussion, other members of the ERP can also be considered to be 'lay people'.

ii) Lay members' involvement in the various functions of the ERP

Several people felt that their ERPs are focusing too much on project review, to the detriment of broader issues - although it was suggested that this might change as more experience of the ERP is gained. It was agreed that there is a need for documented evidence of positive outcomes from the ERP, such as examples of implementation of the 3Rs within the establishment (section 4 and 5.1).

Participants were keen to discuss possible approaches to cost-benefit analysis in the review of project licence applications, and there was uncertainty about how to approach on-going review of wider welfare issues within the establishment. Further discussion on these aspects is reported in sections 2 and 3 below. It was widely agreed that variation in the quality of the summaries provided with project licence applications is affecting lay members' involvement in the review process, and ideas for improving summaries are given in section 2.2.

iii) Resources to support the work of lay members

Lay members reported variable workloads - as might be expected, since establishments vary considerably in size and in number and rate of project licence applications. It was noted that large volumes of paperwork are generated in many ERPs and that it is important to manage paperwork effectively, so as to ensure that it does not dominate the process, at the expense of thinking or discussion time. The majority of people said that a lot of their time is taken up in trying to understand 'science speak' and that, again, clear, jargon-free summaries are needed (section 2.2).

The possibility of some form of training/induction process was raised, though there was considerable debate about whether it is appropriate to 'train' lay members. In particular, it was suggested that there is a need to ensure that the

process of training does not compromise lay members' independence. In spite of this reservation, it was widely agreed that specific resources would be useful - for example, a glossary of terms (one committee provides medical dictionaries for members), thoughts on approaches to cost-benefit analysis, and ideas on what to look for in animal house visits. Further proposals for resources to support the work of lay members are noted below.

Above all, participants emphasised the value of opportunities for informal discussion, both of applications and the wider issues addressed by the ERP. It is important that lay members feel able to approach scientists, named people and others with relevant expertise to ask questions, discuss issues and gain information to help them in their work. Lay members particularly value opportunities for dialogue with, and the support of, other lay people, and it was agreed that it is beneficial for ERPs to include more than one lay member. Opportunities for wider discussion, such as this Forum, were also considered very helpful.

2. Practical approach to ethical review of projects

2.1 Assessing costs and benefits

The review of project licence applications is one of the main tasks of the ERP and carrying out a 'cost-benefit' assessment process (involving 'weighing' the 'costs' to animals against the likely benefits of the work) is an integral part of this. Some aspects of this assessment are also addressed, at various stages in the development of a project, by a variety of other formal or informal review processes, which will approach the issues from different perspectives (Box 2). Most of these are likely to focus mainly on the quality of science and the potential or actual outcomes of the work.

It is important for each ERP to consider how it can add value to what is already being done. In general terms, ERPs can widen consultation on the ethical aspects, and should provide a broader perspective than any of the individual approaches listed in Box 2. In addition, ERPs examine projects especially with respect to *local* factors, and thus can directly influence practice within their particular establishments (Jennings *et al.*, 1998).

Box 2: Different aspects of review of scientific projects involving animals

- At an early stage, **senior management within the establishment itself** might consider whether the proposed work fits the establishment's aims, or its business portfolio, and this could involve consideration of ethical issues.
- At an early stage, too, the project might be reviewed by an **external funding body**, when it will be in competition with others for limited funds. This review tends to focus on the quality and strategic importance of the science. Ethical issues relating to the use of animals are not usually considered in the detail that is subsequently required in project licence applications.
- As part of a formal application for a licence, the potential **project licensee**, usually together with others involved in the work and those with statutory responsibilities under the Act, should make his or her own assessment of the ethical issues relating to the use of animals.
- The project will then be reviewed within the establishment by the **local ethical review process**, which will advise the establishment's **Certificate Holder** whether or not to support the application. The Certificate Holder bears ultimate responsibility for all work involving animals carried out within the establishment, and will take into account the ERP's advice when deciding whether or not to sign the application and forward it to the Home Office (HO).
- The **Home Office** reviews the application within the legislative framework, which sets out both the permissible purposes for which animals can be used and the legal and administrative prohibitions. (Note: The Animals (Scientific Procedures) Act 1986 does not specify how the cost-benefit assessment should be done and HO practice in this respect is not static but evolving. There is an explanation of current practice in the APC Report for 1997 (Home Office, 1998).
- If the results of the project are eventually published there may be retrospective ethical review and comment by **editorial boards, scientific peers and other interested parties**.

Assessing and weighing costs and benefits

Most participants at the Forum seemed to find that the costs to animals could be described fairly objectively in a way that could be understood. The expected benefit and likelihood of success of a project can also be described but can be more difficult for a non-specialist to 'visualise' and understand. It is hard for anyone outside of the particular scientific field to assess the significance of the research, yet this is a necessary step in weighing costs and benefits. In practice, assessing the overall costs

of a project can also be difficult, for example when ‘worst case’ scenarios are sometimes given in initial applications to avoid having to make subsequent time-consuming amendments. For example, the estimated number of animals to be used may be given as 1,000, when only 500 will actually be used.

Pain, suffering and distress during, and as a result of, procedures is clearly important but so is the denial of pleasurable things.

In assessing costs, relevant factors to take into account in addition to the procedures and their effects include:

- the species and the stage of development of the animals
- the number of animals to be used
- the animals’ husbandry and care
- strategies for monitoring the animals and reducing the impact of the procedures on them
- facilities and training of personnel involved in the project
- other related matters such as the animals’ source, any transport and their fate

Similar lists of ‘points to consider’ have been drawn up for assessment of benefits, but these were not discussed in detail during the meeting. There are a variety of published schemes for assessment of both costs and benefits, and these might prove useful for members of ERPs, as lists of aspects to consider, and as starting points for further thinking about cost-benefit assessment.

The most difficult question, however, is how to weight two disparate things such as ‘harms’ to animals and ‘benefits’ of the projects in a meaningful way, particularly when the benefit is never to the individual animal suffering the harm and are most frequently benefits to humans and/or science. Many lay members have begun to develop their own criteria for making judgements, such as the weight to give to different types of harm and how they would define a justifiable benefit, but it was agreed there are no easy answers on how any of this can be done. A number of questions were offered as starting points for discussion. For example:

- Supposing the proposed research is of high quality and the benefit is a cure for a life-threatening disease, what degree of suffering would not be acceptable?

- What degree of suffering would not be acceptable if the proposed research is of high quality but the benefits are to advance knowledge without any specific application to health problems?

These kinds of thought-provoking questions could be expanded in future publications for the Forum.

Proposal:

It was agreed that carrying out a cost-benefit analysis on a research project was probably the most difficult task the lay member has to address and that guidance on this would be very helpful. This should include notes on the factors to consider when assessing both harms and benefits, and discussion points to help develop thinking about how in practice one can be weighed against the other.

2.2 Obtaining information for review of licence applications

Clearly the first stage in carrying out the ethical review of licence applications is to obtain all the necessary information. Participants at the Forum discussed both what sort of information was necessary and how could it be obtained. Sources of information include:

- written material, i.e. the application itself, and/or a lay summary;
- presentation by and discussion with the applicant;
- consultation with (particularly) relevant staff, such as the Named Animal care and Welfare office (NACWO) and the named Veterinary Surgeon (NVS).

In some ERPs the applicant attends the review meeting, in others all applications are anonymised. The former promotes open discussion and was therefore considered the preferred option by most of those present.

However information is obtained, it is important for all members of the ERP to understand what is presented. If anyone is unclear, it is important for them to go back to the applicant and explain what they do not understand, and why, so that the situation can be resolved quickly. Open and informed dialogue is crucial to the process - though putting such requests for clarification into the right language can be difficult.

Written information

It was agreed that a summary of the project is an essential aid to understanding. There was much discussion on how to describe the level at which this should be written. This was difficult to define, since the term 'lay' is not very informative. However, the main points for consideration are listed in Box 3.

BOX 3: Guidance for writing 'lay' summaries

Participants at the Forum asked that lay summaries include brief but clear descriptions in simple language avoiding acronyms and jargon, of:

- the objectives and reasons for doing the work
- reasons why alternatives could not be used
- the species to be used and reasons for that choice
- the source (where appropriate) of animals
- the number of animals to be used
- what will be done to the animals (the techniques and procedures)
- the likely suffering during and as a result of procedures
- the final fate of the animals

Standardisation of style, format and vocabulary would help to speed up familiarisation with applications.

It would also be helpful to include information on how the project will be funded, together with the applicant's own statement on the cost-benefit analysis, the consideration they had given to alternatives, and how the research related to previous work carried out at the establishment or elsewhere. Amendments should be approached in the same way, with a brief explanation of what they mean and how they relate to the original project.

It was recognised that most of the information described in Box 3 is likely to be in the project licence application (or amendment), but the problem is that it may not be in a form easily accessible for people not familiar with the area of research. A short summary is therefore definitely necessary and it was agreed that this could have a variety of uses, in addition to informing the ERP. For example, a lay summary will soon be required as a part of the Home Office project licence application form which is being revised, and lay descriptions could help establishments answer enquiries from the public or media about research carried out there.

Proposal:

It was agreed that it would be useful for individual establishments to produce guidelines on the sort of material needed by the ERP, including specific guidance on writing summaries. Comparison with existing guidelines from different establishments would also be helpful, and

examples would be collated for the Forum. An annual (internal) meeting to provide feedback to all staff on how the ethical review process is developing would also facilitate communication between all concerned.

It was emphasised that the project licence application should never be viewed in isolation and that ERP members need to be familiar with the overall structure and culture of the establishment, so that they can appreciate how animals are housed and cared for before, during and after procedures, how the 3Rs are continuously applied, and how the results of projects are subsequently progressed. These matters, together with other factors relevant to the application such as staff training and euthanasia, should in any case form part of the overall remit of the ERP.

3. Consideration of animal welfare and the 3Rs

One of the main aims of the ERP is to ensure that “*proper account is taken of all possibilities for reduction, refinement and replacement*” (the 3Rs). This applies to the work of the establishment as a whole, not just to individual project applications when these are reviewed. ERP members will want to understand how the 3Rs are addressed in their establishment.

It was suggested that, when reviewing individual project licence applications, it is important to first identify the welfare issues and think through what they might mean to the animal, considering each ‘R’ both individually and collectively, and recognising potential conflicts between them. Conflicts can arise, for example, between refinement and reduction strategies: e.g. given equivalent scientific results, would it be ‘better’ to use fewer animals in a severe procedure or more animals in a milder one?, would it ‘more acceptable’ to use, say, 10 horses or 100 mice in a particular project? Project licence applicants must now actively find out about the 3Rs, so they need to show awareness of current developments with respect to implementation of the 3Rs in their field.

Lay members are not expected to be experts on these matters (others should be there to provide expert input) but can use their own expertise in shaping the questions. It was agreed that members should ask about anything that concerns them, for example:

- how is similar work done elsewhere?
- how have you refined the standard protocol?

- how might you refine the protocol in future?
- how do you keep informed on the 3Rs in your field?

The answers to such questions can, in part, be gained from discussions in committee, but lay members felt that there is also much to be gained by visiting animal houses and talking to staff working with the animals. (One establishment even uses in-house video footage to demonstrate what was done to animals and how procedures or husbandry can be refined).

It was emphasised that no question is too simplistic, but that it is always helpful to explain why the answer is wanted or needed.

Proposal:

It was agreed that a list of questions to consider asking and ideas of where to find ‘user friendly’ information on the 3Rs would be desirable resources for the Forum.

4. Visiting animal houses

All participants in the ERP need to be familiar with all of the animal houses at their establishment. It is impossible for the ERP as a whole to carry out its duties or for individuals to comment knowledgeably if this is not the case. There is no substitute for actually seeing what goes on. Visiting animal units can seem a daunting task for those not involved directly in animal use and it was agreed that it would be useful to have some guidance on what to expect and what to look for. There were several helpful talks on this subject during the day. A few key points are mentioned here but the ideas will be summarised more fully in a separate document.

General points

Aim to be able to talk informally to the staff who work with the animals, rather than making a formal conducted tour. Try to get a feel for the culture of the place. Everyone should care - obviously about the animals but also about the staff and the science that is done.

More specific points

There are many issues to think about and not all can be addressed on a single visit.

Ideas include:

- i) general organisational issues, e.g.:
 - how is the animal unit organised and how does it relate to the rest of the establishment?
 - is there good communication between animal house staff, scientists and named persons?
 - how are staff trained and competence assessed?
 - how is compliance with national and local codes of practice ensured?
 - are innovative welfare ideas encouraged and, if so, how?
- ii) husbandry and care of the animals, e.g.:
 - are social animals housed in social groups?
 - do all animals have generous bedding?
 - do cages have solid or grid floors?
 - is environmental enrichment provided and, if there are constraints on this, have staff considered how they could be overcome?
 - are metabolism cages used and for how long?
 - how are standards assessed and against what benchmarks?
- iii) carrying out procedures and monitoring effects
 - who carries out procedures, how competent are they and do they have obvious empathy with the animals?
 - how is refinement of procedures addressed, where does information come from?
 - are scoring systems used to assess suffering and provide trigger points to take action?
 - is appropriate analgesia provided?

It was recognised that it is difficult to judge some of these matters if the lay member has only ever visited one animal house within one establishment, so it is important to have a means of communication between lay members whereby experiences can be shared.

Proposal:

It was agreed that more detailed guidance on what to look for in the animal house, including relevant questions and discussion points, would be provided for the Forum.

5. Other points

5.1 Measuring the success of the ERP

The ERP needs to be effective in achieving the aims set out by the Home Office and the expectations of those who have promoted the concept and supported its introduction (see also Box 1). It is important not to add to bureaucracy merely for the sake of it, with no welfare benefits.

Measuring the success of ERPs could be difficult, but participants in the process, including those whose projects are reviewed, do need to get feedback and be able to contribute comments on how the process is working in practice. Early identification of problems and a willingness to resolve them will help to ensure that the benefits are maximised and the costs (widely interpreted) overcome! There was only time for limited discussion of this aspect at the Forum, but participants felt that some indicators of success could be that:

- people start to come to the ERP and recognise it has value;
- the ERP feels able to publish its minutes and declare its existence to the public at large;
- there is a reduction in the number of times the ERP asks the same questions of applicants, showing that members of the establishment are learning what is expected;
- the Certificate Holder is more informed about the work of the ERP and the establishment, and the dissemination of information in-house is generally improved;
- there is a noticeable change in the establishment's culture, with more concern for animal welfare.

The need for periodic review of the process and its operation was acknowledged.

5.2 Further issues for discussion, both locally and at future Forums

- i) Humane killing; surplus animals - how are production and demand matched?; re-use, rehoming and release of animals from the Act.
- ii) How the HO Inspectors relate to the committee – do they attend meetings; and how do they give and receive feedback?
- iii) How can the ERP be seen to have authority within the establishment?
- iv) Training for lay members, e.g. confidence building, ensuring sufficient knowledge of procedures.

Conclusions and list of proposals

It was broadly agreed that the main advantage of this initial meeting was in providing lay members with an opportunity to get together to share their experiences. Good communication and opportunities for discussion of issues between lay members were highlighted many times as helping lay members fulfil their roles within the ERP.

There were several proposals for practical actions, production of resources and ideas for future discussions. We will be taking these forward in coming months.

It was agreed that:

- i) Carrying out a cost-benefit analysis on a research project is probably the most difficult task the lay member has to address and that guidance on this would be very helpful. This should include notes on the factors to consider when assessing both harms and benefits, and discussion points to help develop thinking about how in practice one can be weighed against the other.
- ii) It would be useful for individual establishments to produce guidelines on the sort of material needed by the ERP, including specific guidance in writing summaries. Comparison with existing guidelines from different establishments would also be helpful, and examples would be collated for the Forum. An annual (internal) meeting to provide feedback to all staff on how the process is developing would also facilitate communication between all concerned.

- iii) A list of questions to consider asking and ideas of where to find ‘user friendly’ information on the 3Rs would be a desirable resource.
- iv) More detailed guidance on what to look for in the animal house, including relevant questions and discussion points, would also be provided for the Forum.

We will be attempting to produce the kind of resources proposed over the next year.

Maggy Jennings
Head of Research Animals Department

Jane Smith
Consultant to the Research Animals Department

References

Home Office (1998). *Report of the Animal Procedures Committee for 1997*. The Stationery Office: London.

Jennings,M. (1999). *Lay members and the ethical review process*. RSPCA: Horsham.

Jennings,M., Moore,G. & Howard,B. (1998). *The Ethical Review Process in Academia. A Laboratory animal Science Association roundtable discussion to assist in setting up an effective system*. LASA: Tamworth.

Appendix I

List of speakers and titles of talks

Chair

Mr Peter Koder (Imperial College)

Experiences of ethical review in practice

Dr Robert Hubrecht (UFAW)

Dr Jon Richmond (Home Office)

Dr Mary-Ann Elston (Royal Holloway and Bedford College)

Mrs Beverley Marczycha (University of Leeds)

Dr Jane Smith (RSPCA Consultant)

Home Office advice on dealing with the 3Rs

Dr Jon Richmond (Home Office)

An animal welfare organisation's perspective

Dr Maggy Jennings (RSPCA)

Dr Robert Hubrecht (UFAW)

What to look for in an animal house

Mr Jim Wallace (Institute of Cancer Research)

Appendix II

Questions from discussion periods

Discussion period 1 – Early experiences of the ERP

- Are you aware of the broad remit of the ERP?
- In practice, what do you consider are your roles within your ERP?
- How involved do you feel in the ERP, and how effectively do you feel you have been able to contribute? Do you feel listened to?
- What time and other resources is the process demanding of you?
- How far do you feel able to keep abreast of the broad picture of work within your establishment?
- Do you have any concerns about the ERP (bearing in mind that the responsibilities of the ‘process’ are for wider, than just the review of the project) or the work being agreed?

Discussion period 2 – Information for ethical review of project licence applications

- What kinds of information do you need in order to understand and review project licence applications? What means do you use to obtain the information?
- Does your ERP require a ‘lay summary’? If so, what form does it take and what information does it include?
- What do you think makes a good ‘lay summary’, and what advice would you give researchers preparing one?
- What ‘access’ to applicants should lay members reasonably expect?
- How much time and effort does it take to understand licence applications, and how might your understanding be helped?

April 2000