

The **APC**
Animal Procedures Committee

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Meg Hillier MP
Parliamentary Under Secretary of State
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From the Chairman
Ms Sara Nathan

Date 26 February 2008

Dear Meg,

RESPONSE TO ADVICE ON THE OPERATION OF THE ANIMALS (SCIENTIFIC PROCEDURES) ACT 1986 – Ethical Review Processes.

In December 2006 the former Parliamentary Under Secretary of State wrote to the Animal Procedures Committee asking for its advice in relation to better regulation, specifically to consider the currently prescribed framework.

The Committee were mindful of the need not to increase the regulatory burden of those involved in work under the Animals (Scientific Procedures) Act 1986 and present the enclosed report offering basic guidelines and suggestions for best practice.

Essentially, the Committee wish to encourage establishments to promote the rationale behind their ethical review processes, and to arrange flexible, transparent, and efficient systems for the operation of local ethical review.

I would like to thank the ERP Working Group members, chaired by Dr Peter Hunt for preparing and the representatives of the Home Office Inspectorate for their advice in writing this report. The Group also received valuable input by way of a voluntary questionnaire from fifty certificate holders and their representatives.

Yours sincerely

Sara Nathan

Title: Summary report of the APC
Working Group on the Ethical Review
Process.

APC Working Group on the Ethical Review Process

Summary report

1. Background to the Commissioning of this paper

The working group was asked to suggest advice that the Animal Procedures Committee (APC) could give to the Minister regarding local ethical review practices and the burdens of providing a local Ethical Review Process (ERP) on designated establishments. Specifically, the group was asked to:

- i. Consider whether there is evidence that some local ERPs may be imposing local requirements that run counter to efficient and effective regulation;
- ii. Propose advice of good ERP practices.

The questions posed at 1 above ideally needs to be answered by empiric study, which was clearly outside the remit and resources of this group. However, the group was able to draw on the group's own knowledge of ERPs in commercial, other non-academic, and academic establishments; a number of studies including studies from abroad already in the public domain, the Animal (Scientific Procedures) Inspectorate Review of ERP (2001) and opinion polling of attendees at the October 2007 Certificate Holders Forum of which the Committee received 50 responses and thank all those for their contribution.

2. Requirements for ERPs

There are 213 (as of December 2006) establishments designated under the Animals (Scientific Procedures) Act 1986 (ASPA) comprising academic organisations such as universities and research institutes, non-academic organisations such as hospitals and government bodies, and commercial organisations such as pharmaceutical companies and contract houses; these groups representing very different operational structures and methods with respect to their use of animals.

The ASPA requirements for designated establishments to operate a local ethical review process is set out clearly in Appendix J of the Guidance to the Act and can be summarised to three key functions¹.

i. To consider applications for project licences, amendments to existing project licences, and additional availabilities, with reference to the justification for the use of animals, and the balance between the likely welfare cost to the animals and the expected scientific benefit: and to promote the development and uptake of the 3Rs.

ii. To provide opportunities for discussion, and to provide a source of support, advice and awareness on these issues. This includes: ensuring that staff are kept up to date: best standards of care and accommodation are sought and

¹ Review of the 'Ethical Review Process' in Establishments Designated under the Animals (Scientific Procedures) Act 1986, Published November 2001.

implemented; managerial systems are appropriate; staff (including personal and project licence holders) are trained and competent; and general aspects of 3Rs are considered with respect to all aspects of animal production, care and use.

iii. Retrospective review of ongoing projects in order to promote the development and uptake of the 3Rs.

3. Overall context for Ethical Review

The Working Group used their knowledge of these three functions and the information from the Certificate Holders' poll in relation to the Better Regulation challenge to identify the following five areas that establishments should consider when planning and implementing the Local Ethical Review Process.

3.1 ERP Ownership

The Ethical Review Process has been established as part of ASPA for almost 10 years. The principle of Ethical Review is generally accepted by those subject to it as a reasonable and potentially helpful aspect of policy, providing useful and structured institutional review of licence applications pending Home Office submission, and informed and considered advice to Certificate Holders on a range of issues relevant to the management of animal use in their establishments.

Whilst there is no Home Office requirement for local ERPs to include any sort of committee, it is understood that all current ERPs do include a committee in some form. The role of these committees varies; many are involved in protocol review, whilst some focus on oversight of the whole process. This diversity should be taken as reminders that Home Office regulation of local ERPs is concerned with output. How the output is reached and what standards are met lies primarily with the 'parent' establishment.

It is the establishment's own responsibility to decide how their ERP should be implemented. Moreover, while the Home Office is obliged to advise if a proposed local ERP does not appear to meet the regulatory controls there is no requirement on establishments to seek advice from the Home Office on local ERP implementation.

3.2 'Localisation'

It is important to reiterate that The Animals (Scientific Procedures) Act 1986 is not prescriptive on how such ERP functions are completed, instead it allows establishments sufficient scope to construct their ERPs so as to accommodate and reflect local needs such as the existing structure of the establishment.

Establishments can differ quite radically in structure and needs, even within the various business sectors. The Working Group therefore recommends that Institutions should clearly define the outputs that they require from their ERP rather than merely identifying ERP structures and methods of working.

It is inevitable that there is variation in quality of the local ERPs that have been established. Nonetheless, it is the Working Group's experience that well designed local ERPs can be conducted in such a manner that licensees and stakeholders view it not as an extra burden to be tolerated but as a valuable resource of considerable local expertise available at the establishment. This can provide a significant

contribution to enhancing the scientific value of the study by ensuring that it is well constructed and that welfare costs are minimised.

3.3 How can local ERP be improved?

There is no requirement that local ERPs should use a committee structure. Over-large committees may become cumbersome, but one advantage of a committee is that they often have reporting lines, which can be used to mobilise resources and high level action in establishments. The use of pre-existing committees has been suggested as a route to avoid duplication and added workload.

New licence applications (Protocol Review) are just one output expected from an ERP and should not be an excessive part of its workload in relation to the other outputs (as highlighted in Appendix J of the Guidance to the Act). Local ERPs provides an opportunity for establishments to ensure that planned research does not fall outside the establishments own comfort area. Review of applications should add value to the establishment's ethical assessment and not manage, refine, or duplicate what the Home Office Inspectorate will subsequently do except in specific cases when the establishment justifies this to applicants. Assessments should be risk-based in their context, scope and speed, and take into account other existing review and assessments, such as independent peer or grant review.

Establishments should consider how to carry out the process both fully and expeditiously. Subgroups, parallel review, the use of locally available information technology, and delegated authority from the Certificate Holder, can be a significant help in avoiding unnecessary delay. Such possibilities are dealt with further in Section 4.3 of this document.

3.4 Transparency

It is important that applicants are aware of their local ERP's structure and operation. If they are not, then it is very unlikely that they will feel that the ERP is a positive process. Institutions should ensure that the ERP's overall assessment criteria, basis of risk assessment, submission processes, expected timelines and outputs are available to applicants within the establishment. In the interests of transparency establishments should consider publicising the rationale and outputs of its local ERP at least internally and, ideally, externally as part of the establishment's statement of its position on the use of animals.

Regular monitoring of the various ERP activities, outputs and resources should be conducted and, if necessary, local policy should be reviewed and refined in response to local circumstances and changing needs.

3.5 Home Office involvement during local ERP consideration of licence applications.

The informal input from the HOI at an early stage of licence applications is generally welcomed by all parties and may allow applications to progress more efficiently through the establishment's ERP as well as their licence approval process. On the other hand, establishments should be careful to avoid any misguided relaxation of ERP's attention on the assumption that the application already meets the HOI's standards for submission. Moreover, ERPs should be aware that waiting for an inspector's response might result in unnecessary delays.

From the applicant's point of view the time taken to turn around an application

depends on the time taken by the local ERP and the Home Office. Many licence applications take up to two months to go through local ERP, and some take considerably longer. The Working Group considers that shorter review times would seem to be an obtainable objective. Amendments to existing licences must also go through local ERP and are usually in response to a change in circumstances, new knowledge, or availability of new research tools. They are therefore often much more urgent than licence applications, the need for which is often known well in advance. It is very important that local ERPs should be constructed so as to minimise delays for licence amendments since this can be very damaging to research projects.

Whilst local ERPs should not try to anticipate the HOI's assessment of applications, some duplication of consideration is inevitable. It is important that local ERPs recognise that their own local perspective on proposals adds value which is distinct from that of the HOI.

4. Specific suggestions from the Working Group

4.1. Systems for running Local ERPs

1. There is no requirement for local ERPs to use any specified method or template in their operation. Whilst discussion between establishments is encouraged and can help stimulate new ideas in ERP, any move towards a national or group standard ERP would be unhelpful and likely to detract from the valuable flexibility of local approach allowed in ERP.
2. Establishments should be encouraged to explore the possibilities of adapting existing systems, such as existing committees, as an alternative to creating an additional and specific ERP committee. However, lay members should normally be represented in review or oversight of review.
3. The ERP's overall assessment criteria, basis of risk assessment, submission processes, expected timelines and outputs should be available to applicants within the establishment, and consideration given to publishing externally the overall desired outputs.
4. Committees may review proposals, or may oversee other systems. Many establishments have utilised or adapted IT systems to expedite the review process rather than wait for scheduled meetings or rely on slower, less flexible postal systems outside committee.
5. The current Home Office guidance in Appendix J of the Guidance on the Operation of the Act advises that ERP should involve "as many people as possible". This is a potential encouragement to unwieldy systems and the guidance should rather encourage a variety of participants from a range of perspectives, possibly drawing upon existing local sources of expertise and knowledge, such as a human ethics committee.
6. The use of appropriate deputies can help to avoid delays, but it is important that deputies are appointed reserve members of ERP and are fully briefed on their role and responsibilities.
7. Scheduled committee meetings with a low licensing workload held throughout the year can help to encourage productive consideration of other important ERP matters, such as promotion of the 3Rs and retrospective reviewing.

4.2. Relationship to Home Office's licence assessment

1. ERPs assessment of Project Licence applications or proposed amendments should be independent of the Inspectorate's assessment.
2. Receiving the HOI's early comments on licence drafts prior to ERP can be very helpful, and applicants are normally encouraged to discuss proposals with the HOI at an early stage.
3. The informed scrutiny of applications by experienced reviewers in ERP will inevitably improve applications at an early stage, and should assist the HOI to reduce subsequent delays.

4.3. Benchmarks for time taken in ERP licence processing

1. It would be unrealistic to suggest hard-and-fast expectations of ERPs in dealing with licence assessments, since applications and establishment circumstances are so widely varied and we encourage diversity of processes, local ownership, transparency perhaps through the publication of written documentation, terms of reference and details of local expertise.
2. Significant reductions in review times can be achieved in licence applications to continue work and/or with mild, moderate or unclassified severity limits. By using review systems outside formal committees and employing electronic communication, ERP output turn-around could be dramatically enhanced.
3. Applications for amendments to licences can be vastly different in scope. A fast-track system of review for the majority of project licence applications, amendments and retrospective reviews can be carried out by a sub-group of ERP. This is important and should be implemented wherever possible to reduce processing times. Such fast-track panels should represent key ERP perspectives, such as the NVS, NACWO, an experienced project licence holder, lay person and statistician.

In situations where there are no likely animal welfare implications in an amendment application (for example substituting a deputy licence holder), an "ultra-fast track" system could even be used, using perhaps only two or three key reviewers;

Fast-track systems should have clearly stated criteria for the eligibility of applications for fast-tracking, agreed by ERP and the Certificate Holder, who takes advice from this sub-group. Full ERP scrutiny may be reserved for potentially contentious applications, such as certain species, substantial severity, or novel procedures;

Fast-track systems should make best use of available technology to expedite reviews. Arranging meetings for such groups is often the cause of frustrating delays, but electronic reviewing can speed up the process significantly, especially if reviews are sent simultaneously to reviewers who can then see others' comments as they are made.

4. Where applications are deemed sufficiently serious to require the attention of a full ERP body, it should be understood by applicants that this is likely to take longer.

5. Establishments may find it productive to establish audit trails so that they may periodically examine their efficiency in carrying out licensing reviews.
6. One concern noted during this review was the delays caused by having to deal with more than one Ethical Review Process, for example where secondary availability is requested. Researchers are often unaware that applications will need to be considered by another establishment, and of any different requirements these may have. ERPs should therefore consider how to deal with requests for secondary availability, for example whether or not a full review is needed, or whether or not to concentrate on only the aspects of the programme of work to be conducted at their establishment, make this process transparent and available to all licensees intending to work at their establishment. Effective communication between the ERPs involved, for example sharing of outputs, should minimise any duplication of effort and minimise delays for applicants.

4.4. Need to promote good practice in ERP

1. Whilst mutual representation between ERPs in different establishments is encouraged, this is usually between limited sets or pairs of establishments, and many ERPs work essentially in isolation. General information on good practice is valuable to ERPs and in short supply. It is also understood that The RSPCA Research Animals Department and the LASA Education, Ethics and Training Sub-committee will be working together to produce guidance on fulfilling the seven core functions of the ERP during 2008.
2. It is important that means are identified for dissemination of information between or drawn from disparate ERPs. The objective should not be harmonisation for its own sake, but sharing of good practice amongst diverse local processes. Internal and external publication of the desired outputs of the ERP would provide a framework for this dissemination.
3. The HOI often routinely sits in on ERP discussions and may be well placed to give advice on good practice, possibly in discussions within ERP meetings. Alternatively the Certificate Holders' Forum may be appropriate, since ERP exists to advise Certificate Holders on ethical issues. However, it seems important to ensure that information is broadcasted to all levels in the ERP.
4. It is suggested that establishments both individually and collectively through groups such as the Certificate Holders Forum, can take far greater ownership of the outputs and process, by examining, developing, defining their local needs and conditions to produce a local process that more closely meets the stated outputs for point 7.2 (Ethical Review Process 1998) efficiently and adds greater local value to the process.

5. Referenced reports on improvements to ERP

APPENDIX J: THE ETHICAL REVIEW PROCESS. PP99-100; GUIDANCE ON THE OPERATION OF ANIMALS (SCIENTIFIC PROCEDURES) ACT 1986.

REVIEW OF THE 'ETHICAL REVIEW PROCESS' IN ESTABLISHMENTS

**DESIGNATED UNDER THE ANIMALS (SCIENTIFIC PROCEDURES) ACT 1986,
PUBLISHED NOVEMBER 2001.**

**THE ETHICAL REVIEW PROCESS 1998; HOME OFFICE EXPLANATORY
STATEMENT;**[http://scienceandresearch.homeoffice.gov.uk/animal-
research/publications-and-reference/publications/guidance/ethical-review-
process/ethicalprocess.pdf](http://scienceandresearch.homeoffice.gov.uk/animal-research/publications-and-reference/publications/guidance/ethical-review-process/ethicalprocess.pdf)

**HOUSE OF LORDS SELECT COMMITTEE ON ANIMAL EXPERIMENTS. 24TH
JULY 2002.**

**APC REVIEW OF COST BENEFIT ASSESSMENT IN THE USE OF ANIMALS IN
RESEARCH. JUNE 2003**

**PRINCIPLES AND PRACTICE IN ETHICAL REVIEW OF ANIMAL EXPERIMENTS
ACROSS EUROPE. DECEMBER 2005.**

Additional background Information

Smith, J.A. and Boyd, K.M. eds. (1991) Lives in the balance: the report of a working party of the Institute of Medical Ethics. Oxford University.

Smith, J.A. and Jennings, M (2002) A resource book for lay members of local ethical review process. Royal Society for the Prevention of Cruelty to Animals: Horsham UK.

Cooper, J and Jennings, M (2007) Perceptions of the ERP – summary of discussions at the 2007 RSPCA Lay Members Forum. Royal Society for the Prevention of Cruelty to Animals: Horsham UK.

Members of Working Group

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Home Office Inspectorate observers