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December 2000

Animals in Scientific Procedures

The Local Ethical Review Process

Supplementary Note by the Chief Inspector December 2000

The Home Office requires that all establishments designated under the Animals (Scientific Procedures) Act 1986 establish and maintain 'local ethical review processes' acceptable to the Secretary of State. The original Home Office commissioning document will be available as Annex B soon.

This requirement is implemented and enforced by a standard condition of issue on all Certificates of Designation (Annex A).which will also be available on this site soon.

Certificate of Designation: Standard Condition

The certificate holder is required to have instituted, and to maintain, local ethical review processes acceptable to the Secretary of State. Details of the processes and records of the outputs from the processes shall, on request, be submitted to the Secretary of State or made available to an Inspector. Any substantial changes to the processes that are proposed must be submitted to the Secretary of State for approval.

This note briefly reviews the Home Office's expectations and requirements. It is intended to provide some insights into current practice that Certificate Holders and others may wish to take into account when reviewing the effectiveness and efficiency of their own processes.

It is not intended to pre-empt or pre-judge the form Home Office review of the efficiency and effectiveness or local ethical review processes.

Origins and Aims

On 6 Nov 1997 Lord Williams, then Parliamentary Under Secretary of State at the Home Office announced that all designated establishments were to be establish and maintain local ethical review processes.

Welfare committees in designated establishments

The Government will require all designated establishments to set up and maintain ethical review processes. These have sometimes been called "welfare committees".

The exact nature of the processes used will depend on the particular establishment. An appropriate form of welfare committee will be mandatory: a standard condition of certificates will ensure that ethical review processes have been justified and demonstrated.

Their function will be to scrutinise the ethics of proposed work; to propose reductions in the numbers of animals used, refinements to the procedures to reduce any suffering, and replacement of animals wherever possible (the 3Rs); and to advise on the care and accommodation of laboratory animals.

Lord Williams of Mostyn, Parliamentary Under Secretary of State, 6 Nov. 1997

The purpose of the 'local ethical review process' is to mobilise institutional expertise and resources to promote good animal welfare and humane science by ensuring that the use of protected animals at designated establishment is justified. The process should ensure that proper account is taken of strategies to identify, and opportunities to apply, appropriate strategies to replace, reduce and refine animal production and use.

The Ethical Review Process - Aims

1. To provide independent ethical advice to the Certificate holder, particularly with respect to project licence applications and standards of animal care and welfare.
2. To provide support to named people and advice to licensees regarding animal welfare and ethical issues arising from their work.
3. 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 3Rs.

Structure and Operation

The Home Office believes that establishments performing live animals research, and those breeding animals for use in research, should ensure that animal production is optimised, and use is justified and humane. Proper account must be taken of all possibilities for replacement, reduction and refinement of animal use. High standards of care and accommodation must be provided. The local ethical review process is intended to provide institutional advice and support to facilitate the high standards of animal welfare and the best science.

The Home Office was careful to describe the requirement as a 'process' rather than as an event or a committee. At scientific procedure establishments the process should be activated when work is at the concept stage, it should inform the planning process, continue once work is in progress, and reflect upon the lessons learned when work has been completed.

It was made clear that at all establishments input from named veterinary surgeons and named animal care and welfare officers was expected. At scientific procedure establishments personal and project licence holders should also be represented. Where possible there should also be input from those who do not have responsibilities under the 1986 Act. The Home Office stressed that it is for each establishment to design, implement and maintain a process suited to its particular needs and resources.

It was appreciated that different establishments would have different requirements, and that flexibility would be required to ensure that appropriate and effective local systems were devised. The Home Office Inspectorate advised on whether the process proposed by each establishment met the Home Office requirements, but did not mandate uniform or specific structures and practices.

The Home Office acknowledged that, subject to any proposed changes being acceptable to the Secretary of State, the processes could evolve and be improved and amended as practical experience was gained.

Objectives and Outputs

The Home Office specified seven responsibilities and activities that should be undertaken by each local ethical review process.

Local Ethical Review Processes - Responsibilities

1. Promoting the development and uptake of reduction, replacement and refinement alternatives 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 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;
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.

It was appreciated that most establishments already had systems in place to deliver some of these, and that in many instances the 'ethical review process' would be

established by co-ordinating and integrating existing practices with any new systems required.

Flexibility was encouraged to enable the local processes to add value by targeting resources at those aspects of animal production, care and use not adequately provided for by other means.

For example :-

- The 'independent ethical advice' offered to the Certificate Holder should be the opportunity to impose the institution's own ethical values and judgements on animal care and use, rather than trying to apply a cost/benefit assessment in precisely the same terms as that subsequently applied by the Home Office.
- Where programmes of work have been peer reviewed and funded by the major UK funding councils the local review process might be better focussing more on ensuring the 3Rs are properly integrated into the proposed animal use than questioning the scientific validity of the hypothesis to be tested.
- Consideration must be given as to how different local ethical review processes are integrated when work is to be conducted at more than one designated scientific procedure establishment.

There is also flexibility as to how resources are partitioned between work at the planning stage, work in progress, and work that has been completed. It is possible to envision local processes where, having dealt with scientific justification, general strategy and generic animal use protocols at the concept stage, the main input of the ERP relating to the 3Rs is achieved by scrutiny of protocols and animal care and use on a study by study basis after the general authorities are approved.

Common Misconceptions

There appear to be a number of common misconceptions relating to the purpose and operation of the local ethical review processes.

- *That the local ethical review process is 'doing the Home Office's work'.* In fact the responsibility for making provision for the most humane science and high standards of care and accommodation has always resided with those seeking authorities under the 1986 Act.
- *That the Home Office defined the structure and means of operation of the local ethical review process.* The Home Office commissioning document clearly set out what had to be achieved, but did not dictate how it should be done.
- *That the Home Office requires formal committee structures be established to deliver the required outputs.* That is not the case. The Home Office clearly outlined the need for a process rather than a committee structure.
- *That the local ethical process as agreed with the Home Office cannot be changed.* Amendments to improve the effectiveness or efficiency of the local processes can be discussed with the Home Office at any time.
- *That there has been a loss of input from the Inspectorate.* The Inspectorate is still available at the early stages to provide advice on the structure, content and format of applications for authorities or plans for new or refurbished animal facilities. The Inspectorate will also offer technical advice where this will enhance the local ethical review process, and provide feedback on requests for authorities that have completed the local ethical review process. The Inspectorate is not prepared, however, to negotiate final authorities whilst proposals set out as licence applications are still being considered by the local

ethical review process.

- *That the local ethical review process is turning scientists into bureaucrats.* The aim of the local ethical review process is to provide institutional support and resources to applicants to facilitate good animals welfare and good science. The assistance this should be providing to applicants is discussed below.
- *That the local ethical review processes are ineffective and inefficient.* The Home Office review of ERPs will review the effectiveness and efficiency of ERPs. Notwithstanding the outcome of that review, examples have been presented at various meetings of welfare and scientific gains without undue delays being caused.

Aspects of Perceived Best Practice

There are some areas where insights can be offered into some aspects of best practice.

- Whenever possible the local processes should co-ordinate and build upon systems and structures that were already in place for the effectively delivery of the key objectives.
- Local processes should focus on those aspects of animal care and production not best catered for elsewhere rather than seeking to repeat or reproduce checks and balances provided by other components of the funding and regulatory systems.
- There should be audit trails to show that the process has been operating as defined in the process agreed with the Home Office. However, the key performance indicator should be examples of high standards of science and animal welfare attributable to the effective operation of the local processes.
- The effectiveness and efficiency of the local ethical review process should be re-evaluated periodically and consideration given as to whether the process can be improved.
- Although some scientific procedure establishments have focused primarily on consideration of the 'project licence', it is important to remember that the process should review all aspects of animal production, care and use.
- When dealing with project licence applications and amendments the local ethical review process should be activated, and preliminary support and advice offered, at the concept stage to identify key concerns and opportunities to implement the 3Rs. Early activation of the process allows the advice and support offered to inform and be integrated into the researcher's planning processes, and to minimise any delays and frustrations introduced by the ethical review process itself. Effective early input offers the most timely advice, minimises delays attributable to the local ethical review process, and sets the scene for signing-off quality assured applications at stage when a formal application to the Home Office has been prepared.
- Any local ethical review process that only begins once an applicant has prepared a formal application to the Home Office is unlikely to be the most effective or efficient way of meeting the aims set out by the Home Office. Such processes will inevitably be offering advice at a stage when applicants may already feel committed to particular strategies and, no matter how efficient the process, it will be perceived as having introduced additional delays.
- When there is genuine urgency fast-track procedures should be in place to allow the rapid consideration and processing of proposals intended to improve the welfare of protected animals bred, kept or used at the establishment.
- The process should provide management visible support for the named persons

(the named veterinary surgeon and the named animal care and welfare officer), and the framework to ensure that their advice on the 3Rs is routinely sought and taken. It should not distract the named persons from their core welfare-related tasks, nor require that they provide 'expert advice' in matters beyond their training and competence.

What Can the Local Ethical Review Process Do for Certificate Holders?

The local ethical review process should supply Certificate Holders with executive oversight of all animal care and accommodation, production, procurement, and use supported or enabled by their organisation. In a number of establishments the scope of the local process has been broadened to allow consideration of work performed at other places by the establishment's staff or financial assistance, and the use of animals in procedures not regulated by the Home Office. For example, tissue collection following humane killing by a method listed in Schedule 1 to the 1986 Act, and work done with collaborators at other institutions.

The local processes should be providing the information and a forum to consider the use being made of the current facilities and resources (including the skills and knowledge of the named veterinary surgeon and named animal care and welfare officer), and to predict and plan for future needs. It should co-ordinate the various systems required to ensure good animal welfare; sound, humane animal use; and compliance with the letter and spirit of the 1986 Act. It should help develop and maintain what is sometimes called a 'culture of care'.

It should be used to stamp the institution's values and standards on animal use and standards of animal care and accommodation, and quality assure proposals for animal use and ongoing work.

What Can the Local Ethical Review Process Do For Named Veterinary Surgeons and Named Animal Care and Welfare Officers?

The ethical review process should be used to provide visible management support and the necessary resources to the named persons.

It should provide the framework for the necessary dialogue between the named persons and other stakeholders, and ensure that their expert advice informs the planning and management of animal production, care and use.

It should identify the level of manpower and other resources required for named persons to function effectively, including identifying and meeting their training and continued professional development needs.

What Can the Local Ethical Review Process Do For Scientists?

The local ethical review process should make provision for good animal welfare and good science. It should provide expert and administrative assistance to better ensure that formal applications to the Home office are 'right first time'.

Scientists should benefit from the improved management of current institutional resources and improved strategic planning. Practical examples include considering the need for new facilities, joint bids for expensive hardware, the central provision of technical support such as tissue culture facilities as services, and advice on other safety and regulatory issues.

Through the local ethical review process scientist should also receive administrative and specialist support. Advice should be available locally on the preparation of applications, and should cover format and content, including methodological and statistical advice. In some instances intranets are already used to make available 'minimum severity protocols' for common procedures and tables of limit volumes for dosing and sampling already accepted by the local ethical review process. These can both safeguard good welfare and good science, and speed up the drafting and internal scrutiny of the application.

Through the named veterinary surgeon and named animal care and welfare officer expert advice should be available on the 3Rs, animal care and accommodation.

In some instances places information services are provided to undertake literature searches and to identify informative material in newly published journals.

As discussed above, advice and input from the local ethical review process is likely to be most timely and effective if support is available from as early in the planning process as possible, and continues to be available once work is underway.

The Future

On November 1 2000 the Home Office announced that the Inspectorate would be leading a formal review of the implementation, effectiveness and efficiency of local ethical review processes.

December 2000

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