Comment

Home Office Licence Abstracts — An Assessment

Barry Phillips and Maggy Jennings

Research Animals Department, RSPCA, Horsham, West Sussex, UK

Summary — Since late in 2004, brief abstracts of projects licensed under the *Animals (Scientific Procedures) Act 1986* have been published on the Home Office website. These are produced by the Project Licence Holders, and their publication is seen by the Home Office as contributing to greater openness and to greater public understanding of the use of animals in science, and how it is regulated. Here, we assess the value of the database for this purpose, based on an examination of the 1400 abstracts published up to January 2008. The abstracts are generally strong on justification, but often very poor at describing the likely effects on the animals used. In many cases, they lack basic information on the procedures applied, and the numbers, and even the species, of animals involved. A significant number of projects lack abstracts altogether. In order to ensure that the database gives a complete and balanced picture of animal use in research, we consider that it should be mandatory to submit an abstract, which should include at least the species and numbers of animals used, the adverse effects they are likely to experience, and the severity limits assigned to the procedures applied to them. The value of the database would also be improved greatly, if it were more readily searchable, at least by species, level of severity, and broad area of research.

Key words: *Home Office, licence abstracts, openness, public information, severity.*

Address for correspondence: *B. Phillips, Research Animals Department, RSPCA, Wilberforce Way, Southwater, Horsham, West Sussex RH13 9RS, UK.*
E-mail: *bphillips@rspca.org.uk*

Introduction

The importance of providing the public with information about the use of animals in scientific experiments has been recognised over recent years by a number of UK bodies, notably the Animal Procedures Committee (APC; 1), the House of Lords Select Committee on Animals in Scientific Procedures (2), and the Nuffield Council on Bioethics (3). The value of such information was defined very concisely by the House of Lords Select Committee:

"The availability of information as to levels of suffering and purpose of each project is crucial to the public understanding of animal procedures. Such information would enable the public to make informed judgements about the justification of animal research. Moreover, information would highlight where there was greatest suffering, and hence where the need to develop replacements, reductions and refinements was greatest." (Ref. 2; page 48, paragraph 9.36.)

The passage of the *Freedom of Information Act 2000* provided a legal stimulus for greater openness and transparency, and in 2001, the APC in its *Report on Openness* (2), recommended consideration of the repeal or relaxation of Section 24 of the *Animals (Scientific Procedures) Act 1986*, which prohibits the disclosure of information relating to animal experimentation. This was regarded as a necessary prerequisite for the implementation of their recommendations on greater (but limited) openness, although, if implemented, it might allow public access to licence applications in their entirety. The APC specifically recommended that project licence application forms should require a summary to be produced that "*should be comprehensive and detailed enough to provide a reader with a clear indication of the costs and benefits of the project*". They recommended that these summaries should be made public.

These APC recommendations were supported a year later by the House of Lords Select Committee on Animals in Scientific Procedures. In relation to the publication of licence summaries, the Select Committee recommended:

"That the substantive details of anonymised project licences, which describe the expected benefits of the research and harms to the animals involved, should be made public after they have been approved and funded." (Ref. 2; page 30, paragraph 5.24.)

Without prejudice to the ongoing debate on whether or not licence applications should be published in full, the publication of summaries has great significance for informing the public understanding of animal research and the ethical and scientific debate about animal use in science. Full licence applications would undoubtedly give a greater amount of information, and the ability to examine statements made in a summary in more detail, by reference to the full text, would be of great value. Nevertheless, the volume and technical nature of the information in licence applications, together with difficulties in presenting it in a searchable form, would limit its usefulness to the general public. Therefore, the provision of short, searchable, easily understood summaries continues to be a valuable objective.

In a written Ministerial Statement on 23 February 2005, Caroline Flint MP announced that a revised project licence application form was being gradually brought into use. This would include provision for an applicant to produce an abstract for publication on the Home Office website, once the licence had been granted. On the new form, the Home Office provided guidance on the content of abstracts (reproduced in Annex 1), but it was clear that provision of an abstract remained voluntary. The Minister described the new measure as *"a major step towards greater openness and more informed public debate about animal experimentation."*

In 2005, the Nuffield Council for Bioethics, in its report on *The Ethics of Research Involving Animals* (3), welcomed the publication of abstracts, but observed that *"the information provided in the first abstracts varies in content, level of detail, and style of presentation."*

The generation of non-technical, plain-English summaries of project licence applications is not only of potential value as public information. In fact, the value of such summaries as a means of assisting the Ethical Review Process (ERP), particularly for lay members involved in the ERP, was widely recognised prior to 2000. Prospective licensees were encouraged to produce 'lay summaries' during the preparation of licence applications. In 2001, the Animals (Scientific Procedures) Inspectorate described lay summaries as "*vitally important*" to the ERP (4), and suggested that the summary requested in Section 17a of the project licence application form current at the time, could be used as a lay summary in the ERP. It also commented, however, that "*Some ERPs find that this is sufficient but many require a longer, more detailed lay summary to be provided.*"

It is important to recognise that the purpose of lay summaries differs significantly from the purpose of the published abstracts. Lay summaries are intended to assist ethical review, and are read in conjunction with the full licence application. Both the application and consequently the summary may change in response to modifications suggested by the ERP. Abstracts, on the other hand, are intended as stand-alone information on projects, after they have been approved by the Home Office. The fact that the recommended style and content of lay summaries and abstracts are similar, has caused some confusion, and begs the question of whether a single abstract/summary can serve both purposes effectively.

In a workshop organised by the RSPCA, as part of its 2005 ERP Lay Members Forum, a sample of published abstracts was examined and assessed. Many deficiencies were identified. In particular, the participants noted that the majority of abstracts did not provide enough information about the procedures to be performed on the animals, the potential adverse effects on the animals, and how any suffering would be controlled. They also commented that a number of the abstracts appeared to overplay the benefits of the project, by implying that the research may impact on areas of particular concern to the general public (e.g. bio-terrorism and Alzheimer's disease), even though this was not the primary goal of the project. However, the abstracts analysed were among the very first to be published.

There are now over 1400 abstracts available on the Home Office website. This paper assesses the usefulness of these abstracts as information for the *general public*, rather than as lay summaries for use in the ERP.

Accessibility

Abstracts are readily accessible on the Home Office website (5), where they can be read, downloaded or printed. They are presented by year and month, and are numbered sequentially within each year (from January 2006 to December 2007). However, they are only searchable by using the general website search facility. Thus, although it is easy to read a selection of abstracts, it is less easy to investigate topics of special interest, such as reasons for the use of a particular species.

As a test, a search was run on the term 'pigs'. This returned a total of 146 documents, of which 51 referred to *guinea*-pigs, 51 were documents other than licence abstracts, and 5 were abstracts that mentioned pigs but did not describe a project involving their use. Of 49 abstracts identified in a detailed systematic search as involving regulated procedures on pigs, 39 were identified by the use of the term 'pigs' in the website search. Some of the 10 missing abstracts did not include the plural and referred only to 'pig'. Better results were obtained by using 'advanced search', with which both 'pig' and 'pigs' could be included, and 'guinea' could be excluded. Of 80 hits, 42 were relevant abstracts. The omission of 7 abstracts was difficult to explain,

but may have been related to the position within the text of the first reference to pigs; sometimes, it was only in the last paragraph.

Obviously, searches by this method need careful construction.

Coverage

The section of the current Project Licence Application Form relating to the provision of an abstract, is prefaced with the following note:

"This will not form any part of the licensed programme of work. However, the Secretary of State considers the project abstract an essential step towards greater openness and expects them to be provided in every case."

Nevertheless, there are gaps in the published list of abstracts. Up until December 2007, missing abstracts were marked either 'No abstract provided' or 'Abstract in course of preparation'. During a systematic study of the available abstracts over several months, it was found that some which were marked as being in preparation, became 'No abstract provided' at a later date.

For the year 2006, 76 abstracts out of 525 (14.5%) are marked 'No abstract provided'. In 2007, the proportion is lower (61 out of 597, or 10.2%). However, 34 were still marked as 'in preparation' in May 2008, and experience suggests that some of these will never be provided.

The submission of an abstract is not compulsory, so a submission rate of 85 to 90% can be regarded as a success. However, it is crucial to the objective of openness that the missing abstracts do not contain a disproportionate number of potentially 'troublesome' or 'sensitive' projects, i.e. those of most concern to the public. No reasons are given for non-submission. In some cases, it may be that an abstract is not submitted because it would inevitably lead to the identification of the laboratory or personnel involved, and would constitute a risk to their security. Alternatively, it may simply be due to laziness or, more charitably, lack of time. As long as the reasons for non-publication are not explained and justified, and 10 to 15% of projects have no abstracts, it will be legitimate to question whether the overall impression given by the published abstracts might be misleading. The public may want to know, for example, how many of the missing abstracts concern experiments involving substantial severity, have purposes which might be regarded by some as trivial, and/or involve species of particular concern, such as non-human primates.

There seems to be no reason why the Home Office should not fill in some essential information on projects lacking an abstract; at least by providing the species and number of animals, basic purpose and severity banding of the project. In the absence of such information, the Home Office might be accused of allowing a situation to develop in which the publication of only a proportion of abstracts gives a misleadingly 'rosy' view of animal use. Making the provision of an abstract compulsory would, of course, avoid the problem altogether.

Information Requirements

Guidance on the preparation of an abstract is given on the Project Licence Application Form (see Annex 1). It is not possible to give a detailed assessment of compliance with all the points of the guidance in this paper. Instead, our comments will focus on the adequacy of the published abstracts with regard to the description of the procedures involved in each project, the animals to be used, and the likely effects on these animals.

Animal species and numbers

The examination of abstracts for 2006 and 2007 identified 38 abstracts (15 in 2006, 23 in 2007) which did not identify which species of animal would be used. Although this is a small proportion (3.4%), it is astonishing that licensees could write a summary of their project without naming the species of animal involved. Some abstracts include 'other species', in addition to named species, but these are licences which generally require a certain amount of flexibility (e.g. for testing vaccines in a wide variety of 'target' species, or the production of biological tissues to order), and have not been included in the 38 mentioned here.

Estimates of the numbers of animals to be used were found in only about 40% of the abstracts for 2006 and 2007. The format of the data, when given, varies considerably, and numbers are expressed as either the total number or the number used each year. Estimates of the number of animals to be used are least common for regulatory studies, ecological research, the production of biological materials, and training. In some of these cases, there may be a valid reason for not being able to predict accurately the demand for tests, but presumably some estimate is required when the licence application is submitted.

Procedures and effects on animals

The published abstracts vary enormously in the amount of detail they give about the procedures to be applied and their likely effects on the animals used. At one extreme, some abstracts give no indication at all of what will be done to the animals involved, nor which animal species will be used. For example, *Mechanisms underlying diabetic complications* (2007,

October, No. 500) has the objective of increasing the understanding of the long-term complications of diabetes by using animal models, but which models will be used, or what will happen to these animals, is not stated. Similarly, *Synaptic physiology and small circuit behaviour* (2007, November, No. 559) explains the need for a 'circuit map' of the neocortex to help understand brain disorders, but fails to explain how the information necessary for building such a map will be obtained, or which animals will be used. *Brain damage/repair and influences of gender/ageing* (2008, January, No. 29) gives very brief details of the objective of studying brain damage after stroke, but makes no mention of animals or the procedures which might be applied to them.

Four abstracts from 2007 and 2008 relate to brain research on non-human primates. None of these gives a clear description of either the procedures applied or the likely effects on the primates used. *Neurophysiology of sequential behaviours* (2007, May, No. 257) refers to the need for 'invasive experiments' and 'temporarily inactivating a small portion of the brain', but gives no further details. *Brain mechanisms of memory in monkeys* (2007, April, No. 171) makes a number of references to 'selective lesions', but, for details of the procedures involved, refers the reader to 'published papers' which are not fully referenced and cannot therefore be located and consulted. *Frontal lobe mechanisms of decision making and social cognition* (2008, January, No. 6) involves 'examining the effect of disruption of frontal brain areas'. Although refinements in the experimental procedures are mentioned, the procedures and their effects are not described. *Proteasome inhibition model of Parkinson's disease* (2008, January, No. 39), concerns the development of a new primate model of Parkinson's disease and claims that the new model would be a 'considerable refinement over existing primate models of PD'. It does not, however, explain why this is so. Neither does it detail what is likely to happen to the primates, apart from a brief description of the symptoms of the disease in humans and the statement that the animals will be 'assessed behaviourally for up to a year before being killed by a humane method'. There is, however, a short paragraph on care and husbandry, which is not found in the other examples given.

In contrast, some abstracts give a reasonably detailed description of the procedures used and the care of the animals involved. For example, a high proportion of projects in pain research give details of the procedures used and how pain will be minimised, perhaps because there is unavoidable animal welfare concern about projects with pain in the title. Examples of the more detailed abstracts are: *Changes in the spinal cord that underlie pain states* (2005, August–October); *Chronic pain* (2006, June, No. 222); and *Peripheral and central mechanism underlying acute and persistent pain states* (2008, January, No. 16).

An example of a clear and frank description of a procedure classified as 'substantial' is found in *Towards laryngeal transplantation* (2006, October, No. 398). Unfortunately, this abstract omits to tell us what type of animal is involved, except that it is 'large'!

How useful are the abstracts?

The quotation from the House of Lords Select Committee, with which we began, identifies three main functions for public information on animal experiments. These can be paraphrased as:

1. To provide information on how much animals suffer in experiments and why the research is carried out;

2. To allow the public to assess whether the use of animals is justified;

3. To help identify priority areas for developing alternatives.

In terms of 'open government', there is a more specific function related to point 2, and that is to allow the public to scrutinise the 'cost–benefit assessment' underlying approval of a licence application by the Home Office. Crucial to all of these purposes is an objective description of what will be done to animals, and how much they will suffer as a consequence (the Select Committee's "*levels of suffering*"). For most people interested in the information, *how much animals suffer* comes first, and the reasons and justification for it come second. The current form of the abstracts reverses this order and puts justification first, and what is actually done to animals is often glossed over or omitted altogether.

There are, of course, many possible explanations for the paucity of details on the likely experience of animals in research projects. For example:

— Assessing and describing animal suffering in an objective and balanced way is difficult;

— Adverse effects may be unpredictable, and not all possibilities can be described, e.g. in the testing of novel drugs;

— Scientists may feel that the symptoms of the human disease or condition they study are well known, and the effects expected in an animal model therefore need no description;

— Licensees fear for their security, if they describe animal suffering in detail; and

— Details may be omitted in the interests of brevity, or to save time and effort.

The submission of an abstract is voluntary, and the inclusion of details on what animals might experience

cannot be enforced, even if an abstract is provided. In terms of guidance on content, it is perhaps unfortunate that mention of the likely effects on animals appears well down the list of points in the Home Office guidance, which gives priority to the purpose of the research and its intended benefits. In fairness, lists of information requirements devised by the APC, the Nuffield Council and the Home Office, all follow approximately the same, no doubt logical, order. Most licensees take full advantage of the opportunity to explain the importance and benefits of their work in their abstracts, whereas far fewer give similar attention to issues of animal welfare.

It is undoubtedly very difficult to assess, classify and communicate levels of suffering or 'severity': see, for example, the Boyd Group/RSPCA report on severity classification (6). As was suggested in that report, better narrative descriptions of procedures in abstracts would be an improvement. However, while the Home Office continues to apply a system of overall severity banding and severity limits for projects and procedures, it would seem logical to make reference to this system in the abstracts. Imperfect though these severity assessments may be, they are highly relevant to the decision to licence a project.

A very important point, explained by Dr Jon Richmond of the Home Office in a paper presented at the *6th World Congress on Alternatives and Animal Use in the Life Sciences* (7), is that project licence applications contain descriptions of what is *predicted* to happen to animals. They contain *prospective* assessments of severity, which, as he says, "*are often premised on the worst possible case, even when the worst effects might not be seen in practice*". Describing in licence abstracts the worst that might happen to animals, could give a misleading impression to the public. Nevertheless, Home Office approval of a project is based on the use of this prospective information in a 'cost–benefit assessment'. It is therefore appropriate and necessary information in relation to openness, i.e. for members of the public to reach their own conclusions about the decision-making process.

There is a stronger argument that prospective information is of less use in terms of the other functions of public information. As mentioned above, information on the predicted level of suffering in a project could misinform the public on the levels of suffering actually experienced by animals. Incorrect predictions of severity could also distort priorities for the development of Three Rs alternatives, although it seems unlikely that action would be taken unless and until the actual severity of a procedure became apparent by repeated use.

In line with his main thesis that the information supplied to the public should be carefully tailored to their needs, Dr Richmond says:
"It is my belief the public understanding and public debate is best informed by plain-English case-studies."
and:

"For the time being the public's understanding of what is actually happening in practice is possibly best informed by timely and clearly presented retrospective information…"

However, this begs the question of how case-studies would be chosen. There is surely an argument that the public should have some choice concerning which projects are selected for retrospective reporting. Unless details of all projects, including the predicted severity, are made available, it is difficult to see how such choice could be exercised.

Conclusions

The abstracts will certainly be of interest to members of the public who want to know more about what goes on in UK laboratories in general. However, the abstracts are only there because the associated projects involve procedures which have the potential to cause pain, suffering, distress or lasting harm to animals. As such, they describe only a small part of the overall research effort in medical, veterinary and toxicological research, and even if the abstracts were searchable, the perusal of projects on a particular topic would give a completely false impression of the overall field of research.

The real purpose of the abstracts should be to inform the public specifically about what is done to animals in research and why this is considered justified. Currently, most abstracts are strong on justification, but weak on explaining what is being justified. This does not allow people to make up their own minds on the assessment and weighing of harms to animals against the benefits to humans or other animals.

Furthermore, the lack of consistent information on animal suffering, the incompleteness of coverage, and the lack of an efficient search facility, all detract from the usefulness of the abstracts as a means of identifying where the need for Three Rs developments is greatest. This may not be particularly pertinent to the use of the abstracts by the general public, but is of considerable concern to animal welfare groups, such as the RSPCA, and alternatives groups, such as FRAME.

In their current form, and presented as they are, the abstracts are of very limited value to either the general public or to those more closely involved in applying the Three Rs. Their publication may be "*a major step towards greater openness and more informed public debate about animal experimentation",* but one step is certainly not enough.
Three immediate improvements can be suggested:

— The abstracts should be easily searchable, at least by species, level of severity, and purpose of the research.

— To allay concerns that research of particular concern to the public may be under-represented in the published abstracts, it should either be made mandatory to submit an abstract, or the Home Office should provide brief, but pertinent, details about projects for which no abstracts have been submitted.

— Licensees should be *required* to include certain types of information in each abstract. When such information is omitted, it should be added by the Home Office. This would apply to the species and numbers of animals to be used, the adverse effects they are likely to experience, and the severity limits assigned to the procedures.

References

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7. Richmond, J. (2008). Thought before action — What do the public and others really want to know? *AATEX* **14**, Special Issue, 705–709.

Annex 1: Home Office guidance on the provision of an Abstract

Abridged Project Information

Note: This will not form any part of the licensed programme of work. However, the Secretary of State considers the project abstract an essential step towards greater openness and expects them to be provided in every case.

In about 2 pages provide paragraphs or groups of paragraphs to:

Summarise the project: 1–2 sentences explaining what it covers and why.

Explain why you are doing this.

a) *Scientific unknown(s) or clinical or service need to be addressed*
b) *Brief scientific background or other rationale for the work*
c) *Broad statement of benefits/advances from achieving the project's objectives*

— Indicate why animals have to be used and human or tissue studies or computer simulations could not be used.

— Outline the general sequence of the work and how different options, including non-animal studies, contribute *(e.g. cell culture studies before/alongside animal ones, pilot experiments precede definitive experiments)*

— Explain how you are going to keep animal suffering to a minimum.
What strategies are to be used to minimise adverse effects and numbers
Why the protocols and the way they are carried out should involve the least suffering.

— Explain why the species or types of animals were chosen.

— Give a realistic estimate of numbers of each species or type of animal to be used, with what will happen to them in general terms *(such as typical experience and likely range of adverse effects)*.

— Outline in a few sentences how science will advance or people or animals benefit from this project.

— Use lay terms and avoid confidential material or anything that would identify you or your place of work.

This Home Office guidance is in found in the notes associated with the Abstract Section of the form: Animals (Scientific Procedures) Act 1986: Application for a Project Licence vFeb07*, which is available at: http://scienceandresearch.homeoffice.gov.uk/animal-research/publications-and-reference/publications/licences/project-licences/. Examples of abstracts can be seen on the Home Office website, http://scienceandresearch.homeoffice.gov.uk/animal-research/*