The **A P C**
Animal Procedures Committee

ANIMAL PROCEDURES COMMITTEE

February 2009

Guidance to Project Licence Applicants referred to the APC Applications sub-committee

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This guidance has been prepared by the APC Applications sub-committee (ASC) to help those with project licence applications referred to the APC to understand and prepare for ASC review of the application. It gives some background to the review and sets out some questions commonly asked of project licence applicants.

Background

It is the duty of the APC to advise the Secretary of State (SoS) on such matters concerned with the Animals (Scientific Procedures) Act 1986 and her functions under it, as the Committee may determine or as may be referred to the Committee by the SoS.

The APC has requested, and the SoS agreed to the referral of specific categories of project licence applications for consideration and advice.

Since 2004, the categories of application to be referred include:

1. Any involving the proposed use of wild-caught non-human primates;
2. Any involving the proposed use of cats, dogs, equidae or non-human primates in protocols of substantial severity;
3. Any with a substantial severity banding, or major animal welfare or ethical implications, involving a) xenotransplantation of whole organs, b) chronic pain models, or c) study of the central nervous system;
4. Applications of any kind raising novel or contentious issues, or giving rise to serious societal concerns (for example, any application involving the genetic modification of non-human primates or embryo aggregation chimaeras involving dissimilar species).

Typically, the applicant is invited to meet with members of the ASC to discuss the application in person. ASC members are scientists and non-scientists (www.apc.gov.uk/aboutapc/workgroups.htm). The ASC does not wish to create additional work for project licence applicants, but has found it very helpful if applicants prepare the following in advance of the meeting:

1. A lay summary of the proposed project written so as to be readily comprehensible by a member of the general public (see Abstract section of the Project licence application form http://scienceandresearch.homeoffice.gov.uk/animal-research/publications-and-reference/publications/licences/project-licences/).

2. A schematic (e.g. graph, flow chart, GANTT chart) showing the number and scheduling (and if possible, relative severity) of all procedures involved in the project that impact on the welfare of the animals.

Preparation of these documents is, of course, voluntary, but assists the ASC to understand and explore the scientific justification for the project procedures and their costs to the animals.

Invariably, the ASC wishes to estimate the total suffering experienced by the animals on the project, during their whole life-times, and to rationalise this against the expected benefits.

Common questions asked of applicants

Background, objectives and benefits

- What are the key objectives of the project, and the likely benefits (e.g. in terms of scientific knowledge, human or animal health, the 3Rs)?
- How does the project relate to progress made under previous or current project licences?
- To what extent has previous research (*in vivo/in vitro*) and existing data, literature and knowledge influenced the licence application? How has unnecessary duplication of previous work been avoided?
- What is the likelihood of achieving the project objectives, and what factors are critical for success?
- What are the key ethical issues?

Experimental design and the 3Rs

- How was the experimental design decided, and how have each of the 3Rs been integrated into the entire plan of work?
- Why is it necessary to use animals to achieve the project objectives? Why are non-animal alternatives unsuitable?
- What is the justification for use of the particular animal species/model?
- Was the advice of a statistician taken on minimising the number of animals to be used per experiment, and the appropriate methods for data analysis?
- How else has animal use been optimised?

Scientific procedures and animal welfare

- What is the justification for the particular scientific procedures to be used, and what are their effects on the animals involved?
- How many animals will undergo each procedure?
- How will pain, suffering, distress or lasting harm be avoided, recognised, alleviated and managed?
- Will anaesthesia and analgesia be used? Has advice been taken on the most appropriate agents and regimens?
- How frequently and by whom are the animals monitored before, during and after each procedure?
- What are the relevant clinical signs and the humane endpoints that will be applied?
- How are the animals acclimatised to, or trained to co-operate with, procedures?
- What are the standards of animal accommodation, environmental enrichment and care?
- Will single housing of animals be necessary?
- From where will the animals be sourced?
- What will happen to the animals when the work is completed?
- What is the rationale for nomination of the project severity band?