RESPONSIBILITY IN THE USE OF ANIMALS IN MEDICAL RESEARCH

GUIDANCE ISSUED BY THE MEDICAL RESEARCH COUNCIL

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1. INTRODUCTION

This booklet is intended to provide general guidance to MRC-supported medical researchers using animals or animal products in their research, and to MRC Board and Committee members involved in reviewing applications for support. The guidance covers:

- the legal position
- the diversity of research involving animals
- the ethical issues that arise
- the principles and procedures adopted by the MRC

This guidance does not aim to be comprehensive. Rather, it sets out some general principles and refers to other publications that give guidance or instructions on specific aspects, or explain statutory requirements.

The guidance is additional to the legal requirements imposed by the Animals (Scientific Procedures) Act 1986. The Council strongly advises all applicants for funding to discuss any research project involving animals with their Home Office Inspector before submitting detailed proposals. The Home Office will also be able to advise on best practice in the areas covered in this booklet.

2. THE MRC AND THE LEGAL FRAMEWORK

The MRC only supports research work involving the use of animals on the basis that researchers and those administering funding comply with legal provisions, any related codes of conduct or guidance issued by government departments, and the specific conditions of licences and certificates. Support for any project is on the absolute condition that no work controlled by the Animals (Scientific Procedures) Act 1986 will be begun until the licences and certificates required under that Act have been obtained, and that it will be terminated if any such licences and certificates are subsequently withdrawn. The Home Office inspectorate has a legal responsibility to designate breeding and research establishments, license projects and individual experimenters and to enforce the Act.

In directly managed MRC establishments and teams the particular responsibilities imposed by the 1986 Act are in addition to and must be met within the context of the duties of MRC Unit Directors and External Scientific Staff team leaders to manage all research activities properly. Where the work of the MRC staff is carried out under a Certificate of Designation granted to a Host Institute then mechanisms must be put in place so that the Director or team leader can exercise that duty to Council in the context of the Certificate holder's overall responsibilities under the Act.

For grant-aided work, the institution administering the grant is responsible for work that is subject to the Act.

3. DIVERSITY OF RESEARCH INVOLVING ANIMALS

Medical research involves the use of animals for specific purposes. The types of animal used in medical research vary from the simplest, such as protozoal parasites, through insects (such as the fruit fly and the malaria-carrying mosquito) to cold blooded vertebrates (such as the frog and South African clawed toad), to mammals (especially mice and rats, but also dogs, cats and monkeys). The procedures used may vary:

- animals may be conscious (eg vaccination or administration of drugs)
- procedures may be conducted under full anaesthesia with subsequent recovery
- procedures may be conducted under full anaesthesia without subsequent recovery
- animals may be used for the supply of tissues for in vitro culture (such as tumour cells)
- animals may be used for the supply of materials (such as antibodies, enzymes, and blood products).

4. ETHICAL CONSIDERATIONS

In using animals in research, all those involved should consider the problems and concerns associated with:

- keeping animals in captivity
- killing animals
- causing the animals distress or pain, either in the research or the husbandry

Researchers must recognise that there are many different views on these points, especially in the extent to which they are weighed against other considerations; for example, whether they are applied in circumstances other than research (such as keeping pets, eating meat, culling wild animals to avoid overpopulation), in the extent to which individuals consider that their own views should apply to other people, and in whether or not they would use the products of research or tests using animals, such as drugs.

Medical research has as its ultimate goal the maintenance or improvement of human health. It is because much of the research that is needed would not be ethically acceptable using humans themselves that animals are used instead.

Two arguments against the use of animals for this purpose are often put forward. The first that research involving animals can be done using alternatives such as cell cultures, human tissue or computer modelling. Indeed, much is now done in this way. (Further information on alternative techniques may be obtained from FRAME, the Fund for the Replacement of Animals in Research, and the RSPCA). But there are some types of question which simply cannot be addressed in this way; for example, it is often necessary to observe the results of an experimental technique or therapy in a whole living organism.

The second argument is that results cannot be extrapolated because animals are not the same as humans, and therefore animals should not be used. Yet the common evolutionary origin of animals, including humans, has resulted in there being much that is common, and a great deal of the knowledge which is applicable to humans has been derived from the study of animals. That there are also differences is clear, and it is in the nature of scientific research that one cannot be certain in advance when differences will be important. But there is extensive evidence from past work that properly controlled medical research involving animals, by adding to general understanding, will prove relevant to increasing knowledge of human health in the future, as it has in the past.

The MRC accordingly endorses the view, which has been reflected in legislation since 1876, that research using animals may bring benefits that cannot be realised in any other way, and that such research must be regulated, in particular to minimise any distress or pain that may be caused.

5. PRINCIPLES AND RESPONSIBILITIES

The Council requires all those involved in the peer review process, as well as the investigators themselves, to ensure that the principles set out below are applied in the design of research and its implementation.

DESIGN OF RESEARCH

The ultimate objective for research supported by the MRC should be the maintenance and/or enhancement of human health.

The research must address an important question relevant to the Council's overall objectives.

All experimental work should seek where possible to avoid the use of animals, and the researcher must advance sound scientific reasons for their use, explaining in proposals for support why no realistic alternative exists. In proposing and assessing research the guidelines on research design which follow must be complied with.

All studies must take full account of the welfare of the animals.

Research should be designed so that:

- The objective is feasible, and clearly defined. The Council believes that such decision-making on the use of animals in research is an integral part of good research and laboratory practice.
- Species with the most appropriate physiology for the work are used. Scientists should where possible use simple organisms.
- The number of animals used in an experiment must be the minimum sufficient to create adequate statistical power to answer the question posed.
- The severity of the procedures performed upon animals is kept to the minimum. The experiment must be as short as possible, and analgesia/anaesthesia used to minimise pain wherever possible.

USE OF ANIMAL PRODUCTS

Researchers must also observe the requirement to minimise animal usage when working with materials derived from animal sources.

RESPONSIBILITIES OF MRC COMMITTEE AND BOARD MEMBERS INVOLVED IN REVIEWING PROPOSALS FOR SUPPORT

When considering proposals for support, MRC Committee and Board members have a key role in applying the principles outlined above consistently across the research spectrum. Members must first satisfy themselves that the research proposal as a whole represents science worthy of MRC support. The specific points raised above are designed to provide both researcher and assessor with a means by which a proposal may be judged on ethical grounds. If these principles are not adhered to the Committee or Board must not approve funding for the research. Committee and Board members also have a duty to provide researchers with detailed feedback where proposals involving the use of animals are unsatisfactory.

PERSONAL RESPONSIBILITY

In addition to their legal responsibilities, everyone using animals in research, whether for experimentation, testing or the provision of tissue, is responsible for ensuring they are afforded the highest levels of welfare and protection. Those involved in the care and transportation of animals, as well as experimentation, should ensure the facilities within which they are kept are of high quality and that conditions of care and management are equally high.

TRAINING

All staff involved in animal research, both at a scientific and research support level, and those involved in the breeding, handling and care of animals, must be trained to the level of responsibility they are required to exercise. They must possess relevant professional or other recognised qualifications. Licence applicants and new research staff must be given good access to facilities for education and training.

SUPPLY OF ANIMALS

Animals must only be obtained from a source approved by the Home Office. Under the terms of the Animals (Scientific Procedures) Act 1986, all vertebrate animals used in research must come from a registered breeder or supplier. In addition, the Council expects individuals to ensure that:-

- Species caught from the wild are not used for research unless there are very special circumstances. Where the investigator sees no alternative, special Council permission will be required.
- Breeding must be carefully regulated to meet research needs, with respect to number, uniformity, and health. In particular, there must be no overbreeding and unnecessary culling, and the quality of the animals must be high enough to allow them to be used in minimum quantities.

ACCOMMODATION AND TRANSPORT

Those in charge of animals, whether permanently or temporarily housed, or in transit, should ensure that scrupulous husbandry is observed. Animals should be properly fed, watered and cleaned. They should have a suitable environment which is not subject to extremes of temperature, humidity or pollution. Animals should not be kept or transported in overcrowded conditions.

ANIMAL WELFARE AND HEALTH

Animals should be given due respect and care by all who look after, handle or perform experiments upon them. Their health should be maintained and monitored, and any deterioration attended to immediately. All staff are responsible for maintaining these standards.

Pain, including injury, physiological and psychological stress, and significant discomfort, whether immediate or in the long term, should be kept to the minimum at all times.

Animals should be kept healthy before and, as far as is in keeping with the aims of the research, during the experiment.

Where recovery is planned this should result in no lasting suffering to the animal. Where lasting pain, suffering or distress will be caused, the animal should always be humanely and painlessly killed at the end of the experiment.

THE ANIMALS' ENVIRONMENT

Given that most laboratory animals spend most of their time confined to pens and cages, investigators should ensure that conditions for holding and experimentation are of high standard. Immediate housing, e.g. cages, and the surrounding environment, should provide animals with spacious, high quality living space conducive to general welfare and to minimising stress. Species-specified considerations, together with behavioural requirements and environmental enrichment, need to be given appropriate weight.

THIRD PARTIES

When collaborating with other laboratories or where animal facilities are provided by third parties in the UK or abroad, researchers must ensure that standards consistent with those set out in this booklet are in force and maintained. The facilities provided by third parties should be at least equal to those provided by the investigator's host institution and not be regarded as an easy or cheap alternative.

COMMUNICATION OF IMPROVEMENTS IN TECHNIQUES

All scientists supported by the MRC must ensure that any new procedure which reduces the number of animals needed for research, testing or diagnosis, or the severity of procedures, is communicated to other researchers. Scientists should make a point of including in their published papers information which would be likely to be of help to others conducting similar experiments. The objective should be to record every-day practice and note pointers for best practice.

6. STATUTORY REQUIREMENTS AND CODES OF PRACTICE

The legal position on the supply and use of animals in research is set out in a number of Acts of Parliament, and associated Codes and Guidance and some of the principal references are given in Section 7 below. The main points to note are:

- It is an offence for any person to cause unnecessary suffering to any captive animal (1)
- Any experimental (scientific) procedure which may cause a vertebrate animal pain, suffering, distress or lasting harm can only be carried out legally as a regulated procedure:

  in a designated establishment which must have a named certificate holder, or place approved by the Home Secretary. The establishment must have named day-to-day care persons and a named veterinary surgeon;

  as part of a scientific programme set out in a valid project licence with the holder(s) named. The Home Secretary must be satisfied that the likely benefits will justify the use of animals involved. The licence will set out the work to be done, animals to be used and how they will be used;

  by a person holding a personal licence of competence.

The Home Office has issued guidance on the operation of the Animals (Scientific Procedures) Act 1986 (3) and a Code of Practice for the housing of and care of animals used in scientific procedures (4).

Those in charge of all types of animals being transported are obliged to protect the animals, having regard to the needs and characteristics of the species or individuals, from any injury and unnecessary suffering (5).

Work involving genetic manipulation falls within the 1986 Act, in addition to being controlled by Health and Safety legislation (9).

7. REFERENCES

ANIMAL WELFARE

1 The Protection of Animals Act (England and Wales 1911, Scotland 1912)

2 The Animals (Scientific Procedures) Act 1986

3 Home Office, Guidance on the Operation of the Animals (Scientific Procedures) Act 1986

4 Home Office, Code of Practice for the Housing and Care of Animals used in Scientific Procedures – HMSO 1989

5 The Transit of Animals (General) Order 1973, No 1377 made under the Diseases of Animals Act 1950

HUMAN HEALTH

6 Health and Safety at Work etc Act 1974

7 The Genetically Modified Organisms (Contained Use) Regulations 1992

8 The Genetically Modified Organisms (Deliberate Release) Regulations 1992

9 Advisory Committee of Genetic Manipulation – ACGM/HSE/ Note 9 Guidelines on work with Transgenic Animals, January 1989

10 The Management of Simians in relation to infectious hazards to staff – statement by the Medical Research Council (1990)