



Research Using Animals: The Role of Ethical Committees

From 2001, the Health Research Board requires ethical approval for all research using either animals or human subjects. This approval should be obtained from the institution or institutions in which the research will be carried out. The purpose of this paper is to provide background information and guidelines on the role and composition of ethical committees working at institutional level.

Background

Research using animals is controlled at present by the Department of Health and Children. Legislation in force (SI 17/94) requires that any person using an animal for scientific purposes is required to obtain a licence from the Department of Health and Children for the project and to perform the work in a designated premises using purpose-bred animals (except where the licence permits exceptions).

The elimination of animals in research is a goal shared by many scientists and people opposed to the use of animals in research. This goal is best summarised by reference to the proposals of Russel and Burch commonly known as the 3 R's. These stand for Reduction, Refinement and Replacement of animals in research.

These principles have been embodied in the EU Directive 86/609 'On the approximation of laws, regulations and administrative provisions of the Member States regarding the protection of animals used for experimental and other scientific purposes' and incorporated in national Irish legislation by Statutory instrument 17/94.

- Article 7(2) requires that an experiment will not be performed if an alternative non- animal method is available.
- Article 23 (1) requires that Member States should encourage research in the development of alternative methods.

Current processes

The criteria which are used to assess the acceptability of a specific animal research protocol fall into 3 categories:

1. Scientific validity
2. Welfare cost to the animals.
3. Ethical considerations.

Currently the scientific validity and welfare considerations are subject to assessment by the signatures of the licence and by the Department of Health and Children inspectorate. Ethical considerations, on the other hand, are not formally assessed although informally, several research institutions have ethical committees which comment on the ethical aspects of a research grant application.

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Remit of ethical committees

The objective of an ethical committee or ethical review group for animal projects is to examine a proposal to determine if the reasons proposed justify the use of animals within the ethical parameters determined by that group.

The starting point of any consideration should be that the use of animals must be avoided unless no valid or practical alternatives are available. To this end the group should consider:

- The scientific validity of the procedure
- The welfare cost to the animals
- The proposed benefits which will be achieved
- The social / community acceptability of the procedures

Specific responsibilities include:

- Ensuring compliance with the law
- Determining the acceptability of individual projects
- Establishing institutional policies which can be used to fast track non-contentious proposals
- Monitoring the use of animals in the institution and ensuring that appropriate standards and procedures are adhered to.

Composition of ethical committees

It is important that the people who make up the committee represent the various interests involved, including both those with animal research expertise and those without (some of who should be independent of the research institution).

In general the following interests should be represented on a committee although it is recognised that this may or may not be practical at a local level. The specific composition may vary from time to time depending on circumstances, but would be expected to include:

- The Veterinary Surgeon who is nominated for the health and welfare of the animals in the unit
- The Named competent person in charge of day to day care in the designated premises
- Representatives of the research community
- Persons independent of the establishment (a 'lay' person)
- Persons with specific expertise such as a statistician or ethicist
- Department of Health Inspector (as appropriate)

The Chairperson should be a senior person in the institution.

Functions of specific committee members

The Veterinary surgeon

This person should be an individual with experience of laboratory animal medicine and ideally will have specialist training in the area. This person may be part of the institution or may be an outside person who is contracted to provide for the duties of the NVS as written in the legislation.

Representative of the research community

This will be one or more persons, not directly connected with the project under discussion,

who can comment on the validity of the proposed protocol and attest to the proposed benefits which may accrue.

A public interest representative

This person's role is to give a public or non-scientific view of the proposal. It is important that the individual is appropriately trained to contribute to the committee and feels able to ask pertinent questions.

Persons with special expertise

It is becoming more accepted that statisticians should have an input into experimental design at an early stage. In the past it has been the practice to apply statistical assessment to data which has been collected. However this can lead to a very wasteful use of animals. The design of the experiment may have been faulty, either using more animals than necessary or not using enough and thereby wasting the animals which have been used.

Other specialists such as ethicists may also be required from time to time to help develop policies.

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