

International Bioethical Conference
"The responsible conduct of basic and clinical research"
June 3 - 4, 2005, Warsaw

SESSION III

Ethical and welfare aspects of animal experimentation

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Ethical and welfare aspects of animal experimentation

Structure

1. Some historical remarks
2. The 3Rs concept
3. Ethical and welfare principles in legislation on animal research
4. Ethical evaluation of animal experiments: ethics committees
5. Outlook / issues for discussion

Some historical remarks

“painful, physical experiments for the pure purpose of speculation, if the aim can be reached without them, are to be abhorred”

Immanuel Kant, *Metaphysics of Morals*, 1797

Some historical remarks

German priest Adam Dann (1822):

“Replace animal experiments by examination of human bodies !”

Some historical remarks

William M.S. Russell & Rex L. Burch (1959):

The principles of humane experimental technique

→ 3Rs concept

The Three Rs



Reduction: 'lowering the number of animals used to obtain information of a given amount and precision'

Refinement: 'decrease in the incidence of severity of inhumane procedures applied to those animals, which have to be used'

Replacement: 'employing non-sentient material which may replace methods which use conscious living vertebrates'.

W.M.S. Russell and R.L. Burch:
The Principles of Humane Experimental
Technique (1959)

Directive 86/609/EEC and
Council of Europe - Convention ETS 123
*for the protection of animals used for experimental and other
scientific purposes*

Main ethical principles:

- Experiments must be indispensable for specified purposes
- Pain, suffering or distress must be ethically justifiable
- 3Rs must be applied wherever possible

Directive 86/609/EEC for the protection of animals used for experimental and other scientific purposes

Experiments must be indispensable for specified purposes

Article 7

2. An experiment shall not be performed if another scientifically satisfactory method of obtaining the result sought, not entailing the use of an animal, is reasonably and practicably available.

Directive 86/609/EEC for the protection of animals used for experimental and other scientific purposes

Pain, suffering or distress must be ethically justifiable

Article 12

2. Where it is planned to subject an animal to an experiment in which it will, or may, experience severe pain which is likely to be prolonged, that experiment must be specifically declared and justified to, or specifically authorized by, the authority. The authority shall take appropriate judicial or administrative action if it is not satisfied that the experiment is of sufficient importance for meeting the essential needs of man or animal.

Directive 86/609/EEC for the protection of animals used for experimental and other scientific purposes

3Rs must be applied wherever possible

Article 7

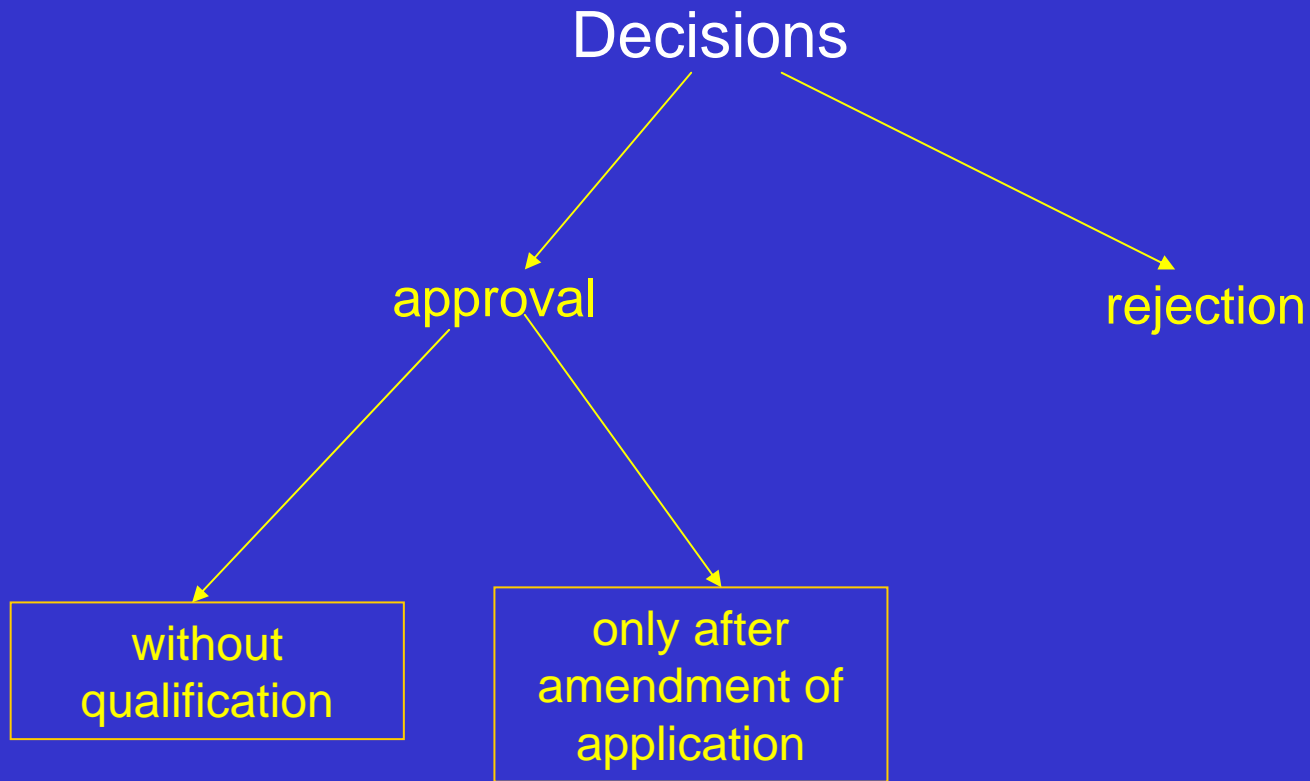
3. ... In a choice between experiments, those which use the minimum number of animals, involve animals with the lowest degree of neurophysiological sensitivity, cause the least pain, suffering, distress or lasting harm and which are most likely to provide satisfactory results shall be selected.

Ethics Committees

3 main tasks:

1. Approve that the animal experiment is indispensable for the specified purpose
→ exclusion of alternatives
2. Approve that pain, suffering or distress are ethically justifiable
→ weighing of cost and benefit
3. Approve that 3Rs are applied
→ check concrete measures for replacement, reduction and refinement

Ethics Committees



Applications for Animal Experimentation

- What is needed?

All relevant info to be provided in a plausible manner:

- sound justification for species chosen
- estimation of pain, suffering or distress to be based on existing schemes
- ethical justification to specify benefit
- 3 Rs application described in detail (alternative methods, statistics, housing conditions, anaesthesia; humane endpoints etc.)

Ethics Committees for Animal Experimentation

- What is needed?

1: information of members

- knowledge on (education in) ethics
- expertise in the field of the 3Rs
- expertise in the research field concerned
- information on past, ongoing, and future animal experiments

Ethics Committees for Animal Experimentation

- What is needed?

2: Critical view of members

- no involvement in the proposed research project
- independence from the institution concerned
- only minority should be involved in animal experimentation
- appropriate participation of animal welfare representatives

Ethics Committees for Animal Experimentation

- What is needed?

3: Consistent application of the principles

- weighing of cost and benefit
 - problems:
 - comparing apples and oranges?
 - where is the balance?
 - no limit for the cost, no minimum standard for the benefit
- consideration of all relevant factors
 - benefit (*inter alia*: is a product needed?)
 - cost (*inter alia* : suffering from birth to death; surplus animals; origin [primates!]; specific problems of transgenics)

Outlook

Some questions to be discussed:

- Legally demanded animal experiments: how can they be ethically evaluated in practice?
- Where and how can a minimum standard for the justifiability of animal experiments be defined? (→ cosmetics)
- Should there be an absolute limit to animal experiments?

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Ethical Principles and Guidelines for Scientific Experiments on Animals

4.6 Experiments apt to cause the animal severe suffering must be avoided by modifying the hypothesis to be tested in such a way as to allow the choice of alternative experimental procedures, or by forgoing the anticipated gain of knowledge. Severe suffering is to be construed as any state which would be unbearable without palliative measures.

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Thank you for your attention !

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