

# Animal Research Ethics

IRB animal research & welfare sub-committee  
Alfaisal University



# Menu



Introduction



History



Overview of animal research



Governing principles of animal research



Law and penalties



Persons responsible for animals



Animal well-being



What happens to animals at the end of the experiment?



Summary

# Introduction

- As an investigator, you must ensure your research is up to the highest ethical standards
- Research ethics is vital when conducting research
- Unethical research may put animals / research subjects at risk and potentially affect the validity of the findings

The following terms and phrases – wherever used in this course – shall have the meanings assigned to them, unless otherwise required by context:

- Law: Law of Ethics of Research on Living Creatures
- Regulations: Implementing Regulations of the Law of Ethics of Research on Living Creatures
- National Committee: National Committee of Biomedical Ethics

# Definitions

- Monitoring Office: Research Ethics Monitoring Office.
- Local Committee: Committee for licensing research formed at an establishment in accordance with the provisions of this Law.
- Establishment: A public or private corporate entity engaged in research activities on Living Creatures
- Living Creatures: Human beings, animals and plants

## Definitions cont'd.

- The word ethics is derived from the Greek word “ethos,” which means custom
- Ethics is a study of values, principles, and beliefs
- The ethical requirement of clinical research:
- Minimize the risk to subjects
- Respect the rights and welfare of subjects

## Definitions cont'd.

# History

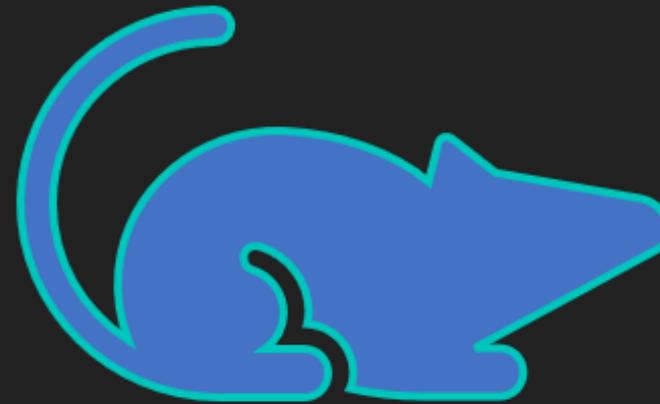
- Animals have been used repeatedly throughout the history of biomedical research:
  - Aristotle (384 – 322 BC) and Erasistratus (304 – 258 BC) performed experiments on live animals
  - Galen (129 – 199 / 217 AD) used animals to explore anatomy, physiology, pathology, and pharmacology
  - Ibn Zuhr (Avenzoar) performed test-surgical procedures
  - Claude Bernard: established animal experimentation as part of the standard scientific method.

# The Belmont Report

- The Belmont report outlines ethical principles and guidelines for the protection of human participants in research
- The 3 principles of the Belmont report can also be applied to animal research:
  - Respect – this must underpin all decisions and actions involving the care and use of animals for scientific purposes
  - Beneficence – to act towards the benefit of others
  - Justice – fair treatment

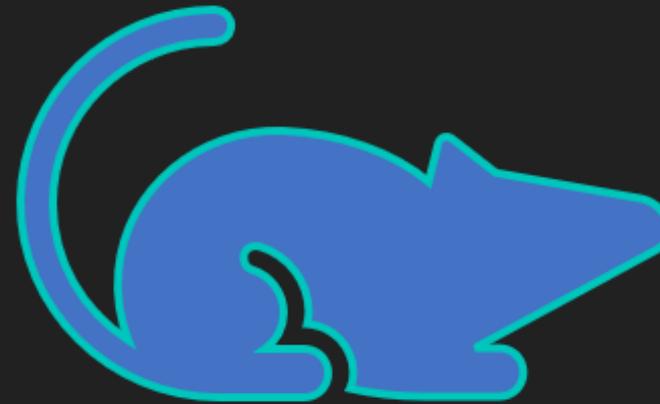
# Overview of animal research

- Animal research has helped with multiple medical advances – e.g. understanding physiology, development of new treatments
  - used as a means of testing for example, new medications, to better understand side effects and effectiveness prior to human trials
- Note that results from animals cannot be directly applied to humans due to innate differences – however animal research still adds valuable insight into investigations



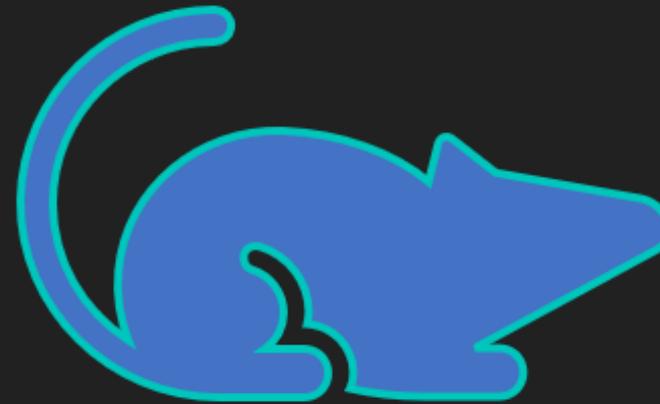
# Overview of animal research

- Animal research is a very controversial topic
  - Important to note is that some animal rights groups do not feel that the potential benefit of animal research to humans does not justify the harm caused – or, that even if animal research helps to contribute to science and treatments it still should not be carried out



# Overview of animal research

- Animal research is conducted according to established ethical frameworks
- Laws are in place to help make animal practice ethical and humane, to protect animals
- If possible, we always want to avoid any unnecessary suffering, and avoid using animal research altogether



# Principles of animal use



**RESPECT** – this must underpin all decisions and actions involving the care and use of animals for scientific purposes. This respect is demonstrated by the following below:



Using animals only when it is justified



Supporting the wellbeing of the animals involved



Avoiding or minimising harm, including pain and distress, to those animals



Applying high standards of scientific integrity



Applying the 3Rs (next slide)



Knowing and accepting one's responsibilities

# 3Rs

- The 3Rs should be used at all stages of animal care and use
- Replacement, Reduction and Refinement

# 3Rs

## Replacement

- Replacement: the *Replacement* of animals with other methods
  - Methods that permit a project to be performed without the use of animals – eg, instead of doing muscle twitch tests on animals, can we imitate these tests in another way like a simulation?
  - Although animals can't be replaced, it's important that researchers maximize reduction and refinement. (the other x2 Rs)

# 3Rs

## Reduction

- Reduction: methods which involve aiming to use fewer animals in scientific procedures
- We can achieve the above via good science and experimental design
  - eg looking at what is the minimum number of animals required for statistical significance
  - eg can we reduce the number of animals used by sharing animal tissues with other colleagues/other laboratory groups
- Note however, that good experimental design is paramount - a sufficient sample size number still needs to be used to enable precise statistical analysis and to generate significant results
  - If the above is not attained, there's a chance this could lead to further experiments being required, and therefore even more animals used

# 3Rs

## Refinement

- Refinement: methods that help to alleviate or minimise potential pain and distress, and enhance animal wellbeing
  - eg ensuring you have the skills and techniques required, to make sure experiments are conducted well
  - eg making sure you have people with the right expertise to look after the animals
- Careful handling of the animals, and administration of appropriate anaesthetics and analgesics during the experiment, can help to reduce any pain experienced by the animals
- Adequate training is an important aspect of the refinement of animal research, and should continually be reviewed and improved

# Principles of animal use cont'd.

- The care and use of animals for scientific purposes must be subject to ethical review
  - eg the care and use of animals is reviewed by ethics committees, and regularly revisited and monitored
- A judgement as to whether a proposed use of animals is ethically acceptable must be based on information that demonstrates the principles mentioned earlier, and must balance whether the potential effects on the wellbeing of the animals involved is justified by the potential benefits

# Principles of animal use cont'd.

- Each experiment is assessed, according to whether or not it not only meets the principles as mentioned before (respect, the 3Rs, etc.), but also whether or not you can justify the use of an animal. Do the benefits outweigh the costs of using an animal's life?
- The obligation to respect animals, and the responsibilities associated with this obligation, apply throughout the animal's lifetime, including acquisition, transport, breeding, housing, husbandry, use of the animal in a project, and provisions for the animal at the conclusion of their use

# The Law for research on animals (article 38)

1. Animals may be used for research employing all experimental or scientific means not causing unusual pain to the animals.
2. Use of animals shall be restricted to research whose objectives cannot be realized without such use.
3. Endangered animal species may not be subject to negative use. The Regulations shall specify ethical conditions and procedures for use of animals in research.

# Penalties

(article 44)

Without prejudice to any severer penalty prescribed by other laws, a person violating any provision of this Law (article 38) shall be subject to one or more of the following penalties:

1. Warning,
2. Suspension of research until the effects of the violation are rectified;
3. Barring the researcher from conducting the research subject of the violation;
4. A fine not exceeding two hundred thousand (200,000) riyals;
5. Imprisonment for a period not exceeding six months.

These are just a few of the people that may be involved in assisting with animal research. There are multiple people that assist with the care of animals in research – not just the investigator themselves:

- Institutions regarding the governance of an animal ethics committee
- Animal ethics committees
- Investigators (including supervisors/teachers and people involved in studies)
- Animal carers
- Institutions with respect to developing an application form to an animal ethics committee

**Persons  
responsible  
for animals**

# Animal wellbeing

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Supporting and safeguarding the wellbeing of animals

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Supporting the wellbeing of animals during their care and management

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Safeguarding the wellbeing of animals during the conduct of specific procedures.

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Provisions for animals at the conclusion of their use

# What happens to animals at the end of the experiment?

- Rehousing (rehoming)
- Return to normal husbandry conditions or natural habitat
- Humane killing (euthanasia)
- Reuse
- Tissue sharing

# Summary

- All personnel involved in conducting research on animal shall abide by the law
- At this the research stage, animals can't be completely replaced
  - We don't understand enough physiology to be able to make a representative model, and we are unable to simulate an animal's response to different situations
- Importance of the 3Rs
- Animal research is bound by an ethical framework

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