

Ethical Guidelines for the Use of Animals in Research



ETHICAL GUIDELINES FOR THE USE OF ANIMALS IN RESEARCH

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ABOUT THE GUIDELINES

These guidelines have been prepared by the National Committee for Research Ethics in Science and Technology (NENT). Their purpose is to provide ethical guidelines for researchers and other people who are considering experiments on animals. The guidelines will be useful when planning projects, assessing them, and when reporting and publishing findings and results. They are also intended to contribute to reflection on research ethics and the use of animals in research in both research communities and in the public debate.

The overarching framework for these guidelines is provided by the *Guidelines for Research Ethics in Science and Technology* (2016), particularly guidelines 12 and 13. A consultation process and a subsequent workshop organised by NENT in the autumn of 2016 found that relevant players see a need for a set of guidelines that can systematise and elaborate on the ethical responsibility inherent in the use of animals in research. This is the background for the current guidelines.

In Norway, the use of laboratory animals is governed by the Regulations Relating to the Use of Animals in Research, which follow from the Animal Welfare Act. The EEA Agreement obliges Norway to implement EU Directive 2010/63/EU on the Protection of Animals used for Scientific Purposes. These rules provide a zero vision for research using animals. In Norway, the Gene Technology Act provides the legal framework for research on such organisms. Many of the ethical obligations stipulated in these guidelines are also laid down in applicable legislation. Researchers who violate the guidelines can face legal sanctions. In that case, it is because they have broken the law, not primarily because they have violated the guidelines for research ethics. NENT does not have access to any sanctions of its own. NENT's role in following up the guidelines is to provide advice and recommendations, help increase awareness of animal welfare, and to stimulate continued discussion about research that involves animals.

ETHICS AND EXPERIMENTS ON ANIMALS

The ethical assessments related to the use of animals in research are wide-ranging. It is generally thought that it may be necessary to use laboratory animals in some cases in order to create improvements for people, animals or the environment. At the same time, the general opinion is that animals have a moral status, and that our treatment of them should be subject to ethical considerations.

Such views are reflected in the following positions:

- (i) Animals have an intrinsic value which must be respected.
- (ii) Animals are sentient creatures with the capacity to feel pain, and the interests of animals must therefore be taken into consideration.
- (iii) Our treatment of animals, including the use of animals in research, is an expression of our attitudes and influences us as moral actors.

The guidelines reflect all these positions, and stipulate principles and considerations that can be used as tools when balancing between harm and benefit. The three Rs (Replace, Reduce, Refine) are established principles that are also enshrined in legislation. These principles can establish absolute limits for experiments on animals, even when there are great benefits. These principles also state what can reasonably be considered harm and benefit, and the principles thus facilitate good assessments. Assessments of harm and benefit associated with experiments on animals are particularly demanding, because experiments may result in researchers intentionally causing actual harm to animals, while the future benefits are often uncertain.

The guidelines are dynamic and must be reviewed in line with technological developments and the appearance of new ethical issues. New gene technology methods create new opportunities for the use of genetically modified animals in research, which is a growing trend. Genetically modifying laboratory animals, i.e. changing the genetic material of laboratory animals using gene technology, gives rise to a special responsibility in that this method entails a double intervention: first, intervention in the animal's genetic material and second, use of the animal as a research object. This practice has the potential to change our view of humans and our attitudes towards generating or eliminating genetic characteristics in ourselves. These guidelines provide a framework that also covers ethical questions associated with the use of genetically modified animals in research.

DEFINITIONS

In these guidelines, the term «research» must be understood broadly, and include planning, execution and dissemination. The guidelines primarily address the «researcher» but apply to any person involved when animals are used for research, including funding and approval bodies, which are also responsible for making ethical assessments of projects involving experiments on animals.

The guidelines cover «laboratory animals», as defined in the Regulations Relating to the Use of Animals in Research, but also cover all animals that are otherwise impacted by research activities.

GUIDELINES

1. Respect for animals' dignity

Researchers must have respect for animals' worth, regardless of their utility value, and for animals' interests as living, sentient creatures. Researchers must be respectful when choosing their topic and methods, and when disseminating their research. Researchers must provide care that is adapted to the needs of each laboratory animal.

2. Responsibility for considering options (Replace)

Researchers are responsible for studying whether there are alternatives to experiments on animals. Alternative options must be prioritised if the same knowledge can be acquired without using laboratory animals. If no good options are available, researchers should consider whether the research can be postponed until alternative methods have been developed. When justifying experiments on animals, researchers therefore must be able to account for the absence of options and the need to acquire knowledge immediately.

3. The principle of proportionality: responsibility for considering and balancing suffering and benefit

Researchers must consider the risk that laboratory animals experience pain and other suffering (see guideline 5) and assess them in relation to the value of the research for animals, people or the environment. Researchers are responsible for considering whether the experiment may result in improvements for animals, people or the environment. The possible benefits of the study must be considered, substantiated and specified in both the short and the long term. The responsibility also entails an obligation to consider the scientific quality of the experiments and whether the experiments will have relevant scientific benefits.

Suffering can only be caused to animals if this is counterbalanced by a substantial and probable benefit for animals, people or the environment.

There are many different methods for analysing harm and benefit. Research institutions should provide training on suitable models, and researchers are responsible for using such methods of analysis when planning experiments on animals.

4. Responsibility for considering reducing the number of animals (Reduce)

Researchers are responsible for considering whether it is possible to reduce the number of animals the experiment plans to use and must only include the number necessary to maintain the scientific quality of the experiments and the relevance of the results. This means, among other things, that researchers must conduct literature studies, consider alternative experiment designs and perform design calculations before beginning experiments.

5. Responsibility for minimising the risk of suffering and improving animal welfare (Refine)

Researchers are responsible for assessing the expected effect on laboratory animals. Researchers must minimise the risk of suffering and provide good animal welfare. Suffering includes pain, hunger, thirst, malnutrition, abnormal cold or heat, fear, stress, injury, illness and restrictions on the ability to behave normally/naturally.

A researcher's assessment of what is considered acceptable suffering should be based on the animals that suffer the most. If there are any doubts regarding perceived suffering, consideration of the animals must be the deciding factor.

Researchers must not only consider the direct suffering that may be endured during the experiment itself, but also the risk of suffering before and after the experiment, including trapping, labelling, anaesthetising, breeding, transportation, stabling and euthanising. This means that researchers must also take account of the need for periods of adaptation before and after the experiment.

6. Responsibility for maintaining biological diversity

Researchers are responsible for ensuring that the use of laboratory animals does not endanger biological diversity. This means that researchers must consider the consequences to the stock and to the ecosystem as a whole. The use of endangered and vulnerable species must be reduced to an absolute minimum. When there is credible, but uncertain, knowledge that the inclusion of animals in research or the use of certain methods may have ethically unacceptable consequences for the stock and the ecosystem as a whole, researchers must observe the precautionary principle.¹

7. Responsibility when intervening in a habitat

Researchers are responsible for reducing disruption and any impact on the natural behaviour of individual animals, including those that are not direct subjects of research, as well as of populations and their surroundings. Certain research and technology-related projects, like those regarding environmental technology and environmental surveillance, may impact on animals and their living conditions, for example as a result of installing radar masts, antennas or other measurement instruments. In such cases, researchers must seek to observe the principle of proportionality (see guideline 3) and minimise the possible negative impact.

8. Responsibility for openness and sharing of data and material

Researchers are responsible for ensuring that there is transparency about research findings and facilitating the sharing of data and material from experiments on animals. Such transparency and sharing are important in order to avoid unnecessary repetition of experiments. Transparency is also important in order to ensure that the public are informed and is part of researchers' responsibility for dissemination.

In general, the negative results of experiments on animals should be public knowledge. Disclosing negative results may give other researchers information about which experiments are not worth pursuing, shine a light on unfortunate research design, and help reduce the use of animals in research.

9. Requirement of expertise on animals

Researchers and other parties who handle live animals must have adequately updated and documented expertise on animals. This includes specific knowledge about the biology of the animal species in question, and a willingness and ability to take care of animals properly.

10. Requirement of due care

There are national laws and rules and international conventions and agreements regarding the use of laboratory animals, and both researchers and research managers must comply with these. Any person who plans to use animals in experiments must familiarise themselves with the current rules.

¹ *Guidelines for Research Ethics in Science and Technology (2016).*

References and useful resources

Directive 2010/63/EU of the European Parliament and of the Council of 22 September 2010 on the protection of animals used for scientific purposes. <http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:32010L0063>

Regulation on the capture and collection of wild animals for scientific or other special purposes (Forskrift om innfangning og innsamling av vilt for vitenskapelige eller andre særlige formål). 2003. <https://lovdata.no/dokument/SF/forskrift/2003-03-14-349>

Regulation on Animal Experimentation (Forskrift om bruk av dyr i forsøk). 2015. <https://lovdata.no/dokument/SF/forskrift/2015-06-18-761>

Act of 2 April 1993 No. 38 Relating to the Production and Use of Genetically Modified Organisms, etc. (Gene Technology Act)
(Lov om framstilling og bruk av genmodifiserte organismer m.m. 1993. <https://www.regjeringen.no/en/dokumenter/gene-technology-act/id173031/>

The Animal Welfare Act. 2009. <https://www.regjeringen.no/en/dokumenter/animal-welfare-act/id571188/>

The ARRIVE Guidelines (Animal Research: Reporting of In Vivo Experiments). 2010. <https://www.nc3rs.org.uk/sites/default/files/documents/Guidelines/NC3Rs%20ARRIVE%20Guidelines%202013.pdf>

The Norwegian Food Safety Authority's instructions on the management of the Regulation on Animal Experimentation (Mattilsynets instruks om forvaltningen av Forsøksdyrforskriften): https://www.mattilsynet.no/dyr_og_dyrehold/dyrevelferd/forsoksdyr/instruks_om_mattilsynets_forvaltning_av_forsoksdyrforskriften.21015/binary/Instruks%20om%20Mattilsynets%20forvaltning%20av%20forsoksdyrforskriften

The Norwegian National Committee for Research Ethics in Science and Technology (NENT). Guidelines for research ethics in science and technology (2007) 2016. Oslo.

PREPARE (Planning Research and Experimental Procedures on Animals: Recommendations for Excellence) guidelines- 2017. <https://norecopa.no/prepare>

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Ethical guidelines on the use of animals in research were developed by The Norwegian National Committee for Research Ethics in Science and Technology in 2018. The overarching framework of these guidelines is The Guidelines for Research Ethics in Science and Technology (2016). A consultation process and a subsequent workshop organised by NENT in the autumn 2016 found that relevant actors see the need for a set of guidelines that can systematise and elaborate the ethical responsibility inherent in the use of animals in research. These guidelines do not oppose, but supplement relevant legal regulations.

NENT is part of The Norwegian National Research Ethics Committees. The Committees are independent and advisory bodies in research ethics. The guidelines are a basic tool in this work.