UNIVERSITY OF COPENHAGEN
FACULTY OF HEALTH SCIENCES

Instructions to researchers about the use of animals in research

UCPH Animal Care and Use Programme
Department of Experimental Medicine

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Content

Roles and Responsibilities in the use of animals in research at AEM – The Copenhagen Animal Care and Use Programme

How to get started

If you have not used the Department's services or facilities before, you are advised to book a meeting with one of AEM's veterinarians for a discussion of your project and the necessary things to do before you can get started. To book a meeting, please send an e-mail to emed-vet@sund.ku.dk.

Concern for animal care or welfare

Concern regarding animal care or animal welfare in experiments can be directed to persons in AEM that are found at AEM's website www.emed.ku.dk , Animal Welfare and Ethics.

Accreditation of AEM

AEM (Copenhagen Animal Care and Use Program) is accredited by AAALAC International, a private, nonprofit organization that promotes the humane treatment of animals in science, and the quality of scientific projects using animals, through voluntary accreditation and assessment programs. The accreditation necessitates adherence to high standards and oversight by AEM also in laboratories and housing rooms outside AEM, where experimental animals are used or kept.

OLAW Assurance ID

This ID is relevant for certain research grant applications. OLAW stands for Office of Laboratory Animal Welfare of the US Public Health Service (PHS), NIH (National Institutes of Health). AEM's Legacy Assurance ID is F16-00203 (A5846-01).

Dyreforsøgstilsynet – the Danish Animal Experiments Inspectorate

The Inspectorate is the centralized Danish Competent Authority regarding the use of animals in research. The Inspectorate issues licenses and conducts inspections, which can be announced or unannounced. The AEM veterinarians have established good communication with the Inspectorate and assist researchers in questions related to licenses and inspections.

The Copenhagen Animal Care and Use Program

(Department of Experimental Medicine, Afdeling for Eksperimentel Medicin, AEM)
AEM is responsible for legal compliance relating to buildings, rooms, animal enclosures, environmental parameters, and animal husbandry and care.
AEM animal caretakers are responsible for the daily observation, care and husbandry of animals in these facilities, and AEM's veterinarians are responsible for the provision of veterinary oversight.

AEM is governed by the Programme Board and executes the policies and decisions decided by the Board, including pricing. AEM provides a range of animal housing environments to provide support for research projects.

Animal Welfare Committee (Dyrevelfærdsorgan DVO, Animal Welfare Body, Institutional Animal Care and Use Committee)

The Animal Welfare Committee is constituted under the Danish law (Bekendtgørelse om dyreforsøg) to ensure that the use of animals for research purposes conforms to the standards of the legislation. The role of the Committee is detailed in the law, including the duty to promote the principles of Replacement, Reduction and Refinement. The Committee provides input to policies and husbandry processes to the management team of the animal facility.

Ethical review of projects

In Denmark, the ethical review rests with the Danish Council for Animal Experimentation (Rådet for Dyreforsøg), and results in the issue of a license, which is specific with respect to project activities and limitations including adherence to humane endpoints. AEM does not

have legal authority to permit activities not included in the license.

AOD: Responsible person for compliance with animal experimentation legislation (Ansvarlig person for overholdelse af dyreforsøgsreglerne AOD)

The AOD is the person, who on behalf of AEM, is responsible for compliance with the law on animal experimentation and rules relating to this law. The Animal Experiments Inspectorate, Dyreforsøgstilsynet, interprets this to mean that AEM shares the responsibility for legal compliance during the experiment with the license-holder. The AOD in AEM is the Head of Department of AEM.

Basic division of responsibilities

AEM provides housing and care for animals and is responsible for this. Furthermore, AEM is overall responsible for compliance with Danish legislation including experimental activities.

Researchers perform research with animals and are responsible for matters relating to experiments. The responsibility is however, shared with the AOD (see above). Breeding of animals is comparable to experiments, meaning that researchers are also responsible for matters relating to breeding.

AEM veterinarians

AEM's veterinarians provide veterinary expertise and advice to researchers on matters relating to the care, use and welfare of animals, including specific advice prior to the preparation of applications for animal experimental licenses. The veterinarians also provide prescriptions for pharmaceutical drugs to be used in research projects. The veterinarians approve project plans prior to experiments and may also monitor projects in progress. The veterinarians have access to all animals in AEM and can intervene, including euthanasia, in projects where animal health or welfare, or major AEM rules or policies are compromised.
See www.emed.ku.dk, Services, Veterinary Advice for further information.

Technical assistance and veterinary assistance

Researchers can take advantage of the possibility to have technical procedures done by AEM's technicians who are all specially educated to work in laboratory animal sciences. Researchers can also request veterinary assistance. See www.emed.ku.dk, Services, Technical assistance for further information.

AEM policies and rules

AEM policies can be found at AEM's website www.emed.ku.dk About the Department, Policies and Regulations. Researchers are obliged to follow the policies and rules of AEM.

Caging of animals

Caging of animals is decided by AEM. Considerations include number, sex, and age of animals, type of experiment, and the need to establish and maintain a harmonious social group. Male mice may need to be housed singly because of conspecific aggression.

Biosecurity

AEM defines the biosecurity measures which are intended to protect the animals from infection and maintain a defined health status. Researchers are obliged to support these measures. This includes compliance with quarantine times, and the traffic of animals, persons, and materials between animal housing units. In the case where animals are housed outside AEM, researchers are obliged to implement routines to prevent the transfer of possible infection to AEM.

GMO microorganisms (GMO1 and GMO2)

Researchers must receive written instructions from AEM veterinarians as well as physical instructions from the animal caretakers at the relevant animal unit before they may commence the work with GMO1 or GMO2.

Written communication about important issues

Researchers must give important instructions to AEM staff as clear and unambiguous emails, which must be sent to function mailboxes, not personal mailboxes.

Occupational health

Researchers must inform AEM about the use of drugs, chemicals, micro-organisms, or radioactive substances, or

any other factors used in experiments that may pose a risk to persons. AEM decides the type and duration of necessary protective measures. Researchers are expected to follow AEM's guidelines and support efforts to prevent the spread of animal allergens to areas outside AEM.

Likewise, researchers are expected to contribute to a healthy psychological work environment, including polite and respectful communication with AEM employees.

Experiments

Researchers have personal responsibility for all matters related to the welfare of the animals they use. This responsibility begins when the animal is allocated to a project and ends with its fate at the completion of the project.

License-holders are responsible for ensuring that persons working on projects are qualified, both in general and for their specific tasks in the project. This may entail supervision for a period.

When the monitoring of animals is delegated by the researcher to someone else with appropriate technical expertise, for example by prior arrangement with an AEM technician, this does not remove the researcher's primary responsibility for the welfare of their animals.

Experimental license

Researchers apply for experimental license via the Danish Veterinary and Food administration's electronic AIRD system. The application can be written in Danish, Swedish or Norwegian. English is allowed in the technical part, "Beskriv type, art og forløb". The processing time is 40 working days starting from the day an adequate application has been received. The application is discussed by the Council for Animal Experimentation at a monthly meeting. Following the Council meeting, the license is issued. In practice the processing time can be several months.
https://dyreforsoegstilsynet.fvst.dk/Pages/default.aspx

Breeding

Researchers have personal responsibility for all matters related to the welfare of the animals they breed. This responsibility begins when the animal arrives in AEM and ends with its use in a research project or its fate in the breeding project. The researcher must write a breeding plan (se AEM project plan for breeding in this document) Breeding of mice is optimally done via rederivation to clean status into AEM´s breeding barrier (SPF 10.2 or 10.4). Tissue from earmarking is the standard sample for genotyping. For breeding of GMO animals, a license from the Danish animal experiments authority and a permit for GMO research project from the Danish work environment authority are required.

Registration of experiments and/or breeding with genetically modified animals or micro-organisms

Researchers must register their GMO work (breeding and/or experiments) with the Danish work environment authority, Work Environment in Denmark. Assistance is available from the faculty´s work environment consultants, Campus Service SUND.

Journal-keeping and reports to the authorities

License-holders are required by law to keep a detailed journal of experimental activities. The data must be submitted every year to the Animal Experiments Inspectorate. Researchers who kill GMO animals for cell, organ or tissue harvest must include these animals in the journal. Researchers who breed GMO and non-GMO animals must keep a record of the numbers of animals. The details are described in the law (Bekendtgørelse om dyreforsøg).

AEM project plans for experiments (P-plans)

The researcher must write project plans, which are internal work documents providing AEM with information about concrete experiments. The project plan should not be a copy of the license, but describe in concrete terms what the researcher plans to do with the animals in the individual experiment. The project plans are mailed to the AEM veterinarians for approval, and the researcher receives a P-number which must be put on the cage card of the animals. A researcher cannot order animals without an approved project plan. Ordering of animals must always be done via the animal caretakers. The researcher is responsible for the presence of a relevant and valid P

number on his or her cages. The P-number is valid for two calendar years, during which time it must be updated in case of changes in the experiment. After two years, a new plan must be forwarded for approval.
See www.emed.ku.dk, How to get started, Project plans for further information.

AEM project plans for breeding (A-plans)

AEM project plans for breeding are internal work documents providing AEM with information about breeding. The project plans are mailed to the AEM veterinarians for approval, and the researcher receives an A-number which must be put on the cage card of the animals. The researcher is responsible for the presence of a relevant and valid A number on his or her cages. . The A-number is valid for two calendar years, during which time it must be updated in case of changes in the experiment. After two years, a new plan must be forwarded for approval.
When animals are transferred from breeding to an experiment, the researcher is responsible for supplying the correct P-number and making sure it is present on the cage card.
See www.emed.ku.dk, How to get started, Project plans for further information.

Availability of researcher for contact

When an experiment is ongoing, there must be a researcher available for contact at all times including weekends and holidays, and AEM must be informed of their identity and contact information.

Observation of animals in experiments

The researcher is responsible for observations, actions, and information related to the experimental activities. Researchers must comply with the humane endpoints stated in the license, and observe animals accordingly.

Daily observations of animals

AEM animal caretakers perform daily observations, which are restricted to cage-side check of animals and the state of the cage, including the presence of feed and drinking water.

Survival surgery and surgical competencies

In order to ascertain that persons engaged in surgical procedures have the best prerequisite for surgical success AEM instructs researchers to complete one or more relevant courses before engaging in surgical activities. The department offers courses that covers basic principles of surgery as well as advanced surgical techniques and microsurgery. The courses are offered on a regular basis. A dispensation from the requirement to complete AEM's surgery course can be granted by AEM's veterinarians to veterinarians and medical doctors with documented surgical skills, researchers who have completed a similar course in experimental surgery, and researchers with surgical experience and where AEM's veterinarians, after evaluating the researcher's surgical skills, find these sufficient

Observation and treatment of animals after anaesthesia and surgery

The researcher is responsible for observing the animals until they are able to stand on their feet. Until the animal is able to stand, a person must be present at all times. The researcher is responsible for the provision of postoperative care including repeated administration of analgesia with appropriate intervals.

Procedure rooms and holding rooms

The animals in the holding rooms must have a quiet environment with as little disturbance as possible. Therefore, procedures may not be performed in holding rooms, but must occur in procedure rooms.

Animal experiments in laboratories outside AEM

In general, only terminal procedures are possible, as animals can only return to AEM by special agreement. Animals may only stay in the external laboratory for one working day. See www.emed.ku.dk, About the Department, Policies and Regulations, External Laboratories for details.
In those instances where there is an agreement with AEM that animals can be housed outside AEM, AEM's animal caretakers and veterinarians are still responsible for daily observation, care and veterinary oversight of the animals.

Restricted feeding and other deviations from standard husbandry

Researchers are responsible for ensuring that animals are properly cared for with respect to the deviation, and for displaying necessary information to AEM on the cages. AEM animal caretakers are instructed to correct deviations unless there is a clear agreement with AEM, which ensures that no animal can be deprived of care by mistake.

Education and training

According to Danish law, only persons who are educated or trained to the specifications in the law may have responsibility for projects or perform practical procedures on experimental animals. The Faculty offers several such courses. Please see www.emed.ku.dk, Courses for description and registration.
License-holders are responsible for ensuring that persons working on projects are qualified. The Danish Animal Experiments Inspectorate must be contacted regarding researchers coming from other countries. Students working on projects must be qualified to the same level as researchers.

AEM response times

Animal caretakers are instructed to read and respond to emails only once per day in order to work efficiently. Researchers can find details about response times for different types of inquiries at www.emed.ku.dk, About the Department, Policies and regulations, Response/processing time concerning various inquiries.

Pricing and billing

Principles for pricing are decided by the Programme Board. The price list can be found at www.emed.ku, Prices. Researchers will receive a monthly invoice.

Terms of business

AEM does not compensate users who suffer any losses in connection with the use of AEM's facilities and services. AEM is in no case responsible for operating losses, loss of profits, lost earnings or other indirect losses. Further details can be found at www.emed.ku, Prices, Terms of business.