

Policy on Animal Experiments

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1 Scope

This document describes the policy, vision and ambitions of Utrecht University (UU) and the University Medical Center Utrecht (UMC Utrecht) with regard to experiments on animals, the 3Rs (Replacement, Reduction and Refinement) and the transition to animal-free innovations. This policy document was written for both organisations by the Animal Welfare Body Utrecht (*Instantie voor Dierenwelzijn Utrecht*), has been endorsed by both organisations and accordingly applies to everyone in both organisations who is involved in animal experiments or works with laboratory animals.

2 Positioning

2.1 Utrecht University

UU offers world-class education and research aimed at giving young people an academic education, training academics and researchers, conducting innovative research and helping to find solutions to social and societal issues. At the time of writing this document, the main [research themes](#) are: Dynamics of Youth, Institutions for Open Societies, Life Sciences and Pathways to Sustainability. The [Life Sciences](#) theme makes the most use of laboratory animals, mainly in the fields of One Health, cancer, regenerative medicine and stem-cell research.

2.2 University Medical Center Utrecht

The UMC Utrecht has three core tasks: research, education and patient care. [Strategic themes in research](#) are Circulatory Health, Regenerative Medicine & Stem Cells, Cancer, Infection & Immunity, Brain, and Child Health. Laboratory animals are used for research and education. Research produces advances for individual patients and for society, or the fundamental scientific knowledge that underlies and enables these advances. The UMC Utrecht is strongly committed to connecting with patients and other stakeholders. In addition, the institute ensures that developments in knowledge and technology within these strategic areas are actually, and quickly, brought into practice. All these themes are guided by the principle of listening to society to identify where the needs are and what problems they involve. Animal experiments are also used to give medical specialists in training practice in using new techniques and technologies before they use them on humans.

2.3 Collaboration between UU and UMC Utrecht

The UMC Utrecht and UU collaborate in education and medical and biomedical research. These research tasks are carried out in the UMC Utrecht, under the UMC Utrecht's responsibility. The university's Science and Veterinary Medicine faculties work with the UMC Utrecht in various divisions of the Life Sciences such as regenerative medicine. Because UU and the UMC Utrecht work so closely together in education and research, the two institutions share a common policy for the use of laboratory animals and for encouraging and implementing animal-free methods. The AWB, set up jointly by the two organisations, is legally vested with supervising and advising on animal-experiment policy.

3 Mission and vision on animal experiments

The general vision, mission, core values and ambitions of [Utrecht University](#) and the [UMC](#) are reflected in the following shared vision, mission and ambition with regard to experiments on animals and animal-free research and education:

- We aspire to conduct **cutting-edge research and provide top-quality education** benefitting human and animal health and welfare, maintaining our core values of **conscientiousness, integrity and openness** in our work. These aspects are given special focus in our educational curriculum, continuing education and training (LifeLong Learning or LLL) for staff, evaluations of project proposals and internal quality-improvement programmes, in appropriate and innovative ways.
- We see that using laboratory animals is still unavoidable for some research questions. However, we feel that we must continue to be **critical** in examining the rationale and quality of this research. We recognise **the intrinsic value of the animal and the 3Rs** (Russell & Burch 1959) as basic principles whenever laboratory animals are being used. In doing so, we make sustained efforts to increase the reliability of animal experiments, limit the animals used to a responsible minimum, and to optimally safeguard and improve the animals' welfare within the given context.
- Responsibly designing and conducting animal experiments is formally and legally the responsibility of the establishment licence holders. However, our daily operations require the full efforts of **everyone involved in the chain**, that is, the researchers, instructors, animal technicians, animal caretakers, AWB and management. We aim to provide a safe and open working environment in which everyone involved takes responsibility and can address others as to their responsibilities.
- The aim of our policy is to **develop and apply innovative animal-free methods** whenever possible. It is reflected in an infrastructure that encourages people to take this direction, innovative educational activities, professorships in line with policies, and an active involvement in national and international operations in this area.
- We strive to be as **open** as possible, both about the research and education in which animals are used, and about the dilemmas and considerations underlying them.
- We aim to play a **leading role** in each of these areas: **responsible use of laboratory animals** when they still must be used, the **transition to animal-free innovation** and **openness**.

Of course our work also complies with the legislation, internal and external codes of behaviour, and regulations relevant for this area of policy.

The following sections describe how we give form to the above principles in our policy and operations.

4 3Rs and Transition to animal-free innovation

Collaboration between parties within and outside our own institutes helps us to fulfil and propagate our ambitions in the 3Rs and the transition to animal-free innovations.

4.1 TPI Utrecht

Wherever possible, we aim to develop and apply innovative animal-free research and educational methods. To give these aims structural and coordinated substance, we and the Hogeschool Utrecht (HU) have established the Transition to Animal-free Innovations Utrecht ([TPI Utrecht](#)) working group. The group consists of representatives from Life Sciences. TPI Utrecht promotes innovations, collaboration across disciplines, positive discussion and looking beyond traditional boundaries. The guiding principle is that everyone in the biomedical field is striving for excellence.

The working group makes recommendations to managers about such matters as developing relevant professorships, educational activities, facilities and infrastructure that align with these ambitions. TPI Utrecht also provides practical support to researchers and instructors. There is a [helpdesk](#) to facilitate contact with experts. The group also organises ‘Helpathons’, sessions in which participants from different disciplines come together to search for animal-free answers to a particular scientific question. TPI Utrecht also helps to promote and continue developing existing animal-free methods, using the expertise available from the various [Life Sciences hubs](#).

Within its own establishments, TPI Utrecht explicitly engages in dialogue with all research groups in (or related to) the Life Sciences. Whenever possible there is collaboration with similar initiatives by other academic institutions and with the Netherlands Ministry of Agriculture’s [national TPI programme](#).

4.2 U-AIM

The Utrecht Advanced In Vitro Models Hub ([U-AIM](#)) aims to replace animal experiments by developing, applying and marketing animal-free models. To achieve this, the U-AIM brings together scientists, students, policy makers and industry. Among those involved in this network are UU, UMC Utrecht, HU, RIVM, TNO, Proefdiervrij and patients’ organisations. The group has five main areas of focus: education and knowledge sharing, marketing & entrepreneurship, research & development, applicability and predictability, and management & support.

4.3 3Rs Centre

The 3Rs Centre is a subsidiary of the AWB and promotes the development, application and adoption of methods that can Replace, Reduce and/or Refine (the 3Rs) the use of laboratory (and other) animals in education and research. The Centre’s work includes providing information, giving recommendations, bringing researchers together and initiating interdisciplinary and other types of mono- or interdisciplinary activities that help to implement the 3Rs and/or animal-free research and educational models. The centre publishes a monthly newsletter, manages the [Interspecies Database](#), the [Humane Endpoints website](#) and the [FCS-free Database](#), and participates in teaching Laboratory Animal Science education and the use of animal-free methods. The centre is an active participant in the European network of 3Rs centres.

4.4 3Rs Stimulus Fund

The UU and UMC Utrecht have jointly established the 3Rs Stimulus fund, with which we support small-scale research on possible ways to Replace, Reduce or Refine (3Rs) the use of laboratory

animals. The Fund also encourages sharing ideas and knowledge about and experience with 3Rs models. Small-scale research can sometimes be the stepping stone to applying for a larger grant from external funding bodies. Project proposals can be submitted by researchers, animal technicians and students at UU or UMC Utrecht.

5 LifeLong Learning

Working in research that involves animal experiments requires professionalism. Having the proper education and training, and thus the right knowledge and skills to choose models and use laboratory animals responsibly, is an absolute prerequisite.

The Netherlands' Experiments on Animals Act (*Wet op de dierproeven*, hereafter 'the Act') states that only people who are qualified and competent to do so may design and conduct an animal experiment, unless they have an exemption for a particular competency, or are working to acquire a particular competency under direct supervision of someone who is qualified and competent.

5.1 Qualified and competent

The LifeLong Learning (LLL) policy document and its implementation regulations describe the procedures and requirements that must be complied with by everyone who works with laboratory animals. This provides guidance for these people and their supervisors in setting up systems for continuing professional development. The core idea is that everyone has a personal LLL portfolio.

In accordance with the law, we have appointed a 'competence officer' (CO), a position within the AWB. The CO sees to it that anyone working with animals continues to be educated, and is supervised until they have proven the required competency, and that they have the necessary education and competence for the animal experiments they are involved with. The CO is aware of and publicises the opportunities to take appropriate training and refresher courses, in particular about 3Rs-related subjects and scientific validity.

5.2 Continuing education and training

'Utrecht' has a history as an international leader in education aimed at responsible use of laboratory animals and applying the 3Rs, and we intend to keep playing this leading role in the future as well. This ambition, our obligations arising from the Act and current developments in animal-free innovation compel us to continue working on an innovative and forward-looking LLL programme for people involved with designing and conducting animal experiments and animal-free methods. LifeLong Learning is the standard.

On a structural basis, we allow our staff to take the courses necessary to enable them to responsibly complete their work tasks, and that are in line with their own ambitions. In addition, we encourage exchanges of knowledge and experience, both within our institutes and nationally and internationally, for instance through the professional associations [\(Dutch\) DALAS](#) and [FELASA](#).

We encourage employees who are responsible for their department's qualification and competency system to be actively involved in national and international activities in this area. An overview of the

educational and training opportunities in animal experiments and animal-free methods can be found on the AWB website.

6 Openness and responsibility

We strive for the greatest possible transparency about the animal experiments that we carry out, as well as about our efforts to implement the 3Rs and to use animal-free methods more and more. As part of these efforts, we aim to share information with other scientists and with the public. The foundation underlying this is in the Animal Experiments Openness Code, drawn up in 2008 by (then) the Association of Universities in the Netherlands (VSNU, now *Universities of the Netherlands*), the Royal Netherlands Academy of Arts and Sciences (KNAW) and the Netherlands Federation of University Medical Centres (NFU). However, in several areas we go further than merely complying with this code, aiming to actively contribute to the dialogue about animal experiments and the transition to animal-free methods. An open conversation with the greater public encourages others to take a critical attitude and encourages us to keep searching for animal-free methods. We use a wide range of instruments, described in the following sections, to sustain this openness.

6.1 Open Science

We feel that [Open Science](#) is extremely important, and we have started the Open Science programme and an [Open Science community](#), aimed at encouraging and facilitating researchers in putting Open Science into practice. Open Science encourages accountability, reproducibility, integrity and openness in scientific research.

To add some focus, the Open Science programme was designed around four subjects: Open access, FAIR data and software (Findable, Accessible, Interoperable and Reusable), Public engagement and Recognition and Rewards. One of the goals is for 100% of our publications to be published as open-access.

Open Science is of paramount importance for an area like animal experiments and animal-free methods. This is why we systematically organise activities that raise awareness of its importance and of its instruments, both within and outside the educational world. One of our activities is promoting the use of PREPARE and ARRIVE guidelines, preregistration of experiments and publishing negative results through various channels (see 7.2).

6.2 Websites, newsletters and social media

The AWB has a comprehensive website providing information about animal experiments and the 3Rs. The website supports all UU and UMC Utrecht employees involved in animal experiments, as well as providing information to outsiders. It contains information about such matters as administrative procedures, forms, legislation and regulations, guidelines, best practices, current events, annual reports, internal policy and new developments in the 3Rs. Various parts of the UU website have information about animal experiments and animal-free methods.

Researchers are also kept up to date about relevant developments in animal experiments and animal-free methods by newsletters from (among others) the AWB, the 3Rs Centre and Utrecht Life Sciences.

We are proactive in using various social media such as LinkedIn, Twitter and YouTube, and occasionally Instagram and Facebook. The AWB has its own YouTube channel with videos about animal experiments and related subjects. We also add our videos to the offerings on the nation-wide website tpi.tv.

6.3 Annual reports and licences for animal experiments

We post registration data on the AWB website about numbers of animal experiments, information which we are legally required to submit to the Netherlands' Food and Consumer Product Safety Authority (NVWA) every year. Since 2010, we have published an Annual Report on Animal Experiments. All annual reports can be found on the websites of the [AWB](#) and [UU](#).

In the name of openness as well as efficiency, since 2017 the AWB website has also provided the following documentation from all project licences issued to UU and UMC Utrecht by the Central Authority for Scientific Procedures on Animals (*Centrale Commissie Dierproeven* or CCD): the complete project proposal, the recommendations from the Animal Ethics Committee (*Dierexperimentencommissie* or DEC), the licence and any correspondence between researchers and the DEC or CCD. Before this information is made public, the researchers involved are informed of measures they can take to protect their privacy and intellectual property rights. We adhere to the principles of the [Open Government Act \(*Wet open overheid* or Woo\)](#).

6.4 Contact with media and other stakeholders

In principle we are happy to answer questions from the media or comply with their requests to view animal facilities, and the AWB is generally the first point of contact. We also offer various kinds of help to researchers speaking with the media, including media training and personal support. We also actively seek contact with the media through press releases and reports in the UU's biweekly news update sent out to journalists. The spokespersons of relevant organisational divisions of UU and UMC Utrecht have a network, in which everyone keeps each other informed and up to date about current internal developments in animal experiments and animal-free methods, and interest in them from and in the media.

Besides contact with the media, we also maintain frequent contact with interested members of the public. On request and by invitation, we organise guided tours of the various animal facilities and research divisions for groups from UU/UMC and outside, where we encourage visitors to exchange ideas with the staff. We also enter into direct dialogue, both solicited and unsolicited, with animal-protection organisations several times a year. Every year, we take part in the '*Weekend van de Wetenschap*' (Science Weekend) with a game that makes children and those accompanying them think more about the dilemmas around animal experiments.

7 Culture of Care

When there is no alternative to using animals in research, we take our responsibility to ensure their optimal welfare seriously. This responsibility goes beyond simply carrying out experimental procedures in as 'refined' a way as possible; it covers the animal's entire lifespan, touching on a multiplicity of facets that can affect its life. We strive to create a culture in which all parties involved take responsibility for animal welfare, scientific integrity and respect for legal boundaries. Openness, trust and safety are core concepts of this culture, which we promote to our employees, our organisations and to society at large.

We consider the legal framework and codes of behaviour as the bare minimum, and in both animal welfare and scientific excellence we strive to go beyond this minimum. Agreements about these efforts are laid down in [internal policy guidelines](#) and disseminated to all those involved. The internal policy is written by the AWB and approved by both licence holders. Depending on the subject, staff from the laboratory animal facilities and/or research divisions may also be involved in drawing up policy. Twenty employees are in the Sounding Board group, which regularly provides the employees' perspective on matters of communications and policy.

The policy document [Tasks and responsibilities in the animal-experiment chain](#) describes the tasks and responsibilities of all people and parties who play a part in animal experiments. It lists the tasks that are legally required and those that are not required but desirable, creating clarity for all those involved and serving as a frame of reference.

7.1 Ethical considerations

Before any research or educational activity involving animals can take place, there is an ethical consideration, in which the following bodies are involved:

- **CCD:** If the activity fits the legal definition of an animal experiment, the CCD conducts a formal ethical and scientific review, taking into consideration the DEC's advice.
- **DEC Utrecht:** Although set up by the establishment licence holders UMC Utrecht and Utrecht University, the DEC operates from an independent position. It is accredited by the CCD on the basis of article 18a, section 1 of the Experiments on Animals Act. At the CCD's request, the DEC conducts an ethical review of a project for which the CCD has received an application for a licence. The DEC will then make a recommendation either in favour of or against issuing a licence. The committee prevents unnecessary animal experiments, promotes laboratory-animal welfare and suggests alternatives. Dilemmas that are identified are raised with CCD. In conformance with the Act, the AWB's animal-welfare officers are advisors to the DEC.
- **AWB:** On behalf of establishment licence holders UMC Utrecht and UU, the AWB monitors the laboratory animals' welfare, the quality of research and education, and compliance with the law. It provides solicited and unsolicited advice to all parties involved in the chain. The AWB's [quality improvement policy](#) states in a transparent way how the AWB fleshes out its tasks. If there has been any deviation from the agreements, whether set out in policy or in laws or regulations, the AWB discusses the infringement with those directly involved and management, and documents the reasons for the deviation. If necessary, corrective measures are taken.

- **Other experts:** The content of projects and the design of experiments in the work protocols they require is determined by researchers who are qualified and competent to do so. The quality of both animal welfare and research itself in the experiments is internally ensured by the AWB. The body works with the researchers to maximise the quality and validity of the proposed experiments and to make the most of opportunities for replacement, reduction and refinement. At the project level, it incorporates the advice of an expert on alternatives, a peer reviewer, a pathologist and a communications consultant. At the work-protocol level, the AWB incorporates the advice of a statistician, a veterinarian, animal technicians, animal caretakers and a biological safety officer.
- **AWBs of other licence holders:** If studies being conducted at one of our facilities fall under the responsibility of another licence holder, or vice versa, the AWB Utrecht and the AWB of that licence holder jointly ensure beforehand that the project is ethically sound, and that any other due diligence requirements regarding research quality and animal welfare have been met.

If the use of animals is for a purpose other than an animal experiment as defined by the Animal Experiments Act, or if the experiment is covered by one of the exceptions listed in Art. 1 of the Act, the AWB will check to ensure that all due diligence requirements with regard to quality and welfare have been met. These exemptions include the breeding of laboratory animals, education or research with laboratory (or other) animals which does not constitute an animal experiment under the Act, and trialling a new medicine on animal patients from the Veterinary Medicine faculty. If necessary, the AWB will take into account recommendations from the Medicines Evaluation Board.

We do not carry out research for third parties under our own project licences unless the parties are collaborating with one of our institutes.

7.2 Scientific excellence

A systematic review of relevant literature, also known as a **Synthesis of Evidence**, before an animal experiment is carried out, helps to ensure the excellence and useability of the results it produces. We agree on the importance of systematic reviews, and encourage and facilitate young researchers in particular to do a systematic review (or have one done) and to train themselves to do them. We regularly hold workshops on this subject and refer researchers to workshops given elsewhere.

As co-initiators, we continue to be actively involved with preclinicaltrials.eu. The idea is that researchers **register their animal experiments in advance** in it, so that animal experiments that have not, or not yet, resulted in a full or partial publication will nevertheless be accessible. This helps reduce publication bias and reporting bias, and makes data exchange possible. It also helps to avoid unnecessary repetitions of animal experiments, and will improve the research results and promote collaboration. We endorse these objectives and support the platform, and we encourage our researchers to register their research beforehand.

We aim to have animal experiments meet the **PREPARE** guidelines for good design and preparation, and we actively disseminate these guidelines. We also strive to ensure that scientific publications comply with the **ARRIVE** guidelines, which ensure that studies are described in enough detail to make a worthy contribution to science. In addition, we encourage the publication of negative data.

7.3 Purchasing and breeding laboratory animals

We stress that the laboratory animals' quality and welfare affects the quality of the research. Our policy with regard to [purchasing and breeding laboratory animals](#) ensures quality and welfare of purchased laboratory animals or those bred in-house, as well as animals bred for us by accredited breeders. The main points of this policy pertain to ensuring the quality of breeders, optimally matching supply with demand for animals, and keeping unique breeding lines for science and society.

We are a member of Animal Supplier Audit Partners, a consortium of institutes that carry out audits of accredited breeders and other companies that supply essential materials such as animal feeds.

7.4 Ensuring animal welfare

The housing and care of laboratory animals at our facilities meets the legal standards and is regularly evaluated. In this way we ensure as much as possible that the animals' physiological and ethological needs are being met and that new developments in this field are put to use. When medical or scientific grounds necessitate single housing of animals, our internal policies ensure that its impact on the animals' welfare is as negligible as possible.

In handling animals, our aim is for the procedure to have a minimal impact on the animal. We do this by:

1. implementing national and international guidelines and Codes of Practice about refining procedures,
2. sharing new knowledge and insights about refining procedures with all parties involved; this includes training people who will be working with laboratory animals in the future,
3. if necessary, promoting and supporting pilot studies of the impacts of refined procedures on animal models,
4. bringing researchers and experts together to exchange information,
5. seeing to it that employees are competent to conduct animal experiments with as little discomfort as possible for the animals (3Rs).

All laboratory animals are checked daily by a qualified and competent animal caretaker. What action to take in the event of expected or unexpected suffering has been discussed beforehand and laid down in internal procedures, which also ensures action or reaction from veterinarians, AWB and researchers. Using various kinds of audits, we test whether the internal procedures have been adequately set up. Our [quality improvement policy](#) describes how we do this in more detail.

Any incidents and shortcomings in ensuring quality and animal welfare discovered during procedures audits are recorded centrally, as is follow-up action taken. If necessary, we adjust procedures and tighten policy, so that we can ensure that animal experiments at UU and UMC Utrecht are conducted in accordance with best practices.

7.5 Evaluation of the animal experiment and recording data

We record the data about animal experiments at several levels.

- **Welfare evaluation:** done after every study, this gives an idea of unexpected events or deviations in the experiments. This helps us to better plan any future studies based on these results.

- **Annual report:** This information, which we must provide for national and European annual figures, gives an idea of the total number of animal experiments conducted in our institutes. We share this data on the websites of UU and the AWB. We also seize this opportunity to also publish information about re-homing ex-laboratory animals and developments in alternative educational and research methods.
- **Retrospective evaluation:** we provide this information after a project has been completed, for experiments in which animals experienced severe discomfort or if the CCD finds it necessary to evaluate a project for other reasons. We also share this information on our website.

The guiding principle is that all results of animal experiments are documented in a way that is accessible to other researchers (open source/access publications, data repositories, presentations).

7.6 Best use of the animals

Our policy aims to use laboratory animals as efficiently as possible. We therefore encourage the reuse of animals and tissues, insofar as the law permits.

- Since 2021, we have encouraged reuse by providing an online internal platform which matches supply and demand for laboratory animals and animal tissues (fresh and preserved) in an easily manageable format. We envisage providing this platform ([ATEX](#)) at national level in the next few years, so that more people can repurpose and reuse more animals.
- If animals must be killed, it is done humanely.
- Animals not killed or reused for another experiment, and who are suitable for re-homing, are put up for adoption.

The requirements for making the best use of laboratory animals and tissues have been laid down in the policy on [Surplus laboratory animals, reuse and rehoming](#). We conduct audits at the professional shelters housing rehomed laboratory animals, and ask for feedback from private shelters using surveys.

7.7 Comprehensive audits and inspections

Our institutes are regularly inspected by the NVWA which, on behalf of the minister, supervises compliance with the Animal Experiments Act. On request, inspection reports are made public by the NVWA. We are also open to internal and external audits and inspections by other stakeholders, in the following ways:

- One of our animal facilities, the Central Laboratory Animal Research Facility (CLARF) has a 9001 accreditation from the ISO, as well as from [AAALAC international](#), both of them internationally recognised organisations for voluntary accreditation and assessment. ISO 9001 focuses on quality management, AAALAC on animal welfare and occupational safety. If possible, we incorporate any suggestions for improvement from these organisations in our other facilities. Our veterinary education programme has international accreditations from the American Veterinary Medical Association (AVMA), the Accreditation Organisation of the Netherlands and Flanders (NVAO) and the European Association of Establishments for Veterinary Education (EAEVE). The Laboratory Animal Science course, as well as the related species-specific courses, are accredited in accordance with [FELASA](#).

- In 2021 we participated in, and helped evaluate, a pilot by the Beyond Animal Testing Index (BATI). BATI is a transparent, objective and independent benchmark that provides insight into opportunities for improvement in animal-free initiatives and refining existing animal experiments.
- The AWB Utrecht is involved as an initiator in a peer-to-peer audit programme for AWBs in the Netherlands. AWBs act as a mirror for each other and exchange best practices.

8 Professionalism

We value integrity and professionalism in our staff and students. This also takes the form of professional responsibility for animal welfare and scientific integrity of research involving experiments on animals. If staff, students or interns encounter situations which they feel do not meet these standards, and do not feel heard when they attempt to discuss their concerns with people immediately around them, they can turn to one of the confidential advisors at UU or the UMC Utrecht or the [‘Professional Behaviour and Animal Welfare Help Desk’](#), depending on the nature of the situation.

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