

## Application to the Ethics Committee

Research on and with animals

### Guidance on the distinction between “Research on and with Animals” and “Animal Testing”

#### Overview

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According to § 13b of the BOKU Statutes, the Ethics Committee does not accept applications for research projects on or with animals for which an application for animal testing must be submitted. Therefore, for research projects involving animals, the applicant must clarify – before submitting an application to the Ethics Committee – whether the project constitutes animal testing as defined by the Animal Testing Act (TVG 2012). There are four possible cases:

1. The criteria for animal testing *clearly do not apply* because § 1 para. 2 TVG 2012 clearly applies to the research application (see point A on the next page). This must be clearly justified in the application.
2. The criteria for animal testing according to § 2 item 1 TVG 2012 (see below) *do not apply*. This is clearly justified and explained in detail in the application to the Ethics Committee with reference to points B and C (see next page).
3. If there is any doubt as to whether an activity constitutes animal testing under the TVG, a statement must be obtained from the Office of the Federal Ministry of Education, Science and Research (BMBWF) responsible for animal testing (see contact details on page 3). If the BMBWF Office determines that it is not animal testing, this proof must be attached to the application submitted to the Ethics Committee.
4. If the research involves animal testing, the Ethics Committee is not responsible.

#### What is animal testing?

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Animal testing under § 2 item 1 TVG 2012 is any use of animals for experimental, educational, or other scientific purposes (“principle of purpose limitation”, see explanations to § 1 TVG 2012) with a known or unknown outcome that:

- a) may cause the animals pain, suffering, fear, or permanent damage to an extent equivalent to or greater than that caused by a needle prick according to good veterinary practice; or
- b) is intended to or may result in an animal being born or hatched in a condition referred to in lit. a; or
- c) is intended to or may result in a genetically modified animal line being created and maintained in a condition referred to in lit. a.

This definition of animal testing allows for some room for interpretation, and the assessment always depends on the specific circumstances of the individual case. Note that there is no official catalog of investigative methods that do not constitute animal testing within the definition of the TVG 2012.

## Guidance on how to distinguish research on and with animals

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To assist applicants in assessing their research projects:

- A. reference is made to practices that are not subject to the TVG,
- B. examples of research on and with animals classified as animal testing of “mild” severity by the BMBWF are listed, and
- C. additional aspects such as the principle of purpose limitation and possible relevant differences between wild animals and domesticated animals are pointed out.

### A) What is not subject to the TVG?

The TVG applies solely to living vertebrates and cephalopods (§ 1 para. 1 TVG 2012). Therefore, experiments with invertebrates, for example, are not subject to the TVG.

Pursuant to its § 1 para. 2, the TVG 2012 does not apply to:

1. non-experimental agricultural practices
2. non-experimental veterinary clinical practices
3. practices applied for recognized purposes of animal husbandry
4. practices primarily applied for the identification of animals
5. practices where it is not expected that they will cause pain, suffering, fear, or permanent damage equivalent to or exceeding that of a needle prick according to good veterinary practice, and
6. animals according to § 1 para. 1 TVG 2012, that have been released or privately housed under the provisions of § 10 TVG 2012.

The killing of animals solely for the purpose of using their tissues or organs is not animal testing (§ 2 item 1 TVG 2012).

### B) Examples of Classification as “Mild” Severity

The BMBWF has published “Examples for the Classification of Severities” ([full list in German available on the BMBWF website](#)). Here, some examples of investigative methods from submitted research applications which have been classified as “mild” severity animal testing:

- application of external telemetry devices that only slightly affect the animals or restrict normal activities and behavior only slightly
- administration of substances via subcutaneous, intramuscular, intraperitoneal routes, with a gastric tube, or intravenously into superficial blood vessels, where the substance has only a minor effect on the animal and the volume is adapted to the species and size of the animal
- feeding with modified food that does not cover the entire nutritional needs of the animal and is expected to cause minor clinical abnormalities during the study period
- short-term (less than 24 hours) confinement in metabolic cages
- studies where the animal is temporarily separated from its social partners; short-term housing of adult rats or mice of socially living breeds in individual cages
- models where animals are exposed to harmful stimuli that briefly cause mild pain, suffering, or fear, which the animals can successfully avoid
- a combination or accumulation of the following investigative methods: assessment of body composition through non-invasive measures and minimal restriction; monitoring ECG with non-invasive methods that cause minimal or no impairment in acclimated animals; application of external telemetry devices that do not affect socially adapted animals and do not restrict normal activities and behavior; breeding of genetically modified animals where no clinically detectable adverse phenotype is expected; addition of inert markers to the food to trace its path through the digestive tract; food deprivation for a maximum of 24 h in adult rats; open field test.

### C) Additional aspects to consider

It should also be taken into consideration:

- When assessing whether an activity constitutes animal testing, the main criterion is the purpose for which an animal is used (“principle of purpose limitation”, see explanations to TVG Art 1 § 1 “Subject”).
- Stress or fear caused to wild animals (or even feral domesticated animals) solely through capture and/or restraint are not comparable to the stress caused to domesticated animals or animals living in captivity. How this affects the research project submitted to the Ethics Committee must be assessed and explained on a case-by-case basis. It is possible that the same procedure may be unproblematic for domesticated animals but for wild animals lead to a research application being classified as an animal testing requiring legal approval.

## Further Information

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### Federal Ministry of Education, Science and Research

Attn. Dr.<sup>in</sup> Silvia Bader  
[tierversuche@bmbwf.gv.at](mailto:tierversuche@bmbwf.gv.at)

### Legal bases, explanations, forms etc.

[www.bmbwf.gv.at/Themen/Forschung/Forschung-in-Österreich/Services/TierV.html](http://www.bmbwf.gv.at/Themen/Forschung/Forschung-in-Österreich/Services/TierV.html)

### BOKU Animal Welfare Committee (Tierschutzgremium)

[tierschutzgremium@boku.ac.at](mailto:tierschutzgremium@boku.ac.at); <https://boku.ac.at/tierschutzgremium>

The Tierschutzgremium advises on the well-being of animals regarding their acquisition, housing, care, and use. It can assist in the preliminary assessment of whether an activity qualifies as an animal experiment or not. For detailed information on conducting animal testing at BOKU, please refer to the website of the Tierschutzgremium (after login).