

# Good Scientific Practice

## Ethics in Science and Research

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Decided by the Rectorate on 13 November 2013 pursuant to the draft of the Ethics and Animal Welfare Committee (ETK) of the University of Veterinary Medicine, Vienna.

## Foreword

The following guidelines were first agreed upon in 2005, then reworked in 2013 and brought into alignment with the Animal Experiments Act 2012 (TVG 2012). Based on "Good Scientific Practice. Ethics in Science und Research"<sup>1</sup> published by the erstwhile medical school of the University of Vienna, the original version was modified in consideration of the specific requirements of the University of Veterinary Medicine, Vienna. Anyone affiliated with the University of Veterinary Medicine, Vienna is obliged to adhere to the precepts of Good Scientific Practice.

## Preamble

The University of Veterinary Medicine, Vienna is committed to complying with the most rigorous requirements of scientific ethics. This includes striving to establish what is true, accuracy and honesty with regard to data and publication, reliability, the unfettered exchange of ideas and opinions, as well as the handling of animals in conformance with animal welfare standards and with the greatest possible sparing of the animals used for scientific purposes<sup>2</sup>. The following guidelines serve to preserve these values within the applicable legal framework in the context of an increasingly complex research setting and competitive financial environment.

## Objectives

1. Establishment of generally applicable and binding guidelines for people affiliated with the University of Veterinary Medicine, Vienna (Section 1);
2. Establishment of the procedures to be followed in cases of suspected misconduct (Section 2);
3. Establishment of evaluation mechanisms as regards quality management (Section 3).

Currently applicable legal specifications pertaining to the areas covered by these guidelines shall remain in force.

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<sup>1</sup> These guidelines were developed by the Strategic Planning working group (subgroup Scientific Ethics) between 1999 and 2001 and agreed to on 12 October 2001 by the faculty council of the University of Vienna Medical School. In the meantime, a new version of the GSP guidelines of the Medical University of Vienna has been brought out.

<sup>2</sup> Similar to the core provisions of the Animal Protection Act (§§ 1 through 6 and also § 32) the guidelines for GSP pertain to all animals.

# Implementation

These guidelines are binding for anyone affiliated with the University of Veterinary Medicine, Vienna.

# 1. Guidelines

## 1.1. General Information

- The guidelines for proper conduct in a scientific area apply to all scientific work, the execution, documentation and publication thereof.
- The University of Veterinary Medicine, Vienna fosters innovative, high quality scientific research that is supported by teamwork. Project- or goal-oriented teams are—inasmuch as required—multidisciplinary, in order to leverage the intellectual expertise and material resources of various specialty fields and departments.
- Teamwork serves to leverage existing expertise, and also to guide and integrate the next generation of scientists. The guidance and education of scientific progeny should be given priority in terms of the overall responsibilities of experienced scientists. Every project must be assigned to a project leader named as the responsible party. This project leader bears responsibility for the integrity of the project.
- Within the framework of the research, the project leader takes an active role in directing and monitoring newer scientific talent, and, for projects that are executed under his/her direction by both academic and non-academic staff, has primary responsibility for the experimental design; data acquisition, analysis and documentation; the selection of methods of statistical analysis; drafting of manuscripts; scientific publications and for the observance of the guidelines for ethically appropriate conduct.
- Research freedom is a basic principle. When utilizing an institution's resources (staff, instruments, funds), researchers are required to get approval from the department head. Should approval be withheld, an appeal may be made to University leadership.
- The University of Veterinary Medicine, Vienna considers clinical research on patients to be an indispensable element for the advancement of medicine with benefits for animals as well as humans. Should animals be involved in scientific investigations, the University of Veterinary Medicine, Vienna ensures that the animal owner (patient owner) is adequately informed about any planned procedures and that the animal owner has verifiably given his/her consent (“informed consent”).
- Founded based upon the University Act of 2002 the Ethics and Animal Welfare Committee (Ethik- und Tierschutzkommission—ETK) of the University of Veterinary Medicine, Vienna was established in 2005. The ETK reviews all animal experiments planned by anyone affiliated with the University and advises them as regards any matters pertaining to living animals (cf. § 1 of the ETK Rules of Procedure<sup>3</sup>). With additional members in its expanded form, the ETK takes on a

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<sup>3</sup> ETK Rules of Procedure (version dated 15 October 2013) (GO).

role of animal welfare council in accordance with § 21 of the Animal Experiments Act 2012<sup>4</sup> (cf. § 1, subparagraph 2 of the ETK Rules of Procedure). With regard to projects that extend to human medical questions, the ETK cooperates with the Ethics Commission of the Medical University of Vienna (cf. Standard Operating Procedures of the ETK<sup>5</sup>).

- In 2012 the University of Veterinary Medicine, Vienna created a role for a person charged with responsibility for the keeping of animals. In the framework of an internal audit and based on the principles of Good Scientific Practice as well as the Code of Conduct for Animal Welfare<sup>6</sup>, the person assigned to this role serves as an internal, independent and objective advisor and auditor for matters concerning the keeping of animals and animal welfare (§ 1 subparagraph 2 and § 2 subparagraph 2 of the audit rules of the University of Veterinary Medicine, Vienna<sup>7</sup>).
- As regards research and teaching and any activities in the clinical area, all persons affiliated with the University of Veterinary Medicine, Vienna are expected to adhere to the directives stipulated in the Code of Conduct for Animal Welfare.

## **1.2. Execution of a scientific project: Contents of a project plan**

### **1.2.1. General information**

Every scientific project must be documented by means of a project plan. This plan must be drawn up prior to commencing work on the project and must be stored at the project site (ideally in a documents centre) so that it is accessible to all members of the project team.

If a project proposes to use live animals, the following procedure must be followed:

- The completed project plan (cf. 1.2.2) together with the application form of the Ethics and Animal Welfare Committee (ETK) must be submitted to the University of Veterinary Medicine, Vienna by way of the Rectorate. The ETK does a preliminary evaluation of the project plan and lends its support in clarifying open questions.
- The ETK may return a project plan due to insufficient scientific quality or insufficient justification (in terms of a harm-benefit analysis) or it may give its approval for the undertaking. A project plan that has been returned may be modified and resubmitted to the ETK.

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<sup>4</sup> Federal law on live animal experiments ( Animal Experiments Act 2012 – TVG 2012), Federal Law Gazette I No. 114/2012 of 28 December 2012, Art. 1.

<sup>5</sup> Standard Operating Procedure (SOP) for the working methods of the Ethics and Animal Welfare Committee (ETK) of the University of Veterinary Medicine, Vienna (version dated 11 July 2012).

<sup>6</sup> Code of Conduct for Animal Welfare dated 14 September 2012.

<sup>7</sup> Audit rules of the University of Veterinary Medicine, Vienna (version dated 14 September 2012).

- The ETK will inform the applicant in writing of the results of its appraisal.
- Subsequent to receiving a positive evaluation from the ETK, the project application—inasmuch as it pertains to an animal experiment according to § 2 cit. 1 of the TVG 2012—must be submitted for approval to the Federal Ministry of Science, Research and Economy (BWF) as the official channel and agency responsible for approval of such undertakings. The application must be accompanied by the opinion of the ETK regarding the results of its appraisal.

Completed documentation is required for patent registration and also for third-party funding applications; furthermore, it serves to document who owns the copyright for an idea for a scientific project.

### **1.2.2. Contents of the project plan**

An application for the approval of a project in accordance with § 2 cit. 2 of the TVG 2012 must include the information and documentation as set forth in § 26 subparagraphs 2 and 3 of the TVG 2012 and in § 21f. of the Ordinance on Animal Experiments (TVV 2012).

Notwithstanding these specifications and independent of the type of animal experiment or approval requirements pertaining to an undertaking, a complete project plan consists of the following elements:

#### 1.2.2.1. Synopsis

- Title page (date, signature)
- Summary
- Table of contents
- Project team members and associated tasks
- Project financing
- Authorship (ideally in order, inasmuch as this is possible to determine prior to the start of the project—this is subject to change)

#### 1.2.2.2. Scientific-medical section

- Introduction
- Goals and hypotheses of the project
- Preliminary data/Pilot experiments
- Project design or experimental protocol
- Basic principles and description of the project design
- Description of the sample
- Number of patients/subjects (in the case of clinical studies), number of animals to be used in experiments
- Number of *in vitro* observations

- Criteria for inclusion/exclusion (in the case of clinical studies)
- Treatment, intervention
- Description of outcome variables
- Evaluation methods (description of methodology)

#### 1.2.2.3. Experiment planning, statistics and data analysis

- Determination of the number of animals to be used in experiments
- Calculation of the required sample size (determination of effect size)
- Handling of missing values/handling of unexpected values
- Description of methods to be used (descriptive or inferential statistics?)

#### 1.2.2.4. Requirements as stipulated by policies for the protection of animals used in experiments (in the case of clinical studies and animal experiments)

- Ranking of the stresses to be inflicted on the animals in the course of the experiment; the assignment of a rank must be done in accordance with § 3 of the TVG 2012.
- Ethical assessment of the project undertaking according to § 6 subparagraph 3 of the TVG 2012 (in terms of the balance between the necessity and appropriateness of the planned animal experiment versus the burden to be placed on the animals involved in the experiment) with a view to the harm-benefit analysis to be performed in the context of the project by the agency in charge evaluation (§ 29 subparagraph 2 cit. 4 TVG 2012).
- Statement about the indispensability of the experiment involving animals (§ 5 of the TVG 2012) and also about the circumstance that no suitable or, if required, validated alternative methodology for the proposed investigation is neither known nor available according to the most up-to-date body of scientific knowledge (cf. § 4 cit. 1 of the TVG 2012).
- Information about the conditions for keeping animals used in experiments before, during, and, if required, after carrying out the experiment.<sup>8</sup>
- Information about the identification methods of animals used in experiments (cf. 1.3.4.4.3.)
- Conformance with the principles of Good Scientific Practice
- Correct planning of experiments

#### 1.2.2.5. Administrative section

- Notification regarding serious side effects (in the case of clinical studies)
- Monitoring and review procedures (in the case of clinical studies)

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<sup>8</sup> In particular, this should include information about housing (group or individual housing), the proposed size of the group, population density and available space; for rodents, required information includes the type of Makrolon cage and population density.



- Possible insurance coverage (in the case of clinical studies)
- Plans for publication

#### 1.2.2.6. Bibliography

#### 1.2.2.7. Attachments (charts, tables etc.)

If an application of equivalent quality has already been drafted in connection with the Vetmeduni's research profile areas (Profillinien) funding applications or for submission to the FWF or another accredited institution for the promotion of research, this may be presented to the ETK for evaluation.

### **1.3. General information for consideration by the Ethics and Animal Welfare Committee (ETK) and guidelines for the application to be submitted to the Federal Ministry of Research and Science**

#### **1.3.1. Area of responsibility**

The Ethics and Animal Welfare Committee (ETK) at the University of Veterinary Medicine, Vienna reviews all experiments involving animals, including clinical research projects and also projects planned in the areas of teaching, research and services at the University of Veterinary Medicine, Vienna, in which animals are to be used in a manner that goes beyond medical treatment and care or monitoring (cf. also Point 1.3.5).

#### **1.3.2. Legal provisions**

Experiments on live animals are governed by the Animal Experiments Act 2012 (TVG 2012)<sup>9</sup> and a number of ordinances<sup>10</sup>. Animal experiments involving genetic procedures or biological materials are also subject to the Genetic Engineering Act (Gentechnikgesetz—GTG)<sup>11</sup> and the Ordinance on Biological Materials (Verordnung über biologische Arbeitsstoffe – VbA)<sup>12</sup>.

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<sup>9</sup> Cf. footnote number 4.

<sup>10</sup> Ordinance of the Federal Minister for Science and Research regarding the implementation of the Animal Experiments Act of 2012 (Ordinance on Animal Experiments 2012 – TVV 2012), Federal Law Gazette II No. 522/2012; Ordinance of the Federal Minister for Education, Science and Culture regarding the statistical assessment of experimental animals (Ordinance on Animal Experiment Statistics), Federal Law Gazette II No. 199/2000.

<sup>11</sup> Federal law for regulating work with genetically modified organisms, release and marketing of genetically modified organisms and the application of gene analysis and gene therapy in humans (Genetic Engineering Act – GTG), Federal Law Gazette No. 510/1994 (version currently in force).

<sup>12</sup> Ordinance of the Federal Minister for Labour, Health and Social Affairs regarding the protection of employees against endangerment through biological materials (Ordinance on Biological Materials), Federal Law Gazette II No. 237/1998.

Furthermore, attention is drawn to the [EU] Directive on animals used for scientific purposes<sup>13</sup>, to recommendation 2007/526/EG<sup>14</sup> [of the Commission of the European Communities] and to the Council of Europe’s “European Convention for the Protection of Vertebrate Animals used for Experimental and Other Scientific Purposes”<sup>15</sup>.

Attention should also be paid to the Animal Materials Act<sup>16</sup> und laws regarding animal plagues, in particular the Animal Plagues Act<sup>17</sup>.

### 1.3.3. Legal principles and institutional obligations

According to the terms of the TVG 2012, no experiments using live animals may be done without project approval. The Federal Ministry for Science, Research and Economy is responsible for issuing project approvals for matters concerning higher education and for scientific facilities and furnishings at the federal level; however, the Office of the Rector is the official channel through which the project application must be submitted.

In 2001 the University of Veterinary Medicine, Vienna appointed a commission that met the provisions for consultation on and audit of research proposals involving animal experiments as defined by the University Organization Law (UOG) to review and give advice as to various scientific, ethical and legal aspects. After the University Act of 2002 (UG 2002) went into effect, this commission was disbanded and replaced with a council of experts (the ETK) to advise the Rectorate. Since the ETK is not a decision-making body, it must forward its professional opinion and its legal and ethical analysis pertaining to applications for experiments to the Rectorate. The ETK is a body composed to a great degree of professional who are affiliated with all groups present at the University of Veterinary Medicine, Vienna; its orientation is, to a great degree, professional. Members of the ETK are bound by a non-disclosure obligation.

### 1.3.4. Guidelines for animal welfare

The University of Veterinary Medicine, Vienna is of the opinion that bad science *ipso facto* is unjustifiable and that research involving animal experiments and *in vitro* procedures are subject to the principles of Good Scientific Practice as much as clinical studies.

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<sup>13</sup> Directive 2010/63/EU of the European Parliament and of the Council on the protection of animals used for scientific purposes, Official Journal of the European Union L 276 of 20 October 2010, p. 33ff.

<sup>14</sup> Recommendation 2007/526/EC of 18 June 2007 on guidelines for the accommodation and care of animals used for experimental and other scientific purposes, Official Journal of the European Union. L 197/1 of 30 July 2007, p. 1.

<sup>15</sup> European Convention for the Protection of Vertebrate Animals used for Experimental and Other Scientific Purposes (ETS No. 123).

<sup>16</sup> Federal law regarding hygiene rules for animal by-products and materials not intended for human consumption (Animal Materials Act – TMG), Federal Law Gazette I No. 141/2003 (version currently in force).

<sup>17</sup> Law dated 6 August 1909 regarding the defense and mitigation of animal plagues (Animal Plagues Act – TSG), Imperial Law Gazette No. 177/1909, (version currently in force).

#### 1.3.4.1. Preamble

All persons and institutions involved in animal experiments agree to adhere to the provisions of the Austrian Animal Experiments Act of 2012<sup>18</sup> and associated ordinances<sup>19</sup>, the Animal Protection Act<sup>20</sup> and associated ordinances<sup>21</sup>, as well as the following guidelines.

Furthermore, any other legal regulations, for example, regarding the purchase, trade, transport or import of animals, as well as any national or international laws for species preservation, are to be obeyed. Leaders of working groups involved in animal experiments are responsible for ensuring that these rules and regulations are observed within their sphere of influence.

#### 1.3.4.2. Animal Welfare

1.3.4.2.1. Animals are sentient beings with intrinsic value<sup>22</sup> that must be respected by all persons involved in the planning and carrying out of animal experiments. Persons utilizing animals for experimental or other purposes are to a particularly great degree responsible for the keeping and treatment of these animals in conditions that are in conformance with state-of-the-art findings regarding animal welfare.

1.3.4.2.2. Animal experiments serve to elucidate and influence biological processes and represent a way of utilizing animal life. The knowledge gained in this way protects and secures human as well as animal life, enables prevention of and protection against disease, enables healing, relieves suffering and can contribute to the preservation of functioning ecosystems and habitats and to improving the environment.

1.3.4.2.3. The preservation and protection of the health and life of animals and people is a core responsibility of the University of Veterinary Medicine, Vienna. Rising to this task includes acknowledging that some animal experiments in basic and applied research (in conformance with the relevant legal principles) are indispensable.

1.3.4.2.4. The University of Veterinary Medicine, Vienna is fully committed to the 3R precept (*Refinement – Reduction – Replacement*). All persons responsible for the planning and carrying out of animal experiments pledge to:

- Contribute to reducing the burden borne by the experimental animals, to improving their living conditions in the framework of the

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<sup>18</sup> Cf. footnote number 4.

<sup>19</sup> Cf. footnote number 10.

<sup>20</sup> Federal Act on the Protection of Animals; (Tierschutzgesetz- TSchG), Federal Law Gazette I No. 118/2004, Art. 1, (version currently in force).

<sup>21</sup> In particular these include: Ordinance regarding the minimum requirements for the keeping of horses and equine species, pigs, cattle, sheep, goats, hoofed game (artiodactyls), llamas, rabbits, domesticated fowl, ostriches and commercial fish (1st Ordinance on the keeping of animals), Federal Law Gazette II No. 485/2004 (version currently in force); Ordinance on the keeping of vertebrates not covered by 1st Ordinance on the keeping of animals (2nd Ordinance on the keeping of animals), Federal Law Gazette II No. 486/2004 (version currently in force); Ordinance on the welfare of animals to be slaughtered or killed (Animal Protection/Slaughter Ordinance), Federal Law Gazette II No. 488/2004 (version currently in force).

<sup>22</sup> Cf. Recital No. 12 of RL 2010/63/EU.

experiment in which they are taking part, to improving their breeding conditions and the conditions in which they are kept, and also to their care during and after the experiment, as well as in the case of their euthanasia, if applicable (*Refinement*);

- Reduce the number of experimental animals through the concomitant development, parallel usage and adoption of alternative procedures (*Reduction*);
- Employ applicable or validated alternative and supplemental procedures as substitutes for experiments using live animals (*Replacement*) and, within their area of responsibility, to work on the development of alternative and supplemental procedures.

#### 1.3.4.3. Admissibility of animal experiments

Animal experiments are only allowed if they are designated as indispensable for one of the purposes outlined in § 5 cit. 1 – 7 of the TVG 2012 (§ 5, 1st clause, TVG 2012).

- All persons taking part in the execution of an animal experiment are obliged to examine the necessity and suitability of a proposed experiment on animals and to weigh this against the burden placed on the animals (cf. § 6 subparagraph 3, TVG 2012).
- Animal experiments must correspond to generally recognized principles of research in the natural sciences. The hypothesis to be tested and the corresponding procedure must be meaningful; the current state of knowledge in the applicable scientific field must be taken into consideration. (cf. § 6 subparagraph 1 cit. 1 und 2, TVG 2012).
- An animal experiment is expressly inadmissible if a scientifically acceptable and legally admissible procedure or experimental strategy already exists that can yield the desired results without utilizing living animals or if no new or additional findings are to be expected (cf. § 4 cit. 1 and cit. 3 lit. a), TVG 2012). An animal experiment may only be repeated if the results of an equivalent animal experiment are not available for de facto or legal reasons or if the repetition is required as a control experiment (cf. § 4 cit. 2 and cit. 3 lit. b), TVG 2012). The necessity of a repeat experiment must be sufficiently justified.

#### 1.3.4.4. Implementation of admissible animal experiments

1.3.4.4.1. According to the legal regulations governing animal experiments, these must be performed so as to maximize knowledge gained while minimizing the number of animals utilized; further, experiments must be structured so as to place the least amount of burden on the animals (cf. 1.3.4.2.5). This obligation follows most especially from §§ 6 subparagraph 1 cit. 3, 7 und 8 of the TVG 2012. Compliance with this obligation presumes detailed planning, preparation and professional implementation of every individual animal experiment. All persons involved in animal experiments are under an obligation to ensure the well-being of the animals in a responsible manner and to keep the burden on the animals to a minimum. Only colleagues with adequate professional competence and personal reliability may be entrusted with the

performance of animal experiments and with the care of the animals used in experiments.

- 1.3.4.4.2. Experimental animals are to be properly housed and cared for in a manner appropriate for their species (cf. § 25, TVG 2012).
  - 1.3.4.4.3. Experimental animals are to be tagged in a sparing way. This is mandated by the principle of *Refinement* enshrined in particular in § 1 subparagraph 3 cit. 2 of the TVG 2012 and also in § 6 subparagraph 1 cit. 8 of the TVG 2012, whereby animal experiments are to be designed in such a way as to cause the least amount of pain, suffering, fear or permanent damage. Tagging methods that involve loss of body parts (amputations) are principally only warranted when they are done in connection with another necessary purpose of the experiment such as genotyping. In such cases, care should be taken to ensure that the number of interventions is kept to a minimum.
  - 1.3.4.4.4. Every experimental animal must be able to give expression to its sensations and perceptions, so that its burden may be assessed visually and appropriate countermeasures may be taken. Immobilizing an animal for experimental purposes is only then defensible if no other procedure is available. Severe pain and suffering in experimental animals are to be ended at the earliest possible point in time by euthanizing the animal in conformance with animal welfare laws (“humane endpoint” or “criteria for termination”, cf. § 6 subparagraph 1 cit. 10 of the TVG 2012).
  - 1.3.4.4.5. Any procedures or interventions on experimental animals that have the potential of causing pain must—so long as the experimental purpose does not preclude it—be performed under general or local anaesthesia (§ 8 subparagraph 1, TVG 2012). Pain, suffering and fear are to be reduced to a minimum at every stage of the animal experiment through analgesia or other suitable methods (cf. § 8 subparagraph 2, TVG 2012).
  - 1.3.4.4.6. Unavoidable pain, suffering, fear or permanent harm are to be restricted to extent necessary to achieve the experimental objective (cf. § 6 subparagraph 1 cit. 8, TVG 2012).
  - 1.3.4.4.7. Persons who are involved in experiments leading to permanent impairment of the animals or necessitating repeated procedures and interventions are subject to a particular obligation regarding the care of these animals. If, in the course of an experiment involving animals, severe impairment or injury should occur that is not likely to lead to an exact experimental outcome or where the data are not likely to be usable, these animals are to be euthanized without delay in conformance with animal welfare regulations.
  - 1.3.4.4.8. The acquisition of experimental animals must be clearly verifiable and comprehensible. Principally, no animals of unknown origin may be used (cf. § 15, TVG 2012).
- 1.3.4.5. Obligations and responsibilities
- Pursuant to § 6 subparagraph 3 of the TVG 2012, all persons involved in experiments on animals bear ethical and scientific responsibilities in the framework of their activities. Furthermore, the person leading the animal

experiment bears legal responsibility for the necessity, planning and execution of experiments on animals.

- The researcher is duty-bound to avoid unnecessary animal experiments and to take into account the current state of knowledge available nationally and internationally, as well as cultivating—inasmuch as possible and required—the exchange of experiences and scientific collaboration. Additionally, she or he is tasked with constantly monitoring with a critical eye the significance and applicability of animal experiment models and with bringing them into alignment with the current state of scientific knowledge (cf. § 6 subparagraph 2, TVG 2012).
- By drawing on the latest findings of in the fields of behavioural research and experimental animal science as well as by applying state-of-the-art measurement methods and laboratory procedures, all researchers are under obligation to structure and refine their experimental models in a way that reduces the burden on the experimental animals to a minimum (cf. § 6 subparagraph 2, TVG 2012).
- All researchers at the University of Veterinary Medicine, Vienna are tasked with developing experimental procedures that lead to a reduction of the number of experimental animals used or that render animal experiments partially or wholly unnecessary (alternative or supplemental procedures, cf. also 1.3.4.2.5).
- All researchers have an ongoing duty to critically examine the suitability of legally ordered animal experiments designed to protect humans, animals or the environment from harm, and, as appropriate, to dedicate themselves to changing these directives.

### **1.3.5. Projects requiring ETK approval**

All project proposals for projects to be undertaken at the University of Veterinary Medicine, Vienna that fall into one of the following categories must be submitted to the ETK for a preliminary review:

- Animal experiments;
- Clinical research proposals;
- All projects, wherein live animals are to be used in a manner that goes beyond medical care and treatment;
- All measures carried out on live animals that are performed for the purposes of knowledge acquisition and that therefore are not done solely for the purposes of promoting the health of the animals on which these measures are applied;
- Killing or euthanizing animals for the purpose of removing organs and/or tissues.

The approval requirement also applies to the use of transgenic animals.

### **1.3.6. Projects NOT requiring ETK approval**

The ETK does not need to approve veterinary activities performed solely in the interest of individual patients. In other words, the purpose of the measure employed is not knowledge acquisition or the utilization of results for projects. Such veterinary activities are not viewed as research undertakings, but as diagnostic and therapeutic

measures that are not governed by the TVG 2012 and are not subject to review by the ETK. Since the motive behind certain activities cannot always be clearly delineated as being in service to knowledge acquisition versus therapeutic treatment, the following groupings of cases should help to clarify the distinction:

- Ad hoc measures and treatment measures performed in response to a specific circumstance: in these cases, the treatment of a sick or injured animal is in the foreground. Even if treatment measures are to be employed which might be burdensome for the animal or which have not been utilized in a specific context (e.g., for a certain species of animal or in connection with a specific illness), the proposed treatment cannot be considered to be an animal experiment in the sense of the TVG 2012, but as a therapeutic measure employed in service to the well-being of the animal, inasmuch as no tested and proven alternatives are available or these have already been tried. These treatment measures are principally employed—after obtaining the consent of the animal owner (“informed consent”)—at the discretion of the veterinarian responsible for treatment. The circumstances of the case remain unchanged even if the data obtained in this way are used to add to the current state of knowledge<sup>23</sup>.
- The term “experimental treatment” encompasses veterinary treatment measures in the framework of which untried remedies are employed on patients that have not responded to established therapeutic methods. Such methods—that are performed with the consent of the animal owner—do not fall in the category of animal experiments since their primary purpose is curative, even if the knowledge gained in this way is of scientific interest.

If, however, additional burdens (such as blood draws, for example) are placed on the animal in the context of therapeutic attempts, and these burdens are not primarily in service of the animal’s well-being, then such undertakings are fundamentally to be regarded as animal experiments requiring prior approval.

**Also NOT requiring ETK approval:**

- Observations about the application of already approved medication in the context of an indicated veterinary treatment;
- Blood drawn as an emergency measure, e.g., as a reserve against possible blood loss during an operation;
- Blood drawn from animals whose owners have made an individual animal available for this purpose; and
- Harvesting and utilization of animal material (organs, tissues and the like)

Animal material that:

1. Stems from animals that were treated at one of the Clinics of the University of Veterinary Medicine, Vienna and died there or were euthanized due to veterinary medical indications;

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<sup>23</sup> An application pursuant to § 26 subparagraphs 2 and 3 of the TVG 2012 cannot be done in these cases because the process would lead to an unjustifiable time delay.

2. Was transmitted by external persons or institutions for the purposes of scientific examination at the University of Veterinary Medicine, Vienna.

In cases where animal material that (1) is harvested from patients in the course of veterinary medical treatment or collected *post mortem* is to be used for scientific study, the respective institution must document in the submission form that the animal owner has given express consent for the analysis of the material and for the publication of data.

In cases where animal material that (2) is transmitted to the University of Veterinary Medicine, Vienna by external persons or institutions is to be used for scientific study, the respective institution must document in the submission form that the animal owner has given express consent for the analysis of the material and for the publication of data. Written consent must also be obtained from persons who donate a dead animal to an institution at the University of Veterinary Medicine, Vienna, inasmuch as material is to be harvested from the corpse and data are to be evaluated and published.

### **1.3.7. Opinion of the ETK in cases of research projects of insufficient scientific quality or with insufficient justification**

The ETK views clinical research on patients as an indispensable prerequisite for medical advances and as a research area with importance for society. The ETK is of the opinion that research on animals is only warranted in the context of projects which promise to answer relevant research questions in a comprehensible, objective manner.

The ETK takes it as a matter of duty to examine every project application as to its ethical and legal aspects and to assess its medical and scientific qualities. The ETK holds the view that bad science is *ipso facto* indefensible. The ETK's view is that a false or misleading finding causes more harm to medical advancement and patient care than a cancelled project. This is of particular relevance for contentious therapeutic approaches with high commercial significance. Thus, the ETK rejects projects where a possibility for bias exists, even in cases where the risk for the experimental animal appears to be negligible. This applies to projects without a control where a randomized control trial would be possible, and also to open projects where blinding would be possible.

The ETK views the adequate collection, administration and statistical analysis of data as an essential prerequisite for knowledge acquisition. Thus, the ETK does not approve projects that do not appear to meet the basic requirements in this area.

The ETK acknowledges that it can be difficult to implement medical projects within individual specialty areas. Thus, the ETK expressly encourages inter-institutional or multi-centric research in order for projects to yield results with sufficient scientific weight.



## 1.4. Guidelines for matters concerning the Genetic Engineering Commission

### 1.4.1. Prerequisites for working with genetically modified organisms (GMOs)

The Genetic Engineering Act (GTG)<sup>24</sup> governs, *inter alia*, activities involving genetically modified organisms (GMOs). The following count as activities involving GMOs: production, utilization and propagation, as well as storage and interoffice transport.

Activities involving GMOs include working with single-celled and multicellular organisms whose genetic material has been modified in a manner that does not occur naturally through cross-breeding, natural recombination or other traditional breeding techniques. Procedures for modifying genetic material include, for example, recombinant DNA techniques using a vector system, introduction of genetic information into an organism using macroinjection, microinjection, microencapsulation, electroporation or by employing microprojectiles, as well as cell fusion and hybridization procedures.

### 1.4.2. Registration and approval requirements

All activities involving GMOs require registration and approval. The GTG sets forth four security levels (1, 2, 3, 4) and a large or small scale (A and B) for every security level. Depending upon the security classification of the organisms, the vectors and the scale, notification or approval is required.

1.4.2.1. Pursuant to § 19 of the GTG, the following are subject to the notification requirement:

- Initial activities involving GMOs in a genetic engineering facility classified as security level 1
- Initial activities involving GMOs in a genetic engineering facility classified as security level 2
- Ongoing activities involving GMOs in a genetic engineering facility classified as security level 2
- Initial activities with transgenic plants or animals in a genetic engineering facility
- Initial activities with transgenic plants or animals in a genetic engineering facility with the exception of security level 1
- Ongoing activities with transgenic vertebrate animals in a genetic engineering facility classified as security level 1

Prior to commencing work, the operator is mandated to register the undertaking with the Federal Ministry of Science, Research and Economy using the Rectorate as the

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<sup>24</sup> Federal law governing activities involving genetically modified organisms, releasing and marketing genetically modified organisms and the application of gene analysis and gene therapy in humans (Genetic Engineering Act—GTG), Federal Law Gazette No. 510/1994, version currently in force.

official channel. The registration must be accompanied by all documents necessary for evaluating the proposed undertaking.

1.4.2.2. Pursuant to § 20 of the GTG, the following are subject to the notification requirement:

- Initial or ongoing activities involving GMOs in a genetic engineering facility classified as security level 3
- Initial or ongoing activities involving GMOs in a genetic engineering facility classified as security level 4

Prior to commencing work, the operator is mandated to apply for approval of the undertaking with the Federal Ministry of Science, Research and Economy using the Rectorate as the official channel. The application must be accompanied by all documents necessary for evaluating the proposed undertaking.

Applications for approval of initial or ongoing activities at security level 3 on a large scale, as well as for initial activities at security level 4 and ongoing activities at security level 4 on a large scale are subject to a hearing.

### **1.4.3. Agency procedures pursuant to the Genetic Engineering Act**

1.4.3.1. Basic principles

The agency examines whether the registration or application is in conformance with the stipulations of the GTG, especially as concerns the accuracy and completeness of the documents submitted and information provided, the validity and assessment of the security level classification and the suitability of the security measures, including waste disposal and emergency measures. Initial activities at security levels 1 and 2 (§ 19 cit. 1 and 2 of the GTG) may be commenced 45 days after registration, if the agency does not reach a different decision within this time period pursuant to § 23 subparagraph 2 or 3 of the GTG.

Initial activities at security level 1 may begin immediately following registration, provided that the protocol of the Committee for Biological Safety as regards clearance is enclosed (§ 16 subparagraph 4 cit. 4 of the GTG). Ongoing activities with GMOs or transgenic plants or animals may be commenced without a new registration. Ongoing activities with GMOs in a genetic engineering facility at security level 2 may be commenced immediately provided that the protocol of the Committee for Biological Safety as regards clearance is enclosed (§ 16 subparagraph 4 cit. 4 of the GTG).

The prerequisites for commencing any other activities requiring registration or approval are governed by § 24 subparagraph 4 and 5 of the GTG. Activities requiring approval may not be commenced prior to approval by the agency.

1.4.3.2. Particulars of agency procedures as regards working with transgenic animals

For activities with GMOs requiring project approval according to the TVG 2012, the application for project approval must be accompanied with the documentation specified in the GTG, Attachment 1 lit. B.

The agency responsible for approving projects pursuant to the TVG 2012 must obtain an opinion from the scientific panel of the Commission for Genetic Engineering using the Federal Minister for Health as the official channel:

- If there are doubts as to the classification of the work as security level 1;
- If the work is for other than biomedical purposes;
- If the work is for purposes of developmental biology research and there is reason to assume that the species barrier will be crossed.

Activities with transgenic animals are governed by § 26 of the GTG. It is to be taken into account that activities with transgenic animals at security level 1 are governed by the Animal Experiments Act.

#### 1.4.3.3. Agency decisions regarding work with transgenic animals

Approval pursuant to the TVG 2012 and associated regulations within its scope of application replaces the registration required by the GTG for work with transgenic animals.

The implementation of the animal experiment is prohibited when, in the case of activities involving GMOs, the prerequisites specified in §§ 9 and 10 of the GTG are not fulfilled.

#### 1.4.4. Committee for Biological Safety (§ 16 GTG)

- For every genetic engineering facility, a designated representative for biological safety of the University of Veterinary Medicine, Vienna as well as at least one deputy must be appointed and made known to the local fire department (in Vienna: main fire station “am Hof”) pursuant to § 16 of the GTG. A department may decide not to make such an appointment if a professionally qualified person employed by the University in another department is available to take on this task. The designated representative for biological safety is charged with regularly overseeing that safety measures are followed and with promptly informing the University of Veterinary Medicine, Vienna about any deficiencies related to safety.
- For all activities with GMOs in security levels 2, 3 or 4 and for every work series, a project leader with sufficient practical experience working with GMOs and with adequate knowledge about ensuring safety is to be appointed.
- If a member resigns from the Committee for Biological Safety, the operator must promptly appoint a new member to the Committee.

#### 1.4.5. Observation of safety measures

Pursuant to § 10 of the GTG, activities with GMOs may only be performed in compliance with the applicable measures for ensuring safety (§ 1 cit. 1 of the GTG) from harm due to GMOs as corresponds to the state-of-the-art of science and technology. Accident and emergency regulations are set forth in § 11 of the GTG.

#### **1.4.6. Requirements for record keeping**

All activities with GMOs must be documented. For activities in security levels 1 and 2 on a small scale, record keeping may be in the form of laboratory journals.

## 1.5. Data

### 1.5.1. General information

- The careful collection, processing and storage of data from the field of health research are of great importance for medical scientific advances. Researchers must be able to access original data (on paper as well as electronically) in order to answer questions—also as to the validity of the data—as they arise.

The University of Veterinary Medicine, Vienna assumes that anyone involved in collecting, storing, transferring and processing data does so in accordance with applicable legal standards, as well as in compliance with the Guidelines for the Investigation of Alleged Scientific Misconduct.<sup>25</sup>

- Beyond that, the following principles are in effect:

### 1.5.2. Data Collection

- The criteria for data collection for projects should be stipulated in the respective project plan.
- Data acquisition instruments (such as data collection forms) should be prepared to document data collection; if possible, these instruments should be standardized. These data acquisition instruments should contain the original data in a directly readable format.
- In the case of clinical research, inasmuch as possible, the data should be pulled from the patient’s medical record and documented therein.

### 1.5.3. Data storage

- Project plans, modifications, supplements, original data and reports are to be kept electronically and (if possible) on paper for at least 10 years after completion of a project by the department responsible for implementation of the project. Information about the data acquisition methodology and quality control methods are to be stored in a similar fashion.
- Each institution is responsible for implementing a suitable system for data archival and for identifying data usage and data users.
- Records should be kept regarding corrections, calculations and statistical analysis of data, so that it is possible to identify original data that were incorporated in published papers.

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<sup>25</sup> Cf. Austrian Agency for Scientific Integrity (ÖAWI), Annex I to the Rules of Procedure of the Commission for Research Integrity: Guidelines for the investigation of alleged scientific misconduct; Austrian Agency for Scientific Integrity: [http://www.oeawi.at/downloads/Richtlinien\\_zur\\_Untersuchung\\_von\\_Vorwuerfen\\_wissenschaftlichen\\_Fehlverhaltens\\_e.pdf](http://www.oeawi.at/downloads/Richtlinien_zur_Untersuchung_von_Vorwuerfen_wissenschaftlichen_Fehlverhaltens_e.pdf)

#### **1.5.4. Data usage rights**

- The University of Veterinary Medicine, Vienna, assumes that, in the absence of other agreements, the rights to the scientific and commercial use of data collected and processed in the framework of a research project remains with the department responsible for implementing the project.
- The rights of the University of Veterinary Medicine, Vienna, shall remain intact, and also the rights accorded the originators (lead authors, project leaders) by the provisions of copyright law (in particular the right to be named as lead author or inventor, as well as the right to appropriate remuneration in cases of inventions created by an employee during the term of employment for his employer).
- If a primary usage right (license) has been granted to another legal entity, it is necessary to ensure that the University of Veterinary Medicine, Vienna and the department responsible for implementing the research project are accorded at least the data usage rights necessary for fulfilling its duties pertaining to data storage.
- The transfer of anonymized data for use in overlapping research projects (e.g., meta analyses) should take place in agreement with the participating institutions and the person(s) responsible for the research project.
- The person responsible for the implementation of a research project must be granted the possibility to produce copies of the data, even after departing from the institution at which the research project was done. A prerequisite in such cases is notifying the University of Veterinary Medicine, Vienna represented by the Office of Research Support and Innovation (FFI) as well as the institution on whose behalf the research project was done.

#### **1.6. Materials**

The University of Veterinary Medicine, Vienna uses Material Transfer Agreements (MTAs) to regulate the storage and transfer of materials. As opposed to data, as a rule, materials can neither be copied nor propagated. On the one hand, however, materials are required for the purposes of documentation; while on the other hand, there is an expectation that materials will be transferred, for example, to ensure reproducibility of data. Further, third parties have the possibility of using the materials to develop commercial applications.

Basic principles as regards Material Transfer Agreements, as well as a sample of a contractual agreement are presented in Annexes 1 and 2.

#### **1.7. Publication and authorship**

##### **1.7.1. General information**

- Publication and clarity about the legal rights of the authors or originators of the project are of decided importance for every scientific project.

- The University of Veterinary Medicine, Vienna assumes that anyone affiliated with the University will adhere to the legal regulations concerning copyright protection when publishing scientific papers. Further, The University of Veterinary Medicine, Vienna requires that the following procedures, which, in alignment with international scientific practice, ensure protection of copyright, be observed:

### **1.7.2. Copyright**

- Copyright as regards scientific publication covers not only to the original paper, but extends to project plans, submissions to the ETK, documentation for third-party funding proposals, applications for Vetmeduni's research profile area funding and published abstracts.
- The University of Veterinary Medicine, Vienna considers the drafting and/or publication of a project plan in a suitable format (at a minimum through safe-keeping in a publicly accessible location) to be the first step in documenting copyright.
- To avoid ambiguity about copyright, it is recommended that the tasks of individual project team members are defined as early as possible prior to beginning work on a project and that these be amended on a regular basis.

### **1.7.3. Authorship**

#### **1.7.3.1. General information**

Being named as author of a scientific work is done in connection with playing an active intellectual and practical or procedural role on a project.

#### **1.7.3.2. Being named as author**

Being named as author requires that the criteria for at least 3 of the points named from 1.7.3.2.1. to 1.7.3.2.5. have been fulfilled:

- 1.7.3.2.1. Preliminary initiative for taking up a scientific project, with a substantial contribution made to project concept and design;
- 1.7.3.2.2. Acquisition, processing, interpretation and formalizing of data, when this goes beyond the routine application of well-known and established methods;
- 1.7.3.2.3. Concept, drafting and/or critical revision of the manuscript;
- 1.7.3.2.4. Personal approval or release of the final version of the manuscript prior to sending it for publication;
- 1.7.3.2.5. Instruction and supervision of younger colleagues (both academic and non-academic) during preparation of data.

#### **1.7.3.3. Right of authorship**

- A person who fulfils the requirements for qualification as author listed under point 1.7.3.2. has the right to be named as author provided that his or her contribution to the project is deemed as substantial.

- Administration of a scientific area, recruiting or funnelling in patients, data collection and data aggregation are not criteria that *per se* bestow a right to authorship. The granting of authorship on the basis of patient referrals or the bestowal of honorary authorship should be avoided.
- Neither the preparation of generally available or published clones or techniques nor the reading of a manuscript justifies authorship; instead, such contributions should be noted in the “Acknowledgments” section. Third-party funding donors are also to be included in the “Acknowledgments”.
- Institutional approval is not an entitlement to authorship.

#### 1.7.3.4. Order of authors

##### 1.7.3.4.1. First author

First authorship goes to the project team member who made the most significant contribution to the project procedurally, intellectually or conceptually.

It is the duty of the first author to draft at least a preliminary manuscript, including illustrations. If the person responsible for drafting the manuscript does not do so within a reasonable timeframe, he or she gives up the right to first authorship.

Using a footnote to mention that the first and second author contributed to the compilation of data in equal measure should be done only on an exception basis.

##### 1.7.3.4.2. Authorship of the project leader

The authorship of the project leader can be documented as a second or last authorship in line with international practices. This position recognizes the person in this position for his or her contribution to the realization of the project(s) in terms of ideas and concept, and also for infrastructure support (education and direction of academic and non-academic team members, access to laboratories and equipment, fundraising and other support, founding of a topically independent working group). This place in the list of authors is reserved for the team member who contributed the most to the realization of the project or its publication with regard to points 1.7.3.2.1. to 1.7.3.2.5.

##### 1.7.3.4.3. Corresponding author

Corresponding author refers to the author carrying on the correspondence with the person at a publisher responsible for printing the manuscript. In general, the first author or project leader should be named as corresponding author (except in cases involving a graduate student or doctoral candidate). Only on an exception basis should a person other than the first author or project leader be named as corresponding author.

##### 1.7.3.4.4. Authorship in alliances

In the case of an alliance involving multiple institutions, if possible, the key members of the author list and their positions on a potential joint manuscript should be discussed and provisionally determined.



#### **1.7.4. Publication policies**

- The guidelines for published scientific works apply to every type of written or spoken communication. This includes presentations, scientific abstracts, original works, case reports, letters to the editor, overviews, book chapters and any other scientific work submitted for publication by persons affiliated with the University of Veterinary Medicine, Vienna.
- An original scientific work is characterized by the attempt to provide an innovative answer to a concrete question or the testing of a hypothesis in the context of a search for truth. This necessitates a clear research plan, ensuring the reproducibility of results through unambiguous descriptions of the methodology used, careful statistical analysis of the acquired data, critical discussion of the resultant findings with a view to the available literature and the derivation of well-founded conclusions.
- Published scientific works are expected to be coherent and comprehensible in service of clearly formulated questions.
- Scientists affiliated with the University are expected to refrain from publishing preliminary or incomplete findings or fragmented data in the sense of publishing the smallest possible reporting unit.
- Because of the often limited significance of purely descriptive reports or case studies, scientists are expected to be especially careful when assessing whether it makes sense to publish in these situations.
- Duplicate publication of any kind and varying (alternating) authorship for published synopses and the corresponding original work composed later are prohibited.
- Scientists are expected to comply with recommendations concerning authorship and scientific works.

## 2. Scientific misconduct („fraud“)<sup>26</sup>

### 2.1. Definition

Scientific misconduct is deemed to have taken place:

**2.1.1. In cases of deliberate or grossly negligent inclusion of false information in a scientific context; the deciding factors are the circumstances of each individual case. In particular, the term “false information” encompasses:**

- a. Fabrication of data;
- b. Falsification of data, e.g.,
  - i. through the omission of unwanted results, without disclosing such omissions;
  - ii. through the manipulation of an illustration or representation of the data;
- c. The inclusion of incorrect information in an application for employment or an application for third-party funding (this includes submitting false information to a publishing house or for publication in print);
- d. Dishonest assertions that work submitted for publication has been examined by (specific) scientific experts;
- e. Endorsement for publication of work submitted by others, without having examined it.

**2.1.2. Violations of the intellectual property rights of other scientists. In particular, this includes:**

- a. Claiming authorship for the purposes of unauthorized exploitation (plagiarism);
- b. Exploiting the research approaches and ideas of others, especially if done in the capacity as an examiner (intellectual property theft);
- c. Claiming or accepting unwarranted scientific authorship;
- d. Unauthorized publication of or unauthorized granting of access of a work, findings, hypothesis, prevailing thought or research approach to third parties —prior to their publication by the originating author;

**2.1.3. Deliberate or grossly negligent obstruction of the research activities of other scientists, as well as careless or dishonest attempts to damage the scientific reputation of others;**

**2.1.4. Sabotage of research activities (including damaging, destroying or tampering with experimental arrays, instruments, documentation, hardware, software,**

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<sup>26</sup> In accordance with §§ 4 and 5 of Annex I pursuant to point 1.8 of the Rules of Procedure of the Commission for Research Integrity for the investigation of alleged scientific misconduct; Austrian Agency for Scientific Integrity (ÖAWI): [http://www.oeawi.at/downloads/Richtlinien\\_zur\\_Untersuchung\\_von\\_Vorwurfen\\_wissenschaftlichen\\_Fehlverhaltens\\_e.pdf](http://www.oeawi.at/downloads/Richtlinien_zur_Untersuchung_von_Vorwurfen_wissenschaftlichen_Fehlverhaltens_e.pdf).

chemicals or other items required by another scientist in order to do his/her research);

- 2.1.5. Eradication of primary data and violations of the requirements for record keeping and storage pursuant to 1.5.3.

## **2.2. Joint responsibility**

Joint responsibility for misconduct may be found in cases of:

- a. Participating in the misconduct of others;
- b. Being an accessory to falsifications by others;
- c. Co-authoring publications containing falsifications;
- d. Gross negligence with regard to supervisory responsibilities.

## **2.3. Procedures and legal consequences**

In case of a suspicion of scientific misconduct, the Office of the Ombudsman for Good Scientific Practice at the University of Veterinary Medicine, Vienna is to be entrusted with clarifying the matter. If this is not successful, the matter will be referred to the Austrian Agency for Scientific Integrity (ÖAWI) with an appeal for judgment.

In cases where premeditated misconduct is proven, the University of Veterinary Medicine, Vienna has the right to initiate disciplinary legal proceedings.

## 3. Evaluation

### 3.1. General information

- In order to ensure that the principles of scientific ethics are observed and followed, it is necessary to implement concrete measures that are based upon the precepts of quality assurance and quality management. Evaluation is an essential part of these measures.
- Evaluation in the sphere of science rests upon two components: a debt to be paid on the part of the scientists doing research at the University of Veterinary Medicine, Vienna and a debt to be collected on the part of the University.

### 3.2. Evaluation measures

Every person doing research at the University of Veterinary Medicine, Vienna is under an obligation to provide access to acquired data (raw data, databases, statistical calculations) in response to a request from an authorized person or institution (see below). Thus, agreement must be reached with the institution responsible for a given project to store collected data in such a way that they are accessible at any time. Data must be stored for 10 years after completion of a project.

**The following evaluation measures are envisaged:**

- Access to scientific original source data and protocols by appraisers in the framework of recruitment procedures.
- Access to original source data and protocols of habilitation applicants granted to members of the habilitation commission, represented by the chairperson.
- Access via spot checks of original source data and protocols (in an audit) by scientists selected via random sampling by appointees of the Rectorate of the University of Veterinary Medicine, Vienna. In this way, it should be possible to designate as evaluators members of the Commission for Good Scientific Practice, members of the ETK or prominent external scientists.
- Assessment of outcomes: All project leaders conducting research projects subject to ETK review (cf. Point 1.3.5) are required to:
  - a. Promptly inform the ETK when an experiment involving living animals is approved by the BMWF in accordance with § 26 of the TVG 2012; promptly inform the ETK via the Rectorate as the official channel about the completion of every experiment involving living animals;
  - b. One year after completion of an experiment involving living animals, present a report to the ETK about the results of the animal experiment, especially about papers published as a result of the research, as well as about the actual severity of the experiment. If the approval timeframe is more than two years or the project application is extended, an interim report is to be presented to the ETK.

- If a project done by University affiliates was selected for a retroactive assessment pursuant to § 30 subparagraph 1 of the TVG 2012, the result of this assessment is to be forwarded to the executive board of the ETK, which is responsible for archival of the assessment and for granting access to members of the ETK upon request.

# Annexes

**Annex 1: Material Transfer Agreements for non-commercial purposes**

**Annex 2: Agreement for the transfer of biological material (MTA)**

# Annex 1:

## Material Transfer Agreements (MTA) for non-commercial purposes

### **Basic principles governing the transfer and receipt of biological material between academic or scientific partners**

The transfer and receipt of biological material between academic or scientific partners should always be contractually regulated, with due consideration given to the interests of all parties.

A party to a contract should not demand terms from a partner that he or she would not find acceptable if the situation were reversed. It is imperative that the following points be regulated in detail in a Material Transfer Agreement:

#### **1. Ownership of material**

a. The original material:

If the original material is not modified, the original owner retains ownership of the material.

After conclusion of the research efforts, the supplied material must either be returned to the original owner or be destroyed, unless the original owner has expressly waived these rights.

b. Modification:

If the recipient modifies the material, i.e., creates new substances, which, however, continue to contain the material originally supplied, the original owner and recipient may jointly share ownership of the modification.

An appropriate settlement in individual cases may thus be indicated. In particular, it would be advisable to verify whether the material contributions to the modification can indeed be separated or whether an indivisible material has been created.

c. Newly created material:

Newly created material, in which none of the originally supplied material is present after processing, becomes the sole property of the recipient.

#### **2. Ownership of intellectual property**

Intellectual property includes patentable inventions, technical improvements and simple know-how not covered by legal protections.

a. Results produced solely by the recipient of the material:

Results produced solely by the recipient of the material through usage of the material are owned by the recipient.

- b. Results produced jointly by the recipient of the material and the original owner:

Joint results are jointly owned by both parties. Portions are to be determined by consensus. In individual cases it may be fair to view the provisioning of material as a contribution towards the mutually realized result.

- c. Usage rights:

Commercial usage of the results pursuant to 2a) and b) ought to take place on a payment basis. The details are to be worked out in the course of negotiating a [separate] agreement governing [commercial] exploitation.

At the same time, the original owner of the material should be granted non-exclusive usage rights for research purposes from the right of the recipient of the material.

### **3. Publication**

When publishing papers about the supplied material or its modifications, the source of the material, thus, the original owner (institution as well as the scientist responsible), shall be named. Other than that, the usual conventions (informing the supplier prior to publication, etc.) are to be observed.

### **4. Usage of the material**

- a. Usage:

The Material Transfer Agreement should specify that the material is to be used on for the purposes of research or education. Additionally, the parties to the agreement should be in agreement as to the scientific tasks for which the material is being supplied.

In particular, legal proscriptions of certain uses are to be observed (e.g., usage on/in humans). It is especially important to be judicious in the case of international agreements, since in the framework of the international legal situation, laws not only are not unified, but occasionally in conflict with each other. Therefore, specific individual cases require intense scrutiny.

Commercial usage is precluded in this context.

If the recipient of the material wishes to use the material or a modification thereof for commercial purposes, a separate agreement should be drawn up. However, the original owner is not required to consent to such an agreement. Additionally, the agreement should stipulate that a transfer of the material to third parties is disallowed (unless the original owner of the material gives express written permission).

- b. Liability:

In case of non-contractual usage the recipient of the material is liable for all consequences arising from usage of the material that was not agreed upon.

Additionally, the recipient of the material is liable for all damages he or she caused by using the material, inasmuch as the damages cannot be



attributable to gross negligence or premeditation on the part of the original owner of the material (basically an exclusion of liability for the original owner and provider).

Also to be taken under consideration would be an indemnification of the supplier against third-party claims.

Where contracts are entered into with international partners, special care should be taken to review the applicable laws.

Lastly, the original owner cannot be liable for guaranteeing that the material is free from the property rights of third parties.

## **5. Costs/Payments**

If applicable, the Material Transfer Agreement should clearly specify details as to costs and payments in cases where the recipient assumes the transport costs.

## **6. Conclusion**

A two-party agreement is assumed in the principles outlined above, i.e., cases where there is only one supplier (who at the same time is the original owner) and one recipient.

In the case of a chain of suppliers and recipients, separate individual agreements should be drawn up in order to do justice to the interests of the respective suppliers and recipients.

## Annex 2: Agreement for the transfer of biological material (MTA)

between

the provider of the source material

**Name of the provider of the source material**

Address of the provider of the source material

(hereinafter "Provider")

and

the recipient of the source material

**Name of the recipient of the source material**

Address of the recipient of the source material

(hereinafter "Recipient")

### Preamble

In the course of scientific research, the **Provider** has developed **Biological Material** as described below. The **Recipient** intends to conduct non-commercial **research** with said **Biological Material**.

The **Provider** agrees to make this **Biological Material** available to the **Recipient** under the following prerequisites and conditions.

1. The following biological material is designated as **Biological Material**:  
**[FormText]**, and includes progeny, subclones and derivatives thereof. A more detailed description of **Biological Material** is provided in Attachment A to this Agreement.
2. This **Biological Material** may be used by the **Recipient** only for the following non-commercial research purposes and studies:  
**[FormText]** (hereinafter "**Research**").  
  
The **Biological Material** is provided exclusively for the purposes of research with laboratory animals or for *in vitro* experiments, but not for experiments on humans. The **Recipient** expressly states that the material will not be used for any other purpose. Neither the **Biological Material** nor any biological or other materials treated therewith may be used on humans.
3. All rights to the **Biological Material** remain with the **Provider**. No rights are accorded or licenses granted by this Agreement. The Recipient agrees to inform the **Provider** in writing promptly as soon as a commercially exploitable and/or patentable technology, invention, material or product is discovered or produced in the course of research using of this **Biological Material**.

The **Recipient** further states that this Agreement establishes no rights to:

- Patents of the Provider;
- Other usage rights for the **Biological Material**; or
- Technologies, inventions, products and other materials resulting in the course of research and through usage of the **Biological Material**.

Any usage of the **Biological Material** by the **Recipient** to that effect requires a separate contract between the **Provider** and the **Recipient**, which the parties to the contract intend to negotiate in a spirit of mutual cooperation and which includes suitable provisions for remunerating the **Provider** for such usages. The Recipient agrees not to undertake any profit- or marketing-oriented activities prior to such a contract being finalized.

4. In no way does this Agreement limit the rights of the **Provider** to make the **Biological Material** available to other third parties.
5. The **Recipient** agrees that in the absence of the express, prior written permission of the **Provider**, the **Biological Material** will be not be made available in any way to persons or organizations not under his or her direct supervision. The Recipient further agrees to impose this obligation upon all team members and contract partners.
6. The **Biological Material** is made available for **research purposes** for a maximum of **[FormText] year(s)** from the entry into force of this Agreement, unless the Agreement is mutually and explicitly extended. Any extension of the Agreement is to be initiated by the **Recipient**.

In the following cases, the **Recipient** agrees either to return the **Biological Material** or residues thereof to the **Provider** or to dispose of the **Biological Material** in accordance with regulations:

- The Recipient does not use the **Biological Material**;
  - The Recipient intends not to use the Biological Material;
  - The conclusion of the research;
  - The termination of this Agreement.
7. The rights of the **Provider** to publish documents in connection with the **Biological Material** shall not be restricted in any way by making available the **Biological Material**.
  8. The **Recipient** agrees to transmit to the Provider transcripts of all manuscripts and synopses, which are intended for publication and could disclose research results in connection with the **Biological Material**, at least 30 days prior to publication. This gives the **Provider** the opportunity to register intellectual property rights. With reference to the furnishing of the **Biological Material** or other direct contribution to the research efforts, the **Recipient** agrees to name the scientific co-workers of the **Provider** in the Acknowledgements section of any scientific publication.
  9. The **Recipient** acknowledges that the **Biological Material** is experimental in character and thus no warranty or guarantee is made on the part of the **Provider**.

Insofar as legally admissible, the **Provider** assumes no liability for defects of any kind. In particular, the **Provider** is not liable for:

- The infringement of the intellectual property rights of third parties;
- For disadvantages incurred by the Recipient in connection with this Agreement;
- For disadvantages incurred by the Recipient due to the storage or use of this Biological Material.

The **Recipient** fully indemnifies and holds harmless the **Provider** and his or her representatives and employees in the context of and in connection with this Agreement and the obligations assumed thereunder, and agrees to reimburse these parties for any payments made.

10. This Agreement is governed by Austrian law excluding conflict of law rules of private international law and the United Nations Convention on Contracts for the International Sale of Goods and shall be interpreted accordingly. The place of jurisdiction is Vienna.
11. Alterations and amendments to this Agreement, including this point, must be in written form.
12. Upon the signing of this Agreement, all prior declarations of intent or knowledge made by the parties to this Agreement are null and void as concerning—directly or indirectly—the object of this Agreement. The exception is any confidentiality agreement between the contract partners, which shall continue to remain in force.
13. Should one of the provisions of this Agreement be or become invalid or unenforceable, the remaining provisions shall remain in force. The parties to this Agreement shall replace the provisions in question with valid and enforceable provisions, which best achieve the purpose originally intended.

For the **Recipient**:

Name/Position of the Recipient

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Location, Date

Signature of the Recipient

For the **Provider**:

Name/Position of the Provider

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Location, Date

Signature of the Provider