

**Recommendations for the announcement of animal experiments on vertebrates, cephalopods or decapods according to Section 8 (1) and (3) TierSchG at the Eberhard Karls University Tübingen**

Notifiable are procedures according to Section 8a TierSchG. The announcement must be submitted in written form **in German language** to the Regierungspräsidium (R.P.) (TierSchVersV Section 36). The same form is to be used for the announcement of animal experiments as for procedures requiring approval.

Legal basis for notifiable experimental projects:

1. Section 8a (1) No.1 TierSchG; legally required
2. Section 8a (1) No.2 TierSchG; diagnostic measures / vaccine tests etc.
3. Section 8a (1) No.3a TierSchG; interventions and treatments according to already tested procedures for the production, preparation, storage or reproduction of substances, products or organisms; not for experimental purposes
4. Section 8a (1) No.3b TierSchG; removal of organs and tissues - in whole or in part - according to proven methods for scientific/ diagnostic purposes; not for experimental purposes
5. Section 8a (1) No.4 TierSchG; interventions and treatments according to proven and tested procedures for training, continuing and further education purposes
6. Section 8a (3) TierSchG; experiments on decapods

Please note, that announcements according to point 5 must be proven methods which are established in this institution (procedures not established on site are classified by the authority as requiring a license). Animal experiments for education, further training and continuing education purposes are only allowed if the educational objective cannot be achieved in any other way (indispensable, Section 7a (1) sentence 1).

Experimental projects with primates or projects with other vertebrates, if the burden on the animals is classified as severe, require a project license (Section 8a (2) TierSchG), even if they can be counted as one of the cases in Section 8a (1) Nos. 1-4.

In the case of procedures which are subject to the duty of announcement, the authority must issue a announcement of acceptance before the expiry of 20 working days from receipt by the R.P. (in addition to the processing time by the Animal Welfare Officer (TSchB) and the usually several-day postal route), unless the authority informs in advance that it has no objections (TierSchVersV Section 36 (2)). Announcements are generally confirmed by the regional council by e-mail. It is recommended to contact the TSchB in the case that experiments are to be performed within the framework of an announcement before this confirmation is received.

## **I. Required application documents for discussion, examination and consultation with the animal welfare officer**

Please first submit the following documents and application forms to the Animal Welfare Officer (TSchB) in printed, single copies or electronically by e-mail. Under point II. of this recommendation "Final Application Forms - Checklist" you will find a detailed list of all required documents (with number of copies), which have to be submitted after consultation with the TSchB.

- 1) Complete announcement
- 2) Personal data sheet ("Personenbogen") for all contributors named under 1.2 and, if applicable, for the test designer named under 1.1.3 (not required for supervisor and deputy)

Please mark the personal data sheet if it has been updated and does not correspond to the version available at RP.

- 3) Key publications (max. 5 publications)
- 4) Current final assessment of genetically modified breeding lines when working with genetically modified animals (even if the TSchB already has an assessment from previous projects, please always enclose a copy)
- 5) If already determined: Information on biometric planning, alternatively biometric expertise

If you have difficulties filling in specific Sections, please mark them in colour. We will be happy to help during a joint discussion of an initial draft of the application.

### **General Considerations:**

The purpose of an animal experiment announcement is to estimate the burden on the animals in relation to the benefit for the scientific question. Therefore, it must be clearly stated which burdens the animals will experience within the framework of the project and which interventions will be carried out. It must also be explained what will be done to minimize pain, suffering and harm and when animals will be prematurely withdrawn from the experiment.

The scientific purpose of the project should be described in as precise a manner as possible, without requiring your specific expertise, but that of a normal bio-medical academic education. It must be clear from the text that alternative methods (e.g. in vitro experiments) are out of the question or have already been exhausted and it must be explained why this question can only be answered in an intact organism.

It is helpful to have the completed application read by someone who is not familiar with the specific question, but who corrects spelling and translation mistakes and recognizes passages of text that are difficult to understand.

Initially, the general scientific purpose is to be described and then followed by an explanation of how the planned experiments can contribute to the clarification. Specific details, as they are common in scientific papers or in proposals for research funds, can possibly lead to comprehension problems for readers not familiar with the subject. The use of finished text blocks from DFG proposals (or comparables) is generally not advisable.

**Please pay attention to the what is specifically asked in every section and always answer all questions completely, especially if several things and aspects are asked in one point at the same time. This information can be regarded as a recommendation.**

### 1) Announcement of animal experiments

Please tick the second box on the first page, if the planned project is subject to announcement. The applicant does not have to be the same as the project supervisor. However, he/she will become the license holder and the authority will issue the official approval to the applicant (not the project leader). Please note that correspondence (including queries from the authority) will be addressed to the applicant and not to the project leader. The applicant does not formally need to have the technical knowledge and skills required of supervisor, deputy, planner and staff.

#### **1.1.1 Project leader/supervisor**

##### **1.1.1.1 Professional education**

Please check the appropriate profession (veterinarian, physician, scientist (which branch?), other) and check if the certificate is attached to this application or if it was already sent with the application for project no. ....

##### **to point 1.1.1.2 and 1.1.2.2 respectively (knowledge and skills):**

Please list the activities of the project leader and the deputy leader with regard to the animal experimental interventions and treatments to be carried out in the project and indicate where they have the knowledge from (e.g. projects requiring a license, announcements, and notifications according to Section 4 TierSchG can be listed in which these animal experimental interventions or killing methods have already been carried out).

(See also the recommendations for the qualification of experimenters).

Certificate is attached / was sent with application no....

##### **to point 1.1.1.3 and 1.1.2.3 respectively (participation in a course on laboratory animal science):**

Among other things, it must be stated whether a course on laboratory animal science with teaching content in accordance with Annex 1, Section 3 TierSchVersV was attended. If no, this can only be accepted by the authority if the same knowledge and skills have been demonstrably acquired elsewhere. If yes, indicate the course name and scope (in hours) and attach a certificate. All details for the supervisor and deputy must be noted on the application form itself and no separate personal data sheet must be enclosed.

##### **to point 1.1.1.4 (special permit if applicable):**

Please describe for which procedures, a special permit was issued.

**to point 1.1.1.5 (expertise for the killing of laboratory animals):**

Yes or No. This expertise is usually imparted during a course on laboratory animal science or may be acknowledged through a small exam in front of an animal welfare officer.

**1.1.2 Deputy supervisor / leader**

For an explanation of the following points regarding the deputy supervisor see the equivalent points for the supervisor above.

**to point 1.1.3:**

Usually the supervisor or deputy is also the test planner at the same time. In this case, no personal data sheet should be enclosed. Please note that the test planner must also have the laboratory animal knowledge and skills in accordance with Annex 1, Section 3 TierSchVersV. For further details, please refer to our recommendation on the qualification of experimenters.

**to point 1.2:**

Please indicate here other persons who carry out operations and treatments as well as killing of animals within the framework of this project (contributors). In principle, it is also required that these persons have the knowledge in accordance with Annex 1, Section 3 TierSchVersV. A personal form must be enclosed for each involved person. Please describe in detail for each person the individual procedures and treatments, including anesthesia and killing procedure, which are carried out as part of the animal experiment and are therefore subject to approval. Breeding is only subject to approval in the case of animal strains with genetic burden. Removal of organs and other interventions on already dead animals should not be indicated here. If applicable, please enter in the right column of the table the application number with which a personal data sheet was submitted to the RP Tübingen. If no application number has yet been assigned, please enclose a duplicate of this person sheet with the new project.

**to point 1.3.1:**

Are the mentioned persons employed by the institution? If "No" please name the appropriate person(s). The term "institution" ("Einrichtung") refers to the entire university including the associated institutes and departments.

**1.3.2 If No, are they allowed by the responsible head of the department to use the facility?****to point 1.4.1:**

veterinary care for the animals

<u>Name:</u>	<u>Dienstliche Anschrift:</u>	<u>Qualifikation:</u>
Tierärzte der Einrichtung für Tierschutz, tierärztlicher Dienst und Labortierkunde (ggf. Name des tierärztl. Leiters der Einrichtung)	Calwerstraße 7/4, 72076 Tübingen	Tierärzte und Fachtierärzte für Versuchstierkunde und für Tierschutz

**to point 1.4.2:**

Name and address of the expert or veterinarian to assess the surviving animals after the experiment. This is only applicable if there are surviving animals. If the animals are killed at the end of the experiment, nothing should be entered here.

In the case of primates, ungulates (even-toed and equids), dogs, hamsters, cats, rabbits and guinea pigs, a veterinarian has to see the animal immediately after the experiment.

**In the end of part 1 you will find the following**

**Declaration of commitment:**

With the signature the project leader and his deputy commit themselves to assume the responsibility for the compliance with the regulations according to Section 9 (6) TierSchG in connection with Section Section 15-31 (resp. with announcements Section 36)

TierSchVersV as well as if applicable for obligations according to Section 8 TierSchG and explanations or changes concerning this application/this announcement, which were transmitted by the project leader/deputy in writing to the RP Tübingen after further inquiries and to consider the recording obligation according to Section 9 (5) TierSchG in connection with Section 29 (1) and (2) TierSchVersV.

At the same time the knowledge of the TierSchG and the TierSchVersV is confirmed.

With the signatures it is confirmed that the licensing requirements according to Section Section 7, 7a and 8 TierSchG, which are set out in the application including all annexes, are met.

**to point 2:**

On request, third parties, such as animal welfare associations and other organisations, can be given access by the RP to the application from point 2 onwards (Freedom of Information Act of the federal state of Baden-Württemberg (LIFG), Act on Participation Rights and the Right of Action for Animal Protection Organisations (TierSchMVG)). We therefore advise you not to mention any names after this point, except in the form of literature quotations. Also, comments which could lead to conclusions about individual persons or our university (clinic) should be avoided if possible. Of course, it is not always possible to anonymise the document completely, since in Baden-Württemberg, for example, not many institutions work with certain animal species and certain research areas may also be assigned to scientists at our university.

**to point 2.1:**

Please remember to re-enter the title here (identical to title on page 1), as this is mandatory for administrative reasons.

**to point 2.2:**

Please indicate here the legal basis of the announcement, i.e. the legal regulation according to which the animal experiments must be carried out.

**2.3 Scientific background**

**to point 2.3.1:**

The purpose to which the experimental project is to be assigned according to Section 7a (1) TierSchG must be ticked here (several crosses are also possible).

**to point 2.3.2:**

After the purpose of the experimental project was marked with a cross under point 2.3.1, the purpose must now be described in detail in the field "Erläuterungen". The "Erläuterungen" field must also be filled in for an announcement. It is important that the actual purpose of the

announcement is described in detail. It should be explained how the planned project can contribute to answer the question.

**to point 2.3.3:**

Points 2.3.1 and 2.3.2 explained the purpose of the experimental project. Here, the indispensability shall be described, i.e. why the results are absolutely necessary and cannot be obtained otherwise. Special attention should also be paid to individual interventions and treatments, whether they are burdensome and whether they can be dispensed with. Furthermore, it should be checked whether all partial experiments or control groups are indispensable. Reference should also be made, where appropriate, to your own preliminary studies and those of other working groups.

**to point 2.3.4:**

Here it should be explained how certain results obtained with the experimental setup support or disprove the hypothesis. In the case of several hypotheses, this must be done for each of them.

**to point 2.3.5:**

Here it should be explained why it is not possible to use other methods to meet the purpose of this project (e.g. cell culture, isolated organs, meta-analysis of clinical data, etc.).

**to point 2.3.6:**

Here the previous scientific work of the working group shall be outlined in relation to the proposed project and, if possible, one or more publications with a key function shall be referred to and attached.

**to point 2.3.7.1:**

Please explain which databases and resources you have used for literature research, the keywords used, last date of research and number and relevance of the publications found.

**to point 2.3.7.2:**

Here the "scientific gap" is to be described by explaining what was found under point 2.3.7.1 as knowledge from the literature in the marginal area of the knowledge gap.

**to point 2.3.7.3:**

Here should be specified, if the intended experiments are a repetition (retry) or double test. If yes, a scientific justification has to be given, that the planned experiments are indispensable.

**2.3.8 Specie(s) and number of animals to be used**

**to point 2.3.8.1:**

Please state and justify your choice here:

- (a) the intended species of animal
- (b) age or weight
- (c) sex

**to point 2.3.8.2:**

Please enter the name of the strain in the official form (scientific nomenclature). This is particularly important for genetically modified animal strains and sublines.

Please attach the form „Abschlussbeurteilung genetisch veränderter Zuchtlinien“ (Final assessment of genetically modified breeding lines) for each genetically modified animal strain

in order to prove whether or not there is any genetical burden. Please always use the exact strain and line name. You can find help on the Jackson Laboratories page.

<http://www.informatics.jax.org/mgihome/nomen/strains.shtml>

#### **to point 2.3.8.3 and 2.3.8.4**

The planning of the number of animals on the basis of the case number estimate for each group and all groups in total of laboratory animals shall be presented. Normally the group size is calculable by scattering, relevant differences of mean values, etc. If this is not possible due to the scientific question (e.g. feasibility study without statistical data evaluation), this must be explained particularly thoroughly. Please note that in most cases only very few animals can be applied for in the context of feasibility studies and pilot experiments. "Feasibility studies" are about whether something is "feasible" in principle. Here it would be sufficient to prove the "feasibility" on one animal. However, if it does not work on one single animal, the maximum number of animals one would like to use must be considered and well justified in order to be able to prove the basic "feasibility" at least once.

For better overview, it is advisable to use tables.

It must be clarified whether any "back-up animals" applied for lead directly to an increase in the group size in order to compensate for probable failures and ensure a certain number of samples for statistically relevant results, or whether these are real reserves which are only used if animals have actually failed. The indispensability of back-up animals must be scientifically justified.

For biometric planning, members of the Medical Faculty can take advantage of advice from the Institute of Clinical Epidemiology and Applied Biometry (<http://www.medizin.uni-tuebingen.de/Mitarbeiter/Institute/Klinische+Epidemiologie+und+angewandte+Biometrie/Beratung.html>). If you would like to calculate the size of your groups yourself, you can also make use of freely available programs such as SISA (<http://www.quantitativeskills.com/sisa/calculations/sampshlp.htm>) or G\*Power (<http://www.gpower.hhu.de/>). With WinEpi (<http://www.winepi.net/>) a calculation can be carried out directly online.

#### **to point 2.3.8.5**

Here the origin of the ancestors of the animals used in the experiments is not asked, but the origin of the individuals used in the experiments. If these were born inside the institution, please write "Eigenzucht".

#### **to point 2.3.8.6:**

Here it is asked, if the intended animals have already been used for other projects according to Section 18 TierSchVersV and if so, please specify type, duration and burden of the procedures and interventions, reference number and responsible authority.

### **2.4 Practical realization**

#### **to point 2.4.1:**

Address of animal facility and place (address), start and planned duration of the experiments should be entered here.

The announced project can have a duration of a maximum of 5 years.

A maximum of two extensions for a maximum of one year each is possible if the project was originally announced for only 3 years or less.

#### **to point 2.4.2:**

Here it should be described, how the animals are housed: Number of animals per cage, single housing, cage size, equipment and possible deviations from the housing standard.

Equipment refers to environmental enrichments, such as tunnels, houses, etc. Please note that male mice should only receive enrichment (tunnels, houses) in single housing, but not in group housing, due to territorial fights.

**to point 2.4.3.1:**

Depending on how the animals are housed, specify how they are to be monitored for hygiene. As a rule, "random samples" of mice and rats in open housing and "litter sentinels" in IVC cages are tested serologically, bacteriologically, mycologically and parasitologically twice a year by the veterinary service. In addition, samples are usually taken from sick animals and tested for the pathogens mentioned in point 2.4.3.2. Please also comment on the following points: Barrier status, protective clothing and controlled access.

**to point 2.4.3.2:**

Please enter here a list of pathogens for which these animals have been tested and from which these animals should be free (SPF). These can be found in the user and hygiene regulations of the respective animal husbandry. Please note that the pathogens listed in the health certificates only contain the laboratory diagnostic findings and are therefore not complete. The complete list can be obtained from the respective person responsible (according to Section 11 TierSchG) for the animal facility, but can also be obtained from the veterinary service if necessary.

**to point 2.4.3.3:**

Please tick "yes", "no" or "not evaluated" (explanation why?) to the question if there were found organisms in the animal facility room which should not be there according to the defined hygiene standard.

If the answer was "yes", which organisms? Are they able to influence the outcome of the experiments? Which measures were taken in order to prevent the infection of the animals, planned for this project.

**2.4.4 Interventions**

**to point 2.4.4.1:**

Here the practical realization of the experiments is to be described. Also the duration of the experiments considering the chosen anesthesia protocol. It may be useful to outline in a time axis which measures are to be carried out over time. Depending on the experiment, this can possibly begin with the birth or stabling of the animals. All interventions should be described here precisely and completely, i.e. operations, applications including indication of quantity, type and localisation of the application on the animal, etc. The active substances used should be described in terms of dosage, volume and route of administration. It should also be described when and how often the animals are checked after the procedure and which parameters are collected. The duration of the observation period and the method of killing the animals at the end of the test should be stated. The reader must be able to form a picture of what happens to each individual animal. In the case of unusual procedures with increased stress, the indispensability for this unusual procedure should be explained here again.

**to point 2.4.4.2:**

All parts of the experimental setup described under 2.4.4.1 that are performed under anesthesia should be listed here. It should be described how and with which active substances and dosages the anesthesia is performed (induction, maintenance, duration, depth of anesthesia) and how long the procedure lasts overall. Possible after-treatment of the animals

with analgesics or other substances should be discussed. Since the anesthesia is described here in great detail, it can only be mentioned in point 2.4.4.1.

**to point 2.4.4.3:**

Are there any painful interventions carried out without anesthesia?

Here it must be taken into account that not only very severe painful interventions are meant, but also less severe pain (e.g. through injections, etc.). One possible reason for not using anesthesia would be, for example, that the burden caused by the injection pain is less than the burden on the animal caused by the anesthesia.

**to point 2.4.4.4:**

Description and explanation of actions for pain relief and, if applicable, explanation of why no such actions are to be taken.

**to point 2.4.5:**

Describe and evaluate the stress on the animals (intensity and duration of pain, suffering or harm) during the experiment. Assign these to the categories (a-d) of the classification of severity levels according to Annex VIII of Directive 2010/63/EU.

(a) No restoration of vital function:

Procedures carried out entirely under general anesthesia from which the animal no longer awakens shall be classified as 'no restoration of vital function'.

(b) Minor:

Procedures which are expected to cause animals mild pain, suffering or distress for a short period of time and procedures which do not significantly impair the welfare or general condition of the animals shall be classified as "Minor".

(c) Moderate:

Procedures which are likely to cause animals short-term moderate pain, moderate suffering or distress or prolonged mild pain and procedures which are likely to cause animals to suffer moderate impairment of welfare or general condition are classified as "moderate".

(d) Severe:

Procedures which are expected to cause severe pain, suffering or distress, or prolonged moderate pain, suffering or distress in animals, and procedures which are expected to cause severe impairment of the welfare or general condition of animals, are classified as "severe".

The burden due to genetic deficiencies in the animals must also be indicated here. The sum of individual exposures must be taken into account. In this case it is advisable to draw up a score sheet (see point 2.4.7).

If a weight loss is given as a criterion, the reference weight must be given. In case of a longer test period, we recommend that the initial weight be used as reference value corrected for the expected increase in weight of same-age, same-sex, unburdened animals of the same strain in the observation period.

**to point 2.4.6:**

Please describe here the health control protocol (time, frequency, monitored parameters and executing persons). Only the measures which are carried out by the experimenters are asked here. The daily inspections by animal keepers or health checks by veterinarians are not required here.

**to point 2.4.7:**

If necessary, specify specific concrete endpoints, i.e. circumstances in which an animal is no longer used or at which threshold experimental animals are killed without pain (= definition of so-called humane endpoints). With the help of a score sheet and regular inspection of the animals and/or measurements (e.g. laboratory parameters, tumor size, blood pressure, body weight, etc.) it can be ensured that the necessary time of termination is recognized in time for all animals. Among other things, the reduction of body weight, as described under point 2.4.5, can also serve as an endpoint criterion.

You will find assistance for the creation of a score sheet and endpoint criteria under the following link: <http://www.charite.de/tierschutz/download/2013Empfehlungen-der-Berliner-TschB-zu-Score-Sheets+Abbruchkriterien.pdf>

An example of a score sheet can be found in Appendix I of this document. It may have to be modified and supplemented for specific experiments.

Please note that the Score Sheet and the termination criteria must relate to the parameters collected under 2.4.4.1 and 2.4.6.

### **to point 2.5.1:**

Here an ethical consideration of the two goods is expected: "well-being of the animals" versus "announcement purpose, e.g. indispensability of training or scientific interest". Describe your assessment of this relationship and explain why you consider this to be ethically justifiable.

## **2.6 Procedures at the end of the experiments**

### **to point 2.6.1:**

- In a final experiment (no restoration of vital function – “Terminalversuch”), no animal may have undergone surgery or treatment prior to anesthesia (other than the induction of anesthesia) and the animal may not awaken from this first anesthesia. In the case of burdened strains, an experiment may begin with the transport from the breeder to the scientist, with the mating, or with the birth of the animals. Experiments with such genetically burdened animals can therefore only be carried out as final experiments if the animals have previously been produced for this purpose in another independently approved experimental project.
- Killing after an observation period of...: Here, the total period from the first intervention, which leads to a stress, plus adaptation time if necessary, to the death of the animal is relevant.
- Continuation of life without any impairment of well-being.
- Continuation of life with justifiable impairment of well-being (to be described further)
- Alternative accommodation according to Section 10 TierSchVersV (with explanations/annotations)

### **to point 2.6.2:**

Describe the planned killing procedures in such a way that it is clear what stress will be caused to the animals.

If, for example, killing with CO<sub>2</sub> is chosen, this should preferably be done by introducing the gas into the “home cage” of the animals, in order to cause the animals (the animal) as little distress as possible. If only one animal from a group is to be killed, the other animals from the same cage are transferred to a new cage before killing and the animal to be killed remains in its familiar environment. For mice and rats, the most important factor is the familiar smell of their used bedding. The CO<sub>2</sub> should also be introduced as quickly as possible, but as slowly as

necessary so that the animals are not disturbed by hissing noises and air and bedding turbulences. A too slow introduction of CO<sub>2</sub> should also be avoided, as the animals would be exposed for an unnecessarily long time to a tingling or stinging sensation on the mucous membranes of the nose and mouth and the subsequent feeling of dyspnea before becoming unconscious.

### **3. Anonymization of the application**

It has to be stated if the applicant wishes to pass on the anonymization of his/her announcement. Usually this should be answered with “yes”, if there is no reason not to do so.

### **4. Bibliography**

### **5. List of abbreviations**

## 2) Personal data sheet

For each person involved in the test (test planner - point 1.1.3 and other persons - point 1.2) a personal data sheet must be enclosed. This is not necessary for the project supervisor and deputy, as the information for these two persons must be entered directly in the announcement form (items 1.1.1 - 1.1.2.2). A personal data sheet must be resubmitted as long as it has not yet been accepted by the authority as part of an application for a project license or announcement. It must also be updated, if necessary, if new interventions and qualifications are to be notified for the person.

## 4) Key publications

At two places in the form you will be asked for key publications (item 2.3.3 and 2.3.6). Please do not enclose more than 5 publications. As a rule, it is sufficient to enclose one basic publication and one publication of your own.

## 5) Biometric Expertise

It is recommended to include a biometric expert opinion to justify the number of animals. Experience has shown that in the absence of a biometric report, the Commission often has to ask questions about biometric planning. We recommend that the biometric expertise only be prepared after the initial meeting with the Animal Welfare Officer, as experience has shown that there may still be changes in the number of animals.

## 6) Final assessment of genetically modified breeding lines

Please add this form for each genetically modified animal strain. This form must be used to clarify whether there is any burden and the level of burden caused by the genetic modification. Assistance with the final assessment can be found on the homepage of the Animal Welfare Officer.

## **II. Final announcement forms - Checklist**

As soon as the Animal Welfare Commissioner has agreed the draft application with you, the completed application will be submitted to the Regierungspräsidium via the TSchB. Please note the following checklist:

- 1 complete animal experiment announcement**  
1x in printed form with original signature
- 2 copies of the complete announcement**
- 1 Confirmation of objective means**  
1x in printed form with original signature
- 3 Personal data sheets for all contributors named under 1.2 and, if applicable, for the test planner named under 1.1.3, if these are not already available to the RP in the current version.**  
1x in printed form with original signature for every contributor
- 1 copy of key publication(s)**  
1x in printed form und 1x via e-mail to the animal welfare officer in order to forward them to the Regierungspräsidium (max. amount 5 MB) or 3x in printed form
- 3 copies of the biometric expertise / forms "Angaben zur biometrischen Planung" (1x original and 2 copies)**

### **In case of genetically modified lines additionally:**

- 1 final assessment of genetically modified breeding lines without genetic burden**  
1x in printed form

**According to the current interpretation of the TschG by the competent authorities, the breeding of strains with a burden requires approval of an animal experiment application and is generally not accepted by the authorities within the scope of a Section 8a announcement.**

The regional council examines the announcement and, if necessary, confirms by e-mail that there is no need for obtaining a license.

### **III. Amendment requests**

Amendments must also be submitted through the Animal Welfare Officer. Please note that you must use the special, ready-made amendment form to request a substantive change. Extensions and personnel changes may still be requested/notified by means of informal letters.

*We will be very grateful for any suggestions and improvements regarding this recommendation. Please contact the office of the Institution for Animal Welfare, Veterinary Service and Laboratory Animal Science: Tel 07071-29-80125 or E-Mail <mailto:sekretariat.tschb@med.uni-tuebingen.de>*

## Appendix I:

Score sheet example	Assessment	Score	Date
Care condition	smooth, glossy	0	
	no coat care, dull coat	1	
	no coat care, dirty	2	
	no coat care, dirty, erecting the body hairs (piloerection)	3	
Eyes	normal	0	
	moderately sunken in, swollen	1	
	closed eye lids	2	
	heavily sunken, lids closed, sticky (discharge)	3	
Posture	normal	0	
	moderately crooked	1	
	crooked back,	2	
	strongly humped, legs placed under the belly	3	
Mobility	normal	0	
	slow forward movement of the limbs	1	
	unsteady gait	2	
	movement hardly provokable by touch, strongly restricted or wobbly movement	3	
<b>Nutritional condition</b>			
Body condition score	vertebrae, pelvis palpable only with light pressure	0	
	vertebrae, pelvis palpable, lateral abdominal retraction visible	1	
	vertebrae are visible and pelvic bones can be felt	2	
	vertebrae, pelvis and ribs visible	3	
Weight in relation to the initial weight, corrected for the expected increase in the weight of same-age same-sex animals of the same line during the observation period	normal, continuous increase (variations by 5%)	0	
	Weight reduction 5-10%	1	
	Weight reduction >10 to <20%	2	
	Weight reduction by a maximum of 20%	endpoint	
Respiration	regularly	0	
	regular, slightly increased	1	
	significantly increased	2	
	difficult breathing, pumping	3	
Behaviour/ Activity	normal	0	
	slight modification	1	
	little movement, isolated	2	
	apathetic, indifferent	3	
Experiment-related criteria e.g. tumour size/condition	no tumor growth	0	
	tumor diameter <10 mm	1	
	tumor diameter <15 mm	2	
	tumor diameter > 15 mm or ulcerated	endpoint	
<b>Points total:</b>			
<b>Extraordinary measures</b>	With 20% weight loss With tumor diameter n >15mm With allocation of 2x 3 points	endpoint	
<b>Assessment</b>			
0 -2 points	normal		
3 -8 points	increased monitoring, if necessary seek veterinary advice (administration of painkillers, increase in the frequency of weight control)		
9 and more points	Animal suffering reaches defined humane endpoint -> Euthanasia		