

Application for licence to perform animal experiment

art. 18 Animal Welfare Act (SR 455), art. 141 Animal Welfare Ordinance (SR 455.1),
art. 30 Animal Experimentation Ordinance (SR 455.163)

National no. Cantonal no.
[Nat. no.] [Cant. no.]

(To be completed by the authorities)

Basics 01-08

01 Address of the applicant

Institute

Name	Enter name
Street	Enter street
Postal code	Enter postal code
Town	Enter town
Company	Enter company name

Resource Manager

Name	Enter name
E-mail	Enter e-mail
Tel. no	Enter tel. no.

Study Director

Name	Enter name
E-mail	Enter e-mail
Tel. no	Enter tel. no.

02 Address of the cantonal authority

Name	Enter name
Street	Enter street
Postal code	Enter postal code
Town	Enter town
Delegated application input by the canton in animex-ch	☐ Yes ☐ No

03 Intercantonal experiment

Is the experiment performed in more than one canton?	☐ Yes ☐ No
If yes: Secondary canton(s)	Enter secondary canton(s)

04 Title of application

Indication of application title	Enter indication of application title
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05 Title for the publication

Informative title to be used for the publication according to art. 20 let. a Animal Welfare Act (SR 455) after the end of the experiment.

Indication of application title used for the publication

Enter application title used for the publication

06 Application type

Corresponding application type

- ☐ [N] New application
- ☐ [R] Renewal application
- ☐ [SC] Supplementary application
- ☐ [SR] Personnel supplementary application for
Resource Manager or Principal Study Director
- ☐ [SP] Personnel supplementary application
- ☐ [SV] Supplementary application for extension of validity

07 Maximum prospective degree of severity

Indication of the maximum
prospective degree of severity of this
application

- ☐ 0
- ☐ 1
- ☐ 2
- ☐ 3

08 Duration of project and date of start

Duration of project

y years / mm months / dd days

Date of proposed start

Enter date of proposed start

Animals 9-10

09 Animal list

Animal category (species)	Sex	Genetically modified ¹⁾	If yes, national no. of data sheet	Newly established	Constrained line ²⁾	Requested number of animals	Origin type ³⁾	Place type ⁴⁾
Animal category	Mixed	Select	Data sheet no.	Select	Select	Number	Select	Select
Animal category	Select	Select	Data sheet no.	Select	Select	Number	Select	Select
Animal category	Select	Select	Data sheet no.	Select	Select	Number	Select	Select
Animal category	Select	Select	Data sheet no.	Select	Select	Number	Select	Select

Insert new row

¹⁾ If yes, data sheet has to be attached (Form D).

²⁾ If yes, Form M has to be attached.

³⁾ Select from a: From previous experiment; b: Approved animal facility (incl. own breeding) or c: Non-approved animal holding

⁴⁾ Select from a: Approved animal facility or b: Non-approved animal holding

Data sheet information and related forms

Attached documents/forms

File name

File name

File name

Insert rows

Information about the origin of the animals (origin type)

a) From previous experiment

☐ Yes

☐ No

If yes:

National number

Cantonal number

National number

Cantonal number

b-1) Approved animal facility(ies) from Switzerland (incl. own breeding)

☐ Yes

☐ No

If yes:

National number of animal facility

Name

Address

National number

Name

Address

National number

Name

Address

Insert rows

b-2) Approved animal facility(ies) from abroad

☐ Yes

☐ No

If yes:

Name of animal facility

Address

Name

Address

Name

Address

Insert rows

c-1) Non-approved animal holding(s) from Switzerland ☐ Yes ☐ No

If yes:

Name of animal facility	Address
Name	Address
Insert rows	

c-2) Non-approved animal holding(s) from abroad ☐ Yes ☐ No

If yes:

Name of animal facility	Address
Name	Address
Insert rows	

c-3) Other non-approved origin(s) of the animals ☒ Yes ☐ No

If yes:

Description of animal origin
Description
Insert rows

Information about the place where the animals are kept (place type)

a) Approved animal facility(ies) ☐ Yes ☐ No

If yes:

National no. of anim. facil.	Name	Address	Room no.	Permit access to HAF in animex-ch
VD-H11	Name	Address	Room no.	Select
National number	Name	Address	Room no.	Select
Insert rows				

b-1) Non-approved animal facility(ies) ☐ Yes ☐ No

If yes:

Name of animal holding	Address	Description
Name	Address	
Insert rows		

b-2) Other non-approved place(s) of animal holding(s) ☐ Yes ☐ No

If yes:

Description of animal holding
Description
Insert rows

10 Location of the experiments

Address	Room no.	Description
Address	Room no.	Description
Address	Room no.	Description

Insert rows

Personnel 11-14

11 Personnel details

The appendix to this application “Persons involved and certificates of education and training” must be duly filled and copies of education and trainings have to be attached, if not yet submitted.

12 Resource Manager

Name

Enter name

Statement of responsibility

The Resource Manager confirms that the persons named in the list of persons are familiar with the regulations of the Animal Welfare Act (SR 455) and Animal Welfare Ordinance (SR 455.1) applicable to animal experiments and that they satisfy the educational and further training requirements.

Place, date:

Signature:

13 Principal Study Director

Name

Enter name

Statement of responsibility

The Principal Study Director confirms his / her responsibility as stated in art. 131 Animal Welfare Ordinance (SR 455.1).

Place, date:

Signature:

Name of Deputy Study Director:

Enter name

14 Animal Welfare Officer

Name

Enter name

Statement of completeness

By submitting to the cantonal veterinary office, the Animal Welfare Officer confirms that the application has been completed in full and contains the information required to assess its necessity (art. 129 let. a Animal Welfare Ordinance (SR 455.1)).

Place, date:

Signature:

Purpose of the experiment ¹⁵⁻²²

In Sections 16-18, mark only one entry in each category and, where appropriate, enter a further mark in a sub-category.

15 Field of study

Indication of the scientific field

Ecotoxicology

If "Others": Specify scientific field

Specify scientific field

16 Area of application

The project is associated with following area of application

- ☐ Biological (including medical) studies in the field of basic research
- ☐ Research, development and quality control (excluding safety testing) of products or devices for human and veterinary medicine
- ☐ Diagnosis of disease
- ☐ Education and training
- ☒ Protection of humans, animals and the environment by toxicological or other safety tests for substances sub-categories:
 - ☐ Pharmaceutical products (including medical devices)
 - ☐ Agriculture
 - ☐ Industry
 - ☐ Private households
 - ☐ Food additives
 - ☒ Environmental contaminants
 - ☐ Other uses, please specify:
Specify
- ☐ Other studies, please specify:
Specify

17 Association with diseases or disorders

The project is associated with following diseases or disorders

- ☐ Human diseases
 - ☐ Cancer (excluding carcinogenicity studies)
 - ☐ Cardiovascular diseases
 - ☐ Nervous and mental disorders
 - ☐ Other human diseases, please specify:
Specify
- ☐ Animal diseases, please specify:
Specify
- ☒ No association with human or animal diseases

18 Associated procedures required by law

Indication of the regulatory requirements

- ☐ For Switzerland only
- ☐ For other countries only
Please, specify countries:
Specify
- ☐ For Switzerland and other countries
Please, specify countries:
Specify
- ☒ No association with procedures required by law

Indication of the guideline(s) or test method(s)

Enter guideline(s) or test method(s)

19 External expertise

Has the project been appraised?

☐ Yes ☐ No

If yes: Expertise rendered by

Enter name

20 Objective of the experiment and background

Brief description of the objective of the experiment (maximum one page). To assess **compliance with the indispensability** (see section 38 to 40) of the experiment according to art. 17 Animal Welfare Act (SR 455): (1) Description of the **aim**, (2) **Current state of research**, (3) Anticipated **knowledge to be gained**.

Objective of the experiment :

- ☐ is related to the preservation or protection of human or animal life and health
- ☐ is expected to provide new knowledge about fundamental life processes
- ☐ serves to protect the natural environment
- ☐ serves to replace animal experiments, to reduce the number of laboratory animals or to minimize the burden of animal experiments (3R Research)

21 Results of the previous application

Maximum one page must be completed in the case of renewal applications. Brief summary of the results of the previous licensing procedure including the number of animals used, the degree of severity, and the rationale for renewal of the application.

22 Hypothesis

Formulate the research question to be answered in the experiment or the hypothesis (hypotheses) to be tested (confirmatory study).

Course of the experiment (Method I) 23-27

23 Course of the experiments: Schematic representation

Description of the course of the experiment from a **temporal perspective**. Representation of the course of the experiment or individual steps (e.g. flow chart, workflow diagram, table). To include: animal model, animal groups, the overall duration of the experiment for each group.

24 Preparation of animals for the experiment

Assessment of the preparation of animals for the experiment (art. 119 Animal Welfare Ordinance (SR 455.1)): Description of screening examination, preparation to the experimental conditions, method of marking or identification and combination with the method of genotyping.

25 Procedures / manipulations on the animal

Assessment of licence conditions (art. 140 Animal Welfare Ordinance (SR 455.1)) and suitability (section 38) of the method (art. 137 para. 3 Animal Welfare Ordinance (SR 455.1)): Indicate the details of the various manipulations/interventions on the animal.

26 Anaesthesia and / or analgesia

Assessment of the application in accordance with the implementation provisions (art. 135 Animal Welfare Ordinance (SR 455.1)): Indicate the medications to be used, the dose and volume, the intended routes of administration and consider the need of continuing administration.

Rationale of anaesthesia / analgesia

Reasons for selecting or for not using analgesics and anaesthesia should be stated.

27 Methods of euthanasia

Assessment of the application concerning the proper conduct of euthanasia (art. 135 Animal Welfare Ordinance (SR 455.1)): Indicate the method of euthanasia, stating the substance used, the dose and route of administration, and the procedure to ensure the death of the animal.

Evaluation of the experiment (Method II) (28-31)

28 Recorded parameters

Brief description of the parameter, importance, relation to research question.

Recorded parameter	Comment
Parameter	Comment
Parameter	Comment
Parameter	Comment
Parameter	Comment
Parameter	Comment
Parameter	Comment
Parameter	Comment
Parameter	Comment
Parameter	Comment
Parameter	Comment
Parameter	Comment

Insert rows

29 Experimental set-up and study design

Description of the study design and planning: Number of animals per experiment/series of experiments, number of groups and number of animals per group. To indicate a description of each group. Specific considerations to include: allocation concealment / randomization, blinding, sample size calculation (rationale to be entered in section 30), in- and exclusion criteria, definition of primary outcome variables, statistical analysis plan.

30 Rationale for the numbers of animals

Indicate the **reasons** for the planned numbers of animals, including the method used for statistical analysis (e.g. t-test, ANOVA, mixed-effects model, etc.). If possible, indicate the test parameters (statistical coefficients, level of significance, power).

Justification for the number of animals to be used in the experiment

Enter text

Justification for the number of animals to be bred

Enter text

31 Expertise for statistical analysis

Indicate whether the experimental design and the planned statistical analysis have been verified by a person with expertise in biostatistics

Has the experimental design been
verified by a statistician

☐ Yes

☐ No

If yes:

Enter name

Handling of animals 32-37

Indicate the effects of the experimental methods on the animals, stress-reducing measures and use of the animals after the end of the experiment.

32 Downgraded husbandry conditions

Assessment of the necessity of restricted housing (see art. 117 Animal Welfare Ordinance (SR 455.1)): Details and reasons for any deviations from conditions in which animals are kept as defined in the Animal Welfare Ordinance (SR 455.1).

33 Effects on the animals

Assessment of all expected adverse effects on the animals (art. 19 para. 4 Animal Welfare Act (SR 455)) and of further strain imposed on the animals through humiliation, through major interference in their appearance or their capabilities or through excessive instrumentalisation (art. 25 and 26 of the Animal Experimentation Ordinance (SR 455.163)).

34 Monitoring of well-being

Assessment of the monitoring and documentation (art. 135 and 144 Animal Welfare Ordinance (SR 455.1)): To indicate are the criteria for **intervention** and **termination (humane endpoints)**, and the frequency of checks (who carries out checks, documentation and how often during which study phase?). Add a **score sheet** if appropriate.

35 Mitigating measures

Assessment concerning implementing rules **under the specific experimental conditions** according to art. 135, 137 para. 4 and 144 Animal Welfare Ordinance (SR 455.1). To indicate the details of mitigating measures or reasons for not using such measures. Which mitigating measures are taken to reduce stress or minimize any harm imposed on the animals under the specific experimental conditions?

36 Distribution by degree of severity

Summary evaluation of the expected maximum stress on the animals (art. 26 Animal Experimentation Ordinance (SR 455.163)): Indicate the maximum expected degree of severity for each animal category and group. The expected number of animals for each anticipated degree of severity should be given as a percentage. The allocation is based on FSVO technical information no 1.04.

37 Use of the animals at the end of the experiment

Assessment of the application concerning the implementing rules with regard to the further use of animals after an experiment (see art. 20 Animal Welfare Act (SR 455); art. 141 para 4 Animal Welfare Ordinance (SR 455.1)).

Rationale and weighing of interests 38-40

Details of the reasons and justifications for selecting the experimental method and animal category.

38 Suitability

Reasons for selecting the animal model with regard to the experimental objective and depiction of scientific validity (i.e. construct validity, internal validity, and external validity) and reproducibility of the expected findings, if appropriate. Show the extent to which it is possible to generalise or extrapolate to other study conditions, populations of animals or species, incl. humans. For regulatory experiments, indicate if an experiment is required by the authorities.

39 Necessity (3R)

Reasoning why the intended aim of the experiment **cannot be achieved by methods that comply better with the 3R criteria**. Explain also why a method that does not require animals does not exist (**Replace**), why the experiment cannot be carried out with fewer animals (**Reduce**), and how all possibilities to reduce the strain on the animals are exploited (**Refine**).

40 Weighing of interests

Assessment of the application with regard to the balance between expected gains in knowledge or other results (interests) and the pain, suffering, harm, injury or anxiety inflicted (strain on the animals) in accordance with ethical considerations. For more details on the weighing of interests, see the "Explanatory notes to Form A" and the document "Weighing of interests in animal experimentation" [\[LINK www.blv.admin.ch\]](http://www.blv.admin.ch).