# PROJECT APPLICATION WITH EXPLANATIONS - SIMPLIFIED

These instructions are intended to help you to complete your project application. You can prepare your application with these instructions and copy the text to the portal. The application must be completed in Finnish or Swedish.

ELLA = Project Authorisation Board

ESAVI = Regional State Administrative Agency for Southern Finland

A simplified form is used when the project only involves a small number of procedures with mild or moderate severity or pilot experiments. The experiments are simple, the number of animals is small, or the same procedure is repeated.

Such projects may involve blood sampling and euthanasia or the use of animals in the same repeated course work. The price of the decision is lower than normal. The presenting officer or the Board may categorise the application as standard application.

**Parts of the application**

1. Persons responsible for the project
2. Basic details of the project
3. Execution of the procedures and ensuring the welfare of the animals
4. Evaluation by the Board will be included in the decision

Hint: Select in Word: View > Navigation panel

# PERSONS RESPONSIBLE FOR THE PROJECT

## Name of the applicant (licence holder)

Name

Email

Organisation

E-invoicing address

E-invoicing operator

Invoice reference

License holder has overall responsibility for the project. Personnel changes must be reported on the notification of changes form.

## Contact person and email

## Name and email of the person responsible for implementing the project

The person is responsible for the practical implementation of the project:

The persons carrying out the procedures are qualified, all procedures are in compliance with the law and the licence, new 3R tools are effectively used, severity classification and record keeping are properly done, the medicines administered to the animals are entered in the records, and data for retrospective assessment is delivered to the Regional State Administrative Agency for Southern Finland within three months of the end of the project. Personnel changes must be reported on the notification of changes form.

## Name of the person responsible for planning the project and procedures

**Academic degree and courses taken (name, place, year):**

The project planner must have appropriate higher education degree and he or she must have taken appropriate animal experimentation courses. If the required courses have been taken in a country other than Finland, the project planner must apply for the required qualifications in Finland.

## Qualifications of the other persons carrying out procedures in the project

How were the qualifications acquired and verified? (names of the persons are not needed here).

## Operators’ facilities and animal units where the project is carried out

For example:

Operator = university

Establishment= Animal unit = facility where the procedures for the animals will be carried out. Use the names of the units listed in the operator’s licence. If experiments are carried out elsewhere, give the places where they will be performed.

# BASIC DETAILS OF THE PROJECT

## Name of the project

The title should briefly describe the purpose of the project.

Subproject purpose code

Use only one purpose code for each subproject giving its main purpose.

Haettu alkamispäivä, haettu loppumispäivä – Proposed start date and proposed end date

The licence is usually granted for three years. Longer licences (max five years) may only be granted for simple projects involving procedures with mild severity.

## Attach non-technical project summary: separate excel sheet

Download the excel form for non-technical summary. After completing it, attach it to the application from ‘Attach non-technical summary’.

Describe the objectives and expected benefits of the project in the non-technical summary. [Read the guide](https://ec.europa.eu/environment/chemicals/lab_animals/pdf/Endorsed%20NTS.pdf).

# EXECUTION OF THE PROCEDURES AND ENSURING THE WELFARE OF THE ANIMALS

**Material on the website:**

Commonly used purpose codes

Best practices

Table for procedures - example

Welfare scoring table - example

The Board publishes best practices for experimental techniques, and if they are followed, only reference to appropriate guidance is needed.

## Species, strains, origin of animals, age/developmental stage (incl. fetal forms)

## Animal reuse Describe the procedures that have already been done to the animals and that will be carried out in this project

An animal may be reused if the severity of the previous procedures has been mild or moderate and the severity of the new procedures is moderate at most. It is also required that the animal’s general state of health and welfare have been fully restored. Reuse must be in accordance with advice of a named veterinarian.

Definition of reuse:

[Commission Implementing Decision](https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=uriserv:OJ.L_.2020.129.01.0016.01.ENG&toc=OJ:L:2020:129:TOC)

Annex III B Part B Data input categories – chapter 2

Also:

<https://ec.europa.eu/environment/chemicals/lab_animals/pdf/Consensus_document.pdf>

## Procedures

Describe the steps of procedures in chronological order and the duration of the procedure.

**Exemptions from normal animal husbandry**

The breeding, maintenance and care of the animals are described in the operator’s licence. Give all exemptions from normal animal husbandry

Single housing

Conventional metabolic cage > 7 hours

Light cycle

Feeding

Fasting/food or water restriction

Temperature

Justify the exemptions

Describe the marking methods used

**ADMINISTRATION, SAMPLING, ANALGESIA, EUTHANASIA**

**Administration**

Do you follow the recommendations for conventional administrations issued by the Board, or the instructions for large animals given by a named veterinarian?  **Yes**

Describe administration routes and frequencies in the procedures and the administrations requiring surgery (for example minipump). Also state if you deviate from the recommendations.

|  |  |  |  |
| --- | --- | --- | --- |
| **Sampling blood and tissues by species** | | | |
| Species, sample type | Sampling site and volume | Number of samples and frequency | Anaesthesia, analgesia or other |
|  |  |  |  |
|  |  |  |  |

|  |  |  |
| --- | --- | --- |
| **Methods of analgesia by species**  Give the reasons if analgesia cannot be used. Give the anaesthesia method and the use of analgesia in procedures. | | |
| Species and substances | Route and dosing | Time and frequency (for example, at the end of operation, 1x per day for 2 days) |
|  |  |  |
|  |  |  |

**Methods of euthanasia**

Which anaesthesia method is used and how do you ensure the appropriate level of anaesthesia during perfusion or other procedures?

Permitted methods are described in [Annex 2 to the Regulation](https://finlex.fi/en/laki/kaannokset/2013/en20130564.pdf). Use of other methods must be based on the project licence.

## NUMBER OF ANIMALS; HARM THAT CAN BE CAUSED AND SEVERITY CLASSIFICATION

**Experimental design**

Give justification for the number of animals needed. Describe why all treatment groups are necessary and give the number of animals required for each treatment group. Are the group sizes based on previous experience, resource equation method, or power analysis? Does the estimate include the number of animals that may be lost during the experiments? Is it necessary to use animals of both sexes in the experiments?

**Describe the harm caused to the animals by the procedures and your suggestions for procedure severity classes.**

**Animal numbers used – you must not exceed the total number given for each animal species.**

Give in the table the estimated number of animals according to their severity classes.

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Species** | **Non-recovery** | **Mild** | **Moderate** | **Severe** | **Total** |
|  |  |  |  |  |  |
|  |  |  |  |  |  |

## WELFARE MONITORING and HUMANE END POINTS

**MILD SEVERITY: Can the rules below be followed?**

**Yes**

Eläimet tarkistetaan päivittäin:

Animals must be **monitored daily** for:

**general appearance** (for example dehydration, weight loss, abnormal posture, coat or skin condition, facial expressions indicating pain),

**activity** (for example unwillingness or difficulty to move),

**behaviour** (for example lack of movement, abnormal behaviour towards cagemates or humans, swimming behaviour of fish), and

**basic functions** (for example eating, drinking, urination, defecation).

If any clear change is noticed, the animal must be **monitored frequently** in cooperation with the care personnel. **Appropriate care** must be given if needed (for example increased temperature, hydration, analgesia). The animal must be **followed for 1-2 days**. If no recovery is apparent, the animal can be euthanized. The monitoring may be continued longer on a case-by-case basis according to the guidance of the named veterinarian. The animal can be **euthanized/removed from experiment** if the harm is assessed to be **moderate**.

**Additional specifications for humane end points, if needed**

**MODERATE SEVERITY**

Describe the expected harm, how the welfare is monitored, how harm is prevented or minimized, and which humane end points you apply. Use a welfare score sheet if appropriate and define scoring for euthanasia.

# JUSTIFICATION OF THE BOARD IN THE DECISION

The benefits from the project are regarded as ethically acceptable in relation to the harm caused to the animals.

yes  no justification:

**Retrospective assessment must be prepared**  yes  no

**Justification:** Reason for retrospective assessment and which procedures and issues should be considered.