# PROJECT APPLICATION WITH EXPLANATIONS

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. Short explanations for each question are given in blue text.

ELLA = Project Authorisation Board

ESAVI = Regional State Administrative Agency for Southern Finland

Hint: Select in Word: View > Navigation panel

**Parts of the application**

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

**Standard, simplified or extensive application**

You can choose between standard or simplified application. Simplified application is required if only a small number of procedures with mild or moderate severity will be carried out, such as pilot experiments or one or two blood samples and euthanasia.

Standard and extensive application must be submitted on the same standard application form. The application can be considered extensive, if the project includes extensive entities, involves a large number of animals and procedures and the project is substantially more extensive than a normal project.

# PERSONS RESPONSIBLE FOR THE PROJECT

## Name of the applicant (licence holder after the application has been approved)

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 designing the project and procedures

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

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

## Competences 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 and animal units where the project is carried out

Operator = university, research institute

Establishment=Animal unit = facility where the procedures for the animals will be carried out. The operator may have several separate animal units. Use the names of the units listed in the operator’s licence. If experiments are carried out elsewhere, name 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.

## 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 – [LINK](https://ec.europa.eu/environment/chemicals/lab_animals/pdf/NTS%20guidance%20document%20endorsement.pdf)

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

**Material on the website**

Commonly used purpose codes

Best practices (= Ella-tekniikkakuvaukset)

Table for procedures - example

Welfare scoring table - example

If the project includes several subprojects, complete this section 3 separately for each subproject. The project may have a maximum of five subprojects from the same research.

If the project includes maintenance of genetically altered lines with harmful phenotype, describe them as the first subproject, using the purpose code PG43.

Steps of the procedures repeated in several subprojects/procedures (such as imaging and surgical procedures) can be described as a separate subproject. Very long descriptions of procedures may be given as an attachment. The Board publishes best practices for experimental techniques, and if they are followed, only reference to appropriate guidance is needed.

## Give the number of subprojects

## Give general description of the project: How it is executed, which subprojects are included?

## SUBPROJECT 1

Copy this part if you have several subprojects

### Name of the subproject

### Person responsible for this subproject

### Purpose code of the subproject

Give only the main purpose of each subproject.

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

Give general description of gm lines used, and the tissue sampling method for genotyping and additional genotyping, including the analgesia used.

### Lines with harmful phenotype

Describe the strains/lines which may involve risk of harm: Type of harm and how it is minimised. Justify the need for these strains.

### 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 categories – 2 Reuse

Also:

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

### Procedures

Describe the experiments and all steps of the procedure in chronological order, and the duration of the experiment per animal. Give the sites and frequencies of administrations, sampling, anaesthesia and analgesia. The text must clearly describe all technical steps that an animal can be subjected to. Illustrate the procedures with diagrams or tables where appropriate.

### The breeding, maintenance and care of the animals is 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**

### Give the marking methods

### Administration, sampling, analgesia, euthanasia

 **Administration**

How is the dose selection for used substances done? For example, by utilizing literature, *in vitro* testing or piloting before actual tests.

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 and the administrations requiring surgery (for example minipump) in Procedures (3.3.7). 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 (3.3.7).  |
| Species and substances | Route and dosing | Time and frequency (for example, at the end of operation, 1x per day for two 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. A project licence is required for other methods.

### 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 non-animal methods and approaches that you have used: Which tests, for which purposes (for example, for estimating the maximum dose of study substance). Estimate how much the use of these alternatives has decreased the use of animals.

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

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

Give in the table the estimated number of animals used in this subproject according to their severity classes. The numbers are automatically summed at the end of this application for the whole project. Give them in the non-technical summary

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

### Welfare monitoring and humane end points

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

[ ]  **yes**

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 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 OR SEVERE 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.

## OSAHANKE 2. Paina painiketta: samat kysymykset - SUBPROJECT 2. Press the button: same questions

# TOTAL NUMBERS OF ANIMALS

**Give also the total numbers in the non-technical summary.**

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Species** | **Non-recovery** | **Mild** | **Moderate** | **Severe** | **Total** |
|  |  |  |  |  |  |
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# 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 perustelut - justification:

**Retrospective assessment must be prepared**

[ ]  yes [ ]  no

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