

GUIDANCE FOR PROJECT AMENDMENTS

1. AUTHORISED AMENDMENTS

An amendment can only be applied for in order to make the following changes and on the basis of an appropriate justification:

- Prolongation of the project (new end date)
- Change in the person responsible for the project / lab director or change in partner establishment
- Procedural change (with no change in the severity or number of animals, unless an exception applies)

1.1. Prolongation of the project

Project authorizations shall be granted for a maximum period of five years. Adjustments to the project duration can therefore only be requested if this duration is not exceeded. However, if the project could not start on the planned date because, for example, not enough animals or cages were available, adjustments had to be made to the installations, etc., the intended start date can be revised.

1.2. Change in the person responsible for the project / lab director or change in partner establishment

Only changes to the person responsible for the project / the laboratory director or partner establishment can be requested by ticking this box. Modifications to the list of personnel must be made by means of an adaptation of Annex III. This adaptation should, however, still be communicated to the Ethical Committee.

1.3. Procedural change (with no change in the severity or number of animals, unless an exception applies)

Procedural changes can only be requested if there is no negative impact on animal welfare. If there is a need to change the project in such a way that it may have a negative impact on animal welfare, the person responsible for the experiments must submit a new project evaluation. Procedural changes shall be defined as:

- Change in cell line, (mouse) strain (not species!) if there is no change from a non-harmful phenotype to a harmful phenotype
- Change in compound or treatment (with the same aim)
- Change in procedure
- Applying for additional animals **only** under exceptional circumstances (see below)

Applying for additional animals can only be allowed under exceptional circumstances, such as when complications occurred during the experiment, for example:

- Technical defects: e.g. ventilation of IVC cages or isoflurane vaporizer malfunctions resulting in loss of animals; ...
- Unwanted infections or injuries: e.g. loss of animals due to aggression; mouse hepatitis infection outbreak in liver research; ...
- Assessment of the effect was found to be incorrect: e.g. new power analysis required on the basis of newly acquired or generated data (that has become available through literature or was self-generated).

The above-mentioned amendments can, of course, only be allowed for approved experiments that were already part of the original project.

2. UNAUTHORISED AMENDMENTS

An amendment to an approved project cannot be requested for the following changes:

- Adding new (additional) experiments
- Changes to the original purpose of the project or research question
- Procedural changes resulting in an increase of the estimated severity level
- Use of another animal species (e.g. change from mouse to rat).