

Policy AWB notifications and amendments

This is a document of the Animal Welfare Body Leiden (AWB Leiden).

Introduction

During the term of a project license, it may occur that one or more adjustments are needed to the project application or an associated research plan (ozp). It is also possible that during the execution of an ozp, changes are needed because the experiment no longer fits the description in the ozp due to unforeseen circumstances.

Purpose

The purpose of this document is to clarify which steps must be taken for submitting an (internal) amendment or notification to a project application or ozp.

Internal amendment

This is an adjustment that only concerns an ozp. We assume that the execution of the research plan will be the same as described in the research plan (this applies to all fields in the research plan).

Examples of amendments relating to a research plan are: addition of personnel to the ozp, the extension of an ozp, more or less animals in experiment, more or less procedures or welfare monitoring, but also changes in humane endpoints.

In case of an internal amendment to the ozp, the ozp still fits the framework described in the project application.

Internal amendments must be submitted to the AWB prior to the execution of the adjustment.

Please note: In case of unforeseen circumstances, please contact the AWB immediately.

Notification

This is an adjustment that concerns one or more documents of the project application (possibly in combination with an adjustment of an ozp). A notification is an adjustment that fits within the main objective of the project where neither cumulative discomfort of the animals or the number of animals required increases.

Examples of this are: the addition of procedures which are not described in the application or a structural deviation of the experimental design such as the expansion of the age range of the animals.

Notifications must be submitted to the AWB prior to the execution of the adjustment. If the IvD decides that the adjustment fits within the framework of a notification, the experiment can be started.

Notifications may be bundled and submitted to the CCD a maximum of 2 months after making the adjustment.

Amendment

This is an adjustment that concerns one or more documents of the project application (possibly in combination with an adjustment of an ozp). An amendment is an adjustment that fits within the main objective of the project where the research strategy changes, the cumulative discomfort of the animals or the number of animals required increases.

Examples of this are: the addition of an appendix, the addition of a sub-objective, the use of a different species, an adjustment that on the one hand leads to a reduction of the number of animals required, but on the other hand has a negative effect on the cumulative discomfort of the animals and vice versa.

Amendments must be submitted to the AWB and the CCD prior to the execution of the adjustment and follow the same procedure as a new application. In case of an amendment please allow for extra time and costs for the review by the CCD. Find information from the CCD [here](#).

New application

In case one or more objectives change or are added, a new permit must be applied for. Find information on albinusnet [here](#) (LUMC) or online [here](#) (LEI).

Steps:

Internal amendment

1. An internal amendment can be requested by sending an amendment form (the form can be found [here](#) (LUMC), on local drive or surfdrive (LEI)) together with the modified research plan to the AWB.
2. Any questions and / or suggestions from the reviewers will be sent to the applicant.
3. When the AWB has approved the internal amendment, the modified research plan will be activated and the experiment can be started.

Notification

1. A notification can be requested by sending an amendment form (the form can be found [here](#) (LUMC), on local drive or surfdrive (LEI)) together with the modified documents of the project application (and if necessary, the modified research plan) to the AWB.
2. Any questions and / or suggestions from the reviewers will be sent to the applicant.
3. When the AWB has approved the internal amendment, the modified research plan will be activated and the experiment can be started.
4. The AWB sends the amendment to the CCD.

Amendment

1. An amendment can be requested by sending an amendment form (the form can be found [here](#) (LUMC), on local drive or surfdrive (LEI)) together with the modified documents of the project application (and if necessary, the modified research plan) to the AWB.
2. Any questions and / or suggestions from the reviewers will be sent to the applicant.
3. The AWB sends the amendment to the CCD.
4. The CCD requests advice from a DEC.
5. Any questions and / or suggestions from the DEC and / or CCD will be sent to the applicant.
6. After the CCD has issued a permit for the amendment the modified research plan will be activated and the experiment can be started.

For questions regarding the policy above please contact the AWB (ivd-Leiden@lumc.nl).

