



English translation for guiding purpose

Application for amendment

[Change preselection](#)

1.1. Details of previous applications

1.1.1. State the reference number and approval date of the initial application that has been approved.

Max 100 characters.

1.1.1.1. State which board/authority processed the initial application

--- choose an alternative ---

1.1.2. State the title of the initial application that has been approved.

Enter the title of the previously approved application to which the modification relates. If the title has been changed in a previous substantial amendment, the most recently approved title must be entered.

Max 500 characters.

1.1.2.1 Is the title of the project to be changed?

- Yes
- No

1.1.2.2 State the new title of the project.

1.1.3. Enter the reference number and decision date of any previous amendments and give a summary of the content. If the number of previous amendments exceeds five, a separate document listing the amendment applications must be attached.

Max 2000 characters.

1.1.4. Enter EudraCT number if applicable.

1.1.5. Enter CIV-ID if applicable.

1.2 Parties

1.2.1 State the name of the principal investigator in the initial application that was approved.

Enter name and e-mail address.

1.2.2 If a change of principal investigator has taken place in a previous substantial amendment: state the current principal investigator.

Enter name and e-mail address.

1.2.3. State the name of the entity responsible for the research in the initial application that has been approved.

When you click the drop-down list, you can start typing the first letters of the entity's name to quickly find it. If the entity is missing from the list, select Other and fill in the field below. Then also enter the organization number if it is a Swedish organization.

Specify

1.2.3.1 Authorized representative of the entity responsible for the initial application.

1.2.3.2 Authorized representative – title that implies operational responsibility.

1.2.4. If a change of research entity has taken place in a previous change application: state the current entity.

When you click the drop-down list, you can start typing the first letters of the entity's name to quickly find it. If the entity is missing from the list, select Other and fill in the field below. Then also enter the organization number if it is a Swedish organization.

--- choose an alternative --- 

Specify

1.2.4.1 Authorized representative of the current entity.

1.2.4.2 Current representative – title that implies operational responsibility.

1.2.5 State the new principal investigator.

1.2.6.1 State the authorized representative of the new entity.

1.2.6.2 New authorized representative – title that implies operational responsibility.

1.3. Provide a brief description of the amendment that is proposed with regards to the initial application that has previously been approved.

Max 2000 characters).

1.3.1. Summary of amendment.

Summarize in one sentence, two at the most, what the amendment is about. This brief description will appear in the decision. Example: The change refers to a change of responsible researcher/an addition of study centers/an addition of register data.

Max 200 characters.

1.4. Provide reasons for the proposed amendment.

Max 2000 characters.

1.5. Make an assessment on whether the relationship between the risks and anticipated benefits of the project will change as a result of the proposed amendment.

Max 2000 characters.

1.6. Will the information provided to the research participants be changed because of the proposed amendment?

- Yes
- No

1.6.1. Describe how the information provided to the research participants will be changed because of the proposed amendment.

Max 2000 characters.

1.7. Will other information/annexes be changed because of the proposed amendment.

- Yes
- No

1.7.1. Describe how other information/annexes will be changed because of the proposed amendment.

Max 2000 characters.

1.8. State, if applicable, what annexes accompany the application.

Insert your own list of documents attached to the amendment application. When changing the principal investigator, the CV for the new principal investigator is mandatory. Other appendices that may usually need to be submitted are revised informed consent form, research plan, radiation dose appendix, description of biological samples and a list of variables. Name attachments according to the list.
Max 500 characters.

Attach relevant annexes

Add attachments

New principal investigator's CV

Attach new principal investigator's CV.
IN SWEDISH OR ENGLISH.

Add attachments

Enter the names and email addresses to invite the persons who will sign the application.

1.9 Principal investigator (contact person):

State new principal investigator.

Add collaborators

State authorized representative for the entity responsible for the research.

Cancel

Save

Send and sign the application
