

# Application for amendment

- 1 The first step when applying to make an amendment is to complete an [Application for amendment](#) form (this document). This part of the application may be printed out on paper so it can then be signed by the Chief Investigator. An authorised representative may also apply to make an amendment and then sign the application. The signed application is then to be scanned and made searchable, i.e. saved as a searchable PDF file. Name the application 'Amendment' and the title of the project.
- 2 The next step is to identify which annexes are to be amended. These annexes are to be attached to the application. All amendments in the attached documents must be clearly shown, for example by using the 'track changes' function. If the annexes are voluminous, which pages have been amended must be shown.

All annexes must be saved as searchable PDF files. If they are voluminous, they should also include bookmarks (indexed). Name all annexes with the annex number and name of the annex, for example '02 description of research project', '03 research plan'.
- 3 The scanned [Application for amendment](#) form and all annexes saved as searchable PDF files are to be sent in electronic format to the email address [ansokan@etikprovning.se](mailto:ansokan@etikprovning.se). The email should have the subject heading 'Amendment application' and the reference number of the initial application.
- 4 If the application concerns a clinical trial of a medicinal product, you can use Eudralink when you send in your application (for more information about Eudralink see the Medical Products Agency's website regarding clinical trials). Set the expiry date as far forward as possible and ensure that the files are not password-protected. These applications must also be sent to [ansokan@etikprovning.se](mailto:ansokan@etikprovning.se).
- 5 The agency is able to accept a maximum of 153,600 KB (153.6 MB) by email. If your application is larger than this, we would ask you to try to reduce the size and divide up the application into several emails. State clearly that the emails relate to the same application and indicate how many messages are being sent that relate to the application.
- 6 When the Ethical Review Agency has received your application, we will send a confirmation by email to the Chief Investigator. The confirmation will include information about which reference number your application has been allocated and how you should go about paying the application fee. Payment must always be effected with an OCR number as the reference.
- 7 We will only start dealing with your application when the fee has been paid in with the correct OCR number and the payment has appeared on the authority's account.
- 8 When we have made a decision regarding your application, we will send the decision by email to the Chief Investigator.
- 9 Remember that your application must always be completed in Swedish and that the application must be comprehensible to a layperson.



# Application for ethical approval

## Application for amendment

- 1.1. **State the reference number on the initial application that was approved earlier.**  
Max 100 characters
- 1.2. **State the Chief Investigator given in the initial application that was approved earlier.**  
Name Surname
- 1.3. **State the entity responsible for the research given in the initial application that was approved earlier.**  
Name
- 1.4. **State the title of the initial application that was approved earlier.**  
Max 500 characters
- 1.5. **Provide a brief description of the amendment that is proposed to the initial application that was approved earlier.**  
Max 2,000 characters
- 1.6. **Provide reasons for the proposed amendment.**  
Max 2,000 characters
- 1.7. **Make an assessment on whether the relationship between risks and anticipated benefits of the project will change as a result of the proposed amendment.**  
Max 2,000 characters
- 1.8. **Describe, if applicable, how the information provided to the research participants will be changed as a result of the proposed amendment.**  
Max 2,000 characters
- 1.9. **Describe, if applicable, how other information/annexes will be changed as a result of the proposed amendment.**  
Max 2,000 characters
- 1.10. **State, if applicable, what annexes accompany the application.**  
Max 500 characters

*By signing the application you, as the Chief Investigator, certify the following:*

*That the information provided in the application concerning ethical approval and all accompanying annexes are complete and correct.*

*That accountable managers in all areas involved have been informed about the content and execution of the research project and have agreed to take part in the study.*

*That you have ensured that there are resources in all the areas involved guaranteeing the safety and privacy of the research participants when the research described in the application is carried out.*

*That you have read the Ethical Review Agency's information about their processing of personal data on the agency's website.*

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Signature of Chief Investigator (or authorised representative of the entity responsible for the research)  
Name and title  
Date