Etikprövningsmyndigheten

Main application

1. The first stage of your application for ethical review is to complete the Application for ethical approval – general information and signatures form (this document).

   This part of the application is to be printed on paper and then signed by the Chief Investigator and authorised representative of the entity responsible for the research. The signed application should then be scanned and saved as a searchable PDF file. Name the application '00 Application for ethical review'.

2. The next step is to complete the Application for ethical approval – Description of research project (annex 1). This part of the application is compulsory and must always accompany the application. The description is to be saved as a searchable PDF file with bookmarks.

3. Depending on the research you intend to undertake, you must then consider which other annexes you need to attach to your application. All annexes are to be saved as searchable PDF files. If they are voluminous, they must also include bookmarks. Name all annexes with the annex number and name of the annex, for example '02 description of research project', '03 research plan'.

   Compulsory annexes for all projects are:

   A. Research plan (annex 3) aimed at professionals.

   B. CV of Chief Investigator (annex 12).

   You may need to attach the following annexes:

   C. If biological material is to be collected or existing biological material is to be used in the research project, you must complete and attach the Application for ethical approval – description of biological material form (annex 2).

   D. If you are to use advertising material (annex 4) in your recruitment of research participants, the advertising material must always be attached to the application.

   E. The information that will be given to the research participants when they are asked about their participation, the research participant information, (annex 5) must always be attached to the application.

   F. If you are to use surveys, questionnaires, interview guides or interview questions in the project, these must also be attached (annex 6). These must always be in Swedish.

   G. A variable list (annex 7) is not compulsory but it may be helpful to attach one to the application.

   H. If the research project is a clinical trial, you must attach the following:
   - Common EU form (annex 8)
   - Summary of the protocol in Swedish (if the research plan/protocol is in English) (annex 9)
   - Investigator's brochure (IB), information leaflet or summary of product characteristics (annex 10)

   I. If the research involves the research participants being exposed to ionising radiation, the radiation dose annex (annex 11) must be completed and attached to the application.

   J. Any other annexes that you consider the agency should consider in its assessment of the project.

4. The scanned Application for ethical approval – general information and signatures form and other parts and annexes saved as searchable PDF files are to be sent in electronic format to the email address ansokan@etikprovning.se. Attach the application and annexes in separate files. The subject of the email must always be the title of the research project.

5. If the application concerns a clinical trial, 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.

6. 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 to as part of the application.

7. When the Ethical Review Agency has received your application, we will send a confirmation by email to the Chief Investigator and authorised representative. 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.

8. 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 agency's account.

9. When we have made a decision regarding your application, we will send the decision by email to the Chief Investigator and authorised representative of the entity responsible for the research.

10. Remember that your application must always be completed in Swedish and that both the title and the application must be comprehensible to a layperson.

Application for ethical approval
General information and signatures

1. General information and signatures

1.1. Title of the research project

Provide a descriptive title in Swedish. The title must be comprehensible to a layperson.

Max 500 characters

CATEGORIES OF FEES

1.2. How many entities responsible for the research will be involved in the project?

Entity responsible for the research: The government agency or physical or legal person in whose organisation the research is being carried out. A physical person can only be the entity responsible for the research in exceptional cases.

☐ One
☐ Several

If there is one: The application fee is SEK 5,000.

1.2.1. [If there are several] Have all the research participants a direct connection to only one of the entities responsible for the research?

Research participant: The living people who will be the subjects of the research.

Direct connection: Research participants are included in the research by only one of the entities responsible for the research.

☐ Yes
☐ No

If yes: The application fee is SEK 5,000.

If no: The application fee is SEK 16,000.

1.3. Does the research relate to a clinical trial of a medical product?

Clinical trial: Clinical research on people about the properties of a medical product.

☐ Yes
☐ No

If yes: The application fee is SEK 16,000 regardless of whether one or several research entities are involved in the project.

1.3.1. [If yes to 1.3] State EudraCT number

YYYY-NNNNNN-CC

1.4. Are only existing personal details to be included in the project?

A 'yes' answer means that the project is only going to handle (e.g. process, compile or cross-check) personal data that is already included in various registers. I.e. no new personal data is going to be collected in order to carry out the research.

☐ Yes
☐ No

If yes: The application fee is SEK 5,000 regardless of whether one or several research entities are involved in the project.

1.5. Is an advisory opinion required?

If the research that is the subject of the application is assessed to be of a kind that does not require approval by the Ethical Review Agency, the agency may provide an advisory opinion. An advisory opinion may, for example, state that the Ethical Review Agency does not consider there to be any ethical obstacles to the research being carried out.

☐ Yes

☐ No

CHIEF INVESTIGATORS AND OTHER RESEARCHERS AND THE ENTITY RESPONSIBLE FOR THE RESEARCH

1.6. Entity responsible for the research

Entity responsible for the research: The government agency or physical or legal person in whose organisation the research is being carried out. A physical person can only be the entity responsible for the research in exceptional cases.

Max 100 characters

1.7. Authorised representative of the entity responsible for the research

Name Surname
Title
Email address

1.8. Other entities responsible for the research taking part in the project:

The participating entity responsible for the research is taken to be the entity in whose area of activity the research is going to be carried out, i.e. where the research participants are going to be included and/or where data is going to be processed.

Max 2000 characters

1.9. Chief Investigator for the project (contact person):

Name Surname
Email address
Mobile telephone number

1.10. Has the Chief Investigator defended their doctoral thesis in the relevant subject area?

The main rule is that the Chief Investigator should have defended their doctoral thesis in the relevant subject area or have equivalent skills and competence. The Chief Investigator is responsible for ensuring that other participating researchers who will be carrying out the research have adequate skills and competence (scientific and clinical). In the case of clinical trials of medicinal products, the Chief Investigator must also have sufficient knowledge of "Good Clinical Practice" (GCP).

Exceptionally, researchers who have not defended their doctoral thesis in the relevant subject area may be approved provided another participating researcher who has done so has stated that the research is to be undertaken under their active supervision. The statement must be in writing and the CV of the person who has defended their doctoral thesis in the relevant subject area must be attached.

Insofar as the applicant requests that the research should be carried out without a researcher who has defended their doctoral thesis in the relevant subject area being involved, an assessment must be made of all circumstances pertaining to the individual case. Skills and competence are to be assessed in relation to the research in question and to the ethical issues that the research may give rise to. It is to be expected that the person in question should be proficient in current scientific methods and that they should have been shown to be suited to manage such responsibility. The researcher in question should also have experience of taking a view on ethical issues in conducting research (see prop. 2002/03:50 s. 100).

☐ Yes
☐ No

1.10.1. [If no to 1.10] Provide the name of a researcher [who has defended their doctoral thesis in the relevant subject area] who will actively supervise the research.

A written statement concerning the active supervision of the person who will be the active supervisor must be attached to the application together with their CV.

Name Surname
Title
Email address

1.11. Other researchers involved:

Provide the names, titles and functions of the researchers who whill be taking part in the project.

[Name, position, organisation, qualifications] Max 500 characters

OTHER INFORMATION

1.12. Does the application concern research that involves egg donation?

☐ **Yes**
☐ **No**

1.13. Does the application concern medicinal products for gene therapy or somatic cell therapy or medicinal products that contain genetically modifying organisms?

☐ **Yes**
☐ **No**

1.14. Does the application concern research involving xenogeneic cell therapy?

☐ **Yes**
☐ **No**

1.15. Is ionised radiation included in the research project?

Ionised radiation is taken to mean particle radiation or electromagnetic radiation that contains sufficient energy to ionise matter. If ionised radiation is included in the project, the radiation dose annex must be attached to the application.

☐ **Yes**
☐ **No**

LIST OF ANNEXES

1.16. State what annexes accompany the application.

	Annex number	Name of annex	Element heading
☐	1	Application for ethical approval – Description of research project	*Application for ethical approval – a description of the research project is compulsory and must always be attached to the application*
☐	2	Application for ethical approval - Description of biological material	*If biological material is to be collected afresh or existing biological material is to be used in the research project, the form entitled 'Application for ethical approval – description of biological material' is compulsory and must always be attached to the application.*
☐	3	Research plan aimed at professionals.	*The summary description of the research project must be comprehensible to all the members of the Ethical Review Agency. It should preferably be set out as follows:* *Scientific issue to be investigated: An explanation of the overall purpose of the proposed research project together with specific objectives (primary and secondary issues to be investigated).* *Overview of subject matter: Provide a summary of your own and others' research and earlier results within the field of research. The overview must demonstrate the relevance of the current project. Key references must be provided.* *Description of project: Provide a summary of the project/its plan. The selection of research participants, procedures, methods, etc. must be clearly described. How the methods, selection and procedures might provide answers to the specific questions must be demonstrated. If there are to be several subprojects, the sequence of how they are to be carried out must be stated, together with an indication of how the composition of a subsequent subproject might depend on the results of a prior one.* *Significance: Provide a short account of the significance of the project for the field of research.* *Preliminary results: May be stated if available.*
☐	4	Advertising material for the recruitment of research participants	*The Ethical Review Agency must always have sight of all advertising material that is to be used for recruitment. The material is to be written in Swedish.*
☐	5	Information that will be provided to the research participants in connection with invitations to take part	*The Ethical Review Agency must always have sight of all information that is provided to the research participant in connection with an invitation to take part. This applies both to information that is to be given verbally and that which is in writing. If guardians are to approve participation, the information that is given to guardians must also be attached. If next of kin are to have the option of opposing the participation, the information that is given to the next of kin must also be attached. The information is to be written in Swedish.*

☐	6	Surveys, questionnaires, interview guides or interview questions that are going to be used in the project.	*The material is to be set out/written in Swedish.*
☐	7	Variable list	*The Ethical Review Agency does not always need a report including the variable level to make its assessment, but it can sometimes facilitate matters for recordkeeping purposes if the complete variable list is available when the ethical review is undertaken.*
☐	8	Common EU form	*Must be attached if the research relates to a clinical trial of a medicinal product.*
☐	9	Summary of protocol in Swedish	*Must be attached if the research relates to a clinical trial of a medicinal product.*
☐	10	Investigator's brochure, information leaflet or summary of product characteristics	*Must be attached if the research relates to a clinical trial of a medicinal product.*
☐	11	Information relating ot ionised radiation, radiation dose annex	*As regards ethical approval of medical, biomedical or dental research involving exposure to ionised radiation, the Ethical Review Agency must establish dose restrictions for research participants who are not expected to have any direct medical benefit from the exposure. If the research includes ionised radiation, the "radiation dose" form is to be completed and attached to the application.*
☐	12	Chief Investigator's CV	*Attach Chief Investigator's CV.* *Exceptionally, researchers who have not defended their doctoral thesis in the relevant subject area may be approved provided another participating researcher who has done so has stated that the research is to be undertaken under their active supervision. The statement must be in writing and must be attached. The CV of the person who has defended their doctoral thesis in the relevant subject area must also be attached.*
☐	13	Other attachments	State what annexes accompany the application

SIGNATURE AND CERTIFICATION

1.17. Certification

By signing the application you, as the Chief Investigator and authorised representative, certify the following.

That the information provided in the application concerning ethical review 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 that guarantee the safety and privacy of the research participants when the research described in the application is carried out.

That the Chief Investigator has the right to represent the entity responsible for the research in all future contact with the Ethical Review Agency with regard to this research project and to apply for amendments to be made to the research project.

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

_____

Signature of Chief Investigator
Name and title
Date

_____

Signature of authorised representative of the entity responsible for the research
Name and title
Date