

# Application for ethical approval – Annex 1

## Description of research project

### 2. Type of research

#### 2.1. In what way(s) does the project involve research according to §§ 3-4 Swedish Ethical Review Act?

- 3 § 1 The research will collect sensitive personal data.
- 3 § 2 The research will collect personal data relating to criminal offences.
- 4 § 1 The research involves a physical intervention on a research participant.
- 4 § 2 The research is to be carried out in accordance with a methodology that aims to have a physical or psychological effect on the research participant, or there is a clear risk that the research could harm the research participant.
- 4 § 3 The research concerns studies of biological material that has been taken from a living person and may be traced back to that person.
- 4 § 4 The research involves a physical intervention on a dead person.
- 4 § 5 The research concerns studies of biological material that has been taken from a dead person and may be traced back to that person.

The research does not fall under the scope of the Ethical Review Act.

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

*Personal data: All kinds of information that can be traced directly or indirectly to a physical person who is alive.*

*Sensitive personal data: Sensitive personal data is information that reveals race or ethnic origin, political views, religious or philosophical convictions, trade union membership, health, a person's sex life or sexual orientation, genetic information and biometric information that unequivocally identifies a person.*

*Personal data concerning criminal offences: Personal data concerning criminal offences includes crime, criminal convictions, pre-trial supervision measures or administrative detention.*

#### 2.2. [About 3 § 1] State what type of sensitive personal data will be processed in the project.

- race or ethnic origin
- political views
- religious or philosophical convictions
- trade union membership
- health
- a person's sex life or sexual orientation
- genetic information
- biometric information that unequivocally identifies a person.

*Personal data: All kinds of information that can be traced directly or indirectly to a physical person who is alive.*

*Sensitive personal data: Sensitive personal data is information that reveals race or ethnic origin, political views, religious or philosophical convictions, trade union membership, health, a person's sex life or sexual orientation, genetic information and biometric information that unequivocally identifies a person.*

*According to the definition in the EU's Data Protection Regulation.*

*NB If no sensitive personal data is going to be processed in the project, this question does not need to be answered.*

### **3. Purpose and issues to be investigated**

**3.1. Write a summary of the research project in terms intended for a general audience (max 300 words).**

*Describe the project in summary. Remember that the text must be comprehensible to people who do not have scientific knowledge and expertise. Terminology that requires specialist knowledge should therefore be avoided.*

Max 4,500 characters

**3.2. What is the scientific purpose of the project?**

*Describe the overall purpose of the project. Explain what research problem the project is to address and what limitations have been placed on it.*

Max 2,000 characters

**3.3. What are the scientific issues to be investigated?**

*State clearly the scientific issue(s) to be investigated in the project.*

Max 2,000 characters

## 4. Method

### 4.1. Explain the methodology incl. procedures, technique or treatment.

*It is necessary to show how the project is to be carried out. Describe the nature of the data to be collected and state how the data's authenticity is to be ensured.*

*If surveys and interviews are included, the procedure, the content of the questions and how conclusions are drawn must be described. Attach surveys and rating scales.*

*For medical research the types of intervention, measuring methods, number of visits, time taken, doses and mode of administration of any medicinal products must be stated.*

*If the project is a collaboration with foreign countries, which part of the research is to be carried out in Sweden and which part is to be carried out outside Sweden must be clearly stated. The Ethical Review Agency can only assess research that is to be carried out in Sweden.*

Max 4,500 characters

### 4.2. Explain how the methodology differs from a clinical routine procedure or standard treatment.

*State what the research project does that deviates from or adds to standard procedures.*

Max 2,000 characters

### 4.3. Explain earlier experiences (your own and/or those of others) of the procedure, technique or treatment to be used.

*Explain what experience and competence the researchers involved have of using the procedure, technique or treatment that will be used in the project. Also explain what experience exists generally or globally.*

Max 2,000 characters

## 5. Timetable

### 5.1. Expected starting date of the project:

*State, if possible, the expected starting date of the project.*

Max 100 characters

### 5.2. Expected closing date of the project:

*State, if possible, the expected closing date of the project.*

Max 100 characters

### 5.3. Timetable for the different parts of the project:

Max 1,000 characters

*Explain the timetable for the project and how the various parts relate to one another – if necessary, an explanatory flow diagram can be attached.*

## 6. Data collection

### 6.1. Explain how data will be collected and describe the nature of the data.

*Explain how the data will be collected. Describe the data that is to be collected and how it is going to be collected.*

Max 4,500 characters

### 6.2. Explain the statistical basis for the study population/size of the research material.

*Explain the calculations used and the issues considered in arriving at the number of participants required so as to attain adequate statistical significance. The explanation of how a representative sample was reached must describe the scope of the project in terms of addressing the issues to be investigated.*

Max 2,000 characters

### 6.3. How will the research procedures be documented?

*Explain how the investigations and any interventions will be documented. State whether audio and video recordings will be used.*

Max 2,000 characters

### 6.4. How will the data that is collected be managed and stored?

*Explain how the data will be managed once it has been collected. If the data is going to be pseudonymised ('coded'), the coding procedure must be described. Where the lists of codes/code keys will be stored must be stated and who will have access to them. How long the data will be stored must be stated, and whether it will be de-identified (by destroying the code keys) or destroyed completely.*

Max 2,000 characters

## 7. Ethical considerations

### 7.1. What risks might the research participants run by taking part in the research project?

*Risks can be of various types. For example, there can be short- or long-term physical or psychological harm, pain, discomfort or privacy breaches. State which risks might be present for the participants in this research project.*

Max 4,500 characters

### 7.2. What benefit can taking part provide to the research participants involved in the project?

*State what help research participants who are involved in this project can receive as a result of the research project.*

Max 2,000 characters

### 7.3. Make an assessment of the relationship between risks and anticipated benefits of the project.

*According to the Ethical Review Act, research may only be approved if the risks run by the research participants in terms of their health, safety and privacy are outweighed by its scientific value.*

Max 2,000 characters

### 7.4. Describe how the project has been designed to minimise the risks for the research participants.

*According to the Ethical Review Act, research may only be approved if the expected result cannot be achieved in another way that involves fewer risks for the research participants in terms of their health, safety and privacy.*

*The treatment of personal data covered by § 3 may only be approved if it is necessary for the research to be carried out.*

*Note that if a treatment is to be trialled on humans for the first time, this must be clearly shown and the relevant safety procedures must be clearly described.*

*State what risks might be involved in taking part in the research project. Are there risks for people being included in a control group, for instance?*

Max 2,000 characters

### 7.5. Identify and specify whether any ethical problems (disadvantages/advantages) may occur in a wider perspective of the research project.

*Explain, for example, whether certain groups (besides the research participants in the research project) may come to feel singled out or receive help as a result of the project. This covers both indirect risks and indirect benefits. For example, genetic impact on future generations or whether the results could damage certain groups in some other way.*

Max 2,000 characters

## 8. Research participants

### 8.1. How are the research participants selected?

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

*Describe the research participants who will be included in the project. Explain what was considered when the selection of research participants was made. If certain groups were excluded from participating in the project, reasons must be given for their exclusion.*

*Also explain how the researcher will contact or become aware of suitable research participants.*

Max 2,000 characters

### 8.2. How many research participants will be included in the project?

*State how many research participants in total will be included in the project and if appropriate how many will be included in different subprojects.*

Max 500 characters

### 8.3. What selection criteria will be used for inclusion?

*State what criteria must be fulfilled for a research participant to be included in the project.*

Max 4,500 characters

### 8.4. What selection criteria will be used for exclusion?

*State what criteria must be fulfilled for a research participant to be excluded from the project.*

Max 4,500 characters

### 8.5. State the relationship between the researcher and the research participants.

*State the researcher's role in relation to the role of the research participant. This may be as a practitioner (doctor, psychologist, physiotherapist, etc.) and patient/client, as teacher and student or employer and employee. All types of relationships must be described that could introduce a risk of influence. According to the Ethical Review Act, particular attention must be paid to information and consent if the research participant is dependent on the entity responsible for the research, or the researcher, or is considered to have difficulty defending their rights.*

Max 500 characters

### 8.6. What insurance cover is available to the research participants who are involved in the project?

*The entity responsible for the research is responsible for checking that there is insurance cover against any potential injuries or harm that may occur in connection with the research. State what insurance cover the research participant will have and what protection the insurance cover provides to the research participant.*

Max 500 characters

### 8.7. Explain what preparations are in place to manage unexpected incidental findings or events during the research process that may imperil the safety of the research participants.

*Describe what access the research project has to equipment, staff and expertise to manage any potential unexpected complications or incidental findings. Describe what plans are in place to manage any potential unexpected complications or incidental findings.*

Max 4,500 characters

### 8.8. Will the research participants be paid any financial compensation or other benefits?

*Research participants may receive compensation for pain and discomfort in addition to compensation for travel, lost earnings or other expenses. The compensation must be reasonable. If children or young people under the age of 18 are taking part in the research project, such compensation may not be substantial and should not be offered when they are recruited. In cases of clinical trials of medicinal products involving children and young people under the age of 18, no incentive or financial benefits may be provided, the only exception being the refunding of expenses.*

Yes

No

#### 8.8.1. [If yes to 8.8] What financial compensation will be paid and when?

Max 500 characters

## 9. Information and consent

### 9.1. Will the research participants be given information about the research project and be asked whether or not they want to be involved?

*The basic rule, according to the Ethical Review Act, is that research may only be carried out if the research participant has been informed and has consented to being involved. Information may be given to research participants either verbally or in writing.*

- Yes  
 No

#### 9.1.1. [If yes to 9.1] How, when (at what stage) and by whom will the research participants be informed and consulted?

*Describe the procedure whereby the information is given and consent is obtained. Who asks the question, when does this happen and how is consent documented? What is done to ensure that the research participant is given time for reflection and the opportunity to ask questions?*

*A detailed explanation is particularly important when there are children or people with impaired decision-making capacity involved in the research project.*

Max 4,500 characters

#### 9.1.2. [If no to 9.1] Give reasons why the research participants should not be informed and consulted.

*Provide a detailed explanation of the issues that have been weighed up and the reasons for the decision that the research participants should not be informed and consulted. Note that research without informed consent is only permissible in exceptional circumstances and when the research is covered by § 3 or § 20–22 of the Swedish Ethical Review Act.*

Max 4,500 characters

### 9.2. Will children under the age of 18 be included in the research project?

*Children under the age of 15 must have the permission (consent) of all their guardians to be allowed to take part in the research project.*

*Children between the ages of 15 and 18, who understand what their participation in the research involves, must be informed about and give their own consent to the research. In other cases, all guardians must give their permission (consent) for a child to be allowed to take part in the research project.*

*Despite the guardians' permission (consent), the research may not be carried out if the child is opposed to the research being carried out.*

- Yes  
 No

#### 9.2.1. [If yes to 9.2] State the age of the children.

Max 500 characters

### 9.3. Will research participants whose views cannot be obtained owing to medical conditions, mental disorder, weakened state of health or any similar reason, be included in the research project?

*State whether the research project will involve people who are not able to consent to their own participation for reasons of a medical condition, mental disorder, weakened state of health or similar condition.*

- Yes  
 No

**9.3.1. [If yes to 9.3] Give reasons for this group of research participants being included in the project.**

*Research without consent by this group of research participants may only be carried out if the research is expected to provide knowledge that it is not possible to acquire by means of research with consent.*

*The research must also be expected to lead to a direct benefit for the research participant. Alternatively, the research must contribute to an outcome that may be of benefit to the research participant or other person who suffers from the same or a similar medical condition and involve insignificant risk or discomfort for the research participant. The research participant must as far as possible be provided personally with information about the research.*

*Next of kin must be consulted. Any trustee or legal guardian must also be consulted if the issue is part of the trustee's or legal guardian's remit. The research may not be carried out if the research participant expresses in any way that they do not want to take part or if anyone who has been consulted is opposed to it.*

Max 2,000 characters

**9.3.2. [If yes to 9.3] Describe how next of kin, trustees or legal guardians are to be consulted.**

*In instances of research involving research participants where it is not possible to obtain their views, next of kin must be consulted and have the opportunity to oppose their participation. Any trustee or legal guardian must be consulted if the issue is part of the trustee's or legal guardian's remit.*

Max 2,000 characters

## 10. Record details

### 10.1. Will the project be requesting data from an existing register?

*This refers to all types of register containing personal data or data that had been personal but was later de-identified.*

- Yes  
 No

#### 10.1.1. [If yes to 9.1] Which register(s) will this data be requested from?

*Name the register(s) from which the data will be requested. Also state the entity responsible for each register.*

Max 2,000 characters

#### 10.1.2. [If yes to 9.1] What data will be requested and why?

*Describe what type of data will be requested and why it is needed to answer any questions raised in the project.*

*It might be helpful to attach a complete variable list as an annex. 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.*

Max 4,500 characters

## 11. Results from animal tests

### 11.1. Are there relevant results from animal tests?

*This refers primarily to clinical treatment trials. If no animal tests have been carried out, state the reason for this.*

- Yes
- No
- N/A

#### 11.1.1. [If yes to 11.1] Explain the outcome of the animal tests

*Provide an overall report on the animal tests that have been carried out and what their outcome was. It is mainly the results that are relevant for this research project that must be explained.*

Max 4,500 characters

## 12. REPORTING THE OUTCOME

### 12.1. How is access to data guaranteed for the entity responsible for the research and other researchers involved?

*Normally whoever has responsibility for carrying out the research has full access to the data. If several researchers are collaborating in contract research, the researcher who has overall responsibility for the project should agree the position in advance as regards access to data with the other researchers.*

Max 2,000 characters

### 12.2. Who will be responsible for data processing and the written report of the results?

*State who will be processing and analysing the research data and who will be drawing up the written report. Normally whoever has responsibility for carrying out the research has full access to the data.*

Max 2,000 characters

### 12.3. How and when will the results be published?

*State what form publication of the results is to take. For example, scientific publication with peer review, open access, internal report. If possible, provide a timetable for publication.*

Max 2,000 characters

### 12.4. In what way will the research participants' right to privacy be guaranteed when the material is published?

*Explain how the data will be presented when it is published and how the research participants' privacy is to be protected on publication.*

Max 4,500 characters

## 13. FINANCIAL MATTERS

### 13.1. Explain any financial agreements with contributors or other financiers (name and amount).

*Explain all financial agreements that have been concluded with the person/people carrying out the research. State what amount will be received for the research project and what that payment is to cover. Also state any amount per research participant.*

Max 4,500 characters

### 13.2. Explain the financial interests of the entity responsible for the research, the Chief Investigator and other researchers involved.

*Explain any financial interests (e.g. shareholdings, employment, consulting contracts in the company being financed) whereby the person's own company may profit directly or indirectly from the research.*

Max 4,500 characters