Guide to the Ethical Review of Research on Humans

2023
Abbreviations

CEPN  Central Ethical Review Board (Centrala etikprövningsnämnden)
GDPR  EU General Data Protection Regulation
IMY   Swedish Authority for Privacy Protection (Integritetsskyddsmyndigheten)
Önep  The Ethics Review Appeals Board (Överklagandenämnden för etikprövning)

Revision history

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Guide

to the Ethical Review of Research on Humans
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Foreword

This Guide has been produced within the context of the government mandate that the Swedish Ethical Review Authority received in the summer of 2022, which charges the Authority with increasing the knowledge among researchers and research principals about the regulatory framework for ethical review.

The purpose of the Guide is to explain how basic principles of research ethics are applied in ethical review and what this means for people who plan or work with research involving human participants.

The Guide provides an overview of the relevant legislation and how it is applied. It describes and elucidates aspects that often arise or raise questions. Not least, it endeavours to explain potential sources of misunderstandings.

The aim of the Guide is to answer key questions, such as:

- What do I need to consider when planning my research?
- When do I need to apply for ethical review?
- How do I apply for ethical review?
- What do I need to consider after a decision is issued?

» The Guide provides an overview of the relevant legislation and how it is applied.
The descriptions in this Guide are based on fundamental principles of research ethics and reflect what the Authority considers to be applicable law in the area. What constitutes applicable law changes over time, and sources of law include current legislation, legislative history, official practice, and doctrine. “Doctrine” refers to jurisprudential literature, usually legal commentaries, dissertations, and legal articles. As a result, some of the Guide’s descriptions of how the Ethical Review Act is applied are based on guiding decisions from the Ethics Review Appeals Board (Överklagandenämnden för etikprövning, abbreviated in Swedish texts to Önep; since 2019), while others describe decisions issued by the former Central Ethical Review Board (Centrala etikprövningsnämnden, abbreviated in Swedish texts to CEPN; 2004–2018). Illustrative examples from decisions by the Swedish Ethical Review Authority or a Ethical Review Board are sometimes used. All such commentaries must be read with the knowledge that each research project is unique, and that the specific circumstances of each case may affect a future assessment of an application.

The information in this Guide is by no means intended to be exhaustive. For each issue, aspects are described that may serve as sources of knowledge for researchers planning to apply for ethical review. It has not been possible to cover all the provisions and possible circumstances.

Finally, on behalf of everyone at the Swedish Ethical Review Authority, I wish to express our heartfelt gratitude to the author of this Guide, Ulf Görman, Professor Emeritus of Ethics. Ulf has a extensive experience of research and research ethics issues. Moreover, the skilful style, tone, and voice of his writing captivate the reader, making this a document that hopefully will be of great importance to many researchers whose work involves human participants.
The Authority would also like to express its gratitude and appreciation for the thoughtful and important input provided by representatives of various institutions and networks within the scientific community, as well as by members and staff of the Authority, with the aim of improving this Guide. The level of engagement they have shown in their response clearly underscores the great need for guidance of this kind.

Uppsala, 8 December 2023

Johan Modin
Director of the Swedish Ethical Review Authority
Fundamental Tenets

1. Research may only be approved if it can be carried out with respect for the value of human beings (Section 7 of the Ethical Review Act).

2. Human rights and fundamental freedoms must always be considered in ethical reviewing, as must the scope for new knowledge through research (Section 8, first sentence).

3. Human welfare should always be given precedence over the needs of society and science (Section 8, second sentence).

These fundamental ethical principles are based on assessments expressed in the largely consistent international conventions and other guiding research ethics documents that have emerged over the past century. The original documents put forward general expressions of fundamental values and other ethically based positions. In some cases, the organisation behind them has deliberately refrained from specific wording, to leave room for various related interpretations and applications.

The manner in which these principles are formulated in the Ethical Review Act is also of such a nature that they often cannot be used directly to determine the assessment of an individual research project. It is thus an important task of the department to make an assessment based on the overall competence and experience of its members, in order to apply the values and other standpoints expressed in the principles.
Research may only be approved if it can be carried out with respect for the value of human beings

What is the value of human beings? In explanations of this concept, reference is usually made to the equal value of all humans, which points to a demand for equal treatment. Often the concept of “dignity” is used in place of “value”, as the term “human dignity” makes it clearer that there should be a limit to what treatment is acceptable. The different terms also suggest that there may be different justifications for this principle. It is probably easiest to achieve conceptual clarity by focusing on what lies at the heart of this principle. Its aim is to ensure respect for people’s integrity and their right to freely choose how they live, within a framework limited by respect for the human dignity or value of others.

The principle makes it unequivocally clear that care for the individual comes first. Research with shortcomings in this regard must not be authorised.

Human rights and fundamental liberties must always be considered in ethical reviewing, as must the scope for new knowledge through research

What is meant here by human rights and fundamental liberties? Declarations of human rights vary in their degree of detail. The 2010 Charter of Fundamental Rights of the European Union identifies the following rights relevant to ethical review: personal integrity, respect for private life, protection of personal data, and protection of children, the elderly and persons with disabilities.

This principle expresses that it is the task of ethical review to take into account both human rights and the public interest in new knowledge. This indicates that human rights are not perceived as absolute; instead, room is left for limitations. From this point of view, an ethical review must give human rights primary consideration, but in the event of a conflict, it should strike a balance between these rights and the public interest in new knowledge.
**Human welfare should always be given precedence over the needs of society and science**

The concept of “welfare” is a collective term for people’s living conditions. Thus, when this principle stipulates that people's well-being should be given precedence, it is referring to respect for people’s quality of life in a broad sense, as an amalgamation of objective and intersubjective circumstances and personal experiences.

This principle is ascribed great importance in many research ethics conventions and guidelines. The focus is on ensuring that the welfare of research participants takes precedence over the interests of society and science. Research can lead to groundbreaking discoveries, but it should not be carried out at the cost of the quality of life of research participants.

The commentary on this statute states that the aim is to protect both human dignity in general and the well-being of individual research participants, while at the same time taking into account the public interest in the development of new knowledge through research. No assumption is made that there is always or even often a contradiction between these interests. In many cases, research can be the best way to ensure people’s well-being.¹

See the section *Why does ethical review exist?* for more information about the fundamental ethical principles, documents that express them, and their importance for research and ethical review.

¹ Government Bill 2002/03:50, p. 196.
Research may be approved only if the risks it may pose to the health, safety and personal integrity of research participants are counterbalanced by its scientific value (Section 9).

Research cannot be approved if the anticipated result is attainable by some other means that entails lesser risks for the health, safety, and personal integrity of the research participant (Section 10, first paragraph).

Processing of sensitive personal data and personal data about violations of the law may only be approved if this is necessary for the research to be carried out (Section 10, second paragraph).

The research may be approved only if it is to be conducted by, or under the supervision of, a researcher who possesses the requisite research expertise (Section 11).

The Guide explains in detail how these conditions are applied in ethical review and what they mean for people who plan or work with research involving human participants.
What do I need to consider when planning my research?

The Guide focuses on research involving human participants or personal information. This chapter describes ethical issues that arise in a number of areas in the course of such research. You need to consider all these issues, regardless of whether your research may require ethical review.

The basic principles of research ethics are the same for all research. Ethical review is a control system for research that entails specific risks. This means that even if the research you are planning does not require authorisation, you and your research principal are still responsible for ensuring that these principles are followed in your forthcoming work.

When the following section describes the information a researcher must provide in an application for ethical review, this means that even if your research is not deemed to require authorisation, it remains your responsibility and that of the research principal to ensure that these issues are considered and handled in accordance with applicable regulations and general principles of research ethics.

Many of the concepts used in this chapter are explained and discussed later in the text.

See also the section The role of the research principal.
Good research practice and research misconduct

Everyone who works with research needs to be well acquainted with the general rules of research ethics that are expressed in a number of laws, codes of ethics, and other quality requirements. These issues are well described in the booklet *Good Research Practice* [God forskningssed], published by the Swedish Research Council. It is only available online [in both English and Swedish], and can be downloaded from the Swedish Research Council's website, vr.se. At the time of writing, the most recent edition was published in 2017, but a new one is being completed.³

*Good Research Practice* describes in detail the ethical issues that need to be taken into account in all research and provides references to other important documents. The booklet also describes what is meant by “research misconduct”, how it should be avoided, and what sanctions apply in the event of misconduct.

The following text requires that readers have a good knowledge of the general research ethics issues that are dealt with in *Good Research Practice*.

Identify, prevent, and address risks

Research may only be approved if the risks it may pose to the health, safety and personal integrity of research participants are counterbalanced by its scientific value (Section 9 of the Ethical Review Act).

When planning your research, you need to carefully consider the risks that the project you want to start may entail. In an ethical review, potential research risks are of great importance. Even very important research may be rejected if its risks are not well managed. On the other hand, research with no or negligible risks may be approved, even if it has only limited scientific value.

³ Please note that the 2017 edition of *Good Research Practice* was published prior to the entrance into force of the EU's General Data Protection Regulation (GDPR) the following year, and therefore could not take it into account.
In many respects, risks to health and safety are a familiar and commonly acknowledged aspect of research. Especially in medical and psychological research, there is a professional regulatory framework that can serve as a guide in ethical reviews. Many clinical specialties have established their own systems for conducting research and risk analyses. Psychological injuries are also a known and noted risk of research.

However, there may be reason for researchers to specifically review and report on potential long-term side effects of both medical and psychological studies. A few examples can illustrate this. Taking a blood sample is associated with limited risks of physical harm, but the stored blood sample and the genetic information it carries may contain risk dimensions of a much more serious nature. Psychological studies may include or recall unpleasant experiences, and participants can thus be harmed by their participation long after it took place. It is therefore often necessary to go one step forward in your research ethical reasoning and considerations in an ethical approval application, taking into account such future risks, more than what is common today.

In other fields of research, such as the humanities and social sciences, the risks that research may entail are not as widely acknowledged. However, even mere participation in a research project can pose risks to health and safety. In a context that is in somehow charged, other people may react if it becomes known that a person is participating and providing information. This is especially true when the research concerns people who live in difficult conditions, e.g., those in vulnerable areas with honour-based oppression or criminal networks, or children who experience violence in the home. People who are interviewed about traumatic events may also be at risk of strong reactions that subsequently harm their mental health.

**Risks tied to personal integrity**

Risks related to the personal integrity of research participants have proven more difficult to understand. Such risks exist in all research that involves the processing of personal data.
What is meant by personal integrity? Often described as an aspect of human dignity, this complex, collective term encompasses a person’s values, conceptions, opinions and desires, beliefs and mental life. Personal integrity is protected by declarations of human rights and national laws. The right to personal integrity refers to the right of every human being to have his or her individuality and inner sphere respected and not to be subjected to unwanted intrusion.

As soon as you use a database of personal data, you must always consider that for one reason or another, someone may have an interest in the information contained therein:

- to find out who is registered in a database or who certain interesting information concerns
- to collect more data on one or more already known or identified individuals
- to act on the basis of the information obtained about the individual(s).

The researchers themselves may already have such an interest, anyone else who becomes aware of the contents of the register could also be interested in them. Often this is just a matter of curiosity, but sometimes more serious intentions are at play.

Identification facilitates access to personal data. Both identification and access may violate the right to personal integrity, which is why they are often described as invasion of privacy or a breach of personal integrity. Common risks related to personal integrity include

- identification
- access to information about a known individual
- undermining personal integrity
Such information may also result in harm to health and safety, for example if it is used for more far-reaching purposes, e.g.:

- discrimination
- slander
- opposition
- exploitation
- fraud
- harassment
- persecution.

Some typical and common paths to identification are:

- improper use of a code key
- the data in the register are so distinctive that it is possible to pinpoint who the information refers to
- cross-referencing of multiple registers, which increases the possibility of indirect identification.

Many breaches of personal integrity start with some form of data leak, i.e., when unauthorised persons gain access to sensitive data, or when people with legitimate access to data process it in an improper way. Common reasons for personal data leaks include:

- login protection is lacking or inadequate; e.g., there are no logs recording which individuals have had access to the data
- insufficient or nonexistent protective measures when storing data on personal devices
- portable devices containing personal data are stolen or lost
- security is not maintained during repair and servicing.
You must assume that the risk of a data leak is always present and endeavour to evaluate the prevailing risks in your own research environment and what weak links there may be in your own current research process.

Methods by which to gain unauthorised access to data are constantly developing, as are security measures to thwart them. The personal data used in different research projects also have varying degrees of sensitivity. For this reason, the reasonable level of assurance for each individual project must always be adapted to its particular circumstances. It may be advisable for you to consult security experts to plan the level of security and measures advisable for your research.

Risks of identification may also arise when reporting research results. For example, the population of certain groups of sexually or religiously persecuted people, refugees, or former offenders may be limited, and the risk of recognition may therefore be high. Data can also be interpreted tendentiously in a way that can cause great damage to personal integrity, and this can be difficult for the victim of such a breach to handle.

The results of correlation searches in datasets related to gender, age, origin, offences, financial situation, education, migration, or health can also be easily misused to foment contempt for or suspicion of groups of people, even if no specific individuals are identified. Such designations at the individual or group level can in turn lead to negative social, economic, and legal consequences.

**Risk analysis**

An assessment of the risks that a research project may entail and a weighing of the relationship between risk and benefit is a crucial part of the ethical review process. You must provide the Authority with a sufficient basis for this assessment.
A well-designed application for ethical review clearly describes the risks that may arise, shows how the researcher has minimised the risks during the planning stage, and demonstrates that the benefits of the project are likely to outweigh the remaining risks. To achieve this, you need to carry out a risk analysis, the results of which are reported in your application.

Your project may have many risks, or just a few. The seriousness, complexity, and probability of these risks can also vary. This makes it virtually impossible to provide a general template for the scope and level of detail of a risk analysis. The level of detail of the risk analysis must be proportional to the severity of the risks your project may entail. Here are the questions that a risk analysis for a project with extensive and complex risks should answer.

- The analysis should specifically address each type of harm that may affect research participants or others, in both the short and long term.

For each type of harm, the following questions should be answered:

- **Degree of severity**: How serious are the consequences if the harm occurs?
- **Probability**: How likely is it that the harm will occur?
- **Minimisation of harm**: What preparations should be made to reduce or eliminate each individual risk?
- **Measures**: What action plan is in place if some form of harm does occur?
In the application for ethical review, you must present your risk analysis in its entirety. The information provided to research participants must also include a brief but clear description of the risks their participation entails.

Not all risks can be eliminated. In an ethical review, a proportionate level of risks must be accepted if they are necessary to carry out the study, provided that the researcher has adequately minimised the risks, and the remaining risks are outweighed by the scientific value of the research.

Weighing risks against benefits

From an ethical point of view, one of the most crucial aspects of ethical review is the weighing of risks and benefits that must take place in accordance with Sections 9–10 of the Ethical Review Act. To obtain approval to conduct a research project that involves immediate or long-term risks to the health, safety and personal integrity of the research participants, you must demonstrate in your application for ethical review that the scientific value of the project outweighs the risks that participation entails. Here are some common questions that may be of importance, and that you need to consider in an application for ethical review, or otherwise in your deliberations together with your research principal.

Meaningfulness and scientific viability of the research:

- Can the answers to the research questions generate new scientific knowledge?
- Can this knowledge be of theoretical or practical benefit to society and humanity at large?
- Are the methods to be used appropriate and sufficient to provide reliable answers to the research questions?
- Are there sufficient resources for the project to be completed?
The need to engage people in the way envisaged:

- Can the research questions be answered in another way, without recruiting humans or using personal data, human tissue, etc.?
- Can the research questions be answered using another method that involves less risk?

Protection of the safety of the research participants:

- Are there previous studies that make human research permissible or appropriate?
  - Depending on the circumstances, these may include previous experiments on animals, cell studies, or other solid scientific evidence.
- Is the right population proposed?
  - Medical research should primarily be conducted on people it can be presumed to benefit.
- If vulnerable research participants are to be recruited, are data available from other, less vulnerable groups?
  - Whenever possible, adults who are able to provide their own informed consent should be the first to be studied.
- Can the research provoke thoughts of suicide or other destructive acts?
  - What preventive measures are planned?
  - Are they adequate? Is there a need for collaboration with psychiatric care providers?
- Is there a procedure for the systematic recording of adverse side effects?
- Are there adequate measures in place to prevent and address risks of harm?
  - Serious risks, e.g., death or irreversible injury, must be shown to be acceptable in the light of the potential benefits of the research and the measures implemented to minimise such risks. Major benefits can never excuse an unjustifiable risk to research participants.
Protection of the personal integrity of the research participants:

- Is the processing of personal data limited to what is actually necessary for the research?
- Are appropriate safeguards planned to make it more difficult or impossible to identify the data?
- Are appropriate security measures planned to prevent data leakage, theft, etc?

Research cannot be approved if the anticipated result is attainable by some other means that entails lesser risks for the health, safety, and personal integrity of the research participants. Such risks must also be counterbalanced by the scientific value of the research. Thus, you must keep these questions in mind as you prepare your project and application and, if necessary, revise your original plans for the design of the project to maximise its benefits and minimise its risks. In your application, you must provide a clear basis for the risk-benefit assessment that the Authority will make.

**Recruitment and selection of research participants**

- In your application, you must describe the research participants who will participate in the project. This selection is often described using criteria for inclusion and exclusion.
- You must also elaborate upon the scientific and ethical considerations you have made in the selection of research participants and the reasons for these criteria. Present clear criteria that are specifically relevant to the planned project and that can be feasibly applied to the recruitment process.
- You must also state how you intend to find and come into contact with suitable research participants.
When making your selection, you must pay particular attention to the rules governing the participation of individuals with limited opportunities to exercise their rights:

If a research participant is in a relationship of dependence on the research principal or a researcher, or if the research participant can be assumed to have particular difficulties in safeguarding their rights, issues of information and consent must be given special attention in the ethical review (Section 14 of the Ethical Review Act).

A number of guiding decisions by the Central Ethical Review Board and the Ethics Review Appeals Board clearly demonstrate that the special attention to be paid in the ethical review also includes the risk-benefit assessment, and thus questions related to participation and the ethical acceptability of conducting a particular research project.

**Relationships of dependence**

Clear examples of relationships of dependence include those between teachers and students, between managers and employees, between parents and children, and between physicians and patients. If you plan to recruit research participants from situations in which such dependencies may exist, you need to explain why this is appropriate or necessary.

As regards research involving minors, it is advisable that the researchers (and not, for example, school staff) initiate the contact with guardians and children and present their project, thus bypassing the dependency inherent in the relationship of children and their parents or guardians vis-à-vis their school.

» Such risks must also be counterbalanced by the scientific value of the research.
**Vulnerable people**

The Ethical Review Act’s reference to persons who can be assumed to have particular difficulties in safeguarding their rights reflects the attention that such persons and their participation in research have received in research ethical contexts. In this context, these individuals are most commonly referred to as *vulnerable people*.\(^4\)

This concept lacks a uniform definition, but people who are perceived as vulnerable include:

- children
- pregnant and lactating individuals
- people in social care
- refugees
- people at a disadvantage in hierarchical or authoritative relationships
- people with diseases that lack adequate treatments
- people with mental or physical disabilities
- financially vulnerable individuals
- people who may be at risk of discrimination.

\(^4\) Sometimes the terms “vulnerable individuals” or “vulnerable groups” are also used, with essentially the same meaning.
The risks to which a vulnerable person is exposed in connection with research can be expected to be higher than for others. According to several conventions on research ethics, vulnerable people must therefore be treated with particular care when conducting research, and research involving vulnerable people should only be carried out if the research results can benefit other people in the same situation. For example, the Declaration of Helsinki states that medical research on a vulnerable group is only justifiable if the research meets the group’s health needs or priorities and cannot be carried out on a non-vulnerable group.\textsuperscript{5} The Ethical Review Act addresses related issues in the following ways:

Research cannot be approved if the anticipated result is attainable by some other means that entails lesser risks for the health, safety, and personal integrity of the research participants (Section 10).

If you wish to recruit vulnerable people, you need to include the following information

- the reasons for recruiting these people to the project
- the measures planned to reduce the risks and pressures that may arise from participation in the research.

\textsuperscript{5} Declaration of Helsinki, 2013, Item 19.
Number of participants

One factor that must be examined is whether enough people are involved in the study for the results to be reliable. Since participation in a research project can be a burden for the participants, an unnecessarily large number of research participants should not be recruited.

In the case of quantitative studies, there are established procedures for determining how large a sample is needed to achieve sufficient statistical power to confirm the hypothesis. You need to report how you have carried out such an analysis and what opportunities you have to answer your research questions with the number of participants you propose.

For qualitative studies, for example in interpretive social science research, precise calculations of the number of required participants are often deemed irrelevant. In such cases, it is important that you emphasise that your study is of a qualitative nature and explain your reasons for selecting a certain number of participants.

As for exploratory studies, pilot projects, and the like, you may not yet have sufficient data to calculate statistical power. In such cases, you will need to explain the reasoning behind the planned number of participants in some other way.
**Compensation for research participants**

Most research principals have established their own rules for what constitutes reasonable compensation for research participants. Find out what applies within your organisation.

In an ethical review, the members of the board assess, among other things, whether the compensation is proportionate to the time that the research participants devote to the research through their participation. The compensation must not be so considerable that potential research participants will be attracted to participate for its sake alone. In such cases, the compensation constitutes undue influence aimed at persuading people to participate.

According to the Swedish Tax Agency, financial compensation paid to research participants is regarded as income from employment and is therefore taxable. Exceptions to this rule are payments for the donation of blood, breast milk, or organs, which are tax-exempt. Reimbursements for travel expenses are also tax-exempt. Read more at [skatteverket.se](http://skatteverket.se).

The information provided to research participants must state whether they will be compensated for their participation. It must also be specified whether the compensation is taxable.

» According to the Swedish Tax Agency, financial compensation paid to research participants is regarded as income from employment and is therefore taxable.
Information and consent

Research participant information

An individual who is recruited to a research project must receive information about the research in which they are expected to participate. This information should include a description of everything that the potential participant needs to know in order to decide whether they wish to participate in the project, as well as everything they need to know in order to be able to exercise their rights. The information must be carefully formulated and describe the project objectively. It should not contain any exaggerations or persuasive elements.

Section 16 of the Ethical Review Act describes the rules regarding this information:

The research participant must be informed about

- the overall plan for the research
- the purpose of the research
- the methods that will be used
- the consequences and risks that the research may entail
- who the principal investigator is
- that participation in the research is voluntary
- the research participant’s right to discontinue their participation at any time.

Information that is to be communicated to research participants must always be formulated using such language and at such a level that it can be thoroughly understood by the intended research participant, ideally in their native language, and, where applicable, adapted to their age or functional variations. An application for ethical review must include a Swedish version of all such material. Whenever appropriate, the researcher is responsible for ensuring that correct and appropriately formulated versions in other languages are used in the project.
As mentioned previously, you need to pay particular attention to the issue of information and consent when it comes to research participants who are vulnerable or in a dependent relationship with the research principal or a researcher. Especially in these cases, the information must clearly describe how the researcher intends to ensure that these people are not adversely affected by either their participation or their choice to refrain from participating, in the course of the research or within the area of their lives in which a relationship of dependence exists.

In their examination of so-called “deception research”, the Central Ethical Review Board and the Ethics Review Appeals Board have assessed that it is incompatible with the Ethical Review Act to provide misleading information that deprives research participants of a fair basis for deciding whether consent can be given.\(^6\)

To help researchers structure the information they provide to their research participants, a support template can be downloaded from the website of the Swedish Ethical Review Authority. This handy template is designed to make it easy to meet all the conditions. It is clearly structured, with headings, standardised text sections, and prompts to help you fill in the required information. When drafting the information you provide research participants in your project, you should always use this support template as a starting point. Only address the questions in the support template that are relevant to the research you will be conducting. Always use the latest version of the support template.

**Consent**

Consent must be voluntary, explicit, and specific to a particular research undertaking. It must be documented. Normally, information for research participants should be provided both orally and in writing and consent should be in writing, but depending on the circumstances, other methods may be used. In your application for ethical review, you must describe and, if necessary, justify the way in which information and consent are to be provided and documented.

A consent form should be concise and not contain any new information. All the information potential research participants need to decide whether they want to participate must be included in the information sheet. Information and consent forms must be drawn up in duplicate, and the research participant must always be able to keep a copy of both. The researcher’s copy of the forms must be retained for future reference. A support template for the consent form is available on the Swedish Ethical Review Authority's website.

Although consent is most commonly provided in written form, it can also be given in other ways. There are no specific formal requirements for how information and consent are provided and obtained. For example, when recording an interview or a sequence of events, consent can be obtained through an audio recording. Special methods can also be used, e.g., if a research participant has reading and writing difficulties due to illness or a lack of education. When, for special reasons, research participants do not wish to reveal their identity or are unable to write, an “X” or similar marking can be used in place of a signature.

Consent must always be obtained before a study begins. Consent obtained only after a study has been carried out will not be accepted.

It is important that researchers see informed consent as a way to ensure that each participant in a study has received sufficient information and that participation is voluntary – not just as a formality.

**Withdrawal of consent**

It is a fundamental principle of research ethics that participation in research is always completely voluntary and that consent can be withdrawn at any time and with immediate effect. This is also stated in Section 19 of the Ethical Review Act. The research participant does not need to offer any reasons for withdrawing their consent. Once an individual has withdrawn consent, they should not participate in any more activities in the research project, and no more data about the person should be collected. However, the data previously collected on the basis of consent may continue to be used in the research, even after consent has been withdrawn.
In some cases, such discontinuing participation in a research project may pose a risk to the health or safety of the participant. In such cases, the person conducting the research must explain the potential consequences. It is always up to the research participant to decide what they want to do.

**Information and consent concerning children and young people**

If a research participant is under the age of 15, their guardian (both guardians in the case of joint custody) must receive the information and make a decision regarding their participation. Children and young people should also be given age-appropriate information and the opportunity to object to participation. The Authority recommends that age-appropriate information for children and young people be divided into three age groups: Ages 6–11 years, 12–14 years, and 15–17 years. If a child understands what the research entails and objects to participation, the research cannot be conducted, even if their guardians have given their consent.

Young people between the ages of 15 and 17 who understand what the research entails for them should be informed and decide for themselves about their own participation. In such cases, there is no legal ground to also provide information to guardians or obtain their consent. It is the researcher’s responsibility to determine whether a person between the ages of 15 and 17 has the ability to understand what the research entails.

> Although consent is most commonly provided in written form, it can also be given in other ways.
Information and consent concerning persons with limited decision-making capacity

If you wish to conduct research that involves people with limited decision-making capacity, for example due to illness, poor health, or mental disorder, you need to take into account the special provisions in Sections 20–22 of the Ethical Review Act.

You must first make an assessment of whether the decision-making capacity of the person in question is so limited that it makes it impossible to obtain their opinion regarding participation. In your application for ethical review, always specify which procedures will be used to determine the decision-making capacity of potential participants.

When the decision-making capacity of potential participants is limited, the research may only be carried out:

- if it is impossible to obtain the expected knowledge by other means, and
- the research can be expected to directly benefit the research participant
  or
- if the research can be expected to benefit people with the same or similar disease or disorder, and
- poses an insignificant risk of harm or discomfort.

You must consult the potential participant’s next of kin as well as their trustee or law guardian, if there is one and it is part of the person’s assignment. The research participant must always receive information about the research that is adapted to their ability to absorb information, and then be given the opportunity to object to participation.
When are research participant information and consent required?

The provisions of the Ethical Review Act regarding information and consent must be followed in all research referred to in Section 4(1)–(3) of the Ethical Review Act, i.e. research that

• involves a physical intervention conducted on a research participant
• is carried out according to a method that aims to affect the research participant physically or mentally, or which entails an obvious risk of harming the research participant physically or mentally
• concerns the study of biological material obtained from a living person and which can be traced back to that person.

The Ethical Review Act does not contain any explicit requirement for information and consent in connection with research referred to in Section 3, i.e., research that involves the processing of sensitive personal data or personal data about violations of the law. However, informed consent to participation in a scientific study is a fundamental principle of research ethics. People who are recruited to participate in a research activity must always be informed about what participation in the research entails. However, in the case of research covered by Section 3 of the Ethical Review Act, there is a certain degree of flexibility when it comes to obtaining consent.

As regards written questionnaires, it is not uncommon for researchers to suggest that the person filling in the questionnaire can also be considered to have clearly expressed their consent. This argument is often accepted in an ethical review, provided that it is also clear that the research participants have received adequate information about their participation.

In online surveys, it is common for the person who logs in to be greeted by a page with complete research participant information, followed by a question about whether they are prepared to participate in the study. Only when they click “YES” do they advance to the survey itself. In an ethical review, this procedure is often perceived as adequate.
Use of previously collected personal data

Researchers often want to use previously collected personal data for their work. Scientific enquiries that primarily or exclusively use previously collected personal data are often referred to as register research or register studies. Yet the same questions apply to all studies in which previously collected personal data are used. This section describes the issues that arise when using previously collected personal data, also referred to as the secondary use of personal data for the purposes of research, regardless of whether it is described as register-based research.

The first decisive factor for ethical review is whether such a scientific enquiry will involve the processing of personal data at all, i.e., whether the researcher will gain access to data at the individual level during the course of their work. If only group-level data (e.g., correlations or statistics) are processed, this does not give rise to a need for ethical review. On the other hand, if the project entails the processing of individual-level data, and these data include sensitive personal data or personal data about violations of the law, an ethical review is required. The processing may involve new personal data to be collected during the project, the continued processing of previously collected personal data, or both.

Please note that this also applies to data you personally collected within the context of a previous study and which you wish to reuse in new research. An ethical approval granting the right to process personal data is limited to the specific project to which the approval relates.
If you want to use previously collected personal data in a new research project, you must apply for ethical review and report your use of these data in the same way as for other personal data. You also need to report

- which data will be reused
- where they were obtained
- why they are necessary to answer the project’s research questions
- the information that has been provided to the persons to whom the data relate, as well as any consent.

Any consent to future research obtained when data for a previous research project were collected cannot eliminate or replace the need for ethical review of the new project.

Open access to research data has become an important element of contemporary research policy. You and your research principal must discuss and resolve how you intend to negotiate the issue of offering the research community access to information about your previous research, taking into account current legislation.

If you are interested in using information made available in this way in your own research, you must first decide whether the open-access data should be viewed as anonymous information or as identifiable personal data. If it is of the latter type, consider whether it could constitute sensitive personal data or personal data about violations of the law. If you are dealing with either of these two types of personal data, you must apply for ethical review in order to be able to use them in your research.

For more on anonymised data, see the section *What are personal data?*
**Information and consent when processing previously collected data**

The question of how information and consent in connection with new uses of previously collected personal data should be assessed in an ethical review is a complex issue that must be assessed on a case-by-case basis. It is therefore important that you provide adequate and sufficient documentation for this assessment when you apply. In its assessment, the Authority examines both the degree of breach of personal integrity and what is required to protect the rights of the data subject, as well as the possibility of contacting the persons to whom the data relates.

Whenever possible, information should always be directly provided to the persons concerned. If this is impossible or would involve a disproportionate effort, the information may instead be made available to the public, for example by posting information on the principal’s website or by means of an advertisement in the daily press.

- In cases of **serious** breaches of personal integrity, informed consent must be obtained in accordance with the rules stated earlier.
- In cases of **limited** breaches of personal integrity, an **opt-out** procedure is often used in this type of research, i.e., research participants are provided with information about the research and the opportunity to decline participation. The researcher must then also provide contact details and information about what they should do if they do not want their personal data to be used in the scientific enquiry. The Ethics Review Appeals Board has assessed that an **opt-out** can be used if the risk of a breach of personal integrity is limited.\(^7\)
- Research based on previously collected personal data that involves an **insignificant** breach of personal integrity can normally be approved without the requirement for informed consent.

It is the Swedish Ethical Review Authority that will ultimately assess the degree of the breach of personal integrity. You need to provide documentation for this assessment in your application.

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\(^7\) See, e.g., Ö 32-2021/3.1.
**Information from registers containing personal data**

Many researchers need access to data from registers, such as those managed by Statistics Sweden (SCB) or the National Board of Health and Welfare.

Be aware that when you want to gain access to data from a register, you need to request the disclosure of this data, and the register holder must then review whether the data can be disclosed, for example by examining whether it is clear that the data can be disclosed without causing harm to an individual or someone close to them (a so-called “detriment assessment”). In other words, you cannot be sure that you be granted access to the data until this assessment has been completed.

You need to provide the disclosing party with proof that you have obtained an ethical approval and specify the data to which the approval refers and the purpose of their use. The best course of action is always to investigate the requirements of the organisation from which you want to obtain the data before you submit your application for ethical review.

In the application form for ethical review, you must fill in the section entitled *Register information*, in which the Authority requests information about:

- the registers concerned
- which data will be requested
- why they are necessary to answer the project’s research questions
- a list of variables.

In this case, you should have already been in contact with the register holder from which you want to obtain the data, and you need to ensure that the information is sufficiently detailed to meet their requirements. If you missed this step, or if details of your research plan have been formulated or amended after you received your ethical approval, you may need to submit an application for amendment.
Use of previously collected biological material

Section 15 of the Ethical Review Act contains a special provision regarding information and consent in research conducted on biological material previously collected from a living person. In such a situation, the Authority must determine the requirements that will apply in terms of information and consent to the use of the material. In general, a new confirmation of informed consent is needed. In some special situations, it may be decided that the donors do not need to be consulted again, but this is unusual. In such cases, you need to clearly explain in the application the reasons why it is unnecessary to inform the research participant and obtain their consent again.

In general, a new confirmation of informed consent is needed.
Research related to deceased persons

*Biological material taken from a deceased person*

In the case of research that involves studies conducted on biological material obtained for medical purposes from a deceased person, the provisions of the Transplant Act (1995:831) regarding information and consent shall apply, instead of the corresponding rules in the Ethical Review Act (Section 13 of the Ethical Review Act).

The Transplant Act states that:

- Biological material may be obtained if the deceased person agreed to this, or if it can otherwise be demonstrated that they had a positive view of such a procedure.
- Material may also be obtained if the deceased person did not object to or speak out against such a procedure in writing, and there is no reason to otherwise assume that doing so would be contrary to their wishes.
- If the deceased person is survived by relatives, the procedure may not be carried out until one of their next of kin has been informed of the intended procedure. However, the procedure may be performed if the deceased person agreed to it, but it has proven impossible to contact anyone of their relatives.
- If there is any contradiction in the information about the deceased person's wishes, the procedure may not be carried out. The same applies if, at the time of death, the deceased person was an adult with a disability of such a nature and degree that it is obvious that even as an adult, they never had the ability to understand the meaning of such a procedure and take a position on it. Moreover, the procedure may not be carried out if there are other special reasons to refrain from doing so (Sections 3–4).
Physical interventions conducted on a deceased person

In the case of research that involves physical interventions conducted on a deceased person, the provisions of the Autopsy Act (1995:832) regarding information and consent shall apply, instead of the corresponding rules in the Ethical Review Act (Section 13 of the Ethical Review Act).

The Autopsy Act states that:

- If the deceased person has given their consent or there is otherwise reason to assume that they would have been in favour of an autopsy, such an autopsy may be performed (Section 8).
- If the deceased person’s attitude is unclear, a close relative must be provided with information and given the opportunity to oppose an autopsy (Section 7).
- If the deceased person was survived by no close relatives, special reasons are required to perform an autopsy (Section 10).
Management, archiving and disposal of research data

In an application for ethical review, you must describe how the collected data will be handled and stored after the data has been collected. This includes a description of

- the safeguards that will be implemented to make it more difficult to identify the data, such as pseudonymisation
- where the data and any code key will be stored
- who will have access to the material, and in what way
- what security measures are planned to prevent data leakage, theft, etc.
- whether additional safeguards will be implemented after the conclusion of the project
- how long the data will be retained.

Avoid using ambiguous terms for safeguards. Words such as “de-identified”, “re-identified” or “decoded” can mean different things in different contexts. Instead, describe the nature of the data and explain how it will be processed.

Archiving is not part of the implementation phase of research and is not part of the aspects of a research project that are ethically reviewed. As a researcher, you need to consult with your principal on such issues. Research data must be archived and disposed of in accordance with the current Archives Act and the regulations of the National Archives of Sweden. The principal usually has a document management plan, setting out their rules for how research data is to be archived and disposed of in its own organisation.
Insurance

The research principal is considered to be responsible for the risks to which research participants are exposed. If a research participant is harmed and it can be proven that the damage was caused by their recruitment and participation in a study, the research principal may be liable for damages. The research principal cannot disclaim this responsibility by referring to any private insurance policy.

When the risks to which research participants may be exposed are not negligible, the research principal and the researchers should consider whether special insurance is justified. For research that only processes personal data, insurance coverage is rarely needed.

Government agencies only take out insurance policies in special cases. For such purposes, the Legal, Financial and Administrative Services Agency (Kammarkollegiet) has an insurance service that offers insurance for special personal injury protection. This corresponds to the accident coverage provided by occupational injury insurance. When conducting research projects that involve special risks, it is common and reasonable for the research principal to take out such insurance.

According to the Patient Injury Act, care providers are obliged to have insurance that covers injuries resulting from health and medical care. The insurance policy that covers Sweden’s regions, known as Patient Insurance, is provided by LÖF, a mutual insurance company owned by its policy holders, the Swedish counties and regions. This insurance also covers injuries that may occur in connection with research conducted on healthcare patients.

The Swedish Pharmaceutical Insurance (Läkemedelsförsäkringen AB) provides compensation for injuries that occur as a result of the use of medical products or placebos. The insurance applies to medical products from companies and organisations that have taken out insurance with them. It also covers injuries arising from research.
Some specific types of research

Observational studies

Qualitative scientific enquiries into human phenomena in their natural social environment are common in several fields of research, especially in social science research. These often involve sensitive personal data, such as political or religious beliefs or matters related to sex.

In such studies, it can be difficult to set clear boundaries for what the research should include. Here are a few examples:

- It can be difficult to know in advance which people can participate in the social environment to be studied. The research may therefore involve people other than the intended participants.
- A person who has been recruited as a research participant can easily reveal more information about themselves and their circumstances than they intended.
- Research participants may have expectations of the researcher that conflict with the researcher’s role.

You need to identify such conditions and plan appropriate measures to grapple with their implications. Describe this in detail in your application for ethical review, so that the Swedish Ethical Review Authority can make a correct assessment based on the relevant conditions for the study in question.
**Photography, filming and sound recordings**

Recordings of sound and images may include personal data. If planned photography, filming, or sound recording may entail the processing of sensitive personal data, an application for ethical review is required.

If you want to photograph or film your research participants, information must always be provided and consent obtained. The information must be clear and include what is to be photographed and how, for what period of time, for what purpose, and how the images are intended to be used. There must be a clear commitment that the images will not be used for any purpose other than what is stated in the information, including how the images will be archived and if or when they will be destroyed.

You also need to take steps to avoid photographing or filming people who have not been recruited to the project. For example, this may be a concern when filming employees as part of research conducted in a workplace, or pedagogical situations in which teachers’ interactions with children are filmed. The ethical approval application should include a description of the measures planned to avoid risks of harm to third parties.

Audio recordings, e.g., of an interview or observation, are also normally considered to contain personal data, even if no names are mentioned, because it is easy for someone who knows a person to recognise them by their voice.

The research principal is responsible for the recordings made in the course of the study. Questions about storage, future use, etc., must be decided in consultation with the research principal and in accordance with their instructions.

Camera surveillance in public places requires a permit from the Swedish Authority for Privacy Protection (IMY). Information on provisions and common practice is available on the Authority’s website, [imy.se](http://imy.se).
**Focus group interviews**

Focus group interviews have become a common instrument in qualitative research. In focus group discussions, it can be difficult to control what is said. This research method therefore creates particular problems, to the extent that the discussions in the focus groups are about, or may concern, sensitive personal data. If you believe that focus groups are an appropriate method for your study, you need to take steps to avoid revealing information about sensitive personal data. If such data are processed nonetheless, measures must be taken to ensure that their scope is minimised and that they are protected during further processing. When applying for ethical review, potential risks of this kind must be identified and clearly reported, and the measures planned to minimise the risks must be described.

**Social media research**

Research using information from the internet, not least from social media, has become commonplace. Such studies also raise a number of questions, not least with regard to the personal integrity of participants. Research on social media can take many forms, such as observational studies, studies in which the researcher collaborates with participants, or experiments involving social influence. The Ethical Review Act may be applicable in all of these cases, and you are obliged to apply for ethical review as soon as one of the situations in Sections 3–4 arises. The information and consent rules described in this Guide also apply.

» If you believe that focus groups are an appropriate method for your study, you need to take steps to avoid revealing information about sensitive personal data.
Moreover, you need to consider that many people who participate in conversations on social media may perceive the social group as a closed environment and share information in confidence. Participants in these conversations often underestimate how public this information can become. Therefore, if you collect information that is already available on a forum of any kind, you should respect the personal integrity of participants by making them aware that information originating from them may be processed. Whenever possible, contributors to these online fora should be given the opportunity to decline participation in your study or to see what has been collected and then object to the use of certain data. This also applies if you passively observe a certain event, or interact with participants in some way, over an extended period of time. On several occasions, after consultation with and approval from the organiser, researchers have received ethical approval to post information on a social media platform about the fact that they are conducting research there and what it entails, so that this information can be read by platform participants.

For vulnerable people in particular, awareness that they are being observed can stimulate undesirable behaviour. For example, in such observational studies, self-harm has been triggered in self-harming people. Undesirable dependencies may also arise, such as the desire for a more personal relationship with the researcher than a professional approach allows. In an application for ethical review, risks of these and similar kinds must be identified and appropriate measures must be planned and described.
**Use of digital tools**

In all fields of research, the use of digital tools, such as survey tools and digital “apps” for self-reporting health data, is becoming increasingly widespread. This raises questions about personal data management and privacy risks. In an application for ethical review, you need to describe as clearly as possible how the research will be conducted, what ethical dilemmas you may face in the course of your research, how you plan to handle these, what risks (concerning privacy and other issues) exist, how great they are, and finally how you think the benefits of the study outweigh the inherent risks. Technical details and structures need only be described to the extent necessary to examine or understand the content of your intended research and application.

**Case reports**

In broad terms, case reports are descriptions of detailed information about a particular person’s circumstances and any associated analysis. Such reports are common in medical contexts, but can also be associated with, e.g., psychological, social science, or historical research. Do such reports count as research? Do they need to be ethically reviewed?

The Ethics Review Appeals Board has reviewed a number of ethical review applications relating to case reports.\(^8\) In particular, the Ethics Review Appeals Board points out that, although descriptions of individual patient cases may serve a purpose, the mere intention to publish treatment results in a scientific article cannot be interpreted to mean that such work is to be regarded as research. If what is intended to be published only contains accounts of diagnostics and treatment or of some other course of events, the Ethics Review Appeals Board’s stance should be understood to mean that such reports do not constitute research subject to ethical review.

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However, the situation may be different if what is planned means that upon the conclusion of care, treatment, or the like, personal information will be subject to analysis and processing, with the aim of answering a scientific question in order to obtain new knowledge. This may fall under the legal definition of research. If your intention is to simply publish work that has already been done, this cannot be approved.

You must also take into account that the person described in a case report could be recognised. Regardless of whether ethical review is required, the protection of personal integrity must be ensured.

**Research involving third parties**

Sometimes researchers plan interviews or surveys in which the research participant is asked to talk about other people. For example, a healthcare worker or close relative might talk about a patient, or a parent about their child. The information collected about such a third person means that this person should be regarded as a research participant, and should thus be given the opportunity to decide on their own participation via informed consent.

In interviews with professional actors, the research participant is likely to use examples from the business in question. Such stories may reveal sensitive personal data about third parties. If a risk of such disclosures may exist and the data is not necessary for the research, you should mention in the information letter you provide to research participants that they should not use examples or disclose other information that can be directly or indirectly attributed to a living natural person.
**Historical research**

If historical research deals only with information about people who are already deceased that cannot indirectly reveal details about their living relatives, the Ethical Review Act does not apply. However, information about living persons is often interwoven in 20th-century and recent history. When, by extension, sensitive personal data is involved, such enquiries are considered to require authorisation. This also applies, e.g., to public data and information in archives.

**Research planned successively**

It has become more common to apply for ethical review of research projects that are not entirely planned out from the beginning, but which are rather developed gradually. This means that the research is conducted in several stages in which the data collected leads to new questions that are studied within the scope of the same project. In action research, for example, the idea is often that the work should emerge step by step, through interaction between the researcher and the practice they are studying. In the case of such research, it may not be possible from the outset to present every study with such a level of clarity and detail that they can be assessed from an ethical point of view.

In such situations, the Authority can usually only review and approve the work described in the application. If a project consists of several scientific enquiries in different sub-studies, and these cannot yet be described in detail but are instead to be planned successively, taking into account experiences from the preceding sub-studies, it is wise to start by submitting an application for the first sub-project and then apply for the approval of subsequent sub-studies once they are finally planned.
In some other cases, the research process itself may be thoroughly described in terms of recruitment and approach, but details may be clarified or adjusted in the course of the work. In your basic application, you need to explain why it may prove scientifically relevant, e.g., to adjust the number of research subjects or the number of questions during your work. You must also address the research ethical considerations associated with doing so. Whether such an application can be approved depends, among other things, on how sensitive the area and the issues are and how well they are described in the application.

If you assess that details of your research plan need to be amended after you have received approval, you must consider whether an application for amendment is necessary. Substantial changes require such an application, especially if the risk-benefit balance or the protection of research participants is significantly affected by the planned changes. You can read more about this in the section Application for amendment.

**Research involving ionising radiation**

When research participants will be exposed to ionising radiation that goes beyond the levels used in clinical treatment and is not expected to provide any direct medical benefit, the Swedish Ethical Review Authority needs to establish a radiation dose constraint in connection with the examination of your application for ethical approval.

Such a restriction need not be established if the radiation exposure resulting from the research is expected to yield a direct medical benefit for the research subjects. However, this is unusual, as it assumes that there is already clear data to support such expectations.

Information about radiation must be described in a separate section of the application. Among other things, you must submit an assessment of the benefits of the research together with the total radiation dose that will be added for research purposes. A general description of the clinical procedure described in the treatment plan must also be provided, and the total amount of radiation used in the treatment must be stated.
The review of these details will be based on the research benefit categories set out in ICRP62, the international recommendations that serve as the basis for all international regulation of protection against the harmful effects of ionising radiation. The Swedish Ethical Review Authority involves medical physicists in the review process, and normally also other members with competence and experience of research involving radiation. The Authority’s decision determines the maximum and total amount of radiation that may be added through participation in the research project.

Be sure to consult radiation experts when planning your research.

**Research on biological material**

If you intend to conduct research on biological material, you need to be aware that it will normally be subject to the legislation of the Biobank Act (2023:38) and that samples that fall under the Biobank Act must belong to and be established in a biobank.

Only when ethical approval for a specific research study exists may samples be collected in a biobank.

Even before you submit an ethical approval application, it is important that you contact the biobank coordinator in your region for advice on the possibilities of using biological material in your research. To ensure that the process of establishing a biobank goes as smoothly as possible, also consult the biobank coordinator about how your application for ethical review should be formulated. Keep in mind that the conditions differ depending on whether you plan to collect new samples in your research or if you want to use samples that have already been collected.
There are two exceptions in which the Biobank Act does not apply.

One is the so-called *nine-month rule*, according to which the Biobank Act does not apply to samples intended for research that are analysed within nine months of sampling and destroyed immediately after analysis. Even if this exception applies to a research project, you must answer all the questions about biological material in your application for ethical review.

The second exception concerns samples that have been substantially modified in the course of research or product manufacture. For this exception to apply, two conditions must both be met:

- The sample donor must have been informed that the sample will be significantly modified thus no longer be covered by the Biobank Act.
- The sample donor must have given their consent to such modification.

otherwise, the samples will be subject to the Biobank Act.

**Research that is to be conducted entirely or partly abroad**

The Ethical Review Act applies to research to be carried out in Sweden (Section 5). As the name implies, in international research projects, researchers are likely to implement different parts of the work in several nations, often in collaboration with researchers in different countries.

The work that you and your colleagues plan to conduct in Sweden requires authorisation in accordance with the rules described previously in this Guide, i.e., if the work constitutes research and falls under Section 3 or 4 of the Ethical Review Act. Otherwise, ethical review is not required in this country.
The storage of research data is part of the research process. Thus, if research data is stored in Sweden, this part of the implementation phase is subject to ethical approval.

The Swedish Ethical Review Authority can only examine the limited part of the research that is to take place in Sweden; its mandate does not extend abroad. This part of the project must be reported and assessed in the same way as all other research conducted in the country. You will therefore need to answer all the relevant questions in the application form and attach all the requisite attachments for this part of the project. All the information in your application must be in Swedish, except for the research plan and CV, which may be submitted in English.

For the Authority to conduct a proper review and assessment of the research in its particular context, a description of the entire international project, from start to finish, is also needed. To this end, you should also include the research plan for your entire project, as well as the principal investigator’s CV. Other documentation regarding the part of the project that will be conducted abroad, such as advertising material, research participant information and questionnaires, do not need to be attached.

If your research involves collaboration with researchers outside Sweden, you also need to report the research principal(s) for the work implemented in Sweden. A foreign organisation can be the principal for work carried out here. Principalship can be joint, in which case all principals concerned must be reported.

As in any other case, the research that is to take place in Sweden may not commence without ethical approval. On the other hand, no such approval is required in Sweden for research conducted abroad. It is therefore no obstacle to ethical review in Sweden that portions of the project that are only being carried out abroad have already been launched or implemented.
The approval from the Swedish Ethical Review Authority only applies to the part of the work that is conducted in Sweden. It is your and your research principal's responsibility to investigate what may be required to carry out research in other countries and abide by these rules.

**Contact with research participants via digital media**

Technology creates new opportunities for remote research. The Authority has concluded that if a researcher located in Sweden and uses the internet or some other communication channel to engage in digital or equivalent contact with research participants who may be abroad, the research should be considered to take place in Sweden, regardless of the country in which the research participants are located. The fact that the research must also be considered to occur in the research participants' location(s) does not affect the requirement for ethical review in Sweden, nor the researcher's responsibility for their welfare and safety under Swedish law.

The research is also deemed to occur in this country in the reverse situation, in which a researcher located abroad has similar contact with research participants in Sweden. Even in such a situation, the question of whether or not ethical review is required must be decided via application of the Ethical Review Act, regardless of the fact that the research can be considered to be conducted in several countries at the same time.

As with any other research project, if the research involves risks for the participants, these risks must be identified, prevented, and limited. If a Swedish researcher involves human beings in research that requires authorisation in or from Sweden, a plan must be drafted and preparations made to manage the risks and consequences that the research may entail for the research participants. Circumstances may demand new solutions. Such questions are discussed in the **Social media research** section above.
Research with foreign funding bodies

Some research projects receive funding from the US National Institutes of Health (NIH) or another funding body committed to their ethical regulations. According to NIH rules, a local ethics committee known as an Institutional Review Board (IRB) must annually review the ethical quality of research projects involving human participants, and the results of the review must be reported to the funding body. Similar requirements may also be imposed by other research funding bodies.

The Swedish Ethical Review Authority cannot take on such a task. If you receive such funding for your research, you should contact your research principal. A number of Swedish universities have already set up their own IRBs in accordance with the US regulations.

A review carried out by such a local ethics committee does not replace the ethical review required by Swedish law; it is merely an annual follow-up review that has nothing to do with the Swedish system for ethical review of research.
When do I need to apply for ethical review?

Research in Sweden that is subject to the requirements of the Ethical Review Act is specified in Sections 3 and 4 of that law. It may only be carried out if it has been approved in an ethical review. This applies to research that

- entails the processing of sensitive personal data or personal data about violations of the law
- involves a physical intervention conducted on a research participant
- employs a method that aims to physically or mentally affect the research subject
- employs a method that exposes the research participant to obvious risks of physical or psychological harm
- concerns the study of biological material obtained from a living person and which can be traced back to that person
- involves a physical intervention on a deceased person
- concerns the study of biological material obtained for medical purposes from a deceased person and which can be traced back to that individual.

Each of these criteria is discussed later in the text.

The term research participant is used in the Ethical Review Act to refer to the living person to whom the research relates. The use of this term, rather than "research subject", is intended to highlight the fact that the people who are involved in research can participate in many different ways, and not just be subjected to tests or experiments.
Is it research under the Act?

The Ethical Review Act only applies to research involving humans or biological material from humans. This is stated in Section 1 of the law. Section 2 defines “research” as comprising

scientific experimental or theoretical work or scientific studies through observation, if the work or studies are conducted in order to acquire new knowledge, as well as scientifically based developmental work, but not such work or studies implemented only within the context of first-cycle or second-cycle higher education.

Experimental work is understood in a broad sense and refers to all types of arranged situations or processes and the collection of resulting information. Interviews are one example of such processes. Theoretical work refers to all forms of structured processing based on existing information. Observation was added in the 2020 update of the law, to make it clear that the collection of data about people in unplanned circumstances or without the intent to affect them also falls under the definition of research.

What is scientifically based developmental work? This usually refers to work that uses scientific methods in the practical application of previous research results. Common designations for such work include “applied research” and “research and development” (R&D). In the preparatory work for the Ethical Review Act, it is stated that the term “scientifically based developmental work” refers to

an imaginative and systematic use of scientific and other knowledge to achieve new products, new processes, new systems, or substantial improvements to existing systems.

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9 Sweden’s regions commonly use the term FoUU, which connotes research, education, and development (forskning, utbildning och utveckling).
The requirement for ethical review shall apply to various types of developmental work that uses scientific methods or results, whether it is carried out within

- a government agency
- a government investigation
- municipal regional operations
- a company
- under other private auspices.

The research conducted by companies is largely considered to constitute such developmental work. The same applies to the research supported and carried out by most of Sweden's government agencies.

If such research entails any of the activities covered in Sections 3–4 of the Ethical Review Act, it must be approved in an ethical review before it can commence.

On the other hand, this provision shall not cover the following activities:

- quality development and quality assurance
- performance follow-up
- the internal evaluation work of public authorities.
Researchers occasionally disagree about the quality of their peers’ research. If a research method is accepted in at least part of the academic world, it can also be viewed as research in a Swedish ethical review. In principle, work that is to form the basis of a doctoral degree or which has received funding from established research funding bodies should always be considered to constitute research.
What research requires ethical review?

According to Section 6, research covered by the Ethical Review Act may only be conducted following approval in an ethical review.

The conducting of research refers to the implementation phase, in which researchers

- recruit research participants
- collect biological material or information relating to humans
- carry out experiments or observation
- process or analyse the material and information collected.

The reason for this is that it is only in the implementation phase of research that risks of harm to the health, safety and personal integrity of research participants arise.\(^\text{11}\)

Research that requires authorisation thus connotes the implementation phase of all research described above that falls under one of the criteria in Sections 3–4 of the Ethical Review Act. Until you have received approval, you are not permitted to commence your research.

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\(^{11}\) See Government Bill 2002/03:50, p. 114.
What is *not* considered to constitute research in an ethical review? Some clear examples include

- the planning of future work
- number calculations for clinical research (i.e., to determine how many people meet certain predetermined criteria and who may therefore be included in the research)
- applying for funding for future work
- reading public material to improve one’s knowledge and get ideas for research
- publishing an already completed manuscript
- sharing and providing access to research data.

This means that you, together with your principal, must find other legal support for carrying out these activities, as they are not covered by the ethical approval requirement.

It is only when you

- start collecting or processing data on humans or biological material
- begin recruiting, i.e., from your very first contact with prospective research participants
- initiate a physical intervention or other procedure

that you start your research in the sense of the word provided in the Ethical Review Act (the implementation phase). If your research requires authorisation, then in order to continue your work from this step, you must have previously received ethical approval following a review.
Experiments that include an activity described in Sections 3–4, which meet the definition of research, and which the researcher intends to carry out only on themselves, also require ethical review.

Research that falls within the scope of the requirements of the Act may only be carried out if it has been approved following an ethical review (Section 6). Only research that has not yet commenced can be ethically reviewed. Otherwise, the review would fail to serve its real-world purpose: to protect the research participants or respect for the value of human beings. Work that has already been carried out and was not initially considered to constitute research cannot subsequently be redefined as research, and thus cannot be approved in an ethical review. Nor can approval be granted simply for the publication of a work that has already been completed.

**In an ethical review, what constitutes a “project”?**

Government Bill 2002/03:50, which underpins the Ethical Review Act and the establishment of the current ethical review process, states in the commentary on the statute:

> In order to be approved, the research that is to be ethically reviewed must be limited in some sense. It is not possible to grant any general approval on grounds of principle to carry out research on a certain material, in a certain area, or the like for unforeseeable future. An assessment based on the fundamental tenets of ethical review cannot be isolated to individual elements of the research; it must be based on a comprehensive evaluation of the particular research to which a specific application relates. In such an assessment, it is necessary to consider, e.g., the research questions, purpose, scientific value, performance, risks to research participants or to the value of human beings, intended contacts with research participants, the competence of the research management team, and the participating researchers (p. 195).
To describe this delimitation, the bill uses the term *project*. It is also this meaning of the term project that is referred to when the Ethical Review Act states that an approval must relate to a certain project or part of a project, or a similarly distinct research undertaking (Section 6).

This is also of great importance for how you should understand what an approval means for your research. To delve deeper into this issue, see the section *What do I need to consider after a decision?*.

A *pilot project* usually refers to a small-scale preliminary study conducted with the aim of preparing or evaluating the feasibility of an idea for a full-scale research project in various ways. A pilot project constitutes research that requires authorisation if it includes activities that meet the Ethical Review Act’s definition of research and the criteria set out in Sections 3–4 therein. Such pilot projects must be ethically reviewed.

**The significance of publication**

According to the common practice developed by the Ethics Review Appeals Board, there is much to suggest that an undertaking constitutes research

- if a scientific question and method exist
- if the project is carried out by a person with scientific competence, and
- if there is an intention to publish the results in a scientific context.
An ethical approval refers to the implementation phase of a project. Among other things, this phase encompasses the analysis of data and drafting of research reports, but not actual publication. However, the intention to publish the results of research work is generally regarded as an important principle of research ethics. In the research world, it is a fundamental tenet that the results of research work must be made available to other researchers. Researchers are thus considered to have an obligation to publish their results. This clearly indicates an expectation to gain new knowledge, which is a central aspect of the definition of research under the Act.

The intention to publish need not refer to a unique publication limited to the results of the scientific enquiry to which an application for ethical review relates. There may also sometimes be good reasons not to immediately publish research results. However, if an intention to publish is lacking in a particular project, this can be perceived as an indication that the work does not constitute research, even if it is conducted by researchers using scientific questions and methods. If the purpose of an undertaking is solely to disseminate the results within an organisation’s own operations, this work is generally not considered to be research in the sense of the law.

What is a scientific context? In ethical reviews, this term primarily points to the context of peer-reviewed scientific journals. Other examples of scientific publications include doctoral theses, scientific monographs, and chapters in anthologies that claim to present scientific results, but not textbooks and other teaching materials. Presenting your research at a scientific conference is also a scientific context. Another example could be a research report published by a research institution, public authority, or other organisation. Popular science literature usually compiles previous research.

12 See Good Research Practice, published by the Swedish Research Council, especially the chapter entitled Publication of research results.
Data collection vs. research

Approval following an ethical review can only be granted for research, and it must relate to a specific research project. This approval may then cover the collection or use of existing data or human tissue required for the project in question. The Swedish Ethical Review Authority cannot approve the collection of more data than is necessary to achieve the expected results of the research in question.

It is also impossible to obtain approval to only collect personal data or tissue samples for future research that has not yet been planned. Such collection, which is not linked to a specific research project, does not in itself constitute research and therefore cannot be approved. For example, the authority cannot approve an application that relates solely to the establishment of a research infrastructure, e.g., creating a register, collecting samples, or founding a video library.

Your application must therefore elucidate how the following factors are related:

- the research questions you want to answer
- the data or tissue samples you want to collect
- why the collected data is necessary to answer the research questions.

Questionable cases

To the best of your ability, you must use your skills and experience and get help from the support offered by your research principal, in order to make as certain an assessment as possible of whether ethical review is required. The research principal is responsible for ensuring that research that falls under the requirements of the Ethical Review Act is not conducted within its organisation without ethical approval. The decision you make regarding ethical review should be documented and included in your study documentation.
The Swedish Ethical Review Authority is neither able nor permitted to provide any advance decisions on the question of whether ethical review is required. Only on the basis of a complete application can the Authority draw any firm conclusions in that regard. Moreover, it is only after examination of an application at an official departmental meeting that the Authority has the right to take a decision.

The “student exception”

The last paragraph of the Ethical Review Act’s definition of research states a clear exception: “such work or studies that are carried out only within the context of first- or second-cycle higher education” do not constitute research (Section 2). This provision, which has come to be known as the “student exception”, has raised many questions and demands a clear and detailed explanation. Especially if you supervise students, it is important that you understand what this exception means and what limitations and possible courses of action follow from it and other provisions.

Why does the student exception exist?

The student exception was introduced in the 2008 version of the Ethical Review Act. The question of whether it should be retained is discussed at length in the later government bill regarding the Act (2018/19:165). In particular, the bill cites three different reasons for retaining it. In view of the time that would be required of supervisors and students to formulate an application and then await a decision, the imposition of an ethical review requirement on student projects would affect a large number of students and complicate their education. It is difficult for students to correctly comply with the rules that apply to research, for example regarding confidentiality and the right of the data subject to access personal data. A requirement for ethical review would also entail higher operating costs and an increased workload for the Swedish Ethical Review Authority.
Key consequences of the student exception

Within the context of first- and second-cycle education, the student exception leaves room for students to carry out projects that would otherwise have required ethical review. To ensure the protection of participants in student work conducted at these levels of study, each higher education institution must carefully consider the forms of work conducted by its students. It is the responsibility of the higher education institution to ensure that the work is carried out in an ethically defensible and secure manner.\(^\text{13}\)

The legislators who drafted the Ethical Review Act have made it clear that, as a general rule, students should not be given responsibility for conducting research activities involving human participants and in which there is a risk of harming these people physically, mentally, or in terms of their personal integrity, or in which sensitive personal data is used. Yet it is also clear that the exception can provide scope for students to carry out work that would have required ethical review if the student exception did not exist. This places great demands on the higher education institutions, in their capacity as data controllers, to ensure that student work is carried out safely and in ethically acceptable forms.

Since the student exception means that activities that otherwise should have been ethically reviewed can be carried out without ethical approval, it must be used restrictively and only in clear situations in which the sole purpose of the work is to serve as part of the student’s education, and nothing more. This has been the case ever since the student exception was introduced, but the word “sole” (italics above) was added to the legal text on 1 January 2020, precisely to emphasise this caveat even further. In other words, the student work must not overlap with a research project, and there must be no opportunity for the work to lead to a research project.

It is therefore very important to start thinking carefully about these issues even from the planning stage of the intended student project. If there is any uncertainty about where the work could lead, it may be wise for the research principal to consider whether an ethical approval application should be made. The student exception cannot be used if the higher education institution wishes to “keep its options open”, because the student’s ideas or execution may subsequently prove so good that they might want to change track and conduct a research project instead of just a purely educational assignment. If the higher education institution wants that flexibility, an ethical approval must be in place before the student starts their work.

**To whom can the exception apply?**

The exception applies to studies conducted only within the context of higher education at the “first- or second-cycle level”. This refers to all higher education studies at the bachelor’s and master’s level, i.e. education leading to a bachelor’s or master’s degree, or further studies of the same kind.

The Central Ethical Review Board has determined that activities in the context of specialist training for physicians must also be regarded as covered by the exception.¹⁴

Supervisors and students who are considering using the student exception also need to take into account the fact that the work must be carried out with other legal support for personal data processing than that required for an ethical approval. Here, your first step should be to familiarise yourself with the instructions at your own university.

**When is the student exception not applicable?**

The exception does not apply to doctoral (third-cycle) students. In this context, doctoral students are thus considered to be working on research, even if they have not yet completed their degree.

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¹⁴ See, e.g., Ö 45-2011.
Likewise, the exception does not apply in a number of specific circumstances that the Central Ethical Review Board and the Ethics Review Appeals Board have had occasion to consider:

- if a work is intended to be included in a future doctoral dissertation, even if the student in question has not yet been admitted to doctoral studies
- if the work is carried out as part of a research project led by an established researcher
- if a student project is intended to be published in a scientific journal.

**Ethical review of work conducted by resident physicians in specialist medical training**

The specialist training of physicians includes components in which a physician must carry out their own work according to scientific principles. The Central Ethical Review Board has ruled that such work is covered by the student exception.

At the same time, many physicians plan to continue their postgraduate education and may see the work they conduct during their specialist training as a first step on that path. Therefore, even before you even start this sort of project, you need to consult with your supervisor and operations manager and decide which way you want to go. If there is a plan to credit the work in your doctoral education and publish the results in a scientific journal or other such publication, and the research will include any of the activities that make it require authorisation, ethical review is required before the start of the study.
Personal data in research

Research that involves the processing of sensitive personal data or personal data about violations of the law requires authorisation under the Ethical Review Act. In order for you to understand what this means and what you need to do to prepare your research and an application for ethical review, you need to be familiar with the legislation that regulates the processing of personal data and how it should be applied. Not least, you need to be aware of the actors that can provide support and advice and verify that you are going about things in the right way.

All processing of personal data is regulated by the General Data Protection Regulation (GDPR) (EU 2016/679).

The research principal is the data controller and must know when personal data is processed in the organisation, which categories of personal data are involved, that there is a legal basis for processing the data, and that the rights of the data subjects are safeguarded. Personal data responsibility also entails an obligation to inform and instruct all employees on how the processing of personal data should and may be carried out in the organisation. Universities and other large data controllers often have special administrators to whom researchers can turn for support and assistance. See also the section The role of the research principal.

The Swedish Authority for Privacy Protection (IMY; formerly the Swedish Data Protection Authority) reviews and enforces the application of data protection rules. The authority supervises the processing of personal data, conducts regular audits, and can issue administrative fines. In the event of a personal data breach, i.e., a security breach involving personal data, the research principal is obliged to report it to Swedish Authority for Privacy Protection.\textsuperscript{15}

\textsuperscript{15} See Article 33 of the GDPR.
Most research principals are required to appoint a data protection officer. The data protection officer’s job is to monitor the organisation’s compliance with the GDPR and national data protection legislation, including by providing information and advice within the organisation. The data subject (i.e., the person whose personal data is processed) must also be able to turn to the data protection officer.

Personal data responsibility means that it must be clear in advance whether personal data will be processed, which categories of personal data are involved, that there is a legal basis for processing the data, and that the rights of the data subjects are safeguarded. Everyone within the organisation who deals with personal data must be aware of the rules and have sufficient knowledge to process personal data correctly.

If you plan to process personal data in the course of your research, you first need to consult with your research principal and data protection officer. Together, you must draw up an accurate plan for personal data processing and data protection within the context of your work. This must be done before you start processing any personal data.
What are personal data?

Personal data are any kind of information that can be directly or indirectly tied to a living, natural person. Names or personal identity numbers are the clearest examples of the kinds of details that allow information to be tied directly to a specific person. But there are also many other circumstances in which, e.g., research data constitutes personal data. Indirect identification means that the person who gains access to the data can find out to whom it relates, even if the information does not contain direct identifiers. Common examples of factors that can make a person indirectly identifiable include:

- information that can easily be attributed to a specific person, such as their mobile phone number, e-mail address, or IP address
- information which, together with one or more other pieces of data, can be unambiguously attributed to a specific person, such as a residential address or GPS data on their home
- information relating to unusual details.

Indirect identification is also possible if the person who gains access to the data is able to pinpoint the person to whom it relates by means of certain specific, but not directly identifiable, information. A number of studies have aimed to determine how much information is required to be able to make such an indirect identification, and it has been estimated that 3–5 specific pieces of information may be sufficient to identify who the data refers to, even when dealing with a large amount of material.
Pseudonymisation means replacing the names of the data subjects with a code and creating a special code list, a so-called “code key”, and storing it in another secure location. Pseudonymised data should be considered identifiable, and the safeguards set out in the GDPR apply. When someone other than the researcher has the code key, the data is often described as linked. Linked data is also personally identifiable. For your work as researcher this means that even if you do not have access to the code key, the data is still identifiable and can be traced back to an individual. This applies regardless of where in the world the code key is stored.

Anonymised data can no longer be traced back to any living person. In the process of anonymisation, all sources of identification have been removed. Such sources may include rare diseases tied to a city, IP addresses, images, videos, or biometric data. Please note that if it is possible to identify a person by means that could reasonably be used, for example by combining several apparently anonymised pieces of data, the data set should be regarded as personal data and no longer be described as anonymised.\(^\text{16}\)

Information about deceased persons is not personal data and is not protected by the GDPR. In other words, these data may be used in research without ethical review. However, data about a deceased person may contain information that secondarily reveals details about their living relatives. In this case, the relative’s personal data comes into play.

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\(^{16}\) See Recital 26 of the GDPR.
Processing of personal data

Processing of personal data is:

any operation or set of operations which is performed on personal data or on sets of personal data, whether or not by automated means, such as collection, recording, organisation, structuring, storage, adaptation or alteration, retrieval, consultation, use, disclosure by transmission, dissemination or otherwise making available, alignment or combination, restriction, erasure or destruction (Article 4(2) of the GDPR).

When a researcher obtains access to information that can be directly or indirectly attributed to a living natural person, all handling of the material constitutes the processing of personal data. The GDPR’s rules and limitations apply to all the working methods described above, not just computerised information processing.\(^\text{17}\)

\(^{17}\) According to Article 2(1), the GDPR applies to the processing of personal data other than by automated means which are or will be included in a register. A register is a structured compilation of data. In a number of decisions, the Central Ethical Review Board has taken the general view that personal data collected for use in research is structured to facilitate its search or compilation.
**Sensitive personal data**

Sensitive personal data\(^{18}\) are the categories of personal data listed in Article 9(1) of the GDPR and which reveal

- racial or ethnic origin\(^{19}\)
- political opinions
- religious or philosophical beliefs
- trade union membership

or involving the processing of

- genetic data
- biometric data for the purpose of uniquely identifying a natural person
- data concerning health
- data relating to a natural person’s sex life or sexual orientation.

The assessment of whether information constitutes sensitive personal data must be made during the planning stage of a research project and in accordance with applicable data protection law. This is therefore a data protection issue, rather than an ethical review issue. Applicable law may change over time. The sources of law include current regulations, legislative history, official practice, and doctrine. IMY is the responsible authority and can provide guidance and support.

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\(^{18}\) The GDPR uses the term “special categories of personal data”, while “sensitive personal data” is the prevailing term in Sweden.

\(^{19}\) The GDPR mentions data that reveals a person’s racial or ethnic origin, but it also makes clear that this does not mean that the EU accepts theories that seek to establish the existence of races (Recital 51). The word “race” is no longer used in Swedish law.
Thus, in the specific context of ethical review, the concept of sensitive personal data has no special meaning of its own. What constitutes sensitive personal data is determined solely by application of the GDPR. Neither the Swedish Ethical Review Authority, the Ethics Review Appeals Board, nor the research principals can have their own common practice that deviates from applicable law. The following are some examples of how the different categories have been interpreted. Be aware that other interpretations are possible.

**Ethnic origin**
The purpose of this provision is to protect persons who may be at risk of discrimination. For this reason, it has primarily been applied to minority groups. In addition to direct information, ethnic origin may be revealed, e.g., by a person’s native language – especially in the case of minority languages – or by several combined pieces of information, such as name and language skills, or nationality together with some other specific piece of data.

**Political opinions**
This provision has been applied to affiliation to or sympathy for a political party, or to a particular perception of how society is or should be organised. Actions such as the exercise of animal rights activism have been considered to reveal a political opinion. However, mere membership in a non-partisan interest group has not been viewed as such.

**Religious or philosophical beliefs**
This provision refers to a religious belief, i.e., a particular conception of religious conditions. It can also apply to explicit atheism. Philosophical belief has been applied to philosophical views relating to a person’s general outlook on life.

**Trade union membership**
This term has been applied to membership in an organisation that is intended to protect the interests of employees.
For the purposes of the GDPR, **genetic data** refers to any personal data relating to the inherited or acquired genetic characteristics of a natural person which provide unique information about the physiology or health of that natural person and which derive, in particular, from the analysis of a biological sample taken from that natural person.

For the purposes of the GDPR, **biometric data for the purpose of uniquely identifying a natural person** means personal data obtained through specific technical processing relating to the physical, physiological or behavioural characteristics of a natural person which enable or confirm the identification of that natural person, e.g., facial images or fingerprint data.

According to the GDPR, **data concerning health** are personal data relating to the physical or mental health of a natural person, including the provision of healthcare services, which provide information about the health status of that natural person. Specific data which, individually or in combination, convey information about a person’s state of health, have been considered to constitute sensitive personal data.

**Data relating to a natural person’s sex life or sexual orientation**

In Swedish law, isolated information about a person’s marital status or gender has not been considered to constitute data about a person’s sex life. However, according to a 2022 judgment by the Court of Justice of the European Union,20 named data relating to a person’s spouse, cohabitant, or partner may constitute data relating to these two people’s sex lives or sexual orientation, presumably because their names are considered capable of revealing their gender and it would therefore be possible to draw indirect conclusions about their sexual orientation. Even people without an active sex life can have a sexual orientation.

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20 Judgment of 1 August 2022, Vyriausioji tarnybinės etikos komisija, C-184/20, EU:C:2022:601, paragraphs 119, 120, and 128.
**Processing of sensitive personal data**

As a general rule, the processing of sensitive personal data is forbidden. Article 9(2) of the GDPR lists permitted exceptions to the prohibition. One of the exceptions, Article 9(2)(e), means that data that has been manifestly made public by the data subject may be processed in various contexts. However, this exception does not apply in the case of research. To be able to use sensitive personal data for research, Article 9(2)(j) requires the existence of appropriate and specific safeguards that are established in Swedish law. Ethical review has been deemed by the legislator to be such a measure. Accordingly, for research in Sweden to be exempt from the prohibition on processing sensitive personal data, the processing must have been approved following an ethical review.  

According to Section 3(1) of the Ethical Review Act, ethical review is required as soon as any of the categories listed above are to be addressed in research. By extension, there is no legal possibility for the researcher to refrain from ethical review, for example with reference to the fact that the data to be processed would be harmless and not particularly worthy of protection, or that they have already been made public.

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21 Ethical review is an appropriate protective measure within the meaning of Article 89(1) of the GDPR, which is established by Swedish law and which, according to Item (j) of Article 9(2), is required for the processing of sensitive personal data for research purposes under the GDPR (Government Bill 2017/18:298, pp. 84–95).
During an ethical review, the question often arises as to the circumstances under which sensitive personal data should be considered to be processed in connection with a particular research project. The common practice that has developed in ethical review work means that processing is considered to occur in the following cases, among others:

- One of the sensitive factors is among the criteria for recruitment to the study; e.g., the researcher is recruiting people with a particular religious conviction or a particular health problem.
- The researcher asks direct questions related to one of the sensitive factors.
- The researcher asks open-ended questions, the answers to which are not unlikely to provide information related to one of the sensitive factors.
- Due to other circumstances of the investigation, it is not unlikely that information regarding one or more of the sensitive factors may be disclosed. For example, studies on the quality of life of people who have previously had a certain disease have been assessed to require authorisation.

In this context, the phrase *not unlikely* means that it is possible to distinguish a risk, but it need not be large.

**Personal data about violations of the law**

The Ethical Review Act applies to research involving the processing of personal data relating to criminal convictions and offences, including crimes, convictions in criminal cases, coercive measures in criminal proceedings or administrative detentions (Section 3(2)).

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22 Ethical review is an appropriate protective measure within the meaning of Article 10 of the GDPR, which is established by Swedish law and which is required for the processing of personal data about violations of the law for research purposes, pursuant to the GDPR (Government Bill 2017/18:298, pp. 97–100).
In its legal position (IMYRS 2021:1) on the meaning of the phrase “personal data relating to criminal convictions and offences” in Article 10 of the GDPR, Swedish Authority for Privacy Protection has made the following guiding assessments:

- Information relating to legal proceedings brought against a natural person constitutes personal data relating to criminal convictions and offences, within the meaning of Article 10 of the GDPR (criminal data).
  - Examples include police reports, preliminary enquiries, prosecutions, or trials.
- Verdicts of acquittal fall within the scope of the concept of criminal data.
- Information about suspected offences can constitute criminal data.
  - This normally requires that the data have a certain degree of specificity, which will have been achieved if the information relates to a specific crime or a certain category of crime.
  - A sufficient degree of specificity can also be achieved by compiling information in such a way that it meets the requirements of a penal provision.

The question of whether research involving the processing of judgments in criminal cases requires authorisation has been a topic of discussion in ethical review circles. The fact that everyone has the right to access official documents does not mean that such information may be freely used for research. Criminal convictions contain identifiable personal data, and case numbers or details of the offence may allow the persons concerned to be indirectly identified. In research, continued processing involves the processing of personal data about violations of the law, which requires authorisation under the Ethical Review Act. 

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23 These issues are discussed in detail in Ö 14-2015.
One particular issue concerns the fact that there is a tradition in jurisprudential research of referring to case law by indicating case numbers. These numbers make it possible to uniquely identify a person. However, in Ö 11-2012, the Central Ethical Review Board found no reason to limit the possibility of stating case numbers when reporting on jurisprudential research.

It is not uncommon for researchers to want to study people who engage in prohibited activities, such as vandalism or the purchase of sexual services, for example through interviews, surveys, or focus group interviews. In such cases, the research may often involve sensitive personal data or information about violations of the law. As such, it requires authorisation.
Conditions for research on personal data, with or without ethical review

Research without ethical review

• If you have designed a study so that no sensitive personal data or personal data about violations of the law will be received and you do not intend to process such data, no ethical review is needed.

• Should such personal data happen to be received, this data can be excluded from the research material and the research may continue without ethical review. (See the decision of the Ethics Review Appeals Board, Ö 18-2023/3.1.)

Ethical review to be able to use all received material

• If you want to be able to use all the material received in the course of your study, an ethical review should be conducted if there is even the slightest possibility that sensitive personal data or personal data about violations of the law may be involved.

If more sensitive personal data or personal data about violations of the law is received than expected, or if this data proves more interesting to the research than expected,

• pause the project and exclude the sensitive personal data or personal data about violations of the law you have received, and

• consider applying for ethical approval in order to later be able to process sensitive personal data or personal data about violations of the law as part of the research

• alternatively, change the set-up of your project so that such personal data does not continue to be received.

The requirement for the preservation of information in public documents must also be taken into account

In any of the situations above, information received by an authority in a public document in violation of the GDPR and the Ethical Review Act may need to be preserved in accordance with the Authority’s archiving and disposal regulations. However, these data may not be used in research.

Continuing to use sensitive personal data or personal data about violations of the law that have been collected without legal support is a clear deviation from good research practice.
Other research methods that require ethical review

Methods aimed at affecting people

Research conducted using a method that aims to affect research participants physically or mentally requires authorisation, pursuant to Section 4(2) of the Ethical Review Act.

The provision on research that aims to affect people applies when the researcher intends to create a change in the research participant. This change need not be permanent. For example, experiments that aim to investigate how people act under stress and that start by inducing stress in the participants have been considered to require authorisation under this provision.

In Ö 24-2007, the Central Ethical Review Board stated that the legislators who drafted the Ethical Review Act did not intend for every type of psychological interaction to be covered by that law. To be covered by the Act, the goal of the research must be for the participant to fall into an abnormal mental state. In the case in question, the research participants were asked to evaluate various facial expressions that were presented to them on a computer screen. This was not considered to constitute such a psychological effect as the Act is intended to address.

Nor have educational interventions or homework help been considered to constitute such a psychological influence. The Central Ethical Review Board has decided that when interpreting the Ethical Review Act, it is necessary to consider its fundamental purpose, namely to protect the individual and respect for human dignity in research. Education and training intended to increase knowledge or skills cannot generally be regarded as having such a character that this purpose asserts itself.\textsuperscript{24}

\textsuperscript{24} See Ö 40-2005 and Ö 16-2016.
**Methods involving a clear risk of harm**

Research that entails an obvious risk of physical or mental harm to participants requires authorisation, pursuant to Section 4(2) of the Ethical Review Act.

What is a *risk of harm*? The provision is broadly applied and is considered to include studies that are physically or mentally demanding for the research participants. In a scientific enquiry in which researchers wanted to show participants potentially anxiety-inducing imagery, the Central Ethical Review Board assessed that an anxious reaction would constitute an injury (i.e., harm). The study was rejected on the grounds that this harm was not outweighed by the gain in knowledge that the study could be expected to provide.25

If a risk is *obvious*, it is clear that the risk exists, but it need not be great. If the risks are obvious, the scientific enquiry requires authorisation and an application for ethical review must be submitted. The existence of an obvious risk of harm must be assessed *before* any protective and security measures are taken. Such research requires authorisation even if the researchers are accustomed to managing the risks that may arise or if there are established safety procedures for a particular activity.

Medicine and psychology are perhaps the main research areas that use methods that can expose the research participant to obvious risks of harm. However, there are many other situations in which this provision applies. One example: On a number of occasions, researchers working on fire safety issues have conducted experiments involving evacuation in the dark from underground spaces. Such research can provide experience and knowledge about how best to construct, e.g., subway spaces and install security structures. These research projects have been considered to require authorisation.

See also the section *Identify, prevent and address risks*.

**Physical interventions**

The Ethical Review Act covers research that

- involves a physical intervention conducted on a research participant (Section 4(1))
- involves a physical intervention on a deceased person (Section 4(4)).

Physical interventions can be of many different types, such as surgical procedures, blood tests, other tissue samples, injections and infusions into the body, and delivery of medicines orally or through the skin.

**Research on biological material**

The Ethical Review Act covers research that

- concerns the study of biological material obtained from a living person and which can be traced back to that person (Section 4(3))
- concerns the study of biological material obtained for medical purposes from a deceased person and which can be traced back to that individual (Section 4(5)).

This means both that the material must have been taken from a person’s body (not from, e.g., their clothes), and that identification is possible. Some common circumstances that may enable identification include the existence of

- a code key associated with the material, or
- personal data tied to the material.

Clinical trials

The Ethical Review Act does not apply to clinical drug trials or clinical trials and performance studies of medical devices. Instead, EU rules and complementary national legislation apply. According to the EU’s one-stop shop principle for simplifying complex dossiers for users, a single application with all the requisite documents must be submitted.

If you are planning such a study, you must therefore be aware that you should not make a separate application for ethical review. Instead, all your contact must be with the Swedish Medical Products Agency, which is the responsible national authority. Submission instructions are available on the agency’s website, lakemedelsverket.se. The Swedish Medical Products Agency will forward to the Swedish Ethical Review Authority the documents it needs to process the application. The Swedish Ethical Review Authority then conducts an ethical review based on the same fundamental tenets as for other research.

Note that the EU regulations contain special rules on information and consent in clinical trials that need to be applied instead of the stipulations of the Ethical Review Act. The basic principles are very much the same, but there are some key differences. In particular, the consent of both guardians is required for all persons under the age of 18 whose guardians share joint custody. Young people between the ages of 15 and 17 who understand what the research means for them must also give their consent in order to participate in research. For an adult who is unable to give consent themselves, informed consent must be provided by the individual’s guardian or trustee.

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26 See Sections 4a and 4b of the Ethical Review Act.
**Clinical drug trials**

In a clinical trial, a selected group of patients tries out a completely new medical product in order to test its efficacy and safety. A clinical trial can also focus on an existing medical product that is being tested for a different medical condition than the one for which it was originally approved.

Since 31 January 2022, the EU Clinical Trials Regulation 2014/536 (CTR) has been in force. Clinical Trials Information Systems (CTIS) is a joint portal and database for clinical trials within the EU/EEA. All communication between the Member States and sponsors occurs via CTIS. The Swedish Medical Products Agency is Sweden’s portal user. Sponsors must apply for a trial via the EU’s CTIS portal.

CTR and CTIS entail a coordinated review procedure within the EU/EEA. In Sweden, applications for clinical trials are reviewed by the Swedish Medical Products Agency, the Swedish Ethical Review Authority, and the Regional Biobank Centre. This review results in a national decision that is then made available in the portal by the Swedish Medical Products Agency. Before a decision is made, the Swedish Ethical Review Authority must report the results of its ethical review in a statement submitted to the Swedish Medical Products Agency.

The application is divided into two sections, Part I and Part II. The applicant may choose to submit Part I and Part II together or separately. Once a conclusion regarding Part I is available in CTIS, the sponsor has two years to submit Part II. Part I focuses on the scientific design and execution of the study. Part II deals with documentation and information related to its national implementation in a Member State.
Clinical trials and performance studies of medical devices

A medical device can be an instrument, apparatus, appliance, software, implant, reagent, material, or other item. The prerequisite is that a medical device is intended to be used on humans and has one or more of the following medical purposes:

- diagnosis, prevention, monitoring, prediction, prognosis, treatment, or alleviation of disease
- diagnosis, monitoring, treatment, alleviation of, or compensation for, an injury or disability
- examination, replacement, or modification of anatomy or of a physiological or pathological process or condition
- the provision of information through in vitro examination of samples taken from the human body, including donated organs, blood, and tissue.

The difference between a medical device and a medical product is that a medical device does not achieve its main intended effect by means of pharmacological, immunological, or metabolic agents. On the other hand, a medical device can be supported in its function by such agents.
In vitro diagnostic medical devices include devices intended for the examination of samples taken from the human body, in order to provide information about

- a physiological or pathological process or condition
- congenital physical or mental disabilities
- predisposition to a medical condition or disease

which makes it possible to

- determine its safety and compatibility with possible recipients
- predict treatment effects or reactions
- establish or supervise therapeutic measures.

A clinical trial of a medical device is a systematic examination involving one or more research participants that aims to assess the safety or performance of a device.

A performance study is a study conducted to determine or confirm the analytical or clinical performance of a product. In this context, “performance” refers to the ability of a product to achieve the intended purpose declared by the manufacturer.

Since 26 May 2021, the EU Medical Device Regulation 2017/745 (MDR) has been in force. As of 26 May 2022, the EU Regulation 2017/746 on in vitro diagnostic medical devices (IVDR) also applies. Both Regulations require sponsors to report or apply for a trial of a medical device or in vitro diagnostic medical device via the EUDAMED EU portal. Until EUDAMED becomes fully operational, the documents must be sent to the Swedish Medical Products Agency.

Depending on the type of trial, the MDR and IVDR provide for different approval procedures and deadlines. The Swedish Ethical Review Authority always conducts an ethical review.
A concerted approach similar to that used for clinical trials applies to

- clinical trials of Class IIa/IIb and Class III invasive devices (where Class IIa are devices with low to moderate risk, and Class IIb and III are devices with high risk potential)
- as well as for performance studies that
  - involve surgically invasive sampling in which the procedure is performed solely for the purposes of the study, if the collection of samples poses a substantial clinical risk
  - is an interventional clinical performance study in which the test results can be used to guide decisions about treatment or patient management
  - entails additional invasive procedures or poses other risks to the research participants
  - concerns treatment-guiding diagnostics – unless the study is conducted using leftover sample material.

The processing time is 45 days, with the possibility of an extension of the investigation time by an extra 20 days.
In other cases, the Swedish Ethical Review Authority renders its own decision following an ethical review. As a starting point, these cases include:

- clinical trials of Class I investigational devices (Class I indicates a low-risk device) or Class IIa or IIb non-invasive devices
- performance studies of non-CE marked devices in which surgically invasive sampling is conducted for the sole purpose of the performance, and the collection of samples does not pose a major clinical risk to the research participant.

The processing time in these cases is 40 days.

In addition, the Swedish Ethical Review Authority reviews:

- follow-up studies of devices that have already been CE-marked and which are conducted within the scope of the intended purpose of the device, but involve additional invasive or strenuous interventions
- performance follow-ups of marketed products involving additional invasive or strenuous procedures.

In these cases, a decision must be made within 30 days.
How do I apply for ethical review?

An application for ethical review is made entirely electronically. Go to the Swedish Ethical Review Authority’s website, etikprovningsmyndigheten.se. The portal for ethical review applications contains useful information for researchers and answers to frequently asked questions. The Authority’s system for applications and other matters is called Ethix. It is currently available only in Swedish. You must start by logging in with BankID or two-step authentication and then upload your personal profile. In Ethix, you can then successively upload your application, save drafts, and submit your completed application. You will also receive notifications, decisions, and other information related to your application via Ethix. The portal features a tab with information on many questions related to applications, as well as a tab with questions and answers to common technical and practical questions. You can have several active cases in Ethix at the same time.

A new application is called a grundansökan [basic application; the reader is reminded that the portal currently exists only in Swedish]. To start an application in Ethix, go to Ansökningar [Applications], select Grundansökan [Basic application] and your type of research project. This will guide you to the application form. It is divided into a number of sections and subsections. Answer all the questions that are relevant to your research. Brief information is provided to support you in this work. There is also a tab for uploading attachments. They must be in PDF format.
When filling in the application form, it is important to describe the circumstances of your particular research project. It is particularly crucial that you

- clearly describe the scientific value of the research you wish to carry out
- describe, to the best of your ability, what risks the project may entail and how you intend to prevent and address them
- clearly state how the research participants will receive the information they need to be able to make a thoroughly considered decision and safeguard their rights.

Explain your reasons for the assessments you have made. The Authority will make its own assessment based on common practice and the information you have provided.

Your application must be written in Swedish, at such a level that it can be understood by laypersons. This is because the application must be easily understood and assessed by all persons involved in the decision-making process, including lay members of the board representing the public interest. Your research plan and CV should be aimed at researchers and may be submitted in Swedish or English. With the exception of these documents, the Swedish Ethical Review Authority does not review texts in languages other than Swedish. See also the section *Research that is to be conducted entirely or partly abroad*.
The Authority needs access to a number of documents that you plan to use in your research. These must be enclosed as attachments to the application, and include:

- research plan
- advertisement material
- information for research participants
- surveys, questionnaires, interview guides, and rating scales
- list of variables, when requesting data from existing registers
- principal investigator's CV
- other project-specific attachments.

Ethix also has support templates for research participant information, consent forms, and consent to future research using samples. For the design of research subject information, see the section Research participant information.

Finally, your application must be electronically signed (using BankID) by an authorised representative of the research principal and by the principal investigator, who certify that all significant circumstances surrounding the project are in order. You need to take note of what has been certified and take it into account in the future. Among other things, the application signatory certifies that it has been ensured that:

all participating organisations have resources that guarantee the safety and personal integrity of the research participants while conducting the research described in the application.

The resources referred to include available finances, skills and manpower to protect the safety and personal integrity of research participants, as well as also to handle any incidents in these respects.
It is of great importance that there are sufficient resources to complete the project. There may be good reasons not to complete a project, but this also means that no benefit has been created that can outweigh the risks to which research participants were exposed before the project was discontinued. Lack of financial resources is not an acceptable reason for failing to complete a study.

**Who can be the principal investigator in an application?**

To ensure that there is sufficient competence in the project, the main rule is that the principal investigator must hold a PhD in a relevant subject area or possess equivalent competence. The principal investigator is responsible for ensuring that other researchers also have sufficient competence and have received specific training regarding the implementation of the project. In addition to scientific expertise, such competence may extend to pedagogical, cultural, linguistic or clinical knowledge and skill, depending on the circumstances. A researcher who has not yet defended their doctoral dissertation may be approved as a project’s principal investigator, provided that the research is conducted under the active supervision of another participating researcher who holds a doctorate. This may be applicable, for example, in the case of a doctoral project. A CV for the supervising researcher must be attached.

If there is a desire to carry out a research project without the participation of a researcher with a PhD, this needs to be specifically examined in the ethical review. In such cases, the Authority needs to make an assessment of all the circumstances of the individual case. Competence must be assessed in relation to the research in question and to the ethical issues to which the research can be assumed to give rise. It should be possible to require that the person in question has mastered relevant scientific methods and has otherwise demonstrated themselves to be capable of shouldering such responsibility. The researcher in question must also have experience of taking a stance on research ethical issues.²⁷

²⁷ See Government Bill 2002/03:50, p. 100.
Multiple scientific enquiries in the same application?

Is it possible to submit a single application for ethical review when several different studies are planned? According to the common practice developed in ethical reviews conducted by the Swedish Ethical Review Authority, it may be possible to obtain approval for several studies described in a single application, but only if they share a clear connection. The connection referred to here is described above in the section *In an ethical review, what constitutes a “project”?*

It is *not* considered sufficient

- that the researchers want to study a broad research area from many different perspectives
- that you want to study many different aspects of a certain material
- that there is joint funding for several different scientific enquiries.

Please note that every step of each scientific enquiry must be fully described according to the instructions in the application template. Sometimes it may be easier to make this description in a separate application for each study. Moreover, if the Authority requests additional information in any respect, the processing of all parts of your application will be postponed, even if the questions only relate to one of several sub-studies.

In many cases, later sub-studies may also be dependent on the findings of the first sub-study. In this case, it may be difficult to describe the content of the subsequent sub-studies in sufficient detail at the outset. The review of these sub-studies must then occur later, once the plan for the research has become more definitive. For more information, see the section *Research planned successively.*
The role of the research principal

Already at an early stage of your planning for a research project, you must determine who will be the research principal, establish your research plan, and draft your application in collaboration with their representatives.

The research principal is the authority, natural, or legal person in the context of whose operations the research is conducted, e.g., a higher education institution, municipality, region, other public authority, or private enterprise. Through internal work or delegation rules, or via a power of attorney, the research principal decides who will serve as its authorised representative. The authorised representative is a head of department, head of unit, or head of operations, or another person with equivalent authority. An application for ethical review must be signed by both an authorised representative of the research principal and the principal investigator.

It is the research principal who has ultimate responsibility for the application. They are responsible for ensuring that research covered by the Act is not conducted without approval. The research principal is also responsible for ensuring that research meets the conditions that have been stipulated in an ethical approval. Furthermore, the research principal must ensure that people in its organisation who work with research receive the necessary training about the Ethical Review Act. To achieve this, the organisation must have procedures for information, follow-up, and control regarding ethical review issues.

Many research projects involve the operations of several research principals. As soon as part of the work in a research project has been conducted within the context of a principal’s operations, the principal becomes a participant in the project. The operations referred to here include the recruitment of research subjects, collection of biological material or information related to living persons, physical interventions on living or deceased persons, and studies conducted on such individuals or previously collected biological material, as well as analysis and processing of the collected data.

28 See Sections 6 and 38 of the Ethical Review Act.
If multiple principals participate in a research project, all of them must be specified in the application for ethical review, and the principals need to agree to appoint one from amongst their group as the applicant in the application. Each research principal is only responsible for the part of the research project carried out in its own operations.

An organisation that has its registered office abroad can be the principal investigator but must have the resources to be able to conduct research in this country, not least to be able to communicate with the relevant research participants in Sweden.

If, for some reason, you want to change your principal, you must submit an application for amendment. These change(s) may not be implemented until the Swedish Ethical Review Authority has given its approval.

**Advisory opinions**

The Swedish Ethical Review Authority can issue an advisory opinion on research that meets the definition of research in Section 2 of the Ethical Review Act, but which is not otherwise covered by the Act. The Authority may also issue advisory opinions on work or studies carried out within the context of first- or second-cycle higher education.

Since such work cannot be examined based on its merits according to the rules of the Ethical Review Act, the review that is performed can only be of a fairly general nature. The Authority often assesses that there are no obstacles to the planned research. However, if there are clear research ethical shortcomings in the design of a project, its advisory opinion will contain advice on what the applicant should do before research can commence.

The decision itself is termed a “dismissal” and can be appealed. On the other hand, the advisory opinion provided in the same decision document as the dismissal is not open to appeal.
If you wish to receive an advisory opinion, you must submit a complete application and tick the box in the appropriate place on the application form to indicate that an advisory opinion is desired. The Authority can only issue an advisory opinion if an applicant so requests in their application.

Even if you do not consider your work to be subject to approval under the Ethical Review Act, keep in mind that regardless of the research area of an article, it is not uncommon for scientific journals to require ethical approval prior to its publication. There may also be other situations when you need proof that a study has undergone an ethical review, even if does not require authorisation. It is precisely for situations such as these that the opportunity to obtain an advisory opinion exists. It is also important to note that an advisory opinion cannot be issued when the research has already been completed and only publication remains.

**Other regulations**

An approval following ethical review means that the research described in the application is compatible with the fundamental tenets set out in Sections 7–11 of the Ethical Review Act and, where applicable, that the procedure for obtaining informed consent meets the requirements relevant to the research in question. Sometimes an approval is subject to certain conditions that must also be met before research can commence. Approval also means that there is legal support for processing sensitive personal data or personal data about violations of the law as part of the research.

However, ethically approved research may not be conducted if it violates any other statute or lacks other necessary permits. It is the task of the research principal and the principal investigator to have full oversight over what other regulations may be applicable to the project in question and to comply with them.
If you receive a request to supplement your application

When it first examines an application, it is not uncommon for the department to assess that it lacks important information necessary to be able to approve it or, strictly speaking, to be able to carry out a review at all. Perhaps the description of how the research will be conducted, or the information that people recruited to the study will receive in order to make an informed decision about participating, is insufficiently detailed. It may also be that the department sees that the expected result of the research could be achieved, but in a less risky way.

If it is impossible to approve the application with citing clear conditions for how its shortcomings are to be rectified, the department will decide to request additional information from the applicant. Such a decision may include a delegation to the chairperson and scientific secretaries to render a decision once supplementary information has been received. At that point, the department must have assessed all aspects of the application. Only then can it give the mandate to decide the matter by delegation. Sometimes it is necessary for the application to be re-examined at a meeting after the supplementary information has been received.

If you receive such a request, you have the opportunity to submit additional information with suggestions for how the study should be amended to respond to the department’s remarks or questions.

If you do not consider that a request for additional information is justified, you should immediately notify the Authority that you do not intend to make the requested supplementation. Instead, you can request that the department make a final examination of the application on the basis of the documentation that has already been submitted. If, in doing so, you also offer an explanation as to why you consider the request for additional information to be unnecessary, the department will have the opportunity to take this into account in its final examination. This will either lead to an approval or to a decision that you can appeal and have reviewed by the Ethics Review Appeals Board.
What help can you get from the Swedish Ethical Review Authority?

The Authority can provide assistance and information about

- what the law says
- what is important to keep in mind when you consider making an ethical approval application and when filling out your application
- in general terms, under what conditions ethical review may be required
- what an ethical approval means
- how different situations have been assessed in the past.

The Authority cannot help provide

- definitive advance rulings on whether or not certain research needs to be ethically reviewed, or how an application will be assessed
- detailed advice on how a research project should be planned in order for the applicant to receive an approval
- the opportunity to discuss the department’s examination and assessment in individual cases.

It is only through a decision that the Authority can, or will, comment on an application or certain research.
What do I need to consider after a decision is issued?

What does the Swedish Ethical Review Authority’s decision mean?

Most applications are approved, sometimes after additional information has been requested to ensure that the project meets research ethical requirements. When an application covers several different scientific enquiries, it is possible that only some of these will be approved.

Sometimes the approval is conditional. Each condition to which it is subject must be fulfilled before the project can commence and must be complied with throughout the lifetime of the project. It is also the responsibility of the principal and the principal investigator to ensure that these conditions are met in the continued work. It is important that you keep track of the conditions for your approval and ensure they are met throughout the project period. Documents proving that a condition is met should not be submitted to the Swedish Ethical Review Authority.

When an application is rejected, this means that the work described in the application may not be carried out. The most common reasons for a rejection are that the risk or burden that the project entails for the research subjects is not justified by the scientific gain that can be achieved, that the questions are not sufficiently clear, or that it is unclear how the questions can be answered using the intended method. Other common reasons include the lack of necessary additional information or that, despite supplementation, it is impossible to conclude that the research is compatible with the fundamental tenets set out in Sections 7–11 of the Ethical Review Act. Glaring deficiencies in the information provided to research participants, for example in terms of the actual risks of participation or how participants can exercise their rights in the project, can also lead to rejection. It is possible to submit a new and revised application at a later date.
An application can also be dismissed. The reason for this is explained in the decision. It is important that you read this explanation carefully, as the decision has different consequences depending on the reason.

- One reason is that the research does not require authorisation. This means that the Authority assesses that the work described in the application constitutes research, but that it does not entail any of the elements that require ethical review. When an application is dismissed for this reason, it means that ethical review is not required for the research to be carried out.

- Another reason may be that the project does not constitute research as defined in Section 2 of the Ethical Review Act. If your application is rejected for this reason, you may not carry out your work on the basis of the specific legal grounds that apply to research.

- An application may also be dismissed for formal reasons, for example if it lacks the signature of an authorised representative of the research principal, or if the application fee has not been paid. In all these cases, it should go without saying that the dismissal decision does not mean that the research may be carried out without ethical review.

See also the section Advisory opinions.

For how long is an approval valid?

When an approval is granted, research must be begun within two years after the decision became final; otherwise, the approval will expire after two years. Once work has begun, the approval remains valid in accordance with what is stated in the decision and the application. It is important to note that the approval is only valid for the specific work that was described in the application. An approval only applies to the limited project to which the application relates. If you want to use any method, data you have collected previously, or material from another research project, this normally means that you must submit a new application for ethical review. See also the section In an ethical review, what constitutes a “project”?
How to appeal

Anyone who is dissatisfied with the decision of the Swedish Ethical Review Authority can lodge an appeal with the Ethics Review Appeals Board. It is the research principal who has the right to appeal. The appeal must be filed within three weeks of the date on which the complainant was notified of the decision. There is no specific form for appeals. The letter must be addressed to the Ethics Review Appeals Board but sent to the Swedish Ethical Review Authority, which examines whether the appeal has been received in due time and then forwards it to the Ethics Review Appeals Board. The Swedish Ethical Review Authority also has the opportunity to reconsider its previous decision in the light of what is stated in the appeal.

The most common reasons for an appeal are that the applicant is dissatisfied with the conditions set out in an approval, that the application has been rejected in whole or in part, or that the application has been dismissed. An advisory opinion cannot be appealed.

Application for amendment

Researchers sometimes need to make changes to a project that has already been approved. When does this require a new approval, and how do you go about getting one?

If the change to an original project is extensive, e.g., you have come up with a new study design or hypothesis, or new groups of research participants with characteristics other than the original ones will be involved, a completely new basic application must be submitted. In a number of decisions, the Ethics Review Appeals Board has expressed its assessment that in the event of clearly amended research questions compared to the basic application, a completely new basic application must be submitted.

As regards other changes that affect the risks or benefits of a project, a new ethical approval is required before the changes can be implemented, in which case you must submit an application for amendment.
The main reasons why an application for amendment is required are that

- new findings during research work affect the safety of the research participants
- new findings have emerged that may affect the scientific value of the study
- recent research has revealed risks that were previously unknown
- a planned change to an ongoing study affects the safety of the research participants.

Other examples of changes that require an application for amendment may include

- you want to change the research principal or the principal investigator
- more research participants need to be included
- research participants need to be involved at new units or study locations
- new methods will be used or new analyses conducted on previously collected material
- new sensitive questions will be asked in surveys or interviews.

» Changes that simply reduce risks do not require an application for amendment.
Changes that simply reduce risks do not require an application for amendment. Other minor changes that do not affect safety or the risks or benefits to research participants may also be implemented without an application for amendment. However, as soon as the research changes in a way that increases its risks or brings to the fore risks that the Authority has not reviewed and assessed, an application for amendment should be considered.

As a rule, in an application for amendment you only need to describe the planned changes to your project. It is also important that you clearly state how the planned change relates to the research outlined in the original basic application and any subsequent approved amendments to the project. An application for amendment is submitted to the Swedish Ethical Review Authority with the necessary attachments and must contain a clear account of how research questions, investigation procedures, risks, data management, and publication plan would be affected by the intended change(s). Forms and instructions are available in the Ethix portal on the website of the Swedish Ethical Review Authority.

An application for amendment is first reviewed by the chairperson and the scientific secretaries, who can decide to approve it, reject it, request additional information, or submit the matter for decision at a meeting. Decisions on applications for amendment can often be processed in a shorter timeframe than a basic application.

If, with the support of your principal, you have made a careful assessment and come to the conclusion that no application for amendment is required, then no application needs to be made “just to be on the safe side”. However, your decision should be documented and included in your study documentation, for example in the data management plan.
Why does ethical review exist?

1932 Historical background

In 1932, the Public Health Services (PHS) of the United States made a decision that would have far-reaching consequences. At the time, syphilis was a very common sexually transmitted disease. The natural history of the disease was only partially known, and the value of treatment was disputed. A PHS working group decided to conduct a prospective study in Tuskegee, a small town in the southern state of Alabama. Six hundred African-American men, most of them farm workers, were recruited and offered free healthcare in exchange for their participation. The 399 participants who were initially diagnosed with syphilis were not informed that they had the disease. They were not offered any treatment, even after penicillin became the recommended standard treatment for syphilis in 1947. The study lasted until 1972, when information leaked to the press generated political attention and prompted hearings in the Senate. That same year, the PHS decided to end the study.

Criticism of the Tuskegee Study led to the introduction of the National Research Act in 1974. The main goal of this federal law was to provide protection to people involved in biomedical and behavioural science research, including through the establishment of a regulated review process with local, institutional review boards.
The reaction to the Tuskegee Study was also decisive when the United States the same year set up a National Commission for the Protection of Humans in Research. The Commission’s conclusions were published in 1979 in the so-called Belmont Report. Its main theses:

- obligation to do good
- fair treatment
- respect for the individual

have become a model for continued reflection on research ethics. The Belmont Report has been a source of inspiration for ethical recommendations and regulations around the world, including the establishment of research ethics committees.

The Tuskegee Study was not an isolated case in research conducted at the time. Many ethically unacceptable experiments on humans were conducted during the 20th century all across the globe, both before and after the Nazi war crimes of World War II.

Modern research ethics emerged after the Nazis’ infamous experiments, in which prisoners in concentration camps were subjected to inhumane research. Some of the first research ethical principles to come out of these atrocities were expressed at the Nuremberg Trials, in the 1947 verdict against the doctors who carried out these experiments. Among other things, the “Nuremberg Code” states that informed consent is required, that the research must have positive consequences for society, and that the risks to the people involved in an experiment must be minimised. It underscores that any participant has the right to discontinue their participation in an experiment at any time, and that the person conducting such an experiment must discontinue it if it appears likely that a participant will be harmed.
In 1964, the World Medical Association (WMA) adopted the Declaration of Helsinki, which contains ethical principles for physicians and others involved in medical research. Even the original concise and general language of this declaration pointed out principles similar to those of the Nuremberg Code. The Declaration of Helsinki has been revised on nine occasions, most recently in 2013, and is now a detailed and authoritative ethical guide for all medical research. It is not legally binding, but it has had a major impact on medical research and national legislation, and continues to do so.

One of the fundamental principles of the Declaration of Helsinki is that the objectives of research must never take precedence over the rights and interests of research participants. The declaration also provides guidance for research involving vulnerable persons, informed consent, the use of identifiable human material or data, the use of placebos, and the publication of research results.

From the end of the 1960s, research ethics committees were gradually established in Sweden at all medical faculties. From the 1970s onwards, research ethics issues in other research areas have also been addressed, largely within the context of Sweden’s various research councils. Within their areas of responsibility, these councils drew up research ethics principles and advice or guidelines and established committees to deal with research ethics issues. Among other things, the Swedish Council for Research in the Humanities and Social Sciences (HSFR), which operated from 1977 to 2000, adopted and developed four principles of research ethics that had a major impact on the Council’s areas of responsibility: the information requirement, the consent requirement, the confidentiality requirement, and the utilization requirement. The latter meant that information about individuals must not be disseminated for non-scientific purposes and must not be used as a basis for decisions or actions that affect the individual.
Sweden is part of international networks that coordinate jointly in many different respects. The international community that has had the greatest impact on the development and design of ethical review is the Council of Europe. The Council of Europe is a broad intergovernmental cooperation organisation, founded in 1949 with the aim of protecting human rights and fundamental freedoms, democracy, and the rule of law. The fundamental principles to which the Council of Europe aspires were expressed as early as 1950 in the European Convention for the Protection of Human Rights and Fundamental Freedoms (ECHR), which is, according to Swedish law, incorporated into the Swedish constitution. The Council of Europe currently consists of 46 Member States, including all the members of the European Union (EU).

The 1997 Council of Europe Convention on Human Rights and Biomedicine covers all interventions in the field of health. It is also known as the Oviedo Convention, after the Spanish city of Oviedo, where the final agreement was signed. Sweden participated in the drafting of the Convention and signed it the same day it was opened for signature.

The Oviedo Convention provides a comprehensive framework for the protection of human dignity and identity and guarantees universal respect for personal integrity and other fundamental rights in the field of biology and medicine. It is perceived as the fundamental European agreement on patients’ rights. Among other things, it establishes the principle that the interests and well-being of the individual must take precedence over the interests of society or science. This principle takes on great importance in the field of research on human participants.

Several additional protocols to the Oviedo Convention have been drafted and entered into force. Among other things, the 2005 Additional Protocol on Biomedical Research sets out a framework for ethical review of research. This Additional Protocol also describes in detail how ethics committees should be established and operated, how information and consent should be developed and provided, how persons who are unable to give consent themselves should be protected, and how risks should be kept to a minimum.
Issues relating to the protection of individuals with regard to information about themselves had risen to the fore after the end of the Second World War. The United Nations (UN) had been established in 1945. As early as 1948, the Member States agreed on a Universal Declaration of Human Rights as a common norm for all peoples and nations. Its aim is to ensure that all people and organs of society promote respect for rights and freedoms. Among other things, it enshrines in law the right to privacy, which is briefly described in Article 12. In 1950, the newly formed Council of Europe gave a virtually identical and general description in Article 8 of the European Convention on Human Rights: “Everyone has the right to respect for his private and family life, home and correspondence.”

On 28 January 1981, the Council of Europe also adopted Convention 108, with the aim of ensuring the individual's right to personal integrity and in connection with automatic processing of personal data. This was the first legally binding international instrument for data protection. It briefly sets out many of the principles of data protection that have since become the norm: Personal data shall be processed in a correct and lawful manner, stored for specified and lawful purposes, and be relevant and not unnecessary for these purposes. Special types of personal data (sensitive personal data) are also defined here, with a ban on automatic data processing as a general rule. The Convention also requires security measures to protect personal data and stipulates the right of the data subject to knowledge of, and access to, their data. The importance of Convention 108 has been highlighted by the designation of 28 January as the annual International Data Protection Day.

The EU also undertook a years-long effort to achieve greater uniformity and clarity in the protection of personal data. The EU’s General Data Protection Regulation (GDPR) came into force in 2018 and is now directly applicable legislation regarding personal data processing in all EU Member States.
The ethical review of research is now an established process in many countries, both in the medical field and in other areas of human research. The guiding principles of these assessments are based on or inspired by the documents mentioned above, but the review process also varies between countries, both in terms of content and organisation.
Lessons from 100 years of research history

The Vipeholm Study

In Sweden, one early post-war study conducted on humans stands out as particularly controversial. General dental care had been introduced in 1938. More than 99.9 per cent of the population suffered from tooth decay, and the associated costs were skyrocketing. In 1945, the National Swedish Board of Health initiated research to investigate how caries could be avoided. Vipeholm Hospital in Lund, a hospital for the "mentally retarded", was judged to be a suitable environment to carry out these experiments. Experiments involving treatment with vitamins and minerals proved ineffective. It was therefore decided to try a provocation study instead. The sugar experiment was launched in 1947. The hospital's institutionalised patients were given large quantities of toffee, chocolate, and sugary drinks. The experiment was carried out with the utmost scientific rigour. The successful study provided wellfounded scientific support that sugar that remains on the teeth causes caries and that exposure time is a crucial factor. This was an international breakthrough and was used as an instrument for successful policies to improve dental health. However, mentally handicapped patients in institutional care were exploited without realising the harm to which they were being exposed, and in the course of the experiment their teeth were destroyed. The publication of the Vipeholm Study 1953 generated attention in the daily press and in the Swedish Parliament, which contributed to the discontinuation of the experiments in 1955.

This study is a prime example of a common view on how human research should be conducted. Research leaders identified an important societal problem. At the time, researchers believed they had a right to design studies that exploited the weakest members of society, in this case people with mental disabilities in institutional care, many of whom were minors. They believed they had a right to design research that was actively aimed at harming the health of the participants. They also believed they had a right to withhold relevant care.
Both the Vipeholm Study and the aforementioned Tuskegee Study were the result of similar priorities. In particular, the ethical problems associated with the Tuskegee Study were the result of an active choice to recruit vulnerable people, the omission of providing participants with adequate information about the study, and the fact that they were deprived of adequate information and treatment for their illness. It was assessed at the time that the expected results of the research made it worthwhile to deceive the research participants and expose them to health risks. These priorities were shared by both researchers and senior administrative decision-makers. Yet perhaps this view applied only to medical research? A well-known psychological experiment demonstrates that the opposite was true.

**The psychological research of Stanley Milgram**

Stanley Milgram (1933–1984) was an American social psychologist and professor at Yale University. He was amazed at how people had been able to carry out the Holocaust during the Second World War, and not least by Adolf Eichmann’s personality, as it emerged during the trial against him in 1961.

Milgram wondered how people could come to obey an authority and perform acts that ran contrary to their own conscience. He set up a series of experiments to investigate this conundrum. Participants were initially recruited in the belief that they would serve as “assistants” in a study, in the course of which they were instructed to use electric shocks as punishments to teach research subjects to remember certain word orders. These “subjects” were actually actors, and none of them really received the electric shocks the “assistants” administered. The latter were the actual research subjects. The studies showed that a surprisingly large proportion of the research subjects were prepared to administer harmful and potentially fatal electric shocks.
Milgram's research was epoch-making, in that it supported the idea that people are much more easily influenced by authority than previously thought. However, the research subjects were given obviously fraudulent information and encouraged to carry out actions that they could be expected to see as grossly unethical, and many were harmed by their participation. At the time, there were no regulations preventing research of this kind, and although the project was controversial, Milgram and other researchers were able to continue working on many similar experiments.

Collection of biological material for research
Henrietta Lacks was an African-American tobacco worker who lived in Baltimore County, Maryland in the United States. She had been feeling a lump on her cervix for some time when, in January 1951, she went to the gynaecological clinic at nearby Johns Hopkins Hospital in Baltimore, which offered free medical care to low-income patients. She was 30 years old at the time. The tissue sample from Lacks’ examination revealed the existence of a malignant tumour, and she was called back to the hospital for a treatment involving radium implant. Prior to the operation, she had to sign a “permission for surgery”, in which she gave her consent to the medical staff to carry out any surgical measures they deemed necessary. In connection with the operation, the doctor took new tissue samples from the tumour and nearby healthy tissue, which were submitted to Johns Hopkins’ research laboratory. Lacks was not provided with any information about the extraction of these samples and their use. Later that year, she passed away with spread cancer and radiation damage.

The laboratory had been working to develop a viable human cell culture, so far without success. The culture of Henrietta Lacks’ cancer cells proved to be the laboratory’s first successful attempt, and it exceeded anyone’s hopes; the cells remained viable and doubled every day. The cell culture was given the name HeLa, and soon the laboratory was sharing it with researchers around the world for use in cancer research. HeLa cells would become an important instrument in many successful research projects, right up to the modern day. However, the cell extraction and all further use of her biological material were carried out without providing her with information or obtaining her consent to the donation.
Research using biological material

One of the many users of HeLa cells was Chester Southam, an immunologist and oncologist who worked in New York City in the 1950s and 60s.

He wanted to test whether cancer could be caused by viruses or immunodeficiency, as he and other researchers hypothesised. To this end, he injected HeLa cells into the arms of a dozen patients who were already ill. As an explanation for the procedure, he simply told them he was investigating their immune systems. Within a few days, cancer nodes formed at the injection sites. Most of them disappeared within a few months, but in some cases the lumps returned, even after Southam removed them several times.

Now he wanted to see how healthy people would react. For his next experiment, he recruited prisoners from Ohio prisons and gathered 150 volunteers. These research subjects’ immune systems fought the cancer cells much better than the previous, cancer-stricken patients. Southam broadened the scope of his research, and in the ensuing years he injected cancer cells into over 600 people, both cancer patients and healthy people, without informing them that they would be injected with cancer cells.

At one of the hospitals with which he cooperated, Southam met resistance from some of the other physicians, who refused to contribute to his work without providing information to their patients and obtaining consent. The conflict attracted the attention of the press, ultimately leading to lawsuits against Southam and one of his colleagues. Most significant for the future, however, was the fact that the publicity garnered by Southam’s research prompted the National Institutes of Health (NIH), which had helped fund his work, to launch a review. By 1966, this led the NIH to require researchers to obtain detailed, informed consent and submit their work to review by an ethics committee before they could be granted funding for research involving humans.

It has since emerged that hundreds of researchers in many countries have conducted similar controversial studies.
The Metropolit Project

Another Swedish study challenged the right to personal integrity. The Metropolit Project was an internationally unique, long-term study conducted by the Department of Sociology at Stockholm University using the automatic data processing (ADP), a novel technology at the time. A total of 15,117 people born in 1953 and who were living in Stockholm ten years later were registered in the project.

Over a period of 20 years, researchers collected extensive data on people from a number of government registers, including birth records, population and housing censuses, criminal and police records, military enrolment data, academic performance records and other information from compulsory and upper secondary and higher education institutions, the municipality’s social register, tax assessments, the National Board of Health and Welfare’s birth announcements, information about sick days from the National Social Insurance Board, national health register information about illnesses, and data from alcohol addiction care providers.

In 1986, the daily newspaper Dagens Nyheter revealed that the project had been going on for years, without the knowledge of the participants. This sparked a heated debate about research ethics, government data collection, and the effect of computer processing on personal integrity.

The Data Act (1973:289) had entered into force over a decade prior, in 1973. It was one of the very first laws in the world intended to regulate computer-based personal data registers. That same year, the Swedish Data Protection Authority was established to monitor adherence to the new legislation. Among other things, it was tasked with monitoring and addressing undue breaches of personal integrity or the risk of such intrusions. According to the law, a person registered in such a public register were entitled to receive information about this upon request. The Swedish Data Protection Authority turned its attention to the Metropolit Project and conducted an inspection. Following this audit, the research was permitted to continue, but with a number of limitations.

The Metropolit Project shows how research using personal data can expose individuals to extensive and serious breaches of their personal
integrity. The project was a pioneering work, in that it examined the relationship between socio-economic factors and, e.g., health and violations of the law. But the study entailed a controversial breach of personal integrity. Large amounts of sensitive personal data were processed without clear limitations and without the parties concerned receiving any information at all.

**The Facebook Study**

Today, social media is blurring the lines between private and public life, creating new opportunities and ethical challenges for research. *The Facebook emotional contagion study* illustrates some of these.

In 2014, a research group from Facebook and Cornell University published an article in the scientific journal *PNAS*, in which they claimed to be able to demonstrate experimental support for the idea that emotions can be transmitted between people without direct personal contact or non-verbal cues. In one experiment, the researchers had controlled the information that reaches Facebook users via their News Feed, which disseminates information from other users about various current events. The researchers had manipulated the content of the news feeds of two groups of users, a total of 689,003 people, over the course of a week. In one group, positive expressions of emotion had been reduced, while negative expressions of emotion had been reduced in the other. The results showed that the participants’ emotional state, as expressed in their own posts in Facebook, were significantly affected by these manipulations. A reduced amount of negative expressions of emotions in the News Feed led to a more positive emotional state, and vice versa.

The researchers claimed that the study was in keeping with Facebook’s data policy, to which all users consent when they create an account, and that this constituted informed consent to participation in the research.

The study led to a lively research ethics debate. The main sources of criticism were the argument that this form of recruitment constituted a violation of the participants’ rights, that the consent procedure was unacceptable, and that it had entailed risks for both the participants and other people close to them.
As history shows, many researchers have designed projects in which the hope of achieving important research results was put ahead of the integrity, health, and welfare of the people affected. Every aspect of today’s regulatory framework, from legislation and international conventions to guiding ethical principles, aims to ensure the reverse prioritisation. In this context, ethical review plays an important role.
The development of the Ethical Review Act

The Act (2003:460) Concerning the Ethical Review of Research Involving Humans (the Ethical Review Act) entered into force on 1 January 2004. When the law was introduced, the area subject to ethical review was largely equivalent to that which is covered by current legislation. The major difference was that the requirement for ethical review of sensitive personal data or personal data about violations of the law initially only applied if the research participants had not consented to the processing of their personal data.

The background to this was that the legislators who drafted the law considered that the issue of ethical review of research in the humanities and social sciences needed to be further investigated. To this end, in the spring of 2003, the Swedish Government had commissioned the Swedish Research Council, in consultation with the Swedish Research Council for Health, Working Life and Welfare, to map research areas that were not covered by Sections 3 and 4 of the Ethical Review Act, and in which the Council considered that there could be a need for review of ethical issues. The Swedish Research Council reported the results of its investigation on 3 November 2003.

On 16 September 2004, the Swedish Government appointed a special investigator tasked with reviewing certain issues relating to the ethical review of research. In September 2005, the investigator submitted a report entitled “Ethical Review Legislation – Certain Amendments” (SOU 2005:78). These investigations led to the expansion of the Ethical Review Act in 2008 to cover all research that involves the processing of sensitive personal data and personal data about violations of the law.

In the preparatory work for the amendment to the law, it was stated that it was intended to address personal data that could entail a breach of personal integrity, and that it is not sufficient that the individuals themselves have had the opportunity to take a position on the processing of their personal data. In addition, the legislators clarified that there should be coherence in how all types of research are reviewed, regardless of subject area, and that as such, there should be no difference between how medical research and other research are reviewed.30

The 2008 legislative amendments also included a revision of the definition of research contained in Section 2. Among other changes, the student exemption was introduced.

In June 2016, the Swedish Government appointed a new investigation commission to review the Ethical Review Act in certain respects. In December 2017, the commission submitted a report entitled “Ethical Review – A Review of the Rules on Research and Health and Medical Care” (SOU 2017:104).

As a result of the investigation, a number of amendments to the Act entered into force on 1 January 2020. One of the amendments meant that the Act’s definition of research was clarified to cover research through observation,31 something that had already applied in practice. The new version of the Act also clarified the research principal’s obligation to take measures to prevent research within its own operations from being carried out without approval in an ethical review or in violation of conditions that have been announced in connection with such approval.

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31 “Observational studies” are studies in which relationships between different variables are studied without any effort on the researcher’s part to affect the course of events. Such research can be conducted using a variety of methods, among them observations, interviews, surveys, or compilations of personal data from various registers. Studies through observation can occur in both medical and other types of research.
From the outset, the provision regarding the supervisory responsibility of the Central Ethical Review Board and later the Ethics Review Appeals Board contained wording stating that their responsibility did not apply to the extent that supervision fell within the area of responsibility of another authority. The practical result of this caveat was a lack of supervision of compliance with the Ethical Review Act. The amendment, which came into force on 1 January 2020, clarified that the Ethics Review Appeals Board would supervise compliance, regardless of whether any other authority was responsible for supervising the activities in the context of which the research was conducted.

The maximum penalty for parties who intentionally conduct research without ethical approval was increased from six months’ imprisonment to two years’ imprisonment. The same range of punishment was also introduced for the representative of a research principal who intentionally fails to take preventive measures, if the research is carried out without ethical approval or in violation of a condition issued in connection with such approval.

Another change that came into force in January 2020 was the introduction of criminal liability for such violations of the Ethical Review Act that are committed as a result of gross negligence.

**From regional boards to a national authority**

The new ethical review procedure under the Ethical Review Act was initially carried out by six regional ethical review boards in Gothenburg, Linköping, Lund, Stockholm, Umeå and Uppsala. An ethical review application was to be examined by the regional ethical review board in the catchment area to which the research principal belonged or where the research was to be conducted.

To streamline the process and ensure a more uniform application of the regulations, in 2018 the law was amended to abolish the six regional ethical review boards. From then on, ethical review of research involving humans would instead be handled by a new authority, the Swedish Ethical Review Authority.
The mission and organisation of the Swedish Ethical Review Authority

The Swedish Ethical Review Authority began operations on 1 January 2019. The Authority’s activities consist of examining applications for ethical review in accordance with the Ethical Review Act\textsuperscript{32} and conducting ethical reviews in accordance with certain other laws.\textsuperscript{33}

The Swedish Ethical Review Authority is based in Uppsala. The head of the Authority is the Director, who is appointed by the Government. Activities are conducted in six operating regions; Umeå, Uppsala, Stockholm, Linköping, Gothenburg and Lund. Each of these regions has between one and five departments that process medical research applications and one department that handles applications related to other types of research.

The Swedish Ethical Review Authority employs administrators who staff the offices in each operating region. It is these administrators who answer questions received from applicants via phone and e-mail.

Fees and payment

Once both the responsible researcher and the authorised representative of the research principal have signed the application in Ethix, their application is automatically sent to the Swedish Ethical Review Authority, where it is registered and recorded. In connection with this, the Authority sends a notification in the system to those concerned. It includes information about the OCR number, a registration number, the application fee, and how it is to be paid. Only once this fee has been paid does the authority begin its handling of the application.

The fees for ethical review of an application are determined by the Swedish Government.

\begin{itemize}
  \item \textsuperscript{32} The Act (2003:460) Concerning the Ethical Review of Research Involving Humans.
  \item \textsuperscript{33} Such ethical review as is set out in the Act (2018:1091) with provisions on ethical review to supplement the Regulation on clinical trials of medicinal products for human use and in the Act (2021:603) with provisions on ethical review to supplement the EU Regulation on medical devices.
\end{itemize}
Current application fees for

research in which only one research principal participates  SEK 5,000

research in which more than one research principal participates  SEK 16,000

research in which more than one research principal participates, but where all research participants or research objects (as defined in Section 4 of the Ethical Review Act) have a direct connection to only one of the research principals  SEK 5,000

research that only entails the processing of personal data  SEK 5,000

application for amendment  SEK 2,000

The deciding factor in determining if research participants or research objects have a direct connection with one or more research principals is whether research participants are recruited to one or more research principals, as well as whether physical interventions or studies on biological material are carried out at one or more research principals. The lower fee only applies if all such activities occur at the same research principal.

If a research project will only be processing personal data, the fee of SEK 5,000 applies no matter how many research principals participate. The fee category applies to all research to which only Section 3 of the Ethical Review Act applies, i.e., both the handling of existing personal data (processing and cross-referencing of registers) and the collection of new personal data.
The ethical review process in brief

Once an application has been received and the payment of the application fee has been registered, an administrative validation is carried out by the Authority's administrators. They check whether certain parts of the application are complete and whether it actually includes all the attachments specified by the applicant. Following this initial review, the applicant may be asked to supplement their application before it is even examined at a meeting. When an application is deemed valid, i.e., complete, it is scheduled for review at a meeting, in a department with room in its agenda. The departments no longer process basic applications from their own region.

The examination of a basic application, i.e., a new application for a planned project, takes place at a departmental meeting. Each department examines up to about 25 cases per meeting, and committee members need two weeks to familiarise themselves with all the material. For this reason, the examination of a new application normally occurs within three to four weeks of the submission of the application. The processing of the application begins when the application fee has been paid.

An application may be approved in whole or in part, conditionally approved, rejected, or dismissed. The Authority can also issue an advisory opinion. In the event of disagreement, the matter may be referred to the Ethics Review Appeals Board for a decision, if at least three members so request. If the applicant withdraws their application, the case is removed from the cause list. If the fee is not paid or correct signatures are missing, the application is dismissed. It also sometimes happens that after their initial processing, the department gives the applicant the opportunity to supplement the application due to shortcomings or ambiguities.
Ever since the Ethical Review Act came into force in 2004, each department has made independent decisions on the applications it receives. The departments are in regular contact with each other and engage in national meetings aimed, among other things, at establishing similar practices. The Swedish Ethical Review Authority also makes other concerted efforts to achieve uniformity and maintain the quality of its reviews. One of the starting points for the ethical review is that the departments must follow precedent-setting decisions from the Central Ethical Review Board and the Ethics Review Appeals Board. Decisions on appealed cases are published on the website of the Ethics Review Appeals Board, onep.se.

**Composition of the departments**

Each department has sixteen members.

- A chairperson (who must be or have been a judge).
- Ten members with scientific competence (of which paediatrics, psychiatry, and geriatrics are special areas of expertise that must be represented in departments handling medical research). From among these members, the chairperson appoints two scientific secretaries with special responsibility for ethical review from a scientific perspective.
- Five members representing the public interest.

The chairpersons are appointed by the Swedish Government.

Naturally, the research element and scientific competence play an influential role in the examination of an application. The process is essentially a peer review. The departments are aware of the great variation that exists between and within various research areas in terms of research strategies and methods, etc. They are highly qualified and well-equipped to review projects in all these different research areas, and this ensures that the ethical reviews they conduct are relevant to all research.

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34 Ordinance (2018:1879) with instructions for the Swedish Ethical Review Authority.
The role of a member

The Authority needs the help of higher education institutions and regions to get good and committed members who can generate high-quality assessments.

The Ordinance (2018:1879) with instructions for the Swedish Ethical Review Authority states that the University of Gothenburg, Karolinska Institutet, Linköping University, Lund University, Stockholm University, Umeå University, and Uppsala University must submit proposals to the Swedish Ethical Review Authority for scientifically competent members and substitutes for each operating region. Before submitting their proposal, each of these higher education institutions must consult with other HEIs within its operating region.

The regions of Västra Götaland, Östergötland, Skåne, Stockholm, Västerbotten and Uppsala counties are tasked with proposing members and substitutes who represent the public interests of their respective regions. They must also consult other regions within the catchment area of the operating region.

All members appointed by the Swedish Ethical Review Authority must have been proposed by a higher education institution or a region. The Council for the Appointment of Members and Substitutes, a special decision-making body within the Authority, is responsible for appointing and dismissing the departments’ members and substitutes. The council consists of the head of the agency, who is the chairman, and six other members, one chairman from each operating region.

As a member of one of the Swedish Ethical Review Authority’s departments, you will have the opportunity to protect and make a difference in the lives of research participants, and by extension, every resident of Sweden.
You will contribute to creating safe conditions, both for people who participate in research and for researchers, for whom ethical review serves as an assurance that their research can be conducted with respect for the individual. All in all, this ensures that members of our society can place their trust in research.

By participating in the activities of the Swedish Ethical Review Authority, you will also receive further training in research ethics. You will have the opportunity to engage in ethical discussions with other researchers and committed representatives of the public.

The examination of applications requires reading time before each meeting, and reporting members are expected to be particularly well versed in the cases they are assigned.

If you are interested in becoming a member, you must notify your university or region during a period when they are preparing new membership proposals. You are also welcome to contact the Authority and we will refer you to the right contact person(s).
In Sweden, we have a law that regulates certain research on humans – the Ethical Review Act. This law aims to protect the people who are involved in research in various ways. Before it can be conducted, the research covered by the law must undergo ethical review and be granted approval.

This guide is the first of its kind since the law was established in 2004. It is intended to serve as a support in the planning of research projects and outlines noteworthy considerations for anyone assessing whether their research project needs to be ethically reviewed. It can also be read in its entirety by those unfamiliar with ethical review.