



Guidance for research participant information

Participation in research projects is voluntary. It is important that the people asked to participate receive clear and extensive information about what participation means.¹ The information is usually given in the form of a written document of research participant information.

It is important that the research participant information is presented in a simple and clear language and do not contain wordings that can be perceived as pressure, or exaggerations about the potential importance of the study. The information should be suited for the person's age and preconditions in general, or any other potential reason for reduced decision-making abilities. In research with children, information should be aimed at both the child (if they can read) and the legal guardians.

Accurate research participant information that meets the requirements of the General Data Protection Regulation (GDPR) is in most cases a prerequisite to process personal data. Insufficient or incorrect information to the research participants can result in illegal processing of personal data. Research collaborations where personal data is transferred/shared between different entities principally responsible for the research, can also prove problematic if insufficient or incorrect information is given to the research participants.

This guide contains certain fundamental concepts and explanations. In addition to the guide, a template for research participant information is available, based on the Swedish Ethical Review Authority's support template, as well as templates for consent forms. It is recommended that these templates are used in research projects where Karlstad University is the entity principally responsible for the research.

1. [Template for research participant information](#)
2. [Template for consent form](#)
3. [Template for consent form - Biobank](#)

The templates contain text in different colours. Black texts are instructions for what kind of information belongs in each section. Green texts are examples of wordings that researchers can use, and you should replace red texts with appropriate text.

The colours are there in order to clearly distinguish between sections with example texts and sections where the text must be completed with your own information - always change all text to black in the finished document.

¹ For more information, see [the Swedish Ethical Review Authority's web page](#).

Participation in research projects is voluntary

From a research ethics perspective, the guiding principle is that participation in research is voluntary. In cases where personal data is not gathered directly from the research subjects, for example in registry-based studies or internet research, it is however not always possible, or would result in a disproportionate amount of work to inform the research participants about the research and collect consent for the participation in the project.

When personal data is collected directly from the research participants, consent for the participation in the research project must be collected. Please note that a consent to participate in a research project is not the same as the lawful basis consent to the processing of personal data in accordance with the GDPR. Consenting to participation in the research is, however, considered to be a so-called *privacy-enhancing measure*, and is usually a fundamental requirement for the processing of personal data in a lawful, fair and, in relation to the research participants, transparent manner.

Lawful basis for processing of personal data - public task or consent?

According to GDPR, you always need lawful basis in order to process personal data. For research conducted by public establishments - such as Karlstad University - there are two valid lawful bases, *public task* or *consent*. The lawful basis chosen for the processing of the personal data shall be given in the research participant information.

- **Public task:** The lawful basis for performing a task in the public interest should primarily be used when Karlstad University is the sole entity principally responsible for the research, or when the only research collaborators are other Swedish universities. However, please observe what applies when it comes to consent for participation in research (see above).
- **Consent:** The lawful basis for *consent* may be needed in research collaborations with private organisations or in international research collaborations, since these actors cannot always call on the legal basis for public tasks, when it comes to the processing of personal data in research. The issue of what legal basis to use within a research project must consequently be coordinated with the other entities principally responsible for the research.

Do you need permission from the Swedish Ethical Review Authority?

The Swedish Ethical Review Act stipulates that approval from the Swedish Ethical Review Authority is required for research conducted in Sweden, if the research:

- includes processing of sensitive personal data or data on criminal offences,
- entails physical procedures in living or deceased persons,
- is conducted using a method that aims to affect a person physically or mentally or carry an obvious risk to injure the research participant physically or mentally, or
- is performed on biological materials from a living or deceased person and can be traced back to this person.

Research projects that fall under the framework of the Swedish Ethical Review Act shall be reviewed by the local research ethics committee at Karlstad University. For more information, see [the Research Ethics Committee's web page](#). For more information about sensitive personal data, see [Swedish Authority for Privacy Protection's web page](#).

One or more entities principally responsible for the research?

The entity principally responsible for the research is the physical or legal person (for example university, municipality, region or private company) in whose organisation the research is conducted. Principal responsibility for the research means being responsible for the part of a research project that is carried out within the framework of the entity's own organisation. The people who conduct the practical research for the entity principally responsible for the research, are the researchers. Karlstad University is the entity principally responsible when the research is conducted by researchers employed by the University.

According to the Swedish Ethical Review Act, this responsibility consists of ensuring that research governed by the regulations in the Swedish Ethical Review Act is not conducted without the approval of the Swedish Ethical Review Authority, and that the research is conducted in accordance with the approved application and the conditions stipulated by the Swedish Ethical Review Authority.

In research projects that involve researchers from other organisations than Karlstad University, it is important to determine which entity or entities are principally responsible for the research, according to the Swedish Ethical Review Act. Every entity principally responsible for the research is fully responsible for the part of the research project that is carried out within the framework of their organisation. Only one application is sent to the Swedish Ethical Review Authority, however. When more than one entity is principally responsible for a research project, they shall agree on tasking one of the entities with sending in an application to the Swedish Ethical Review Authority, which apply to all involved parties, and to inform the other entities about the Swedish Ethical Review Authority's decision and potential conditions for approval.

Individual or joint controllership of personal data

In research collaborations where researchers from different organisations are processing personal data within the framework of a research project, the main rule is that all participating organisations are acting as entities principally responsible for the research and controllers of personal data.

When personal data is shared between two entities principally responsible for the research, the relationship between the one that transfer the data and the one that receives the data can be defined in two different ways.

- **Individual controllers:** This applies when one entity principally responsible for the research process personal data for its own purposes, until it is transferred to another entity principally responsible for the research which, following the transfer, is processing the data for its own individual purpose. This is the most common relationship between parties in research collaborations. Each entity is separately responsible for its own processing of the personal data and that all processing of research data is conducted in compliance with relevant legislation.
- **Joint controllers:** This applies when two or more entities principally responsible for the research jointly determines the purposes and means of a certain type of processing of personal data, for example when processing personal data in a shared research platform within the framework of a research project. It is the conditions of every specific case that determine if there is an individual or joint controllership of personal data. In cases of a joint responsibility for personal data and other research data, the relationship and delegation of responsibilities must always be determined in an agreement regarding joint data responsibility.

Please note that all transfers of personal data and other research data between two entities responsible for the research, must always be carried out via IT services and tools with the adequate level of security for the specific category of information that is being processed.

Personal data processor

Personal data processors handle the processing of data only as instructed by the personal data controller and lacks any authority or meaningful influence over the processing of personal data. When a processor is involved, the relationship must be regulated in a personal data processing agreement (DPA, in Swedish called *personuppgiftsbiträdesavtal*, PUBA). A service contract between the parties is a prerequisite for a personal data processing agreement. Examples of personal data processors are businesses that perform transcriptions or provide different types of cloud services, such as survey tools.

Just as with transfers between two entities responsible for the research, all transfers of personal data and other research data between the controller and the processor must always be carried out via IT services and tools with the adequate level of security for the specific category of information that is being processed.

Before personal information is processed² in a third country

Consult the data protection officer at Karlstad University (dpo@kau.se) before you collect personal data, if you intend to transfer the data to a third country, i.e. countries outside the EU/EEA. Processing of personal data in a third country could, for example, happen through the use of a cloud service based in the US, a transcription company in India or the transfer of personal data to researchers outside of EU/EEA.

Support

Karlstad University has several services in place to support researchers, for example when writing research participant information, managing research data, choosing suitable IT services and establishing agreements. When in need of support, please contact the following services.

- If you have questions about research ethics, contact the ethics advisor at respective faculty etikradgivning.hs@kau.se or etikradgivning.hnt@kau.se
- If you have questions about research data management, contact the research data group forskningsdata@kau.se
- If you have questions about IT services and IT security, contact IT Services 2525@kau.se
- If you have questions about physical security (for example advice on how paper documents or a hard drive can be stored securely), contact security services fysisksakerhet@kau.se
- If you have questions about archives, preservation and weeding, contact the archivist arkiv@kau.se
- If you have questions about public documents, confidentiality and establishing agreements, contact the legal officers jurist@kau.se
- If you have questions about the General Data Protection Regulation (GDPR), contact the data protection officer dpo@kau.se

² Please note that by processing we do not only mean storage of personal data. Processing may also include, but are not limited to, collecting, management, analysis, compilation, sharing and weeding.