

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.

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 **privacyenhancing 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.

- x **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).
- x **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,

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

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