

State the name of the project

# Information to research participants

We want to ask you if you want to participate in a research project. In this document, you will find information regarding the project and what participation in it entails.

# What kind of project is it and why do you want me to participate?

Give a brief but clear description of the background and overarching aim of the project. Provide information about why this specific person is asked to participate, as well as how the project has access to the personal data that made you ask the person in the first place.

The entity principally responsible for the research is Karlstad University also state if there are any other institutions principally responsible for the research together with XXX University and YYY University. By entity principally responsible for the research, we mean the organisation responsible for the study. If there is an approved application from the Swedish Ethical Review Authority, the following text should be added: The application is approved by the Swedish Ethical Review Authority, the registration number at the authority is state the registration number.

# How is the project conducted?

From the perspective of the research participant, describe what participation in the project entails. What is required of the research participant? What methods will be used? Number of visits, interviews, surveys, tests and time spent? Will samples be taken? What sort of samples (tissue) are needed? How many samples?

It should be clear in what way the procedure potentially differs from routine procedures in for example healthcare and elder care.

Describe how the study is conducted, for example a description of an interview: The interview will be performed at your work place, via telephone, via Zoom or some other secluded place of the researcher’s choosing. The interview is estimated to take 30-60 minutes. The interview will be recorded and then transcribed, meaning it will be written down. Or for surveys: The study will be based on an online survey which will take approximately 15 minutes to complete.

# Possible consequences and risks associated with participating in the project

Provide factual information about the consequences and risks of participating in the project. Avoid embellishments and wordings that could result in undue influence. Could participation result in discomfort, pain, emotional effects, breach of privacy, etc.? Describe potential side effects and other effects in both long and short term. Where applicable, it should be stated how the people in charge of the project will deal with any potential problems. Could participation in the project/study be terminated in case of certain effects? What possibilities are there for follow-up examinations or consultations, etc.?

For example: The risks associated with participation in the project are considered low. If there is a question you do not want to answer, you can just skip it. Or: Certain questions might be uncomfortable to answer, but you can refrain from answering them and still remain in the project or end your participation at any time without giving any reason as to why.

# How is my personal data processed?

The project will collect and register data about you.

Explain what kind of data will be gathered, how it will be processed and stored, and for how long. From where will this data be collected? What sources will be used? Will the data be traceable back to the research participant? How can you gain access to the data? How is the data protected?

State the purpose of the processing of the personal data and the lawful basis for the processing pursuant to the General Data Protection Regulation (GDPR).

If the data will be transferred to a country outside of the EU and EEA (a so-called third country) or to an international organisation, this must be specifically stated. It shall also be stated if there is a decision available from the European Commission regarding whether the country or organisation in question can ensure an adequate level of protection, or if not a reference to appropriate or suitable security measures and how documentation of these can be obtained, or where they have been made available.

Remember to **never** promise confidentiality since, as a public authority, Karlstad University cannot guarantee confidentiality. Remember to never use the term de-identification (”avidentifiering” in Swedish) when describing personal data. GDPR uses the terms anonymisation and pseudonymisation. If it is not in any way possible, directly of indirectly, to identify a physical person, then the data is anonymised and no longer considered personal data. Data which could be connected to a person with the help of additional information that enables re-identification, for example, a code key, is pseudonymised personal data. Consequently, you should use the terms pseudonymised. Do not promise anonymity to the research participants, since this is rarely the case.

Your answers and results will be processed in a manner as to prevent unauthorised access, and they will only be processed within IT systems and services with the adequate level of security. The data will be stored for at least 10 years, starting from the ending date of the research project. After that, it can be selected for erasure.

State the lawful basis for the processing, pursuant to GDPR. The lawful basis for the processing of your personal data is to carry out a task in the public interest (research). If you choose to end your participation in the study, no further personal data about you will be collected. The personal data collected before that can as a rule be used in the research. Alternatively: The lawful basis for the processing of your personal data is informed consent. You can withdraw your consent at any point, without giving a reason as to why. This does not affect the lawfulness of the processing of the personal data collected before the withdrawal, however.

The research participant shall receive information about their rights according to GDPR, as well as information about who is responsible for the processing of the personal data. Karlstad University is the entity principally responsible for the research and the personal data controller of your personal data. The personal data will also be processed by personal data processors, as cloud service providers. According to the General Data Protection Regulation (GDPR), you have the right to, free of charge, request information about the personal data relating to you that has been collected for the project, and if needed have any incorrect information rectified. You may also request that data related to you is deleted and that the processing of your personal data is restricted. However, the right to erasure and restriction of the processing of personal data does not apply when the data is necessary for the research in question (this sentence should only be included when the legal basis for the processing is public interest, and must be deleted in cases where informed consent is used as a legal basis). If you want to have access to the data, you can contact the principal investigator of the project (see below). If you are displeased with how your personal data is processed, you have the right to file a complaint with the Swedish Authority for Privacy Protection, <https://www.imy.se/en/> that is a supervisory authority. You can contact Karlstad University’s data protection officer via e-mail: dpo@kau.se, and telephone (exchange): +46 54 700 10 00. For more information about the processing of personal data at Karlstad University, see <https://www.kau.se/en/gdpr>.

If there are more than one entities principally responsible for the research in the study in question, this shall be stated. If so, exchange the first sentence in the example above with the following text: Karlstad University, together with XXX University and YYY University, are the entities principally responsible for the research, as well as the controllers of your personal data. The personal data may also be shared with other entities principally responsible for the research, within the framework of the project. Each entity responsible for the research is independently responsible for its own processing of the personal data, but personal data will be shared/transferred between the different entities responsible for the reserach. Also add information about how to contact the data protection officers of the other entities principally responsible for the research, for example: You can contact the data protection officer at XXX University via e-mail: xxx@xxx.xx, via telephone (exchange): xxx xxxx xxxx. You can contact the data protection officer at YYY University via e-mail: yyy@yyy.yy, via telephone (exchange): yyy yyyy yyyy. And if possible, inform the research participants where they can find more information about how the personal data is processed at the respective entity responsible for the research, for example: For more information on how XXX University processes personal data, see https://xxx.xxx/xxx. For more information on how YYY University processes personal data, see https://yyy.yyy/yyy.

# How are my samples handled?

The samples taken for the project are stored using pseudonymisation in a so-called biobank.

All of the above mentioned samples will be pseudonymised, meaning that they cannot be directly linked to you. The code key that enables re-identification is stored state where the code key is stored. The code key is handled in a manner as to prevent any unauthorised access.

You have the right to, without giving an explanation as to why, decline any storing of your samples. If you consent to the samples being stored, you have the right to, without giving an explanation, withdraw (regret) your consent. Your samples will then be discarded or de-identified. If you want to withdraw your consent, contact the principal investigator, see below.

The samples may only be used in the manner which you have consented to.

If the biological samples will be used in future research, add the following: If you give your permission to us storing and using your samples for future purposes, you must consent specifically to this. If research that is not yet planned is added, the Swedish Ethical Review Authority will decide whether you shall be asked to give your consent again.

If samples will be sent away for analysis within Sweden or abroad, this must be stated. It must be clear whether the samples are to be sent to another EU/EEA country or to at third country. Will the samples be stored at the recipients premises, returned, de-identified or destroyed? For how long will the samples be stored/analysed in Sweden or abroad and within what time frame will the samples be returned or destroyed?

# How will I receive information about the project’s results?

Provide information on how the research participants can access their individual personal data, as well as the results of the project/study as a whole. In certain types of research, it should also be explained how the project will deal with any potential unexpected findings that could affect the research participants.

For example: There will be ongoing publications of the results of this project by means of both Swedish and international research articles and conferences. If you want to see the results, contact the principal investigator of the project (see below). If you include for example quotes, you can add: Neither your name nor anything else that could directly identify you will be included in the results that are published. Or if the results are only presented at an aggregate level: The presentation of the results will be conducted at a group level and it will not be possible to identify any individuals.

General information about the research project and the type of data that has been collected and analysed may also be available in an open research data catalogue.

Insurance and compensation

Provide information about insurance. It shall be made clear if the research participant is entitled to compensation for lost earnings or expenses connected to the project. It shall also be stated whether this compensation is considered taxable income or not.

State whether there is no need for insurance in the project, for example: There is no need for insurance related to your participation in the project. Or: For your participation in this project, you are insured through the Legal, Financial and Administrative Services Agency, through a so-called “särskilt personskadeskydd”, SPS, which covers accidents during the participation in the research project, within the framework of Karlstad University’s activities. The insurance applies to anyone who is a long-term resident in Sweden and has a Swedish personal identity number. The insurance is never valid when the insured person is at home. The complete terms for the insurance can be found at the Legal, Financial and Administrative Services Agency, https://www.kammarkollegiet.se.

State whether there is any financial compensation for participation, for example: No financial compensation will be paid for your participation. Or: No financial compensation will be paid for your participation, but we offer you a cinema ticket for taking part in the survey.

Participation is voluntary

Your participation in this study is voluntary and you can end your participation at any time. If you choose not to participate or if you end your participation, you do not have to give any reason as to why. If the project is conducted in conjunction with health care or treatment, the following information should also be provided: If you end your participation, it will not affect your future care or treatment.

Provide information on how the research participant can stop their participation. If you want to end your participation, contact the project's principal investigator, see below.

# The principal investigator

Always conclude the research participant information by explaining who the project’s principal investigator is, and by providing contact details. The principal investigator for the project is state the name and title of the principal investigator.

Contact details:

xxx.xxx@kau.se, telephone +46 54-700 XX XX

Address: Universitetsvägen 2, 651 88 Karlstad, Sweden

Contact details of other researchers involved in the project can also be included. Contact details of researchers at Karlstad University shall be given by including a @kau e-mail address and the phone number to the researcher’s work phone. Contact details of researchers employed at other entities responsible for the research will be given in accordance to their internal instructions.