

Information for research participants

The form is to contain all the information that a person could reasonably need to know in order to decide whether or not to participate in a research project, but no more than that. The written information is a complement to the information that is to be given orally. There should always be an opportunity to ask questions. The consent form may be separate, but a copy of it, as well as a copy of the information form and any annexes, is to be kept by the person participating in the research.

It is important that the information for a person participating in the research is given in a simple and clear language and does not include words that could be interpreted as coercive or exaggerating the possible worth of the study. The information should be adapted to the age of the person and other general circumstances or any other grounds that would constitute a diminished ability to make a decision. When the research involves children, the information is to be addressed both to the child (if he/she can read) and to the custodian of the child.

The information should not be too long and should only exceed 3-4 A4-sized pages in exceptional circumstances. If, for some reason, the information sheet needs to be considerably longer, a shorter version (1-2 A4 pages), should be supplied as an annex to the longer version, containing the most important information needed by the person participating in the research (see below). If necessary, detailed instructions can be supplied in an annex.

The example below is designed to be suitable for both medical research and other research. The relevant parts may be used.

Headings such as those used below can enhance legibility:

Heading	Comment
<i>1. Background and purpose</i>	Give a brief but clear description with respect to the background and the general purpose of the study.
<i>2. Inquiry concerning participation</i>	Here it should be stated both why this particular person has been asked and how information about the person was obtained which led to the request for their participation being made. (For example: "We found your name in the population register.")
<i>3. How will the study be conducted?</i>	This should be a general description from the participant's point of view: what will be required; what methods will be used; the number of visits to a clinic; any samples that will be taken; interviews; tests, etc. It should clearly be shown in what manner the examination procedures are different from a patient's/client's routine treatment, for example. It should also be clear how tests and the results of analyses will be dealt with and if they will be sent abroad for analysis or storage. If the analyses concern genes, it should be clear what diseases or other attributes are considered to be linked to genes. When blood samples are taken, the amount of blood needed should be clearly stated.

4. Biobank samples

If samples are to be stored in a biobank, how and where the samples are stored should be made clear. It should also be made clear that they are coded and cannot be traced to any individual by anyone without access to the code key and that the samples are only to be used in the manner to which participants in the research have given their consent to. It should also be made clear if samples which are kept may be used for future research as yet unplanned; that in such cases a new ethical vetting will be carried out and that in some cases those participating in the research may be contacted again.

5. What are the risks?

Here it should be clearly stated if discomfort, pain or other adverse reactions can occur after treatment. Long-term effects should also be described. Possible predictable emotional effects that can arise should be mentioned and possible violations of personal integrity should be touched upon. In appropriate cases it should also be clearly stated how those who are responsible for the research will deal with problems such as the interruption of procedures, follow-up talks etc.

6. Are there any advantages?

Here there should be a clarification, without any embellishments, of any possible advantages for the patient. With respect to research concerning treatment, it should be clarified that the possible effects of the new treatment (in this particular context) are unknown or need to be verified.

7. Dealing with data and confidentiality

Here the manner in which data will be dealt with should be clearly stated: how personal information (i.e. information that can be directly or indirectly traced to a particular individual) is to be dealt with and if the information is to be computerised. It should also be clearly stated whether or not information will be made available to principals such as pharmaceutical companies or colleagues at another university in Sweden or abroad. If the information is to be given to a country that is not a member of the EU or the EEA (a so-called "third country"), this is to be clearly stated. If personal information is dealt with, then according to the Personal Data Act (1998:204), information is to be given as to who is responsible for personal data. This is usually the person principally responsible for the research: "Gothenburg University is responsible for your personal data" for example. The purpose behind the treatment of the personal data should also be clearly stated and all other information needed should be provided in order for the persons participating in the research to exercise their rights in accordance with the Personal Data Act. Information of this nature is: where the personal data is obtained; what information or categories of information are dealt with; how long the personal information will be kept; the entitlement of those participating in the research to have access to information from the records used; and their right to demand the correction of any incorrect information. The Personal Data Act should be referred to. The wording concerning confidentiality should read: "Your answers and your results will be dealt with in such a way that no unauthorised person will have access to them". There should also be information about how the results of the study will be presented and how personal identity will be protected.

8. How do i obtain information about the result of the study?

Here it should be clearly stated in what manner those participating in the research can have access to their personal data (the results of their own analyses) or the results of the entire study (e.g. publication in the journal of the Patients' Association; information given verbally to a group, etc). It should also be made clear that those participating in the research can ask not to be told the results of any analysis if they so wish.

9. Insurance, compensation

Here it should be stated if the patient injury insurance scheme applies or if a special insurance has been taken out for the project. In addition it should be clearly stated if those participating in the research are entitled to compensation for loss of earnings or other expenses as a result of the project. It shall also be clearly stated that any additional compensation may be regarded as taxable income.

10. Voluntariness

In conclusion it must be clarified that participation in research projects is voluntary and that one is entitled to withdraw at any moment without giving any explanation. It can also be clarified at this point what items/information are then destroyed. If samples have been taken, it should be clearly stated that participants in the research are entitled to demand that samples are destroyed or marked in such a way that it is no longer possible to trace them to a particular individual. At this point it should also be clarified that if participants in the research who are patients/clients do not wish to participate or wish to end their participation, this will not affect their ordinary treatment or the care given to them.

11. Responsibility

Under this heading should be listed those responsible for the completion of the study (the person principally responsible for the research, researchers and the body responsible for personal data - which is usually the person principally responsible for the research) together with information on how to contact a person who can give additional information (address, telephone number, telephone times, e-mail addresses etc.). If the person responsible for personal information has appointed a so-called personal information representative in their organisation, it is appropriate to provide contact information for this representative.

Consent form

Here it should be stated on it that participants in the research have been given information, have been given the opportunity to ask questions, have been given answers to them and have given their consent to: participation in the study and (where applicable) the processing of personal data and the storage of samples in a biobank. In clinical trials of medicinal products, consent should also be given to allow another person (a study monitor) to have access to medical records in order to check data. If the study consists of various parts, it should be clearly stated if participants in the research choose to limit their participation to certain parts.