Information sheet for participants – useful tips

What is the study participant information sheet?

The participant information sheet provides key information about the study in plain language or language understandable to a lay person. It should include information on the purpose of the study, who is eligible to take part in it, the benefits and risks of participation in the study, what will happen during the study and what tasks the participants will need to perform. This information is designed to help potential participants decide whether to take part in the study.

Before handing out the informed consent form to participate in the study, the investigator should make sure that the participant understands the information provided and answer any questions they may have. If some information cannot be disclosed before the participant decides to participate in the study (e.g. because we suspect that such knowledge may adversely affect the outcome of the study, e.g. influence the subject's responses or behavior), it is essential to conduct a debriefing, i.e. to provide the subject with the previously withheld information after the study is completed.

Informed consent is very important. Therefore, any information about the study provided to participants must be worded clearly and in a way that can be understood by non-professionals. You should avoid scientific jargon and terminology that might be potentially unfamiliar or incomprehensible to your respondents. If the use of professional terms is necessary, they should be explained in the information sheet.

It is recommended that the information sheet contains the elements discussed below. It does not have to be structured exactly as shown below, but all of the listed elements should be included.

INFORMATION SHEET ELEMENTS

1. **Title of the study and the name of the person responsible**
   The title of the study should be worded using simple language so that it is easy to understand and should not contain any abbreviations. Therefore, the title of the study may be a simplified version of the title of a project submitted for evaluation to other scientific bodies.
   The information sheet should include the name of the principal investigator and the contact information in case of questions or problems.
2. **Invitation to participate in the study**
   The information sheet should include a paragraph that explains what the participant will be asked to do and an invitation to participate in the study.

   Example:
   We would like to invite you to participate in our study. Before you decide to do so, we would like to explain what the study will look like and what will be asked of you during the study. Please read the following information carefully. If anything is unclear or you need more information, we will be happy to answer any questions you may have.

3. **Purpose of the study**
   Knowing the scientific purpose of the study is essential to making an informed decision to participate or not. The study purpose should be stated clearly, concisely, and in the context of a given discipline.
4. **Voluntary participation**
   The information sheet should explain that participation in the study is completely voluntary.

Example
Participation in the study is voluntary. Your decision to participate (or not to participate) in the study does not affect your relationship with the institution conducting the study or the researchers in any way.

5. Right to withdraw consent

Participants should be informed that they have the right to withdraw their informed consent to participate in the study at any time and at any stage without consequences.

Example
You have the right to withdraw your informed consent to participate in the study at any time and at any stage. Your withdrawal from the study will not entail any consequences or sanctions.

6. Procedure

It is important to inform participants what will be expected of them during the study (e.g. completing a questionnaire, living a certain lifestyle, adhering to a particular diet). It is worth putting ourselves in the participants' shoes and thinking about what information might be useful to them when deciding to participate in the study.

This section should contain answers to the following questions:

- how long will it take to complete the study, how many stages will there be;
- how many times and for how long the participant will have to meet with researchers, fill out surveys, perform specific tasks, etc.;
- what will the procedure look like, what kind of tasks will the participant have to perform;
- whether the participant will be able to know their individual results;
- what are the specific contraindications for participation in the study (e.g. wearing contact lenses, having a retainer, past illnesses, previous participation in similar studies, etc.).

The methods used in the study should be presented in simple terms. The involvement that will be required of the participants should also be described as clearly as possible.

If the study includes collecting biological material, imaging (e.g., neuroimaging, roentgenograms, etc.), or audio and video recordings, participants should be explicitly informed about this. They should also be informed whether the results will be publicized in a way that may make the identification of study participants possible.

If you know that during the course of the study sensitive information important to the participant may be revealed (e.g. their medical history), the participant should be notified of this possibility beforehand and asked if they would like to be informed in case of such discoveries.

If during the course of the study information indicating that a crime has been committed is revealed (e.g. causing bodily harm, sexual intercourse with a minor, causing a catastrophe, etc.), participants should be informed that the researcher is legally obliged to report this to

the appropriate authorities. This requirement is imposed by the Article 240, section 1 of the Penal Code.

7. **Costs and compensations**
   The participant should be informed of any expenses they might have to cover during the study (e.g. travel expenses, meals) and the possibility of receiving a compensation. Similarly, if remuneration is provided for participation in the study, participants should be explicitly informed of the amount and type of remuneration (money, gift cards, vouchers, books, etc.) as well as about the timing of payment.
8. **Risks associated with participation in the study**
   Study participants should be informed of any risks or inconveniences associated with their participation in the study. In particular, all possible side effects that the investigators are aware of (e.g. possible adverse effects on well-being or health, possible injury or discomfort associated with the study, etc.).
9. **Information on personal data processing**
   This can be a part of the general information sheet or a separate document. A template for this document can be found on the Committee's website under *Information clause on personal data processing and participant informed consent.*