

Presentation material for participants in a scientific study in the health field

Here are examples and instructions on what should be included in the presentation material for participants in a scientific study in the health field. Researchers can use the material at their own discretion and adapt it to the study to be sent to VSN.

The briefing material should be as short and clear as possible:

The text should not be longer than 2-3 pages, with a legible font. If further explanations are needed, they are included in the Annex. If participants are older people or children, it is recommended to use larger fonts. If participants are children under 12 years old, a special information letter with short text in an appropriate language, and then another letter for parents/guardians, should be prepared.

Who is involved in the research:

Please identify the responsible person and the collaborator as appropriate. If the research is a study project, please identify the university and department/field. If the research has received funding, it is good to state this here.

Objective and purpose of the study:

Here you can use the same text as in the application. Objective and purpose in a nutshell, not too far.

How are participants found? - Participation criteria:

Describe the method of finding participants. In the case of patients, state where they were found, at a doctor, a medical facility, etc. Participants have the right to know who gives their name for the study and on what grounds. It is reminded that there are restrictions on providing such information.

Conditions for participation:

The criteria for participation in the study must be stated and disclaimers must be mentioned if any, i.e. who is excluded from participation and why.

What is involved in participation?

- What do participants need to do, e.g., provide samples (blood samples, skin samples of the skin), take medication, carry a device, undergo an effort test, answer questions, other things?

- Please state how many people are expected to participate in the study and how long it will take.
- How often do I need to attend an interview/visit a research site?
- Questionnaire (how long does it take to fill them out)
- Do you specify where the study is being conducted, e.g. at a health or medical institution, at the research centre, in university facilities, at the participants' workplace, at the participants' homes?
- An interview will be recorded on tape or video.
- Other things as appropriate.

Information on the study participant - Investigators confidentiality:

All information provided by participants in the study/survey shall be handled according to the strictest rules on:

- confidentiality and anonymity
- Act on the Protection of Privacy
- processing and deletion of data

Research data shall be stored in a secure location with access control (e.g. locked shelf/institutional computer system) at the responsible person during the course of the investigation. All data will be deleted after the investigation, unless permission is granted to store it for longer. If a biological sample is taken and planned to be stored after the investigation in a biological sample collection authorized by the Ministry of Health, this must be stated in a letter of introduction. Biological samples may not be stored after the investigation is completed except in a collection authorized by the Minister. If biological samples are sent out of Iceland for further investigation, this must be stated in a letter of introduction and that they will either be destroyed in a secure manner or sent back to Iceland for storage in a biological sample collection after processing. If the results of a study are to be published in journals, it is good to mention this here and clearly state that all results will be non-personal.

Benefits and risks/disadvantages for participants:

Here you will find what you can call benefits or risks or possible disadvantages (e.g. sampling, stress tests, difficult interviews recorded, job losses, travel expenses for participation. It will be stated whether there is a refund for expenses, job losses or rewards for participation.)

Insurance:

There is generally no special insurance for participation. In some cases, however, it is necessary to cover participants. The name of the insurance company, the period of insurance

and the reasons for the insurance must be clearly stated, and the insurance shall be valid without charge. The insurance shall cover the entire period of investigation and participants may seek legal action in Iceland if the insurance company is a foreign company.

Permits for the study: It must be stated that the study is carried out with the approval of VSN and, as applicable, that permission is available for others from whom permission must be obtained, that a notification has been sent to the Data Protection Authority or that permission is obtained, the approval of the registry holder, e.g. the Directorate of Health or the director of a bio-sample collection for access to bio samples or data.

On the rights of participants in interviews or questionnaires:

Questionnaire items must be identified by the research number, but not by the names or ID number of the participants, and must always be non-personal. It should be noted that it is not necessary to answer everything in the list if questions cause distress or if an answer is uncertain or if the person just does not want to answer. It is however acceptable to state that it is desirable for the purposes of the investigation that as many questions as possible are answered. It must be stated that if an interview or questions cause distress for a participant and he/she wishes to receive assistance, he/she may contact a specialist who is prepared to take the participants into one interview and/or provide them with crisis assistance, free of charge. The person to whom the possibility will be given may not in general be one of the investigators. Please state the name of the specialist, the workplace and the telephone number. This applies of course only in cases where interviews are used or near-miss questions are asked.

It should be noted that participants are free to refuse or stop participation in the study at any stage, without explanation and without consequences on the treatment to which they are entitled.