Informed consent: instructions for preparing

Informed consent

Informed consent is one of the key tools for ensuring the ethical propriety of research work. It involves an agreement between the participant and researcher, whereby the researcher ensures that the participant is informed of all the key elements of research, and the participant in turn grants the researcher permission to collect the necessary data and use them for the defined purpose. The signed informed consent guarantees for the participant how and for what purpose data will be gathered, and in any breach of the agreement it grants them the means for complaint. The agreement enables the researcher to demonstrate to third persons that the data were collected ethically and with the consent of the participants. Nowadays numerous science and research journals are already requiring that relevant informed consent be obtained for the data presented in research.

The purpose of this document is to describe in detail and underpin the elements of informed consent.

Elements of informed consent

Each informed consent should present all the key elements of the research that are necessary for participants to understand the purpose of the research, what exactly is expected of them, how much time participation will take, what kind of recompense there might be for the time and effort invested by participants in the research, what are the potential direct benefits or risks associated with participation in the research, an assurance that participation is entirely voluntary and may be terminated at any time without consequence, information on how the gathered data will be used and on the guarantee of anonymity and confidentiality, and the contact information of the researcher and the Committee which approved the research and to which participants may address any questions or complaints.

In order to ensure that participants receive information in a transparent and understandable way, the Committee has designed standard forms in which the necessary information is set out in separate points, as presented below. The examples offered under individual points do not cover all the possibilities. For an example that matches your research, check the document Examples of Informed Consent.

1/ Introduction

The purpose of the introductory point is to present who is implementing the research and what its purpose is. When you present researchers, state who is the principle investigator (PI), the person responsible for the plan and supervision of research implementation, and who is the researcher responsible for direct organisation and implementation of the research. Often these two persons are combined into one. In the case of doctoral dissertations and other research projects tied to studies, the role of principle investigator is taken by the mentor, and the role of investigator by the student. In this case you can also note that the research is being conducted as part of a doctoral (or other) dissertation under a mentor. You should also always note the precise title of the researchers and the organisation in which they are employed or within which the research is being conducted.

The purpose of the research should be described in the clearest and most concise way, in one or two sentences. In describing the purpose and also in all other points, take into account the level of education and prior knowledge of the participants. Information should be provided in a way that is understandable to participants with the lowest level of education and familiarity with the topic being addressed. In the descriptions please avoid foreign words, abbreviations and technical terminology.

Example of point 1

1. You are invited to take part in a research project which as part of the doctoral study of Experimental Psychology is being conducted at the Psychology Department of the Faculty of Arts of the University of Ljubljana, under the leadership of Alenka Mraz, dipl. psih., and under the mentorship of Asst. Prof Dr Veronika Brezar. The purpose of the research is to study how the shape and presentation of a face affect the speed of identifying feelings.

2/ Obligations of the participant

The purpose of the second point is to present clearly what you expect from the participant, and what their task and obligation will be in the context of participating in the research. Where this involves a study in which you will use a behavioural test, in this place describe briefly the test the participant will be given. If the study is based on the use of various questionnaires, indicate how many questionnaires will need to be completed and what topics the questionnaires will cover. If the study includes an interview or focus group, describe briefly what topics you intend to discuss and what you will be asking about. If the study includes observation, note in what context the participant will be observed, what will be assessed, and whether you will make audio or video recordings. If the study includes active participation, indicate the expected role and task of the participant. Note whether the participant will be expected to protect confidentiality (about other participants, the research topic or the tools used).

Based on this point it must be clear to the participant what is expected of them and what they in turn may expect as part of their participation. Highlight in particular those requirements, expectations and tasks which given their nature could be especially difficult or unpleasant. In your description remember that later during implementation there should be nothing unexpected and that could surprise the participant. An exception to this is of course studies where the research plan is based on surprises and the 'naivety' of the participant. In these cases a slightly different treatment of the research is required.

Remember that the purpose is not to give detailed instructions for participation, but just to briefly outline the tasks and expectations for the participant. Be as brief, clear and concise as possible.

Example of point 2

2. If you opt to participate, your task will be to perform a computer test in which faces will appear on the screen, presented in different ways (photographs, drawings, sketches) and from different angles. For each display your task will be by pushing the relevant button to answer as quickly as possible what feeling (anger, fear, joy, sadness) the face expresses. After the test is completed your task will be to complete a short questionnaire in which we will ask you about different aspects of dealing with emotional situations.

3/ Scope of obligations and compensation for participation

The aim of the next point is to provide the participant with a helpful estimate of the time and effort that participation will require, and information on whether and what kind of compensation the participant will receive for participating.

In giving your time estimate please be precise. Estimate how much time participation requires on average and how much time for slower participants. Remember that participants are often not skilled in performing tests and that they may complete questionnaires more slowly than you would expect. For this reason make your estimate a bit more pessimistic, or give an anticipated range of time for completion. In any event it is better for participants to finish sooner than they expected, than for participation to drag on longer than they were led to believe.

In this point also state what kind of compensation participants will receive for participating. Be as specific as possible. If the compensation depends on the actual time involved, state clearly how much compensation will be given for each hour of participation. In planning the study take into consideration that compensation should not serve as a kind of inducement to participate. Compensation is in no way a payment for participation, but rather represents simply actual compensation for time spent, effort invested and possible costs directly associated with participation in the study (e.g. travel costs).

If through their participation the participants fulfil part of their study requirements, please also note this clearly, and describe what requirements they can fulfil and in what scope.

If no compensation is envisaged, also state this clearly. Do not forget that the purpose of consent is to clearly define the expectations of researchers and participants.

Example of point 3

3. Participation in the research will require approximately one hour for performing the computer task and 15 minutes for completing the questionnaire. You will not receive any compensation for participating in the research.

4/ Risks and hazards of participation

Participation in research often also involves various hazards and risks. Both need to be understood as any kind of consequence that directly or indirectly negatively affects the individual. If the research covers interviewing those involved in a natural disaster, this may generate negative feelings on re-living a traumatic experience. If you are conducting an experiment in which you study the effect of negative disturbing stimuli on the extent of remembering, these are negative feelings on the presentation of images. If the research involves filling in a large number of questionnaires, these could be feelings of fatigue or boredom.

Whether it involves apparently entirely innocent ‘risks’ or the probability of more serious risks, in any event participants need to be informed of all the possible negative aspects of participating in the research, and also of the methods you will use to reduce the risk or possible negative consequences (in the case of long tests, already anticipated short breaks can suffice). In formulating your wording, take into account that also in terms of the participant’s satisfaction with participation and their willingness to respond at some future point to an invitation to participate, it is much better to overestimate than underestimate the negative factors of participation.

Example of point 4

4. Participation in the research involves no risk. Due to the monotony of the test and the higher level of attention the task requires, you might have feelings of fatigue or boredom while taking it. We will try to reduce this through frequent short breaks during the test.

5/ Benefits of participation

Just as there are potential hazards, you need to present appropriately the possible direct and indirect benefits or, more importantly, their absence. The purpose of describing the benefits is not to stimulate willingness to participate, but to establish realistic expectations. For instance, participation in an alternative form of teaching will not be 'repaid' with a higher grade. In this point, first clearly point out what benefits there will not be, then list the possible direct benefits for participants, and then you can also state the possible indirect benefits of the research.

Example of point 5

5. Participation in the study does not involve any special benefits other than the knowledge and experience you will gain through participation. The results obtained will enable the design of new strategies of teaching foreign languages in primary schools.

6/ Voluntary nature of participation

In terms of meeting ethical standards, the voluntary nature of participation is vitally important. Although it might seem obvious, this fact needs to be especially highlighted. In this point there should therefore be a clear assurance that participation in the research is entirely voluntary, that in any part of the research participation may be terminated and that terminating participation carries with it no negative consequences. It should be stated that participants may request the deletion of data collected, including after the conclusion of their collection, for as long as the data can be identified. It should also logically be emphasised that despite termination, participants will receive the assured compensation for work completed, if this is envisaged.

Example of point 6

6. Your participation in the research is entirely voluntary and may be terminated at any time without consequence. If it is technically possible, you may also request the deletion of data collected after the completion of data collection. Even if for whatever reason you decide to terminate your participation, you will receive compensation for the extent of your participation.

7/ Data protection

By signing the form the participant gives the researchers consent to collect and use the participant's personal data for the purpose of the research. In this point you must clearly set out to participants how their data will be used. Ethical principles dictate that researchers should carefully protect collected personal data and ensure their anonymity vis-a-vis third persons. Anonymity may be additionally ensured through a commitment where on the conclusion of data collection, the data will be completely anonymised, that only group data will be presented publicly and that in the case of publication of data in public repositories it will not be possible to tie them to individuals and that the identity of participants will not be disclosed.

In your wording be careful not to bind yourself to any promise that cannot be fulfilled or that would prevent you from appropriately presenting your results. In a case study or research with a small number of participants, it is hard to avoid stating the data of individual (otherwise anonymous) participants in presenting the results.

If given the nature of the research you wish in the public presentation of results to identify their source (for instance giving a quote from an interview), it is important at this point also to state this as a possibility. Here it should be pointed out that in such case you will ask for explicit consent for publication. You can ask for this in a separate point in the same document or obtain it subsequently in a separate written statement.

In addition to ensuring anonymity, it makes sense in this point to note also the purpose for which data will be gathered and used. You should also especially highlight the possibility of permanent or long-term storage of personal data or their communication to third persons for use in research, if this is logical and necessary for the research plan.

If you envisage storing identified data after the completion of data collection, the participant also needs to be informed of this, and explained how access to the data will be regulated and controlled, and where possible the participant should be expressly asked for permission for such data storage.

Example of point 7

7. We will do everything to protect your privacy. The results of the test and accompanying demographic data will be stored under a research password. In accordance with the principles and guidelines of open science, raw data may also be published in public repositories, where we will ensure that the data can in no way be linked to individuals. In no event will your identity be revealed.

8/ Contact information

The purpose of the final point is to provide the contact details of persons and organisations where participants can obtain additional information on the research, pose questions or address remarks and possible complaints. Normally you need to provide at least an e-mail address and business telephone of either principal investigator or the person conducting the study as well as the contact address of the University of Ljubljana Human Research Ethics Committee (KERL UL) which discussed and approved the proposed research.

Example of point 8

8. Should you have any additional questions, please contact the lead researcher, Alenka Mraz (e-mail: alenka.mraz@ff.uni-lj.si, tel.: 01 241 9999) or the University of Ljubljana Human Research Ethics Committee (e-mail: kerl@uni-lj.si).

Declaration

In presenting all the necessary information the final task is to summarise briefly and concisely the declaration that the participant gives by signing. In this you should clearly state that the participant has read the declaration and has had the opportunity to ask any additional questions related to the research, that the participant confirms their voluntary assent to participation in the described research and permits the use of collected data for the stated purposes.

Example of declaration
By signing I guarantee that I have read the declaration and I have been given the opportunity to ask questions related to the research. I confirm my assent to participate in the described research "The effect of factors of face presentation on the identification of feelings" **and I permit the use of collected data for educational and research purposes.**

Signatures

The declaration is followed by the names, signatures and dates of signature of all those involved in the agreement. The agreement is signed by the participant, and in the case of minors or those without capacity to contract, also by their legal guardian. The declaration is signed by the principal investigator and the person carrying out the study.

Additional declarations

Directly before or after the signatures, the form may also contain additional declarations whereby the participant expressly assents to elements that go beyond the purpose of informed consent. These include for instance:

- assent to being contacted again for participation in the next stages of the same study, in related or other studies;
- assent to audio and video recordings;
- assent to the public statement of quotes;
- assent to the storage of identified data.

Confirmation

The final part of the form is the confirmation of the University of Ljubljana Human Research Ethics Committee, with the date of confirmation and stamp of the organisation, whereby the Committee confirms that the declaration and the proposed research to which it relates meet the ethical rules and standards.

Form

KERL UL has made up a standardised form for informed consent. The form has been created as a Microsoft Word document. In drawing up the consent, use the prepared document, in which you can add or change the wording in places marked yellow. Do not change the form of the document except in special circumstances (e.g. the requirements of international projects), where the form must contain all the above-required elements.

Telephone and online surveys and research

Participants must give informed consent also in cases where they cannot sign a printed version of the informed consent, as is the case in telephone and online surveys and research. In the case of telephone surveys, all the above-mentioned key information must be presented. Here you can assume that the participant has given informed consent when for each section they have confirmed that they understood it and also confirmed the final declaration.

In the case of an online survey or research, on the home page you need to clearly set out all the above-presented elements of informed consent. Next to the button or link to join the research, clearly state that by assenting to the research the participant declares that they have been informed of the text provided and that they give their informed consent to participate in the study.