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Informed consent: instructions for preparation

1. Informed consent

Informed consent is a key tool to provide for ethical compliance of research as laid out by the *Nuremberg Code* from 1947 and the *Declaration of Helsinki* from 1964. Informed consent is basically an agreement between the participant and the researcher whereby the researcher ensures that the participant has been informed on all key elements of the research and the participant grants to the researcher consent to gather the necessary data and use them for the specified purpose. A signed informed consent gives assurances to the participant as to the method and purpose of gathering data and represents the grounds for complaints in the case of a breach of agreement. The researcher can use the consent to prove to third parties that data had been gathered in an ethical manner and in agreement with the participants. Many scientific research journals already require informed consents for data presented in a research.

The purpose of this document is to describe in detail and provide grounds for the elements of informed consent. A part of the document below is also a presentation of the manner of obtaining and keeping consents and a detailed explanation when a consent is needed.

2. Elements of informed consent

Any informed consent should present all key elements of the research, which are necessary for the participant to understand the purpose of the research, what exactly is being expected of the participant and what compensation will be received for the time and effort given by the participant to the research. It outlines any direct benefit or risk associated with the participation in the research, an assurance that the participation is completely voluntary and that it can be terminated at any time without consequences. It also provides information on how data would be used and contact information of the researcher and the committee approving the research to which the participant may address any question or complaint.

To ensure that the participants receive information in a transparent and intelligible manner, please use the standard form, where the necessary information is provided in separate items, as presented below.

1/ Introduction

The purpose of the introduction is to present who is conducting the research and what is its purpose. When multiple researchers are presented, it should be specified who is the primary investigator (PI) responsible for the design and supervision of the conduct of the research and who is the person conducting the research responsible for direct organisation and conduct of the research. Often they are one and the same person. In the case of doctoral theses and other research projects related to studies, the primary investigator is the mentor and the conducting person is the student. In such a case, it may be stated that the research is a part of a doctoral (or other) thesis under a mentor. An exact tittle of researchers and the organisation of their employment, or where the research is conducted, should also be specified in any case.

The purpose of the research should be described in a clear and succinct manner, using no more than two sentences. Please consider the level of education and knowledge of participants when describing the purpose and in other items as well. The information should be presented in a manner that can be understood by participants having the lowest level of education and knowledge of the subject. You should avoid using foreign expressions, abbreviations and expert language in the descriptions.

An example of item one

1. You are kindly invited to take part in the research conducted within the doctoral studies Experimental Psychology at the Psychology Department of the Faculty of Arts of the University of Ljubljana under the leadership of Alenka Mraz, BSc(Psych), and the mentorship of Assist. Prof. Dr. Veronika Brezar. The purpose of the research is to examine how the form and presentation of faces affects the speed of recognising emotions.

2/ Obligations of the participant

The aim of the second item is to clearly present what is expected from the participant and what will be the participant's tasks and obligations when taking part in the research. In the case of a study involving behavioural tests, you should briefly describe the test that will be undertaken by the participant. If the study is based on the use of various questionnaires, you should state how many questionnaires will have to be filled-in and which topics the questionnaires will address. If the study involves an interview, you should briefly describe what will be the topics of discussion and what the questions will be about. If the study involves observations, you should state what will be observed in the participant and what will be assessed.

This item should make it clear to the participant what is expected of him or her and what the participant can expect from taking part. You should particularly highlight those obligations, expectations and tasks that could be of an especially difficult or unpleasant nature. Please take note when making the description that nothing unexpected and surprising should be faced by the participant in the execution of the study. Studies where the plan of research is based on surprise and "naivety" of the participant are of course an exception. In such cases, the study should be handled in a slightly different manner.

Please consider that the purpose is not to provide detailed instructions for participation but to briefly describe the tasks and expectations from the participant. You should be as brief, clear and succinct as possible.

Example of Item 2

1. Should you decide to take part, your task will be to perform a computer test where the screen will show faces presented in various manners (photos, drawings and sketches) and from various angles. Your task in each presentation will be to press a button to give the fastest reply possible as to which emotion (anger, fear, happiness or sadness) is reflected on the face. After the test, you will be asked to complete a brief questionnaire where you will reply to questions related to various forms of dealing with emotional situations.

3/ Scope of obligations and compensation for participation

The purpose of this item is to provide the participant with an estimate of the time and effort required by participation and provide information as to what kind of compensation, if any, will be given to the participant for taking part.

Please be exact in the estimate of the time needed. You should assess the average time it takes to participate and the time needed by slower participants. Please consider that participants are often not skilled in taking tests and that questionnaires may be completed more slowly than might be expected. Your assessment should therefore err on the pessimistic side, or a range of time needed should be given. It is in any case better if participants are finished before it was expected than having the test taking longer than had been stated.

This item should also specify any compensation for the participation. Please be as specific as possible. If the compensation depends on the actual time of execution, you should clearly state the hourly rate of compensation. The planning of the study should take into account that compensation should not be used as a form of luring people to take part. Compensation is by no means payment for participation but only represents an actual compensation for time lost, effort put in and any cost directly linked to the participation in the study (e.g. travel expenses).

If no compensation is due, it should be clearly stated. Please remember that the purpose of consent is to clearly define the expectations of researchers and participants alike.

Example of Item 3

1. The participation in the research will require roughly one hour of your time for the computer test and 15 minutes to complete the questionnaire. You will be entitled to no compensation for participating in the research.

4/ Risks and hazards of participation

Taking part in research projects often entails miscellaneous risks and hazards. Both should be understood as any consequence having a direct or indirect negative effect on an individual. If the research includes interviewing persons who have gone through a natural disaster, they may involve negative emotions from reliving the traumatic experience. In the case of an experiment examining the effect of negative disturbing stimuli on memory, they may involve negative emotions stemming from the presented images. If the research includes completing a large number of questionnaires, they may involve the feeling of tiredness or boredom.

Be it seemingly innocuous “risks” or the probability of serious hazards, participants should be in any case informed on all possible negative aspects of taking part in the research and the methods that would be used to reduce the risk or any negative consequence (short breaks could suffice in the case of prolonged tests). Please consider when preparing the text that it is much better to overvalue than to undervalue any negative aspect of participation, also with a view of participants’ satisfaction with taking part and their willingness to respond to any future invitation to participation.

Example of Item 4

1. Participation in the research bears no risk. The monotonous nature of the test and the degree of attention required by the task may result in feelings of tiredness and boredom in the execution. An attempt will be made to reduce them by frequent short breaks during the test.

5/ Benefits of participation

Similarly to hazards, any direct or indirect benefit or, more importantly, the absence thereof should be appropriately presented as well. The aim of the description of benefits is not to encourage participation but to set up realistic expectations. For example, participation in an alternative form of teaching will not be rewarded by a better grade. This item should first clearly present which benefits would not be accrued, followed by a specification of any direct benefit to the participant and potentially by a list of any indirect benefits of the research.

Example of Item 5

1. Participation in the test will yield no special benefit apart from the knowledge and experience acquired by participation. The results will enable the development of new strategies of teaching foreign languages in primary schools.

6/ Voluntary participation

Voluntary participation is central in terms of meeting ethical standards and should be specifically noted, although it might seem obvious. This item should clearly note that the participation in research is completely voluntary, that the participation can be terminated at any time during the research and that such termination will result in no negative consequence whatsoever. It would be advisable to specifically state that participants will receive promised compensation for the work in spite of termination.

Example of Item 6

1. Your participation in the research is completely voluntary and you may choose to terminate it without consequences at any time. Should you decide for any reason to terminate the test, you will nevertheless receive compensation for participation in relation to the scope of the test performed.

7/ Data protection

By signing the form, participants grant consent to researchers for collecting and using their personal information for the purpose of the research. This item should clearly present to participants

how their information would be used. Ethical principles dictate that researchers should take care to protect the collected personal information and ensure anonymity with regard to third parties. Anonymity may be additionally assured by a commitment that only aggregate data would be presented.

Please be careful when preparing the text not to make promises you will be unable to keep or promises that would prevent you from suitably presenting the results. In case studies or research featuring a small number of participants, it is difficult to avoid the disclosure of information of (otherwise anonymous) individual participants in the presentation of results.

If the nature of the research dictates that the public presentation of results includes an identification of the source (e.g. quotes from interviews), such a possibility should be mentioned in this item. It should be stated that in such a case an explicit consent for publication will be obtained first. Such a consent may be a separate item of the same document or asked for later by a statement in writing.

This item should also specify the purpose of data collection and use in addition to the assurance of anonymity. Any possibility of short-term or long-term keeping of personal information or its forwarding to third parties should be specifically mentioned.

Example of Item 7

1. We will do all in our power to protect your privacy. Results of the test and the accompanying demographic information will be stored under a research password. Only the aggregate results will be made publicly available. Your identity will be in no case disclosed.

8/ Contact information

The purpose of the last item is to present contact information of persons and organisations where participants may obtain information on the research, pose questions or address comments and any complaints. It is customary to list at least the e-mail address and business phone number of the person conducting the research and the contact address of the ethics committee if the latter has discussed and approved the research proposal.

Example of Item 8

1. In the case of any additional questions, please contact the main researcher Alenka Mraz (e-mail: alenka.mraz@ff.uni-lj.si, phone: 01 241 9999) or the Ethics Committee of the Faculty of Arts (e-mail: keff@etika.ff.uni-lj.si.

Statement

After the presentation of the necessary information, the final task is to briefly and succinctly summarise the statement provide by the signature of the participant. It should be clearly stated that the participant has read the statement and has been given an opportunity to ask additional questions related to the research, that the participant has given voluntary consent to take part in the research and permission for the use of collected data for the specified purpose.

Statement example

1. By signing this statement I guarantee that I have read the statement and that I have been given an opportunity to pose questions in relation to the research. I hereby grant consent to my participation in the research "The effect of presentation of faces on recognition of emotions" and agree to the use of collected data for the purpose of teaching and scientific research.

Signatures

The statement is followed by names, signatures and signature dates for all parties to the agreement. The agreement is signed by the participant and, in the case of minors or persons lacking legal capacity, the legal custodian. On the side of researchers, the statement should be signed by the primary investigator and the person conducting the research.

Additional statements

Directly before or after the signatures, the form may contain additional statements whereby the participant gives explicit consent for any elements exceeding the purpose of informed consent. These may, for example, include:

- consent to repeated contact to take part in subsequent stages of the same study, or similar or other studies;
- consent to audio and video recording;
- permission for public citations.

Certificate

If the research is subject to approval by the ethics committee (at your university school), the last part of the form will represent a certificate of the ethics committee featuring the date of adoption and the stamp of the organisation whereby the committee confirms that the statement and the research proposal to which it relates comply with the rules and standards of ethics.

Form

The *Informed Consent* form has been prepared as a Microsoft Word document. Please use the template document when preparing the consent form by adding or changing the text highlighted in yellow.