Document 5.1: Instructions for preparing informed consent

Informed consent is one of the key tools to ensure the ethical relevance of research work and the protection of personal data in accordance with the EU General Data Protection Regulation (GDPR). In this respect, the ethical component of the relevance of the research relates only to the part that falls within the responsibility of the ECRFSS. Basically, informed consent is an agreement between the participant and the researcher to ensure that the participant is aware of all key elements of the research, and the participant gives the researcher permission to collect the necessary, often personal, information and use it for a specific purpose. The signed informed consent assures the participant how and for what purpose the data will be collected, protected, used and stored, and in the event of a breach of the agreement, provides the participant with a complaint tool. Consent enables the researcher to prove that the data were collected ethically and in agreement with the participants. Many scientific journals already require that informed consent is obtained for all data presented in the survey. There are two types of informed consent form: Form 5.1.A should be used when anonymizing personal information after obtaining them, and retaining the originals (pseudonymisation); Form 5.1.B should be used in the event that the personal data is destroyed immediately after anonymization.

The purpose of this document is to further detail and substantiate the elements of informed consent. The following will also include a presentation of how consent is obtained and stored.

Elements of informed consent

Each informed consent should present all the key elements of the research that are necessary for the participant to understand the purpose (content) of the research, what is expected of him or her, how long the participation will take, what will be the possible reimbursement for the time and effort of the participant, what are the potential direct benefits or risks related to the participation in the research, assurance that the participation is completely voluntary and can be interrupted at any time without delay, information on how the collected data will be used and stored, information on ensuring anonymity and confidentiality, as well as the contact details of the researcher (who conducts the survey) and the panel that approved the survey and to which the participant may address any questions or complaints.

In order to ensure that participants receive information in a transparent and comprehensible manner, the committee has prepared two standard forms (5.1.A for non-anonymized data; 5.1.B for anonymized data), in which the necessary information is provided in separate sections, presented below. In the case of standardized surveys, the invitation to participate in the survey (personal, telephone or online) must contain all the above mentioned key information. In this case, we assume that the participant has read (or heard, in a telephone survey) and understood the key information, and that he or she has answered (YES / NO) to all the categories of consent given when he or she agrees to participate in the survey. An example of good practice is an invitation to participate in the European Social Survey and an addition required for GDPR.

https://www.cjm.si/wp-content/uploads/2018/09/20180923_Obvestilno_pismo_anon.pdf

https://www.cjm.si/wp-content/uploads/2018/09/ESS_GDPR.pdf

Introduction

The purpose of the introductory point is to present who is conducting the research and what its purpose is. When presenting researchers, we indicate the PI (Primary Investigator), responsible for the design and control of the conduct of the research, and the research performer, responsible for the direct organization and conduct of the research. Often the two roles are united in one person. In the case of doctoral thesis and other research projects related to the study process, the PI is usually the mentor and the student is the research performer. In this case, it can also be noted that the research is being carried out within the scope of a doctoral (or other) thesis under mentorship. We always write down the exact title of the researchers and the organization in which they are employed or within which the research is conducted.

The purpose of the research should be described as clearly and concisely as possible in one or two sentences. When describing the purpose, as well as in all other points, the level of education and background of the participants must be considered. Information should be provided in a way that is also understandable to the participant with the lowest level of education and familiarity with the topic covered. Foreign words, abbreviations, and professional terminology should be avoided.

Example

You are invited to participate in a research, which is being conducted within doctoral study at the Department of Sociology, the Faculty of Social Sciences, University of Ljubljana, and is led by (title, name and surname of the doctoral student) and mentored by (title, name and surname of the mentor). The purpose of the study is to examine how older people experience and manage risks in old age.

Obligations of the participant

The purpose of the second point is to make clear what you expect from the participant, what his or her tasks and obligations will be as part of the research participation. If the study is based on the use of different questionnaires, write down how many questionnaires will need to be completed and what topics will be addressed. If the study involves an interview or focus group, briefly describe what content you are planning to discuss, what will be asked. If the study involves observation, write down what will be observed and what you will evaluate based on observation.

Based on this point, the participant should be clear about what you expect from him or her and what he or she can expect in the course of participation. Obligations and tasks that may be particularly difficult or unpleasant should be highlighted. When describing, it should be kept in mind that there should be nothing unexpected during the course of the study that would surprise the participant. Of course, exceptions are studies where the research plan is based on the surprise and "naivety" of the participant. In these cases, a slightly different treatment of the research is also required.

Please note that the purpose is not to provide detailed instructions for participation, but to briefly outline the tasks and expectations of the participant. Be brief, clear, concise.

Example

If you decide to participate, your task will be to participate in a focus group or group interview led by a moderator. He or she will ask everyone a few questions to answer or discuss together. At the beginning of the interview, you will be asked to fill in a short questionnaire about your

demographic characteristics. A group interview is usually recorded, but when the interview transcript is produced, your name is replaced with a fictitious name and the real name is deleted. This will ensure that your personal information does not appear anywhere when survey results will be published.

Scope of obligations and compensation for participation

The purpose of this item is to provide the participant with an informative estimate of the time and effort that the participant will require, and to provide information on whether and what compensation the participant will receive for his or her participation.

Be precise when making your timeline. Estimate how long the participation should take on average and how long in case of slower participants. Keep in mind that participants are often not adept at conducting tests and that they complete the questionnaires at a slower pace than you would expect. In any case, it is better for participants to finish earlier than expected than for participants to be dragged beyond what you have presented to them.

If participants receive a compensation for participation, please also indicate what kind of compensation they will receive. Be as specific as possible. If the compensation depends on the actual time, make clear what the compensation for each hour of participation will be. When planning a study, keep in mind that compensation should not serve as a form of incentive to participate. Compensation is by no means a payment for participation, but merely a compensation for lost time, effort and any costs directly linked to participation in the study (e.g. travel expenses).

If no compensation is provided, make a clear note of this. Remember, the purpose of consent is to clearly define the expectations of researchers and participants!

Example

The group interview will last for 1 hour and 30 minutes. You will not receive any financial compensation for your participation in the survey other than reimbursement of travel costs.

Risks and dangers of participation

Participation in research often involves a variety of hazards and risks. Both should be understood as any consequence that has a direct or indirect negative impact on the individual. If the survey involves interviewing people who have experienced a natural disaster, these may be negative feelings when experiencing a traumatic experience. If the survey involves filling in a large number of questionnaires, these may be feelings of fatigue or boredom.

Whether it is a case of a seemingly completely innocent "risk" or the likelihood of more serious hazards, in each case, participants should be made aware of all the possible negative aspects of participating in the research, as well as ways to reduce the risk or potential negative consequences (in the case of lengthy trials shorter, already planned breaks may be sufficient). When drafting the text, keep in mind that even from the perspective of the participant's satisfaction with the participation and his or her willingness to respond to the invitation to participate some other time in some other survey, it is much better to overestimate than underestimate the negative factors of participation.

Example

Participation in the research does not present specific risks. Due to the monotony of the ordeal and the increased level of attention required to perform the task, feelings of fatigue or boredom

may occur when performed. We will try to reduce this by frequent short breaks during the test. Participating in a group interview carries no risks. If necessary, we will take a break during the interview.

Benefits of participation

Like the potential dangers, the potential direct and indirect benefits, or more importantly, their absence, should be adequately presented. The purpose of the description of benefits is not to encourage willingness to participate, but also to set realistic expectations. For example, participation in an alternative teaching format will not be "rewarded" with a better grade. In the first point, make clear what the benefits will not be, then list the potential direct benefits for the participant, and then list the possible indirect benefits of the research.

Example

Participating in a group interview does not bring any specific benefits other than the knowledge and experience you will gain from participating and exchanging views with other participants. The results gathered will allow us to develop an understanding of young people's decision-making abilities to continue their studies at the Faculty of Social Sciences (or, for example, to understand the negative and positive factors in deciding on parenting).

Freedom of choice to participate

Freedom of choice to participate or not is central to meeting ethical standards and, although it may seem self-evident, this fact needs to be emphasized. In this point, it must be clearly ensured that participation in the survey is completely voluntary, that participation can be interrupted in any part of the research, that the participant may request the deletion of the data collected and that such termination of participation does not have any negative consequences. It is also worth pointing out that despite the interruption, participants will receive a reimbursement provided, if foreseen.

Example

Your participation in the survey is completely voluntary and you can cancel at any time without consequences and request deletion of the data collected. Even if you decide to stop the test for any reason, you will receive a reimbursement for your travel expenses.

Data protection

By signing the form, the participant agrees that the researchers may collect, use and store his or her personal data for the purposes of the research. At this point, the participant should be made clear about how his or her data will be used. Ethical principles dictate and the GDPR requires that researchers carefully protect the collected personal information and ensure its anonymity vis-à-vis third parties. Anonymity can also be ensured by the commitment that personal data will be destroyed immediately after anonymization and that only group information will be made public.

When writing, be careful not to commit to a promise you cannot fulfill or which would prevent you from presenting the results properly. In a case study or in studies with a small number of participants, it is difficult to avoid listing the data of individual (otherwise anonymous) participants in presenting the results.

If due to the nature of the research you want to identify the source of the results in the public presentation of the results (such as a quote from an interview, for example), it is important to

mention this option in this section. It should be noted that in such a case you will ask for explicit consent for publication. You can apply for the latter in a separate section of the same document, or you can obtain it later with a separate written statement.

In addition to ensuring anonymity, it also makes sense to record the purpose for which the data will be collected and used. The possibility of storing anonymised personal data or transferring them to third parties for scientific research purposes should be particularly emphasized if this is reasonable and necessary for the research plan.

Example

We will do our best to protect your privacy. The results of the group interview and the accompanying demographics will be stored under a random research code or fictitious name. Only group results will be published and made available. In no case will your identity be disclosed.

Long-term preservation and dissemination of research data

The participant should be informed about the intended further use of the data, outside the project or research in which we collect data. Funders of research and some scientific journals require that data be accessible in one of the field data archives. From 25 May 2018, when the EU General Data Protection Regulation (GDPR) came into force, the consent of the participants or the consent to participate in the research has become an obligation for all collectors of personal data unless there is another legal basis for the processing of personal data.

In view of the retention of the most sensitive data, which could lead to unwanted disclosure of participants and, consequently, the risk of harm, it is important to inform the participant that access to this information will be regulated and controlled.

Example of consent for non-anonymised data

I agree that the collected non-anonymized data is stored in a publicly accessible archive (e.g. in the archive of social science data) for at least 10 years. YES / NO

If YES, please indicate in what format[1]?

a) in a non-anonymized form, i.e. that personal information is not hidden or removed

b) in an anonymous form, i.e. that personal information is hidden or removed

I understand that other users may re-use the collected and stored non-anonymized data for educational and scientific research purposes and publish the results of their analyses in their reports. YES / NO

Example consent for anonymized information:

I agree that the collected data is stored in a publicly accessible archive in an anonymized form (e.g. in the archive of social science data) for at least 10 years. YES / NO

[1] In the event that a participant chooses to agree to the publication and storage of the collected personal data in a publicly accessible archive, he or she may still choose to have his or her identity hidden, i.e. to have his or her personal data published in an anonymous form.

I understand that other users may re-use the collected and stored anonymized data for educational and scientific research purposes and publish the results of their analyses in their reports *YES / NO*

Contact details

The purpose of the last point is to provide the contact details of persons and organizations where participants can obtain additional information about the research, ask questions or send comments and possible complaints. It is common to provide at least the e-mail address and business phone number of the research performer and the contact address of the Ethics Committee that has considered and approved the research proposal.

Example

In case of any additional questions, you can contact the researcher (title, name and surname of the doctoral student, email: _____@fdv.uni-lj.si, tel: xx xx xxx), the project leader (title, name and surname) or the Ethics Committee on Research at the Faculty of Social Sciences.

Statement

After presenting all the necessary information, the final task is to give consent to participate in the research and to use and retain the information obtained. In accordance with the GDPR, explicit consent is required for each of the categories listed in Form 5.1.A and Form 5.1.B.

Signatures

The statement shall be followed by the names, signatures and signature dates of all parties to the agreement. The agreement is signed by the participant and, in the case of minors or incapacitated persons, by their legal guardian. The statement shall be signed by the lead researcher and the surveyor.

Additional statements

Immediately before or after the signatures provided, the form may also contain additional statements whereby the participant gives explicit consent for items that go beyond the purpose of the informed consent. For example, these include:

- consent to be contacted again to participate in the following phases of the same study, as well as in related or other studies,
- consent to record audio and video recordings,
- consent to the public citation of citations.

Approval

The last part of the form is the approval of the research ethics committee, with a date of acceptance, confirming that the research statement and proposal to which it relates comply with ethical rules and standards.

Form

ECRFSS has prepared two standard informed consent forms (5.1.A for non-anonymized data; 5.1.B for anonymized data). When drafting the consent, use the appropriate prepared document in which you add or change the text in the yellow areas. Do not change the format

of the document except in exceptional cases (e.g. international project requirements), where the form must contain the required elements.