



TECHNISCHE
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WIEN

GUIDANCE DOCUMENT

INFORMED CONSENT: GOOD PRACTICE RECOMMENDATIONS

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1 General considerations

Your first contact to your research participants may be your informed consent documentation. This is where you establish a foundation of the relationship with your research participants, bringing to the forefront all the relevant ethical considerations, but also your legal commitments. Therefore, make sure you invest sufficient time in drafting your information sheet with which you create an image of your research and the tasks that you will invite the participants to be involved in.

The information sheet is usually written like a letter, starting with “Dear Participant”. Especially if you are conducting interviews or otherwise involving participants in personal engagement in your research, a friendly information sheet is likely to contribute to the trust building and a good rapport between your participants and yourself. There is no single one correct way to draft an informed consent information sheet and it need not follow a rigid form. More formality, however, is expected of your confirmations (declarations) of consent (see the end of this document). What is important is that you sufficiently communicate the relevant points listed in this guidance note. But it is up to you to make the document a kind invitation to participate in your research. You can be creative, feel free to use pictures, images and colors if you consider it helpful in communicating about your research and participation in it.

Participation is always voluntary

It is good to keep in mind that there is no obligation for anyone to participate in research; therefore, research participants (or, in case of questionnaire studies, respondents) must voluntarily, freely, explicitly and knowingly give their consent to research involvement as well as personal data processing.¹

Two kinds of informed consent

There are a number of similarities between the research ethical requirements and the data protection related legal requirements concerning informed consent. Both kinds of consent are needed for the appropriate involvement of human research participants at TU Wien when the research has to do with processing of personal data. Please note that your informed consent information sheet must include sufficient information that covers both the relevant aspects of research participation and the personal data that will be processed.

As a researcher, you have the responsibility of enabling your participants to arrive at an informed decision about research participation. This includes that you reflect on your research and how it can be made interesting for potential lay participants. Importantly informed consent is a trust building process between the researcher(s) and the participants and it requires some care – you tell them what your research is actually about, what kind of risks are foreseeable, also include benefits, if there are any, etc. Furthermore, this process can also be seen as contributing to overall trust in science.

¹ A key document that underlines the rights of research participants is the Declaration of Helsinki of the World Medical Association. Originally the necessity of voluntary consent was stated in the Nuremberg Code and its first item in 1947. See, for example, Ransome (2013).

You should give participants confidence in that protecting and securing their personal data are of utmost importance in your research. Explain that the processing of their personal data follows the strict principles and requirements of the General Data Protection Regulation (GDPR²) and other applicable laws and that you seek to guarantee the security and the accuracy of their personal data.

Language

Language is an important aspect of your informed consent documentation: any information that you provide must be understandable by your target group. This means: avoid technical jargon and use language that you can expect a person with a 6th grade reading level to understand.

Storing data

Please note that you as a researcher are responsible for the secure storage not only of the personal data that you collect for your research but also for the signed informed consent forms. The principle is to store such forms “under lock and key” and prevent any unauthorized access to the documents.

1.1 Basic requirements of an informed consent process

- “Consent” – the person to be involved must be able to give consent.
- “Informed” – the information sheet must provide a description of the research, its aims and what is expected of the participant, potential risks and benefits, and names and contact addresses of researchers.
- “Understandable” – information must be provided in language that can be easily understood and at a level that is appropriate for the target group. Avoid use of jargon.
- “Voluntary and free” – no one must be coerced, tricked or forced into participating in research; consent can be withdrawn at any time. Even if the law might allow you to pursue using personal data after withdrawal of consent, a responsible research practice requires you to respect the participant’s wish.

1.2 Exceptions to the requirement of written consent

The standard informed consent procedure involves obtaining a signature as a sign of confirmation of agreement to voluntary participation and personal data processing. There are some exceptional cases where obtaining written consent is not advised. Oral consent may be an option if you are working with illiterate persons, for example. If your work is such that obtaining informed consent in writing could place your participants or yourself at risk, you must address this question with your supervisor (students) and approach the TU Pilot Research Ethics Committee for a review (research staff). There are other contexts in which recording an oral consent, for example, at the beginning of an audio-recorded interview and backing this up with written and dated documentation can be an

² Regulation (EU) 2016/679 of the European Parliament and of the Council of 27 April 2016 on the protection of natural persons with regard to the processing of personal data and of the free movement of such data, and repealing Directive 95/46 EC General Data Protection Regulation.

option. If you opt for oral consent for any of your work you must prepare to have good reasons for it and keep documentation of obtaining oral consent. In case of oral consent, the information requirements are the same as with written consent.

1.3 Personal data

When processing your research participants' personal data, bear in mind that breaches of data protection legislation can have serious legal consequences. As a researcher you are responsible for handling all personal data with care. Negligence and breach of law can lead to damages and liability.

- **Personal data are:** any information relating to an identified or identifiable natural person, such as name, email address, date of birth, age, religion, identification number, location data, etc.
- Additional care must be paid to processing so called special categories of data because they are considered particularly sensitive. Special categories of data include the following information: racial or ethnic origin; political opinions, religious or philosophical beliefs, or trade union membership, and the processing of genetic data, biometric data for the purpose of uniquely identifying a natural person, data concerning health or data concerning a natural person's sex life or sexual orientation.

2 Research participation and processing of participants' personal data

2.1 Information sheet

To facilitate decision making about research participation and communicate the rights of research participants, you need to provide your prospective research participants an information sheet. In preparing information sheets³:

- Give participants a clear explanation of the aims, overall purpose, methods and implications of the research.
- Explain the purposes for which you collect/process personal data and the legal basis⁴ for the processing; which personal data are collected (name, e-mail, nationality, etc.). *
- Clearly state the name(s) of responsible researcher(s), institute(s) and the contact person who can answer any queries participants may have.
- Include identity and contact details of the controller. If you and your team determine the purposes and means of the processing of personal data (collection, handling, analysis, storing...), then you are the controller. *
- State the contact details of the data protection officer (DPO). *
- Explain that participation is voluntary. *
- Remind participants that they have a right to withdraw their consent at any time without any consequences and without providing a reason. *
- Explain the degree of benefit, risks, burden or discomfort involved in participation. Give an estimate of the time and effort expected of participants.
- Explain precautions to ensure participants' safety and provide information on insurance, if there is any.
- Explain who is funding the research and for what purpose.
- Disclose who will benefit from the research.
- Give a firm commitment to protecting participants' anonymity and privacy (provided that this can genuinely be guaranteed; otherwise explain how personal data will be protected). *
- State how and to which extent anonymity, pseudonymity will be guaranteed. *
- State duration of storage of personal data; when will data be deleted. *
- Make a clear commitment to treating personal and sensitive information confidentially.

³ Ransome (2013), provides a helpful check list that addresses the relevant aspects related to research participation and consent.

⁴ Please note that all point marked with * are mandatory from the perspective of the GDPR. You must address these points in your information sheet to your research participants.

- Reassure participants that there are secure procedures for storing and analyzing any data gathered.
- Explain clearly who will have access to any data that participants provide. If data are transferred to countries outside the EU or international organizations, please state where. *
- Consider any unintended/unexpected/incidental findings and explain how you intend to deal with such findings.
- Explain briefly where research findings will be published.
- Offer to provide participants with further information about research if they ask for it.
- Clarify possible uses to which data may be put in future (if this is envisaged) and clarify whether participants will be asked for consent again if this is the case. *
- Remind participants that they have a right to appeal: In connection with the processing of their personal data, participants are entitled to information, rectification, erasure, restriction of processing, data portability, and withdrawal. *
- Inform participants that the right to information, rectification, and restriction of processing may be restricted if such rights are likely to render impossible or seriously impair the achievement of the purposes according to Article 89 Sec 2 GDPR. *
- Inform participants that they can contact the Data Protection Authority (Austrian Data Protection Authority (DSB), Barichgasse 40-42, 1030 Vienna) if they believe that the processing of their data violated data protection law. *

2.2 Confirmation of consent

There are two separate confirmation forms to ensure that informed consent has been appropriately obtained: one for participation and one for processing of personal data. You need to have each aspect covered and confirmed with a signature. Keep one copy for yourself and give another to the participant.

2.2.1 Confirmation of consent: research participation

In this section, the participant is asked to confirm with their signature the following:

- Receipt of information about the research and what the participation entails;
- Having understood the information that they have been provided;
- Having had a chance to ask questions and them being answered to the participant's satisfaction;
- Having been informed about the background of the research, names and contact details of contact persons;
- That they voluntarily participate in the research;
- That they have been informed that they can withdraw their consent, at any time, without having to give reasons, and without any consequences.

The confirmation is dated, signed, both by participant and researcher obtaining consent. Do not forget to add the names of the participant and researcher in block letters.

2.2.2 Confirmation of consent: processing of personal data

Minimum content requirements for consent to processing personal data:

- Reference to project;
- Personal data being collected;
- Period for which data will be stored;
- Right to withdraw at any time and procedure / consequences of withdrawal;
- Declaration that consent is being made on voluntary basis and that participant has been advised of information rights under GDPR;
- Name, date of birth, place, date, signature of participant / legal guardian.

The confirmation is dated, signed, both by participant and researcher obtaining consent.

3 References

European Commission (2018). Ethics in Social Science and Humanities (Version 5 July 2021). Online: https://ec.europa.eu/info/funding-tenders/opportunities/docs/2021-2027/horizon/guidance/ethics-in-social-science-and-humanities_he_en.pdf

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Israel, M. (2015). Research ethics and integrity for social scientists: Beyond regulatory compliance (2nd ed.). SAGE Publications Ltd <https://www.doi.org/10.4135/9781473910096>

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