UNIVERZA V LJUBLJANI

Guidelines

# FOR ETHICAL CONDUCT IN RESEARCH INVOLVING HUMAN SUBJECTS

*(Revised in 2025)*

## 1. The need for ethics assessment

The care for the benefit of participants in research represents a fundamental ethical principle of scientific research. The primary concern of ensuring ethical conduct is the responsibility of the person designing and conducting the research. They must be familiar with the relevant legal acts (e.g. Personal Data Protection Act – ZVOP-2 and the General Data Protection Regulation – GDPR) and rules and codes of ethics of professions and scientific disciplines in which they work. The fundamental trust in ethical conduct of researchers notwithstanding, it should be noted, however, that scientific research can be, despite its primary goal of societal progress, occasionally in conflict with the interests and well-being of individuals participating in research, while designers and performers of research can encounter conflicts of interest.

To ensure the optimal protection of the interests and well-being of research participants, it is necessary to protect their personal data and to consider the criteria of ethics assessment in the process of the preparation and implementation of scientific research.

## 2. Personal data protection

For the protection and security of personal data, it is necessary to comply with the applicable legal framework, i.e. the Personal Data Protection Act (hereinafter: ZVOP-2)[1] and the General Data Protection Regulation (hereinafter: GDPR)[2].

According to Article 4. of GDPR, »personal data« means any information in relation to an identified or identifiable natural person; an identifiable natural person is one »who can be identified, directly or indirectly, in particular by reference to an identifier such as a name, an identification number, location data, an online identifier or to one or more factors specific to the physical, physiological, genetic, mental, economic, cultural or social identity of that natural person«.

[1] https://pisrs.si/pregledPredpisa?id=ZAKO7959
[2] https://eur-lex.europa.eu/eli/reg/2016/679/oj/eng

There is a specific category of personal data, known as *special categories of personal data,* such as personal data revealing racial or ethnic origin, political opinions, religious or philosophical beliefs, trade union membership, genetic data, biometric data for the purpose of uniquely identifying a natural person, health data, data concerning the individual's sex life or sexual orientation, data on entry or deletion in/from criminal and misdemeanour records and transfers of such data - the processing of which is, due to their sensitivity, justified only if specific additional conditions are met (see Article 9 of the GDPR and ZVOP-2).

»Processing« of personal data means »any operation or set of operations which is performed on personal data or on sets of personal data, whether or not by automated means, such as collection, recording, organisation, structuring, storage, adaptation or alteration, retrieval, consultation, use, disclosure by transmission, dissemination or otherwise making available, alignment or combination, restriction, erasure or destruction« (Article 4 of the GDPR).

If personal data are to be processed as part of the research, compliance with all principles relating to the processing of personal data, as defined in Article 5 of the GDPR, must be ensured.

If personal data are transferred to other countries (e.g. non-EU countries), compliance with the relevant national and European regulations must be ensured, and the appropriate level of personal data protection in this other country secured.

Scientific research is often based on the analysis of personal data of individuals for whom there is no specific need to be identified. If it is not necessary to disclose the identity of individuals (which is most often the case), we anonymise or pseudonymise their personal data. Anonymisation ensures that individuals can no longer be identified from the data. Anonymised data also no longer have the status of personal data and are therefore not subject to GDPR requirements.
»**Anonymisation** is generally based on the use of specific methods and techniques that we use to de-identify data so that, as a rule, no one can determine to whom they refer. Such methods usually include statistical processing (calculation of averages, proportions, trends, etc.) to derive individual data from multiple personal data, adding noise, generalisation and randomisation, and other methods to ensure that it is no longer possible to identify a specific or identifiable individual from the data. […] **Pseudonymisation** generally means a one-to-one mapping, where raw personal data are replaced with artificial codes (pseudonyms), thereby reducing the likelihood that unauthorised persons will discover to whom the data actually refers. Pseudonymisation secrets that enable data to be attributed to identifiable individuals exist, but access to them is restricted. […] Pseudonymisation should not be considered the same as anonymisation of personal data, as pseudonyms are still considered personal data – pseudonymised data can still be attributed to an identifiable individual, but this requires an additional step.«[3] Where possible, anonymisation as complete de-identification of data should be performed at the time of collection or at the source (e.g., by submitting anonymous surveys); otherwise, the collected data and the list through which the data can be linked to the identity of the participants must always be stored separately. As soon as such a link is no longer necessary, the list must be destroyed, thus preventing the identification of individuals from the collected data.
In practice, the identification list is always kept only by the responsible researcher, who shares the data from the list if needed and only to those research collaborators who require these data for their work. This minimises the number of people who can identify concrete individuals from the data and thus the possibility of misuse.

[3] Translated from the website of the Information Commissioner of the Republic of Slovenia: https://www.ip-rs.si/zakonodaja/reforma-evropskega-zakonodajnega-okvira-za-varstvo-osebnih-podatkov/klju%C4%8Dna-podro%C4%8Dja-uredbe/psevdonimizacija

In practice, we strive to collect only the data that are strictly necessary for conducting the research, and we limit access to identification data to only those individuals and for the period of time for which they need the data. Every researcher who collects data on individuals as part of their research must ensure:
a) the separate collection and storage of the collected data from the additional information (e.g. master keys) that allow identification of individuals from the collected data, and
b) the timely destruction of identification data.

If the de-identification or anonymisation of personal data cannot be applied, the storage and protection of personal data must be ensured in accordance with the applicable legal provisions.

An effective way to control the management of personal and research data throughout the entire research process is to prepare a Data Management Plan (DMP), the format of which may depend on the funder, research organisation, and research field.[4]

## 3. Ethics assessment

Any research involving working with people or the processing of personal data generally requires ethics assessment. The detailed nature of an ethics assessment is determined by specific features of individual research.

The ethics review of the research proposal includes an assessment of whether:

- the proposed study addresses a substantiated question of research
- the recruitment of participants is appropriate
    - participants have the ability and capability to freely decide whether to participate
    - participants are under no pressure to participate
    - participants are not offered remuneration more than compensation of costs
    - participants are not promised unrealistic benefits and advantages
    - participants are appropriately presented with the study
    - an example of an appropriate protocol of addressing candidates for the study is provided with the application
- the method is appropriate
    - the method enables answering the posed research question
    - the process poses no danger to participants
    - the process does not pose excessive burden on participants
    - the process does not involve unnecessary or excessive exposure to stress
    - the process does not involve unnecessary or excessive exposure to offensive or emotionally burdensome stimuli and content
    - an example of appropriate non-standard stimuli or instruments is provided with the application
- transparency of the research is ensured / appropriate additional measures are taken in case of covert research
    - participants are informed on the actual purpose of the research

[4] For doctoral students, the University of Ljubljana has prepared NRRP forms, which are available here: https://www.uni-lj.si/en/study/doctoral-study/research-data-management

    - the purpose of the research is suitably presented before its execution
    - the use/development of artificial intelligence tools is defined, and the risk assessment of their use/development is ensured
    - in the case that covert research or naive participants are required, the justification for using this method is satisfactorily explained, and the protocol includes appropriate debriefing of participants after the completion of the research
- appropriate measures are envisaged in the event of risks to health, the environment or safety
    - in the case of extraordinary or dangerous circumstances/situations (identification of a danger or threat to participants, other persons or the environment), an appropriate mitigation protocol is in place and provided with the application
- competence of performers
    - persons conducting the research have the appropriate knowledge and competence to perform the study
    - persons conducting the research have permits to use the proposed instruments
- informed consent will be suitably obtained
    - the process of obtaining consent is appropriately set up
    - the "Statement of the conscious and free consent to participation in the research" featuring all necessary elements is enclosed
- personal data protection is ensured
    - in the case of anonymisation, data are stored under codes that do not allow identification of the data
    - in the case of pseudonymisation, the keys needed to identify codes/individuals are stored separately from the data
    - the acceptable deadline for data de-identification is specified
- the timeline of the study is acceptable

## 4. Participants

**Number and description of participants**

The number of participants should be sufficiently large to enable the verification of hypotheses. Due to the possibility of participants terminating participation and the loss of results due to technical reasons, it is permissible to plan work with a slightly higher number of participants than would be necessary; however, it is unacceptable to excessively increase the number of participants. When possible, the substantiation of the planned number of participants should be supported by an appropriate power analysis of the study. The description of participants should clearly specify the planned sample of participants and present the inclusion and exclusion criteria for participant selection. These criteria have to ensure that neither inclusion or exclusion from the possibility of taking part in the research are subject to any unfounded bias or discrimination.

**Manner of recruiting participants**

Researchers should describe the method of forming a sample and the way in which participants would be invited to take part in the research. On the one hand, it should be ensured that potentially interested individuals have equal opportunities to take part in the research and, on the other hand, any form of using force to ensure participation in the research or obtaining participants through deceit should be avoided. Participation in a research project should always be a free choice and decision of the individual, based on clearly presented key information on the research.

The assessment of whether participation is truly voluntary should consider that coercion may take various forms, some of which may be difficult to detect. Participants should always be aware that their participation is completely voluntary and that their well-being is in no way dependent on it, in either positive or negative sense. There should be no negative consequences, explicit or implicit, for individuals who refuse to participate in the survey, regardless of whether the likelihood of such consequences is significant or negligible. Particular attention should be paid to prevent participants agreeing to take part in a research project due to social pressure or pressure from an authority. At the same time, individuals deciding to take part in a research project should not expect any benefits exceeding the knowledge and experience gained through participation in the research, or exceeding the minimum compensation for the time and effort invested and reimbursement of costs directly related to participation in the research. High monetary award, promise of a higher grade or privileged treatment represent an inappropriate form of inducing participation in a research project.

The description of the manner planned to recruit participants should explain how participants will be informed about the research, who will approach them, and what information they will receive. In situations where there is a risk that participants may feel pressured to participate, it is particularly important to provide a detailed explanation of how they will be assured that their participation is completely voluntary.

**Possible compensation for participation**

By taking part in a research study, participants offer the researcher their time, energy and good will. In many cases, however, their participation also comes at an additional cost to them. If possible, participants should be offered appropriate compensation for the time spent and reimbursement of their costs. However, care must be taken to ensure that the anticipated compensation does not exceed the actual costs and reasonable remuneration for time spent, as payments and financial incentives for participation, as mentioned above, are not acceptable.

## 5. Research plan

It is advisable that researchers prepare a research plan, presenting the basic outline of the research. The plan should describe the number of groups into which participants would be divided, how the groups would differ, and which variables (factors and their respective levels) would be controlled and measured. It should also present a timeline of the research featuring information on the planned time needed to a) make preparations, b) recruit participants and collect data, and c) analyse data. It should further contain any information on participating organisations and their consent to take part in the research study.

**Procedure**

The procedure contains a detailed description of the execution of the research task. The content of this section depends on the area of research and the approach used to conduct the research. The most often presented topics are descriptions of instruments and tests used, and instructions for participants.

**List of instruments and tools**

Here, researchers list all instruments and tools to be used in the research. A brief description and the purpose of its use should be given for each instrument. An appropriate reference document where the instrument is described should be given for standard instruments and tools. In the case

of instruments developed by researchers themselves, a detailed description of their content and measurement properties should be included. The listing of instruments should include information on who will use them and information on their qualification to operate the instrument. An assessment of the duration of use of a particular instrument should be provided as well.

**Description of experimental tasks and processes**

If the research involves the performance of one or several behavioural tests or other experimental tasks or processes, the researcher should describe each of them in this section of the research plan. The description should contain the stimuli and conditions applied, the course of the test, the tasks of participants and the measured variables. The researcher should also include information on the number of tests and any breaks, and an assessment of the entire time that would be needed to conduct the test.

**Instructions to participants**

In this section, the researcher should describe instructions that will be given for each part of the execution of research. In the case of standardised instructions, they should be added to the research plan as an attachment.

The description of procedure should be concluded by an estimate of the total time necessary for the entire protocol of the conduct of the research.

## 6. Informed consent for participation

Voluntary and informed consent for taking part in a research project is a fundamental ethical principle of scientific research. The key document to ensure it is the *Informed Consent* form, which should be, as a general rule, read and signed by each participant in a scientific research study and/or by their legal guardian.

The consent of participants is generally confirmed by the signature of the *Informed consent for participation in the research* form. The content of the form is described in detail in the document *Informed consent: instructions for preparation.*[5] The task of researchers in this section of the application is to describe the way in which consent will be obtained. In the case of obtaining consent orally, reasoning for not obtaining written consent should be given. In the case of research involving covert investigation or deception, the researcher must justify this appropriately and, additionally, describe the process of debriefing after data collection has been completed.

**Obtaining consent**

The task of researchers is to describe how and when the research task and other elements covered by informed consent will be presented in detail to the participants and how participants will be given an opportunity to pose any questions about the purpose of the research and the details of their participation. If possible, it is important that the researcher presents the research, responds to questions and obtains consent *in person*. Indirectly obtaining consent through mail or through teachers or pupils is not appropriate, as participants and their guardians are then prevented from posing questions and receiving full information on the research *before* giving consent. When the nature of the research prevents the researcher from personally obtaining consent, the presentation

[5] https://www.uni-lj.si/en/research/ethics-and-integrity-in-research/ethical-assessment-of-research-involving-human-subjects

of the research may be entrusted to their collaborator, who must be suitably informed on all key elements of the research. In such a case, the person presenting the research will sign the informed consent form.

It is crucial that the process of obtaining consent is focused on actual participants in the research. This also applies to children, minors or those with a legal guardian: if the participant can read, they should read and sign the informed consent form, and the text of the form should be adapted to suit their level of comprehension. If the participant is unable to read, the task of the researcher will be to present verbally all key elements of consent and ensure that the participant understands them. The best way to ensure understanding is to ask participants to repeat and present, in their own words, the key elements. Parental or guardian consent for a participant's participation in a research study must be obtained only after the participant has given their assent demonstrating a clear understanding of the study's purpose, their role and responsibilities, the potential benefits and risks, as well as the fact that participation is completely voluntary and may be terminated at any time without consequences.

**Omission of the written consent**

In some cases, consent in writing would be undesirable or virtually impossible to obtain. A possible case would be a research project where merely revealing that an individual has participated would represent an unacceptable level of risk for the participant. An example would be a study of sexual behaviour of HIV infected individuals – if oral consent is appropriately obtained, consent in writing may not be required.

In such cases, research may also be conducted without obtaining prior consent if the following conditions are met:

- the research does not pose more than a minimum risk to the participant; and
- the rights and well-being of the participant have not been infringed upon.

Another example includes studies where obtaining consent would have a direct effect on research results and hinder examination of the research problem. This is often the case in observational studies and/or studies where the researcher intentionally guides participants through specific social situations. In such cases informing participants in advance and obtaining consent beforehand could fundamentally alter their individual behaviour and group interactions. Similar applies to studies that involve various forms of deceit and/or require participants to remain unaware of certain stimuli or aspects of the research plan. When this type of covert research poses no more than minimal risk to participants, certain critical substantive elements can be omitted from the informed consent form or the form itself could be omitted entirely, provided that the reasons for conducting covert research are justified and that an appropriate debriefing procedure is planned after the research has been completed.

**Debriefing**

In the case of studies where consent form has been omitted or altered due to the requirements of the research plan, a debriefing of participants should be organised after the research is completed in order to inform them of the actual nature of the study and the reasons for omitting consent or using deceit, and in order to obtain their consent to use the collected data. The task of the researcher is to present in the application for an ethics assessment how and when the debriefing would take place and how the consent to use results would be obtained. If debriefing is made in writing as well, it should be provided with the application. When no consent is obtained prior to the collection of results, the consent to use results should be obtained in writing after data collection has been completed. When consent in writing has been obtained, oral consent to use results should be obtained after debriefing, and participants should be given an option to opt out of the research. In both cases, the procedure should be appropriately presented in the application for an ethics assessment.