

INSTRUCTIONS FOR COMPLETING AN APPLICATION FOR THE APPROVAL OF THE ZRS KOPER ETHICS COMMITTEE

COMPETENCES OF THE COMMITTEE

The ZRS Koper Ethics Committee grants approval for the implementation of research involving human participants as a source of information and data. The Committee considers only applications for which there is a potential risk relating to the protection of research participants; it does not review applications for research involving more invasive “interventions on the body”. In such cases, the application must be approved by an ethics committee for medical matters. The same applies to research involving more complex psychological instruments/interventions; in such cases, it is more appropriate for applications to be decided by the relevant ethics committees (e.g. the Ethics Committee of the Slovenian Psychological Association, the Ethics Committee of psychologists at the Faculty of Arts of the University of Ljubljana, etc.).

The objectives of the Committee are to ensure for research participants:

- respect for human dignity and integrity;
- honest and transparent information;
- respect for human autonomy and the obtaining of voluntary and informed consent and assent;
- protection of particularly vulnerable individuals;
- protection of privacy and confidentiality;
- promotion of fairness and inclusion;
- minimisation of harm and maximisation of benefits;
- respect for and protection of the natural environment and future generations;
- compliance with national and international legislation.

The Committee does not assess the appropriateness of the methodological instruments.

The application submitted to the Committee must contain: a project description, measures for protecting rights, a research data management plan (data protection and privacy), and a checklist.

The individual points are specified below:

1. PROJECT DESCRIPTION

- Title and brief description of the project;
- research leader(s);
- time and place of implementation;
- target group (sample and sampling);
- brief description of the methodology;
- which data are collected and processed in the research.

2. MEASURES FOR THE PROTECTION OF RIGHTS

- Information sheet provided to research participant(s);
- attached informed consent and statement of voluntary participation;
- information on any compensation (monetary or in another form);
- risk assessment for research participant(s); assessment/monitoring and mitigation of potential risks (e.g. description of an intervention protocol).

ADDITIONAL EXPLANATIONS: The information sheet contains all key information about the implementation of the project in a simple, understandable and accessible manner (research title, purpose, place and time of implementation; what data will be collected and how; how the person will participate in the data-collection procedure; who is responsible for implementation, including the responsible person's email address and telephone number). If participants are children or other vulnerable groups, or persons who do not speak Slovenian, the information must be provided in a language they can understand (for preschool children, visual presentations may also be used). The key requirement is to ensure genuine understanding of the purposes of the research.

The information sheet must also specifically highlight the possibility of permanent or long-term storage of personal data or their transfer to third parties or publication in the public domain.

The application must also contain informed consent. Informed consent is one of the key tools for ensuring the ethical appropriateness of research work. Informed consent is an agreement between participants and researchers. It ensures that participants are informed about all key elements of the research and give the researcher permission to collect the necessary data and use them for a defined purpose. Signed informed consent tells participants how and for what purpose the data will be collected.

The wording of the informed consent must be adapted to the level of understanding of the persons included in the research. If a child/person cannot read, it is the researcher's responsibility to present all key points of the consent orally and ensure

understanding. Visual presentations may also be helpful. A participant shall sign the informed consent only once it has been established that they fully understand the purpose of participation, the consequences and any potential risks. In exceptional cases, consent may also be obtained in recorded form.

The informed consent must contain the elements set out in the example below.

I, the undersigned:

- confirm that I have been fully informed about the content of the research and that I have had the opportunity to ask questions concerning the research and have received answers to them;
- consent to participate in the research;
- understand that I may withdraw from the research at any time without giving a reason and without consequences;
- have been informed that the research has been approved by the Ethics Committee of the Scientific Research Centre Koper;
- agree that anonymised data obtained in the research may be used for research purposes (e.g. publication in scientific publications, project reports, long-term storage in repositories);
- agree to the publication of photographs on the project website, etc.

The above text is only an example and must be adapted to the actual research.

A researcher may use data collected in the research only for the purposes for which consent has been obtained.

The informed consent shall be signed by the person participating in the research. In the case of minors, it shall be signed by the child and their parent/guardian/legal representative.

3. RESEARCH DATA MANAGEMENT PLAN — DATA PROTECTION AND PRIVACY

- Description of data anonymisation/pseudonymisation;
- description of how data will be used, stored and transferred in the short term and long term, and the right to long-term access to data (e.g. FAIR access to research data);
- the details of the person responsible for research data management must be provided;
- a plan for handling “unexpected, unintentional and accidental” data/findings must be provided.

ADDITIONAL EXPLANATIONS: Ethical principles require researchers to carefully protect the personal data collected and ensure their anonymity vis-à-vis third parties. Anonymity may also be ensured through publication of group/aggregated data or through anonymisation or pseudonymisation. If, due to the nature of the research, a person wishes their source to be identified in a public presentation of the results, this possibility must also be stated in the informed consent.

It must be specified how the data will be stored in the short term (during the project) — who will have access to the data during this period and how the data will be shared — and in the long term (after completion of the project).

The contact details of the responsible person (first name, surname, personal telephone number and email address) and of the organisations where participants can obtain additional information about the research, ask questions or submit any complaints must also be provided. These details are also included in the informed consent.

The application must contain a brief protocol/plan for dealing with “unexpected, unintentional and accidental” data/findings that may arise during the research (e.g. what will be done in the event of suspected abuse or violence involving a child or adult participating in the research, or if information is obtained indicating a criminal offence or an intention to commit a criminal offence, etc.).

4. CHECKLIST

Does my application contain ... YES NO

1. title and brief description of the project
2. details of the research leader
3. time and place of implementation
4. target group (sample and sampling)
5. description of the methodology
6. description of the data collected and processed in the research
7. information sheet
8. informed consent
9. information on any compensation
10. risk assessment
11. description of data anonymisation/pseudonymisation
12. description of how data will be used, stored and transferred in the short and long term, and the right to long-term access to data

13. details of the person responsible for research data management

14. plan for handling “unexpected, unintentional and accidental” data/findings

When preparing the application, you may consult the following documents:

1. Ethics in Social Science and Humanities:

https://ec.europa.eu/info/sites/default/files/6._h2020_ethics-soc-science-humanities_en.pdf

2. H2020 Online Manual on Ethics:

https://ec.europa.eu/research/participants/docs/h2020-funding-guide/cross-cutting-issues/ethics_en.htm

Chair of the ZRS Ethics Committee Prof. Dr Mateja Sedmak, Research Counsellor

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