



ZRC SAZU

This is an unofficial translation of the original document in Slovenian; in the event of any discrepancies, the original Slovenian document shall prevail.

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Pursuant to the ZRC SAZU Code of Research Ethics and Integrity (no. P-2023-5) and Article 14 of the Statute of the Research Center of the Slovenian Academy of Sciences and Arts (no. S-2024-3), at its tenth meeting held on November 28th, 2024, the Board of Directors of the Research Center of the Slovenian Academy of Sciences and Arts adopted the following

RESEARCH ETHICS REVIEW POLICY AT ZRC SAZU

Article 1

This policy specifies the procedure for the ethics review of research (research projects) conducted at ZRC SAZU that involves human participants.

An ethics review is carried out by the ZRC SAZU Ethics, Integrity, and Equal Opportunities Committee (hereinafter: the EIEO Committee) when this is applied for by individuals carrying out research projects at ZRC SAZU.

Article 2

The purpose of an ethics review is to examine in advance the aims and methods of the planned research to check whether it complies with the internationally established principles, standards, and guidelines of research ethics.

The EIEO Committee does not adjudicate on research that falls within the purview of national research ethics review committees.

Article 3

The EIEO Committee follows internationally established ethical guidelines, which are based on respect and concern for the wellbeing of individuals participating in research. It assesses whether the following principles have been adhered to:

a) Research activities raising ethical issues are based on a well-founded research question and appropriate methods, with expected benefits clearly outweighing the potential risks to the participating individuals.

b) The following aspects are considered when recruiting participants for the research:

- Participation in the research is voluntary;
- Participants can withdraw from the research at any time;
- Except in exceptional, justified cases, participants are not promised any remuneration beyond reimbursement of expenses;
- Participants are not promised unrealistic benefits and advantages;
- The research purpose and process are presented in a way that is easy to understand;
- The selection of participants is based on appropriate inclusion criteria; where relevant, different groups of people will be properly represented in the sample;
- Reasons for including vulnerable people and groups are clearly presented.

c) The wellbeing of research participants is properly provided for:

- The research does not endanger the participants;
- The research does not require excessive effort from the participants;
- The research does not expose the participants to undue stress;
- The procedure does not include unnecessary or undue exposure to emotionally stressful stimuli and content;
- When working with vulnerable individuals and groups, measures are in place to prevent risks associated with their vulnerability and potential stigmatization;
- When working with vulnerable groups or traumatized individuals, the research plan includes a supportive conversation and, if necessary, psychosocial support;
- When working with vulnerable groups or traumatized individuals, researchers have access to psychosocial support;
- Reporting the research results is not based on prejudice.

d) Appropriate measures are taken to obtain consent to participate in the research, which is based on informing participants about the research aims and risks:

- An appropriate procedure for obtaining consent is defined;
- It is clarified how consent will be obtained from minors and adults that are unable to provide consent on their own.

e) Appropriate measures are taken to protect, store, and archive personal data:

- An appropriate data anonymization or pseudonymization procedure is defined;
- If data are not anonymized, appropriate justification must be provided;
- Data are stored under codes that do not allow identification;
- Information required to identify the codes is stored separately from the data;
- An acceptable deadline for destroying the identification codes and other data is defined;
- Data storage in trusted repositories is described;
- Only data relevant to the purpose of the research are collected.

f) The research is conducted transparently:

- Participants are informed about the research purpose;

- If the research requires deliberate nondisclosure of its objectives or subject matter while engaging with participants, the participants are informed of the true objectives and subject matter of the research after it has been completed.

g) The individuals conducting the research have the appropriate knowledge, competence, and authorizations to use the proposed instruments, procedures, and materials.

h) In the event of an emergency or unforeseen findings (e.g., identifying dangers or risks to participants, researchers, or third parties; disclosure of criminal offences, abuse, etc.), an appropriate procedure for handling such situations is foreseen.

For all other ethical issues, the EIEO Committee follows internationally recognized ethical guidelines in the relevant fields and seeks additional expert advice where necessary.

Article 4

The application for a research ethics review is submitted by the individual that will conduct the research. The application, submitted in written electronic form, is addressed to the EIEO Committee.

The application contains the following elements:

1. Basic information about the research project:

- Research title;
- Research funder(s);
- Principal investigator and individuals conducting the research;
- Research field.

2. Research plan:

- A brief summary of the research;
- A definition of research problems, objectives, and methods;
- Expected contributions to science and society;
- Research timeline;
- Research data management plan;
- Competences and authorizations of individuals conducting the research.

3. Individuals participating in the research:

- Method of recruiting and sampling participants;
- Number of participants;
- Criteria for selecting the research participants;
- Presenting reasons for including vulnerable individuals and groups;
- Manner in which individuals will be invited to participate in the research;
- Information on whether the participants will receive compensation for participating in the research.

4. Individuals' consent to participate in the research and have their personal data collected:

- A description of how participants will be informed in advance about the research objectives, methods, potential risks, and benefits;
- A description of how consent will be obtained;

- A consent form and an information sheet must be attached;
- Procedure for studies requiring deliberate nondisclosure of research objectives or subject matter.

5. A description of research activities involving participants:

- A detailed description of the methods, procedures, and instruments used for data collection;
- A description of the procedure and duration of the research involving participants;
- A description of quantitative/qualitative data analysis procedures.

6. Ethical issues:

- An assessment of the risks and benefits for the individuals participating in the research;
- A presentation of the measures taken to prevent or reduce the risks;
- Measures to protect vulnerable individuals and groups during and after the research (supportive conversations, psychosocial support, etc.);
- A description of the procedure to be followed in the event of an emergency or unforeseen findings (e.g., identifying dangers or risks to participants, researchers, or third parties; disclosure of criminal offences, abuse, etc.).

7. Data protection and confidentiality measures:

- A description of the types of data to be collected;
- A description of how data will be coded and stored;
- A description of data anonymization or pseudonymization procedures;
- Justification for not anonymizing data;
- A description of how data will be stored in trusted repositories.

The EIEO Committee may post additional instructions and forms related to the application on its website.

Article 5

The EIEO Committee appoints a person to examine the research ethics review applications. This is to determine whether the applications contain all the elements specified in Article 4 hereof.

If the application submitted is incomplete, the person examining it must, within seven days, request the applicant to provide the missing information. After confirming that the application is complete, they notify the EIEO Committee's Chair.

Article 6

The EIEO Committee's chair assigns the research ethics review application to two members of the committee for review.

The members review the application and submit the following to the EIEO Committee's chair:

- An assessment of the key elements of the application that are subject to ethical review;
- Any additional comments and instructions for the applicant;
- Any additional comments for the chair of the EIEO Committee and its members;

- A proposed decision on the application.

The members of the committee present one of the following decision proposals to the chair:

- The research is ethically appropriate, which means that the researchers are aware of the ethical issues raised by the research and have prepared appropriate measures to address them;
- Ethical appropriateness of the research can be confirmed if the comments of the EIEO Committee have been taken into account and appropriate modifications have been made to the application or research plan;
- The application requires extended review in accordance with Article 7 hereof;
- The application does not fall within the purview of the EIEO Committee.

Article 7

The chair assigns a research ethics review application requiring extended review to at least three committee members.

Extended review is conducted if:

- More complex ethical issues are involved and the research poses a significant risk to participants;
- Additional expert opinion should be obtained for proper assessment;
- If the two reviewers assigned (Article 5) cannot reconcile their positions.

If a specific expert opinion is required for the review, the EIEO Committee obtains the opinion of an external expert specializing in the relevant field (this person does not have to be employed by ZRC SAZU).

The members to whom an application is assigned for review carry out the activities outlined in the second paragraph of Article 6 hereof.

They submit one of the following decision proposals to the EIEO Committee's chair:

- The research is ethically appropriate, which means that researchers are aware of the ethical issues raised by the research and have prepared appropriate measures to address them;
- Ethical appropriateness of the research can be confirmed if the comments of the EIEO Committee have been taken into account and appropriate modifications have been made to the application or research plan;
- The research is ethically inappropriate;
- The application does not fall within the purview of the EIEO Committee.

Article 8

A research ethics review application cannot be assigned to an individual that is conducting the planned research or if circumstances exist in relation to this individual that could affect or appear to affect the impartiality and objectivity of the review.

Article 9

The individuals reviewing the application are bound by confidentiality.

Article 10

The individuals assigned to review the application present it at an EIEO Committee meeting, appointing a reporter for this purpose.

Article 11

The EIEO Committee adopts an opinion on the research compliance with the ethical principles at its meeting in the form of a decision. The decision is normally adopted unanimously by all the members present at the meeting. Only in exceptional cases, when unanimity cannot be reached after an exhaustive discussion, is the decision made by a majority vote.

The EIEO Committee, after discussing the application at its meeting, adopts one of the following decisions:

- The research is ethically appropriate;
- The application must be revised or modified;
- The research is ethically inappropriate;
- The application does not fall within the purview of the EIEO Committee.

Article 12

In the event of complex ethical issues, the EIEO Committee may require that, while conducting the research, researchers submit a report on implementing measures to address the ethical aspects of the ongoing research.

Article 13

After adopting a decision, the EIEO Committee forwards it to the applicant.

A decision confirming the appropriateness of the research may contain an explanation and additional advice.

A decision to revise and/or modify the application contains comments, explanations, and further guidance. The applicant must clearly mark changes in the revised application.

Decisions declaring the research ethically inappropriate or that the application is outside the EIEO Committee's purview include an explanation.

Article 14

The EIEO Committee adopts a final opinion on the application within two months of receiving it.

This deadline may be extended in cases of lengthy application revisions, a greater number of applications received in a short period of time, and during the summer vacations (between July 15th and August 15th).

Article 15

If the applicant disagrees with the EIEO Committee's decision or the substantive modifications and additions requested, they may request that the application be reassessed. The request must include arguments explaining the contested elements of the application.

The EIEO Committee reviews the request and the comments made at its meeting and makes a decision. This decision is final and cannot be appealed.

Article 16

The EIEO Committee's decision confirming the ethical appropriateness of the application assumes that, in all aspects affecting ethical issues, the research will be conducted as described in the application. The principal investigator is responsible for how the research is conducted.

The decision does cover later deviations in the research if these affect the manner of addressing ethical issues of the research. Researchers may seek a new opinion from the EIEO Committee before carrying out the modified parts of the research.

Article 17

This policy shall be posted on the ZRC SAZU intranet and website. It shall enter into force the day after it has been posted on the ZRC SAZU intranet.

Janez Kranjc

Chairman of the ZRC SAZU Board of Directors