Pursuant to Articles 52 and 53 of the Statutes of the University of Ljubljana (Official Gazette of the Republic of Slovenia, No. 4/17 as amended) and on the motion of the University of Ljubljana Human Research Ethics Committee, the Senate of the University of Ljubljana at its 21st session of 22 October 2019 adopted the following

Rules for the Processing of Applications by the University of Ljubljana Human Research Ethics Committee (KERL UL)

I. General provisions

Article 1
(purpose)

With the aim of ensuring optimal protection of the interests and wellbeing of participants in research under the aegis of the University of Ljubljana (hereinafter: UL) the procedure of preparing it shall involve the University of Ljubljana Human Research Ethics Committee (hereinafter: the Committee).

The Committee shall decide on applications for assessment of the ethical propriety of proposed research projects (hereinafter: research), where the (co)implementers or (co)authors request such assessment from UL.

The Committee shall decide on applications for assessment of the ethical propriety of research being conducted within UL or in which students or employees of UL are involved as researchers, that includes work with people and which needs to be performed at the university level due to the multidisciplinary nature of the research or because the researchers conducting the research are from member faculties where such a committee does not exist.

Article 2
(subject of regulation)

These Rules serve to regulate the criteria for assessing the ethical propriety of research, the types of assessment, elements of the application, the element of ethics assessment and the procedure for processing applications.

Article 3
(gender reference)

Terms used in these Rules in the masculine gender shall apply equally to men and women as gender-neutral terms.

Article 4
(definition of terms)

The terms used in these Rules shall have the following meanings ascribed to them:

1. applicant is the person who submitted the application for assessment of the ethical propriety of the research and who has the approval of the principal investigator and project group to represent it in communication with the Committee;

2. principal investigator is the person who heads the proposed research and is responsible for its appropriate plan, preparation and implementation;
3. researcher is a person who collaborates in and substantively contributes to the formulation of the research in an individual or every stage;
4. investigator is the person who under instruction from the principal investigator or other researchers in the project group carries out specific tasks for the needs of implementing an individual stage or several stages of the research;
5. project group is a group of researchers that includes the principal investigator and other researchers participating in the preparation, planning and implementation of the proposed research;
6. participant is a person whose data is collected and analyzed in the research;
7. informed consent is an agreement between the participant and researcher, whereby the researcher ensures that the participant is informed of all the key elements of research, and the participant in turn grants the researcher permission to collect the necessary data and use them for the defined purpose.

Article 5
(assessment criteria)

Ethics assessments are required by those research projects that include interaction with people or are based on the collection of personal data, except for research that meets the conditions under point a of the next article. Personal data includes information on behaviour in an environment in which the individual may justifiably expect not to be observed, and data which the individual may justifiably expect not to be disclosed to the public. The details of the ethics assessment are determined by the specific features of the research.

II. Types of assessments of the ethical propriety of research

Article 6

Research studies differ in their scope and type of participation required of participants, and also in the nature and scope of potential dangers, discomfort or harm to which participants are exposed through their involvement. The procedure and scope of the ethics assessment are adjusted to this. In terms of the nature and scope of assessment of the ethical propriety of research the following differentiations are made:

a) research that does not require assessment:
the research does not go beyond normal everyday (occupational, educational, leisure and other) activities of participants or requires only minimal participation of those involved in the research, and it does not involve the collection of identified personal data;

b) research with minimal risk to participants:
the research goes beyond normal everyday occupational, educational, leisure and other activities, requires active participation of those cooperating in the research, or it involves the collection of identified personal data, while the scope and type of potential dangers, discomfort or harm do not exceed the level to which the individual is exposed in everyday life;

c) research that goes beyond minimal risk
the research includes elements that go beyond minimal risk or for other reasons the Committee members assess it to be ethically sensitive or controversial.

III. Elements of application for ethics assessment

Article 7

An application for assessment of the ethical propriety of research includes two documents: the application for ethics assessment of research (hereinafter: application) and the form Informed consent to participate in research (hereinafter: informed consent).

In the first part of the application the applicant provides the basic information about the application and the research, defines and justifies the necessary type of treatment and highlights and explains possible discrepancies from set standards. In the second part of the application the applicant presents the basis for the research along with all the essential elements relevant for its ethics assessment.

In the case of a positive opinion, the Committee confirms this by stamping the form Informed Consent. During data collection, it is then exclusively the confirmed form that is used. Informed consent can be omitted only in cases where obtaining written consent is not possible, where it is not practically feasible or where obtaining it would constitute an unacceptable risk for the participants, regarding which the Committee shall issue an opinion.

In addition to the listed documents, where necessary and in accordance with the individual discretion of the applicant the application may also include other annexes.

Detailed requirements regarding the form and content of the application and form are defined in the instructions for preparing the application for ethics assessment and the instructions for preparing informed consent, which are prepared and adopted by the Committee.

IV. Elements of ethics assessment of research

Article 8

The assessment of the ethics of the proposed research is guided by the following criteria:

1. the proposed study addresses a justified research question;
2. recruitment of participants is appropriate:
   - participants have the option and are capable of freely choosing their participation;
   - participants are not under any pressure to participate;
   - participants are not promised any reward that exceeds reimbursement of costs;
   - participants are not promised any unacceptable and unrealistic benefits and privileges;
   - the study has been appropriately presented to participants;
   - attached to the application is an example of an appropriate protocol for addressing candidates for the study;
3. the methodology is appropriate:
   - the proposed methodology facilitates answers to the set research question;
   - the procedure poses no danger to the participant;
   - the procedure involves no excessive effort for the participant;
   - the procedure does not involve any unnecessary or excessive exposure to stress;
   - the procedure does not involve any unnecessary or excessive exposure to insulting or emotionally charged stimuli and content;

- attached to the application is an example of stimuli or instruments, except in the case of prior adequately validated and professionally tested stimuli and instruments;

4. deception / transparency of the research:
   - participants are informed of the actual purpose of the research;
   - the purpose of the research is appropriately presented prior to data collection;
   - in the case that the research requires deception or naive participants, the protocol includes an appropriate debriefing with participants after the research is complete;
5. emergencies:
   - in the event of emergencies (identifying a danger or threat to the participant or other persons), an adequate protocol for handling the situation has been envisaged and attached;
6. competences of those conducting the research:
   - the investigators have appropriate knowledge and competences for conducting the study;
   - the investigators have appropriate authorisation to use the proposed instruments;
7. adequate provision has been made for informed consent:
   - an appropriate procedure is defined for obtaining consent;
   - informed consent, together with all the necessary elements, has been attached;
8. adequate provision has been made for personal data protection:
   - data are stored under codes that prevent identification of the data;
   - the information necessary for identification of the codes is stored separately from the data;
   - an acceptable deadline for de-identification of data has been defined (destruction of identification codes);
   - in the event that de-identification is not possible, appropriate archiving of data is defined;
9. adequate provision has been made for storage and archiving of data;
10. the timetable for the study is acceptable;
11. the proposed study envisages feedback on the results to participants of the research:
    - the dissemination and publication of results does not increase the risk of transmitting negative stereotypes about the social groups that are subject to the research;
12. the proposed study ensures that it will be conducted in accordance with the ethical principles of non-discrimination and social justice:
    - where relevant, the sample will have a sufficient number of various groups, with emphasis on those that are normally excluded;
    - research plans which include participatory mechanisms should adequately deal with participants to the extent that the method allows. Participants should not be dealt with as objects of research without the possibility of participation.

V. Procedure of processing applications for ethics assessment

Article 9
(submission of application)

The applicant should submit the application in electronic form according to the instructions given on the Committee's website. In the event that the research is conducted in a wider project group with multiple researchers, the applicant should submit the application with the approval of the principal investigator and project group. In the case of student research as part of undergraduate or postgraduate study, the application should be submitted by the student with the approval of the mentor, who on electronic submission of the application is listed among recipients of the application.

Article 10
(verification of formal completeness of application)

A professional associate shall review the application and check whether the application contains all the necessary documents and whether the documents include all the required elements.

If a submitted application is not formally complete, the professional associate shall call on the applicant to complete it.

The professional associate should submit the complete application within a deadline of five working days to the relevant member of the Committee, or to the chairperson of the Committee if it involves research that goes beyond minimal risk.

Article 11
(research that does not require assessment)

In the event of a member of the Committee judging that the application falls within research that does not require an assessment of ethical propriety in accordance with the criteria under point a of Article 6, they shall notify accordingly the chairperson of the Committee, who shall issue an opinion.

Article 12
(addressing research with minimal risk)

A member of the Committee who has been assigned an application (hereinafter: assessor) shall review the application and formulate:

- category assessments of the key elements of the application that are the subject of ethics assessment;
- possible additional notes and instructions to the author of the application;
- possible additional notes to the chairperson of the Committee and its members;
- a draft opinion.

In the event of the assessor taking the view that the application is not acceptable in ethical terms or it goes beyond minimal risk, they shall forward the application to the chairperson of the Committee for full processing.

If the assessor judges that processing of the application will require specific research and/or expert knowledge, the application shall be submitted to the chairperson of the Committee with the proposal that the assistance of an external expert be requested.

Where the application can be accepted with minor or major changes, the application shall be returned to the applicant with notes and instructions. When the applicant submits the additions and modifications, they shall be submitted to the assessor for a new assessment.

In the case of ethical propriety of the research, the assessor shall formulate a draft opinion and submit it to the chairperson.

The professional associate shall prepare the relevant documents, obtain the signature of the Committee chairperson and forward the opinion to the applicant.

Article 13
(addressing research that goes beyond minimal risk)

After receiving the assessment of the assessor as referred to in the second paragraph of the preceding article, the chairperson of the Committee shall send the application to all members of the Committee, who shall review the application, assess it and formulate:

- category assessments of the key elements of the application that are the subject of ethics assessment;
- possible additional notes and instructions to the author of the application;
- possible additional notes to the chairperson of the Committee and its members;
- a draft opinion.

In the case referred to in the third paragraph of the preceding article, the chairperson of the Committee shall send the application to an external associate who is expert in the field to which the application relates. After receiving the opinion, the chairperson shall send the application and opinion of the external associate to the Committee members.

The possible draft opinions of the Committee as referred to in the fourth indent of the first paragraph of this Article are:

- the application is appropriate;
- the application must be supplemented or modified;
- the application needs to be discussed at a meeting of the Committee;
- the application is not appropriate.

In the event of differing opinions among members of the Committee, additional remarks on the application, or on the proposal of a member, the application shall be addressed at a meeting of the Committee.

The application shall be addressed at a meeting of the Committee also in the case of research that involves greater risk for the participants, that is ethically sensitive or due to the nature of the research it is not possible to include the standard elements of ensuring ethical criteria.

The Committee shall confirm the application, reject it or request supplementation or modification of it.

A decision shall be adopted at the meeting of the Committee through a unanimous vote of the members present.

If a meeting cannot be held in person, a video conference meeting may be held, using information and communication technology. Notwithstanding the provisions of these Rules, in the event of a video conference meeting, a secret ballot shall be held via information and communication technology that enables such voting.

All the persons who in accordance with the provisions of these rules are present at the meeting must ensure that during a video conference meeting, in the space they use information and communication technology to communicate, they are alone.

Unless otherwise provided, all the other provisions of these Rules shall apply mutatis mutandis for video conference meetings.

Article 14
(submission of opinion)

Once the opinion of the Committee has been adopted, it shall be sent to the applicant.

In the case of a positive assessment of the application, the applicant receives a confirmation of the ethical propriety of the proposed research and the approved form Informed Consent. In the case of research that requires full assessment, the applicant also receives a substantiation of the opinion.

In the case of applications that require modification or supplementation, the applicant is sent notes and instructions for the necessary modifications.

In the case of a negative assessment and rejection of the application, the Committee's substantiation is sent to the applicant.

Article 15
(new review of application)

The applicant should re-submit a modified or supplemented application according to the instructions given on the Committee's website.

In the application the author should clearly indicate which parts of the text have been modified or supplemented (use of the track changes function is recommended) and the modifications should be described in a separate file.

The professional associate shall send the modified or supplemented application to the assessor.

Article 16
(timeline of assessment)

The assessor or Committee shall decide on the application within 30 days of receiving a formally complete application. In the event of a request from the applicant for faster processing, the assessor or Committee shall endeavour to respond within the deadline set for the applicant by an external stakeholder (funding provider, client, etc.). The assessment of applications that have been supplemented or modified in accordance with the instructions of the assessor or Committee shall be performed by the assessor or Committee within 14 days of receipt of a new version of the application.

The anticipated time of processing may be extended in the event of a large number of applications submitted in a short period of time, in the event of a large number of required revisions of an application, in the event of an application requiring deliberation at a meeting of the Committee and during the summer holiday period from 15 July to 20 August.

For candidates that require an ethics assessment of a doctoral research project, it is recommended that they submit their application at least two months prior to the deadline for submitting their plan, taking into account the summer holiday period.

VI. Appeal

Article 17

In the event that the applicant does not agree with required substantive changes to the research or mandatory forms, they may request a reassessment of the application by the Committee and may submit with the final revision a written argumentation of the disputed elements of the application.

The Committee shall address the application and comments submitted in the same procedure and same deadlines as for an application that goes beyond minimal risk.

Upon reassessment the Committee's opinion is final.

VII. Researcher's commitment

Article 18

The application represents the applicant's commitment regarding the type of research that will be conducted and in what way. Any deviation from the confirmed application automatically annuls the approval of the Committee.

If elements presented in the application need to be changed, prior to implementation of the research the opinion of the Committee must be obtained for the planned changes. The Committee should also be sent notification of any early termination of the research and the reasons for it.

VIII. Final provision

Article 19

These Rules shall enter into force on the day they are adopted and published on UL website.

Prof. Dr Igor Papič
Rector
Chair of the Senate of UL