

Rīga Stradiņš University
Research Ethics Committee
REGULATIONS

1. General provisions

1.1. The Regulations of RSU Research Ethics Committee (hereinafter - the Committee) (hereinafter - the Regulations) shall define the principles of the Committee's activity, tasks and competence in assessing ethical aspects of scientific research, responsibility, establishment and decision-making procedure. The Committee itself shall decide on the procedural matters not specified in these Regulations.

1.2. The Committee shall comply with the legislation of the Republic of Latvia and international law in the field of research ethics and personal data protection.

1.3. The aim of the Committee's activity shall be to protect the rights, health, safety and dignity of research participants, to prevent harm to research participants, society and the environment, while respecting the scientific freedom of researchers and the scientific goals of research.

1.4. The activity of the Committee shall be directed towards ensuring that the basic principles of academic morality and ethics, as well as

RSU Academic Integrity Policy

(https://www.rsu.lv/sites/default/files/imce/Dokumenti/RSU_Akademiska_godigu_ma_politika.pdf);

RSU Code of Ethics

(https://www.rsu.lv/sites/default/files/imce/Dokumenti/general/rsu_etikas_kodekss.pdf);

and RSU Privacy Policy (<https://www.rsu.lv/rigas-stradina-universitates-privatuma-politika>) are observed in the study and research activities of RSU.

1.5. The Committee and its members shall be autonomous and independent in their activities and decisions.

1.6. The Committee shall cooperate with the competent authorities of the Republic of Latvia and of other countries in the field of research ethics and personal data protection.

II Tasks of the Committee

2.1. The Committee shall examine applications from RSU academic staff and students. The Committee shall, if necessary, advise on ethical aspects of research.

2.2. The Committee shall express its opinion on:

2.2.1. research with human involvement in which personal data are obtained and processed;

2.2.2. research with human involvement in which the physical participation of research participants in the research, observation or inquiry of an opinion is taking place;

2.2.3. research in which tissues, cells or other biological samples of live or dead people or animals (vertebrate) are obtained and/or used;

2.2.4. research which poses a risk to the environment;

2.2.5. research involving a dual-use risk, where the results of research are used not only for the benefit of the public but also cause harm of any kind.

2.3. The Committee shall, if necessary, consider information on the progress of the research following a positive decision of the Committee regarding the research concerned.

2.4. If the opinion of an external research ethics committee has been received in accordance with the procedure established by the laws and regulations of the Republic of Latvia, RSU Committee shall, if necessary, provide an opinion on the part of the research for which the opinion of the external research ethics committee has not been obtained.

2.5. The Committee shall consider the compliance of changes in the conduct of the research with the laws and regulations of the Republic of Latvia and the principles of research ethics, if such changes are planned during the course of the research.

III Members of the Committee

3.1. The Committee shall be composed of seven members.

3.2. If necessary, the Committee may invite and be advised by experts who are not members of the Committee.

3.3. The members of the Committee must be highly qualified professionals or persons with a research degree. The Chairperson and the members of the Committee shall be elected by the Senate upon the recommendation of the Council of Science for a period of three years. Re-election shall be admissible.

3.4. The Committee shall elect a Vice-Chairperson and a Secretary by a majority vote.

3.5. Representatives nominated by RSU Student Union shall be entitled to participate in the meetings of the Committee.

IV Committee activity

4.1. The Committee shall meet in person. If necessary, meetings may be held remotely, using online videoconferencing (real-time image and sound transmission) and ensuring confidentiality and personal data protection requirements in accordance with the laws and regulations of the Republic of Latvia and RSU.

4.2. The communication of the Committee, the circulation of documents, including the signing of documents and the issuance of a decision, shall be organised electronically,

in accordance with RSU administrative provisions. If necessary, the decision of the Committee may be prepared and issued in printed form.

4.3. The meetings of the Committee shall be closed. The Committee members and the representative nominated by RSU Student Union who participate in the Committee meetings shall preserve confidentiality.

4.4. Minutes of the Committee meetings shall be taken, indicating the most essential information on the issues discussed. Minutes of the meetings and correspondence shall be kept in accordance with RSU Document Management Rules.

4.5. The Committee shall be managed by the Chairperson, who shall:

4.5.1. draw up the Committee's work plan and the agenda of its meetings;

4.5.2. organise the examination of applications and other matters;

4.5.3. convene meetings of the Committee;

4.5.4. sign decisions and other documents of the Committee.

4.6. In the absence of the Chairperson of the Committee, the Vice-Chairperson shall replace him/her.

4.7. The Secretary of the Committee shall have the following responsibilities:

4.7.1. register incoming and outgoing correspondence;

4.7.2. take the minutes of the Committee meetings;

4.7.3. communicate with and circulate correspondence among the members of the Committee, applicants, RSU staff and other institutions;

4.7.4. inform applicants of the documents to be submitted to the Committee and the requirements for the receipt of the Committee decisions;

4.7.5. issue the Committee decisions.

4.8. If a member of the Committee has a conflict of interest, he/she shall inform the members of the Committee thereof and shall not vote or express an opinion on the research in question.

4.9. Members of the Committee shall not accept gifts, hospitality offers or any other material benefits for the use of their family members from RSU employees and students, as well as researchers and students from other institutions. Members of the Committee shall not accept any kind of benefits related to the applications under examination and intended for legal entities, including medical institutions, to which members of the Committee are affiliated.

4.10. The Committee shall publish the procedure for the examination of applications, the time of the Committee meetings, the documents to be submitted, the list of research titles for which the Committee's opinion has been issued, except for commercially confidential or restricted information on RSU website.

4.11. The Committee shall be financially provided by RSU.

V Examination of applications and decision-making

5.1. The Committee shall act on the basis of the principle of the applications received. The applicant may change the application or take it back. The application may be submitted by the individuals referred to in the Paragraph 2.1 of the Regulations. Application forms shall be prepared by the Committee and approved by the Rector's Decree. The applicant shall attach the following documents, if appropriate, to the application: the informed consent documents of the research participant for research with human involvement, the research protocol and instruments (questionnaire, interview questions, etc.) and other documents relevant to the research.

5.2. The Committee shall check the completeness of the data submitted, including the statement of the informed consent from individuals (patients, participants), the compliance of the research with the requirements of the General Data Protection Regulation and other international and Latvian legislation. The Committee may request additional data and documents from the applicant and invite the applicant to a consultation meeting. The Committee may ask for amendments to the submitted research documents with regard to compliance with ethical principles. If the applicant fails to comply with the requirements of the Committee within the time limit set, the Committee shall be entitled to reject the examination of the application.

5.3. The Committee shall have a quorum if more than half of its members participate in the meeting.

5.4. The Committee shall take its decisions by consensus or, if no consensus can be reached, by open majority vote. In the event of an equal number of votes, the Chairperson shall have a casting vote. Voting may be done by a secret ballot at the request of a member of the Committee. A member of the Committee who has a specific dissenting opinion on a decision, shall draw it up in writing, and it shall be attached to the minutes of the meeting.

5.5. The decision of the Committee shall be in writing and signed by the Chairperson. The decision shall enter into force on the day of signing thereof.

5.6. The decision of the Committee shall include a Minutes Part and a Decision Part. A positive decision of the Committee shall be expressed as *Agree to conducting the research*. A negative decision of the Committee shall be expressed as *Do not agree to conducting the research*. In the case of a negative decision of the Committee, the reasons shall be stated in the Minutes Part.

5.7. The decision of the Committee shall be final within the scope of its competence.

5.8. The Committee shall be entitled to leave the application without a decision, informing the applicant thereof and stating the reasons.

5.9. The Committee shall take and notify its decision no later than 60 days from the date of registration of the application.

5.10. If significant changes occur during the conduct of the research, the applicant must notify the Committee in writing.

5.11. Upon receipt of information on the non-compliance of the research with the principles of research ethics, the Committee shall have the right to request a written report during the conduct of the research. On the basis of the information received or

the absence thereof, the Committee shall be entitled to take a new decision in the context of the research in question.

Chairperson of the Senate

J.Gardovskis

J. Vētra
(67326203)

AGREED:
at the Rectorate meeting of 9 May 2022,
Minutes No 1-PB-1/17/2022

**THIS DOCUMENT IS ELECTRONICALLY SIGNED WITH A SECURE
ELECTRONIC SIGNATURE AND CONTAINS A TIME STAMP**