APPROVED
at Rīga Stradiņš University
Senate meeting as of 17 March 2020,
Minutes No. 2-1/3/2020

Rīga Stradiņš University
Research Ethics Committee
REGULATIONS

1. General Provisions

1.1. The Regulations of RSU Research Ethics Committee (hereinafter - the Regulations) shall determine the principles, procedure and tasks of the Committee activities in RSU.

1.2. The Committee shall act in accordance with national and international legislation concerning biomedical research in humans and animals and clinical trials on medicinal and pharmaceutical products (Declaration of Helsinki, the World Health Organisation (WHO) Guidelines, The Code of Ethics for Doctors in Latvia, Law on the Rights of Patients, General Data Protection Regulation, the International Conference on Harmonisation Good Clinical Practice Guidelines, the Decree of 6 August 1998 by the Ministry of Welfare on the Principles of the Model Regulations for the Medicinal and Pharmaceutical Products Clinical Trial Ethics Committees and other regulatory enactments in the sector referred).

1.3. The Committee and its members shall be self-reliant and independent in their activities and decisions.

1.4. The Committee shall cooperate with the Ethics Committees of the Laboratory Animal Research of the Latvian Council of Science, Latvian Medical Association, Central Medical Ethics Committee and research ethics committees of other countries.

2. Tasks of the Committee

2.1. The Committee shall evaluate the applications of the teaching staff and students of RSU and other institutions of higher education, advising, where necessary, on the ethical aspects of medical research conducted with humans without absolving doctors and students from the responsibility for the purpose of research and its execution.

2.2. The Committee shall express its opinion on:

2.2.1. medical research in relation to professional care (clinical trials), which is of significant diagnostic and therapeutic importance in treatment of the patient;

2.2.2. scientific research without direct diagnostic or therapeutic value to the person subject to the research (non-clinical biomedical research);

2.2.3. the inviolability and safety of the rights of the research subjects involved in the process of clinical trials of medicinal and pharmaceutical products;

2.2.4. the use of laboratory animals in biomedical trials;

2.2.5. the respect for and provision of protection of personal data, confidentiality and privacy.

2.3. At the suggestion of the Research Department, medical research doers shall apply new diagnostic and therapeutic techniques, including trials on unauthorised (unlicensed, unregistered) and authorised (licensed, registered) but not yet sufficiently approved

medicinal products, as well as new methods of scientific research on humans only if there is an approval of the Committee.

2.4. The work of the Committee shall be aimed at respecting the basic principles of morality and ethics between a student and a lecturer, the learning object and the learner and at observing the principles of ensuring personal data protection in the course of implementation of study programmes at RSU.

2.5. The Committee shall evaluate students' research applications regarding the use of personal data in research in order to ensure correct processing of personal data in research work conducted within the framework of the study process - in conformity with the Article 6.3 of the Regulations.

3. Composition

3.1. The Committee shall be composed of seven members.

3.2. The Committee shall have the right to invite any specialist(s) not represented on the Committee for the purpose of evaluating ethical issues related to the planned research or training process.

3.3. The members of the Committee must be highly qualified professionals or with a research degree. The President and the members of the Committee shall be approved 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-President and a Secretary by a majority vote.

3.5. Observers of RSU Students' Union shall be entitled to participate in the meetings of the Committee.

4. Activity and Competence of the Committee

4.1. In taking its attitude, the Committee shall pay particular attention to:

4.1.1. the prospects and risks for the respective person (patient) in the biomedical research;

4.1.2. the significance of the potential research results in medicine;

4.1.3. professional requirements for conducting the intended research;

4.1.4. good scientific practice, humane attitude to a laboratory animal, so that the animal does not suffer pain and is not subject to suffering and distress.

4.2. The Committee shall have the power to express an opinion and to take a decision on scientific research and to give a conclusion on clinical trials of medicinal products in accordance with the Article 2.2 of the Regulations.

4.3. The Committee shall act on the basis of the principle of the applications received. The application may be changed or withdrawn. he application may be submitted by the persons referred to in the Article 2.1 of the Regulations.

4.4. The President of the Committee or a member of the Committee shall abstain from the performance of his or her duties or from taking a decision, if the decision taken or prepared may affect or is likely to affect:

4.4.1. the personal or material interests of the members of the Committee or of their family members;

4.4.2. material interests of a private person with whom a member of the Committee is associated or the material interests of its sponsors.

4.5. The Committee shall ensure that all the teaching staff and students of RSU and other institutions of higher education who are interested in deciding on a particular issue are given equal opportunities to meet decision makers and get the necessary information.

4.6. Members of the Committee shall not accept gifts, hospitality offers or other benefits, and any other material goods from the teaching staff and students of RSU or other institutions of higher education, for their own or their family members' needs or for the private person (hospital) to which he or she is associated.

4.7. The Committee shall be financially provided by RSU.

5. Content of the Application

5.1. In order to obtain the Committee's approval, the researcher must submit a dated application in the official language (in the event of a foreign student/researcher also in a foreign language) to the Committee in accordance with the Article 5.2 prior to commencing the work (research).

5.2. The application shall contain:

5.2.1. the names of the research supervisor and researchers, their positions and research degrees; the consent of the Head of the Department; the consent of the medical institution to conduct the research; clinical trials; a CV;

5.2.2. the purpose of the research;

5.2.3. a signed draft research protocol (a description of the methodology and data recording, as well as signed amendments to the protocol in the Latvian language (if the application of a foreign student/researcher - also in a foreign language);

5.2.4. an outline of methods and technical equipment used in the research and comparison with the previous experience;

5.2.5. expected results in health care and disease prevention;

5.2.6. ethical considerations of the research, which include a statement that the research will be carried out in compliance with the Declaration of Helsinki, legislation (Regulations) of the Council of Europe and the European Union, laws and regulations of Latvia and other normative acts; reflection on prospects and risks to a person; a description of security measures to prevent damage caused by research, as well as the criteria for informed consent and voluntary inclusion and exclusion of people/participants;

5.2.7. a written explanation (in the event of a foreign student/researcher's application - also in a foreign language), which includes the purpose, type and extent of the examination, intervention (treatment), positive prospects and the possible degree of risk of the examination (treatment);

5.2.8. a form containing a statement that the person involved in the research has received an explanation of the research and has agreed to be involved in the research, and that he or she shall have the right to withdraw his or her consent at any time (without affecting treatment). The form shall be signed by the person involved in the research and the researcher;

5.2.9. methodology for attracting the research subject (including advertisements), the researcher's brochure (if necessary, also in a foreign language);

5.2.10. documents related to the payments to be made to the research subject, including a document certifying the guarantee in the event of the harm to health (if appropriate, also in a foreign language).

5.3. In the case of simple biomedical research, adults and persons having decision making capacity may give their oral consent, provided that the explanation is given in the presence of a witness. In that case, the form may be signed by the researcher and the witness.

5.4. Simple biomedical research is allowed to be carried out with minors. After the explanation, the written consent shall be given by one of the parents or the legal representative.

5.5. In the case of adult patients incapacitated of decision making, simple biomedical research is permitted in accordance with the principles of tacit consent, if it is indicated by medical conclusions in order to save the patient's life, restore health or ease his or her suffering. This should be specifically reflected in the application to the Committee.

5.6. In animal experiments, the research protocol should include:

5.6.1. justification for the choice of laboratory animal species, strain and number;

5.6.2. experimental conditions, animal husbandry, feeding and an adaptation period;

5.6.3. the model of the experiment and intended procedures and a method of euthanasia.

6. An Application for Use of Patient Data Registered in Medical Documents for Research Purposes

6.1. In order to meet the requirements of the General Data Protection Regulation and national laws and regulations governing the processing of personal data, the Committee shall evaluate the applications of students for the use of patient data registered in medical records for research work within the study process, provided that at the same time the following conditions are met:

6.1.1. the research work has been drawn up in the public interests within the framework of the first or the second level professional, Bachelor, Master or doctoral higher medical education study programme;

6.1.2. it is not possible to obtain the consent of the patient by reasonable means;

6.1.3. the benefits of the research for public health are commensurate with the limitation on the rights to privacy.

6.2. A student, who wishes to receive a permit, shall submit an application (a form) to the Committee, accompanied by a research protocol outlining the theoretical methodological requirements.

6.3. When assessing the compliance of the research work with the ethical principles and personal data protection requirements, as well as its scientific and social value, the Committee shall take a decision on the issue of an authorisation, provided that at the same time the following conditions exist:

6.3.1. the intended use of patient data is necessary for the achievement of the research objectives and is proportionate;

6.3.2. the purpose of the research cannot be achieved by using unidentifiable patient data in various databases and registers;

6.3.3. the qualification of the student is adequate for successful research work.

7. Consideration of Applications

7.1. The Committee shall verify the completeness of the application data, paying particular attention to the confirmation of the informed consent of patients/participants; compliance of special categories of personal data protection and confidentiality with

the requirements of the General Data Protection Regulation, as well as compliance with other international and national legislation; and/or in compliance with them the Committee may take a positive decision to conduct the research under consideration. The Committee shall have the right to return or refuse an application without deciding on the research, stating the reasons The Committee may invite the applicant to advisory meetings.

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

7.3. The Committee shall take its decision by open majority vote. In the event of an equal number of votes, the vote of the President shall be decisive. Voting may be done by a secret ballot at the request of a member of the Committee. A member of the Committee who has an opposing decision may submit an account of his or her opinion in writing.

7.4. The decision of the Committee must be notified in writing not later than 60 days after the date of registration of all the documents required.

7.5. The Committee shall consider the application and prepare a decision regarding the use of patient data registered in medical records for research works drawn up within the study process within 1 (one) month from the date of registration of the application, if the application has been received for the first time.

7.6. If significant changes occur during the execution of the research, they should be reported to the Committee and a new approval of the Committee shall be required. The State Agency of Medicines must be notified in writing of any negative clinical trial conclusion regarding the medicinal products.

7.7. The Committee may, in addition, request a written report during the execution of the research. The Committee shall have the power to take a new decision.

8. Decision Making

8.1. The Committee shall draw up its decision in writing, after hearing the opinion of at least one expert and by consulting the research materials submitted. If the Committee takes a favourable decision on the conduct of the research, this means that the research will be conducted in accordance with the Article 7.1 of the Regulations. For clinical trials of medicinal products, the following shall be given: a positive conclusion in the event of positive assessment; a positive conclusion with an indication of the need to make amendments to the documents submitted, and a negative conclusion in the event of unfavourable assessment.

8.2. The minutes of each meeting of the Committee must be taken, showing the main points of the negotiations. Minutes of the meetings and correspondence shall be kept for at least three years after the end of the trial.

9. Non-Disclosure Obligation - Confidentiality

9.1. The meetings of the Committee shall be closed. The members of the Committee must ensure confidentiality. The members of the Committee whose research is being discussed shall not participate in taking the decision.

Chairperson of the Senate J.Gardovskis

O. Brūvers

AGREED
at Rectorate meeting of 24.02.2020,
Minutes No. 5-2/8/2020