	COMENIUS UNIVERSITY BRATISLAVA JESSENIUS FACULTY OF MEDICINE IN MARTIN	Int. doc. No.: VP 3/2020
	Statute of the Ethics Committee of the Jessenius Faculty of Medicine of Comenius University in Martin	Copy No.: 1 Period of storage: 10 years


INTERNAL REGULATION NO. 3/2020

Statute of the Ethics Committee of the Jessenius Faculty of Medicine of Comenius University in Martin

Elaborated by: MSc. Lúbia Červeňová Prof. MUDr. Mgr. Juraj Mokrá, PhD.	On: 31 January 2020	Signature:
Negotiated by: Management Board of JFMED CU	On: 3 February 2020	Signature:
Approved by: Prof. MUDr. Andrea Čalkovská, DrSc., Dean of JFMED CU	On: 3 February 2020	Signature:
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In accordance with Article 22(2)(j) of the Statute of the Jessenius Faculty of Medicine of Comenius University in Martin, in accordance with Section 5(7) of Act No. 576/2004 Coll. on Health Care, Services Related to the Provision of Health Care and on Amendments and Additions to Certain Acts, as amended, and after discussion in the Management Board of JFMED CU in Martin on 3 February 2020, I hereby issue the following

**STATUTE
of the Ethics Committee of the Jessenius Faculty of Medicine of**

Comenius University in Martin Preamble


The Ethics Committee of the Jessenius Faculty of Medicine of Comenius University in Martin (hereinafter referred to as "JFMED CU") was established on 19 March 2000 by the Dean of JFMED CU for the purpose of assessing the ethical aspects of clinical trials of drugs, medicinal preparations and any other type of biomedical research as well as the assessment of experimental activities on animals.

In its work, the Ethics Committee of the JFMED CU (hereinafter referred to as "the Ethics Committee" or "the Committee") respects the values and principles of human rights protection, in its decision-making it applies and follows the Nuremberg Code, the Declaration of Helsinki, the Charter of Fundamental Human Rights and Freedoms, the Protocol on the Prohibition of the Cloning of Human Beings, the Patient's Bill of Rights, and national legislation (including Act No. 362/2011 Coll., Act No. 576/2004 Coll., Government Regulation No. 377/2012 Coll. and Decree No. 436/2012 Coll., as amended) concerning the observance of ethical principles in experimental work using laboratory animals.

The Ethics Committee is an independent committee and works independently when deliberating, deciding and adopting opinions.


**Article 1
Committee's mission and terms of reference**

- 1) The main task of the Ethics Committee is the collective assessment of research projects. Projects of experimental, clinical or any other biomedical research are developed by responsible researchers, who are university teachers, researchers, erudite clinical experts and students of JFMED CU.
- 2) Projects of clinical or any other biomedical research shall be submitted to the Ethics Committee for review on a designated and prescribed form, which is published on the Faculty's website. The application must be accompanied by a project protocol with a clearly defined objective, a proposal for the method and conduct of the clinical trial, the person responsible for conducting the clinical trial, a list of investigators, information for the patient in the local language, and the provision of insurance. The personal attendance of the Principal Investigator at the Ethics Committee meeting is absolutely necessary.
- 3) The Ethics Committee mainly expresses its opinion on the objectives and justification of the prepared clinical research, clinical trials of drugs or any other biomedical research that may affect a living organism in the field of biology, medicine, pharmacy,

	COMENIUS UNIVERSITY BRATISLAVA JESSENIUS FACULTY OF MEDICINE IN MARTIN	Int. doc. No.: VP 3/2020
	Statute of the Ethics Committee of the Jessenius Faculty of Medicine of Comenius University in Martin	Copy No.: 1 Period of storage: 10 years


nursing, midwifery and psychology (grants, dissertations and theses). It consistently ensures that the rights of human subjects (patients or volunteers) are respected in studies.

- 4) The Ethics Committee shall comment on the use of all new diagnostic and therapeutic methods that are related to health care, even if they are not of a research nature. It consistently ensures that the benefit outweighs the risk and discomfort of the new method with respect for the patient's will and adequate information.
- 5) When considering a request for an opinion on the ethics of biomedical research or a request for an opinion on a change to the data in the protocol, the Committee shall in particular take into account:
 - a) the relevance of biomedical research and its organisational support,
 - b) the method for evaluating the expected benefits and risks referred to in Section 30(1)(a) of Act No. 362/2011 Coll. on medicinal products and medical devices, as amended, and the justification of the conclusions,
 - c) the protocol or a proposed change to the data in the protocol,
 - d) the competence of the examiner and his/her associates,
 - e) the set of results and conclusions of pharmaceutical testing and toxicological-pharmacological testing and clinical trials conducted to date on the investigational product or investigational medicinal product that are relevant to the clinical testing of that product or medicinal product in humans,
 - f) material equipment and staffing of the health care facility,
 - g) the adequacy and completeness of the written information provided to the participant and the procedures for obtaining informed consent and for justifying research on participants incapable of giving their informed consent according to the specific limitations set out in Sections 31 and 32 of Act No. 362/2011 Coll.,
 - h) the provisions of a specific regulation on compensation or indemnification in the event of damage to health or death caused by a clinical trial,
 - i) a health care facility's liability insurance contract for damages that may be caused to the participant,
 - j) the aggregate amount, the method of any remuneration or indemnity arrangement for examiners and participants, and the terms of any envisaged contract between the sponsor and the health care facility in which the site is located,
 - k) the method of recruiting participants,
 - l) proof of eligibility to carry out biomedical research (clinical trials).
- 6) When approving clinical trials, the Ethics Committee at JFMED CU in Martin makes decisions either as a Local Ethics Committee or as a Multicentre Ethics Committee.
- 7) For a multicentre clinical trial, an opinion on the ethics of the clinical trial or an opinion on the change of data in the protocol is required from only one ethics committee, the so-called multicentre ethics committee, for all sites in the Slovak Republic participating in the multicentre clinical trial. An opinion on the ethics of the clinical trial or

	COMENIUS UNIVERSITY BRATISLAVA JESSENIUS FACULTY OF MEDICINE IN MARTIN	Int. doc. No.: VP 3/2020
	Statute of the Ethics Committee of the Jessenius Faculty of Medicine of Comenius University in Martin	Copy No.: 1 Period of storage: 10 years

an opinion on the change of the data in the protocol shall be given by the Ethics Committee requested by the sponsor, which shall explicitly state in its request that the clinical trial is a multicentre clinical trial. Before issuing its opinion on the ethics of the clinical trial or its opinion on the change of data in the protocol, the Ethics Committee must consult the content of the opinion in question with the ethics committees of all sites in the Slovak Republic participating in the multicentre clinical trial, requesting their partial opinion as a local ethics committee before issuing its opinion.


- 8) The submitter of the clinical study is obliged to keep the medical records for 15 years after the end of the study.
- 9) Experimental research projects shall be submitted to the Ethics Committee for review on a designated and prescribed form, which is published on the Faculty's website. The application must be accompanied by a project protocol with a clearly defined objective, evidence from international registries verifying the existence of alternative methods, a detailed description of compliance with the 3 R's (substitutability, analgesia, reduction of the number of laboratory animals), the precise organisation of the experiment and a list of the persons involved in the experiment. The personal attendance of the Principal Investigator at the Ethics Committee meeting is absolutely necessary. After the approval of the Ethics Committee, the Principal Investigator will apply to the State Veterinary and Food Administration of the Slovak Republic in Bratislava for accreditation of the research project using the experimental animals mentioned in the project.
- 10) The Ethics Committee mainly comments on the objectives and validity of the planned experimental research. It consistently ensures that the welfare of experimental animals is respected in the studies and that they comply with the requirements pursuant to Section 36 of Government Regulation No. 377/2012 Coll. When approving a study, it requests that the numbers and type of animals to be used in the experiment are clearly declared.
- 11) The Ethics Committee evaluates all types of experiments using experimental animals. In case of non-compliance of the experimental project with the requirements for animal protection according to Government Regulation No. 377/2012 Coll. and Decree No. 436/2012 Coll., as amended, it shall recommend the submitter of the experimental project to modify the part of the project in which the non-compliance has been detected.
- 12) The Ethics Committee shall, where appropriate, also give its opinion on the introduction of new methods of testing medicinal products or medicinal preparations using experimental animals.
- 13) Members of the Ethics Committee, in agreement with the head of the experimental menagerie, shall have the right to inspect the experimental menagerie in order to check the housing of the animals, the care of the animals, the control of the performance of euthanasia and the handling of the animals. The result of the inspection shall be a record of the inspection, which shall be given to the head of the menagerie and the other managers concerned.
- 14) The Ethics Committee is required to issue a written opinion on a submitted project, grant, experimental study, thesis or dissertation within 60 days of receipt of the application. It must comment in writing within 35 days on the change of data in the protocol and within 90 days on the adoption of the gene therapy decision.

	COMENIUS UNIVERSITY BRATISLAVA JESSENIUS FACULTY OF MEDICINE IN MARTIN	Int. doc. No.:
	Statute of the Ethics Committee of the Jessenius Faculty of Medicine of Comenius University in Martin	VP 3/2020 Copy No.: 1 Period of storage: 10 years

15) The decision of the Ethics Committee is final and cannot be appealed.

Article 2 Composition and membership of the Committee

- 1) The Ethics Committee shall be a collective independent body, composed of at least 7 members, and its total number of members shall always be odd.
- 2) The members of the Ethics Committee are appointed and dismissed by the Dean of the Faculty.
- 3) Membership of the Committee is voluntary. The function of a member of the Committee shall be irreplaceable.
- 4) Members of the Ethics Committee may include health professionals from various medical disciplines, disciplines relevant to medical ethics, health care ethics and bioethics, professionals from other professions whose expertise is required for the work of the Ethics Committee, and persons without medical (biomedical) or health care qualifications.
- 5) The number of members of the Ethics Committee without professional competence to practise a health profession or in the field of research shall not exceed an absolute majority of the total number of members of the Ethics Committee.
- 6) Membership of the Committee is subject to:
 - a) integrity,
 - b) the education, experience and professional experience required to serve on the Committee,
 - c) the proposed person's written consent to appointment as a member of the Committee,
 - d) a written commitment of confidentiality concerning all facts of which they become aware in the performance of their duties; the obligation of confidentiality shall not apply where they communicate such facts with the consent of the person to whom they relate,
 - e) a written commitment to disclose to the Dean of JFMED CU any facts that constitute or could constitute a conflict of interest.
- 7) The assessment of the ethical acceptability of biomedical and experimental research must be based on the appropriate expertise and experience of the members of the Ethics Committee. In assessing the scientific, legal and ethical aspects of planned biomedical and experimental research, due account shall be taken of scientific and professional considerations and of those members of the Committee who are not qualified to practise the health profession.
- 8) The Ethics Committee shall be composed of a Chairman, a Vice-Chairman, a Secretary and members of the Committee.
- 9) The term of office of the Chairman, Vice-Chairman, Secretary and members of the Committee shall be unlimited. Membership of the Committee shall be terminated:
 - a) by the removal of the Chairman, Vice-Chairman, Secretary or members of the Committee by the Dean of JFMED CU,
 - b) by written resignation of a member,
 - c) upon termination of the Ethics Committee,
 - d) upon death of a member.

	COMENIUS UNIVERSITY BRATISLAVA JESSENIUS FACULTY OF MEDICINE IN MARTIN	Int. doc. No.: VP 3/2020
	Statute of the Ethics Committee of the Jessenius Faculty of Medicine of Comenius University in Martin	Copy No.: 1 Period of storage: 10 years

- 10) A member of the Committee shall act freely, according to his/her conscience, shall not be bound by orders and shall be independent of political, economic and other influences.
- 11) The Ethics Committee of JFMED CU works in accordance with this Statute and the Rules of Procedure of the Ethics Committee in such a composition that theoretical, pre-clinical and clinical disciplines, as well as non-physicians and a lawyer are represented.


Article 3

Chairman and Vice-Chairman of the Committee

- 1) The Chairman and the Vice-Chairman of the Ethics Committee are appointed and dismissed by the Dean of JFMED CU. The Chairman and Vice-Chairman of the Committee are accountable to the Dean for their activities.
- 2) The term of office of the Chairman and the Vice-Chairman of the Committee shall be unlimited.
- 3) The Chairman of the Committee shall manage the activities of the Committee and shall perform in particular the following tasks:
 - a) represents the Committee externally,
 - b) convenes and chairs meetings of the Committee,
 - c) manages the activities of the Committee in the period between its meetings,
 - d) prepares the agenda of the Committee meetings, materials and verifies the accuracy of the minutes in cooperation with the Secretary of the Committee,
 - e) on the basis of the request of the Dean of JFMED CU prepares documents on the activities of the Committee,
 - f) informs the Dean of JFMED CU about the most important facts, professional and legislative issues, trends in the field of ethics, medicine, healthcare and biomedical research.
- 4) The Chairman and the Vice-Chairman of the Committee must not be from the same experimental facility.
- 5) In the absence of the Chairman of the Committee, the Vice-Chairman of the Committee shall act in his/her place in the entirety. The Vice-Chairman shall also represent the Chairman of the Committee if the Chairman of the Committee is the Principal Investigator or Co-Principal Investigator of a specific biomedical research project.
- 6) The Chairman of the Ethics Committee shall be a person independent of the experimental facility whose experimental design is being evaluated. In the case of consideration of a project submitted by an employee of an experimental facility whose employee is the Chairman of the Ethics Committee, the Vice-Chairman of the Ethics Committee shall automatically become the Chairman of the Ethics Committee for the project.

Article 4 Secretary of the Committee


- 1) The Secretary of the Ethics Committee is appointed and dismissed by the Dean of JFMED CU on the proposal of the Chairman of the Committee. The Secretary of the Committee is an employee of JFMED CU.
- 2) The Secretary of the Committee shall be a member of the Committee with full voting rights.
- 3) In particular, the Secretary of the Committee shall perform the following tasks:

	COMENIUS UNIVERSITY BRATISLAVA JESSENIUS FACULTY OF MEDICINE IN MARTIN	Int. doc. No.: VP 3/2020
	Statute of the Ethics Committee of the Jessenius Faculty of Medicine of Comenius University in Martin	Copy No.: 1 Period of storage: 10 years

- a) attend every meeting of the Committee,
 - b) draw up the minutes of the meetings of the Committee,
 - c) archive documents relating to the Committee's activities in accordance with the relevant legislation,
 - d) on the basis of instructions from the Chairman of the Committee, carry out basic administrative and some technical work necessary for the work of the Committee,
 - e) be responsible for ensuring the protection and confidentiality of data, information and documentation related to the Committee's activities.
- 4) The term of office of the Secretary shall not be limited in time. In the event of termination of office pursuant to Article 2(9)(a) to (c) or by termination of employment, the Secretary shall, in a timely and responsible manner, hand over the agenda, documentation and archives of the Committee to the newly appointed Secretary in liaison with the Chairman of the Committee.

Article 5 Committee meeting

- 1) The Committee shall meet as necessary, normally once every two months, but at least four times a year.
- 2) The Committee's meetings shall be convened, chaired and declared closed by the Chairman of the Committee.
- 3) The agenda and the documents for the Committee's meeting must be communicated to the members of the Committee at least 7 days before the start of the Committee meeting. In extraordinary cases, the Chairman of the Committee may decide to shorten the time limit.
- 4) The submitter is required to submit a written form of the application to the Ethics Committee at least 14 days prior to the Ethics Committee's meeting.
- 5) The Committee shall deliberate if an absolute majority of all its members is present.
- 6) In justified cases, when dealing with certain serious technical issues, the Chairman of the Committee may invite experts of different scientific specialisations - experts who have the right to express their views on the issues under discussion without the right to vote. The expert shall submit to the Chairman a signed declaration of confidentiality pursuant to Article 2(6)(d) of this Statute.
- 7) Meetings of the Committee and all materials associated with the meeting are closed to the public.
- 8) In exceptional and extraordinary situations, the Chairman of the Committee may, on matters which cannot be postponed, ask the members of the Committee for an opinion "per rollam". The conclusions of the per rollam vote shall be recorded and reported to the next ordinary meeting of the Committee.
- 9) The Committee adopts its opinions by an absolute majority of the members present, unless otherwise provided by law (Act No. 576/2004 Coll. and Act No. 362/2011 Coll. - by a two-thirds majority of all members).
- 10) A member of the Committee who disagrees with the adopted opinion of the Committee shall have the right to have his/her dissenting opinion, with reasons, appended to the adopted opinion.

	COMENIUS UNIVERSITY BRATISLAVA JESSENIUS FACULTY OF MEDICINE IN MARTIN	Int. doc. No.: VP 3/2020
	Statute of the Ethics Committee of the Jessenius Faculty of Medicine of Comenius University in Martin	Copy No.: 1 Period of storage: 10 years


- 11) Further details are regulated in the Rules of Procedure of the Ethics Committee issued by the Dean of JFMED CU.

Article 6
Material, technical and financial support for the Committee's activities

- 1) The JFMED CU spatially, technically and administratively ensures the activities of the Ethics Committee, in particular by providing:
 - suitable premises for the regular meetings of the Committee and the work of its Secretary,
 - premises for the proper archiving of documentation related to the Committee's activities, in accordance with ensuring the protection of data and information in accordance with the legislation in force,
 - adequate quantities of office supplies, photocopying and IT equipment.
- 2) The JFMED CU provides financial support for the activities of the Committee (e.g. payment of travel reimbursements to invited experts, travel allowances to members of the Committee for participation in professional events related to the activities of the Ethics Committee).
- 3) Fees for assessing the ethical acceptability of biomedical research projects from applicants who are not employees or students of JFMED CU are invoiced. The amount of the fees is regulated in the Rules of Procedure of the Ethics Committee.
- 4) The income thus generated is intended to cover the costs associated with the activities of the Ethics Committee, the peer review of the study, its administration and oversight throughout the duration of the clinical trial. It can be used for e.g.:
 - payment of remuneration to members of the Committee, invited experts, for the preparation of reports and expert opinions, remuneration for professional acts to experts from the relevant medical field, to the Secretary of the Committee, depending on the quality and scope of the work carried out,
 - contribution to the operating costs of JFMED CU,
 - expenditure on the acquisition of technical literature, basic legislation, consumables,
 - adequate refreshments during the Committee's deliberations,
 - other expenditure relating to the Committee's activities.
 - other expenditure relating to the Committee's activities.

Art. 7
Transitional and Final Provisions

- 1) The Internal Regulation No. 4/2018 Statute of the Ethics Committee of JFMED CU in Martin for the assessment of experimental activities on animals of 16 April 2018, as amended, and the Internal Regulation No. 3/2018 Statute of the Ethics Committee of the Jessenius Faculty of Medicine of CU in Martin for clinical research and clinical trials of pharmaceuticals and any other type of biomedical research are hereby repealed.

	COMENIUS UNIVERSITY BRATISLAVA JESSENIUS FACULTY OF MEDICINE IN MARTIN	Int. doc. No.: VP 3/2020
	Statute of the Ethics Committee of the Jessenius Faculty of Medicine of Comenius University in Martin	Copy No.: 1 Period of storage: 10 years

- 2) This Statute may be amended, supplemented and updated by written amendments.
- 3) This Statute enters into force on the date when it was discussed in the Management Board of JFMED CU and comes into effect on 1 March 2020.

Prof. MUDr. Andrea Čalkovská, DrSc.
 Dean of JFMED CU in Martin