

Measure of the Dean of the Faculty of Medicine of Masaryk University No. 2/2016 on the Statute of the Ethics Committee of the Faculty of Medicine of Masaryk University

Article 1

Establishment of the Ethics Committee of the Faculty of Medicine of Masaryk University

- (1) This measure of the Dean of the Faculty of Medicine of Masaryk University implements MU Directive No. 5/2015 Research Ethics at MU.

Article 2

Competence of the Ethics Committee of the Faculty of Medicine of Masaryk University

- (1) The Ethics Committee of the Faculty of Medicine of Masaryk University (hereinafter referred to as "the Committee") is an independent body of the Faculty of Medicine of Masaryk University (hereinafter referred to as "LF MU") and is an integral part of the system for quality assurance and compliance with ethical standards of research at LF MU.
- (2) The committee deals with ethical aspects of research conducted at MU Faculty of Medicine involving human subjects in any way, including biological material of human origin and personal components of the subject falling under the protection of personality and personal data, with the exception of activities falling within the scope of other ethics committees operating at MU.
- (3) The Commission does not deal with the issue of ethics of scientific work, which is within the competence of the MU Ethics Committee in connection with the MU Code of Ethics for Academic and Professional Staff.
- (4) The committee acts on the initiative of the proposer or principal investigator of the research project requiring assessment, who is an employee or student of LF MU, another employee or student of LF MU or on its own initiative.
- (5) The Commission may invite other experts who are not members of the Commission for the purpose of consultation. They shall also be under an obligation of confidentiality with regard to the facts which come to their knowledge in the context of their work for the Commission. They shall confirm their agreement to confidentiality by means of a written declaration.

Article 3

Membership of the Commission

- (1) The Commission shall consist of at least five members, including the Chairperson of the Commission.
- (2) Membership of the Commission is by appointment. Members of the Commission are appointed by the Dean of the MU Faculty of Medicine.
- (3) Only a person who:
 - a) agrees to be a member of the Commission;
 - b) accepts the obligation of confidentiality regarding the content of the projects under consideration so that the information contained in the project cannot be misused;

- c) undertake to disclose any circumstances or facts that could lead to a conflict of interest or directly give rise to a conflict of interest.

- (4) The activities of the Commission shall be directed by its Chairman or by a member of the Commission designated by him. The Chairperson of the Commission is appointed by the Dean on the proposal of the majority of the Commission members.
- (5) Membership of the Commission shall terminate by removal, by resignation of a member at the member's own written request, or by death of the member.
- (6) Members of the Commission have a duty to participate actively in its activities.
- (7) The list of Commission members is kept by the Commission Chairperson and is published on the LF MU website.

Article 4

Activities of the Commission

- (1) The basic activity of the Commission is to supervise the application and observance of ethical standards in research conducted within the MU Faculty of Medicine and in any way involving human subjects.
- (2) The Commission within its competence at LF MU in particular:
 - a) ensures that research projects requiring ethical review for any reason submitted to it for comment are evaluated by a competent, objective and independent process;
 - b) assesses whether the research project proposal submitted to the Commission complies with ethical standards and issues a written statement to that effect;
 - c) is entitled to monitor the progress of a research project on which it has issued a recommendation;
 - d) assesses whether research conducted at the MU Faculty of Medicine in any way involving human subjects, including biological material of human origin and personal components of the subject falling under the protection of personality, complies with ethical standards and whether the dignity, freedom, health, privacy, quality of life and safety of all persons participating in the research are respected.
 - e) Pay special attention to the protection of vulnerable or dependent persons participating in research.
- (3) Upon request, the Commission provides consultation to MU Faculty of Medicine researchers and students on the recognition of potential ethical risks in research and relevant preventive or corrective measures.
- (4) The Commission's activities are administratively handled by the Commission's Secretariat. The Commission has its administrative officer - secretary. He or she shall also be bound to maintain the confidentiality of any facts which come to his or her knowledge in connection with the performance of that activity.

Article 5

Commission meeting

- (1) The meetings of the Commission are closed to the public.
- (2) The meetings of the Commission shall be convened and chaired by the Chairman of the Commission.
- (3) There is no minimum quorum for a quorum of the Commission.
- (4) A written record shall be made of the proceedings of the Commission. The Commission shall draw up a written opinion on the project proposals submitted. The Commission's opinions and statements shall be archived.
- (5) The opinion of the Commission shall be delivered to the proposer of the research project.

Article 6
Final provisions

(1) This Statute of the Ethics Committee of the Faculty of Medicine of Masaryk University shall come into force on the date of its publication.

In Brno on _____

Prof. MUDr. Jiří Mayer CSc.,
Dean of LF
MU