

STATUTE

*of Ethics Committee of the UPJŠ
Faculty of Medicine in Košice
for experiments on animals,
clinical research and clinical trials of
medicinal products and any other type
of biomedical research*



Košice, June 2007

Statute of the UPJŠ FM Ethics Committee

Official name of the Committee: Etická komisia Lekárskej fakulty UPJŠ

v Košiciach (abbreviation: EK LF UPJŠ)

**English name of the Committee: Ethics Committee, Faculty of Medicine,
Šafárik University in Košice**

Article 1

General Provisions - Mission and Purpose of the Statute:

1. In accordance with Article 69 of the Statute of the UPS Faculty of Medicine, the Ethics Committee (EC) is an initiating and advisory body of the UPJŠ Faculty of Medicine. The main mission of the EC is:
2. Determination of the procedure for medical research on human subjects, ensuring the binding of any research, study, verification of new procedures for approval by the Ethics Committee in accordance with the applicable legislation (Law Acts of the National Council of the Slovak Republic No. 576/2004; Decree of the Ministry of Health of the Slovak Republic No. 239/2004. and the National Council of the Slovak Republic No. 289/2003 Coll.), and ethical standards (Nuremberg Code, Declaration of Helsinki, Ovid Treaty). Similarly, it acts in the field of experiments on animals, as well as in other areas of research (research ethics and research direction, e.g. development of biological warfare agents or substances harmful to health for military or other orders). It shall decide on issues of ethics of teaching at UPJŠ FM, considering academic freedoms. In doing so, it shall consider the current state of knowledge and solutions to ethical issues both nationally and internationally.
3. It documents that the provisions (rules of procedure, procedure for dealing with submissions, etc.) correspond to the legal regulations applicable to the activities of ethics committees:
 - Law Act of the National Council of the Slovak Republic No. 576/2004 Coll. on Health Care, Section 5.,
 - Decree of the Ministry of Health of the Slovak Republic No. 239/2004 Coll. on Requirements for Clinical Trials and Good Clinical Practice Sections 5 and 6.
 - Government of the SR Decree No. 289/2003 Coll. laying down requirements for the protection of animals used for experimental or other scientific purposes Section 20.
3. The Committee takes note of the Ovideo Treaty of the Council of Europe of April 1997 on the rights and dignity of the human being and on the protection of the human being with regard to use in biological or biomedical research, in particular:
General rules concerning scientific research:
 - Scientific research may be freely carried out in the field of biology and the medical sciences, provided that all the rights of the human being (patient, experimental subject) are preserved within the intent of the above Treaty."
 - Protection of persons voluntarily submitting to research.
 - Protection of persons incapable or deprived of the capacity to give such consent.
4. Similarly, it adopts the provisions of the World Medical Association enshrined in the Declaration of Helsinki.
5. The objectives of the Commission include the protection of the interests and rights of the human being, including personal freedom and the right of the patient to decide for him/herself, professional assistance in the professional drafting of experimental protocols and their strict control, and the endeavour to maximise the use and utilisation of the results of experiments and to avoid duplication and unnecessary experimentation. Special attention is also paid to ethical issues in the formulation and presentation of scientific results.

6. The EC of the UPJŠ FM may also hold joint meetings with the ethics committees of other departments (e.g., the Faculty Hospital).

Article 2

Provisions and Definitions

1. The basic task of the EC is to assess the legal-ethical and medical-ethical aspects of the submissions and to discuss and draw up expert opinions on:
 - a. biomedical and clinical research projects,
 - b. the way in which these projects are carried out,
 - c. publication of the results of experimental and clinical research,
 - d. implementation of research results in practice,
 - e. addressing ethical issues related to the general duties of teachers, teacher-physicians, researchers, students and other categories of professionals, and on interpersonal relations,
 - f. other ethical issues that may arise (new methodological practices, publishing, public speaking, etc.).
2. The EC shall also carry out advisory or consultancy activities for teachers, researchers. and students.
3. The EC shall also popularise information on medical ethics relevant to the UPJŠ FM, draw attention to existing ethical issues in practice, launch discussions at the meetings of the management, the Academic Senate, the Academic Board of the UPJŠ FM, at the meetings of chairpersons and other faculty forums, and determine the ethical aspect of the relations between the UPJŠ FM and the medical institutions and the public.

Article 3

Composition and Operation of the EC

1. The number of members of the EC shall be at least 5. The members of the Ethics Committee shall be experienced, and morally impeccable teachers and researchers employed at the UPJŠ FM on a full-time basis or independent members who do not have an employment relationship with the UPJŠ FM. The member shall have sufficient time available to work in the EC. Membership in the EC is honorary.
2. Members of the EC shall be elected and removed by the UPJŠ FM management in accordance with Article 69 of the UPJŠ FFM Statute on the motion of the Dean of the UPJŠ FM. Once elected, they shall be appointed by the Dean of the UPJŠ FM.
3. At least one member of the EC shall be independent of the UPJŠ FM and at least one member shall not have a medical degree (this condition may be implemented by ad hoc appointment in cases of consideration of a problematic issue that legally requires such a composition).
4. Membership in the EC shall be terminated by written removal from office by the Dean of the UPJŠ FM (usually triggered by a resolution of the EC), by written resignation of the member or by death of the member. Reasons need not be given for the removal of a member.
5. The Dean of UPJŠ FM shall the Chairperson of the EC, and upon his/her motion, the Committee shall elect a Secretary by secret ballot (by a supermajority of all the votes) at the inaugural meeting, unless the UPJŠ FM management has directly appointed him/her.
6. The EC may invite another expert as a consultant (an expert in medical ethics and bioethics, an expert in ethics in the field of law, a doctor of veterinary medicine, a lawyer, a psychologist, a philosopher, a sociologist, a theologian, etc.), who, however, shall not have the right to vote.
7. The Chairperson shall receive and include in the agenda of the meeting motions and requests for consideration by the EC.

8. After the discussion, depending on the content and nature of the request, he/she shall submit the opinions and conclusions of the EC in writing to the UPJŠ FM management, the UPJŠ FM Academic Board, or the applicant, as appropriate.

Article 4 Proceedings

1. the EC shall meet as required (as a rule once a month, except for the months of July and August, but at least once a quarter).
2. A quorum shall be present if at least half of all the EC members are present.
3. The EC shall be chaired by its Chairperson or Secretary. In their absence, a chairperson shall be elected from among the members of the EC.
4. Minutes shall be taken of the proceedings of the EC.
5. The EC, as a collective body, shall adopt its conclusions, as a rule, on the basis of discussion (dialogue) and consensus of all its members.
6. In the absence of consensus, it shall adopt its conclusions by public vote.
7. A decision shall be valid if a majority of the members of the EC present vote in favour of it.
8. Members of the EC who voted against the conclusion reached shall have the right to request that their opinion be recorded in the minutes of the EC meeting.
9. Decisions of the EC shall be in the form of a resolution, which shall be numbered in ascending order and shall form part of the minutes, which shall be publicly available.
10. In exceptional cases, the EC may request the opinion of ethics committees of other medical faculties or methodological and consultative bodies (the Section for Medical Ethics under the Council of the Minister of Health of the Slovak Republic, the EC of the Institute of Preventive and Clinical Medicine in Bratislava, etc.).
11. The costs necessary for the activities of the EC shall be borne by the UPJŠ FM.

Article 5 Final Provisions

1. This Statute is in accordance with the Principles for the Establishment and Operation of Ethics Committees in the Ministry of Health and the Ministry of Education of the Slovak Republic and may be supplemented and amended according to the needs of the UPJŠ FM.
2. Amendments and additions to this Statute shall be subject to the approval of the UPJŠ FM management.
3. The Statute for the activities of the Ethics Committee at the UPJŠ FM shall enter into force on the date of its approval by the UPJŠ FM management.

In Košice, dated 20/06/2007

Prof. MUDr. Leonard Siegfried, CSc.,
UPJŠ FM Dean