

**AMENDMENT No. 2**  
**to the Statute of the Ethics Committee of the UPJŠ FM in Košice**  
**for Work with Laboratory Animals**

**PURPOSE**

Pursuant to Decree No. 436/2012 Coll., laying down requirements for the protection of animals used for scientific or other educational purposes, the requirements for the activities of the ethics committee for the user facility are hereby amended. Therefore, this Amendment to the Statute of the Ethics Committee for Work with Laboratory Animals is hereby issued.

**FIELD OF APPLICATION**

The UPJŠ FM in Košice Ethics Committee for Work with Laboratory Animals is a professional advisory body for the assessment of projects of the UPJŠ Faculty of Medicine in Košice with competence for all the units falling under the organisational structure of the UPJŠ FM in Košice.

**TASKS OF THE ETHICS COMMITTEE**

The Ethics Committee's approval of the project is a recommendation to the person in charge of the project or the user for submission for approval.

The evaluation of the project depends on the type of project. It verifies that the project meets the following criteria:

- (a) it is justified from a scientific or educational point of view or from the point of view of its necessity under a special regulation,
- (b) its purpose justifies the use of animals; and
- (c) it is designed to enable the procedures to be carried out in the most humane and environmentally acceptable manner.

The evaluation of the project shall include in particular:

- (a) evaluation of the objectives of the project, the scientific contributions presented or the educational value,
- (b) assessment of the project's compliance with the requirement for replacement, reduction or refinement,

- (c) assessment and assignment of the cruelty classification of procedures,
- (d) analysis of the project in terms of the harm-benefit ratio to assess whether the harm caused to animals in terms of suffering, pain and distress is justified by the anticipated outcome, taking into account ethical considerations, and whether it may ultimately benefit humans, animals, or the environment,
- (e) the assessment of the justification referred to in Articles 5 to 11, 13, 15 and 31 of Government Regulation No 377/2012 Coll.
- (f) determination of whether and when the project should be reassessed.

Only after the Ethics Committee agrees with the experimental project, the authorised person (project leader) may submit the project for approval by the State Veterinary and Food Administration of the Slovak Republic in Bratislava. In this way, the authorised person shall apply to the institution for approval of the research project using the experimental animals specified in the project.

In the event of non-compliance of the project with the requirements pursuant to Section 36 of Government Regulation No 377/2012 Coll., the Ethics Committee shall recommend to the person in charge of the project or the user to modify the parts of the project in which the non-compliance has been identified.

The Ethics Committee shall draw up a written statement on the assessment of the submitted project. The report shall also include a statement of agreement with the project under development and shall form part of the application in the process of approval of the project by the State Veterinary and Food Administration of the Slovak Republic in Bratislava.

The Ethics Committee shall carry out an annual review of the projects already approved at the user establishment, which are approved for a period longer than one year.

### **ORGANISATIONAL COMPOSITION OF THE COMMITTEE**

The Ethics Committee shall be composed of scientific staff and persons independent of scientific work, at least one third of the members of the Ethics Committee being staff independent of the user establishment whose project is being evaluated or of its founder, and members of the Ethics Committee who are employees of the user establishment shall be disinterested in the project under review.

The number of members of the Ethics Committee shall be odd. The Chairperson of the Ethics

Committee shall be a person independent of the user establishment whose project is being assessed.

In addition to its standing members, the Committee shall also have at its disposal experts and advisers in the legal field who are invited to attend meetings of the Ethics Committee in cases of qualified solutions to issues in areas of expertise that are not occupied by the standing members of the Committee, as well as in cases where a decision of the Committee leads to a divergence of opinion among its members on a matter under discussion or to a conflict of opinion among its standing members.

Members of the Commission shall be appointed for a term of 5 years and shall be eligible for reappointment. In the event of resignation of a member of the Commission during the term of office, the Dean of the UPJŠ FM shall appoint a new member of the Committee. The office of a member shall be irreplaceable and honorary.

All the members and invited guests shall be bound by confidentiality of the information they learn in the course of the deliberations from the documentation provided and in the course of supervising the progress of the study or research project.

The Committee shall be composed in such a way as to be able to ensure, in the light of the above objectives:

- competent assessment of the project/study documentation from an ethical point of view
- objectivity of the assessment, taking into account the professional objectives of the studies/projects under consideration
- impartiality and to exclude bias in the assessment
- exclusion of external influences that would limit the objectivity of the assessment

The Committee shall operate pursuant to the Statute and shall keep a written record of all its decisions. The Committee shall meet on an ad hoc basis as necessary - as soon as possible.

## **APPOINTMENT OF MEMBERS**

All of the Committee members shall be appointed and removed by the Dean of the UPJŠ FM.

The membership in the Committee is conditional upon:

- (a) civic integrity,
- (b) the required education and experience to serve on the Ethics Committee,
- (c) the proposed person's consent to appointment as a member of the Committee,
- (d) consent to the disclosure of name, surname, and place of employment in the materials and opinions of the Committee,
- (e) undertaking of confidentiality of any information of a confidential nature of which the member becomes aware in connection with his/her membership of the Committee,
- (f) undertaking to disclose any circumstance or fact which might give rise to or directly create a conflict of interest in relation to membership of the Committee or in relation to a particular issue under consideration by the Committee.

**Members of the Ethics Committee of the Academic Board of the P.J.  
Šafárik University Faculty of Medicine in Košice**

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**The following shall be invited:** experts and advisers in the field of law, or in cases of a qualified solution of a problem from areas of expertise not occupied by the standing members of the Committee, as well as in cases where, in the context of a decision of the Committee, there is a divergence of opinion among its members on the subject under discussion or a conflict of opinion among its standing members.

## **ASSESSMENT OF APPLICATIONS**

The Ethics Committee shall assess draft projects based on an application submitted in writing by the principal project applicant.

The necessary documentation in Slovak or English shall be handed over to the Chair or Vice-Chair of the Committee.

The Committee shall request the following documentation from the applicant for project assessment:

- Letter of request for assessment
- Application form for project approval - Annex 2 of Decree No 436/2012 Coll.
- Study protocol including all addenda

If necessary, the EC may also request other materials needed for the assessment of the project. It shall also keep a record of all applications received according to the date of receipt and inform the applicant in due time in case of incompleteness.

The EC shall communicate its requirements to the applicant, together with a warning that the project may not be started without the prior approval of the State Veterinary and Food Administration of the Slovak Republic.

The Chairperson or his/her designated representative shall inform all its members by e-mail of the date of the next meeting of the Ethics Committee.

## **COMMITTEE MEETING**

The Committee shall not meet in public. It shall be attended by the members of the Committee and, where appropriate, by invited external experts. In particular, the Committee shall assess the completeness of the information provided by the project/study applicant, the risk-benefit

balance for the subjects of the evaluation, the appropriateness of the proposed protocol, the qualifications and experience of the principal testing investigator or principal investigator of the research project, and the ability of the user facility to perform the proposed study.

### **COMMITTEE DECISION**

The Ethics Committee shall take its decision by vote. Only the appointed members of the Ethics Committee shall take part in the vote. A quorum shall be present if a majority of the members is present.

If the Committee requires further information for its decision, it shall notify the applicant, who shall be obliged to complete the documentation within 2 weeks of receipt of the notification. Otherwise, the application shall be deferred.

Minutes shall be drawn up of each decision of the Commission, which shall include a comprehensive assessment of the project in accordance with the requirements of the National Regulation No 377/2012 Coll., the date and place of the proceedings, and the signature of the chairperson.

### **NOTIFICATION TO THE APPLICANT OF THE COMMITTEE DECISION**

The Ethics Committee shall notify the applicant in writing of its opinion with a comprehensive assessment of the project within 15 days of receipt of the application.

The letter of the decision shall contain a comprehensive assessment of the project pursuant to the requirements of the Slovak Republic Regulation No. 377/2012 Coll. and the conclusion - the decision of the Committee.

### **AMENDMENTS TO OR CHANGES OF THE PROJECT**

Amendments to, or changes of, the project shall be forwarded to the Chairperson of the Committee for discussion at the next working meeting of the Committee. The project leader in charge of the project shall be obliged to attend the meeting and shall inform the Committee of the requested amendments to or changes of the project submitted.

## ARCHIVING

The Ethics Committee shall keep the following documentation:

- list of Committee members, EC Statute
- all the documents sent by the applicant to the Committee
- all correspondence from the Committee to the applicant and interested parties
- minutes of all the meetings of the Committee
- the Secretary of the Committee shall oversee the proper archiving. The documentation shall be kept on electronic media for a period of 5 years.

On request, the documentation may be made available for inspection by authorised inspection bodies.

This addendum to the Statute of the Ethics Committee of the UPJŠ FM for work with laboratory animals was approved in Košice on 12/06(2018).

Prof. MUDr. Daniel Pella, PhD.

UPJŠ FM Dean