

## How to apply

For the correct and complete application to the ethics committee, we would like to acquaint you with the rules and the correct procedure for their submission.

The project proposals and requests for the opinion of the EC on the planned biomedical or animal research are submitted in written (EC chairman) and in the electronic form (EC Secretary [darina.petrasova@upjs.sk](mailto:darina.petrasova@upjs.sk)).

All applications are registered according to the date of delivery. In case of incomplete application or formal imperfections in the application, the EC will invite the applicant to complete it.

For clinical studies, it is required to document the approval of the EC project of clinical workplaces (e.g. University hospital LP Košice; East Slovak Institute of Heart and Vascular Diseases; East Slovak Institute of Oncology; HCSA; Slovak Academy of Sciences; ...)

Within the cooperation with non-state ambulances, the project is assessed by the EC of the Office of the Košice Self-Governing Region.

International projects must also be submitted to the ethics committee in accordance with the internationally agreed principles in accordance with the applicable legislation of the Slovak Republic.

**The clinical study / project to be approved by the ethics committee must include:**

**1. Application to the ethics committee and approval of this project / task**

(Recipient:

doc. MUDr. Pavol Joppa, PhD., Chairman of the EC UPJŠ FM, SNP 1, 040 11 Košice)

**2. Research project / tasks**

(Project name: ....., Project sponsor: ....., Institutes and workplaces cooperating on the project: ....., Responsible researcher: ....., Project focus: ..... , Solution time: ....., Set goals: ....., Annotation: ....., Project characteristics: .....,)

**3. Completed basic form**

**4. Instruction and written informed consent of the patient** according to §6 of Act No. 576/2004 Coll.

**5. Instruction and informed consent of the patient** according to § 27 of Act no. 576/2004 Coll.

**6. Patient consent to the processing and use of personal data and data from medical documentation** for biomedical, historical research, scientific research and development, for the purposes of statistics and education of health professionals and student training (Act No. 18/2018 Coll. - GDPR)

**7. Consent of the research participant to the storage and use of samples of biological materials** for purposes other than those for which they were taken (Act No. 576/2004 Coll. Act on Health Care, Services Related to the Provision of Health Care and on the Amendment of Certain Acts).

8. Other documents that you deem attached at your discretion.

**Experimental – animal projects** are carried out exclusively at the approved workplace – Laboratory of Research Biomodels for all workplaces of UPJŠ FM only on the basis of a valid project decision approved by the State Veterinary and Food Administration of the Slovak Republic.

**Official number assigned: SK UCH 06023**

(Projects: APVV, VEGA, internal grants, GSS, GSD, higher education or vocational training in order to acquire, maintain or improve the skills needed to pursue the profession)

**The experimental study / project to be approved by the EC must include:**

1. Application to the ethics committee and approval of this project / task  
(Recipient: doc. MUDr. Pavol Joppa, PhD., Chairman of the EC UPJŠ FM, SNP 1, 040 11 Košice)

2. It is required to enclose the "Application for project approval – the Annexe No. 2 to the Regulation No. 436/2012 Coll.,"

[https://www.svps.sk/dokumenty/legislativa/v\\_436\\_2012.pdf](https://www.svps.sk/dokumenty/legislativa/v_436_2012.pdf) together with the elaborated project, which must meet the content requirements of the application for the project approval according to **the Annexe No. 6 NV č.377 / 2012 Coll.**

[https://www.svps.sk/dokumenty/legislativa/nv\\_377\\_2012.pdf](https://www.svps.sk/dokumenty/legislativa/nv_377_2012.pdf).

3. **The an affirmative standpoint of the EC UPJŠ FM** is attached as an annex to the application, which is sent to the State Veterinary and Food Administration SR.

The application prepared in this way, with the required attachments, is confirmed by the person authorized to submit projects, responsible for the overall implementation of the project, the head of the accredited workplace Laboratory of Research Biomodels UPJŠ FM and is sent to the address:

MVDr. Bernadeta Jurkanin, PhD.  
Department of Animal Health and Welfare  
State Veterinary and Food Administration of the Slovak Republic  
Botanická 17, 842 13 Bratislava

Notes:

- Expected start date of the project – SVFA SR has 40 working days for the project evaluation and elaboration of the decision on the project approval (excluding weekends, public holidays, church holidays ....) only working days.
- The project is approved for a maximum of 5 years, no more.
- The project can be implemented by researchers who have obtained a Certificate of completion of the accredited educational programme "Protection of animals used for scientific or educational purposes" on the basis of the Slovak and EU legislation.

**Veterinary supervision – contracted veterinarian of the facility**

MVDr. Silvia Mateova, PhD.

Chamber of Veterinary Surgeons of the Slovak Republic; Certificate No.1618

## **HOW TO APPLY – BACHELOR’S AND THESIS WORKS**

For the correct and complete submission of applications for approval of the bachelor's / thesis by the Ethics Committee, we would like to acquaint you with the rules and the correct procedure for their submission:

### **The project, for retrospective clinical trials, must include:**

- Application to the Ethics Committee for approval of the submitted clinical study. The application must be signed by the applicant, i.e. student.
- Annotation of the project with a clear definition of the objectives of the clinical study and how to achieve them. The annotation must be signed by the submitter, i.e. the student and thesis supervisor.
- Completed [basic form](#).

### **The project, for prospective clinical trials, must include:**

- Application to the Ethics Committee for approval of the submitted clinical study. The application must be signed by the applicant, i.e. student.
- Annotation of the project with a clear definition of the objectives of the clinical study and how to achieve them. The annotation must be signed by the submitter, i.e. student and thesis supervisor.
- Completed [basic form](#).
- Patient information in Slovak language.
- Informed consent in the Slovak language.

### **The project, for experimental studies, must include:**

- Application to the Ethics Committee for approval of the submitted clinical study. The application must be signed by the applicant, i.e. students with clearly marked contact details (phone number or e-mail).
- Annotation of the project with a clear definition of the objectives of the clinical study and how to achieve them. The annotation must be signed by the submitter, i.e. student and thesis supervisor.
- Completed [basic form](#).
- To submit a request for experiments using experimental animals in accordance with the Collection of Act No. 377/2012 and paragraph 36 of the Regulation of the Government of the Slovak Republic in all its points.