RULES OF PROCEDURE

of the Ethics Committee of the Jessenius Faculty of Medicine
CU in Martin

for animal experimentation,
clinical research and clinical trial of drugs and any other type of
biomedical research

Martin, 2013
Rules of Procedure of the Ethics Committee of JFMED CU

Article I. Committee Meeting

1. Meeting of the Committee is called by the chairman usually every two months, at least four times a year. In case of emergency, the chairman of the Ethics Committee may call an extraordinary meeting.

2. The chairman of the Committee notifies the members of the Committee (in writing or via e-mail) of the date of a forthcoming meeting one week prior to the meeting at the latest as well as of the agenda of the meeting.

3. Committee meeting is not public. Only the members of the Ethics Committee and invited applicants of research projects and clinical trials, or invited external experts participate in the meeting. If necessary, the Ethics Committee invites a specialist to attend a certain point of the program, who does not have a right to vote. In justified cases, representatives of subjects involved in a trial are also invited. The chairman or authorized member of the Committee decides whether they will be invited.

4. Records and all materials related to the activities of the Committee are confidential, with the exception of statements, opinions and other documents directly intended for publication.

Article II. Reviewing the application

1. Committee assesses proposals of clinical studies on the basis of a written application submitted by the responsible investigator or sponsor of the clinical study, clinical research projects proposals, implementation of new diagnostic and therapeutic methods, research project proposals using experimental animals or any other type of projects of biomedical research.

2. To review given projects by the Ethics Committee, the following documentation is required:

- written application of principal investigator - completed form, prepared in advance by the Ethics Committee. The form can be obtained on the website of the Ethics Committee of JFMED CU in Martin,

- in case of submission and approval of projects of research grants, whether experimental, clinical or other type of biomedical research, it is necessary to attach all project documentation,

- when assessing the clinical trial of a drug, which is not registered in the Slovak Republic, it is necessary to attach complete documentation relating to the pharmacodynamic, pharmacokinetic and toxicological aspects of examined drug in the scope of Information for the investigator (Clinical Investigator Brochure - CIB)
3. The Committee primarily assesses completeness of information provided by the applicant of grant project/clinical study, ratio between risk and benefit to subjects involved in a trial, appropriateness of the proposed protocol, qualification and experience of the responsible investigator and the head of the research project, capability of health facility to carry out the proposed study, adequate medical follow-up of subjects, the adequacy of monitoring the course of the clinical study, completeness and adequacy of information given to subjects, selection of subjects for clinical trials, rewards and reimbursement of trial subjects, the method of obtaining informed consent from subjects or from their legal representatives.

4. In evaluating the research projects using laboratory experimental animals, the Committee assesses whether the proposed project is not in conflict with the protection of animals that resulted from the Decree of the Government of the SR No. 289/2003, No. 23/2009 and later adopted Law No. 377/2012 of November 14, 2012.

5. Required documentation to be discussed by the Ethics Committee shall be submitted in Slovak or English directly to the Chairman of the Committee at least 10 days prior to the meeting of the Ethics Committee at which the project is to be approved.

6. The Committee registers all applications according to the date of delivery and informs the applicant in case of incompleteness. If necessary, the Committee may request additional materials required for the assessment of the study / project.

7. The Ethics Committee notifies the applicant about its requirement together with a warning that a study or project must not be commenced without prior approval of the Ethics Committee.

8. Fees for reviewing a clinical study by the Ethics Committee at the Jessenius Faculty of Medicine in Martin are defined as follows:
a) multicenter clinical assessment in which the Ethics Committee of the Jessenius Faculty of Medicine in Martin works as a multi-center: 1330 EUR

b) multicenter clinical assessment in which the Ethics Committee of the Jessenius Faculty of Medicine in Martin works as a local: 665 EUR

c) monocenter clinical assessment: 665 EUR

d) a new assessment of revised clinical trial (new application of clinical trial, which has already been rejected once and has the same number EduraCT): 166 EUR

e) assessment of protocol amendment to: 166 EUR

f) projects of experimental, clinical or other biomedical research, which are submitted by the staff of the Jessenius Faculty in Martin within grant projects, the Committee assesses without payment.

9. Payment of fee is a condition to include a clinical study or an amendment to the agenda of the Ethics Committee.

10. Payments are intended to cover the costs associated with activities of the Ethics Committee. Most of the costs are related with the peer review of the study, the administration and supervision throughout the clinical study period.

11. The chairman of the Committee or the authorized representative shall appoint a member of the Committee or an external consultant to review submitted documentation of the project / study and shall present his/her opinion at the Committee meeting.

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**Article III.**

**Committee decision making**

1. Committee makes decision by voting.

2. Only appointed members of the Committee can vote. Committee is quorate if an absolute majority of its members is present, including the chairman of the Committee.

3. Decision is made by an absolute majority of present members of the Committee. The Committee member who votes against the proposal, has the right to have his/her opinion recorded in the minutes of the meeting.

4. Members of the Committee who have a conflict of interest when considering the proposal of a particular project / study, do not participate in discussions and voting.
5. If the Committee requires further information to make a decision, it shall notify the applicant, who is obliged to supplement the documentation within 1 month from the receipt of the notice. Otherwise, the application is postponed.

6. Record is made from each meeting of the Committee that contains the date and venue, a list of attendees (attendance list), a list of invited guests, main points of discussion, a record of decision including voting results, signed by the chairman of the Committee.

7. Members of the Committee are obliged to respect all measures to ensure the protection and confidentiality of information, data and documentation associated with the activities of the Committee in accordance with legal regulations and rules of procedure of the Committee.

**Article IV.**

**Notification to the applicant of Committee decision**

1. The Committee shall notify the applicant in writing of its decision and shall state the reason within 60 days of receipt of the application.

2. Written decision must include:
   - name and address of the Committee,
   - exact title of the project grant/clinical study, which protocol was assessed (protocol identifying number),
   - applicant’s name and name or title of sponsor,
   - list of documents that were assessed (date of protocol evaluation),
   - names of the committee members present at the meeting
   - conclusion/decision of the Committee,
   - in case of approval of the Committee, notification to the responsible examiner or principal investigator of an obligation:
     - Ø before the study/project begins, to obtain approval of the SIDC (State Institute for Drug Control) to the given study,
     - Ø to submit, for consideration of the Committee, all new protocol amendments before they are implemented in project/study; with the exceptions of amendments intended for elimination of imminent risk to subjects involved in a study and administrative amendments - these must be additionally reported to the Committee,
     - Ø to submit, for consideration of the Committee, protocol changes,
     - Ø immediately report to the Committee all serious unexpected events (side effects which caused serious damage to health or death of the subject involved in a trial)
Ø to notify the Committee of all new information that may adversely affect the safety of the subjects or the conduct of the clinical trial,

Ø submit a report to the Committee on the progress of the clinical trial (including adverse event reporting) once a year during its period and at the end.

• in case of disapproval, to state clear reasons for rejection,
• date and signature.

3. Committee may announce its decision also on the form which shall be submitted by the sponsor of the project / study.

Article V.
Clinical Trial Progress Report

1. Committee requires clinical trial progress report once a year. In justified cases, the report may be required more often. The report shall be sent to the chairman of the Committee or its authorized member.

Report must contain:
Ø brief description of the progress of a trial,
Ø administrative changes and changes of examiners,
Ø number of subjects involved in a trial out of the total planned number,
Ø a summary of serious adverse drug reactions observed in the centre, to which the Committee granted approval,
Ø a summary of serious adverse drug reactions in all participating centres,
Ø new knowledge about medication in relation to the profile of the drug, its safety and effectiveness
Ø information on possible interference of the Ethics Committees in the progress of trial in other centers,
Ø information on possible interference of the sponsor and all changes of the protocol and amendments
Ø number and results of audit.

2. Amendments or changes to the protocol are continuously sent to the chairman of the Committee, who shall submit them for consideration at the next committee meeting. Meeting
will be attended also by responsible examiner or the authorized examiner who shall inform the Committee about required amendments or revisions to the protocol.

3. Chairman of the Committee notifies the applicant in writing of the decision of the Committee within 35 days from receipt of request for amendment or modification of the protocol.

4. The Committee confirms receipt of amendments of administrative character in writing.

5. Reports on serious unexpected adverse drug reactions, on new information which may adversely affect the safety of the subjects or the progress of clinical trial, on changes that increase the risk of subjects or significantly affect the progress of the study are sent to the chairman of the Committee, who considers them and shall submit them for discussion at the next committee meeting. If necessary, chairman immediately acts on behalf of the Committee. He/she shall submit any such decision for assessment at the next Committee meeting.

6. After discussion, the Committee shall consider whether written response to submitted information is required.

7. In case of written answer, it is sent to the chairman of the Committee or other authorized members of the Committee within 10 days after discussions.

8. The Committee may cancel approval to conduct clinical trial, if information proving a negative effect on the risk-benefit of clinical study arise. The chairman immediately informs the applicant about cancellation of approval.

9. Written decision of the Committee must contain the requirements pursuant to Art. IV, point 2.

10. Committee requires written notice of completion of project task, clinical study or other forms of biomedical research.

Article VI.
Archiving

1. Committee keeps the following documentation:
   - list of Committee members, the Statute, Rules of Procedure,
   - all documents sent by the applicants to the address of the Committee,
   - all correspondence between Committee, applicants and involved parties,
   - minutes from all committee meetings,
   - all documents and correspondence relating to the monitoring of clinical study / project grant or other form of biomedical research,
   - notice of termination or early termination of study / project grant or biomedical research, including the grounds for early termination.

2. Chairman of the Committee is responsible for proper archiving.

3. The documentation must be kept in a locked room.
4. Documentation shall be kept for at least five years from the date of completion of clinical study, grant research project or other form of biomedical research.

5. Upon request, the document may be provided for inspection by authorized Slovak or foreign control body.

Article VII
Effectiveness

This Rules of Procedure comes into force on 12.5.2009.

Rules of Procedures of the Ethics Committee of the Jessenius Faculty of Medicine in Martin Comenius University in Bratislava of 19. 3. 2000 is cancelled.

In Martin, May 12, 2009

Prof. Gabriela Nosáľová, M.D.,DSc.
Chairperson of the Ethics Committee

Updated:

in Martin, July 1, 2011

Štefan Krivuš, M.D., PhD.
Chairman of the EC for evaluation of animal experiments

in Martin, November 25, 2013

Prof. Gabriela Nosáľová, M.D.,DSc.
Chairperson of the Ethics Committee

In Martin, November 25, 2013

Štefan Krivuš, M.D.,PhD.
Chairman of the EC for evaluation of animal experiments