Reference documents:
Education Act no. 1/2011
Law no. 206/2004 regarding good practices in scientific research, technological development and innovation
Law no. 398/2006
Charter of the George Emil Palade University of Medicine, Pharmacy, Science, and Technology in Târgu Mureş
Professional Ethics and Deontology Code of the George Emil Palade University of Medicine, Pharmacy, Science, and Technology in Târgu Mureş
Directive 2010/63/UE of the European Parliament and European Council regarding the protection of animals used for scientific purposes

REGULATION OF THE RESEARCH ETHICS COMMITTEE

Regulation of the Research Ethics Committee

Regulation code: UMFST-REG-74

Edition 02

Draftedt:	Research Ethics Committee	Date: 01. November 2013
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Date of withdrawal	

Chapter I.

General statements

Art. 1. The Scientific Research Ethics Committee is an independent body within the university, whose main objective is to supervise the observance of ethical principles in scientific research conducted on human subjects and experimental animals and to promote scientific research in this spirit.

Art. 2. The Scientific Research Ethics Committee has the role of monitoring the good conduct in scientific research

Art. 3. The Scientific Research Ethics Committee cooperates with the University Ethics Committee.

Chapter II. Organization

Art. 4. The structure of the ethics committee is proposed by the Administrative Board and approved by the University Senate, in accordance with the legislation in force.

Art. 5. The Scientific Research Ethics Committee is composed of 9 members who must have the necessary qualification and experience to evaluate the scientific, medical and ethical aspects of the studies proposed for approval.

Art. 6. The members of the Committee for the Scientific Research Ethics Committee elect the chair of the committee.

Art. 7. The Scientific Research Ethics Committee appoints a secretary who organizes the activity of the committee and is responsible for the evidence and transmission of information and decisions specific to the activity of the committee.

Article 8

1. The Ethics Committee shall carry out its activities in accordance with written working procedures.

2. The Ethics Committee shall keep written records of its activities and the minutes of meetings.

3. The Ethics Committee shall act in accordance with the rules of good practice in the field and the legal regulations in force following a request made in accordance with Appendix 1 (for clinical research) and Appendix 2 (for experimental research).

Chapter III. Operation mode

Art. 9.

1. The Scientific Research Ethics Committee shall meet monthly if requested to do so. The committee may also meet in extraordinary meetings, in special situations, when convened by the chair of the committee. The information between the members of the commission is transmmitted by e-mail.

(2) The convening of the meetings of the Scientific Research Ethics Committee is made at least 2 days before the proposed date, by telephone, by written address or by e-mail, except for extraordinary meetings where this interval may be reduced depending on the degree of urgency.

3. The Committee shall issue a written resolution for a request for approval of the research within a maximum of 30 calendar days of receipt of the complete dossier, with a clear identification of the study and the documents verified. The reasoned opinion of the Scientific Research Ethics Committee can be:

a) approval;

b) modifications requested in order of approval;

c) rejection.

(4) Based on a reasoned opinion, the Scientific Research Ethics Committee may at any time decide to conclude / suspend a previous approval.

(5) The Scientific Research Ethics Committee may send a study for evaluation to the national ethics committee, if it deems it necessary or if the legal provisions require it. In this case, the evaluation deadline of the research proposal is extended accordingly.

6. The decisions of the Scientific Research Ethics Committee, formulated in accordance with Appendix 3, shall be published on the University website and communicated in writing to the applicant. In the case of animal experiments, the decision must be communicated to the Biobase.

Art. 10.

1. The decisions of the committee shall be adopted by a simple majority of votes (half plus one of the number of members present), if at least 5 members are present at the committee meeting;

(2) Only the present members of the committee may vote;

(3) Only those members of the committee who are independent of the investigator (s) and the sponsor of the study may vote; any conflict of interest MUST be declared before the meeting;

Art. 11

1. The Committee may invite experts in various fields in the field under discussion for consultations.

2. At the request of the committee, the investigator or sponsor may be asked to provide additional information or clarification on any aspect of the study, but may not participate in the committee's debate or vote.

Art. 12. The relevant records (written procedures, lists of members, lists regarding the occupation / membership of members, CVs, documents submitted, minutes of meetings and correspondence) shall be kept for a period of at least 3 years after completion of the study for which approval was requested.

Art. 13. The Scientific Research Ethics Committee will be audited according to the legislation in force and the regulations of the UMFST Tg. Mures.

Art. 14.

The Scientific Research Ethics Committee has the attributions established according to art. 12 of Law no. 206/2004 on good conduct in scientific research, technological development and innovation, amended and supplemented by Law no. 398/2006: the evaluation from the ethical point of view of the research-development and innovation projects is carried out by their evaluation committees and will obligatorily include the verification of the conformity of the respective projects in terms of:

(1) generally applicable ethics regulations, relating to:

a) protection of the human person:

- use of human embryos, as well as other human biological samples;

- use of personal data for biological banks, including gene banks;

- the use for clinical trials of persons (individuals or population) in the following categories: persons who cannot consent, in particular children, pregnant women, healthy volunteers and vulnerable categories (persons with disabilities, prisoners of war and prisoners of civil society: persons hospitalized in a controlled regime: quarantine, rehabilitation, detoxification, de-alcoholization, etc.);

- protection of personal data;

b) protection of animals, including transgenic animals and non-human primates;

c) environmental protection;

(2) specific ethical internal and international regulations, applicable to the respective research and which must be explicitly specified by the project**.**

Chapter IV. Duties regarding clinical studies

Art. 15.

(1) The mission of the Scientific Research Ethics Committee is to protect the rights, safety and comfort of participants in a clinical trial, as well as to guarantee this protection to the general public;

2. The Scientific Research Ethics Commission shall exercise its mission by formulating an opinion on the study protocol, the quality of the research facilities and the methods and documents used to inform the study participants, in order to obtain their informed consent.

(3) The Scientific Research Ethics Commission shall receive the following documents relating to clinical trials for which a favorable opinion is requested:

a) the clinical protocol and any amendments;

b) the written information that will be provided to the subjects;

c) the informed consent form;

d) the procedures for recruiting the subjects;

e) the investigator's brochure;

f) the available information on the safety of the methods and products to be used;

g) information on payments and compensations available to subjects;

h) the CVs of the investigators and, if applicable, documents proving their qualification;

i) any other necessary documents.

(4) The Scientific Research Ethics Committee must evaluate the qualification of the investigator

(5) The Scientific Research Ethics Committee may request additional information if it is considered that it would help to improve the understanding of the situation regarding the protection, rights, safety and / or comfort of subjects;

(6) If the protocol provides that the prior informed consent of the subject or his / her legal representative cannot be obtained, the Scientific Research Ethics Committee shall require that the proposed protocol and / or other documents adequately address relevant ethical issues and comply with legal requirements.

(7) In the case of a non-therapeutic study conducted with the consent of an accepted legal representative of the subject, Scientific Research Ethics Committee must require that the proposed protocol and / or other documents adequately address relevant ethical issues and meets legal requirements.

(8) The Scientific Research Ethics Committee may carry out a new evaluation at different time intervals of each study, intervals that will be established according to the study protocol and the existing degree of risk for the subjects.

(9) The Scientific Research Ethics Committee also evaluates the amendments to the protocol that appear during the study;

(10) The Scientific Research Ethics Committee may at any time decide to conclude / suspend a previous approval if new data related to the study or the general scientific context of the studied field have appeared that could create research ethics problems not initially identified.

Chapter V. Duties regarding experimental studies on experimental animals

Article 16

(1) At the George Emil Palade University of Medicine, Pharmacy, Science and Technology of Târgu Mureş all animal experiments must comply with the standards imposed by Directive 2010/63 / EU of the European Parliament and of the Council on the protection of animals used for scientific purposes and must be approved by the Scientific Research Ethics Committee.

2. The aim of the Scientific Research Ethics Committee shall be to protect animals in scientific experiments, with a view to minimizing suffering, reducing the number of animals used in experiments or replacing them with other experimental models where possible, and accounting for these protective measures in front of the general public.

3. The Scientific Research Ethics Committee shall exercise its mission by formulating an opinion on the study protocol, the qualification of the investigators, the quality of the research facilities and the methods used.

(4) In order to approve the experimental studies on animals, the Scientific Research Ethics Committee must receive the documentation of the study prepared according to the specifications in Appendix 2. Any modification of the project must be approved by the Scientific Research Ethics Committee.

Chapter VI. Sanctions

Art. 17.

If it finds deviations from the professional ethics within the scientific research activity, the Scientific Research Ethics Committee notifies the University Ethics Committee in order to analyze and solve the situation.

Chapter VII. Appeals

Art. 18. The appeals will be submitted within 24 hours from the decision of the Scientific Research Ethics Committee and will be resolved within 7 working days.

Chapter VII. Final provisions

Art. 19. The approval of the present regulation is made by the University Senate.

Art. 20. The present regulation can be modified with the approval of the University board and the approval of the University Senate at the notification of the Research Ethics Committee or of other bodies**.**

The Senate of the University approved this regulation on November 7, 2013 and it enters into force on November 8, 2013.

Appendices

Appendix 01: UMFST-REG-74-F01-Ed.02 - Application for approval of clinical research

Appendix 02: UMFST -REG-74-F02-Ed.02 - Application for approval of research on experimental animals

Appendix 03: UMFST -REG-74-F03-Ed.02 - Form for the Decision of the Scientific Research Ethics Committee

Appendix 01: UMFST-REG-74-F01-Ed.02

Application for approval of clinical research

Applicant: Name, first name, contact data (e-mail, telephone number):

Position and workplace:

Destination of request:

• Graduation paper

• Doctoral thesis

• Other: specify (research study, research project, etc.)

Study title:

The people involved and the period of the study

Motivation:

 necessity

 scientific evidence

Description of the study

 Type of study

 Scope:

 Material, method

I enclose copies of the following documents:

1. The agreement of the study mentor - if applicable
2. The agreement of the affiliated institution of the research subjects
3. Description of the study - at the request of the Commission
4. Informed consent form

Original documents: Declaration of interests

1. Source of funding - if applicable
2. Possession of material interests in connection with this research.
3. Other: specify

All documents are submitted in printed format to the Rector's Office Registry and are sent by e-mail to etica_cercetarii@umfst.ro

Appendix 02: UMFST-REG-74-F02 Ed.02

Application for approval of research on experimental animals

Applications for authorization of projects involving animal experiments must contain at least the following:

1. Applicant: Name, surname, contact details (e-mail, telephone)

2. Position and workplace:

3. Destination of the application (specify: graduation paper, doctoral thesis, research study, research project, grant no. If applicable, etc.). the people involved and the period of development.

4. A non-technical summary of the project (information on the objectives of the project, including expected benefits and harms).

5. Provenance, species, breed, sex and number of animals required.

6. Evidence that the project has been analyzed in terms of the principles of replacement, reduction and improvement, and that measures have been taken to ensure that the use of animals has been carefully assessed in terms of scientific or educational validity, usefulness and relevance of results expected. It must be borne in mind that there is a balance between the possible harm to the animal and the expected benefits of the project. It must be demonstrated that it has been ensured that the number of animals used in the project is kept to a minimum without compromising the objectives of the project.

7. Description of the manner in which the procedures were chosen, compliance of the procedures with the requirements below:

- uses a minimum number of animals;
- involves animals with the lowest capacity to feel pain, suffering, stress or to present lasting injuries;
- causes the lowest level of pain, suffering, stress or long-term injury;
- are most likely to give satisfactory results

8. Detailed description of the method of anesthesia, while demonstrating that the following principles will be followed.

Unless inapplicable, procedures should be performed under general or local anesthesia or analgesics or another appropriate method should be used to ensure that pain, suffering or distress is minimized. Procedures that can cause serious injury that can cause severe pain are not performed without anesthesia. Ensure that animals do not receive any medication that stops or restricts their pain without an adequate degree of anesthesia or analgesia. An animal that may suffer from pain once the effect of the anesthesia has disappeared will benefit from preemptive analgesia or other appropriate palliative methods, provided that this is compatible with the purpose of the procedure. As soon as the purpose of the procedure has been achieved, the necessary measures shall be taken to minimize the animal's suffering.

9. Specify the severity of the procedures, using the classification criteria set out in Appendix VIII of the EU Directive.

The severity of a procedure is determined by the intensity of the pain, suffering, distress or lasting damage expected to be suffered by an individual animal during the procedure. Procedures must be classified as "non-recovery", "superficial", "moderate" or "severe" in each case. The assignment of the severity category must take into account any intervention on an animal or any manipulation of it in a defined procedure. This is based on the most severe effects that an individual animal is expected to experience after applying all appropriate enhancement techniques.

10. Explicit specification of the euthanasia method according to Appendix IV of the EU Directive (if applicable).

Death as the end point of a procedure is avoided as much as possible and is replaced by early and humane end points. If death cannot be avoided as an endpoint, it must be demonstrated that all measures will be taken to kill the animals with a minimum of pain, suffering or stress.

11. Specifying the type of experiment (acute or chronic).

12. Explicit demonstration that the standards of care and shelter set out in Appendix III of the EU Directive will be met.

In the case of chronic experiments, it must be demonstrated that the sheltering and care of the animals will be done according to the needs and individual characteristics of the species. To this end, measures shall be taken to ensure that:

- all animals benefit from shelter, the environment, food, water and adequate care for their health and well-being;
- restrictions on the extent to which an animal can meet its physiological and ethological needs must be limited to what is strictly necessary;
- the physical conditions in which the animals are bred, kept or used are checked daily;
- any deficiency or pain, suffering, stress or injury of a lasting duration which can be avoided are eliminated as soon as possible.

13. Where appropriate, description of procedures for preventing the risk of contamination of the environment with hazardous chemicals or biological substances.

14. Assuming the obligation to keep records of records that contain at least the following data:

- number and species of animals used in the procedures;
- the origin of the animals, including whether they have been bred for use in procedures;
- the dates on which the animals were purchased;

- projects in which animals were used.

The above - mentioned registers shall be kept for at least five years and, upon request, shall be made available to the Scientific Research Ethics Commission and the competent authorities.

All documents are submitted in printed format to the Rector's Office Registry and are sent by e-mail to etica_cercetarii@umfst.ro

Directive 2010/63 / EU of the European Parliament and of the Council on the protection of animals used for scientific purposes can be studied on EUR-Lex which provides free access to European Union legislation:
http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2010:276:0033:0079:RO:PDF

http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2010:276:0033:0079:HU:PDF

http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2010:276:0033:0079:EN:PDF

Appendix 03: UMFST-REG-74-F03-Ed.02

Decision of the Scientific Research Ethics Committee

no._____of _____

The Scientific Research Ethics Committee within the George Emil Palade University of Medicine, Pharmacy, Science, and Technology of Târgu Mureş evaluated from the perspective of observing the ethical norms of scientific research the study proposal entitled

_____

_____

Addressed to the Committee on _____by Mr./Ms _____ position _____ employed by _____

Following the evaluation of the documents submitted, the Committee decides:

a) the approval of the study;

b) making the following changes to the proposed study and sending the new proposal back to the Committee:

_____

_____

_____

_____

c) failure to approve the study for the following reasons:

_____

_____

_____

_____

The approval is valid only under the conditions described in the study proposal submitted to the Committee, for a maximum period of _____ months

President of Scientific Research Ethics Committee

_____