



Reference documents:

Higher Education Act 199/2023

Law no. 206/2004 regarding good practices in scientific research, technological development and innovation, with subsequent amendments and additions

Law no. 398/2006

Law no. 43/2014 regarding the protection of animals used for scientific purposes with subsequent amendments and additions

Directive 2010/63/UE of the European Parliament and European Council regarding the protection of animals used for scientific purposes

Charter of the George Emil Palade University of Medicine, Pharmacy, Science, and Technology in Târgu Mureș

Professional Ethics and Deontology Code of the George Emil Palade University of Medicine, Pharmacy, Science, and Technology in Târgu Mureș

REGULATION OF THE RESEARCH ETHICS COMMITTEE

Regulation code: UMFST-REG-74

Edition 04

Drafted: Research Ethics Committee

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<i>Date of withdrawal</i>	



Chapter I. General statements

Art. 1. The Scientific Research Ethics Commission, a subcommission of University Ethics commission is an independent body within the George Emil Palade University of Medicine, Pharmacy, Science, and Technology of Târgu Mureș, whose main objective is the surveillance 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 seeks the implementation of ethics policies in research, in accordance with the regulations of the ethics of scientific research stipulated by the Charter of UMFST G.E. Palade Tg. Mureș.

Chapter II. Organization

Art. 3. 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. 4. The Scientific Research Ethics Committee is composed of 9 members, which must have the necessary qualification and experience to evaluate the scientific, medical and ethical aspects of the studies proposed for approval.

Art. 5. The members of the Committee for the Scientific Research Ethics Committee elect the chair of the committee.

Art. 6. The Scientific Research Ethics Committee appoints an academic secretary to organize the activity of the committee. The secretarial work of the commission is provided by the General Secretariat of the university.

Art. 7.

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.
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 Annex 1 (for clinical research), Annex 2 (for experimental research) and Annex 3 (for research carried out on biological samples and on data obtained from biological banks including banks of genetic material).



Chapter III. Operation mode

Art. 8.

(1) The requests for approval (Annex 1, Annex 2 or Annex 3) will be digitally edited. Applications which are not filled properly or didn't have all the mandatory documents attached are automatically rejected, without evaluation by the commission. All documents are holographically signed and scanned.

(2) Requests must be submitted strictly online through the dedicated platform (at the following link: <https://apps.umfst.ro/Cetica.php?oper=Login>). Upon submission, the documentation will receive a registration number. Requests sent through other way (email, physical format, etc.) will not be evaluated. As a rule, must be requested the approval of projects and research studies of laboratories, research centers or collectives and not of individuals from a specific project.

(3) Requests for approval are submitted at least 30 days before the start of the activity and research projects cannot be started before obtaining the approval of the Research Ethics Commission. Retroactive approvals are not granted, requests of this type are rejected de facto, without evaluation by the Scientific Research Ethics Commission.

(4) Any request to change the study period will be accompanied by a declaration on the applicant's own responsibility detailing and justifying the reason for this request.

(5) The Scientific Research Ethics Commission will notify the University Ethics Commission in the case of reasonable suspicion of falsification of documents.

(6) The members of the Scientific Research Ethics Committee evaluate online through the dedicated platform the projects submitted by applicants.

(7) The Scientific Research Ethics Committee shall meet on-site or on-line convened by the chair of the committee. The information session between the members of the commission is transmitted by e-mail. The convening of the meetings of the Scientific Research Ethics Committee is made at least 5 days before the proposed date, by phone, by written communication or by e-mail, except for extraordinary meetings where this period of time may be reduced depending on the degree of urgency.

(8) The Committee has the obligation to issue a resolution for a request for approval of the research within a maximum of 30 calendar days of receipt of the complete file, with a clear identification of the study and the checked documents. The reasoned opinion of the Scientific Research Ethics Committee is sent according to Annex 4, and can be:

- a) approval;
- b) changes requested in order of approval;
- c) rejection



d) declension of competence;

e) exemption (waiver), for studies where is not required the approval of the ethics committee (request form according to Annex 06).

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

(10) 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 period of the research proposal will be extended accordingly.

(11) The approvals of the ethics commission are valid for the requested period or a maximum of one year and they are extended annually, if necessary, based on a request which will also contain the justification of it.

(12) The decisions of the Scientific Research Ethics Committee, formulated in accordance with Annex 4, are issued via the dedicated platform and available for download by the applicant. The decision shall be published on the University website. The posted notice will include, in addition to the notice number, the name of the applicant and the title of the project. In the case of animal experiments, the decision must be communicated to the Biobase. respectively to the person designated for monitoring the welfare of the animals.

Art. 9.

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 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 previously;

Art. 10.

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. 11. 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. 12. The Scientific Research Ethics Committee will be audited according to the legislation in force and the regulations of the UMFST G.E. Palade Tg. Mures.



Art. 13.

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 banks of genetic material;
- 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.

Chapter IV. Duties regarding clinical studies

Art. 14.

(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) In addition to Annex 1 completed, 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 (for studies involving online data collected anonymously, is not required a signed informed consent form; however, at this stage must be uploaded, the respondent's agreement regarding data processing at the time of submitting their response);

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) consent of the study mentor, in the case of students, master's students and PhD. students;

i) consent of the institution of origin of the research subjects;

j) the declarations of interests of all the members involved in the study (with the mention of the source of funding and with the detailing of the material interests in relation to this research);

k) the CVs of the investigators and, if applicable, documents proving their qualification, , at the commission's request;;

l) any other necessary documents, at the commission's request.

(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 and is mandatory to notify the committee of any changes;

(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.



(11) The approvals issued by the Ethics Committees of SCJU Tg. Mureș and SCJ Tg. Mureș are recognized for conducting studies carried out in a hospital under the coordination of a university staff member, in where the already recorded processed data in the patients' source institutions' documents, the provided data confidentiality is respected. For these studies, it is not necessary to obtain a separate approval from the Scientific Research Ethics Committee of UMFST G.E. Palade Tg. Mureș (is not required the submission of documentation to the Scientific Research Ethics Committee of UMFST G.E. Palade Tg. Mureș).

Chapter V. Duties regarding experimental studies on experimental animals

Art. 15

1. At the „George Emil Palade” University of Medicine, Pharmacy, Science, and Technology of Târgu Mureș 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. For the approval of experimental studies on animals, the Scientific Research Ethics Committee must receive the study documentation prepared according to the specifications in Annex 2. To the completed Annex 2 must be attached:

- a) the consent of the study mentor, in the case of students, master's students and PhD. students;
- b) agreement of the veterinarian of G.E. Palade UMFST Tg. Mureș, for studies carried out at Biobase (requested through Annex 05):
- c) the declarations of interest of all members involved in the study (mentioning the source of funding and detailed material interests in relation to the research);
- d) the CVs of the investigators and, if requested by the committee, documents proving their qualifications;
- e) any other necessary documents, at the request of the committee.

4. 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 infrastructure and the methods used.



5. The opinion of the Scientific Research Ethics Commission will include the number, species, sex and age of the animals for which approval was obtained. These data are also communicated to the Biobase at UMFST G.E. Palade Tg. Mures.

6. After obtaining the approval of the Ethics and Scientific Research Commission, the responsibility of obtaining the project authorization from DSV Mureș belongs to the applicant.

7. At the annual audit of the Biobase will also be attended by a person delegated by the Scientific Research Ethics Commission who will check the Biobase's registers. Also, whenever it is considered necessary, the Scientific Research Ethics Commission can request the verification of the Biobase registers.

8. The Scientific Research Ethics Commission can verify the traceability of the results obtained following the implementation of the projects. In this sense, the applicants are obliged to make all the requested documents available to the members of the Research Ethics Commission.

9. Any subsequent modification of the project requires re-approval by the Scientific Research Ethics Committee.

Chapter VI. Tasks for studies carried out on biological samples or using data from biobanks

Art. 16.

(1) The Scientific Research Ethics Committee will ensure mandatory verification of project compliance with the generally applicable ethical regulations concerning the use of human embryos and other human biological samples and the use of data from biobanks, including genetic material banks.

(2) For the approval of studies carried out on biological samples or using data from biobanks, the Scientific Research Ethics Committee must receive the study documentation drawn up in accordance with the specifications in Annex 3. The completed Annex 3 must be attached:

- a) the approval of the study mentor, in the case of students, masters and Phd. students;
- b) the consent of the institution of origin of the biological samples or biobank data;
- c) the declarations of interest of all members involved in the study (indicating the source of funding and detailing material interests in relation to the research);
- d) CVs of the investigators and, if requested by the committee, documents proving their qualifications;
- e) any other necessary documents, at the request of the committee.

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



Chapter VII. 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 VIII. Appeals

Art. 17. 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 IX. Final provisions

Art. 18. The approval of the present regulation is made by the University Senate.

Art. 19. 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 George Emil Palade University of Medicine, Pharmacy, Science, and Technology of Targu Mures approved this regulation on 25th July, 2025 and it enters into force on 28th July, 2025.

Annexes

Annex 01: UMFST-REG-74-F01-Ed.04 - Application for approval of clinical research

Annex 02: UMFST-REG-74-F02-Ed.04 - Application for approval of research on experimental animals

Annex 03: UMFST-REG-74-F03-Ed.04 - Application for approval of research using human biological samples or biological banks, including the banks of genetic material

Annex 04: UMFST-REG-74-F04-Ed.04 - Decision of the Scientific Research Ethics Committee Form

Annex 05: UMFST-REG-74-F05-Ed.04 - Biobase Agreement Form

Annex 06: UMFST-REG-74-F06-Ed.04 - Request for exemption from the approval of the Scientific Research Ethics Commission



Annex 01: UMFST-REG-74-F01-Ed.04

Application for approval of clinical research

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

Position and workplace:

Destination of request (please choose):

- Graduation paper
- Doctoral thesis
- Other: specify (*research study, research project, etc.*)

Study title:

Period of the study:

Involved persons:

Motivation:

- necessity
- scientific evidence

Description of the study

Type of study

Scope:

Material, method (*target population, sample, data collection methods, analyzed variables, inclusion and exclusion criteria, as applicable*).

Attach the required documents according to Art. 14. Para. 3 of the Regulation of the Ethics Committee for Scientific Research



Annex 02: UMFST-REG-74-F02 Ed.04

Application for approval of research on experimental animals

Note: Text in *Italic* are explanatory notes which will be deleted and replaced by the appropriate description at each point.

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.*).
4. People involved and the period of development.
5. A non-technical summary of the project (*information on the objectives of the project, including expected benefits and harms*).
6. Provenance, species, breed, sex and number of animals required.
7. 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.*
8. 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, suffer, stress or to present long-term injury;*
 - *causes the lowest level of pain, suffer, stress or long-term injury;*
 - *are most likely to present satisfactory results*
9. Detailed description of the method of anesthesia, while demonstrating that the following principles will be respected.

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.

10 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.

11. 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, suffer or stress.

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

13. 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 benefits a shelter, 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, suffer, stress or injury of a lasting duration which can be avoided are eliminated as soon as possible.*

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



15. 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 registers mentioned above 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.

Attach the required documents according to Art. 14. Para. 3 of the Regulation of the Ethics Committee for Scientific Research

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>



Annex 03: UMFST-REG-74-F03-Ed.04

Application for approval of research using human biological samples or biobanks, including the gene banks

Note: Text in *Italic* is an explanatory note which will be deleted and replaced by the appropriate description.

Applicant: *Surname, first name, contact details (e-mail, telephone):*

Function and place of work:

Destination of application (please choose):

- Bachelor's thesis
- Doctoral thesis
- Other: please specify (*research study, research project, etc*):

Title of study:

Period of study:

Involved persons:

Motivation:

- Need for the study:
- Evidence from the literature:

Description of the study:

- Purpose:
- Material, method: (*detail how biological samples were obtained, describe the biobanks or genetic material banks used, as appropriate*)

Attach the necessary documents according to Art. 16. Para. 2 of the Regulation of the Ethics Committee for Scientific Research



Annex 04: UMFST-REG-74-F04-Ed.04

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 Mureș evaluated from the perspective of observing the ethical norms of scientific research the study proposal entitled

Addressed to the Commission 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:

d) declining jurisdiction on the following reasons:

e) waiver, 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 12 months. For multiannual projects/studies shall be submit a request for an extension, including a detailed report of the study progress.

President of Scientific Research Ethics Committee

*in the case of experimental studies must be specified the number, species, sex, and age of the animals for which approval was obtained.



Reg. No. /

Coordinator Center Approval

(it will be completed by the veterinary doctor)

To,

The Experimental Studies and Imaging Center – Experimental Station – Animal Facility

I, the undersigned,, as the project director of the project entitled
“.....”, kindly ask for
your approval to conduct the experiment within the Biobase / Experimental Station.

1. **Contact details:**
2. **Position and workplace:**
3. **Purpose of the request:** *(please specify: graduation paper, doctoral thesis, research study, research project, grant number, etc.)*
.....
4. **Involved persons:**
5. **Duration of the project:**
6. **Project description – aim, objectives, materials, and methods (briefly)**
.....
7. **Required animals**
Species:
Sex:
Number:
Age:
8. **Infrastructure needed for project implementation (spaces, equipment, etc.)**
.....
9. **Any remarks and observations (to be completed by the veterinarian)**
.....



Request for Waiver of Approval from the Scientific Research Ethics Committee

Note: Texts marked in Italics are explanatory notes that will be deleted and replaced with appropriate descriptions.

Applicant: *Name, surname, contact details (email, phone)*

Position and workplace:

Purpose of the request (please choose):

- Bachelor's thesis
- Doctoral dissertation
- Other: specify (research study, research project, etc.):

Study title:

Study period:

Investigators:

Motivation:

- necessity of the study:
- evidence from literature:

Study description:

- Type of study:
- Aim:
- Materials, methods (*target population, sample, data collection methods, variables analyzed, inclusion and exclusion criteria, as applicable*):

Motivation for requesting a waiver/exemption from approval:

The following examples illustrate the nature of projects that might lead to such a waiver. The list is not exhaustive. It is emphasized that the following are only typical examples. It should be noted: in all cases, the data source must be considered the ONLY source. If are added other sources, which may directly involve humans, animals, or the environment, the possibility of a waiver disappears and the standard procedure will be followed.

- The study involves only literature research (*e.g., medical literature*).
- Meta-analysis study.
- The study is based on questionnaires applied to students and does not use personal data.
- The research involves a critical analysis of creative works already in the public domain (*e.g., analysis of poetry, novels, films, TV programs, art exhibitions, etc.*).
- The research involves archiving activity, the access to the archive is either public (obviously when the archive is in the public domain) or permission to access has been granted. The request must be supported by proof of obtaining such permission. There are situations where the archiving activity requires more than this; these additional requirements are established by the archive staff.



The research uses existing publications with the purpose of critical analysis of the arguments formulated in them. The notion of "publication" indicates that the document is already in the public domain.

The consulted databases are in the public domain / publicly accessible (*such as Stats SA or other official sources*).

The research may address issues related to law, court decisions, the Constitution, the Official Gazette, and other similar documents. These include all government policy documents that are in the public domain.

Others (please describe): _____

In all cases, the required documents according to Article 14, Paragraph 3 of the Scientific Research Ethics Committee Regulations must be attached.