REGULATION OF ORGANIZATION AND OPERATION OF THE COMMISSION OF ETHICS IN SCIENTIFIC RESEARCH

AT THE ”VASILE GOLDIȘ” WESTERN UNIVERSITY OF ARAD

Chapter I. General Provisions

Art. 1. The Commission of Ethics in Scientific Research (CECS) is a body set up within the University, whose main objective is to monitor compliance with the principles of ethics in scientific research and to promote scientific research as such.

Art. 2. CECS operates during the mandate of the Senate in compliance with the legal provisions, being subordinated to the University Senate.

Art. 3. (1) CECS conducts its activity in accordance with the provisions of the UVVG Code of Ethics in Scientific Research, the legislation, the national and international regulations in the field, the recommendations of the National Ethics Council for Scientific Research, Technological Development, and Innovation.

(2) CECS has the following attributions:

a) monitors the observance of the Code of Ethics of scientific research in the University;

b) analyses and solves the deviations from the good conduct in the research-development activity, based on the received notifications or by self-notification, where applicable;

c) analyses the requests for approval of research/ studies/ scientific research projects and issues opinions regarding their development;

d) appoints review commissions for the examination of the notifications regarding the deviations from the good conduct in the research-development activity brought to their attention following the notifications or based on self-notification, where applicable;

e) draws up in the first quarter of the year a report regarding the situation of observing the ethics of research activities, which is submitted to the Rector, the University Senate and constitutes a public document;

f) contributes to the modification/ updating of the Code of Ethics in Scientific Research, where applicable;

g) monitors the implementation of the sanctions it has decided, as a result of solving the complaints regarding deviations from the ethics norms in research, including, if necessary, by appeal to the University Senate or, ultimately, to the National Ethics Council of Scientific Research, Technological Development, and Innovation;

h) responds to any specific requests addressed to it by the National Ethics Council, after informing and obtaining the Rector’s prior approval;

i) may participate in inter-institutional or at national or European level working meetings or other similar events, which have as object topics related to research ethics, with Rector’s

prior approval; draw up reports, following any such participation, containing the main conclusions, which they submit to the Rector;

j) upon Rector's request, prepares, training materials on ethics in scientific research, which it submits at the periodic training convocations with the university management or executive staff, especially at those on the occasion of the opening of each new academic year;

k) fulfils the attributions set by Law no. 206/2004, with subsequent amendments and completions;

l) fulfils other attributions derived from possible new national regulations, in its field of competence.

Art. 4. In its activity, CECS collaborates with the UVVG University Ethics Commission.

Chapter II. Organisation

Art. 5. The membership and structure of the UVVG Commission of Ethics in Scientific Research is proposed by the Board of Directors, endorsed by the Senate, and approved by the University Rector, in accordance with the legislation in force.

Art. 6. CECS is composed of 9 members - teachers and researchers of the University faculties and departments, with qualification, experience, and notable results, able to evaluate correctly and objectively the scientific, medical, and ethical aspects of the studies proposed for evaluation.

Art. 7. The CECS structure includes: the President together with 8 members, one of them fulfilling the position of secretary.

Art. 8. The CECS president has the following attributions:

(1) Ensures the organization and operation of the Commission;
(2) Convenes and chairs CECS meetings;
(3) Establishes the agenda;
(4) Draws up and signs Commission decisions,
(5) Represents CECS in relation to the University Senate and Board of Directors;
(6) Coordinates the secretariat of the Commission and is responsible for archiving the Commission data and documents.

Art. 9. The CECS appoints a secretary from among the members of the commission.

Art. 10. The CECS Secretary has the following responsibilities:

(1) Writes the minutes of the meetings;

(2) Drafts the documents elaborated by the commission;

(3) Organizes the archive of documents prepared by the commission, generally ensures the logistics necessary for the proper operation of the CECS;

(4) Keeps records of Commission data and communicate decisions, decisions, opinions, and other documents resulting from the work of the Commission to the staff concerned.

Art.11

(1) The CECS shall conduct its activities in accordance with this Regulation and on the basis of the principles and procedures set out in the UVVG Code of Ethics in scientific research.

(2) The notifications and requests for endorsement of the studies/ research/ research projects addressed to CECS shall be submitted to the Registry of the UVVG Rector's Office. In the case of clinical and experimental studies, the format of the applications is contained in Annex no. 1, respectively Annex no. 2 to this Regulation.

(3) CECS shall keep written records of the carried-out activities and the minutes of the meetings.

Chapter III. Way of working

Art. 12

(1) CECS shall meet monthly, if required.

(2) CECS may also meet in extraordinary meetings, in special situations, when convened by the president of the commission.

(3) CECS meetings are convened at least 5 days before the proposed date, by telephone or SMS, by e-mail, except for extraordinary meetings when this time may be reduced depending on the degree of urgency.

(4) The meetings take place at the UVVG headquarters, but can take place, if necessary, in the virtual environment, via Skype.

(5) The rector and vice-rector who coordinates the scientific research activity may participate as guests or ex officio at the CECS meeting, and, as guests, University teaching staff, researchers, specialists in fields of interest with outstanding scientific

professional performances, members of partner networks/ universities in the country and abroad or representatives of the economic environment.

(6) Upon the Commission request, the investigator or funder may be asked to provide additional information or clarification on any aspect of the study but may not participate in the committee's discussions or vote.

Art. 13. The working quorum of the CECS shall be half plus 1 of the total number of members of the Commission.

Art. 14.

(1) In the exercise of its powers, decisions of the CECS shall be taken by simple majority by open or secret ballot in cases where the confidentiality of the vote is required.

(2) Only members of the Commission present at the meeting may vote.

(3) Only those members of the Commission who are independent of the investigator(s) and the funder of the study may vote; any conflict of interest must be stated before the meeting.

Art. 15.

(1) The CECS has the obligation to give a written resolution for a request for approval of the research within maximum 30 calendar days from the receipt of the complete file, with the clear identification of the study and the verified documents.

(2) The CECS reasoned opinion may be:

a) opinion without mentions;

b) opinion with mentions;

c) negative opinion.

(3) Also, on the basis of a reasoned opinion, the CECS may at any time decide to withdraw definitively or temporarily a previous opinion.

(4) The CECS may send an evaluation study to the National Ethics Council if it deems it necessary. In this case, the deadline for evaluating the research proposal shall be extended accordingly.

(5) The CECS opinions, formulated according to Annex 3 shall be published on the University's website and shall be communicated in writing to the applicant.

Art. 16. The relevant records (written procedures, lists of members, lists regarding the occupation/ membership of members, CVs, submitted documents, 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 sought. After the 3 years, they are handed over to the UVVG archive.

Art. 17. The ethical endorsement of the research-development and innovation projects will mandatorily include the verification of the respective projects compliance with:
1. generally applicable ethical rules 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;
- 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-alcoholism, etc.);
- personal data protection;

b) animal protection;
c) environmental protection;
2. internal and international specific ethical regulations, applicable to that research and which must be explicitly specified in the project.

Chapter IV. Attributions on clinical studies

Art. 18.

(1) The mission of the CECS 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) CECS 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, with a view to obtaining their informed consent.
(3) CECS must receive the following documents relating to the clinical trials for which its opinion is sought:

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) available information on the safety of the methods and products to be used;
f) information on payments and compensations available to subjects;
g) investigators' CVs and, possibly, documents proving their qualification;
h) any other necessary documents.

(4) CECS may request additional information if it is considered that it would help to improve the understanding of the situation regarding the subject’s protection, rights, safety and/ or comfort;

(5) If the protocol provides that the prior informed consent of the subject or his/ her legal representative cannot be obtained, the CECS will require that the proposed protocol and/ or other documents adequately address the relevant ethical issues and meets legal requirements.
(6) In case of organizing a study without therapeutic benefit that is conducted on the basis of the consent of an accepted legal representative of the subject, CECS will require that the proposed protocol and/ or other documents adequately address relevant ethical issues and comply with legal requirements.
(7) CECS may conduct a new assessment at different time intervals of each study, intervals that will be established according to the study protocol and the degree of risk existing for the subjects.
(8) CECS also evaluates the amendments to the protocol that appear during the study;
(9) CECS may at any time decide to withdraw temporarily or definitively a previous opinion if new data relating to the study or the general scientific context of the field of study have appeared which could create ethical issues for research not initially identified.

Chapter V. Attributions on experimental animal studies

Art. 19.

(1) At the "Vasile Goldiș" Western University of Arad, all animal experiments must comply with European and national legislative standards and must be endorsed by the Commission for the Ethics in Scientific Research (CECS).
(2) The aim of the CECS is to protect animals used 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.
(3) In order to approve the experimental studies on animals, CECS must receive the documentation of the study prepared according to the specifications in Annex no. 2 to this Regulation. Amendments to the study protocol must be endorsed by the Commission for Ethics in Scientific Research.

Chapter VI. Sanctions

Art. 20. If it finds deviations from professional ethics in the scientific research activity, the Commission for Ethics in Scientific Research shall notify the University Ethics Commission in order to analyse and solve the situation.

Chapter VII. Appeals

Art. 21. Appeals against the Commission's opinions and resolutions may be submitted within 72 hours of their communication (signature or receipt in the electronic mailbox) and will be resolved within 7 working days by a Commission appointed by the Senate for this purpose.

Chapter VII. Final Dispositions

Art. 22. The UVVG Senate is to approve this regulation.

Art. 23. This regulation may be amended ex officio with the Board of Directors' opinion and the approval of the University Senate, at the proposal of the Commission for Ethics in Scientific Research.

This Regulation was endorsed accordingly in the Board of Directors' meeting of December 18, 2017, and approved in the Senate meeting of December 19, 2017.

Annexes

Annex no.1 Application for approval of clinical trials
Annex no.2 Application for approval of research on experimental animals
Annex no.3 Opinion form of the Commission for Ethics in Scientific Research (in case of clinical and experimental studies)
Annex no.4 Informed consent form
Annex no.5 Agreement on the use of personal data

This Regulation was endorsed accordingly in the Board of Directors' meeting of December 18, 2017, and approved in the Senate meeting of December 19, 2017.

PRESIDENT OF THE SENATE,
Assoc. prof. Sorin Aristide BAŞCHIR, MD PhD

Endorsed by the COMMISSION FOR CODES,
REGULATIONS AND LEGAL MATTERS,
President,
Assoc. prof. Daniel Berlingher, MD PhD

Annex no. 1

To the Regulations of organization and operation of the Commission of ethics in scientific research

Application for approval of clinical trials

1. Applicant: name, surname, contact details (e-mail, telephone):
2. Position and place of work:
3. Destination of the application: Bachelor's paper/ Doctoral thesis / Other (specify: research study/ research project / etc.)
4. Study title:
5. The people involved and the duration of the study
6. Motivation, necessity, relevant literature
7. Description of the study:
   - Type of study
   - The purpose and objectives of the study
   - The material and method to be used
   - Estimated results
8. Source of study funding

I enclose the following documents
In copy:

- Agreement of the study coordinator (if applicable)
- Agreement of the research subject's institution of origin
- Informed consent form

In original:

- Declaration regarding the existence of the conflict of interests

All documents are submitted in printed format to the Registry of the UVVG Rector's Office and are sent by e-mail to eticacercetarii@uvvg.ro

Annex 2

To the Regulations of organization and operation of the Commission of ethics in scientific research

Contents of the Application for approval of research on experimental animals

I. Application for approval of experimental animal research

1. Applicant: name, surname, contact details (e-mail, telephone)
2. Position and place of work:
3. Destination of the application (specify: bachelor's paper, doctoral thesis, research study, research project, grant no. if applicable, etc.):
4. Persons involved and duration of development:

II. Annex to the application

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

a) Provenance, species, breed, gender, and number of required animals:

b) Demonstration that the project has been analysed 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 damage 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:

c) Description of the manner in which the procedures were chosen, respectively compliance of the procedures with the requirements below:

- use 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;
- they are most likely to give satisfactory results.

d) Detailed description of the method of anaesthesia, demonstrating at the same time that the following principles will be observed:

Unless this is inappropriate, procedures should be performed under general or local anaesthesia or analgesics or another appropriate method should be used to ensure that pain, suffering, or distress is minimized. Procedures that can cause serious injury leading to severe pain are not performed without anaesthesia. Ensure that animals do not receive any medication that stops or restricts their pain without an adequate degree of anaesthesia or analgesia. An animal that may suffer from pain once the effect of anaesthesia has disappeared will benefit from pre-emptive 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 suffering of the animal.

e) Specification of the severity of the procedures, using the classification criteria set out in Annex VIII to 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 consider any intervention on or manipulation of an animal in a defined procedure. It is based on the most severe effects that are expected to be felt by an individual animal after applying all appropriate enhancement techniques.
f) Explicit specification of the euthanasia method according to Annex 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 humanly possible 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 distress.
g) Specification of the type of experiment (acute or chronic):
h) Explicit demonstration that the standards of care and housing set out in Annex III of the EU Directive will be met:
In the case of chronic experiments, it must be demonstrated that the housing and care of the animals will be done according to the individual needs and characteristics of the species. To this end, measures shall be taken to ensure that:

- all animals benefit from shelter, environment, food, water and proper 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 reared, kept, or used are checked daily;
- any deficiency or pain, suffering, stress, or injury of lasting duration that can be avoided to be eliminated as soon as possible.

i) Where applicable, description of procedures to prevent the risk of contamination of the environment with hazardous chemicals or biological substances:
j) Undertaking 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 records shall be kept for at least five years and shall be made available to the Commission for Ethics in Scientific Research and the competent authorities upon request.
All documents are submitted in printed format to the Registry of the UVVG Rector's office and are sent by e-mail to: eticacercetarii@uvvg.ro

Annex 3

To the Regulations of organization and operation of the Commission of ethics in scientific research

OPINION OF THE COMMISSION OF ETHICS IN SCIENTIFIC RESEARCH

Of the ”Vasile Goldiș” Western University of Arad

No. of

The Commission of ethics in scientific research of the ”Vasile Goldiș” Western University of Arad assessed in terms of compliance with the rules of ethics of scientific research the study proposal entitled.....
Submitted by .....
on .....
having as annexes .....

Opinion ☐ Opinion with mentions ☐ Negative opinion☐

Mentions:

OPINION OF THE COMMISSION OF ETHICS IN SCIENTIFIC RESEARCH

After reviewing the application submitted by you regarding the authorization to conduct in Romania a ....., registered with the number..... ..... and the attached documents, we inform you that we approve the development of the study according to the protocol submitted by you.

COMMISSION OF ETHICS IN SCIENTIFIC RESEARCH

President

Assoc. prof. OLIMPIA NEAGU, PhD

Annex 4

To the Regulations of organization and operation of the Commission of ethics in scientific research

INFORMED CONSENT FORM

MODEL

Project title	
Purpose of the study	*This research is conducted by .... (specify the name of the Main Investigator) from the University of…. . We invite you to participate in this research project because you _____. The purpose of this research project is _____. Study duration_____, Project results will be used at_____*
Procedures	*The procedures involve __.*
Potential risks and possible discomfort	*There is a possibility that participation in this project may come with certain potential risks or certain degrees of discomfort, during the study or after its completion, such as: …… ..*
Possible benefits	*There are no direct benefits for participants. However, potential benefits include: …… .**OR** ……. the direct benefits to you will be ……. We hope that in the future other people can benefit from this study through a better understanding of*
Confidentiality	*Any potential disclosure of confidential data will be minimized by: …… .. (storing data in a secure location, such as: locked office, locked cabinet, computer and for a period of time in accordance with applicable law; stored data will be destroyed after the expiration of the legal archiving period etc.)*
Medical therapy	*If we draft a report or paper about this research project, your identity will be protected as much as possible. Your information may be shared with representatives of the University, or/ and with government authorities, if you or someone else may be in danger or if the law requires it.*
Subject's right to withdraw and ask	*Your participation in this research is entirely voluntary. You can decide not to participate at all. If you decide to participate in this research, you can withdraw at any time. In both cases (i.e., if you decide not to participate at all, or if you decide to participate, but withdraw at some*

<table>
<tr><td>questions</td><td colspan="2">point) you will not be penalized in any way and you will not lose any benefit you qualify for.

If you decide not to participate in the study, if you have questions, concerns, or complaints, or if you would like to report a research injury or abuse, please contact the principal investigator.:

[Main Investigator]

[Main investigator’s contact details: address, telephone number, email address. Information on the Coresearcher will also be listed]</td></tr>
<tr><td>Participants’ rights</td><td colspan="2">If you have questions about your rights as a participant in the research or would like to report a research harm, please contact:

University …
Commission of Ethics in Scientific Research
Address: …
E-mail: …
Telephone: …
This research was reviewed in accordance with the University procedures of …., based on internal research models involving human subjects.</td></tr>
<tr><td>Statement of consent</td><td colspan="2">Your signature indicates that you are of legal age (you are at least 18 years old), that you have read this consent form or that it has been read to you, that you have received satisfactory answers to your questions, and that you voluntarily agree to participate in this research. You will receive a copy of this signed consent form.

If you agree to participate, please sign at the bottom of the page:</td></tr>
<tr><td rowspan="3">Date and signature</td><td>Participant’s name</td><td></td></tr>
<tr><td>Participant’s signature</td><td></td></tr>
<tr><td>Date</td><td></td></tr>
</table>

Annex 5

To the Regulations of organization and operation of the Commission of ethics in scientific research

STATEMENT OF CONSENT
On the agreement to personal data use and processing

I, the undersigned, ...……..…….....…….....…, Personal Number ……, holder of the identity document/ card series …… no. ……..…., issued by.....……..., on ....., with the domicile in ….....……..…… St. ……. no. ….. bl. ..... apartment …. telephone …….....mobile no....….....…….e-mail ……, as a participant in the project „..... .... ”I have been informed of the obligation to provide my personal data in compliance with legal provisions.”

I declare that I agree that my personal data will be used and processed in order to implement the project activities ....

I declare that I have been informed in writing and orally about the purpose of data use and processing, the categories of processed data, categories of data of a special nature, the recipients of such data, as well as about the rights I have under current legislation, the Regulation for ensuring the security of personal data processing and the Security Policy for personal data processing within the "Vasile Goldiș" Western University of Arad.

The agreement is valid only if the "Vasile Goldiș" Western University of Arad complies with Law no. 677/2001 on the protection of individuals with regard to the processing of personal data and the free movement of such data, with subsequent amendments and completions, as well as the Law no. 506/2004 on the processing of personal data and the protection of privacy in the electronic communications sector, with subsequent amendments and completions.

the “Vasile Goldiș” Western University of Arad is registered in the Register of evidence of personal data processing under no. 5345, of the National Authority for the Supervision of Personal Data.

Date Signature