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REGULATIONS ON THE WORK
OF THE RESEARCH ETHICS COMMITTEE
AT THE MEDICAL UNIVERSITY OF VARNA

2018

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I. GENERAL PROVISIONS

Art. 1. These Regulations lay down the terms and procedures governing the work of the Research Ethics Committee (REC) at the Medical University – Varna (MUV). It specifies the application of national and international legal acts that protect the rights, safety, well-being, and human dignity of all participants in scientific research, and ensure that all researchers and members of research teams uphold established standards of ethical conduct at every stage of the research process, including the publication of research results.

Art. 2. The activities of the REC shall be carried out in compliance with:

– the Universal Declaration of Human Rights;

– the Declaration of Helsinki of the World Medical Association (WMA) on ethical principles for medical research involving human subjects;

– the Oviedo Convention on Human Rights and Biomedicine (1997);

– the Health Act of the Republic of Bulgaria;

– Ordinance No. 31 of the Ministry of Health (2007) laying down the rules of Good Clinical Practice;

as well as other applicable national and international documents regulating ethical standards in scientific research and scientific publications.

Art. 3. *(Amended 25.02.2021)*

(1) "Scientific research" refers to all activities aimed at generating and developing human knowledge through the application of scientific methods of observation and generalization. Medical research involves the development and implementation in medical practice of new knowledge in the areas of health promotion, prevention, diagnosis, treatment, rehabilitation, and patient care, as well as the assessment of the outcomes of these activities.

(2) *(New – 25.02.2021)* For the purposes of these Regulations, medical research includes medical-biological, medical-clinical, and medical-social studies related to human health.

II. POWERS OF THE RESEARCH ETHICS COMMITTEE

Art. 4.

(1) *(Amended – 25.01.2018; supplemented – 29.10.2025)* The REC at MUV is an expert and consultative body established by order of the Rector. It performs an initial ethical assessment of scientific research projects and issues an opinion on their ethical acceptability, as well as carries out periodic oversight of studies involving researchers from MUV, including doctoral candidates preparing their dissertation projects.

(2) *(Supplemented – 29.10.2025)* The REC shall conduct expert evaluation of clinical and non-clinical biomedical and medico-social research involving human participants, as well as research using personal biomedical data or human biological material.
(3) *(Supplemented – 29.10.2025)* The REC shall also consider ethical issues related to the protection of public interests against unethical or dishonest behaviour by researchers in the production, reporting, submission, and publication of research results that have received an initial REC assessment.
(4) *(Amended – 25.01.2018; amended – 29.10.2025)*
Clinical trials of medicinal products and medical devices conducted by research teams within the meaning of the Medicinal Products in Human Medicine Act (SG No. 31/2007) and the Medical Devices Act (SG No. 46/2007) are not subject to expert review by the REC.
(5) *(New – 25.09.2014; amended – 27.09.2018; amended – 29.10.2025)* Research initiated without obtaining initial ethical approval from the REC may undergo expert review by the Committee, and may receive an ethical opinion solely for the purpose of publishing the results of the study.
(6) *(New – 29.10.2025)* In its work, the REC ensures equal treatment and equal opportunities for all researchers and all study participants, regardless of gender, nationality, religion, disability, age, cultural background, or sexual identity.

Art. 5.
The REC develops standard operating procedures (SOPs), guidelines, and forms for assessing the ethical aspects of scientific research in accordance with Bulgarian legislation, international standards, the principles of the World Medical Association (WMA) Declaration of Helsinki, and the rules of Good Clinical Practice.

Art. 6.
The REC develops ethical standards for publications in the scientific periodicals of MUV and contributes to the establishment of good scientific publishing practices.

Art. 7.
The REC carries out activities aimed at developing the capacity of research teams to address ethical dilemmas arising in scientific research and scientific publishing, including through consultations and training.

III. COMPOSITION, FUNCTIONS, AND PROCEDURES OF THE RESEARCH ETHICS COMMITTEE

Art. 8.
(1) *(Amended – 07.11.2013; 30.04.2015; 25.02.2021)* The REC shall consist of an odd number of members, but not fewer than seven, including a Chairperson and regular members, appointed by order of the Rector of MUV. The same order shall also designate a Secretary and alternate members.
Alternate members shall participate in REC meetings when a regular member is unable to attend due to objective reasons (temporary incapacity, statutory leave, official travel, etc.).
(2) Members of the REC shall be notified of scheduled meetings at least one week in advance. The notice shall include the date, time, venue, agenda, and materials for review.
(3) Meetings of the REC shall be open.

(4) *(Amended and supplemented – 25.01.2018)* A meeting shall be considered valid when at least two-thirds of the total membership of the REC are present. Decisions shall be adopted by a simple majority through open voting.
(5) *(Amended and supplemented – 25.01.2018)* Members of the REC who are involved as researchers in the study under review, or who have financial or administrative ties to the research team, shall not participate in the discussion nor vote on the decision concerning that project.
(6) *(Amended and supplemented – 25.01.2018)* Extraordinary meetings may be convened at the proposal of the Chairperson, one-third of REC members, or the Rector of MUV.
(7) *(Amended and supplemented – 25.01.2018; amended – 29.10.2025)* Meetings may also be held remotely using appropriate technical means. Such meetings are convened by the Chairperson. Decisions are taken through a conference vote, minuted and documented by the Secretary, and signed by the Chairperson.

Art. 9.
(1) The Chairperson shall be a habilitated academic who leads and coordinates the Committee's work and represents the REC during inspections or meetings with external parties.
(2) The Chairperson determines the place, date, and time of REC meetings, prepares the agenda, and organises the meetings with the assistance of the Secretary.
(3) *(Amended and supplemented – 25.01.2018; amended – 29.10.2025)* The Chairperson presides over REC meetings. In their absence, a regular member authorised for this purpose shall perform the Chairperson's duties.
(4) The Chairperson is responsible for ensuring quorum and for the continuous development of the ethical expertise and qualifications of REC members.
(5) The Chairperson ensures the participation of external experts, where the REC has decided such expertise is necessary.
(6) The Chairperson instructs the Secretary to distribute meeting materials and documentation to all REC members no later than one week before the meeting.
(7) The Chairperson signs all meeting minutes and official REC correspondence.

Art. 10.
(1) The Secretary assists the Chairperson in the activities described in Art. 9, para. 2 and 6.
(2) *(Amended and supplemented – 25.01.2018)* The Secretary prepares and maintains REC documentation, keeps the minutes of all meetings, and prepares certified extracts of adopted decisions for investigators.
(3) The Secretary prepares and distributes REC correspondence under the instructions of the Chairperson and maintains the incoming and outgoing mail of the REC.
(4) The Secretary establishes and maintains the REC archive in accordance with these Rules.

Art. 11.
(1) REC members must have the necessary qualifications and experience to evaluate the ethical aspects of proposed research projects.
(2) At least one member must have a non-medical background, and at least one must be a legal counsel.

(3) REC members shall attend meetings, review all documentation submitted, participate in discussions, and prepare expert assessments assigned by the Chairperson.
(4) REC members may propose items for inclusion on the meeting agenda and may raise significant ethical issues for consideration.
(5) *(Amended and supplemented – 25.01.2018)* When an application for initial ethical review is submitted by an external sponsor, the sponsor must pay an administrative fee determined by decision of the Academic Council and by order of the Rector.

Art. 11A.
(1) *(Amended and supplemented – 25.01.2018)* An REC member may be relieved of duty by order of the Rector in any of the following cases:

1. Upon written request of the member;
2. In cases of objective inability to perform REC duties for more than six months;
3. Upon proposal of the Chairperson and the Rector in cases of systematic non-compliance with REC rules;
4. In the event of a conviction for an intentional criminal offence;
5. *(New – 29.10.2025)* Upon termination of employment with MUV.

(2) In case of release or death of an REC member, a new member shall be appointed following the procedure set out in Art. 8.

III. PROCEDURE FOR CONDUCTING EXPERT EVALUATION

Art. 12.
(1) The REC conducts initial and periodic (ongoing) ethical assessments of scientific research projects.
(2) Ethical assessments shall be carried out in accordance with written Standard Operating Procedures (SOPs) adopted by the REC and compliant with relevant legislation and regulatory requirements.

Art. 13.
(1) To initiate an ethical review, the Principal Investigator (PI) shall submit to the REC an application form (as per the approved template), together with all specific documentation required under the relevant SOP for the type of study in question.
(2) *(Amended and supplemented – 25.01.2018)* The documentation is received by the REC Secretary, who reviews it for completeness and assigns it an incoming registration number and date.
Applications lacking the minimum required documentation shall not be accepted and will be returned to the PI by the Secretary.
(3) At the next scheduled REC meeting, the Chairperson presents the submitted application and assigns it to a Committee member to prepare an expert evaluation report**,** using the REC-approved template. The report must include a written recommendation for a decision.
(4) *(Supplemented – 29.10.2025)* If the study requires expertise beyond that available within the REC, the Chairperson may propose that the Committee invite an external expert**.**
External experts must:
– have recognised scientific or practical expertise in the relevant field;
– have no conflict of interest**;**

– not participate in the study;
– be independent of the research team and research sites.
External experts may attend only the part of the meeting concerning the relevant agenda item and do not take part in the voting of the REC.
(5) Where additional information is needed due to the specificity of the study, the Chairperson may propose additional review procedures**.**
(6) *(Amended and supplemented – 25.09.2014)* The authorised REC reviewer may request the PI to correct minor technical deficiencies in the documentation or to provide additional documents needed to complete the review.
(7) The review of the submitted documentation shall take place at scheduled REC meetings, following the relevant SOPs, within 60 days of the date of submission.
(8) The PI may attend the REC meeting and provide clarifications, but may not participate in deliberations or express opinions during decision making.
(9) *(Amended and supplemented – 25.01.2018; amended – 29.10.2025)* The reporting REC member presents a summary of the planned research and an ethical assessment, including ethical considerations related to the future publication of results. The written report and proposed decision are presented to the Committee.

Art. 14.
Following review of the submitted documentation, the expert report, and the discussions held, the REC shall adopt one of the following decisions:

1. Approval or reasoned refusal of the research project at the stage of initial review. If approved, the REC determines the frequency of periodic monitoring, based on participant risk, study duration, and study type, but no less than once per year.
2. Approval or refusal of proposed amendments to research plans of already approved studies.
3. A decision on ethical issues related to the production, communication, submission, and publication of scientific results.

Art. 15.
(Amended and supplemented – 25.01.2018) The Secretary shall prepare the minutes of REC meetings, documenting discussions, justifications for decisions, and the start and end times of deliberations. The Secretary signs the meeting minutes.
The PI may obtain a copy of the minutes relating to their project and the adopted decision within one week of the REC meeting.
Where necessary, such documentation may also be provided to regulatory authorities.

Art. 16.
(1) *(Amended and supplemented – 25.01.2018)* When the REC adopts a decision refusing approval of a scientific study, the Principal Investigator (PI) may submit a single written objection within one week of receiving the decision.
(2) The REC shall consider the objection only if it is accompanied by additional information and/or modifications to the study that:
– eliminate the ethical concerns identified by the REC, or
– remove elements associated with unacceptable risk.
The objection shall be reviewed at the next scheduled meeting of the REC.
The final decision of the Committee shall be issued within 30 days from receipt of the objection.

Art. 17.
(1) *(Amended – 29.10.2025)* The REC conducts periodic monitoring of all approved research, in accordance with the frequency determined at the time of initial approval. The PI must submit at least once per year a written report including:
– number of participants enrolled to date;
– number and type of adverse reactions/events;
– number of discontinued participations and reasons;
– assessment of benefits and risks for participants;
– any changes made to the approved study;
– published results;
– any new relevant information;
– a final report upon completion of the study.
(2) A designated REC member prepares a written ethical assessment of the annual report, including:
– the progress of the study;
– any deviations from criteria applied during initial review;
– any unauthorised amendments to the study or its documentation.
(3) The REC verifies whether all serious and unexpected adverse events have been reported in accordance with the requirements specified in the approval decision.
(4) After reviewing all information collected, the REC adopts conclusions and recommendations. These, together with the meeting minutes, are provided to the PI and stored in the study file.
(5) *(Deleted – 29.10.2025)*

Art. 18.
(1) If the research team plans any changes to the methods, procedures, or design of an already approved study, the PI must notify the REC in writing.
(2) Proposed amendments shall be reviewed at the next scheduled REC meeting, where a decision is taken to approve or reject them.
(3) If urgent changes are required to eliminate an immediate risk to participants, the Chairperson shall convene an extraordinary REC meeting for expedited review.
Art. 19.
(1) The REC requires the PI to provide written notification in the following cases:
1. Within three days, in cases of:
   – unexpected increases in participant risk;
   – violations of informed consent procedures;
   – changes in methods or procedures of an approved study.
2. *(Amended and supplemented – 25.01.2018)* Within 24 hours of becoming aware of a serious adverse event**.**
   Notifications may be submitted to the REC's official email address**:** keni@mu-varna.bg**,** indicated on the MUV website.
3. Within three days, in cases of non-initiation or premature termination of an approved study.

Art. 20. *(Amended – 29.10.2025)* When serious and/or persistent violations of an approved study occur, or when participant risk increases unexpectedly, the REC shall notify the management of the host institution and may decide to suspend or terminate the study.

Art. 21.
(1) *(Supplemented – 29.10.2025)* The REC shall consider written requests from individuals or institutions concerning research misconduct—including unethical actions in the production, reporting, submission, or publication of results—related to studies that have received initial REC approval.
(2) The Chairperson submits the request for discussion at the next meeting.
If serious violations are identified—such as data fabrication or falsification, plagiarism, or manipulation of authorship order—a three-member investigative committee shall be appointed.
(3) The committee conducts the necessary investigation and submits a written opinion within one month**,** after which the REC adopts a final decision on the case.
(4) *(Amended – 29.10.2025)* The interested parties shall be notified in writing within five days of the decision.
Art. 22.
(1) *(Amended and supplemented – 25.01.2018; supplemented – 29.10.2025)* The REC provides ongoing advisory support in response to written or verbal requests submitted to the Secretary concerning ethical issues arising in studies previously approved by the Committee.
Consultations may be provided to PIs, research teams, institutional units, or other stakeholders.

Art. 23.
(1) *(Amended and supplemented – 25.01.2018)* The REC organises thematic educational lectures and training courses for researchers at MUV on ethical issues in scientific research.
These activities are conducted within the framework of the Doctoral School of MUV and may include:
– training on ethical standards in human research;
– workshops on good scientific and publication practices;
– case-based discussions of ethical dilemmas;
– updates on national and international regulatory changes.

Art. 24.
The maximum time period for issuing a final ethical opinion and expert assessment by the REC is 60 days from the date of submission of the application.

V. DOCUMENTATION AND ARCHIVE

Art. 25.
The REC develops and maintains the following official documentation:
1. *(Amended and supplemented – 25.01.2018)* A List of REC Members, containing academic degree, institutional affiliation, date of appointment, and assigned role within the Committee.
2. Professional CVs of all REC members.
3. The **Regulations** of the REC.

4. *(Amended – 29.10.2025)* Written Standard Operating Procedures (SOPs) for:
   – initial ethical review of human research;
   – periodic monitoring of clinical and non-clinical studies;
   – review of research misconduct in the production, reporting, submission, and publication of scientific results.
5. A Register of SOPs**,** including titles, dates of adoption, and dates of revision.
6. *(Supplemented – 29.10.2025)* Ethical standards for publication in the scientific journals of MU–Varna.
7. Minutes of REC meetings.
8. All forms required under the SOPs, including:
   – Application form;
   – Study plan/protocol;
   – Declaration of accuracy of submitted documents;
   – Notification of initiation of an REC-approved study;
   – Notification of completion of an REC-approved study;
   – Notification of planned amendments;
   – Interim/final progress reports;
   – Reviewer report for initial ethical assessment.
9. Instructions, guidelines, and requirements for research teams.
10. Training materials on topics related to medical ethics.
11. *(Amended – 29.10.2025)* A Register of submitted applications and decisions**.**
12. Standard templates for official correspondence, and other administrative documents.

Art. 26.
(1) SOPs are detailed written instructions designed to ensure consistency in performing specific functions. They must be signed by the Chairperson of the REC and made available to all REC members.
(2) The REC shall ensure that interested parties have the opportunity to access and review the SOPs.
(3) *(Amended – 29.10.2025)* Written SOPs are drafted by the REC and adopted by simple majority vote.
Review, updating, or revision of SOPs may be initiated:
– upon proposal of REC members;
– upon request from research teams;
– upon recommendation from external experts;
and must be approved by decision of the REC.

Art. 27. *(Amended – 29.10.2025)* All REC meetings shall be documented in official minutes, including:
– a list of attending members;
– studies reviewed;
– summary of discussions;
– expert opinions and recommendations;
– voting results (number of votes “for” and “against”).

Art. 27A. *(Amended and supplemented – 25.01.2018)* An REC member who disagrees with a Committee decision shall sign the minutes and submit a written dissenting opinion, which is attached to the meeting record.

Art. 28.
(1) All documents submitted to the REC by research teams shall be stored securely for 10 years after the completion of the study.
Each study submitted for review shall have a dedicated study file, which is archived upon study completion.
(2) The REC shall take all necessary measures to safeguard the confidentiality of research documentation.
The REC shall not provide, copy, or reproduce study documentation or information at the request of third parties.
Access may be granted only to:
– external independent experts appointed as reviewers;
– regulatory authorities, as required by law.
Art. 29. The financial provision of the administrative activity of REC shall be at the expense of MUV.

Art. 30. (*Amended and supplemented. – 25.01.2018*) The REC is directly subordinate to the Vice-Rector for Scientific Activity of MUV.

Art. 31. The REC presents once a year written information about its activities to the Academic Council of MUV.

Art. 32. (1) The Regulations of the Research Ethics Committee at MUV shall be adopted at a meeting of the Committee and shall be approved by the Rector of MUV.
(*New - 30.04.2015*) (2) Amendments to the Regulations may be made in the order of their adoption and approval.

ADDITIONAL PROVISION

§1. For these Regulations:
1. **Medical-biological studies** include studies on general biological and physiological patterns of health and disease (biological existence of health); research relevant to medical science and education, the scientific contribution of which is mainly theoretical and characterised by new knowledge of processes and phenomena and an expansion of the existing knowledge of processes and phenomena.
2. **Medical-clinical studies** include studies on the personal and biosocial existence of health and disease (study in qualitative and quantitative aspect of the specific characteristics of processes related to health and disease processes); studies generating information on the state of certain health problems, ending with recommendations for corrections; research relevant to health, medical science and education, the scientific contribution of which is predominantly practical and characterised by a new knowledge of processes and phenomena and an expansion of the existing knowledge of processes and phenomena.
3. **Medical and social studies** include studies on the correlation between the biological and social functions of man and society; the impact of major societal phenomena and the

environment on health and disease processes; research related to the optimization of the organization and management of medical science, practice and education; research relevant to health, medical science and education, their scientific contribution being practical and theoretical and characterised by a new knowledge of processes and phenomena and an expansion of existing knowledge of processes and phenomena.

FINAL PROVISION
TO THE REGULATIONS AMENDING AND SUPPLEMENTING
THE REGULATIONS ON THE WORK OF THE RESEARCH ETHICS COMMITTEE
AT THE MEDICAL UNIVERSITY OF VARNA
(Decision No 39 of 25 September 2014)

§1. These amendments were adopted at meetings of the Committee held on 25.09.2014 and enter into force on the date of approval by the Rector of MUV.

FINAL PROVISION
TO THE REGULATIONS AMENDING AND SUPPLEMENTING
THE REGULATIONS ON THE WORK OF THE RESEARCH ETHICS COMMITTEE
AT THE MEDICAL UNIVERSITY OF VARNA
(Decision No 43 of 10 March 2015)

§2. These amendments were adopted at meetings of the Committee held on 10.03.2015 and enter into force on the date of approval by the Rector of MUV.

FINAL PROVISION
TO THE REGULATIONS AMENDING AND SUPPLEMENTING
THE REGULATIONS ON THE WORK OF THE RESEARCH ETHICS COMMITTEE
AT THE MEDICAL UNIVERSITY OF VARNA
(Decision No 44 of 30 April 2015)

§3. These amendments were adopted at meetings of the Committee held on 30.04.2015 and enter into force on the date of approval by the Rector of MUV.

FINAL PROVISION
TO THE REGULATIONS AMENDING AND SUPPLEMENTING
THE REGULATIONS ON THE WORK OF THE RESEARCH ETHICS COMMITTEE
AT THE MEDICAL UNIVERSITY OF VARNA
(Decision No 71 of 25 January 2018)

§4. These amendments were adopted at meetings of the Committee held on 25.01.2018 and enter into force on the date of approval by the Rector of MUV.

FINAL PROVISION
TO THE REGULATIONS AMENDING AND SUPPLEMENTING
THE REGULATIONS ON THE WORK OF THE RESEARCH ETHICS COMMITTEE
AT THE MEDICAL UNIVERSITY OF VARNA
(Decision No 77 of 27 September 2018)

§5. These amendments were adopted at meetings of the Committee held on 27 September 2018 and enter into force on the date of approval by the Rector of MUV on 28 September 2018.

FINAL PROVISION
TO THE REGULATIONS AMENDING AND SUPPLEMENTING
THE REGULATIONS ON THE WORK OF THE RESEARCH ETHICS COMMITTEE
AT THE MEDICAL UNIVERSITY OF VARNA
(Decision No 100 of 25 February 2021)

§6. These amendments were adopted at meetings of the Committee held on 25 February 2021 and enter into force on the date of approval by the Rector of MUV.

FINAL PROVISION
TO THE REGULATIONS AMENDING AND SUPPLEMENTING
THE REGULATIONS ON THE WORK OF THE RESEARCH ETHICS COMMITTEE
AT THE MEDICAL UNIVERSITY OF VARNA
(Decision No 20 of 20.10.2025)

§7. These amendments were adopted at a meeting of the Committee held on 20 October 2025 and shall enter into force on the date of approval by the Rector of MUV on 29 October 2025.