

East European University

Regulations of the Research Ethics Committee

Chapter I. General Provisions

Article 1. Purpose and Scope of the Regulations

1. These Regulations determine the composition, organizational structure, rules of formation and operation, records management, reporting, and the use of relevant forms and documents of the Research Ethics Committee of East European University.
2. These Regulations constitute an institutional act expanding upon the University's Code of Research Ethics and shall be applied in conjunction with it.
3. The status, core principles of activity, authority, and fundamental procedures for ethical review of the Research Ethics Committee are defined by the University's Code of Research Ethics.
4. These Regulations apply to the activities of the Committee concerning research planned, ongoing, or conducted under the responsibility of the University that is subject to ethical self-assessment, submission of an ethics application, formal verification, ethical review, monitoring, or reassessment.

Article 2. Status of the Committee

1. The Research Ethics Committee is a standing collegial body of the University.
2. The Committee carries out the ethical review, assessment, and monitoring of research planned and conducted at the University.
3. In performing its activities, the Committee acts on the basis of the University's Code of Research Ethics, these Regulations, ethical principles, applicable legislation, and the internal legal acts of the University.
4. The Committee submits an activity report to the Rector of the University; however, it is functionally independent and free from any undue influence in the process of ethical review, assessment, and decision-making..

Chapter II. Composition and Formation of the Committee

Article 3. Composition of the Committee

1. The Research Ethics Committee shall be multidisciplinary and consist of at least 7 members possessing appropriate qualifications.
2. The composition of the Committee shall, to the extent possible, ensure:
 - a) Disciplinary diversity;
 - b) Gender balance;
 - c) Diverse professional and academic experience;

- d) Methodological competence in research;
 - e) Competence in ethics, law, personal data protection, or other relevant fields;
 - f) Sectoral competence required for the ethical assessment of biomedical, clinical, or health-related research.
3. The Committee may include:
- a) Representatives of the academic staff;
 - b) A research methodology specialist;
 - c) An ethics or law specialist;
 - d) A representative of social sciences, humanities, or other relevant fields;
 - e) A specialist in data protection, information security, or other relevant fields;
 - f) A person with appropriate qualifications in the biomedical, clinical, or health sector;
 - g) Representatives of other academic or professional institutions.
4. If necessary, particularly when reviewing biomedical, clinical, or health-related research, the Committee is authorized to invite an external independent sectoral expert to assess a specific research application.

Article 4. Formation of the Committee and Term of Office of the Members

1. The members of the Research Ethics Committee, including the Chair and the Secretary of the Committee, are approved by the Rector of the University for a term of 3 years.
2. The same person may be re-approved as a member of the Committee by decision of the Rector of the University.
3. The authority of a Committee member may be terminated:
 - a) On the basis of a personal application;
 - b) Upon the expiration of their term of office;
 - c) In the event of a conflict of interest, an ethical violation, or a gross violation of the requirements of these Regulations;
 - d) In the event of an inability to participate in the activities of the Committee due to objective circumstances;
 - e) On the basis of a legal act of the Rector, in the presence of grounds specified by these Regulations.
4. In the event of early termination of a Committee member's authority, the Rector of the University shall approve a new member in accordance with the established procedure

Chapter III. Organizational Structure of the Committee

Article 5. Chair of the Committee

1. The Chair of the Committee leads the activities of the Committee and ensures the organization of its work.
2. The Chair of the Committee:

- a) Convenes and presides over the meetings of the Committee;
 - b) Draws up the agenda for the Committee meetings;
 - c) Ensures the organization of the application review process;
 - d) Coordinates the work of the Committee;
 - e) Signs the decisions, conclusions, and other official documents of the Committee;
 - f) Supervises the process of delivering the Committee's decisions to the applicant;
 - g) If necessary, carries out a preliminary ethical assessment or determines the appropriate form of review in accordance with the rules established by the Code of Research Ethics.
3. In the absence of the Chair, their functions shall be performed by a member designated by the Committee.

Article 6. Secretary of the Committee

1. Organizational and administrative support for the activities of the Committee is provided by the Secretary of the Committee.
2. The Secretary of the Committee:
 - a) Receives and registers applications;
 - b) Conducts formal verification of applications in accordance with the rules established by these Regulations and the Code of Research Ethics;
 - c) Ensures the advance distribution of the agenda and documentation to the members of the Committee;
 - d) Maintains the minutes of the meetings;
 - e) Ensures the administration, secure storage, and archiving of the Committee's documentation;
 - f) Ensures communication with applicants;
 - g) Performs other functions related to the organization of the Committee's activities.

Chapter IV. Rules of Operation of the Committee

Article 7. Principles of the Committee's Activity

1. The Committee carries out its activities on the basis of the principles of fairness, transparency, independence, professional impartiality, proportionality, confidentiality, and professional ethics defined by the University's Code of Research Ethics.
2. The decisions of the Committee are based on the University's Code of Research Ethics, applicable legal norms, relevant internal legal acts of the University, and the results of the ethical assessment of the submitted research.
3. All participants in the Committee's activities are obliged to act in good faith, in compliance with confidentiality, and within the scope of their authority

Article 8. Committee Meetings

1. The Research Ethics Committee shall meet as necessary, but at least once per semester. In the presence of a research application involving high risk, biomedical, clinical, or health-related fields, the Committee meeting shall be held within a reasonable timeframe.
2. Meetings of the Committee shall be convened by the Chair of the Committee.

3. Committee members shall be notified of the meeting agenda in advance, and the documentation required for review shall be forwarded to them.
4. A meeting of the Committee shall be deemed quorate if more than half of the Committee members are present.
5. Decisions shall be adopted by a majority vote of the members present, unless otherwise established by the internal legal acts of the University.
6. In the event of a tie vote, the Chair of the Committee shall have the casting vote.
7. A member of the Committee has the right to record their dissenting opinion in the minutes of the meeting.
8. Committee meetings may be conducted in physical, electronic, or hybrid formats, provided that the confidentiality of the review process, procedural propriety, and compliance with the proper decision-making rules are ensured.

Article 9. Conflict of Interest

1. A Committee member is obliged to declare in advance any real, potential, or perceived conflict of interest.
2. In the presence of a conflict of interest, the Committee member shall not participate in the review and decision-making process regarding the respective research application.
3. A conflict of interest may include, inter alia, a Committee member's participation in the research, scientific supervision, co-authorship, financial interest, personal or professional relationship, or any other circumstance that may affect their impartiality.
4. Information regarding a conflict of interest shall be recorded in the relevant documentation and, where necessary, reflected in the minutes of the meeting.
5. Conflicts of interest shall be managed in accordance with the relevant policy and internal legal acts of the University.

Article 10. Ethical Consultation

1. In accordance with the rules established by the Code of Research Ethics, a researcher has the right to apply to the Research Ethics Committee at an early stage of research planning to obtain a consultation on ethical issues.
2. The purpose of ethical consultation is the preliminary identification of potential ethical risks, improvement of research design, and facilitation of the proper consideration of ethical requirements.
3. Ethical consultation constitutes an advisory procedure and does not replace formal ethical review in cases where the research is subject to mandatory ethical review.
4. Recommendations issued within the scope of ethical consultation do not constitute ethical approval and do not exempt the researcher from the obligations established by the Code of Research Ethics.

Chapter V. Administration of Applications and Documentation

Article 11. Receipt and Formal Verification of Applications

1. An ethics application shall be submitted using the relevant form approved by the University and, where necessary, accompanied by supporting documentation.
2. Formal verification of the application shall be carried out by the Secretary of the Committee or a person authorized by the Committee, in accordance with the rules and timeframes established by the Code of Research Ethics.
3. The purpose of formal verification is to determine the completeness of the application and the submission of the mandatory documentation provided for by this Code and these Regulations.
4. Within the scope of formal verification, the following shall be checked:
 - a) Completeness of the application form;
 - b) Provision of the research description and core methodological information;
 - c) Presence of the required documentation;
 - d) Provision of informed consent forms, a data management plan, and other necessary documents, if required by the nature of the research.
5. In the event of an incomplete or formally non-compliant application, the applicant shall be notified of the identified deficiencies and granted a reasonable timeframe for their rectification.
6. A formally compliant application shall be forwarded to the appropriate stage of ethical review.

Article 12. Organization of Application Review

1. Preliminary ethical assessment of the application and determination of the form of review shall be carried out in accordance with the rules established by the Code of Research Ethics.
2. The Committee ensures the organization of the application review through either an expedited or a full ethical review process, in accordance with the risk level and content of the research.
3. Biomedical, clinical, or health-related research involving the direct participation of humans, health data, diagnostic material, biological material, or increased ethical risk shall, as a rule, be subject to a full ethical review, unless a different approach is justified by the Code of Research Ethics or a reasoned decision of the Committee.
4. Decisions of the Committee shall be adopted in accordance with the grounds and criteria defined by the Code of Research Ethics.
5. The decision of the Committee shall be executed in writing and communicated to the applicant in accordance with the established procedure.

Article 13. Records Management and Archiving

1. The activities and decisions of the Committee shall be subject to proper documentation.
2. The Committee shall maintain and store, inter alia:
 - a) Ethics applications and accompanying documentation;
 - b) Formal verification materials;
 - c) Assessment forms;
 - d) Minutes of meetings;
 - e) Decisions of the Committee;
 - f) Correspondence with applicants;
 - g) Monitoring materials and reports

3. All applications, decisions, and relevant documentation shall be registered in the appropriate institutional registry of the University.
4. Documentation of the ethical review shall be stored securely, in compliance with confidentiality requirements, and may be used in ethical monitoring, reporting, and quality assurance processes.
5. The rules for the storage, archiving of, and access to documentation shall be determined by the internal legal acts of the University and relevant legal requirements

Chapter VI. Monitoring, Reporting, and Improvement

Article 14. Monitoring

1. The Committee shall monitor approved research in accordance with the rules established by the Code of Research Ethics.
2. The Committee is authorized to request interim or final reports, additional explanations, or other relevant information.
3. Information obtained within the scope of monitoring shall be used to ensure the protection of the rights, safety, and well-being of research participants, as well as to improve research ethics practices.
4. In the case of biomedical, clinical, or health-related research, the Committee is authorized to request additional information regarding the safety of research participants, protection of health data, adverse events, or modifications to the approved protocol

Article 15. Annual Report and Transparency

1. The Research Ethics Committee shall prepare an annual activity report.
2. The annual report shall be published on the University's website and shall be publicly accessible, in compliance with the requirements for the protection of personal data and confidential information.
3. The annual report shall, at a minimum, include:
 - a) The number of reviewed research applications;
 - b) The types of decisions adopted;
 - c) The results of ethical monitoring;
 - d) Key trends and recommendations related to research ethics.
4. In the preparation and publication of the report, the protection of the personal data of research participants, researchers, and other individuals shall be ensured.
5. The University ensures the accessibility of the core principles of activity, procedures, and application submission rules of the Research Ethics Committee for the university community.

Article 16. Continuous Improvement and Quality Assurance

1. The Committee, in cooperation with the Quality Assurance Service, periodically assesses ethical review practices, the efficiency of procedures, and compliance with ethical requirements.

2. The results of the assessment may be used for:
 - a) Improving the regulations, annexes, and working practices;
 - b) Developing recommendations for the improvement of the Code of Research Ethics and relevant internal acts;
 - b) Raising ethical awareness among researchers, students, and academic staff;
 - d) Developing the University's research governance and quality assurance systems.
3. The Committee promotes the development of a culture of research ethics, research integrity, and responsible research practices within the University

Chapter VII. Final Provisions

Article 17. Appendices

1. Forms, documents, and appendices defined by the Code of Research Ethics shall be used in the process of ethical review of research.
2. The aforementioned forms and documents shall be used in the process of submission, formal verification, ethical assessment, decision-making, monitoring, and reporting of an ethics application.
3. Appendices shall be used in accordance with the type, stage, risk level of the research, and the necessity of ethical review.
4. To support the activities of the Committee, these Regulations may be accompanied by the Committee's internal working forms and documents.
5. Updates of an editorial, technical, or administrative nature to the appendices of the Regulations are permissible based on the relevant institutional rule, provided that such amendments do not alter the substantive standards of ethical governance.

Article 18. Approval, Entry into Force, and Revision of the Regulations

1. These Regulations shall be approved by the Representative Board of the University and shall enter into force immediately upon approval.
2. Amendments and additions to the Regulations shall be approved in accordance with the procedure established by the Representative Board of the University.
3. The Regulations may be revised based on the recommendation of the Research Ethics Committee, the Quality Assurance Service, or another authorized structural unit.
4. When revising the Regulations, the following shall be taken into account:
 - a) The Code of Research Ethics;
 - b) Needs identified in practice;
 - c) Applicable legislation;
 - d) Internal policies of the University;
 - e) Relevant international ethical standards;
 - f) Experience and recommendations resulting from the activities of the Research Ethics Committee.

East European University

Annual Report of the Research Ethics Committee (Template)

Reporting Period _____

I. General Information

Name of the Committee: Research Ethics Committee

Reporting Period: _____

Chair of the Committee: _____

Number of Members: _____

II. Activity Statistics**1. Applications Received**

Type	Quantity
Total Applications	_____
Bachelor's	_____
One-cycle Educational Program	_____
Master's	_____
Doctoral (PhD)	_____
Academic Staff	_____

2. Types of Review

Type	Quantity
Expedited Review	_____
Full Review	_____

3. Decisions Adopted

Decision	Quantity
Approved	_____
Approved with Conditions	_____

Decision	Quantity
Deferred	___
Rejected	___

4. Consultations

Type	Quantity
Ethical Consultations	___
Preliminary Consultations	___

III. Monitoring

Research Projects Under Monitoring: ___

Progress Reports Requested: ___

Identified Violations (if any):

IV. Key Ethical Issues

Key ethical challenges identified during the reporting period:

V. Recommendations

Committee recommendations for the improvement of research ethics practices:

VI. Additional Information

VII. Key Trends

Chair of the Committee: _____

Signature _____

Date _____

Conflict of Interest Declaration for Members of the Research Ethics Committee**I. General Information**

Name, Surname of the Committee Member: _____

Position/Status: _____

Date of Review: _____

Title of the Research: _____

II. Declaration

Please check the appropriate box:

- ☐ I do not have a real, potential, or perceived conflict of interest regarding the mentioned research
- ☐ I have a conflict of interest

III. Description of Conflict of Interest and Management Measures (if applicable)

IV. Obligation

I confirm that in the event of a conflict of interest:

- I will not participate in the review;
- I will not participate in the decision-making process.

Signature _____

Date _____

East European University

Research Ethics Committee

Individual Ethical Assessment Form (For Committee Members)

This form constitutes the individual assessment of a member of the Research Ethics Committee and is used during the application review process.

The final decision shall be adopted collegially and reflected in the minutes of the Committee meeting and the official decision document

I. General Information

Title of the Research _____

Applicant (Researcher / Student): _____

Faculty / Program / Unit _____

Level of Research

- ☐ Bachelor's
- ☐ Master's
- ☐ One-cycle Educational Program
- ☐ Doctoral (PhD)
- ☐ Academic / Scientific Staff

Application Number _____

Date of Receipt of Application _____

Date of Assessment _____

II. General Assessment of the Research**1. Purpose and Scientific Justification of the Research**

- ☐ Fully understandable and justified
- ☐ Requires minor clarification
- ☐ Insufficiently presented

Comments:

2. Methodological Compliance

- ☐ Methodology is appropriately described
- ☐ Requires additional explanation

☐ Insufficiently presented

Comments:

3. Participant Selection Process

- ☐ Ethically and methodologically sound
- ☐ Requires clarification
- ☐ Problematic

Comments:

III. Assessment of Ethical Issues

4. Mechanisms for the Protection of Research Participants

- ☐ Appropriately provided
- ☐ Requires additional clarification
- ☐ Insufficient

5. Informed Consent Procedure

- ☐ Fully complies with ethical requirements
- ☐ Requires minor modification
- ☐ Insufficiently presented

6. Data Protection and Confidentiality

- ☐ Appropriately provided
- ☐ Requires clarification
- ☐ Insufficient

7. Ethical Risk Assessment

- ☐ Risks are appropriately assessed
- ☐ Requires additional explanation
- ☐ Insufficiently assessed

8. In the case of biomedical, clinical, or health-related research: assessment of participant safety, health data protection, and additional ethical requirements

- ☐ Appropriately provided
- ☐ Requires clarification
- ☐ Insufficient

9. Use of Artificial Intelligence (if applicable)

- ☐ Appropriately declared

- ☐ Requires clarification
- ☐ Does not comply with ethical requirements

IV. Overall Risk Assessment

- ☐ Low risk
- ☐ Medium risk
- ☐ High risk

V. Individual Recommendation

- ☐ Approval
- ☐ Approval with conditions
- ☐ Deferral requesting additional information/modifications
- ☐ Rejection

VI. Comments and Recommendations

VII. Conflict of Interest

- ☐ None exists
- ☐ Exists (please specify):
- ☐ The member recused themselves from the review

VIII. Assessor

Name, Surname of the Committee Member: _____

Signature _____

Date _____

East European University

Minutes of the Research Ethics Committee Meeting (Template)

I. General Information

Date of the Meeting _____

Format of the Meeting

- ☐ Physical
☐ Online
☐ Hybrid

Location of the Meeting / Platform _____

II. Participants**Committee Members:**

1. _____
2. _____
3. _____

(Please specify all members present)

Invited Persons / Experts (if applicable):

III. Quorum

- ☐ Quorum is present
☐ Quorum is not present

IV. Agenda

V. Reviewed Issues**1. Research Application**

- Title of the Research _____
- Applicant: _____
- Application Number _____

- **Type of Review:**

- ☐ Expedited
- ☐ Full
- ☐ Involvement of an external sectoral expert became necessary

Summary of the Review

VI. Committee Decision

- ☐ Approved
- ☐ Approved with Conditions
- ☐ Deferred
- ☐ Rejected
- ☐ Review suspended pending receipt of additional information

VII. Justification of the Decision

VIII. Additional Conditions (if applicable)

IX. Voting

In favor: ____

Against: ____

Abstained ____

X. Conflict of Interest

- ☐ None recorded
- ☐ Recorded (please specify details):

XI. Signatures

Chair of the Committee _____

Signature _____

Secretary of the Meeting (if applicable) _____

Signature _____

Date _____

East European University

Research Ethics Committee

Notification of Ethical Decision

- Title of the Research: _____
- Applicant _____
- Faculty / Program _____
- Application Number _____
- Date of the Decision _____

Committee Decision

- ☐ Approved
- ☐ Approved with Conditions
- ☐ Deferred pending submission of additional information
- ☐ Rejected

Justification of the Decision

Conditions (if applicable)

Additional Requirements

- ☐ Introduction of amendments to the research protocol
- ☐ Submission of additional documentation
- ☐ Improvement of the informed consent form
- ☐ Clarification of data protection measures
- ☐ Submission of a declaration on the use of artificial intelligence
- ☐ Other: _____

Validity Period of the Ethical Approval _____

Obligations of the Applicant

The researcher is obliged to:

- Comply with the conditions of the approved research;
- Inform the Committee regarding any significant modification;
- Submit a progress or final report, as required.

Contact Information

Research Ethics Committee

Email _____

Chair of the Committee _____

Signature _____

Date _____