



INTERNATIONAL EUROPEAN UNIVERSITY

REGULATIONS ON THE BIOETHICS COMMITTEE

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<i>Regulations on the Bioethics Committee</i>	<i>REGULATION</i>
	<i>Quality management system ISO 9001:2015</i>

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This Regulation regulates the activities of the Bioethics Committee at the International European University and is mandatory.

1. GENERAL PROVISIONS

1.1. The Bioethics Committee (from now on referred to as the Committee) operates based on the International European University (from now on referred to as the "IEU") as a public association without the formation of a legal entity.

1.2. The Committee in its activities is guided by the Constitution and laws of Ukraine, acts of the President of Ukraine and the Cabinet of Ministers of Ukraine, the Order of the Ministry of Health of Ukraine and the Academy of Medical Sciences of Ukraine No. 313/59 of 01.12.2000 "On the further development of medical genetics and bioethics in Ukraine," taking into account the provisions of the Council of Europe Convention for the Protection of Human Rights and Dignity of the Human about Biomedicine (1997) and its protocols. Other normative documents of the Council of Europe, the Universal Declaration of Human Rights (1948), the Universal Declaration of Human Rights (1948), the Convention for the Protection of Human Rights and Universal Freedoms (1950), the Helsinki Declaration (1964), the "Ethical Principles of Medical Scientific Research with the Involvement of Human Subjects" adopted by the 52nd Assembly of the World Medical Association (2000), the recommendations of UNESCO, the World Health Organization and other organizations of the UN system and the Council of Europe, European Convention for the Protection of Vertebrate Animals Used for Experimental and Other Scientific Purposes, the Committee on Bioethics under the Cabinet of Ministers of Ukraine, the Committee on Bioethics at the Presidium of the National Academy of Medical Sciences of Ukraine, as well as these Regulations.

1.3. The Regulations of the IEU Bioethics Committee establish the basic requirements for organizing the Committee's work and functioning.

1.4. The relevant order of the Rector establishes the IEU Bioethics Committee.

1.5. The subject of the Committee's expertise is all biomedical scientific research with the participation of a person as a research subject. The Committee carries out its work in close coordination with the Ethics Committees of medical institutions, which are the clinical bases of the IEU.

2. GOALS AND OBJECTIVES OF THE BIOETHICS COMMITTEE

2.1. The main objectives of the Committee are:

- ensuring the implementation of scientific research conducted with the

involvement of patients and (or) volunteers in compliance with the principles of high morality, respect for their dignity, safety guarantees, and protection of the rights of each research subject;

- ensuring the use of the principles of deontology in everyday professional activities in the relationship of doctors and medical staff with patients, their relatives, and between medical workers.

2.2. To achieve these goals, the Bioethics Committee systematically conducts ethical expertise and moral and legal assessment of research work carried out at the IEU, from the planning stage to its completion, and solves the following tasks:

- study of legal and ethical issues related to research projects and related technologies;
- protection of the rights and interests of study subjects involved in biomedical trials;
- protection of the rights and interests of researchers;
- ensuring ethical, moral, and ethical assessment of scientific research materials;
- advising employees on bioethics;
- assessment of ethical, moral, and legal aspects of the program (protocol) of scientific research;
- Consider materials before the beginning, in the process, and at the end of scientific research.

3. POWERS OF THE BIOETHICS COMMITTEE

3.1. The Bioethics Committee can examine all research projects (plans) and write a conclusion. With a favourable decision from the Committee, the research plan can be submitted for consideration by the IEU Academic Council. The Committee may put forward its comments and demands regarding possible amendments to the draft and return it for revision and reconsideration.

In case of an adverse decision of the Committee on the submitted project, research work cannot be started.

3.2 The Committee systematically monitors the level of awareness of patients (volunteers) about the scientific research in which they are involved and the availability of documented consent from each of them to participate in the study voluntarily.

3.3 The Committee organizes and controls the implementation of the principles of protection of human rights and dignity in the aspect of biomedicine in all departments and subdivisions of the IEU.

3.4. If necessary, members of the Committee participate in considering conflict situations between patients, their legal representatives, and medical professionals related to violating the principles of bioethics and deontology in the light of moral values.

3.5. The Committee evaluates ethical, moral, and legal aspects before starting research on the dissertation topic and during its implementation. It provides an expert opinion at the end of the dissertation research.

4. STRUCTURE AND PROCEDURE FOR THE FORMATION OF THE BIOETHICS COMMITTEE

4.1. The Bioethics Committee is established at the initiative of the IEU management.

4.2. The Committee is composed of at least five members. It includes a sufficient number of persons who have the necessary experience and qualifications to assess the ethical, moral, and legal principles for conducting scientific research, have enough experience in research work, and are familiar with international practice in protecting the rights, safety, and dignity of people or in the field of protecting animals from cruelty.

4.3. The Chairman heads the Commission; among the members of the Committee, there is also a secretary.

4.4. The Chairman is the official representative of the Committee and guarantees the compliance of the Committee's activities with these Regulations and normative acts of Ukraine, conducts meetings of the Committee, and is responsible for the correct maintenance and storage of documentation.

4.5. An executive secretary may be appointed in the structure of the Committee to communicate with all interested persons to provide advice and disseminate knowledge about internationally established recommendations for compliance with biomedical ethics in scientific research. Secretary of the Committee: registers applications and application documents submitted by the researcher; convenes meetings of the Committee and prepares documents for consideration; keeps all documentation and organizes the issuance of duplicate research permits; Conclusions.

4.6. The membership duration in the Committee is 5 years, except for a representative from the public, who is invited for 1 year with the possibility of continuing or replacing his activities. This period may be extended for a further 5-year period if a member of the Committee continues to participate in the work of the Committee actively.

4.7. Additions and changes to the personal composition of the Bioethics Committee are made by order of the Rector of the IEU.

5. PROCEDURE OF THE BIOETHICS COMMITTEE

5.1. The main organizational form of the work of the Bioethics Committee is meetings, which are held as necessary or according to the work plan once a quarter.

5.2. Acceptance of applications from researchers and other documents by the plan of scientific research, which is carried out with the involvement of patients and (or) volunteers, is carried out by the Secretary of the Committee during reception hours.

5.3. The Secretary submits the received documents to the members of the Committee for familiarization and preliminary examination.

5.4. The Chairman of the Committee decides to hold meetings of the Committee.

5.5 Meetings of the Bioethics Committee are held behind closed doors in compliance with a quorum.

5.6. The current results of the work of the Bioethics Committee are drawn up in the form of extracts from the minutes of meetings. They are communicated to the Applicant within one week after the decision of the Committee.

5.7. The results of the work of the Bioethics Committee for the year are recorded in the form of annual reports, which the Committee keeps.

5.8. All Committee and technical staff members must maintain confidentiality in matters related to the decision-making procedure and the details of the research applications discussed.

6. REGULATIONS OF THE BIOETHICS COMMITTEE

6.1. The Committee carries out its activities by these Regulations, approved by the order of the Rector, as well as the current legislation of Ukraine and international law.

6.2. The Secretary of the Committee informs the Committee of the date and time of the meeting and its procedure by one week before the meeting.

6.3. The meeting is considered valid in the presence of a quorum, defined as more than 50% of the accounting staff, except for discussion of issues expressly stipulated in these Regulations.

6.4. A supervisor, an independent expert, and researchers whose projects are subject to ethical examination may be invited to the meeting.

6.5. The Committee may invite scientific consultants, experts on specific issues, experts on ethics and jurisprudence, public representatives, etc., to the meetings on a case-by-case basis.

6.6. Engaged independent consultants may participate in the Committee meetings in person or by announcing their conclusion, subject to an agreement on confidentiality.

6.7. All submitted applications for scientific medical and biological research are considered by the Committee collectively based on documents submitted to the Committee by the study's head (responsible executor). The head (responsible executor) of the survey submits these materials to the Committee one month before the planned work starts.

6.8. Members of the Committee must personally study and analyse the documents planned for consideration at least a week before the meeting to reasonably express their point of view.

6.10. The conclusion on the admissibility or inadmissibility of the study is made based on an analysis of the application's compliance with the current Ukrainian and international regulatory documents. The Committee's opinion may be preliminary or final.

6.7. The Committee, while performing the assigned tasks, interacts with the researcher, independent expert, and scientific supervisor of the study.