

Appendix 1

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Regulations of the Research Ethics Commission of the
International Black Sea University LLC

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Research Ethics Commission Regulations

Article 1. Definition of Terms

1) The following definitions apply to the terms used in this Regulation for its purposes:

a) " International Black Sea University" - University-LLC.

b) School: the university's primary educational structural unit;

c) Conducting scientific or creative activities, including basic research, such as writing scientific articles for peer-reviewed publications, writing monographs, authoring or co-authoring a chapter in a book, publishing an article in a collection of materials from scientific conferences or meetings, presenting a paper at a scientific symposium, conference, or research seminar, or editing individual chapters and subsections of a scientific publication or publication. Applied research includes writing a scientific article and getting it published in a journal, newspaper, or electronic publication; co-authoring or writing a chapter in a scientific book; giving important presentations at conferences and professional meetings; and editing a professional book, journal, newspaper, or electronic publication. The development of learning, teaching, and pedagogical activities through research: case study preparation; making a study guide; writing, translating, and editing textbooks; creating a chapter in a textbook; carrying out research to produce educational resources, manuals, and/or software; producing instructional resources;

d) Researcher: a member of the university's academic community and/or affiliated staff who conducts research and publishes findings on the university's behalf. The term "researcher" refers to both an individual researcher and a team of researchers for the purposes of this Regulation;

e) The Research Ethics Commission, which may be referred to as the Commission in this Regulation, is a structural unit created in compliance with and for the purposes of this Regulation. It is subordinate to the relevant school.

f) Academic staff - a professor, associate professor, assistant professor and assistant selected through a contest procedure provided for by the Georgian legislation on higher education, who is affiliated/not affiliated with the university, is employed full/part-time on the basis of an employment contract and participates/leads the research, academic, consulting/administrative process;

g) Affiliated staff members—professors, associate professors, assistant professors, and assistants chosen through a contest process outlined in Georgia's higher education laws—who work full- or part-time under an employment contract, are involved in or lead the academic, research, consulting, and administrative processes;

h) Research ethics: the degree to which the researcher's work complies with the guidelines established by these Regulations on Ethical Research, Georgia law, and global norms.

2) The definitions of all other terms used in the Regulations are found in Georgia law and the University Regulations.

Article 2. General provisions

1) 1) This regulation governs the creation, composition, operations, methods of accomplishing the objectives, and execution of the duties of the Research Ethics Commission in the relevant university school. It lays out the composition, duties, and roles of the Research Ethics Commission;

2) The regulation's goal is to control how academic and/or affiliated staff adhere to the standards and guidelines of ethical research when conducting or publishing research on behalf of the university;

3) The primary role of the Research Ethics Commission is to evaluate whether research in the university is ethically compliant with Georgian law and international standards for research ethics, as well as whether it is appropriate to conduct the study on the university's behalf;

4) The purpose of the Research Ethics Commission is to be a guarantor that:

a) the research conducted by the researcher will be conducted with the responsibility and high standards established by the rules defined by Georgian legislation and international norms in the field of research ethics;

b) The planned research complies with generally accepted ethical standards;

c) The safety, personal autonomy, dignity and other rights of the individuals participating in the research are protected and ensured;

5) Academic and affiliated staff members of the university who are permitted to carry out research activities within the parameters of their authority and to disseminate or publish research findings on behalf of the university are subject to the requirements of this regulation. Since the School of Medicine is governed by the particular ethical standards that apply in the field, this regulation does not apply to research carried out by the School;

- 6) The Ethics Commission conducts its activities in accordance with the legislation of Georgia, legal acts of the University and this Regulations;
- 7) The activities of the Research Ethics Commission are based on the principles of legality, equality and integrity, collegiality and confidentiality;
- 8) The Research Ethics Commission ensures the achievement of the goal set forth in this Regulation through an assessment of the ethics of the research, within the framework of which the Commission reviews the application submitted by the researcher, assesses its ethical aspects, prepares an assessment, and determines the compliance of the research with ethical norms;
- 9) Research is ethical and, accordingly, the Ethics Committee determines compliance with ethical norms/standards if the research meets all of the following criteria:
 - a) The research is consistent with the fields of study at the university;
 - b) The research does not contradict generally recognized moral goals and principles;
 - c) The research does not violate human rights and freedoms;
 - d) No part of the research contains information that is defamatory of the dignity or reputation of others;
 - e) The research does not use methods that may violate the rights of third parties and/or mislead;
 - f) The research does not contradict the current legislation and legal principles of Georgia;
 - g) The research is the direct result of the researcher's research activities;
 - h) The research complies with generally recognized ethical norms and principles for conducting research in a specific field.

Article 2¹ . Incorporation of international practices, norms and principles in the field of research ethics

- 1) This policy is in accordance with the code of conduct and research ethics established by the British Educational Research Association (BERA), ¹ as well as the internet research ethics established by the Association of Internet Researchers. ²
- 2) The principles and provisions outlined in other sources (such as international treaties, conventions, etc.) that may be directly or indirectly related to aspects of research ethics are also shared by this provision, which is not restricted to the documents listed in the article's first paragraph.

¹ British Educational Research Association [BERA]. (2024). *Ethical Guidelines for Educational Research* (5th ed.). www.bera.ac.uk/publication/ethical-guidelines-for-educational-research-2024

² British Educational Research Association [BERA]. (2023). *BERA handbook: Member code of conduct*. www.bera.ac.uk/wp-content/uploads/2023/10/Code-of-Conduct-2023.pdf

3) The Ethics Commission is permitted to use the sources listed in the first and second paragraphs of this article as a guide if this regulation does not specify any issues pertaining to research ethics.

Article 3. Composition of the Ethics Commission

- 1) The university rector's order and the school dean's recommendation are the basis for the commission's approval.
- 2) The number of members of the commission must be odd and consist of at least 5 members;
- 3) The Ethics Commission shall be composed of:
 - a) the Dean of the School (Chairman of the Commission);
 - b) School affiliated staff;
 - c) Head of the relevant program;
 - d) Specialist(s) in the field;
 - e) Invited expert (as needed).
- 5) The Ethics Commission will hold a meeting no later than five working days after its composition has been approved, during which it will choose a Deputy Chairman and a Secretary from among its members;
- 6) The Ethics Commission will operate independently; if the Commission deems it necessary, it may invite a specialist or specialists in the pertinent field or area of the submitted research for consideration (henceforth referred to as the "invited expert"), who will be able to participate in the Commission's operations and vote in deliberative sessions.
- 7) The Chairperson of the Ethics Commission, within the scope of his/her authority:
 - a) chairs the meetings of the Ethics Commission;
 - b) submits the research to be considered to the Ethics Commission;
 - c) develops the Ethics Commission's activity plan;
 - d) ensures the performance of other functions.
- 8) The Secretary of the Ethics Commission, within the scope of his/her authority:
 - a) Provides procedural and technical support to the Ethics Commission's work in accordance with the Chairman's directives, including: creating documents for the Commission, setting up meetings, sending the agenda to Ethics Commission members, creating meeting minutes, and carrying out other procedures;
 - b) is required to give at least five working days' notice to the commission members regarding the meeting's time, location, composition (if an expert is invited), and agenda;
- 9) The term of office of the Ethics Commission shall be determined for a period of one year from the date of approval of the Rector's order.

10) Extraordinary (before the expiration of 1 year) renewal of the composition of the Ethics Commission shall be carried out upon termination of the authority of a member of the Commission, namely:

- a) based on a personal statement of a member of the Ethics Commission;
- b) In accordance with the Ethics Commission's or member's decision (recusal/conflict of interest, avoidance of bias);
- c) A Commission member's death;
- d) A court's recognition of a Commission member as a support recipient who is incapacitated, missing, or deceased;
- e) A Commission member's termination from an administrative role that involves Commission membership.

[Article 4: Ethics Commission Procedure Rules](#)

1) The Research Ethics Commission shall hold meetings as often as necessary to perform its functions.

2) Proceedings in the Research Ethics Commission shall commence upon the application of the researcher and shall proceed in accordance with the procedure established by this Regulation. 3) The meeting of the Research Ethics Commission shall proceed in accordance with a pre-established agenda. The meeting shall be chaired by the Chairman of the Commission, and in the absence of the Chairman - by the Deputy Chairman.

3) The meeting of the Research Ethics Commission shall be held on the basis of a pre-established agenda. The meeting shall be chaired by the Chairman of the Commission, and in the absence of the Chairman - by the Deputy Chairman.

4) The members of the Research Ethics Commission shall be sent the agenda of the meeting and the necessary documentation (if any) 3 working days prior to the date of the meeting.

5) The Chairman of the Research Ethics Commission may invite persons specified in these Regulations who are not members of the Ethics Commission to participate in the work of the Commission meeting (as necessary). Information about the invited persons shall be provided to the members of the Commission together with the agenda.

6) The Research Ethics Commission shall have the power to make decisions if the Chairman (or Deputy Chairman), a specialist in the relevant field and the Secretary of the meeting are present at the meeting.

7) The Research Ethics Commission shall make decisions by open voting. The decision shall be deemed adopted if the proposal is supported by the majority of members present at the meeting. In the event of an equal distribution of votes, the vote of the Chairman of the Commission shall be decisive.

8) The activities of the Research Ethics Commission shall be reflected in the minutes of the meeting, which shall be indicated:

a) The Chairperson of the Research Ethics Commission may invite persons specified in these Regulations who are not members of the Ethics Commission to participate in the work of the Commission meeting (as necessary). Information about the invited persons shall be provided to the Commission members together with the agenda.

b) The Research Ethics Commission is competent to make decisions if the meeting is attended by the chairman (or deputy chairman), a specialist in the relevant field, and the secretary of the meeting.

c) The Research Ethics Commission shall make its decisions by open vote. The decision shall be deemed adopted if the proposal is supported by the majority of members present at the meeting. In the event of an equal distribution of votes, the vote of the Chairman of the Commission shall be decisive.

9) The activities of the Research Ethics Commission are reflected in the meeting minutes, which the following is indicated:

a) Date of the meeting;

b) Persons present at the meeting;

c) Agenda of the meeting;

d) The Commission's conclusion on the issue included in the agenda;

e) List of accompanying documents (if any).

10) The minutes of the meeting of the Research Ethics Commission shall be signed by all members present at the meeting.

11) The procedures for the work of the Research Ethics Commission that are not specified in these Regulations may be established directly by the Ethics Commission in the form of a written decision and notified to interested parties.

12) Information/documentation submitted for the purpose of determining compliance with the ethical principles of research, including the minutes of the Ethics Commission meeting, may contain personal data, information related to intellectual property, the secure and confidential placement of which must be ensured in accordance with the legislation of Georgia.

13) The Research Ethics Commission is authorized to issue recommendations, as necessary, on issues regulated by the Regulation.

14) In addition to ensuring that reviewed applications (research) are registered, the Research Ethics Commission is responsible for creating and submitting an annual report on its work to the Rector. It will give other structural units a copy of the report if needed.

15) The Research Ethics Commission will use additional authority granted by these Regulations and Georgia law to accomplish the objectives outlined in the Regulation.

Article 5. Submission of an application to the Ethics Commission

- 1) The researcher must submit a written application outlining the key elements of the study, including the research field, research subject, relevance, research methods, research objectives, and research results, before the Research Ethics Commission will begin its proceedings. The researcher may include additional research-related documents with the application, depending on the particulars of the study topic.
- 2) An initial formal review of the researcher's application and any supporting documentation is carried out by the secretary of the research ethics committee.
- 3) The Secretary of the Commission will draft a written response outlining the deficiency within three working days of the application date if the researcher does not provide the information requested in the application or provides it insufficiently
- 4) In case of a deficiency, the researcher is given 5 working days to submit a complete application.
- 5) The secretary of the meeting registers the researcher's application in the electronic database, assigning a registration number to the application, indicating the name of the school and the research, the personal data of the research supervisor/principal researcher (name, surname, academic position, degree), the date of submission of the application, and the name of the research initiative group (if any).
- 6) The Secretary of the Commission, in agreement with the Chairperson, sends the completed application to the members of the Ethics Commission by e-mail.
- 7) The ethics committee may request any other additional information necessary for the ethical assessment of the research.
- 8) The application form for requesting a determination of compliance with research ethical standards is presented as Appendix No. 1 to these Regulations and constitutes an integral part thereof.

Article 6. Decision of the Ethics Commission

- 1) No member of the Ethics Commission has the right to evaluate the research if there is a possible conflict of interest. In such a case, the relevant member of the Ethics Commission is obliged to refuse to evaluate the research - to declare self-recusal.
- 2) If a member of the Ethics Commission, despite the existence of grounds for recusal, does not declare self-recusal, the Ethics Commission has the right to request the recusal of that person at any stage of the Commission's activities by a reasoned written application. The issue

- of the recusal of a person included in the Ethics Commission is decided by the Commission without that person, with the participation of all other members.
- 3) In the event of a possible conflict of interest, the researcher is entitled to declare recusal against a specific member of the Ethics Commission.
 - 4) When making a decision, the Ethics Commission must be guided by the principles of objectivity, impartiality, and equality of parties.
 - 5) The decision of the Ethics Commission must be substantiated and based on the application and documents submitted by the researcher (if any), the factual circumstances surrounding the case and relevant evidence.
 - 6) A member of the Ethics Commission who disagrees with the decision of the Commission has the right to express a different opinion, which must be reflected in the minutes of the Commission meeting.
 - 7) The Ethics Commission shall issue one of the following conclusions:
 - a) The study complies with the norms/standards of ethical research;
 - b) The study complies with the norms/standards of ethical research subject to the fulfillment of the reservation (conditional consent with amendments), which gives the researcher the right to begin the study only after making specific changes to the plan recommended by the Ethics Commission and/or submitting the requested additional information. In such a case, the submitted changes are evaluated by an expert in the relevant field (within the deadline set by the conclusion), who will confirm in writing to the Ethics Commission that the researcher has fulfilled the reservation;
 - c) The study does not comply with the norms/standards of ethical research.
 - 8) The conclusion of the Ethics Commission is made known to the interested party no later than 5 working days after the Commission meeting.
 - 9) In special cases, the term for evaluating the study may be reduced or increased, for which a reasoned decision of the Ethics Commission is necessary.
 - 10) The conclusion of the Ethics Commission is reflected in the protocol of the commission.
 - 11) The researcher is given a copy of the protocol of the commission or an extract from the protocol, which indicates the result of the study review and the conclusion of the Ethics Commission.
 - 12) The researcher is obliged to inform the Research Ethics Commission about any substantial (radical) changes made to the research, which may necessitate a repeated ethical assessment of the research. Otherwise, the researcher shall not be entitled to publish the research on behalf of the university.
 - 13) The terms of storage of research ethics records are determined by the legislation of Georgia, the Order of the Minister of Justice of Georgia No. 72 of March 31, 2010, and the Unified Procedures for the Conduct of Proceedings of the International Black Sea University LLC.

Article 7. Appealing the Decision

- 1) If the researcher disagrees with the conclusion of the Ethics Commission, he/she has the right to appeal the conclusion to the relevant school council within 3 working days of becoming acquainted with the decision.
- 2) The complaint must be substantiated. The complaint must present all the factual circumstances necessary for its consideration.
- 3) When considering a complaint by the relevant school council, a conflict of interest must be avoided. A person who is also a member of the ethics commission or was a member of the commission at the time of making the appealed decision may not participate in the consideration of the issue.
- 4) The complaint shall be considered and a decision shall be made in accordance with the regulations of the school council, within 5 working days from the date of submission of the complaint.
- 5) The complaint shall be considered without the presence of the complainant.
- 6) The relevant school council shall have the right to make one of the following decisions:
 - a) on satisfying the complaint, which means leaving the conclusion adopted by the research ethics commission unchanged;
 - b) on refusing to satisfy the complaint, which means changing and/or completely canceling the conclusion adopted by the research ethics commission;
- 7) The decision adopted by the council is final and not subject to appeal.
- 8) The decision made by the relevant school council shall be sent to all interested parties within 3 working days of the decision.

Article 8. Final Provisions

- 1) Issues not regulated by this Regulation shall be regulated by the Law of Georgia “On Higher Education” and other internal normative documents of the International Black Sea University LLC.
- 2) This Regulation shall be interpreted in accordance with the legislation of Georgia, as well as the Law of Georgia “On Higher Education” and other internal normative documents of the International Black Sea University LLC, as well as the University’s Regulations and Research Development Policy.
- 3) This Regulation, as well as any amendments and additions made to it, shall be approved and enter into force by the University