

Approved
by the Board of the Faculty of Natural Sciences and Medicine of
LEPL Ilia State University
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By the Academic Council of
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(the decision on the amendments was made at the sixth meeting of the Faculty Research Ethics Committee,
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Bylaws of the Research Ethics Committee of the Faculty of Natural Sciences and Medicine of LEPL Ilia State University

Chapter I: Definition of Terms and the Objective

Article 1. Definition of Terms

Name of the Committee: Research Ethics Committee of the Faculty of Natural Sciences and
Medicine (hereinafter referred to as the “Committee”)

Name of the Faculty: Faculty of Natural Sciences and Medicine (hereinafter referred to as
the “Faculty”)

Name of the Dean: Dean of the Faculty of Natural Sciences and Medicine (hereinafter
referred to as the “Dean”).

Article 2. Objective

The objective of the Committee is:

2.1. To ensure the supervision and guidance of ethical norms adherence in research and
clinical trials conducted within the Faculty of Natural Sciences and Medicine and its
structural units, including the School of Medicine.

2.2 To ensure that all activities involving human participation, animals and biological
materials comply with established ethical standards.

2.3 To ensure the development of policy and the granting of recommendations on ethical norms of research, education and clinical practice within the Faculty.

2.4 The Research Ethics Committee is an advisory body to the Faculty Board and the Dean on issues of adherence to the ethical norms of fundamental and clinical research in the fields of natural sciences and healthcare.

Chapter II: Authority and Accountability

Article 1. Scope of Authority

1.1 The Committee is authorized to:

- a) consider applications regarding ethical norms adherence in research involving human and animal participation, as well as the use of biological materials. Make a decision on compliance with the ethical norms of the research instrument(s) and prepare a corresponding conclusion;
- b) monitor and make recommendations regarding the ethical norms of the ongoing research and clinical trials to ensure compliance with research ethics standards;
- c) develop and recommend policies and guidelines on ethical norms adherence in research.
- d) Research that uses/processes previously collected completely anonymous or depersonalized data is exempted from the review of the ethics committee. Taking into account the above, research for the purpose of secondary processing of anonymous or depersonalized data does not require additional determination of the ethics of the research by the Research Ethics Committee of the Faculty of Natural Sciences and Medicine of Ilia State University. In this case, the Research Ethics Committee is authorized to issue a written response that this type of research/research instrument/s is exempt from the review of the issue. The decision is notified to the addressee with the signature of the chairman and secretary (in English, if necessary), the decision will be recorded on the letterhead of the faculty. This type of application must be accompanied by organizational consent (**Appendix 6**) and a letter of permission/agreement on the use of the collected and anonymized data by the organization.

Article 2. Accountability

2.1. The Committee is subordinate to the Dean of the Faculty of Natural Sciences and Medicine.

2.2. The Committee is accountable to the Faculty Board and the Dean.

Chapter III: Membership

Article 1. Composition

1.1. The Committee should consist of an odd number of members, including:

- a) Academic staff of the relevant research areas of the Faculty of Natural Sciences and Medicine;
- b) Specialists familiar with the norms of research ethics and with experience in bioethics;
- c) At least one person who does not conduct research in any of the areas mentioned above and has no experience in this regard, which ensures the impartiality of the Committee.
- d) After reviewing the application, depending on the specifics of the issue, the Committee might make a decision to invite an external expert to the session. The qualifications of the invited candidate and the experience in relation to the issue under consideration must be confirmed at the beginning of the session by a majority of the Committee members on the basis of the professional biography submitted by the candidate.

Article 2. Qualifications

2.1 Members must have experience in the process of reviewing established ethical norms or education in the relevant fields: medicine, natural sciences, ethics; public health;

2.2. Qualifications are confirmed on the basis of the professional biography (CV) submitted by the members.

Article 3. Appointment

3.1 The Dean of the Faculty must submit candidates for Committee membership to the Faculty Board for consideration and approval every 4 years. In the process of consideration and approval of candidates for Committee membership, their expertise must be taken into account. The Committee must consist of academic staff and specialists in the relevant research field/area.

Article 4. Term of Office

4.1. The term of office of Committee members is 4 years, with the right to re-nomination and appointment.

Article 5. Termination and Replacement

5.1. Conditions for termination of the authority of a Committee member:

- a) On the basis of a personal statement;
- b) Expiration of the employment contract;
- c) Gross or systematic violation of the Code of Ethics and disciplinary liability norms;
- d) Entry into legal force of a court verdict convicting a Committee member;
- e) Death;
- f) Recognition by the court as having limited legal capacity or recognition as a recipient of support, unless otherwise determined by a court decision;
- g) Due to discrediting the committee/faculty.

5.2. Filling of a vacant position

In order to maintain the constancy of the number of members in the Committee, the Dean must submit a candidate(s) to the Faculty Board to fill a vacant position arising from one of the reasons specified in Article 5. The new member will take the place of the removed member for a term of 4 years.

Chapter IV: Management

Article 1. The management structure of the Committee takes into account the following positions:

- Committee Chairman;
- Deputy Chairman;
- Committee Secretary.

Article 2. Selection of Members

Members for the above-mentioned positions of the Committee are elected by a majority vote at the first meeting of each academic year.

Article 3. Responsibilities

3.1 The Committee Chairman presides over all Committee meetings and ensures the effective performance of the Committee's functions.

3.2 The Deputy Chairman performs the duties of the Committee Chairman in their absence.

3.3 The Committee Secretary keeps accurate records of the Committee's meetings, decisions and discussions, draws up minutes of the meeting and prepares a final document on the basis of the decisions made by the Committee.

Chapter V: Committee Meeting and Minutes

Article 1. Organization of the Committee Meeting

1.1. A Committee meeting must be convened by the decision of the Chairman or at the request of 1/3 of the Committee, at a specified time and place.

1.2. The agenda of each committee meeting should preferably not exceed three issues for consideration. If the number of issues submitted for consideration exceeds three, an extraordinary meeting shall be convened by the decision of the committee.

1.3. The committee meeting may be held remotely. A remote meeting shall be held using technical means that enable the participants in the case to establish real-time audio and video communication with each other.

1.4. The agenda of each meeting shall be drawn up for the consideration of the submitted applications/issues and for the adoption of decisions and shall be sent to the committee members within a reasonable time;

Article 2. Quorum and Decision-Making

2.1 The meeting is authorized if more than half of the list of Committee members are present, and the decision is made through open vote by a majority of the votes of the present Committee members.

Article 3. Minutes of the Committee Meeting

3.1. After each meeting, minutes of the Committee meeting are drawn up, which are prepared by the Committee Secretary. Within 10 working days of the Committee meeting, the Secretary is obliged to send the minutes to all members of the Committee.

3.2. The decision adopted by the Committee members shall be communicated to the addressee with the signatures of the Chairperson and the Secretary (in English, if necessary). The decision shall be issued on the Faculty's official letterhead.

Chapter VI: Review of the Ethical Norms Adherence

Article 1. Submission of Research Applications

1.1. The Committee is authorized to review research applications submitted by students of all levels of the Faculty, academic staff, and members of research units at the Faculty. Applications submitted by invited staff will be considered only if the research is planned to be conducted on the bases of research units at the Faculty, which must be confirmed by the head of the research unit in question.

1.2. All applications regarding the ethical norms adherence in research involving human or animal participation or biological materials must be submitted to the Committee for review and decision-making.

1.3. To initiate the process of reviewing an application regarding ethical norms adherence in research, an application is written in the name of the Rector or the Dean of the Faculty, and is registered in the university chancellery;

1.4. The following information must be attached to the application regarding ethical norms adherence in research:

a) A detailed description of the research and research instrument(s) (protocol);

b) A statement signed by the student's scientific supervisor to the Dean, confirming that the research project documentation submitted by the student complies with the requirements/criteria set forth in the same regulation and is ready for review.

c) If the documents submitted for review are rejected by the Ethics Committee, the applicant shall be granted one additional opportunity only to revise and resubmit the documentation to the Research Ethics Committee for further consideration.

d) A document of **Informed Consent and Information Sheet** requested by the Committee, depending on the specifics of the research instrument (if necessary);

i) A risk-benefit analysis of the results obtained from using the research objects in the application regarding ethical norms adherence in research;

f) Procedures for protecting personal data (including anonymity);

g) Relevant ethical opinions to be taken into account for the research.

Article 2. Evaluation of the Research Project by the Research Ethics Committee

2.1 The research project is evaluated according to the following criteria:

- a) Compliance with the ethical standards and legal requirements established by the guiding standards in Chapter 7 of these Bylaws;
- b) Protection of the rights, anonymity and well-being of research subjects;
- c) Scientific validity and social value of the research;
- d) Adequacy of the informed consent document and/or the process for obtaining consent;
- e) Consideration of animal welfare and environmental impact.

Article 3. Decision

3.1 The Committee makes a decision on ethical norms adherence in research no later than 60 days after receiving the application.

Decisions may include the following:

- a) Approval of the issue/research instrument;
- b) Approval of the issue/research instrument (with subsequent periodic monitoring);
- c) Conditional approval of the issue/research instrument with necessary changes;
- d) Request for additional information or clarification;
- e) Rejection of the issue/research instrument.

Article 4. Monitoring

4.1. The Committee may, during the decision-making process, plan further monitoring, based on the specifics/needs of the application, to ensure ongoing compliance with research ethical standards;

4.2. The process may include regular progress reports, on-site visits and audits;

4.3. The monitoring period and deadline are determined at the time of the first decision.

Article 5. Appeal

5.1. The applicant may appeal the decisions of the Committee by submitting a written request to the Rector;

5.2. The complaint application is considered by the Committee of Establishing Ethical Norms Adherence in Research Projects of Ilia State University;

5.3. The period for considering the complaint application must not exceed 30 calendar days.

Chapter VII: Guiding Standards

The Committee must be guided by the following standards in the review and supervision processes of research and clinical practice:

Article 1. Subject – Human

a) Standards and Operational Guidance for Ethics Review of Health-Related Research with Human Participants — this document, published by the World Health Organization (WHO), provides comprehensive guidelines for the ethical review of health-related research involving human participants. The Committee ensures that these guidelines are followed in all research involving human subjects.

Source: <https://www.who.int/publications/i/item/9789241502948>

b) The WHO/AHPSR guidance on “Ethical Considerations for Health Policy and Systems Research” — a resource for public health and healthcare systems. Publication from the Alliance for Health Policy and Systems Research (WHO) with the Global Health Ethics Unit (WHO).

Source: <https://ahpsr.who.int/publications/i/item/2019-12-02-ethical-considerations-for-health-policy-and-systems-research>

c) Guidance on the Use of Protected Health Information in Research.

Source:

a) US Privacy Rules HIPAA <https://www.hhs.gov/hipaa/for-professionals/privacy/laws-regulations/index.html>

b) EU General Data Protection Regulation <https://gdpr.eu/>

c) Georgian Law on Personal Data Protection -

<https://www.matsne.gov.ge/document/view/5827307?publication=4>

Article 2. Subject – Animal

a) Guide for the Care and Use of Laboratory Animals, 8th Edition — this guide, published by the National Research Council, sets forth ethical principles and standards for the care and use of animals in research. The Committee must ensure that all research involving animals conforms to these guidelines, which promote the humane treatment of animals. National Research Council, Division of Earth and Life Studies, Institute for Laboratory Animal Research, Committee on the Update of the Guide for the Care and Use of Laboratory Animals.

Source: <https://nap.nationalacademies.org/read/12910/chapter/1>

b) The Public Health Service (PHS) Policy on Humane Care and Use of Laboratory Animals (Policy) — the Public Health Service Policy on Humane Care and Use of Laboratory Animals (PHS Policy) provides a regulatory framework for the use of live, vertebrate animals in any activity.

Source: <https://olaw.nih.gov/sites/default/files/PHSPolicyLabAnimals.pdf>

Article 3. Biological Material

a) OECD Best Practice Guidelines for Biological Resource Centers — published by the Organization for Economic Co-operation and Development (OECD), provide best practice in the handling, storage and research of biological materials. The Committee must ensure that the use of biological materials in research is in accordance with these Guidelines, ensuring safety and ethical compliance.

Source: <https://www.oecd-ilibrary.org/docserver/9789264128767-en.pdf?expires=1726586135&id=id&accname=guest&checksum=1DE240B68AEA41D40E5F3CEB09D11606>

Chapter VIII: Confidentiality and Conflict of Interest

Article 1. Confidentiality

1.1. All information considered by the Committee: research proposals, discussions and decisions are strictly confidential. Members must not disclose information without the written consent of the Committee or the persons participating in the process.

Article 2. Conflict of Interest

2.1. Committee members must notify the Committee in writing of any potential conflict of interest;

2.2. A conflict of interest arises when the applicant is a member of the Committee or their student;

2.3. Members with a conflict of interest must not participate in the discussion and voting on the relevant issue.

Article 3. Conflict of Interest Disclosure Procedure

3.1. Written Statement:

A Committee member must submit a formal, written statement to the Committee Chairman. This statement must include:

- a) A description of the conflict of interest (e.g., supervisor-student, mentor-student).
- b) The extent of their involvement, if any.
- c) Any potential influence that may affect the impartiality of the review process.

3.2. The review of the Chairman of the Committee:

- a) The Committee Chairman reviews the information received in the disclosure statement and determines appropriate steps to manage the conflict of interest. The disclosure, with the steps taken to manage the conflict, must be documented in the minutes of the Committee meetings. This will ensure transparency in the resolution of the conflict of interest.
- b) A Committee member who has a disclosed conflict of interest must abstain from all discussions, evaluations and decisions related to the submitted proposal. They must not participate in any part of the review process in order to ensure an impartial review process.

3.3. Transparency of Committee Activities:

- a) The existence of a conflict of interest and the actions taken to manage it must be disclosed to the other members of the Committee so that all members are aware of the situation.
- b) Sample of the conflict of interest disclosure statement:

“I, [name of Committee member], hereby declare that the application entitled [application title] is submitted by my student/researcher [first name, last name]. Due to my professional relationship with the student/researcher as their advisor, I acknowledge that this constitutes a conflict of interest. I will abstain from all discussions, evaluations and decisions related to this proposal in order to ensure an impartial review process.”

Chapter IX: Amendments

Article 1. Amendments to the Bylaws

1.1. The Committee, the Dean and the Faculty Board have the right to amend these Bylaws;

1.2. Amendments to the Bylaws are approved by the Faculty Board.

Chapter X: Adoption and Implementation

Article 1. Come into Force

The Bylaws come into force upon approval by the Faculty Board.