Approved by Rector's Decree N19 of February 01, 2024

Petre Shotadze Tbilisi medical Academy

of Statutes of the Bioethics International Committee

Article 1. Introduction and general provisions

The Bioethics International Committee (hereinafter - the committee) of the Petre Shotadze Tbilisi Medical Academy (hereinafter - TMA) is a collegial body that discusses and establishes ethical guidelines for planned biomedical research on humans and animals. It aims to ensure compliance with ethical norms established both in Georgia and internationally.

The committee consists of a constant number of five members. In case of need, additional competent individuals may be invited as appropriate.

The committee's decisions are recorded as a protocol, for which the committee chairman is responsible.

The committee is headed by the Vice Rector in Research.

The committee's work rules and conditions are regulated based on principles of equality and humanism, as outlined in the Constitution of Georgia. Relevant laws and guidelines include the Law on Health Protection of Georgia, the Law on Medicine and Pharmaceutical Activity of Georgia, and international standards such as the International Conference on Harmonization (ICH) Good Clinical Practice (GCP) Guideline E6 (R1), the Helsinki Declaration of 1964, the Oviedo Convention on Human Rights and Biomedicine and its additional articles, the Nuremberg Code of 1947, and the Belmont Report. The committee also follows guidelines from the Office for Human Research Protections (OHPR).

The committee is a member of the "International Chair in Bioethics" network.

Article 2. Goals of the Bioethics International Committee

The goal of the committee is to provide guidance on healthcare and biomedical research, ensuring that research activities are conducted ethically and legally according to international standards. The committee aims to maintain compliance with unbiased standards and prepare accurate conclusions.

Committee objectives:

- Independently and impartially assess the safety of planned research and assist in protecting the rights of individuals involved in the research.
- Ensure that research complies with humane and ethical norms.
- Evaluate the adherence of research procedures to international standards and ensure the delivery of complete and informative documentation.
- Prepare recommendations for planned bioethics research in accordance with legislation and standards.
- Participate in the preparation and review of educational resources.

Article 3. Bioethics International Committee work procedure

An authorized person presents the project and/or educational resources in preparation to review the bioethical aspects of the planned activity with the committee as reflected in form (Annex #1).

All committee members are informed and can represent their own opinions. Meetings can be held remotely and/or in a person.

In case of need, the committee is authorized to invite an expert with appropriate competence to discuss the presented project and/or educational resource.

In case of need, the committee is authorized to invite an expert with appropriate competence to discuss and clarify issues raised in the presented project and/or educational resource. The authorized person for preparing the project and/or educational resources are also involved in a discussion.

The committee's decision is accepted by a majority vote and is documented in the protocol.

The authorized person responsible for preparing the project and/or educational resources is notified of the committee's decision in writing, either electronically or by mail.

In any changes occur during the implementation of the project, the authorized person is obliged to inform the committee about them in writing, either electronically or by mail.

The committee is authorized to request information about the implementation of the project from the project superior.

Article 4. Bioethics International Committee discussion forms

Let it be considered by the committee that research is under review, with the possibility of being granted exceptions:

- The committee may consider exceptions for research aimed at obtaining liberation status from committee review, without requiring discussion of bioethical aspects. The project's authorized person will address the committee, providing project information (including name and a brief description). The committee will assess if the research satisfies participant rights protection regulations, particularly regarding coded personal information or biological samples, and may grant exceptions under 45 CFR section 46.101(b). Criteria for assigning appropriate status will be defined and referenced. The responsible person will then present the project's bioethical aspects using the provided form (Annex #1), and the project will be discussed according to its category.
- Simplified in accordance with the subordinate research discussion rule, ensuring compliance with participant rights protection criteria, as outlined in 45 CFR 46.101 and 21 CFR 56.110 for accelerated review. The responsible person for the project will present its bioethical aspects, using form (Annex #1) along with informed consent to the committee. The project will then be discussed and categorized accordingly.
- Fully complying with the subordinate research discussion rule, encompassing all research, including those of at least high risk, that do not fall into the aforementioned categories.
- Extended in accordance with the subordinate research discussion rule, often resulting in an extensive evaluation of research reviews. The committee determines consent review deadlines for such research, occurring at least twice a year or more frequently.

In cases where accelerated committee discussion is invoked according to the rule, decisions may be formulated as follows: permission, conditional permission, suspension pending further discussion, or refusal.

In accordance with the complete committee discussion rule, decisions may be formulated based on acceptance as follows: permission, conditional permission with corrections, or rejection pending further discussion, and final refusal.

The committee, within its competence, categorizes studies and/or educational resources into nine qualified categories:

- Category 1: Studies involving the early use of approved medicine or equipment, wherein their use will adhere to existing procedures.

- Category 2: In research, blood samples may be collected through methods such as finger or heel pick, venipuncture, etc.
- Category 3: Biological sample is obtained through non-invasive methods.
- Category 4: Data collection occurs through non-invasive methods.
- Category 5: When using biological sample in the future, it can be sourced from: a) samples collected independently from prior research, or b) samples collected not only for research purposes.
- Category 6: Research data is collected from signals, video, or digital images.
- Category 7: The research examines individual or group behavior of the learners.
- Category 8: Research for which permission has already been granted: a) participants have completed their involvement and any interventions, although the study remains active for long-term observational purposes; b) participant involvement has concluded, with pre-defined exceptions for any additional risks; c) research continues with data analysis and implementation.
- Category 9: These studies undergo repeated review but do not involve trial medications or the development of new applications for tools.

Article 5. Bioethics International Committee members responsibility and obligations

Members of the Bioethics International Committee are professionally obliged to impartially evaluate research and/or educational resources, ensuring compliance with established legal and bioethical norms.

Committee members are personally responsible for their assigned tasks and performance; delegation of duties to others is not permitted.

Committee members are obliged to discuss issues related to privacy protection with strict adherence.

Committee members are expected to discuss issues pertaining to conflicts of interest with a focus on impartial reasoning and general definition.

The Vice Rector in Research leads the Bioethics International Committee, representing TMA and addressing research bioethical aspects, including the protection of rights and well-being of individuals involved in research.

Among the members of the International Committee on Bioethics, the Vice Rector for Research determines the coordinator on human rights protection issues and the coordinator on bioethics issues, whom the committee approves for a term of four years by a simple majority of votes.

The Vice Rector in Research leads and facilitates committee sessions and activities, ensuring adherence to conflict-of-interest principles. Additionally, they are responsible for producing documentation and protocols for the committee.

Annex #1

პეტრე შოთაძის სახელობის თბილისის სამედიცინო აკადემია
Petre Shotadze Tbilisi Medical Academy

ბიოეთიკის საერთაშორისო კომიტეტი
Bioethics International Committee at Petre Shotadze Tbilisi Medical Academy

კვლევის ბიოეთიკური ასპექტები - სააპლიკაციო ფორმა
Bioethical Aspects of Research - Application Form

სამეცნიერო ხელმძღვანელი: Principal Investigator:	
ახალგაზრდა მეცნიერი (ასეთის არსებობის შემთხვევაში): Young Researcher (If applicable):	
სტუდენტი (ასეთის არსებობის შემთხვევაში): Student (If applicable):	
პროექტის სათაური: Project Title:	
პროექტის განხორციელების პერიოდი: Project realization period:	

პროექტის მიზანი: Project aims:	
კვლევის მეთოდოლოგია (მასალის შეგროვება, მონაცემების ანალიზი და ა.შ.): Research methodology (samples collection, data analysis and etc.):	
საკვლევი ჯგუფი (ზოგადი დახასიათება, ჩართვის და გამორიცხვის კრიტერიუმები, და ა.შ.) Target group of research (common description, inclusion and exclusion criteria, and etc.)	
საკვლევი ჯგუფის მოცულობა Size of target group	
საკონტროლო ჯგუფი (ზოგადი დახასიათება, ჩართვის და გამორიცხვის კრიტერიუმები, და ა.შ.), ასეთის არსებობის შემთხვევაში Control group of research (common description, inclusion and exclusion criteria, and etc.), if applicable	
საკონტროლო ჯგუფის მოცულობა Size of control group	

კვლევა გულისხმობს ბავშვების, ორსულების, შშმ პირების, პატიმრების, ეკონომიკურად ან სოციალურად დაუცველი პირების ჩართულობას საკვლევ და/ან საკონტროლო ჯგუფებში? დადებითი პასუხის შემთხვევაში წარმოადგინეთ დეტალები. Does research envisage inclusion of children, pregnant women, persons with disabilities and mental retardation, economica and social problems, prisoners in traget or control groups? In case of positive answer, please provide detailes.	
გთხოვთ, განმარტოთ პროცედურა, რომლითაც უზრუნველყოფილი იქნება კვლევაში ჩართულ პირთა კონფიდენციალობა Please describe the procedure which will ensure the confidentiality of the study participants	
გთხოვთ, განმარტოთ პროცედურა, რომლის თანახმადაც მიღებული იქნება კვლევაში ჩართულ პირთა ინფორმირებული თანხმობა Please describe the procedure which will ensure obtaining of the informed consent of study participants	