

Regulation of Ethics Committee for the Research on Animals at Tbilisi State Medical University

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Paragraph 1. General Regulations

1. The present regulation defines the competence, its creation and the rule of work of the Ethics committee on animals (hereinafter the Committee) of Tbilisi State Medical University.
2. The aim of the Committee is ensuring the compliance with internationally recognized ethical norms of research on animals at the Tbilisi State Medical University (including the learning process), safety of animals (subsequently - research object), minimizing the physical and psychological suffering through assessment of research plan and methodology.
3. The Committee conducts its activities in accordance with the International Declaration of Animal Rights and its Additional Protocols, International Agreements Concerning the Protection of Animals Rights Used in the Research and Georgian Legislation, based on University charter and Present Regulations.
4. The main objective of the Committee is to ensure compliance of biomedical studies on laboratory animals within the University with internationally recognized ethical and legal standards;
5. The functions of the Committee are:
 - A. Ethical assessment of research plan methodology and formulation of appropriate conclusion;

- B. Elaborate and approve the application form and other forms of documents of research plan;
 - C. Introduction-popularization of ethical-legal issues and committee activities of biomedical studies on animals;
 - D. Registration of studies assessed by the Committee;
 - E. Other activities aimed at establishing modern standards of research ethics at the university;
6. The work of the research ethics committee of animals of the TSMU is coordinated with the TSMU Scientific Work Coordination, Master's, Doctoral Office, and Scientific Skills Teaching Center.

Paragraph 2. Committee structure and Membership

1. The committee consists of 16 members: The academic staff, invited teacher, veterinarian, lawyer, Scientific Skills Teaching Center, representatives of Vladimir Bakhutashvili Institute of Scientific Biotechnology of TSMU and Iovel Kutateladze Institute of Pharmacochimistry of TSMU.
2. A member of the committee can also be a representative of the Ivane Tarkhnishvili Students' Scientific Society of TSMU- with the right of advisory vote.
3. The Academic Council approves the structure of the Committee (members).
 - A. The academic personnel of the committee will be selected and submitted to the Academic Council by the corresponding faculty council. According to the faculties, the representatives are selected by the following quantities:
 - a) From the faculty of Medicine – 6 members;
 - b) From the faculty of Dentistry – 1 member;
 - c) From the faculty of Pharmacy – 1 member;
 - d) From the faculty of Public Health – 1 member;
 - e) From the faculty of Physical Medicine and Rehabilitation – 1 member;
 - B. The rest of the committee members are presented by the head of the relevant structural unit:
 - a) From the Scientific Skills Teaching Center – 1 member;
 - b) From Vladimir Bakhutashvili Institute of Medical Biotechnology of TSMU – 1 member;
 - c) From Iovel Kutateladze Institute of Pharmacochimistry of TSMU – 1 member;
 - d) From Ivane Tarkhnishvili Student Scientific Society of TSMU – 1 member;
 - e) From Legal Service – 1 member;

- f) From Veterinary Service – 1 member;
- 4. The committee has a chairman and a secretary.
- 5. Conclusions and Committee Annual Report made by Committee Members and Expert/Experts are reviewed and approved on the Committee Sitting.
- 6. The Committee's decision is taken at the Committee Sitting.

Paragraph 3. Committee Rules of Procedure

- 1. The Committee conducts the work of the session with a pre-determined agenda. The Committee chairman leads a session (in case of absence – one of the members).
- 2. The Committee is authorized to conduct a meeting and make a decision if at least 1/2 of the committee members attend the session.
- 3. After the vote, the decision is deemed adopted if the majority of the members presented at the meeting support the proposal. In the case of division of votes, the vote of chairman is decisive.
- 4. The agenda of the next meeting of the Committee is elaborated by the Chairman of the Committee with the Secretary, considering the statements made during the previous sitting of the Committee, statements made during the meeting between the sessions and known or generated significant circumstances for other members of the Committee.
- 5. The agenda of the committee meeting is sent to its members no less than 3 days before the meeting.
- 6. The Secretary of the Committee registers the Committee Meeting protocol.
- 7. The Chairman and the Secretary of the Session sign the protocol of the committee session.
- 8. The Chairman of the Committee can invite persons who are not members of the Committee to participate in the work. Information about invited persons will be provided to the members of the Committee together with the agenda.
- 9. The university web site will have a committee's regulation, application forms and etc. and will be permanently updated.

Paragraph 4. Introduction of Biomedical Research Plan

- 1. Application and documentation for the Ethical Assessment and Expertise of the Biomedical Research Plan is transferred to the Secretary of the Committee.
- 2. The following documents must be submitted to the Committee in written and electronic form:
 - a) Statement on Demand for Ethical Assessment of Biomedical Research Plan;

- b) Research Plan, including the following information:
 - Data of Researcher or researchers and other responsible persons, their qualifications and positions responsible for experiments to be conducted at the research site;
 - The main goal, objective and the necessity of carrying research on the number of animals mentioned in the plan, scientific substantiation of the selection and use of a particular species.
 - Research Methods, the volume and duration of experiment, the means of anesthesia and euthanasia, statistical, analytical methods and etc.
 - Information on the results of research, possible use of data or biological material, including for commercial objectives;
- 3. If necessary, the Committee may request any other additional information required for the ethical evaluation and decision making of the research project.
- 4. The application is registered in the journal according to relevant norms, the name of the research, the date of filing of application is fixed, the personal data of the leading researcher (name, surname, position) and the institution, organization, or the name of the initiative organization.

Paragraph 5. Ethical assessment of the biomedical research plan and decision-making

1. The Secretary of the Committee conducts technical expertise of biomedical research documentation:
 - a) Doctoral research program, as a program (since it will be positively assessed by Quality Assurance Service), as well as the electronic version of the program and the application forms filled out by the Program Manager (in accordance with the requirements of the Ethics Committee on Animal Research) will be transferred to the Committee from coordination of scientific work, master's and doctoral service;
 - b) In case of grant project or any other experimental research project, along with the research project, filled application forms and their electronic versions, the application for the evaluation of the project on the name of the Chairman shall be submitted to the Research Ethics Committee on animals of TSMU;
2. Full documentation submitted in agreement with the Chairman is transferred to the expert (committee member or invited specialist who is not involved in this research).
3. The expert will be selected based on a joint decision at the committee sitting.
4. The Secretary transfers the research plan and accompanying documentation to the Expert, on the basis of which it conveys the conclusion of the Committee no later than 1 month.

5. The expert analyzes the research plan based on the submitted documentation according to research content and assessment criteria.
6. The expert should assess the need to conduct research on the presented animal species, its scientific feasibility, the rule of animal selection used in the study, quantity, compliance of planned studies with internationally accepted ethical standards and so on.
7. The committee's conclusion can be the following:
 - a) Approved without change (consent - in case of positive assessment by the expert), which allows the researcher to conduct a study within the framework of the plan without making any changes in it.
 - b) Approved with the agreement (Conditional consent with amendments), which allows the researcher to start research only after submitting the specific changes recommended by the expert and / or after submitting additional requested information. In this case, the changes are evaluated by the chairman of the committee in accordance with the results obtained by the polling, on the basis of which the chairman of the committee will issue consent or refusal to conduct a research.
 - c) Refused until the next session, which implies that this research plan requires significant processing. After consideration of the comments and recommendations, it may be considered at one of the subsequent sessions of the Committee.
8. The conclusion of the Committee on ethical assessment of the plan is issued no later than within one month from the date of submission of the research documentation to the Committee.
9. In special cases it is possible to decrease or increase the assessment period, for which the decision of the committee is necessary.
10. The committee's conclusion is recorded in the form of a report and registered in the committee's journal.
11. An extract from the report as requested is given to leading researcher or its representative, in which the outcome of the review of research plan and the committee's conclusion is indicated.