AVICENNA
Batumi Medical University

„Approved“
By Avicenna LLC- Batumi Medical University,
Partner Meeting 01-03/05 of November 22, 2022,
Appendix №4 of the Minutes of Meeting

The Regulation of Ethics of Scientific Research of Avicenna - Batumi Medical University

Contents:

Article 1. Scope of Regulation

1.1. This regulation outlines Avicenna - Batumi Medical University LLC's ethical principles for scientific research, sets out procedures for evaluating the ethics of research conducted at the university, and establishes the responsibilities of the University's Ethics Commission and its guidelines for ethical research evaluation.

1.2. This regulation aims to safeguard and enhance the rights, safety, dignity, and well-being of research participants at the university, to foster ethical research that benefits science and society equally, and to provide a trustworthy, proportional, and responsible ethical evaluation of research.

1.3. This regulation is based on international and local laws, ethical principles, and standards, including the World Medical Association (WMA) Declaration of Helsinki on Ethical Principles of Medical Research Involving Human Subjects, the UNESCO Universal Declaration of Bioethics and Human Rights, the Oviedo Convention on Human Rights and Biomedicine, and other relevant documents.

1.4. This regulation covers all scientific research conducted by university staff and in collaboration with other institutions, including studies that involve human participants (patients).

Article 2. The Principles of Ethical Research

2.1. The principles of ethical research are:

a) Respect for participant autonomy;

b) The Principle of Beneficence and Non-maleficence**;**

c) Justice

2.2. All scientific research at the University involving human subjects must comply with the ethical principles outlined in this regulation.

Article 3. The Principle of Autonomy

3.1. The principle of informed consent of the research participant includes obtaining informed consent from the research participant.

3.2. The informed consent of the participants in the study must be obtained before participating in the study and prior to providing information and should provide clear, accurate, and sufficient information about the study.

The principle of informed consent requires that potential participants be given accurate, relevant, and comprehensive information about the research project before making a decision to participate and give informed consent.

3.3. The research participant's right to give consent or withdraw from the research must be respected. Informed consent must be obtained without coercion or undue influence.

Article 4. The Principle of Beneficence and Non-maleficence

4.1. The principle of due diligence and safety implies the moral obligation of the researcher in the scientific research conducted at the university to maximize potential benefits to the research participant or society while minimizing potential harm to the research participant.

4.2. At all stages of research project design and research implementation, researchers must ensure the necessary protection of research participants.

4.3. Compliance with relevant professional standards, obligations and university regulations is mandatory in the process of planning and conducting research at the university.

Article 5. The Principle of Justice

5.1. The principle of justice applies to the process of selecting research participants.

5.2. The selection of research participants should be free from bias, discrimination, and should be based solely on the goals of the research and the need for objective and representative representation. Other factors, such as ease of research implementation, should not be considered in the selection process.

5.3. It is not permissible to select research participants based solely on the ease of obtaining their informed consent.

Article 6. The Scientific Research Ethics Commission

6.1. The Scientific Research Ethics Commission evaluates the ethical aspects of scientific research projects and reports conducted at the university, ensuring compliance with international and domestic laws and regulations protecting the rights of research participants. In the research process, the protection of the universal rights of the research participants is assessed by the collegial body created at the university - the Scientific Research Ethics Commission.

6.2. The role of Scientific Research Ethics Commission is to assess the protection of research participants' rights and safety by evaluating the ethical considerations in research conducted at the university, promoting the culture of research, and fostering communication between researchers and the public, while balancing scientific and public interests.

Article 7. The Composition of the Scientific Research Ethics Commission

7.1. The Scientific Research Ethics Commission should comprise of:

a) 2 members with at least 9 years of clinical experience and an academic degree of Doctor of Medicine;

b) 2 members with experience of participation in medical scientific research;

c) 1 member with an academic degree of Doctor of Biomedical and/or Natural Sciences;

d) A Biostatistician or 1 member with an academic degree of Doctor in Public Health;

e) A lawyer with a Master of Laws degree or equivalent is needed;

f) 2 representatives from society/community outside of healthcare are needed;

g) 2 experts from fields specified in clause 7.2 are needed;

7.2. Experts in the field can be part of the Scientific Research Ethics Commission for evaluating research in a specific direction:

a) A Doctor of Pharmacology - for evaluating research on drugs and medicinal products;

b) A pediatrician with 9 years of clinical experience - for evaluating research involving minors.

c) A psychiatrist with 9 years of clinical experience - for evaluating research on persons with mental health problems.

d) A perinatologist with at least 9 years of clinical experience – for evaluating research on the fetus;

e) A gynecologist with 9 years of clinical experience - for evaluating research on pregnant and lactating mothers.

f) A psychologist with 9 years of practical experience - for evaluating research involving potential stress or trauma from assessments or surveys.

7.3. Half of the Scientific Research Ethics Commission members must not be affiliated with the university.

7.4. The academic council approves the commission composition, based on a submission from the head of the university's health and longevity research center.

7.5. The commission chair invites the field expert and reports to the academic council.

Article 8. The Authority of the Scientific Research Ethics Commission

8.1. The Scientific Research Ethics Commission in terms of planned and ongoing research in the university is authorized to:

a) Evaluate the risks and potential benefits of research;

b) Assess the validity of the research project for obtaining reliable and objective information;

c) Evaluate the procedures and tools for obtaining informed consent from research participants.; evaluate the process of selection of research participants by the researcher;

d) Evaluate the methods for incentivizing research participants in the project;

e) Evaluate the measures for confidentiality protection of information collected from research participants;

f) Determine the absence of discrimination risk in the planned research;

g) Ensure the local population's interests are considered in international research;

h) Assess other ethical considerations for conducting the research;

i) Evaluate the final research reports for compliance with ethics requirements in this rule.

Article 9. The Head of the Scientific Research Commission

9.1. The Scientific Research Ethics Commission, in conjunction with the Health and Longevity Scientific Research Center of the University, presents the candidacy for the Chairman of the Scientific Research Ethics Commission to the Academic Council, in accordance with the agreement with this candidate, from among the candidates holding a Doctoral degree.

The Health and Longevity Scientific Research Center presents the commission chair candidate to the academic council, in agreement with the candidate who holds a Doctorate degree.

9.2. Chairman of the Scientific Research Ethics Commission:

a) Convenes and holds Council meetings in accordance with the procedures set by this regulation.

b) Makes decisions about evaluating scientific research in a specific area and about including experts in the field in the commission.

c) Makes decisions for evaluating scientific researches in a specific area and for determining if a candidate should be included as an expert in the commission.

d) Has the authority to make arrangements with relevant organizations and public interest groups for consultation purposes.

e) Provides information to the members of the scientific research ethics commission on the discussed issue. Additionally, it ensures that non-scientists in the relevant field are informed about the issue at a level that enables effective participation in the discussion.

f) Collaborates with the research ethics committees of partnering educational and medical institutions.

g) Endorses the recommendations adopted by the Scientific Research Ethics Commission and the minutes of their meetings.

Article 10. The Secretary of the Scientific Research Ethics Commission

10.1. The Health and Longevity Scientific Research Center of the University, in collaboration with the Scientific Research Ethics Commission and with the approval of the Academic Council and the Rector, presents the Secretary of the Commission candidacy, selected from among the university's representative candidates, to the Ethics Commission.

10.2. The Secretary of the Commission manages the commission's received applications, communicates with stakeholders, maintains the commission's documents, schedules meetings, and handles other organizational tasks related to the commission's work.

10.3. The Secretary of the Commission creates the minutes and draft decisions of the commission's meetings, signs the minutes, and upon approval by the Chairman, submits them to the university office.

Article 11. Presenting the Scientific Project to the Scientific Research Ethics Commission

11.1. The author of a research project must present the project for ethical evaluation by the Research Ethics Commission before conducting the study.

11.2. The obligation specified in this article applies to the case if the research project involves the participation of people (patients) and must be carried out at the university or in partnership with the university.

Article 12. Scheduling the Session of the Research Scientific Commission

12.1. The secretary's role is to review the information provided with the research project to ensure it is complete and sufficient. If necessary, they will inform the chair of the commission to schedule a meeting to evaluate the project.

12.2. The chairman of the scientific research ethics commission will review the project, determine the individuals to be summoned to the commission session, after which the secretary of the commission will inform the members of the commission, the author of the project and the invited persons about upcoming commission session. The author of the scientific project will be invited to the meeting of the commission, if deemed necessary by the commission chair.

12.3. The chairman may invite representatives of the patient group or affected community to the commission session to voice their opinions during discussions, if deemed necessary.

12.4. The meeting of the commission can be held at the university or online, depending on the chairman's decision.

Article 13. Conflict of Interests

13.1. A commission member with a conflict of interest in regards to the project's author or involved researchers cannot participate in the Scientific Research Ethics Commission meeting or the evaluation of related matters.

13.2. A conflict of interest is defined as a family or socio-economic relationship, financial interest, relationship with the project's author/participant, or any other situation that may result in biased decision-making, whether positively or negatively.

13.3. Members of the commission with a conflict of interest regarding a specific research do not participate in evaluating the relevant research project.

13.4. Researchers must supply the Commission with details regarding the financial interests of all individuals involved in the research project.

Article 14. Session of the Scientific Research Ethics Commission

14.1. The Scientific Research Ethics Commission carries out its responsibilities during commission meetings.

14.2. A commission meeting can reach a decision if over half of the commission members are present.

14.3. The chairman of the commission, the secretary, and relevant field experts must be present for discussions on a specific issue.

Article 15. The Rule of Evaluation of the research application

15.1. The Scientific Research Ethics Commission must promptly assess all applications submitted to it using appropriate evaluation techniques.

15.2. When conducting their assessment, the ethics commission members should consider the following factors related to the research project implementation in addition to the requirements set by legislation and these rules:

a) Relevance of the presented information, regarding possible ethical issues;

b) Relevance of the research objectives to the research plan and the information to be collected;

c) The scientific validity of the research (for example, the extent to which it is intended to obtain scientifically valid information with as little involvement of volunteers as possible) and its minimal impact on volunteers, as well as the potential risks to participants and public, should be evaluated in relation to the effectiveness of the research results;

d) Matching the qualifications and experience of the researchers with the research requirements;

e) Adequacy of the research base, including the qualifications of support staff, infrastructure, and first aid methods, is important for meeting research requirements;

f) Adequacy of medical monitoring and administrative control;

g) Ability of volunteers, or if necessary, their legal representatives, to understand written and oral information provided to them;

h) Mechanisms for engaging volunteers, ways of providing information and processes for obtaining informed consent;

i) Forms of consent, including alternate methods for individuals who are unable to provide informed consent in person;

j) Compensation for life and health damage to research participants;

k) The possibility for research participants to seek compensation in case of breach of their rights and harm to their life and health;

l) Measures to guarantee the confidentiality of research participants and the security of collected data;

m) Reimbursement for participation in the study, if applicable;

Article 16. Assessment of risks and benefits

16.1. Risk assessment for research participants should include:

a) physical health risks, including risks arising from experimental treatments and drugs and other interventions used in research

b) psychological risks (for example: risk caused by a questionnaire about traumatic or stressful events);

c) social, cultural and economic risks (for example: the risk of stigmatization or discrimination caused by the disclosure of confidential information).

16.2. Risk assessment for society should consider the potential impacts on specific population groups, including:

a) the risk of discrimination and stigmatization of ethnic or population groups who may be at increased risk for a particular disease;

b) the impact of the research on the current healthcare system, including any potential diversion of resources from other public needs.

Article 17. Ratio of Risks and Benefits

17.1. The goal of ethical evaluation of research is to find practical ways to minimize harm to participants and maximize benefits, without obstructing potentially beneficial research, and to avoid any unnecessary harm to research participants.

17.2. The phases of risk/benefit assessment are:

a) Assessment of expected risks -involves determining the details and scope of risks (the nature, characteristics and extent of risks). The commission looks at the description of risks in the application, but it should not rely solely on the information provided by the applicant, which may be inaccurate or incomplete.

b) Assessment of expected usefulness evaluates the research project's potential to produce valuable scientific information for society. This should be proportionate to the associated risks.

c) Assessing the risk/benefit ratio - weighing the research's risks against its potential benefits for both participants and society. The Commission should not overestimate or underestimate these factors, to prevent harm to participants or hinder valuable research.

17.3. The level and type of risks involved should be described in detail. The level and type of risks must be clearly described.

17.4. The ethics commission's decision shouldn't solely rely on the information in the research project application. It may consider expert opinions and the opinions of other ethics committees/commissions if needed.

Article 18. Confidentiality

18.1. The Research Ethics Commission must secure the confidentiality of information obtained and processed during scientific research.

18.2. The research project must include measures to protect personal information from unauthorized access and disclosure.

18.3. Personal data refers to any information relating to an identified or identifiable individual, either directly or indirectly, using an identification number or based on their physical, psychological, economic, cultural or social characteristics.

18.4. All personal information must be kept confidential, even if the researcher and participant have a doctor-patient relationship.

18.5. The Scientific Research Ethics Commission assesses the protection and confidentiality of research information, including minimizing the risk of disclosure. This includes:

a) information about an individual's participation in a specific study;

b) information collected during research;

c) information revealed as a result of research;

18.6. The research project is evaluated based on compliance with the following principles of personal data protection:

a) The collection of personal data that can identify participants should only be conducted if it is necessary for the completion of the research.;

b) After collecting material containing personal data, it should be encoded by replacing names with codes. The code key should be securely stored in a separate location. Once the need to link the data to individuals has passed, the key must be destroyed;

c) If data containing personal and identifiable information is stored, the reason for storage, the length of time it will be stored, and the group of individuals who have access to it must be defined;

d) Information security should be maintained by limiting access, using secure storage methods, and employing secure communication methods;

e) The information must be destroyed once it is no longer required to be kept;

f) Participants must be informed about the collection of any personal information, who has access to it, the measures taken to protect it, and the potential risks associated with disclosing the information;

18.7. The commission members are required to maintain confidentiality of any information they become aware of while carrying out their duties as outlined in this rule. An agreement on confidentiality must be established following the established procedure.

Article 19. Making a Decision

19.1. The scientific research ethics commission makes a decision after reviewing the research application that is outlined in this rule.

19.2. Once the research project application has been evaluated, the author and invitees exit the commission session. The commission chairman then holds a vote on the matter.

19.3. The decision of the commission is made by the majority of the votes of the members who are present.

19.4. In case of an even split of votes, the vote of the chairperson of the commission will be the deciding factor.

19.5. Each member of the commission has the right to express a dissenting opinion on decisions made through voting and request that their viewpoint be documented in the commission session minutes.

19.6. The commission is authorized to attach its recommendation to the decision.

Article 20. Concluding Provisions

20.1. This provision is approved by the general meeting of partners and any changes or additions to it must be made by the academic council of the university.

20.2. The head of the scientific-research center for health and longevity at the university must submit the candidates for the scientific research ethics commission to the academic council within 6 months of this provision taking effect.