Agreed by
The Academic Council of JASU
named after B. Osmonov
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Approved by
the Rector of JASU named
after B.Osmonov,
Doctor of Technical Sciences,
Professor K. Zh. Usenov
"07" 03. 2026.

REGULATIONS

on the Bioethics Committee of the Scientific-Educational-Production Complex "B. Osmonov Jalal-Abad State University"

Manas, 2026

Regulations on the Bioethics Committee

1. General Provisions

1. The Regulations on the Bioethics Committee (hereinafter referred to as the "BC" or the "Committee") shall be the principal regulatory document establishing the goals, objectives, functions, rights, and responsibilities of the BC and regulating the organization of its activities, as well as the procedure for interaction with other structural subdivisions and officials of the organization that established it.

2. The BC shall be an independent advisory and consultative body under B. Osmonov Jalal-Abad State University (hereinafter referred to as "JASU"). The Committee is based on voluntary membership and the joint activities of specialists, scientists, and physicians specializing in the field of biomedical, preclinical, and clinical research, as well as clinical trials of biologically active substances, medicines, technologies, materials, and medical devices. The Committee has been established and operates on the principles of conscientious conduct of preclinical studies, clinical trials, and biomedical experiments, as well as the protection and humane treatment of laboratory animals by researchers.

3. In accordance with ethical requirements, the BC in its work and decisions shall not be subordinate to the administration of JASU, including the Rector. At the same time, in its activities that do not contradict ethical decisions, the BC shall rely on:

- the Charter of JASU;
- internal regulatory documents of JASU (regulations, instructions, rules, standards, and other documents);
- decisions of the Academic Council;
- orders and directives of JASU;

- and shall be guided by:
- these Regulations.

4. These Regulations shall be a direct-action document and shall be binding from the date of approval.

5. Amendments to these Regulations shall be approved by the Rector of JASU.

2. Regulatory References

These Regulations have been developed on the basis of the following external regulatory documents:

- Constitution of the Kyrgyz Republic dated May 5, 2021;
- Law of the Kyrgyz Republic "On the Protection of Citizens' Health in the Kyrgyz Republic" dated January 12, 2024 No. 14;
- Law of the Kyrgyz Republic "On Education" dated January 30, 2025 No. 103, with amendments and additions;
- Law of the Kyrgyz Republic "On Science and the Foundations of State Scientific and Technical Policy" dated August 8, 2023 No. 170;
- Law of the Kyrgyz Republic "On Circulation of Medicines" dated August 2, 2017 No. 165;
- Law of the Kyrgyz Republic "On Circulation of Medical Devices" dated August 2, 2017 No. 166;
- Technical Regulation "On the Safety of Medicines for Medical Use" dated April 6, 2011 No. 137, as amended by the Resolution of the Government of the Kyrgyz Republic dated March 15, 2017 No. 154;
    - Regulation "On Accreditation of Healthcare Organizations Conducting Clinical Research in the Kyrgyz Republic" dated April 11, 2017 No. 302;
- Code of Professional Ethics of Medical Workers of the Kyrgyz Republic, 2004;
- Declaration of Helsinki of the World Medical Association "Recommendations for Physicians Engaged in Biomedical Research

Involving Human Subjects," adopted by the 18th World Medical Assembly (Finland, 1964) and all subsequent revisions thereof;

- Guidelines and Recommendations of the UNESCO Ethics Office, adopted in 2005, the World Health Organization (WHO), and the European Forum for Good Clinical Practice;
- International Conference on Harmonisation Tripartite Guideline for Good Clinical Practice (ICH GCP);
- Rules of Good Clinical Practice of the Eurasian Economic Union, approved by Decision No. 79 of the Council of the Eurasian Economic Commission dated November 3, 2016;
- Rules of Good Laboratory Practice of the Eurasian Economic Union in the sphere of circulation of medicines, approved by Decision No. 81 of the Council of the Eurasian Economic Commission dated November 3, 2016.

7. These Regulations have been developed on the basis of the following internal regulatory documents:

- Charter of the Scientific-Educational-Production Complex "B. Osmonov Jalal-Abad State University" dated February 7, 2025.

3. Terms, Definitions, and Abbreviations

The following terms, definitions, and abbreviations are used in these Regulations:

Audit of a clinical study of investigational methods and/or products – a systematic, independent, and documented review of the documentation and activities of parties involved in conducting a clinical study of investigational methods and/or products, carried out by experts independent of the clinical study and the research center, in order to confirm that such activities have been conducted and to assess compliance of the procedures for data collection, processing, and reporting with the

clinical study protocol, standard operating procedures, Good Clinical Practice (GCP), and regulatory requirements.

Biological material of preclinical (non-clinical) and clinical studies – samples of biological fluids, tissues, secretions, and waste products of humans and animals, biopsy material, histological sections, smears, scrapings, and washings obtained during preclinical (non-clinical) and clinical studies and intended for laboratory testing.

Investigator's Brochure – a document containing a summary of the results of preclinical (non-clinical) and clinical studies of an investigational method and/or product relevant to its research and/or testing in humans.

Study design – the overall research plan and description of the stages of conducting the study.

Preclinical (non-clinical) study – chemical, physical, biological, microbiological, pharmacological, toxicological, and other experimental scientific studies or a series of studies of a tested substance or physical impact, methods, means, and technologies for the prevention, diagnosis, and treatment of diseases in order to study their specific effects and/or safety for human health.

Individual Registration Form (hereinafter – IRF) – a document in paper or electronic form intended for recording all protocol-required information for each study subject to be transferred to the sponsor.

Inspection of a clinical study – a procedure of official verification of a clinical trial of investigational methods and/or products, documents related to the clinical study, and the clinical site (premises, equipment, and facilities) by an authorized body involving specialists of an authorized organization experienced in conducting clinical trials, in order to assess the quality of the clinical trial and the data obtained.

Patient Information Sheet – a document serving as written confirmation of the conditions under which a patient has agreed to participate in a study. The

document includes the following information: the title of the study; voluntary participation and the possibility to withdraw at any time; the objectives and duration of the study; characteristics of the study subject, mechanism of action, expected and proven properties, and other relevant details; study design and the probability of assignment to a control group; possible benefits of participation; risks associated with the study, inconveniences, and additional burden compared to conventional therapy; responsibilities of the participant during the study, including the need to refrain from using other medicines, certain food products, etc.; expected expenses related to participation in the study, if any; contact addresses and telephone numbers through which the participant may obtain additional information; and information on the confidentiality of participant data.

Informed Consent – a documented, signed, and dated voluntary agreement of a participant to take part in a clinical study and/or trial after receiving information about the medical technology, the nature and duration of the clinical study, the safety and effectiveness of the medical technology, the degree of risk to health, actions to be taken in case of unforeseen effects of the medical technology on health, and the conditions of health insurance for the participant.

Subject – a patient participating in a clinical trial of investigational methods and/or means.

Investigational method and/or means – a method or means for the prevention, diagnosis, treatment of diseases, and medical rehabilitation, excluding biologically active substances, pharmacological and medicinal products, medical devices, and medical equipment, which is subject to preclinical (non-clinical) or clinical investigation.

Clinical trial – a study involving a human subject conducted to identify or confirm the safety and effectiveness of methods, means, and technologies for the prevention, diagnosis, and treatment of diseases.

Biomedical experiment – a study based on the reproduction (modeling) of the structural-functional complex of the studied condition or disease in a simplified form in laboratory animals in order to determine the causes, conditions, and mechanisms of the occurrence of the condition or development of the disease, as well as to develop methods of treatment and prevention.

Medical technology – a method or means for the prevention, diagnosis, treatment of diseases, and medical rehabilitation, excluding biologically active substances, pharmacological and medicinal products, medical devices, and medical equipment.

Multicenter clinical trials – studies of pharmacological and medicinal products, medical devices, and medical equipment conducted at several clinical sites (by more than one investigator) in accordance with a single protocol.

Monitoring – a procedure organized at the level of a research center for controlling the progress of the experiment and/or study, ensuring its conduct, data collection, and submission of results in accordance with the approved protocol of the experiment and/or study and standard operating procedures of the study.

Good Clinical Practice (GCP) – an international ethical and quality standard for designing, conducting, recording, and reporting studies that involve human subjects as participants.

Scientific research work (SRW) – scientific work related to research, investigation, and experimentation aimed at expanding existing knowledge, obtaining new knowledge, testing scientific hypotheses, identifying patterns occurring in nature and society, scientific generalizations, and scientific justification of projects.

Scientific and technical research program (STRP) – the conduct of specific scientific research under conditions stipulated by a contract between the sponsor and the investigator.

Principal investigator – a person directly involved in conducting the experiment and/or study and responsible for controlling and coordinating all study activities, possessing appropriate training, qualifications, and work experience.

Study report – written presentation of the results of the experiment and/or study and their analysis, in accordance with the requirements of these Rules.

Protocol amendment – a written modification or addition to the study protocol, agreed with the Ethics Commission and the Council of the research center (or the Scientific Medical Council of the authorized body – for clinical studies conducted at international and national levels) and approved by the head of the study.

Study protocol – a document outlining the main objectives, methodology, procedures, statistical aspects, and organization of the experiment and/or study, as well as previously obtained data regarding the investigational methods and/or interventions and the justification of the study.

Head of the experiment and/or study (Principal Investigator, PI) – a person responsible for the overall management of the experiment and/or study and for ensuring its proper conduct in accordance with the study protocol.

Standard Operating Procedures (SOPs) – detailed written instructions ensuring the consistent performance of specific actions and functions within the framework of the conducted experiment and/or study.

Here is the full English translation:

4. Establishment and Liquidation

1. The Committee is established and dissolved by order of the Rector of JASU.

2. Proposals are submitted by the Vice-Rector for Science and Innovation. The Committee is established in accordance with international standards for conducting research involving humans as subjects.

3. Membership in the Committee is voluntary. The schedule of meetings and the agenda are approved by the Chairperson of the Committee.

4. Changes in the structure and composition of the Bioethics Committee are considered at a meeting of the Bioethics Committee, agreed with the Chairperson of the Bioethics Committee and all its members, and approved by the Rector of JASU. Proposals are submitted by members of the Bioethics Committee.

5. Changes to the objectives and organizational-functional structure of the Bioethics Committee are agreed with the Chairperson and all members of the Bioethics Committee and approved by the Rector. Proposals are submitted by the Chairperson and members of the Bioethics Committee.

5. Objectives

The objective of the Committee is to protect the rights and dignity of individuals involved in scientific research as subjects, to protect animals from inhumane treatment in scientific research, to review the ethical aspects of proposed scientific research work (SRW), and to ensure safety guarantees.

6. Tasks of the Bioethics Committee (BC)

- Independent expert review of scientific research (SRW) documentation involving human subjects, as well as research involving laboratory animals, in accordance with international and national standards of Good Clinical Practice and Good Laboratory Practice, and the SOPs of this Committee, with regard to compliance with ethical requirements for research;

- Independent and objective assessment of safety and respect for human rights of research subjects at the planning and conduct stages of the study. Legal aspects include compliance with inalienable human rights and fundamental freedoms in accordance with international human rights standards (right to life and health, respect for human dignity, privacy, right to

information), as well as civil rights (access to and refusal of medical care, informed consent);

- Assessment of the qualifications of researchers based on their scientific curriculum vitae and/or other documentation, as well as the technical capacity of the healthcare institution conducting the study;

- Development of recommendations for amendments and changes to documents and materials submitted for ethical review;

- Issuing conclusions on the approval or disapproval of planned and ongoing research, including:

    - review of additions and amendments to study protocols and ensuring ethical oversight of human subject research in accordance with regulatory documents until their completion;

    - review of ongoing studies at intervals corresponding to the level of risk for subjects, but not less than once per year;

    - organization of audits for compliance of conducted research with legal norms and ethical standards applicable to such studies;

    - development of standards for ethical review by the Bioethics Committee and their implementation in practice

7. Structure

In addition to employees of JASU, the composition of the Bioethics Committee (BC) must include persons who have no direct affiliation with JASU, researchers, or sponsors. Members of the BC may include specialists in healthcare, education, science, law, representatives of religious denominations, and public associations.

The Committee is headed by a Chairperson.

The Chairperson of the BC is elected from among its members by direct open voting, requiring more than 50% of votes, with the mandatory condition that the Chairperson has no employment or contractual relations with JASU. The decision of the BC on the election of the Chairperson is subsequently approved by an Order of the Rector of JASU.

The term of office of the Chairperson is 5 years; it may be extended, but not for more than two terms. The Chairperson of the BC appoints a Deputy Chairperson and a Responsible Secretary from among the members of the BC at a regular meeting through open voting for the duration of their membership in the BC.

The issue of early termination of the duties of the Chairperson (Deputy Chairperson or Responsible Secretary) of the BC is considered at a meeting upon their personal request. In the event of early termination of the powers of the Chairperson (Deputy Chairperson or Responsible Secretary), a new Chairperson (Deputy Chairperson or Responsible Secretary) is elected from among the members of the BC.

The size of the BC is from 7 to 15 members. The number of members may be increased depending on the scope and complexity of the tasks. All members of the BC are required to sign a confidentiality agreement. New members, trainees, BC experts, independent consultants, representatives of the investigator and sponsor, inspectors, and other persons granted access to study documentation or BC documentation must read, understand, accept, and sign a confidentiality/conflict of interest agreement form before beginning their work.

The duration of BC membership is 5 (five) years. This term may be extended for another 5-year period if the member continues to meet all qualification requirements.

The powers of a BC member are terminated in the following cases:

- expiration of the term of the BC composition;

- submission of an application by the BC member addressed to the Vice-Rector for Science and Innovation of JASU requesting withdrawal from the BC;

- a decision of the BC regarding violation by the member of ethical standards in conducting research involving human subjects or the use of laboratory animals.

In case of termination of a BC member's powers, at the next BC meeting an appeal is made to the Vice-Rector for Scientific and Clinical Work proposing a new candidate for the BC composition.

If necessary, the Committee has the right to involve independent experts in ethical review without voting rights, provided that they comply with confidentiality requirements.

BC members perform their expert functions independently of their official positions. When performing their duties, BC members:

- have equal rights in discussing and making decisions within the BC;

- carry out their activities in the BC on a voluntary and unpaid basis.

Any pressure or influence on BC members or research participants constitutes a serious violation of scientific research ethics and harms the reputation of JASU. The Committee must immediately notify the Rector of any attempts of such pressure.

8. Organizational Work of the Bioethics Committee (BC)

No fee is charged for ethical review of research submitted by organizers and executors of studies who are employees of JASU. Members of the BC do not receive any special remuneration for their work.

Members of the BC who review submitted documents have the right to request additional information from the principal investigator and/or study personnel if it is necessary to protect the rights and health of research subjects.

The duty of BC members is to conduct a comprehensive and thorough review of approaches to resolving ethical issues proposed in the research plan, based on the submitted documents or issues arising during the course of the study.

Management and Accountability:

- The officials of the BC are the Chairperson, Deputy Chairperson, and Responsible Secretary, who constitute the working body of the BC;
- The Chairperson leads the activities of the BC, presides over meetings, and is responsible for compliance with this Regulation and SOP requirements. The Chairperson has the authority to assign specific tasks to BC members;
- The Deputy Chairperson performs the duties of the Chairperson in their absence or upon their instruction.

The Responsible Secretary is responsible for maintaining minutes of BC meetings, record-keeping, and archiving BC documentation. The Responsible Secretary has voting rights at meetings. In the absence of the Responsible Secretary at a meeting, the Chairperson assigns the task of taking minutes to one of the BC members.

For the purpose of prompt resolution of issues related to the inclusion of additional sites in clinical trials of medicinal products, replacement of investigators, amendments to clinical trial protocols and other biomedical studies, patient information, etc., a Bureau is established within the BC. The composition of the Bureau (three BC members) and its procedures are approved by the Chairperson of the BC.

The decisions of the Committee are aimed at protecting human rights and dignity in research, ensuring humane treatment of animals in research, promoting scientific development, and improving the quality of human subject research conducted within the framework of scientific research work (SRW). The Committee bases its decisions on the principles of objectivity and independence from political, administrative, departmental, collegial, and financial-economic influences.

Review of ethical applications and research documentation from JASU employees is carried out free of charge. Applications from external organizations are considered individually after submission to the Department of Scientific, Innovation, and Clinical Work of JASU.

The Committee itself is an open body. Information about its schedule is published on the official website of JASU.

The Committee develops its own Regulation and Standard Operating Procedures (SOPs), which are discussed at Committee meetings and approved by the Chairperson of the BC.

9. Functions of the Bioethics Committee (BC)

- Conducting independent ethical review of scientific research;
- Providing methodological support, consultation, and training for members of bioethics committees and researchers on research ethics issues;
- Developing and implementing measures to improve the ethical review system;
- Organizing ethical review of projects under scientific and technical programs in the healthcare field of both applied and fundamental nature, regardless of funding sources;
- Conducting ethical and legal review of materials related to preclinical, non-clinical studies, clinical trials, and biomedical experiments involving new medical technologies, medicinal products, medical equipment

and devices, as well as new methods and means of disease prevention, diagnosis, and treatment;

- Reviewing controversial issues arising before, during, and/or after the completion of research and biomedical experiments;
- Organizing meetings, conferences, and symposia;
- Cooperating with other national and international scientific organizations;
- Concluding cooperation agreements in the field of developing ethical review of scientific research with interested organizations;
- Concluding agreements on conducting ethical review of planned human subject research with individual researchers (natural persons) and legal entities.

10. Regulations of BC Activities

- The BC conducts ethical review of scientific research works after approval of the research plan at a departmental meeting, and in certain cases by a specialized committee;
- The Academic Council and Faculty Councils consider research plans and other projects involving human subjects or animals only in the presence of a BC conclusion;
- The BC determines whether a study complies with the principles of research ethics and provides recommendations for its improvement or agrees with the authors' proposed solutions to ethical issues;
- The BC assesses the qualifications of the researcher for the planned study based on their scientific CV and/or other documentation;

- The BC reviews risks associated with the study and possible scientific outcomes but does not consider social, political, or economic aspects, which are addressed by the administration or funding institutions;

- Based on the reviewed research plans, the BC issues a reasoned conclusion to the principal investigator or responsible researcher. If the BC provides recommendations, identified deficiencies must be corrected by the applicants, the revised plan must be approved at a departmental meeting, and an updated plan must be submitted to the Committee;

- The Committee does not have the authority to prohibit research; however, if it is found that BC recommendations were ignored or that research is conducted without BC involvement, the Committee has the right to report such violations to the JASU administration, healthcare institutions, sponsoring organizations, and relevant regulatory authorities;

- If, during an approved study, ethically questionable or non-compliant situations arise due to the fault of the investigator, sponsor, or participating organization, the BC may report this to the Rector of JASU and relevant regulatory authorities and consider suspending its previous approval;

- The BC is required to submit annual reports to the Academic Council summarizing its work and providing recommendations for preventing unethical practices, violations of human rights in research, and improving animal-based research practices.

11. Rights and Powers of the BC

1. The BC is granted all rights and powers necessary to perform its functions. These rights and powers are exercised by the Chairperson of the BC in accordance with this Regulation.

2. The Committee has the right to:

- request from the investigator, sponsor, and/or principal investigator any information regarding clinical trials, preclinical or non-clinical studies, and additional study-related data if, in the opinion of the BC, such information is necessary to significantly improve the protection of the rights, safety, and/or well-being of research subjects;

- seek assistance from other independent experts and consultants specializing in various fields;

- provide clarifications, recommendations, instructions, and make decisions on matters within its competence;

- exercise other rights in accordance with the legislation of the Kyrgyz Republic.

3. The BC ensures:

- independence, quality, and objectivity of the ethical review of all human subject research;

- safety and justification of possible risks and inconveniences to participants in comparison with expected benefits;

- confidentiality;

- prohibition of enrolling a participant in a study/trial before the BC has issued a written conclusion on any disputed issues regarding its conduct;

- written communication to researchers of its conclusions and justifications regarding the study and the procedure for appealing its conclusions and/or recommendations;

- documentation of BC activities, establishment of procedures for conducting meetings, keeping meeting minutes, notifying members of upcoming meetings, organizing meetings, and storing and archiving documents;

- timely and high-quality performance of the functions set out in this Regulation;
- organization of BC activities for the fulfillment of assigned tasks and functions.

12. Relations with Other Structural Units

In its activities, the Committee interacts with academic departments on issues related to the ethical review of the implementation of scientific research work (SRW).

13. Responsibility

The Chairperson of the BC, Deputy Chairperson, Responsible Secretary, and members of the BC are responsible for achieving the established objectives within the scope of their competence, as well as for failure to perform or improper performance of their assigned duties, and for committing offenses in the course of their activities in accordance with the current legislation of the Kyrgyz Republic.