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INTERNATIONAL
BALKAN
UNIVERSITY

CODE OF RESEARCH CONDUCT AND RESEARCH ETHICS

Research and
Academic Ethics
Committee

Updated- 2nd version
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International Balkan University



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Based on Article 94, Paragraph 1 Item 43 of The Law on Higher Education (“Official Gazette of Republic of North Macedonia” number 82/2018, 154/2019, and 178/2021) and Article 32 of the Statute of the University, the Senate of the International Balkan University, on 12.03.2026, adopted the following

CODE OF RESEARCH CONDUCT AND RESEARCH ETHICS

General Information

The International Balkan University’s Code of Research Conduct and Research Ethics establishes a framework for responsible and ethical research across all research activities conducted at, for, or under the auspices of the University. The Code reflects the University’s commitment to research integrity, academic excellence, transparency, and compliance with relevant ethical, legal, and professional standards.

The Code defines the duties and responsibilities of researchers, including their obligations towards research participants such as human subjects, animals, the environment, and cultural or sensitive materials. It also provides a framework for the transparent, accurate, and responsible communication, publication, and dissemination of research findings. The International Balkan University endorses internationally recognized principles and frameworks for research integrity and aligns its policies with best practices in research governance. The University is committed to regularly reviewing and updating this Code in order to further strengthen the quality, credibility, and integrity of research conducted under its auspices.

This Code is aligned with national legislation on higher education and research, as well as with relevant European and international frameworks for research integrity, including the European Code of Conduct for Research Integrity. The Code ensures the application of ethical principles and good research practices across all research activities of the International Balkan University.

Definitions:

Authorized Personnel- People who are officially allowed to access sensitive or private research data. (Research team members, supervisors, or ethics committee reviewers who have permission to see confidential data).

Data Confidentiality- Keeping research information private and secure so that unauthorized people cannot access it.

Data Management Plan- A formal plan that explains how research data will be collected, stored, accessed, shared, and safely deleted after the study.

Dual-Use Research- Research, technology, or knowledge that can be used both for good purposes and for harmful purposes.



- **Enhanced Scrutiny**- Extra careful review and oversight for research that could be risky or misused.
- **Human participants** -are living individuals from whom data are obtained through interaction, intervention, or identifiable private information.
- **Informed consent** - is the voluntary, explicit, and documented agreement of a participant to take part in research after receiving adequate information.
- **Institutional body** means a permanent committee, council, board, or commission established by the institution, authorized to make decisions, conduct reviews, or oversee specific procedures in accordance with institutional regulations and applicable law.
- **Investigation Panel (more than one person, not a single individual)** usually means a small, independent group appointed to formally examine allegations (most often research misconduct, ethics breaches, or procedural violations).
- **Mitigation Strategies**- Planned actions or safety measures to reduce the risk that research could be misused or cause harm.
- **Personal data**- means any information relating to an identified or identifiable natural person.
- **Plagiarism** is the presentation of another's work, ideas, data, or expressions as one's own without proper acknowledgment.
- **Research misconduct** refers to fabrication, falsification, plagiarism, or other serious deviations from accepted research practices.
- **Sample Case Report Forms** or other data collection templates: Researchers must provide example forms or templates that will be used to systematically collect study data. These templates ensure standardization, accuracy, and consistency in data collection, and allow RAEC to review the types of information that will be recorded from participants.
- **Self-plagiarism** refers to the reuse of one's own previously published work without appropriate citation or justification.
- **Unintended Consequences or Risks**-Unexpected problems, dangers, or harmful effects that occur during or after research.
- **Vulnerable populations** -are individuals or groups who have reduced capacity to protect their own interests or make fully informed, voluntary decisions, and who may therefore be at increased risk of coercion, undue influence, or harm in research settings.

SECTION A – GENERAL PRINCIPLES AND SCOPE

Article 1

- (1) This Code applies to all individuals and activities involved in research at International Balkan University (IBU), including:
 - Academic and scientific staff of IBU.
 - Students (PhD, postgraduate and undergraduate) participating in research activities.
- (2) The Code governs research projects that are, funded by IBU, Supported through public funding, grants, or international collaborations. All research projects must comply with,

Institutional regulatory requirements, Professional research guidelines, International frameworks on scientific research ethics.

- (3) The Code of Research and Academic Ethics applies to all research, scholarly, scientific, artistic, and applied activities conducted at or on behalf of IBU. It covers all disciplines, including but not limited to, Natural sciences, Social sciences, Humanities, Engineering, Health sciences, Bio-Medical Sciences, Art, Interdisciplinary research.
- (4) This Code is particularly relevant for research involving human subjects, animals, the environment, and cultural or sensitive materials, where research outcomes may have significant implications for the rights, privacy, status, and reputation of individuals involved.
- (5) This Code defines the scope, principles, and procedures for the ethical review, approval, and oversight of biomedical research (medical and health sciences) conducted under the authority of the Biomedical Ethics Subcommittee (BES). The principles outlined in this Code ensure integrity, responsibility, transparency, and respect for human dignity.
 - The Code applies to biomedical research involving human participants, biological samples, human tissue, medical and dental records, imaging data, and diagnostic, preventive, or therapeutic procedures carried out for research purposes in clinical, laboratory, or educational settings. Research with a medical or health-related background—including biology, chemistry, biochemistry, biophysics, general medicine, dental medicine, pharmacy, and health sciences—must first be approved by the Biomedical Ethics Subcommittee (BES) and then by the IBU Research and Academic Ethics Committee.
 - No biomedical research may commence without prior approval from the Biomedical Ethics Subcommittee. All approved research remains subject to continuous oversight, review of amendments, and compliance monitoring.
- (6) Academic research or projects without human involvement usually do not require formal approval from the IBU Research and Academic Ethics Committee.

Article 2

Research activities related to collecting data and information from human participants (using questionnaires, interviews, platforms, systems, etc.) and biomedical research listed in **Article 1, (4) and (5)**, may only commence and be actively implemented after written ethical approval has been granted by the IBU Research and Academic Ethics Committee (RAEC).

- Ethical approval is granted only when participant recruitment and data collection begin after approval has been obtained.
- Ethical approval applies to research activities that are clearly and explicitly described in the approved application form.
- Any modification to the approved research protocol—including changes in research activities, methodology, instruments, or location of implementation—renders the original ethical approval invalid, and a new ethics application must be submitted and approved by the IBU RAEC prior to continuation.

Article 3

- (1) This Code has been compiled in accordance with:
 - Established ethical principles of scientific research;



- Positive ethical practices adopted by European universities;
- The Code of Conduct for the Recruitment of Researchers¹;
- The European Code of Conduct for Research Integrity²;
- The Ethical Principles of Psychologists and the APA Code of Conduct³;
- Guidelines from the Committee on Publication Ethics (COPE)⁴.

(2) The Committee operates in accordance with internationally and nationally recognized frameworks, including:

- The Declaration of Helsinki⁵;
- Good Clinical Practice (GCP)⁶
- Good Laboratory Practice (GLP)⁷ standards;
- General data protection regulation (GDPR)⁸
- National data protection laws⁹;
- Relevant national regulations governing medical and dental research¹⁰.

SECTION B – ACADEMIC INTEGRITY

Article 4

(1) Academic freedom is the freedom to teach, pursue knowledge, and conduct research without unreasonable interference or restriction by law, institutional regulations, or public pressure. Its fundamental elements include:

- The freedom of researchers to choose any topic of intellectual or scientific concern.
- The freedom to present findings and publish data and conclusions without control or censorship.

¹ **Code of Conduct for the Recruitment of Researchers**, European Commission, 2017. [https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A52017XC0605\(01\)](https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A52017XC0605(01))

² **European Code of Conduct for Research Integrity**, ALLEA (All European Academies), 2017. <https://allea.org/code-of-conduct/>

³ **Ethical Principles of Psychologists and the APA Code of Conduct**, American Psychological Association, 2017. Available at: <https://www.apa.org/ethics/code/>

⁴ **Committee on Publication Ethics (COPE) Guidelines**, 2020. <https://publicationethics.org/resources/guidelines>

⁵ **Declaration of Helsinki**, World Medical Association, 2013 (latest revision). chrome-extension://efaidnbmnnnibpcajpcglclefindmkaj/https://www.wma.net/wp-content/uploads/2016/11/DoH-Oct2013-JAMA.pdf

⁶ **Good Clinical Practice (GCP) Guidelines**, International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH), 2016. Available at: <https://ichgcp.net/>

⁷ **Good Laboratory Practice (GLP) Guidelines**, Organisation for Economic Co-operation and Development (OECD), 2018. [https://www.efsa.europa.eu/en/applications/good-laboratory-practice#:~:text=Good%20laboratory%20practice%20\(GLP\)%20is,GLP%20and%20Compliance%20Monitoring%20Procedures](https://www.efsa.europa.eu/en/applications/good-laboratory-practice#:~:text=Good%20laboratory%20practice%20(GLP)%20is,GLP%20and%20Compliance%20Monitoring%20Procedures)

⁸ **General data protection regulation (GDPR)**- <https://eur-lex.europa.eu/EN/legal-content/summary/general-data-protection-regulation-gdpr.html?utm>

⁹ **National Data Protection Laws**, chrome-extension://efaidnbmnnnibpcajpcglclefindmkaj/https://azlp.mk/wp-content/uploads/2022/12/lpdp_2020.pdf

¹⁰ **Relevant National Regulations in Medical and Dental Research**. <https://iph.mk/en/home/regulativa#:~:text=LEGAL%20REGULATION,89/2010;>

- The freedom to teach in the manner deemed most appropriate by the academic staff.
- (2) Research integrity and responsibility form the foundation of all academic activity. Violations of research standards constitute serious offenses against the scientific community and undermine the pursuit of excellence promoted in Europe.
- (3) According to the Law on Higher Education of the Republic of North Macedonia (“Official Gazette of the Republic of North Macedonia” numbers 82/2018, 154/2019, and 178/2021¹¹), academic staff of IBU and licensed institutions enjoy the freedom to publish the results of their research. This right must be exercised in accordance with the internal regulations of their institutions regarding the use of intellectual property rights and the provisions of the above law.

Article 5

- (1) Academic integrity refers to a commitment to the core values of honesty, trust, justice, respect, responsibility, legality, and fairness in all aspects of research and scholarly activity.
- (2) To support and uphold academic integrity, IBU is committed to:
 - a. Maintaining the highest standards of scientific research integrity in all research activities.
 - b. Ensuring compliance with relevant ethical, legal, and professional frameworks and standards.
 - c. Promoting a research environment based on a culture of integrity, best practices, and institutional support for staff and researcher development.
 - d. Implementing transparent, robust, and fair processes to address allegations of research misconduct.
 - e. Strengthening scientific integrity through regular and open review of research progress.
- (3) Research integrity requires adherence to ethical, professional, and methodological standards that ensure research is reliable, repeatable, valid, and trustworthy. It includes:
 - Proper citation and acknowledgment of sources;
 - Following principles throughout the research process, from design to publication;
 - Unbiased, professional, and honest reporting of findings and data.
- (4) **Researchers are expected to:**
 - Conduct research ethically, responsibly, and with scientific integrity, ensuring the dignity, safety, and well-being of both research participants and researchers;
 - Assess potential risks and benefits in order to protect all individuals involved in the research process;
 - Implement appropriate safeguards to minimize physical, psychological, social, and legal risks for participants and research staff;
 - Provide enhanced protections for vulnerable populations, including minors, individuals with cognitive impairments, pregnant individuals, elderly participants, and other groups identified by the RAEC as being at increased risk of harm;

¹¹ Law on Higher Education of the Republic of North Macedonia (“Official Gazette of the Republic of North Macedonia” numbers 82/2018, 154/2019, and 178/2021¹¹)



- Ensure that research design, conduct, supervision, and reporting comply with ethical principles, scientific validity, and all applicable legal and institutional requirements;
- Uphold voluntary participation and professional integrity by promoting transparency and respect, and by preventing coercion, undue influence, deception, or exploitation;
- Ensure the accuracy, reliability, and integrity of research data and results;
- Identify, disclose, and appropriately manage any conflicts of interest;
- Promote and preserve the dignity, safety, and well-being of all individuals involved in research, including those under the researchers' supervision or mentorship.

Article 6

- (1) IBU provides regular training and education on research ethics, academic integrity, and responsible conduct of research.
- (2) Participation in training programs is mandatory for all researchers, academic staff, and students engaged in research.

Article 7

Researchers applying for external scientific funds on behalf of IBU must:

- Demonstrate familiarity with the research;
- Coordinate with the relevant scientific research office;
- Ensure no conflict of interest or personal benefit.

Article 8

Researchers signing funding applications, whether for IBU or external funds, must ensure that submitted information is clear and accurate. They are responsible for avoiding:

- Plagiarism (including self-plagiarism);
- Fabrication;
- Falsification;
- Misrepresentation of data.

Article 9

When collaborating with external individuals or organizations, researchers must:

- Clearly define collaborator costs;
- Ensure all supporting letters or agreements are transparent and monitorable by IBU.

Article 10

- (1) The RAEC, BES and relevant institutional offices monitor adherence to academic integrity policies.



- (2) Allegations of misconduct, including plagiarism, fabrication, falsification, or unethical conduct, shall be investigated promptly, fairly, and transparently.
- (3) Disciplinary measures for confirmed breaches may include:
 - Formal warnings or reprimands;
 - Suspension of research activities or funding;
 - Reporting to external authorities or funding bodies;
 - Revocation of academic privileges or termination in serious cases.
- (4) All investigations respect due process, confidentiality, and the rights of complainants and respondents.
- (5) The Committee fosters a culture of accountability, transparency, and continuous improvement to uphold high standards of integrity in all research.

SECTION C– CONDUCTING ETHICAL RESEARCH

Article 11

Informed consent is a core ethical requirement and must be obtained prior to participation, except when legally or ethically waived (e.g., in anonymized retrospective studies).

- (1) Consent forms must clearly outline:
 - Purpose and objectives of the study;
 - Procedures participants will undergo;
 - Expected benefits and potential risks or discomforts;
 - Measures to ensure confidentiality and data protection;

- Voluntary participation and the right to withdraw at any stage without penalty.
- (2) Researchers must ensure:
- Consent documents are written in plain, understandable language;
 - Translation is provided if participants do not understand the primary language;
 - Secure storage of consent forms according to data protection regulations;
 - Continuous consent is maintained for long-term studies, and participants are re-informed about significant changes.
- (3) Types of Inform Consent
- a. **Written Consent:** Participants provide their agreement by signing a document detailing the study information.
- b. **Oral (Verbal) Consent:** Participants give their agreement verbally after being informed about the study. Oral consent is appropriate for minimal-risk studies, participants with literacy or language challenges, remote or phone-based research, or where written consent is impractical. Documentation may include audio recording of the consent process or detailed researcher notes. Consent is documented by the researcher, for example: **Audio recording** of the consent (with permission), or Researcher notes stating: (1) Date and time, (2) Participant ID, (3) Statement that oral consent was given. Without the permission of the ethics committee, this method of consent cannot be applied.
- d. **Parental/Guardian Consent:** For research involving children or legally dependent individuals, consent must be obtained from a parent or legal guardian, alongside the minor's assent when appropriate.

Article 12

- (1) Researchers must guarantee confidentiality at all stages of research:
- Data must be collected, processed, and stored lawfully, following the General Data Protection Regulation (GDPR) and relevant national data protection legislation;
 - Personal identifiers must be anonymized or pseudonymized when possible;
 - Access to identifiable data is restricted to authorized personnel;
 - Data breaches must be reported immediately to the Research and Academic Ethics Committee;
 - Data sharing must respect participant consent, contracts, and legal requirements.

Article 13

The use of AI in research must be transparent and documented:

- Clearly describe AI's role in data analysis, manuscript preparation, or simulations;
- Researchers remain fully responsible for AI-generated outputs;
- AI must never be used to fabricate or falsify data, results, or references;
- Validate AI results through peer review, manual verification, or replication;
- Maintain records of AI usage for audit and reproducibility purposes.

Article 14

Research that could be misused or has social, political, or security implications requires enhanced scrutiny. Researcher should:

- Conduct risk assessments for potential dual-use applications;
- Implement mitigation strategies to prevent misuse;
- Ensure compliance with national and international regulations;

- Collaborate with ethics and legal experts for guidance;
- Document and report any unintended consequences or risks to the BES and RAEC.

Article 15

Researchers conducting fieldwork must:

- Comply with all applicable environmental, health, and safety laws;
- Obtain necessary permits for field studies or sample collection;
- Respect local communities, cultural heritage, and ecosystems;
- Minimize environmental impact and disruption to habitats;
- Engage with local stakeholders ethically and transparently;
- Document all environmental and social considerations in research protocols, reports and in application form. (Researchers must write down and record all the ways their research might affect the environment and local communities before and during fieldwork, including: (1) Potential impact on plants, animals, or habitats; (2) Effects on local people, culture, or traditions; (3) Any safety or ethical concerns related to the area).

Article 16

The specified research projects must be conducted under academic and ethical supervision:

(1) Principal Investigators are responsible for:

- Ethical design, methodology, and adherence to approved protocols;
- Obtaining all required ethical approvals, when applicable, before starting research;
- Supervising team members, students, and collaborators;
- Monitoring compliance with the Code and reporting issues to the Research and Academic Ethics Committee;
- Ensuring proper data management, storage, and sharing;
- Addressing conflicts of interest or ethical concerns promptly.

(2) Student research must be guided by qualified supervisors who:

- Teach students to identify ethical risks;
- Ensure adherence to this Code;
- Oversee data collection, storage, and reporting;
- Protect students from undue risk, exploitation, or conflicts of interest.

(3) In collaborative or externally funded projects:

- Clearly define roles, authorship, data ownership, and IP rights in written agreements;
- Ensure ethical standards meet or exceed IBU requirements;
- Maintain transparent financial, legal, and ethical accountability.

Article 17

Investigators in clinical trials must be qualified medical or dental professionals responsible for participant care. Researchers must:

- Conduct research according to the approved protocol;
- Report adverse events or unexpected outcomes promptly;
- Seek prior approval for any protocol modifications;
- Submit progress reports and a final report upon completion (Progress reports are usually submitted at agreed intervals during the research to inform Project office of IBU about the study's status, any issues, or BES and RAEC for any changes at the research process. Final reports are submitted after the research is complete to

summarize findings, outcomes, and confirm compliance with ethical requirements to the Project office of IBU);

- Comply with audits or interim report requests from the Research and Academic Ethics Committee.

Article 18

(4) Principal Investigators (PI) conducting research (according Article 1) must submit the following documents to the Research and Academic Ethics Committee (RAEC) together with all required supporting documents through the University HELLO system:

1. Completed application form.
2. Questionnaires or research instruments, if applicable.
3. Research instruments, if applicable.
4. Informed consent forms to be used with participants.
5. Institutional approval, if required by the hosting or collaborating institution.
6. *Full research protocol describing objectives, methodology, and procedures.
7. *Curriculum vitae (CV) of the principal investigators.
8. *Data protection plan outlining how confidentiality and General data protection regulation (GDPR) compliance will be ensured.
9. *Risk assessment and mitigation measures addressing potential ethical, safety, or dual-use risks.
10. *Sample Case Report Forms or other data collection templates.
11. *Positive opinion from competent authorities (for medicines or medical devices).

*Note: The requirements listed in items 6, 7, 8, 9, 10 and 11 apply only to research conducted in the field of biomedical sciences.

(5) Possible outcomes: Approved; Returned for revisions; Rejected (with written explanation).

Article 19

All research data must be securely stored, anonymized, and protected. Access is restricted to authorized project members and competent authorities. Research involving identifiable personal data must comply with GDPR and national regulations.

Article 20

The Research and Academic Ethics Committee **meets every two weeks** or, exceptionally, at the Chairperson's request. A quorum requires at least half of the members plus one to be present. Decisions are made by a simple majority.

SECTION D – MISCONDUCT AND CONFLICT OF INTEREST

Article 21

This Code establishes a clear, fair, and transparent procedure for receiving, assessing, investigating, and resolving allegations of research misconduct at the International Balkan University (IBU). Its purpose is to:

- Safeguard the integrity of research conducted at IBU;
- Ensure due process for all parties involved;



- Protect the rights, dignity, and professional reputation of researchers, students, and whistle blowers;
- Maintain public and academic trust in the university's research activities.

Article 22

Research misconduct includes, but is not limited to:

- Fabrication, falsification, or fraud in data, results, or procedures;
- Plagiarism and self-plagiarism¹²;
- Misrepresentation of data, results, authorship, or qualifications;
- Undisclosed conflicts of interest;
- Unethical publication practices, including duplicate or redundant publication;
- Serious breaches of approved research protocols.

Note: Honest errors or good-faith differences in interpretation or judgment do not constitute research misconduct.

Article 23

All proceedings under this Protocol shall follow the principles of:

- Fairness and impartiality;
- Confidentiality of all parties involved;
- Proportionality of investigative and corrective measures;
- Timeliness and efficiency in handling allegations;
- Presumption of innocence until final determination;
- Protection of whistle-blowers acting in good faith.

Article 24

Allegations of research misconduct may be submitted in writing by:

- Staff;
- Students;
- External parties.

Key points:

- Anonymous allegations may be considered if sufficient supporting evidence is provided;
- Malicious, frivolous, or knowingly false allegations constitute a disciplinary offence;
- All allegations must be submitted to the Research and Academic Ethics Committee (RAEC).

Article 25

Upon receipt of an allegation, the RAEC shall:

- Conduct a preliminary assessment within fifteen (15) working days;
- Determine whether the allegation falls within the scope of research misconduct;
- Verify if sufficient information exists to proceed;
- Decide whether interim protective measures are required to prevent harm or loss of data.

¹² American Psychological Association (2010) The Publication Manual of the American Psychological Association. Sixth Edition, p. 170 chrome-extension://efaidnbmnnnibpcajpcglclefindmkaj/https://ue.edu.pk/jrre/APA_Manual_6th_Edition.pdf

Article 26

Where a formal investigation is warranted:

- RAEC shall appoint an independent Investigation Panel with appropriate expertise;
- Any member with a conflict of interest must recuse themselves;
- The respondent shall be notified in writing, including:
 - Allegations made;
 - Available evidence;
 - Procedural rights and responsibilities;
- Investigation must be thorough, impartial, and documented.

Article 27

The respondent has the right to:

- Be informed promptly of allegations;
- Respond in writing and orally;
- Present evidence and witnesses;
- Be accompanied by an advisor;
- Be presumed innocent until a final determination is made.

Article 28

The Investigation Panel may:

- Examine research data, publications, funding applications, correspondence, and other relevant materials;
- Conduct interviews with involved parties;
- Review documents and materials provided by external collaborators;
- Ensure all proceedings are thoroughly documented for transparency and accountability.

Article 29

Investigations should normally be completed within ninety (90) days. Any extensions must be:

- Justified in writing;
- Documented in the investigation file.

Article 30

The Investigation Panel shall prepare a written report containing:

- Allegation details;
- Methodology of investigation;
- Findings and conclusions;
- Recommended corrective or disciplinary actions.

The respondent shall have the opportunity to comment on the draft report before finalization.

Article 31

The final decision shall be made by the Senate of IBU or another competent institutional body explicitly authorized by the Senate, in accordance with the Statute.

Sanctions shall be:

- Proportionate to the severity of the misconduct;
- Examples include:
 - Reprimand;
 - Mandatory ethics training;
 - Correction or retraction of publications;
 - Suspension of research privileges;
 - Termination of employment or student enrolment.

Article 32

- Whistle-blowers acting in good faith shall be protected from retaliation;
- Researchers found not guilty of misconduct shall receive institutional support to restore their professional reputation.

Article 33

- Respondents may appeal a decision on procedural or substantive grounds within fifteen (15) working days;
- Appeals shall be reviewed by an independent institutional body, separate from the original Investigation Panel.

Article 34

- All records of allegations and investigations shall be securely stored in accordance with institutional policy;
- Confidentiality must be maintained, except where disclosure is required by law or regulatory authority;
- Documentation shall be retained for a minimum of ten (5) years or as required by law.

Article 35

A conflict of interest arises when personal, professional, financial, familial, or institutional interests may compromise—or appear to compromise—the objectivity, integrity, or independence of research activities.

Article 36

All researchers, supervisors, and RAEC members must disclose any actual, potential, or perceived conflicts of interest.

Disclosure must occur:

- Prior to submission for ethical approval;
- Upon any material change during the research;
- Prior to publication or dissemination of results.

Article 37

The RAEC shall evaluate disclosed conflicts and determine appropriate measures, which may include:

- Approval with conditions;
- Mitigation or management plans;
- Limitation of involvement in research;
- Prohibition from participation in the project.

All decisions shall be:

- Documented, reasoned, and communicated in writing;
- Reviewed periodically if circumstances change.

Article 38

- Failure to disclose a conflict of interest constitutes a breach of this Code;
- If a conflict is identified post-approval, the RAEC shall determine whether it was inadvertent or intentional and recommend corrective or disciplinary measures;
- Sanctions shall be proportionate and consistent with institutional policy.

SECTION E -RESEARCH AND ACADEMIC ETHICS COMMITTEE

Article 39

The implementation, oversight, and enforcement of this Code shall be entrusted to the Research and Academic Ethics Committee (RAEC) of the International Balkan University (IBU), which operates as an independent, expert, and advisory body.

Mission:

The Committee ensures the dignity, rights, safety, and well-being of research participants,

while promoting high-quality, ethically sound research. It serves as the principal body for ethical review, monitoring, and guidance of research conducted under the auspices of IBU.

Article 40

- (1) The Research and Academic Ethics Committee (RAEC) shall consist of five (5) members, comprising one Chair (President) and four (4) members.
- (2) Members shall hold at least the academic rank of Assistant Professor or possess equivalent professional or research experience relevant to the Committee's mandate.
- (3) Members shall act independently, in the interest of ethical integrity, and free from any institutional, financial, or personal conflicts of interest.
- (4) The Biomedical Ethics Subcommittee, operating in coordination with the Research Ethics and Research and Academic Ethics Committee (RAEC) of IBU, shall consist of five (5) members representing biomedical and health-related disciplines.
- (5) In exceptional or highly specialized cases, the Committee may consult an external expert prior to issuing an ethical approval.

Article 41

- (1) Members are elected by the Senate among the candidatures nomination by the Rector.
- (2) The standard term of office is **three (3) years**, renewable once.
- (3) The Committee shall elect a Chairperson from among its members by vote.

Article 42

- (1) Members must declare all potential conflicts of interest.
- (2) Any member with a conflict must abstain from review and decision-making for the relevant project.
- (3) All deliberations, documentation, and decisions are confidential.
- (4) Committee members shall sign Decision appointment and confidentiality declarations upon appointment.

Article 43

The Research and Academic Ethics Committee (RAEC), including its Biomedical Ethics Subcommittee (BES), shall:

- (1) Review and approve research projects prior to initiation.
- (2) Assess scientific rationale, objectives, methodology, and ethical justification.
- (3) Evaluate participant recruitment, informed consent, risk–benefit balance, and data protection.
- (4) Ensure special protections for vulnerable populations and safeguard participants' rights and confidentiality.
- (5) Ensure voluntary participation and the right to refuse or withdraw without penalty.
- (6) Review and oversee clinical trials, including study design, treatment allocation, and invasive procedures, solely for research purposes.
- (7) Monitor approved studies through reports and audits and suspend or terminate non-compliant research.

- (8) Ensure participants or legal representatives are informed of new findings affecting continued participation.
- (9) Complete reviews within thirty (30) days, unless additional documentation is required.

Article 44

- (1) The Committee shall adopt internal Rules of Procedure within two months of constitution.
- (2) Decisions shall be evidence-based, impartial, and documented in writing.
- (3) The Committee may request interim or final reports, conduct audits, and review amendments to ongoing research.

Article 45

The RAEC shall:

- (1) Promote training and awareness of ethical standards among staff, students, and researchers;
- (2) Advise on best practices in ethics, research integrity, and responsible conduct of research;
- (3) Provide annual reports to the Senate summarizing activities, decisions, and trends in ethical oversight.

Article 46

- (1) Research methods, hypotheses, and results should be open to review and debate, unless confidentiality is required by contract or legal obligations.
- (2) Amendments or additions to this code may be proposed by the faculty teaching councils with a recommendation to RAEC.

Article 47

This Code enters into force on the day of its adoption by the Senate of the International Balkan University.

Research Ethics Application – Approval Scheme



