IONIAN UNIVERSITY



Regulation Principles & Operation of the Committee on Ethics and Research Ethics of the Ionian University

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Article 1. Scope of application

1. The Research Committee of the Ionian University (**IU**) draws up the present **Regulation of Principles & Operation of** the Committee on Ethics and Research Ethics (**CERE**) of the Ionian University. The Regulation defines the procedure for the submission of proposals for approval to the CERE of the IU and the procedure for their evaluation by the CERE of the IU. The amendment of this Regulation, if necessary, shall be made after a decision of the Research Committee.

Article 2. Constitution & Mission

- 1. The CERE of the IU is constituted and operates according to the provisions of Law 4521/2018, articles 21-17.
- 2. The mission of the CERE is to provide, on a moral and ethical level, guarantee of reliability of the research projects carried out at the Ionian University. The CERE checks whether a research project is carried out with respect to fundamental human rights, the intrinsic value of human beings, the autonomy of the persons involved, their privacy and personal data, as well as, with care for the natural, man-made, cultural and technical environment.
- 3. The Committee, also, controls compliance with generally accepted principles of research integrity and ethics and the criteria of good scientific practice. The control of the ethics and ethics of research is an essential guarantee of credibility and is a prerequisite for strengthening the trust and acceptance of the research conducted at the Ionian University by society as a whole.

Article 3. Composition & Terms of office

1. The CERE of the Ionian University consists of five (5) or seven (7) full members with their deputies.

- 2. The members of the CERE of the IU should be scientists, with expertise in research, ethics/bioethics and research ethics. At least one (1) member and his/her alternate must have a specialization in ethics/bioethics. At least two (2) members and their alternates must be persons outside the IU. The academic subjects or/and the general research and scientific work of the members of the CERE must ensure, as far as possible, the representation of all the scientific subjects covered by the IU.
- 3. The members of the CERE of the IU shall be selected following a call for expressions of interest drawn up and published by the IU Research Committee on the IU's website to fill the posts, at the latest three (3) months before the expiry of the term of office of each member. The invitation specifies the exact number of CERE members and specifies the qualifications that its members must have, depending on the scientific fields of the IU. The applications and the necessary supporting documents are submitted by the interested parties electronically. The Research Committee of the IU evaluates the applications and decides on the composition of the CERE. According to the decision of the Research Committee will take into account the candidates' experience in the implementation and management of projects as Scientific Directors, the candidates' previous participation in relevant ethics, ethics, bioethics committees, the representation in the composition of the CERE of the academic subjects of the IU' s Faculties, the formation of the final composition of the CERE, in order to ensure the interdisciplinary approach and the comprehensive examination of the ethical and moral issues arising in the context of the research.
- 4. The CERE is constituted by decision of the Rector of the IU. In the decision to constitute the CERE, the President and the Vice President of the Committee, as well as the alternate member of each regular member are appointed.
- 5. The term of office of the members of the CERE is three years and may be renewed only once (1).

If any member of the CERE resigns, is absent or otherwise ceases to hold office, he or she shall be replaced for the remainder of his or her term of office by his or her alternate.

Article 4. Responsibilities

- 1. The competence of the CERE is to determine whether a specific research project to be carried out at the IU does not contravene the legislation in force and whether it complies with generally accepted rules of research ethics and integrity in terms of content and conduct. In particular, the responsibilities of the CERE include:
 - The review of funded research projects in according to generally accepted principles of research integrity and ethics and criteria of good scientific practice, including research:
 - (i) to man,

(ii) the environment, natural, man-made, cultural and technical,

- (iii) to animals, or
- (iv) in material that comes humans, such as genetic material, cells, tissues and personal data.

The project cannot start to be implemented in the IU, without first receiving the relevant approval from the Committee.

- The examination, apart from the research projects of the previous case, of other research project, at the request of an interested person or on complaint.
- The opinion on ethical and ethical issues concerning an article for publication in a scientific journal, monograph, book, any scientific and artistic work, speech, lecture or undergraduate/postgraduate thesis/doctoral dissertation under preparation.

- The protection of individuals or social groups during the processing of their personal data resulting from any relevant research.
- 2. The CERE of the IU is the only responsible for deciding whether or not any matter falls within its remit.
- 3. All members of the IU must assist the Committee in its work.
- 4. The CERE recommends to the Research Committee of the IU the suspension of a research project, if there is a violation of the legislation and the Code of Ethics and Research Ethics of the IU.
- 5. The CERE may provide scientific advice to the Research Committee of the IU on matters within its remit, if requested.
- 6. If the legislation provides for the approval or authorisation of the project by another competent public authority, administrative body or independent administrative authority, the relevant decision of the CERE does not replace such approval or authorisation.
- 7. CERE undertakes initiatives aimed at training on ethical and moral issues in research, addressed to the scientific staff, administrative staff, students and doctoral candidates of the IU.
- 8. The decisions of the CERE are binding on the IU.

Article 5. Operation of the CERE

- 1. The CERE of the IU meets regularly once (1) a month and whenever requested by its President or the President of the IU Research Committee.
- 2. The President of the CERE is responsible for the proper functioning of the Committee and convenes and directs its meetings. The Vice-President shall exercise the functions of the President in the event of the latter's absence. He/she may also be asked by the President to perform additional tasks, such as supervising part of the agenda.

- CERE is in a quorum when at least three (3) members are present, if it has five members, or at least four (4) members, if it has seven members, including the President or Vice-President, and one (1) of its members not belonging to the IU and decides by a majority of the members present.
- 4. In the event that a regular member of the Committee is unable to attend, the alternate member must be notified by the Secretariat.
- 5. Meetings of the CERE may also be held remotely by electronic means.
- 6. Members receive an invitation and all relevant documents to be discussed before the meeting. The invitation shall state the items on the agenda as determined by the President. An item not on the agenda may be discussed if all members present agree.
- 7. The members of the CERE are not entitled to remuneration or other compensation for their participation in its meetings.
- 8. The CERE is supported by the secretariat of the M.O.D.Y of E.L.K.E. I.U.
- 9. In order to facilitate its work, the CERE may cooperate with the National Bioethics Committee and any other competent authority on matters relating to its competences.

Article 6. Incompatibility

1. The membership of the CERE is incompatible with that of the Rector, the Vice Rector and the Dean, as well as with the membership of the Research Committee or the President of a Department of the I.U..

Article 7. Submission of Research Projects

- 1. The research project proposal, submitted for approval by the CERE of the I.U., must include:
 - (i) an application to the CERE,
 - (ii) a questionnaire for approval by the CERE,
 - (iii) research methodology/research protocol (if applicable),

(iv) a consent form (if applicable) appropriately

- formatted for the purpose of the research,
- (v) other approvals from competent authorities (if required).
- 2. The application and the accompanying documents are submitted by the scientific supervisor of the project:
 - electronically via the CERE website, or
 - electronically at ethics@ionio.gr, or
 - in person at the offices of the Research Committee of the I.U., at the secretariat of the CERE.
- 3. If it is a bachelor/ master thesis or doctoral dissertation, the application is submitted by the supervising professor.
- 4. The secretary of the CERE checks whether the application submitted is complete. If it is incomplete, an appropriate recommendation is made to the applicant to make the necessary improvements. In order to be given a protocol number, the application must be complete.
- 5. The President of the CERE appoints a rapporteur for each application submitted, in priority a member of the CERE, depending on the scientific subject of the research project. If the scientific scope of the project cannot be covered by the members of the CERE, an external expert will be appointed to give an opinion.
- 6. The members of the CERE, upon receipt of the research proposal, must inform the President and the Secretary, if there is a conflict of interest that prevents their participation in the evaluation of the proposal.

Article 8. Decision-making procedure

- 1. The rapporteur sends his/her proposal, which should include an assessment of whether the project in question is in line with accepted fundamental principles of ethics and research ethics and with relevant international, European and national legislation.
- 2. The contingencies of the recommendation are:

- The proposal complies with the ethical and moral principles of research and with the relevant legislation and is therefore approved.
- The proposal raises ethical/ethical issues and recommendations are made to revise the research proposal.
- Further clarification is needed.
- 3. The CERE decides within a period of time that may not exceed fifteen (15) days from the submission of the application and all necessary accompanying documents. If the fifteen (15) day period has elapsed without the CERE taking a decision on the request, the application shall be deemed approved.
- 4. If the CERE deems it necessary, it may invite the responsible researcher to present the research protocol or provide clarifications.
- 5. The decision of the CERE shall be taken by the majority of the members present. In case of a tie, the President shall have the casting vote. Voting shall be by open ballot.
- 6. The decision of the CERE must include:
 - the title of the research proposal or thesis / postgraduate thesis / doctoral dissertation,
 - the scientific supervisor of the research project or the supervising teacher,
 - the date on which the decision was taken,
 - the protocol number,
 - the reasons for the decision,
 - the rapporteur, and
 - in the case of obligations, such as periodic or one-off reporting, their listing.
- 7. The decision of the CERE is made known to the applicant within three (3) working days from the day of receipt. The decisions of the CERE are binding on the researchers and the IU.

8. In the case of a complaint about a research project, the CERE shall decide no later than fifteen (15) days from the submission of the complaint. If no decision is taken within this period, the complaint shall be deemed to have been rejected. If the CERE considers the complaint to be well-founded, it shall inform the Research Committee of the IU.

Article 9. Submission of a Treatment Request

1. Any interested party may file, before the CERE, within ten (10) days from the issuance of the decision, a request for remedy against the recommendations of the Committee by submitting new information. In order to examine the request for redress, the CERE shall request the opinion of the National Bioethics Committee, which must give its opinion within fifteen (15) days. If the National Bioethics Committee does not give its opinion within the above time limit, the CERE shall proceed to examine the request for treatment without the opinion of the National Bioethics Committee.

Article 10. Conflict of interest

1. A member of the CERE is barred from participating in the meeting in any case where a conflict of interest may arise. A conflict of interest arises where a member of the CERE has an interest which may affect or appear to affect the impartial and objective performance of his/her duties. This shall be understood as any possible advantage in favor of the individual or his/her spouse or first degree relative. In the event of such an impediment regarding a specific proposal under evaluation, the member of the CERE shall immediately inform the President, who shall arrange for the alternate member to replace him/her. That member shall leave the meeting before the start of the discussion.

Article 11. Duty of confidentiality

1. The members of the CERE have a duty of absolute confidentiality regarding any confidential or

confidential information or personal data are handled or processed or come to their knowledge during the exercise of their duties or the occasion of them and the taking of appropriate measures for the protection and security of this information. The obligation also rests with any external expert(s) or rapporteur(s) invited to provide an opinion/recommendation on a specific research proposal, the Secretary of the Committee and any other member involved in a supporting role. It is not allowed to disclose in any way or use for personal benefit or for the benefit of third parties confidential or secret information or personal data which is accessible to the above persons by virtue or in connection with their duties.

Article 12. Keeping of records - Secretariat

- 1. The CERE is required to keep an electronic record of the following documents:
 - (i) The protocol incoming and outgoing mail.
 - (ii) The CVs of members of the Committee.
 - (iii) The minutes of meetings and agendas.
 - (iv) The applications submitted for approval and the corresponding reasoned decisions.
 - (v) The approved research protocols and accompanying documents.
 - (vi) Copies of correspondence between the CERE and the researchers.

The collection, processing and storage of personal data is carried out in accordance with the applicable legislation on the protection of individuals with regard to the processing of their personal data, with emphasis on the security principles of the processing systems and the storage of personal data and in compliance with the approved policies and guidelines issued by the Ionian University.

2. The storage conditions must guarantee the protection of confidentiality. Members of the secretariat must keep and treat as confidential all information and documents relating to requests referred to it, and not disclose the information or documents to third parties.

Article 13. Basic Principles of Ethics & Research Ethics

- 1. Research is carried out to advance scientific knowledge. It must be conducted in a manner consistent with timeless principles such as respect for scientific truth, academic freedom, the dignity of the human person, the natural and cultural environment, human dignity, intellectual property and personal data.
- 2. The investigation must be carried out freely, unhindered and without dependence or expediency. Independence of research is an individual right of researchers and a public good at the service of society.

Article 14. Terms & Conditions of the Survey

- 1. During the research process, IU researchers must:
 - They have obtained from the relevant bodies the necessary permits to carry out the research in question, without prejudice to the obligation to submit a formal request for approval of the research programme by the IU's CERE, where required.
 - Comply with the applicable national, European and international legislation, all the basic principles of ethics and conduct and the specific rules of their profession.

Disclose the sources of funding for their research activity and not accept conditions that compromise research freedom and autonomy.

- They safeguard the interests of society as a whole, as scientific research does not negate the need to respect fundamental human rights and freedoms.
- Respect the rights of their colleagues, without any form of direct or indirect discrimination based on racial, ethnic or cultural characteristics, language, gender and sexual orientation, religious, political and philosophical beliefs, privacy, health and physical ability, as well as economic or social status.
- Respect the rights and freedoms of the persons with whom they cooperate, rejecting any form of deception or coercion. The same respect shall be shown for the natural and cultural environment.