**RULES AND REGULATIONS**

**OF THE RESEARCH ETHICS AND CONDUCT COMMITTEE**

**of the University of Piraeus**

**Approved by the SPECIAL ACCOUNT FOR FUNDS of the University of Piraeus RESEARCH COMMITTEE (UPRC) on 31-3-2023**

**CHAPTER A**

**ESTABLISHMENT - GOVERNING BODIES OF THE RECC**

**Article 1**

**Establishment - Mission**

In each higher education institution (HEI) and each research and technological institute referred to in Article 13A of Law No. 4310/2014 (A' 258) (hereinafter referred to as the research organisation), a Research Ethics and Conduct Committee (R.E.C.C.) shall be established and operate.

The mission of the Research Ethics Committee is to provide, on an ethical and moral level, a guarantee of the reliability of the research projects conducted at the University of Piraeus and the Hellenic Research Foundation / Special Account for Research Funds. The Committee also monitors compliance with the generally accepted principles of research integrity and the criteria of good scientific practice.

**Article 2**

**Composition - Tenure**

The R.E.C.C. consists of five (5) full members with their deputies. The number of members of the R.E.C.C. shall be determined by decision of the Research and Management Committee of the University of Piraeus. The members must be scientists, with expertise in research, ethics/bioethics and research ethics. At least one (1) member must have a specialisation in ethics/biological ethics. At least two (2) of the members must be persons from outside the University of Piraeus. The disciplines of the members must ensure, as far as possible, that the disciplines of the University of Piraeus are represented.

The members of the R.E.C.C shall be selected as follows:

a. The University of Piraeus Research and Management Committee shall prepare and upload on the University's website a call for expressions of interest to fill the positions no later than three (3) months prior to the expiration of each member's term. The call shall specify the exact number of members of the R.E.C.C. and specify the qualifications that the members of the R.E.C.C. must have.

b. The Research and Management Committee evaluates the candidacies and decides on the composition of the R.E.C.C. For the decision to be reached, the experience of the candidates in implementing and managing projects as Scientific Directors, as well as their previous participation in respective ethics/bioethics committees are taken into account.

The R.E.C.C. is constituted by decision of the Rector, following the opinion of the Research and Management Committee. The decision to set up the Committee shall designate its Chairman and Vice-Chairman.

The term of office of the members of the R.E.C.C shall be three years and may be renewed (1) only once.

If a member of the R.E.C.C. resigns, is absent or otherwise ceases to hold office, s/ he shall be replaced for the remainder of his/her term of office by a deputy member.

The Chair of the R.E.C.C. shall be responsible for the operation of the Committee, shall convene meetings and represent the Committee before the University of Piraeus bodies and wherever else required.

The Vice-Chairman shall perform the Chairman’s duties in the event of the latter's absence. He/she may also be asked by the Chair to perform additional duties, such as supervising part of the agenda.

The R.E.C.C. shall be staffed by the Secretariat, which shall be responsible for preparing the meetings of the Committee, taking the minutes and performing administrative tasks.

**Article 3**

**Conflict of interest**

Membership is incompatible with the Rector, Vice Rector, and Dean, as well as membership of the Research and Management Committee or Department Chair of the University of Piraeus.

A member of the R.E.C.C. is disqualified from participating in the meeting in any case in which a conflict of interest may arise. A conflict of interest arises when a member of the R.E.C.C. has an interest which may affect or appears to affect the impartial and objective performance of his/her duties. This shall be understood to mean any potential advantage in favour of the person concerned or his/her spouse or first degree relative. Where such an impediment is declared in relation to a specific proposal under evaluation, the member declaring the impediment shall be replaced by his/her deputy.

**Article 4**

**Obligation of confidentiality**

The members of the R.E.C.C. shall be bound to observe absolute confidentiality regarding any information which comes to their knowledge in the course of their duties. This obligation also applies to any external expert or rapporteur invited to provide an opinion on a specific research protocol.

The obligation of confidentiality also applies to the Secretary of the R.E.C.C. and any member involved who may be involved in a supporting role. No confidential information or personal data of a confidential nature which are accessible to these persons by reason of their duties may be disclosed in any way.

The obligation of confidentiality extends to the content of the consultations between the members of the R.E.C.C, which are necessary for the evaluation of proposals and the final decision.

**CHAPTER B**

**RESPONSIBILITIES - ASSESSMENT AND APPROVAL PROCEDURES**

**Article 5**

**Responsibilities**

1. The competence of the R.E.C.C. shall be to determine whether a specific research project to be carried out at the HEI/research organisation does not contravene the legislation in force and whether it complies with generally accepted rules of ethics and conduct of research in terms of its content and the way it is carried out. The R.E.C.C. evaluates the research proposal and: a. approves it; or b. makes recommendations and proposals for its revision if ethical and moral impediments arise. Recommendations and proposals must be specifically justified. The R.E.C.C may, whenever it considers it appropriate, request further information or clarifications from the scientific supervisor of the research project and monitor the progress of the research projects it has approved.

2.a. Funded research projects which, according to the statement of the scientific director, involve research on human beings, on material derived from human beings, such as genetic material, cells, tissues and personal data, on animals or on the environment, both natural and cultural, must be submitted for approval to the R.E.C.C and the project cannot begin to be implemented at the University of Piraeus unless it has received prior approval.

b. In addition to the research projects of case 2.a, the R.E.C.C. may, upon request of an interested person or a complaint, examine other research projects and give an opinion on ethical and moral issues concerning an article to be published in a scientific journal or a thesis or dissertation under preparation.

c. The decisions of the R.E.C.C. are binding on the University of Piraeus.

If the legislation provides for approval or licensing of the project by another competent public agency, administrative body or independent administrative authority, the relevant decision of the R.E.C.C. does not supersede such approval or licensing.

The R.E.C.C. shall decide within a reasonable period of time, which may not exceed fifteen (15) days from the submission of the application and the collection of all necessary supporting documents. If the R.E.C.C. does not reach a decision within this period, the application shall be deemed to have been approved.

In the event of a complaint, the R.E.C.C. shall take a decision no later than fifteen (15) days after the complaint has been lodged. If no decision is taken within that period, the complaint shall be deemed to have been rejected.

Any interested party may, within ten (10) days of the adoption of the decision, lodge an application for remedy against the Committee's recommendations with the R.E.C.C., submitting new evidence. In considering the application for redress, the Committee may request the opinion of the National Bioethics Committee, which must deliver its opinion within fifteen (15) days. If the National Bioethics Committee does not give its opinion within the above time limit, the R.E.C.C. shall proceed to examine the application for treatment without the opinion of the National Bioethics Committee.

The R.E.C.C. shall recommend to the Research and Management Committee the suspension of a research project where there has been a breach of personal data.

The R.E.C.C. may provide scientific advice to the Research and Management Committee, if requested.

The R.E.C.C. is responsible for informing the scientific and administrative staff of the University of Piraeus on ethical and moral issues in research through lectures, workshops, and the publication of information material.

The R.E.C.C. may give its opinion on proposals for educational programmes or participation in research programmes on matters within its scope, at the request of the Research and Management Committee.

**Article 6**

**Functioning of the R.E.C.C.**

The R.E.C.C. shall meet regularly once (1) a month and in extraordinary meetings whenever requested by its Chairperson or the Chairperson of the Research and Management Committee.

The Chairman of the R.E.C.C. shall be responsible for the proper functioning of the Committee and shall convene and chair its meetings.

The R.E.C.C. shall act by a majority of those present. A quorum is reached when at least three (3) members of the R.E.C.C. are present, if the committee consists of five members, including the Chair or Vice-Chair and one of the members who do not belong to the University of Piraeus.

In the event of a regular member of the Committee being unable to attend, an alternate member shall be notified by the Secretariat.

The members of the R.E.C.C. shall not be entitled to any remuneration or other compensation for their participation in its meetings.

To facilitate its work, the R.E.C.C. may cooperate with the National Bioethics Committee and any other competent authority on matters relating to its responsibilities.

**Article 7**

**Submission and receipt of proposals**

Applications and accompanying documents shall be submitted by the scientific leader of the project to the Research and Management Committee in order to be forwarded to the R.E.C.C. The R.E.C.C. shall accept applications and accompanying documents for consideration on the first and third Friday of each month during the working hours of the University of Piraeus, except in cases of force majeure.

The Secretary of the R.E.C.C. shall confirm directly to the applicant that s/he has received the research proposal, after having registered it.

The members of the R.Ε.C.C. shall, upon receipt of the research proposal, inform the President and the Secretary if there is a conflict of interest which prevents their participation in the evaluation of the research proposal.

The President of the R.E.C.C shall appoint two (2) rapporteurs for each application submitted, with priority to members of the R.E.C.C, depending on the scientific subject of the research project. If the scientific subject of the project cannot be covered by the members of the R.E.C.C., an external expert shall be appointed to make a recommendation.

The meetings of the R.E.C.C may be held at a distance by electronic means.

**Article 8**

**Procedure for the approval of a research project**

1. In order for a research project to gain approval, each research proposal submitted shall include the following supporting documents:

a. An application to the R.E.C.C. for the approval of the research project, which shall necessarily include a questionnaire prepared by the R.EC.C. and a summary report on the appropriateness and compatibility of the research project with the applicable legislation. In this report, the scientific director shall determine whether the purpose and methodology of the research project are compatible with the principles of scientific integrity, research ethics and legislation.

b. Research protocol/etiquette .

c. Templates of informed consents of participants, if required by the subject matter of the research.

d. Any other documents or supporting materials for the study.

Following the forwarding of the proposal to the R.E.C.C., the designated rapporteurs will undertake an evaluation of the proposal, suggesting necessary additions or corrections and recommendations for its improvement. The Committee shall discuss the recommendations and, if possible unanimously, reach a final decision, which shall be sent without delay to the applicant scientific supervisor, no later than 15 days after the forwarding of his/her application to the Committee. If unanimity is not possible, decisions are taken by the majority of the present members. In the event of a tie, the President shall have the casting vote. Voting shall be open and transparent.

If necessary, the applicant shall be invited to adapt the elements of the research proposal in accordance with the observations of the R.E.C.C. If the applicant disagrees with additions or corrections, he/she has the right to file a request for redress, in accordance with the procedure laid down in Law No. 4521/2018.

After the adjustments, the proposal is resubmitted to the R.E.C.C. for a new evaluation and final approval or re-referral within 15 days.

**CHAPTER C**

**FUNCTIONING AND DECISIONS OF THE R.E.C.C.**

**Article 9**

**Discussion and evaluation of the working methods of the R.E.C.C.**

The President may from time to time convene a meeting to discuss and evaluate the working methods and procedures of the Committee.

During this meeting, members are encouraged to express concerns and suggest ways to improve the work of the Committee.

The meetings may be attended by invited external experts or members of other Ethics Committees of national research organisations or other experts.

**CHAPTER D**

**OTHER PROVISIONS**

**Article 10**

**Record-keeping - Secretariat**

The Secretariat of the R.E.C.C. shall keep an electronic file of the following documents:

a. The following documents shall be kept in the electronic archive:

 - a record of incoming and outgoing correspondence.

b. Minutes of meetings and agendas.

c. Applications submitted for approval and the corresponding reasoned decisions.

d. Approved research protocols and supporting documentation.

e. Copies of correspondence between the R.E.C.C. and the responsible investigators, including possible recommendations to the investigator and all items relating to possible suspension of approved research.

Members of the Secretariat shall treat all information and documents relating to applications/complaints submitted to it as confidential.

Members of the Secretariat shall keep the above confidential information secret and shall not disclose it to third parties. 4. All personal data contained in the electronic and physical records of the Secretariat shall be collected, processed and kept on file in accordance with the applicable legislation.

**Article 11**

**Approval and Revision of the Rules of Procedure**

These Rules of Procedure shall be approved by the Research and Management Committee and will be reviewed 3 years after its first implementation.

Before that time, proposed changes shall be approved, on the recommendation of the R.E.C.C., by the Research and Management Committee, as long as they have the support of 2/3 of its members.