

UNIVERSITY OF PRISHTINA "HASAN PRISHTINA" UNIVERSITETI I PRISHTINËS

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Based on article 6, sub-paragraph 1.4, article 47, sub-paragraph 1.1, as well as the responsibilities defined in article 48, sub-paragraph 1.9 of the Statute, the Senate of the University of Prishtina "Hasan Prishtina", in the meeting held on 22/03/2023, approved:

REGULATION

ON THE ESTABLISHMENT AND FUNCTIONING PRINCIPLES OF THE COMMITTEE FOR ETHICS IN SCIENTIFIC RESEARCH

I. GENERAL PROVISIONS

Article 1 Purpose

The purpose of this regulation is to provide the basis for the establishment and operation of the Committee for Ethics in Scientific Research involving work with human and animal subjects. The Committee for Ethics in Scientific Research has a key role to ensure that research activities undertaken by researchers, students and third parties conducting research on the premises of the University of Prishtina are in accordance with good research practice and ethical principles and are respected throughout time. The Commission also ensures that: framework documents are implemented at the European and national level; to promote public trust in the research activity of the University; fulfill institutional and individual responsibilities and protect the interests of all parties involved in scientific research.

Article 2 Abbreviations

1. The abbreviations used have the following meanings:

- 1.1. UP University of Prishtina "Hasan Prishtina";
- 1.2. CESR Committee for Ethics in Scientific Research.

Article 3 Duties, functions and responsibilities of the Committee

1. Formulate and define policies, procedures and documents based on best practices regarding ethics in scientific research and ensure that these policies are implemented within the areas of responsibility;

2. To promote and monitor the implementation of the approved ethical standards included in the guidelines, as well as to review and revise them while taking into account the development of policies;

3. To promote issues of ethics and integrity in scientific research at UP;

4. Review all applications submitted to the UP for ethical review, ensuring that research practices meet ethical standards from framework documents at the national and European level;

5. Act in the best interest of research participants and communities, taking into account the needs of researchers and taking into account the requirements of relevant regulatory agencies and applicable laws;

6. To conduct an independent, competent and timely review of proposed research by staff and students throughout the University before it is carried out;

7. To take decisions on the validity of research permit approvals issued by other competent bodies at the country level or at the international level;

8. To take care that research proposals become more attractive for financing institutions and to ensure institutional support for staff who have received institutional ethical approval;

9. To ensure that there is a regular evaluation of the ethics of research projects during the implementation of the planned activities (after receiving the approval/permission);

10. To ensure that the research is carried out in the conditions in which the proposal is approved and the necessary steps are taken when there are deviations (including the initiation of the procedure for violation of the Code of Ethics (in the Ethics Council).

II. BOARD COMPOSITION AND APPOINTMENT PROCEDURE

Article 4 Composition (members) of CESR

1. CESR has 9 (nine) members: the vice-rector for scientific research and one member from the 8 (eight) academic units listed below:

- 1.1. Faculty of Philosophy (Department of Sociology or Psychology);
- 1.2. Faculty of Mathematical-Natural Sciences (Department of Biology);
- 1.3. Faculty of Philology
- 1.4. Faculty of Law;
- 1.5. Faculty of Medicine;

1.6. Faculty of Agriculture and Veterinary Medicine (Veterinary Department or Department

of Biotechnology in Zootechnics - Animal Production);

- 1.7. Faculty of Physical Education and Sports;
- 1.8. Faculty of Education.

2. As necessary, the Committee may form sub-committees

3. Academic units can form commissions at faculty level in order to support staff and students in drafting their request for CESR. These commissions will conduct a preliminary review of the applications and will make recommendations to CESR.

4. The Office for Research and Sponsored Projects (ORSP) will perform the administrative part of the work for CESR.

Article 5

The procedure for the proposal and appointment/approval of the composition of CESR

1. CESR members are elected by the Senate, after the proposal by the Rector.

2. The Rector's proposal also includes the nomination for the chairman and vice-chairman of CESR;

3. The mandate of the CESR composition is related to the Senate's mandate.

III. PRINCIPLES OF CESR FUNCTIONING

Article 6

Committee meetings/meetings, review of applications, decision-making, drafting and approval of documents, reporting

1. Within 30 days after its establishment, CESR drafts the work regulations which it proposes to the Senate for approval;

2. The Regulation (among other issues) includes:

2.1. Meetings/meetings and quorum issues;

2.2. Duties and responsibilities of ORSP for administrative matters;

2.3. Duties and responsibilities of sub-committees that may be formed;

2.4. Procedure/instructions to be followed regarding the work permit application research;

2.5. Decision-making procedures that ensure timely and appropriate addressing of requests;

2.6. The procedure in cases of permit validity (when issued by other bodies such as the Center

University Clinic or competent body from a partner institution in the proposals research);

2.7. The procedure in cases where commissions at the faculty level (in cases where there are commissions of

such) have examined the request;

2.8. Appeal procedure;

2.9. Precisely described obligations of members in relation to:

2.9.1. Facilitating ongoing review and discussion of ethical issues and ensuring that researchers are familiar with all relevant best practice and legislation;

2.9.2 Contribution to the work of the Commission;

2.9.3 Regular participation in meetings;

2.9.4 Resignation and replacement of members;

2.9.5. Declaration of any conflict of interest that may affect their role and performance as members of the Commission;

2.9.6. Etc.

4. CESR develops other necessary documents - forms, instructions, etc., which are based on framework documents at the country and international level (addressing such issues according to the laws and regulations in force) in order to facilitate the work of the Commission. The necessary documents will be prepared within thirty (30) days after the approval of the Regulation on Regulations and Procedures.

4.1. During the development of the necessary documents, CESR will carefully consider all ethical and legal aspects of research involving human subjects, the use of biological samples of human origin and the use and/or collection of personal data.

4.2. In developing the necessary documents, CESR will carefully consider all ethical, legal and welfare aspects of the proposed research involving animals, with particular attention to:

4.2.1. The need for animal replacement wherever possible with research that do not use animals;

4.2.2. Reducing the number of animals used to an extent that does not endanger experimental design or results;

4.2.3. Techniques used in research to minimize impact negative in animal subjects.

5. Documents (instructions) for monitoring and reporting on the implementation of research approved through will be drawn up by CESR;

6. In cases where it is necessary, CESR will provide expertise from individuals and institutions (outside CESR) inside and outside the University of Prishtina;

7. CESR reports to the rector of the University of Prishtina.

IV. FINAL PROVISIONS

Article 7 Final provisions

1. This regulation enters into force on the day of its approval by the Senate of the University of Prishtina "Hasan Prishtina".

2. Changing and supplementing the regulation is done with the same procedure by which it was approved.

Chairman of the UP Senate

Prof. dr. Qerim Qerimi, rector