

Pursuant to Article 48, paragraph 5, of the Statute of the Faculty of Pharmacy and Biochemistry (hereinafter: the Faculty), the Faculty Council of the Faculty of Pharmacy and Biochemistry of the University of Zagreb, at its 8th regular session on 18 June 2014 adopts

THE REGULATIONS ON THE WORK OF THE ETHICS COMMITTEE FOR EXPERIMENTAL RESEARCH OF THE FACULTY OF PHARMACY AND BIOCHEMISTRY OF THE UNIVERSITY OF ZAGREB

I General Provisions

Article 1

These regulations govern the competences, the composition and the rules of operation of the Ethics Committee for Experimental Research (hereinafter: PEER), and the procedure for providing opinions on particular ethical matters.

Article 2

PEER is an advisory body which examines matters related to ethical acceptability of biomedical research conducted on humans and laboratory animals, within the framework of the Faculty's scientific, educational and professional activity.

Article 3

- (1) PEER consists of five members holding scientific-teaching titles.
- (2) The Chairman and the members are appointed by the Faculty Council for a period of two years.

Article 4

- (1) The Animal Welfare Committee consisting of a single member operates within PEER.
- (2) The task of the Animal Welfare Committee is to advise in relation to well-being of animals, procurement and use of animals and the implementation of the 3R principle (reduction, replacement, refinement), in accordance with the current legislation.

Article 5

- (1) PEER acts in sessions for which the agenda is published at the start of each academic year.
- (2) PEER's sessions are called by the Chairman.
- (3) A session can be held if a majority of PEER members are present.
- (4) Minutes are taken at PEER sessions.

Article 6

PEER is responsible for providing opinions on:

- ethical matters arising in biomedical research involving humans and while analyzing biological material of human origin,
- ethical matters arising in biomedical research on laboratory animals.

Article 7

In providing opinions on ethical matters arising in biomedical research on humans, PEER adopts and implements the Principles of Good Clinical Practice (Declaration of Helsinki, Recommendations Guiding Physicians in Biomedical Research Involving Human Subjects, Law on the Protection of Patients' Rights (Official Gazette No. 37/08)).

Article 8

- (1) In providing opinions on ethical matters arising in biomedical research on laboratory animals, PEER adopts and implements the International Guiding Principles for Biomedical Research Involving Animals.
- (2) PEER acts in accordance with the provisions of the Animal Protection Act (Official Gazette 125/13) and in accordance with the Regulations on the Protection of Animals Used for Scientific Purposes (Official Gazette 55/13).

II Procedure for Providing Opinions on Biomedical Research

- (1) The procedure for providing opinions concerning matters relating to the ethical acceptability of biomedical research conducted on humans, materials of human origin and animals is initiated by writing a request in both electronic and written, signed form, in two copies.
- (2) Written requests are submitted by legal or natural persons in connection with the scientific research, educational and professional work conducted at the Faculty or associate institutions, before the start of research.
- (3) Requests for PEER's opinion relating to research that has already been conducted in large part or in full will not be considered.

Article 10

- (1) A written request shall include a request to PEER, facts and evidence on which the request is based and other information important for providing an opinion, and shall be submitted in accordance with the instructions for seeking PEER's opinion, given in the Appendix 1 of these regulations.
- (2) All the received material and documentation are considered a trade secret for which the data secrecy regulations apply.

Article 11

- (1) The members of PEER shall receive a written invitation with the agenda proposal and the minutes from the previous session at least seven days before a session is held.
- (2) Documentation is to be delivered to a rapporteur for the particular case.
- (3) The Chairman of PEER sets up the agenda and decides on the rapporteur for the particular case.
- (4) Requests and documentation are published on the wiki pages of PEER and stored in the archives.

Article 12

- (1) PEER has the right to ask the request submitter for additional documentation, all the required clarifications, legal documents and the necessary evidence for providing an opinion.
- (2) Complementing the documentation and providing additional clarifications may take place only once.
- (3) PEER can in certain cases ask for information on the practices and positions of other institutions' ethics committees and other relevant information.

Article 13

- (1) Upon completion of discussion at the PEER session, an opinion shall be adopted. In adopting an opinion, a consensus among all of the committee members is strived for. If that is not possible, an opinion is reached based on the position of the majority of PEER members.
- (2) If the opinion is not reached unanimously, members of PEER with positions different from those of the majority have the right to attach their dissenting opinions to the opinion of PEER.

Article 14

PEER's opinion may be:

- positive: the request is valid in the professional and ethical sense, and all the required documentation has been attached;
- conditionally positive: the request is approved with minor changes and additions. After the additions to the documentation have been made, the Chairman of PEER may issue a positive opinion
- Postponed: the discussion is postponed due to the need for important additions to the documentation, clarifications on the research plan, etc.

Article 15

PEER can, along with a negative recommendation or a negative opinion on ethical matters, propose a suspension or a ban for every biomedical research on humans and laboratory animals for which it finds:

- that it is not correctly planned or is contrary to the given recommendations and principles,

- that it is contrary to the ethical and moral principles or laws,
- that it is not aligned with the scientific methods and principles, so that in the form in which it is presented, it will not answer the raised questions.

Article 16

Exceptionally, if PEER reaches a conclusion that it cannot provide an opinion based on the request or other received information, it is not competent for providing an opinion or if it for any other reason cannot provide an opinion, the Chairman of PEER shall, within 60 days of receiving the request, notify the request submitter, stating in detail the reasons for not providing an opinion.

Article 17

- (1) An opinion contains the decision on the validity of a proposal.
- (2) An opinion is valid if 2/3 of the members voted for it.
- (3) An opinion is signed by the Chairman and it is delivered to the submitter of the request in written form.
- (4) An opinion of the Committee is final.

Article 18

The Chairman may allow access to the records of cases discussed before PEER to a person having a justified interest for it.

Article 19

These Regulations shall take effect on the eight day from the date of their publication on the Faculty's notice board.

Dean:

Prof. Karmela Barišić, PhD

Class: 011-01/14-1/01

Reg. No.: 251-62-01-14-8

Zagreb, 18 June 2014

Appendix I

Instructions for seeking opinion of the Ethics Committee for Experimental Research

Subject: Opinion of the Ethics Committee for Experimental Research of the Faculty of Pharmacy and Biochemistry of the University of Zagreb

The Ethics Committee for Experimental Research of the Faculty of Pharmacy and Biochemistry verifies whether ethical norms are complied with and applied in the proposed research project.

Every proposal submitted for assessment to the Ethics Committee for Experimental Research shall include:

1. Request for an opinion from the Ethics Committee for Experimental Research;
2. Request for Approval of the Topic of Research form (DR.SC.-01 – request for approval of the topic of a doctoral thesis; univ.spec.-01 – request for approval of the topic of a specialist thesis, research plan), filled out and signed;
3. Statements from the candidate and mentor confirming that the biological materials processed will be used in accordance with the rules of "Good Laboratory Practice" and that the medical waste, in accordance with the Regulations on Categories, Types and Classification of Waste with a Waste Catalogue and List of Hazardous Waste ("Official Gazette No. 50/05"), will be disposed of in a non-hazardous way, in keeping with the regulations in the Republic of Croatia.

For clinical trials:

4. Positive opinion of the Ethics Committee of the medical institution where the biological materials will be collected and/or where research study on human subjects will be conducted (issued to the candidate for the research in question) and the documentation on which the positive opinion was based, including the research plan and the informed consent.

For animal testing:

5. Positive opinion of the Ethics Committee of the relevant institution and/or the Ethics Committee of the Ministry of Agriculture, Veterinary and Food Safety Directorate, for the project within which the research is conducted (issued to the candidate for the research in question) and the documentation on which the positive opinion was based;
6. Statement from the candidate confirming that, along with the *International Guiding Principles for Biomedical Research Involving Animals, Council for International Organizations of Medical Sciences, Geneva, 1985*, animal welfare regulations and laws applicable in the Republic of Croatia will be applied (the current applicable law: Animal Protection Act (Official Gazette 125/13)).

It is recommended to have the text of the Request for Approval of the Topic of Research form, the research plan description and the Informed Consent proofread.

All the necessary documentation is to be submitted through the registry of the Student Administration Office of the Faculty of Pharmacy and Biochemistry of the University of Zagreb, Ante Kovačića 1, with the reference: "To the Ethics Committee for Experimental Research of the Faculty of Pharmacy and Biochemistry". Documentation should also be submitted in electronic form.