

Regulations of the Bioethics Committee of the Jan Kochanowski University of Kielce

§ 1

1. The Committee operates and conducts its proceedings pursuant to the relevant regulations and provisions of law, including in particular:
 - 1) Article 21 et seq. of the Act of 5 December 1996 on the professions of doctor and dentist (Journal of Laws of 2023, item 1516, as amended).
 - 2) the Regulation of the Minister of Health of 26 January 2023 on the Bioethics Committee and the Bioethics Appeals Committee (Journal of Laws of 2023, item 218, as amended).
2. The applicant submits a request to the Committee for an opinion.
3. The relevant legal provisions, namely the Act referred to in § 1(1)(1) and the Regulation referred to in § 1(1)(2), comprehensively regulate matters relating, in particular, to:
 - 1) the legal definition of an experiment;
 - 2) the permissibility of conducting the experiment;
 - 3) a person conducting the experiment;
 - 4) restrictions on the participation of specific persons in the experiment;
 - 5) the prohibition on offering participants financial incentives and rewards, and the prohibition on exploiting a position of coercion;
 - 6) compulsory third-party liability insurance for the entity conducting the experiment;
 - 7) information obligations towards the participant or his/her legal representative;
 - 8) the participant's approval for the experiment; participation of minors and persons who are completely incapacitated;
 - 9) the permissibility of conducting the experiment without the required approval;
 - 10) the prohibition on restricting a participant's access to medically necessary preventive, diagnostic or therapeutic procedures; the obligation to use established preventive, diagnostic or therapeutic methods; the use of placebos;
 - 11) termination of the experiment;
 - 12) the use of information obtained in connection with the experiment;
 - 13) the procedure for appealing against a resolution of the Committee,
 - 14) requirements concerning the application;
 - 15) the documentation of the experiment, which shall be available to the Applicant for the purposes of his/her proceedings before the Committee, with the Committee's approval.

§ 2

1. Minutes shall be drawn up of the Committee's meetings and adopted by the Committee at its next meeting.
2. The Committee shall consider applications in the order in which they have been submitted.
3. The Dean of the Collegium Medicum shall designate rooms for the Committee's work and provide it with technical and administrative support.
4. The applicant is obliged to report any changes to the document confirming approval to participate in the experiment, as well as changes to other documents containing information intended for participants. This obligation also applies to significant changes affecting the safety of participants, made to the protocol and the experiment documentation.
5. In matters not covered by the relevant rules or these Regulations, the Committee shall take decisions

or make rulings in the form of a note in the minutes of its proceedings or in the form of a resolution.

§ 3

In the case of research funded by external entities, the entity submitting the application shall pay the fee for the application review prior to the Committee's opinion on the research, but no later than one day before the scheduled meeting of the Committee at which the application will be reviewed. Failure to pay the fee referred to in the preceding sentence shall result in the suspension of the application review. The amount of the fee referred to in the first sentence shall be determined by a separate decision of the Rector.

§ 4

Where the applicant is an employee or a doctoral student of the Jan Kochanowski University of Kielce, and the University has, within the framework of this application, the status of a body conducting a medical experiment within the meaning of the Regulation of the Minister of Finance, Funds and Regional Policy of 23 December 2020 on compulsory civil liability insurance for entities conducting medical experiments (Journal of Laws, item 2412), the applicant is required to indicate the source of funding for the premium for the medical experiment in question.

§ 5

The costs associated with the functioning of the Committee, including personnel, administrative and operational costs, shall be covered from the University's own funds, subject to § 4.

§ 6

1. The Bioethics Committee's cooperation with the representatives referred to in Article 30(3) and the experts referred to in Article 30(4) and (5) and in Article 32 of the Act of 9 March 2023 on clinical trials of medicinal products for human use (Journal of Laws, item 605) shall take place in accordance with the applicable legal provisions and taking into account the available forms of communication.
2. Members of the Bioethics Committee are required to undertake continuing professional development in line with the principles set out, in particular, in relevant professional journals and in relation to the functioning of bioethics committees and regulations concerning medical experiments.
3. The circulation of documentation relating to a clinical trial, the manner of communication between members of the Bioethics Committee, and the way in which it cooperates with the Supreme Bioethics Committee during the preparation of the ethical assessment of a clinical trial shall be conducted pursuant to the rules applicable to the conduct of medical experiments, taking into account the specific nature of the legal regulations concerning clinical trials contained in the Act of 9 March 2023 on clinical trials of medicinal products for human use (Journal of Laws of 2023, item 605).