

Scope of activities of the Rector's Committee for the Ethics of Research Involving Human Participants

The Rector's Committee for the Ethics of Research Involving Human Participants reviews research project that can pose risk to participants' mental and physical health, as well as their privacy, or can result in participants suffering other social or legal losses, including studies that involve personal data and biological material of human origin.

- 1) Subject to the exemptions listed in par. 3, the Committee reviews experimental and observational research, surveys and other non-interventional studies involving human subjects.
- 2) The Committee does not review research projects involving human subjects that:
 - might be considered a medical experiment within the understanding of the Act of 5 December 1996 on the Professions of Physician Doctor and Dentist (Consolidated text: Journal of Laws of 2021, item 790, 1559)
 - are clinical trials of medicinal products within the meaning of Chapter 2a of the Act of 6 September 2001 on Pharmaceutical Law (Consolidated text: Journal of Laws of 2021, item 974, 981);
 - are clinical trials of a medical devices, as described in the section 6 of the Act of 20 May 2010 on Medical Devices (Consolidated text: Journal of Laws 2021, item 1565).
- 3) The Committee reviews scientific research projects involving human participants managed or conducted by either employees of the University of Warsaw or its students, including research projects carried out as part of doctoral and postdoctoral dissertations, own work, statutory tasks and research grants, both state founded and privately financed.
- 4) The Committee reviews research projects involving human participants that have not been previously submitted for evaluation to research ethics committees operating at faculties, institutes and other research units of the University of Warsaw.
- 5) The Committee reviews research projects at the request of the principal investigator.
- 6) Additionally, the Committee issues opinions at the request of other UW bodies on problems related to the ethics of scientific research involving human participants.

Submitting applications

- 1) At least 30 days before the announced date of the Committee's meeting, the principal investigator submits the application to the Committee in an electronic form (Portable Document Format; *.pdf) by sending it to the e-mail address komisja.etyki@uw.edu.pl or by submitting one paper copy to the Office of Research with a note stating "Application for ethical review from the Rector's Committee for the Ethics of Research Involving Human Participants".
- 2) A request for an opinion from the Committee should be written in accordance with the form *Application for ethical review from the Rector's Committee for the Ethics of Research Involving Human Participants concerning the compliance of a research project with ethical principles*. The application needs to contain information about the planned study, in particular:
 - a) the project title,
 - b) information about the principal investigator and other research team members,
 - c) information about participants, recruitment methods and ways of compensating participants for taking part in the study (if anticipated),
 - d) a clear indication of the purpose of the study from both theoretical and practical perspective
 - e) a detailed description of research procedures, including research methods and techniques used, as well as an indication of any invasive methods,
 - f) information about the risks associated with participating in the study, including the risk to the physical or mental health of the participants, the risk of violating their privacy or suffering other social or legal losses, as well as information on the expected physical and mental

- discomfort for participants and the risk associated with undermining the trust participants and other members of the public might have in researchers,
- g) defining the rules and conditions for the collection, storage, processing and protection of personal data of research participants, as well as the accepted methods of anonymizing data or other methods of ensuring anonymity of the participants,
 - h) a copy of the information sheet given to participants that contains, in particular, information about the purpose, course and methods of the study, expected benefits, risks and inconveniences related to the participation in the study, basic rights of a participant, including the right to withdraw from the study at any stage without consequences and the right to the protection of personal data; if the participants of the study are minors or incapacitated individuals, the information sheet should be prepared not only for the participant, but also for their legal representative,
 - i) a copy of the participant informed consent form to taking part in the study, including a statement that the decision to participate is informed (i.e. based on previously received comprehensive and understandable information about the study) and voluntary, and that the participant is aware that they may withdrawal from the study at any stage without consequences; if the participants of the study are minors or incapacitated individuals, the informed consent form should be prepared not only for the participants, but also for their legal representative,
 - j) a copy of the informed consent form for processing of personal data; if the participants of the study are minors or incapacitated individuals, the informed consent form should be prepared not only for the participant, but also for their legal representative;
 - k) defining the rules of providing participants with feedback on the results of the study.
- 3) The Committee may request that the applicant submits additional information or explanations concerning the research project.
 - 4) Incomplete applications will not be reviewed. They can be considered only after any missing information is provided.

Review of the applications

- 1) The Secretary of the Committee must immediately forward all properly submitted applications to the Chairperson of the Committee. If a research project falls within the remit of the Committee, the Chairperson appoints a member of the Committee responsible for preparing an opinion on compliance of the research project with ethical principles. The Chairperson may designate themselves to carry out this task.
- 2) The Committee's preliminary opinion on the compliance of a research project with ethical principles shall be discussed and voted upon at the next meeting of the Committee.
- 3) In the course of its work and discussions on the compliance of a research project with ethical principles, the Committee may seek advice to external experts, including persons who are not employees of the University of Warsaw.
- 4) The Committee gives its opinion on the compliance of a research project with the ethical principles following a vote. For an opinion of the Committee to be valid, a simple majority of votes is required, provided at least half of the total number of members of the Committee, including its Chairperson or Deputy Chairperson, is present. In the event of a tie, the Chairperson or Deputy Chairperson shall have the casting vote.
- 5) In reviewing a research project, the Committee follows generally accepted principles of the scientific conduct concerning research with human subjects, involving the use of human biological material and personal data, as expressed in ethical and legal documents of a national and supranational scope.

- 6) The Committee's opinion on the compliance of a research project with ethical principles may be positive, conditionally positive or negative. Conditionally positive or negative opinions include a justification.
- 7) The Committee's conditionally positive opinion on the compliance of a research project with ethical principles indicates the need for the applicant to make changes to the application within a specified period. If the applicant has made changes to the proposal in a manner consistent with the recommendations and within the specified time limit, the Chairperson concludes that the Committee has given a positive opinion on the compliance of a research project with ethical principles. However, if the applicant has not revised the application in a manner consistent with the Committee's advice, the Chairperson finds that the Committee has issued a negative opinion on the compliance of a research project with ethical principles.
- 8) The Committee provides an opinion on the compliance of a research project with the ethical principles to the Principal Investigator within 30 days from the date of the meeting at which the application was reviewed.
- 9) Any changes made to the research project after the Committee has given its opinion and which affect the safety, welfare or rights of the participants require a re-evaluation by the Committee. In the case of studies lasting longer than 24 months, the Committee reserves the right to request the principal investigator to submit information on the conditions or methods of the study relevant to ethical principles of research involving human participants.
- 10) The Committee does not retain applications after they have been reviewed. The applications are returned to applicants together with the opinion.

Appealing against the Committee's opinion

- 1) A decision of the Committee may be appealed against to the Rector of the University of Warsaw.
- 2) The appeal should be submitted to the Rector of the University of Warsaw via the Committee within 14 days from the date of the opinion. The appeal should explain why the appellant does not agree with the Committee's opinion, the justification for the opinion or the comments contained therein.
- 3) The Secretary of the Committee forwards the appeal to the Chairperson. If the Chairperson deems the appeal well-founded in its entirety, they may prepare a second preliminary opinion, amending the appealed opinion, and submit it to a vote of the Committee. The vote on the new opinion should take place no later than within 30 days of the date of the appeal. The second opinion may be appealed directly to the Rector of the University of Warsaw.