APPROVED BY
Resolution No. (1.15 E) 620000-TPN-17 as of 25 June 2025
of the Vilnius University Kaunas Faculty Board

REGULATIONS OF THE RESEARCH ETHICS COMPLIANCE COMMITTEE OF KAUNAS FACULTY OF VILNIUS UNIVERSITY

CHAPTER I
GENERAL PROVISIONS

1. The Regulations of the Research Ethics Compliance Committee of Kaunas Faculty of Vilnius University (hereinafter referred to as the 'Regulations') regulate the procedures for the organisation of work of the Research Ethics Compliance Committee (hereinafter referred to as the 'Committee') of the Kaunas Faculty (hereinafter referred to as the 'Faculty') of Vilnius University (hereinafter referred to as the 'University'), as well as the criteria and principles for assessing the compliance of research conducted at the Faculty with research ethics.

2. The Regulations have been prepared in accordance with the Guidelines for the Evaluation of Compliance with Research Ethics, approved by Order No. V-60 of the Ombudsperson for Academic Ethics and Procedures of the Republic of Lithuania on 10 December 2020 "On the Approval of the Guidelines for the Evaluation of Compliance with Research Ethics" (as amended) (hereinafter referred to as the 'Guidelines').

3. The objectives and functions of the Committee are outlined in the Description of the Procedure for Organising the Research Ethics Compliance at the Kaunas Faculty of Vilnius University, approved by Order No. (1.1 E) 620000-DV-6 of the Dean of the Kaunas Faculty of Vilnius University on 31 March 2025 (as amended).

CHAPTER II
PROCEDURES FOR THE ORGANISATION OF THE COMMITTEE'S WORK

4. Faculty researchers (hereinafter referred to as the 'Applicant' or the 'Investigator') whose planned research involves human participants must apply to the Committee for an assessment of compliance with research ethics prior to the start of the planned research. Compliance with research ethics in research conducted by undergraduate and graduate students is assessed only in exceptional cases, upon request from supervisors. In such a case, all of the Applicant's duties specified in these Regulations shall be performed by the supervisor, and it is to the supervisor that the excerpt from the minutes of the Committee meeting referred to in Item 14 of these Regulations shall be provided for review.

5. The Committee evaluates only the compliance with research ethics of planned research in the relevant field of study or interdisciplinary research conducted at the Faculty. An exception applies to longitudinal studies initiated before the Committee began its work; however, even in these cases, only compliance with research ethics in future stages of the longitudinal study is assessed.

6. If the Applicant wishes to have a research project evaluated for compliance with research ethics, they must submit an application (Appendix to the Regulations) to the Committee via the University's document management system ("Avilys").

7. Application deadlines and related information are available on the Faculty's website.

8. After the Committee receives an application and the Committee Chair is acquainted with it, the Chair appoints two Committee members to assess the application. Their assessments are discussed at a Committee meeting.

9. After the Committee members have assessed the application, the Committee Chair shall schedule the date and time for the application review, and the Committee Secretary shall inform the Applicant of these details. The Committee meeting shall be scheduled no later than 10–15

business days after receiving the application. Applications submitted after this deadline will be reviewed at the next available Committee meeting.

10. Committee meetings are held on the Faculty premises or remotely via the University's MS Teams platform, and no video or audio recording is made. Minutes are always prepared.

11. The Committee decides on a research project's compliance with research ethics during a closed Committee meeting; however, if questions arise, the Applicant may be invited to attend.

12. In assessing the compliance of research with research ethics, the Committee is subject to these Regulations, Guidelines for the Evaluation of Compliance with Research Ethics, approved by Order of the Ombudsperson for Academic Ethics and Procedures of the Republic of Lithuania, the General Data Protection Regulation, the Code of Academic Ethics of Vilnius University, and other legal acts governing research ethics.

13. When assessing the compliance of research with research ethics, the Committee is guided by the general principles of research ethics set forth in the Guidelines, as well as the following key evaluation criteria:

13.1 when evaluating research, consideration is given to the risks to the research participants and/or the Applicant and the Investigators, as well as to the protective and preventive measures planned in response to these expected risks;

13.2 it is evaluated whether participation in the research will be voluntary, how this will be ensured, and whether participation will be based on informed consent, and how this will be implemented. If informed consent to participate in a research study is obtained not directly from the participants themselves, but from the participants' nurses or guardians/caregivers (e.g., due to health conditions), or if such consent cannot be obtained at all (e.g., in social psychology studies conducted in natural settings), an evaluation is made as to whether and how the safety of the research participants will be ensured. It is also evaluated whether the informed consent form has been prepared taking into account the age, developmental characteristics, health status, cognitive abilities, and other relevant factors of the prospective research participants;

13.3 it is evaluated whether and how the research participants will be informed that they may withdraw from the research at any time without suffering any negative consequences, and whether they have the option to request their data to be removed from the research;

13.4 it is evaluated whether and how research participants are given the opportunity to discuss any aspect of the research in which they are participating or have participated with the Applicant, both during and after its completion;

13.5 if the participants in the research are individuals belonging to socially vulnerable groups (socially vulnerable persons are understood as defined in the Republic of Lithuania Law on Ethics on Biomedical Research, as well as in the 2020–2023 Action Plan for Increasing Social Coverage, approved on December 20, 2019, by the Order No. A1-791 "On the Approval of the 2020–2023 Action Plan for Increasing Social Coverage" of the Minister of Social Security and Labour of the Republic of Lithuania (as amended)) or if factors of vulnerability arise due to the research situation, an evaluation is made to determine whether, when enrolling individuals in the research and conducting it, providing information and obtaining their consent to participate in the research, their rights, dignity, and interests as research participants will be adequately ensured and protected. It is also evaluated whether and how consent will be obtained from the relevant authorities (if the individual is under the supervision or care of an institution) regarding the individual's participation in the research;

13.6 it is evaluated whether the research and the dissemination of its results cause harm to the research participants. If there is a risk of harm, an evaluation is made of how it is planned to be mitigated;

13.7 it is evaluated whether and how the safety, interests, and dignity of research participants are to be ensured when, for methodological reasons, the true purpose of the research is not disclosed to the research participants, or the research procedure may cause discomfort, or when participation in the research is not entirely voluntary (e.g., when the research is commissioned by

the management of an organisation or institution and consent to conduct the study is given by the head of the organisation, etc.);

13.8 it is evaluated whether and how research data will be stored and managed, and whether the protection, confidentiality, and security of personal data will be ensured;

13.9 if participants in the research are to be compensated or rewarded for their participation, it shall be evaluated whether this could become a determining factor in their decision to participate in the research and whether the compensation will be fair and proportionate to the extent of their involvement;

13.10 it is evaluated whether the scientific methods, technical equipment, software, and other tools planned for use in the research are used legally and in compliance with the copyright of their creators.

14. Once the Committee has completed the application evaluation, a decision regarding the research project's compliance with research ethics requirements is made. The Committee Secretary provides the Applicant with an excerpt from the minutes of the Committee meeting, no later than 5 business days after the decision, via the University's document management system ("Avilys").

15. The Committee's decision that the proposed research complies with research ethics is valid for a specific period, determined on a case-by-case basis at each Committee meeting, taking into account the following criteria:

15.1. the duration of the proposed research;

15.2. the deadlines set by other institutions (if required) for permission to conduct the research.

16. If the Committee has comments or recommendations regarding the compliance of a specific research project with research ethics, the Applicant seeking a decision from the Committee shall take the Committee's comments and recommendations into account, revise the research plan and submit an application for re-evaluation, or provide a reasoned explanation if they disagree with the Committee's comments and recommendations, or inform the Committee that they are abandoning the plan to conduct the proposed research. The re-evaluation includes responses to the Committee's questions and comments, along with a completed application form with the changes highlighted. If the Applicant refuses to take the Committee's comments and recommendations into account and plans to carry out a research study whose procedures, in the opinion of the Committee members, contradict research ethics and/or pose a risk of harm to research participants, the Committee may inform the Applicant's direct supervisor of this, reporting on the potential risks and threats.

17. The Committee has the right to carry out an additional assessment of compliance with research ethics at any time on its own initiative, in accordance with the procedure set forth in Items 11–12 of the Regulations.

18. If these Regulations do not address certain matters or conflict with the provisions of the Guidelines, the provisions of the Guidelines shall apply in such cases.

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Appendix of the Regulations of the Research Ethics Compliance Committee of Kaunas Faculty of Vilnius University

(**Application form**)

KAUNAS FACULTY OF VILNIUS UNIVERSITY
(*name of the academic department*)
(*title of position, first name and surname*)

To the Research Ethics Compliance Committee
of Kaunas Faculty of Vilnius University

APPLICATION
_____, 202_

I. General information about scientific research

1. Title of scientific research (hereinafter the 'Research'):
2. Principal investigator (please provide contact details) and investigators: *(Please indicate the workplace and contact details of the principal investigator and the workplaces of all other investigators of the research team.)*
3. Source(s) of funding and/or commissioning body(ies):
4. Research aim and objectives:
5. Start and end dates, stages and deadlines for the implementation of the research:
6. Planned dissemination of research results:
I confirm that the scientific methods, technical and software equipment, and other tools used in the research will be used legally, respecting the copyrights of their creators. **I confirm ☐**

II. Study participants, their selection methods and procedures

1. What data collection and analysis methods will be used? What data collection and analysis procedures will be applied? Where will the data be collected?
If you anticipate that ethical dilemmas and/or risks may arise in the course of data collection and/or analysis, briefly describe them and indicate the anticipated means and measures of resolving/eliminating them.

2. Will vulnerable persons be involved in the research[1]?
Vulnerable persons are those whose consent to participate in this research may be influenced by external circumstances or who are partially or totally unable to defend their interests or consciously express informed consent.

- Persons who, because of a medical condition, cannot be considered able to assess their own interests properly ☐ Yes ☐ No
- Persons under 18 years of age ☐ Yes ☐ No
- Students, if their participation in the research is related to their studies ☐ Yes ☐ No
- People living in social care institutions ☐ Yes ☐ No
- Soldiers during their active military service ☐ Yes ☐ No
- Staff members under the authority of the investigator in the establishments where the research is carried out ☐ Yes ☐ No
- People in prisons or other places of detention ☐ Yes ☐ No
- Persons subordinate to the investigator ☐ Yes ☐ No
- Other vulnerable persons or groups (*please specify*) ☐ Yes ☐ No

3. What methods and procedures will be used to select research participants, and how?
If you anticipate that ethical dilemmas and/or risks may arise during the selection of research participants, briefly describe them and indicate the anticipated means and measures for resolving/eliminating them and how this will be implemented.

4. Can the research cause discomfort and/or physical and/or psychological harm (e.g., pain, psychological trauma, depression, insomnia, etc.) to the research participants that would exceed what they experience in their daily lives?

☐ Yes ☐ No

If "yes", please briefly describe the anticipated discomfort and/or damage, and indicate the planned means and measures for resolving/eliminating them and how this will be implemented.

5. Will the participation in the research be voluntary?

☐ Yes ☐ No

If "yes", please briefly describe and explain how this will be implemented.
If "no", please explain why voluntary participation in the research is not possible.

[1] (Socially) vulnerable persons are understood as defined in the following sources: Republic of Lithuania Law on Ethics on Biomedical Research art. 6 and the Order of the Minister of Social Security and Labour of the Republic of Lithuania on the Approval of the 2020–2023 Action Plan for Increasing Social Coverage art. 2.1.

6. Will the participation in the research be based on informed consent?

☐ Yes ☐ No

If "yes", please briefly describe and explain how this will be implemented. Please attach the informed consent form to your application.
If "no", please explain why it is not possible to base the participation in the research on informed consent.

7. Will the research participants be informed that they can withdraw from the research at any time without suffering any negative consequences?

☐ Yes ☐ No

If "yes", please briefly describe and explain how this will be implemented.
If "no", please explain why it is not possible to inform research participants that they can withdraw from the research at any time without any consequences.

8. Will the research participants have the opportunity to request the withdrawal of their data from the research?

☐ Yes ☐ No

If "yes", please briefly describe and explain how this will be implemented.
If "no", please explain why research participants cannot request that their data be withdrawn from the research.

9. Will the research participants be given the opportunity to discuss any aspect of the research in which they are participating or have participated with the investigator(s), both during and after the research?

☐ Yes ☐ No

If "yes", please briefly describe and explain how this will be implemented.
If "no", please explain why it is not possible to allow the research participants to discuss specific aspects of the research with the investigator(s).

10. Does the research methodology envisage providing research participants with incomplete or actively deceiving information about the research?

☐ Yes ☐ No

If "yes", please explain why it is not possible to provide participants with complete and accurate information about the study.

11. Will the research involve the collection and/or use of personal data, including video recordings, photographs, or other data that could identify a specific individual?

☐ Yes ☐ No

If "yes", please specify what personal data will be collected and attach a Personal Data Management Plan (PDMP)[2] to the Application.
If a personal data protection assessment (PDPA) is required, it must be carried out and attached to this application, along with an order from the Rector of Vilnius University authorising persons to process personal data for scientific research purposes.[3]

[2] VU information on DMP can be found here.
[3] VU information on the processing of personal data can be found here.

12. Is it planned to compensate or reward the participants for their participation in the research?

☐ Yes ☐ No

If "yes", please briefly describe and explain how this will be implemented.

Please confirm that the research will be conducted in accordance with this application and the legislation governing compliance with research ethics.
(Relevant legislation is published on the Faculty's website.)

I confirm ☐

APPENDICES:

(Only the relevant documents listed below shall be submitted for assessment)

1. Informed consent form.
2. An invitation form to participate voluntarily in the study.
3. Request to the head of the organisation to conduct the research within the organisation.
4. Data collection instrument.
5. Personal data management plan.
6. Permission to conduct research from the Lithuanian Bioethics Committee/Vilnius Regional Biomedical Research Ethics Committee/Kaunas Regional Biomedical Research Ethics Committee (including permit additions, if any).
7. Permission to conduct research from the State Food and Veterinary Service.

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(*investigator's name, surname, position*) (*signature*)