APPROVED
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of 27 April 2023
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# PROCEDURE FOR THE ASSESSMENT OF COMPLIANCE OF APPLIED RESEARCH WITH RESEARCH ETHICS

## CHAPTER I
## GENERAL PROVISIONS

1. The Procedure for the Assessment of the Compliance of Applied Research (hereinafter refereed to as Research) with Research Ethics (hereinafter referred to as the Procedure) regulates the general and specific principles of compliance with research ethics and the procedure for implementing such compliance for Research planned to be carried out by employees and/or students of Kauno Kolegija (hereinafter referred to as KK).

2. The purpose of the Procedure is to ensure compliance with the principles of academic integrity applicable to specific Research and to protect the interests of research participants (individuals) as well as animals used in scientific research. The application of the research ethics compliance assessment procedure helps ensure research quality, reliability, integrity, and thoroughness, and enables the evaluation of data management issues and challenges.

3. The Procedure is prepared in accordance with the Law of the Republic of Lithuania on Science and Studies, the Guidelines for the Assessment of Compliance with Research Ethics issued by the Ombudsperson for Academic Ethics and Procedures of the Republic of Lithuania, the recommendations set out in the European Code of Conduct for Research Integrity, the Statute of the KK, and other relevant legal acts.

4. The Procedure applies in the following cases:

4.1. when conducting Research involving people and using personal data;

4.2. conducting research involving animal testing;

4.3. when conducting other Research, the results of which are planned to be published in a scientific journal, one of the requirements of which is to submit confirmation of compliance with research ethics.

5. The Procedure does not apply to research conducted by students in the course of their study programme (when preparing final theses, completing study course (module) assignments, etc.), except in cases where:

5.1. this Research may cause significant psychological or physical harm, or pose safety risks to the research participants;

5.2. the chosen method or manner of publishing the research results may raise other significant ethical issues;

5.3. the research to be conducted complies with Clause 4.3 of this Procedure.

6. The uniqueness of these cases is determined by the lecturer supervising the student's research.

7. Definitions used in this Procedure:

7.1. **Informed consent** – prior and informed consent of an individual to participate in the Research.

7.2. **Application** – a request submitted by the Research Supervisor to the Applied Research Ethics Review Committee (hereinafter referred to as the Committee) to conduct an ethical review of the planned research.

7.3. **Approval** – the authorisation granted by the Committee to conduct the research.

7.4. **Applied research** – experimental and/or theoretical work carried out to acquire new knowledge, primarily aimed at achieving specific practical objectives or solving practical problems.

7.5. **Applied Research Ethics Assessment Committee** (hereinafter referred to as the Committee) – a group of researchers approved by order of the Director of KK, whose primary

function is to assess the compliance of a planned research project with research ethics requirements prior to the commencement of the research.

7.6. **Researcher** – a person with a higher education qualification who conducts research, develops knowledge, conceptualises or creates new products, processes, methods or systems, or leads research and experimental (social, cultural) development projects.

7.7. **The Head of Research** – a researcher who initiated the research or a researcher selected by mutual agreement of the researchers conducting the research jointly.

8. The concepts related to the fundamental principles of child rights protection, a child's legal capacity, participation in decision-making, the right to be heard, response to violations of child rights, and other issues relevant to conducting research involving children are defined in the Law of the Republic of Lithuania on the Fundamentals of Protection of the Rights of the Child.

9. The concept of socially vulnerable persons is defined in the Action Plan for Increasing Social Inclusion for the period 2020–2023.

10. The concepts of a child and the child's legal representatives are defined in the Law of the Republic of Lithuania on the Fundamentals of Protection of the Rights of the Child.

## CHAPTER II
## GENERAL PRINCIPLES OF COMPLIANCE WITH RESEARCH ETHICS

11. All Research, regardless of the field of science and/or the methods selected, shall be subject to the general principles of compliance with research ethics, which are necessary to assess how ethical issues are addressed and how preparedness to address them is ensured. An assessment is carried out to determine whether the planned Research is based on the principles of reliability, integrity, respect, and accountability.

11.1. Implementation of the Principle of Reliability:

11.1.1. Research is designed (conceived, reviewed) and conducted in a manner that ensures quality and consistency and increases the likelihood of obtaining objective results;

11.1.2. Indicating confirmation of compliance with research ethics in the research report (e.g. a publication);

11.1.3. In order to ensure transparency of the Research objectives, appropriate data collection and analysis methods are selected to achieve them;

11.1.4. By anticipating the potential harm and benefits of the Research and taking into account the interests of various research participants (groups), communities, and society, as well as risk-mitigation measures.

11.2. Implementation of the Principle of Integrity:

11.3. by complying with all planned stages of the Research;

11.3.1. by immediately notifying the Committee of any changes in the Research circumstances or any other unforeseen information related to the Research.

11.3.2. by promptly disclosing any conflict of interest to the Committee.

11.3.3. by taking full responsibility for the Research outcomes and their publication, and for the effects and consequences for those impacted.

11.4. Implementation of the Principle of Respect:

11.4.1. By providing research participants with information on the processing of their personal data as data subjects, in accordance with the provisions of Article 13 of Regulation (EU) 2016/679 of the European Parliament and of the Council of 27 April 2016 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data, and repealing Directive 95/46/EC (General Data Protection Regulation, hereinafter referred to as the GDPR), and by providing sufficient information to enable them to decide on their participation in the Research;

11.4.2. by ensuring the voluntary participation of research participants in the Research;

11.4.3. by ensuring that research participants are aware that they may withdraw from the Research at any time without providing a reason and without feeling any pressure to participate in the Research;

11.4.4. by safeguarding the personal data provided by research participants, which are subject to strict confidentiality and anonymity procedures.

11.5. Implementation of the Principle of Accountability:

11.5.1. by registering the planned and conducted Research of KK

11.5.2. by ensuring access to information on the results of conducted Research;

11.5.3. by informing the Committee in the event of a conflict of interest;

11.5.4. by requiring compliance with personal data protection requirements and being able to demonstrate such compliance.

## CHAPTER III
## SPECIAL REQUIREMENTS FOR COMPLIANCE WITH THE ETHICS OF APPLIED SCIENTIFIC RESEARCH

### SECTION I
### BIOMEDICAL RESEARCH

12. A researcher conducting biomedical research shall comply with the Law on Biomedical Research Ethics, the Description of the Procedure for the Issuance of Permits to Conduct Biomedical Research (as approved by Order No. V-27 of the Minister of Health of the Republic of Lithuania of 8 January 2016), and other special legal acts.

13. For confirmation of compliance with research ethics in the field of medical and health sciences, researchers shall apply to a regional biomedical research ethics committee or to the Lithuanian Bioethics Committee if biomedical research is planned to be conducted in the territories assigned to more than one regional biomedical research ethics committee.

### SECTION II
### RESEARCH INVOLVING ANIMALS

14. A researcher conducting Research involving animals shall comply with Directive 2010/63/EU of the European Parliament and of the Council of 22 September 2010 on the protection of animals used for scientific purposes, the Law of the Republic of Lithuania on Animal Welfare and Protection, Order No. B1-866 of 31 October 2012 of the Director of the State Food and Veterinary Service of the Republic of Lithuania on the approval of the requirements for the keeping, care and use of animals used for scientific and educational purposes, and the European Convention for the Protection of Vertebrate Animals used for Experimental and Other Scientific Purposes.

15. For experiments involving animals, the researcher shall apply to the State Food and Veterinary Service (hereinafter referred to as the SFVS), which issues permits to conduct scientific research and experiments involving animals.

### SECTION III
### ETHICAL PRINCIPLES FOR RESEARCH IN THE HUMANITIES AND SOCIAL SCIENCES

16. **Respect for Research Participants**

16.1. **Voluntary Participation**

16.1.1. Participation in scientific research is voluntary and based on informed consent.

16.1.2. Informed consent is defined as a free, prior, and informed agreement to participate in scientific research. Taking into account the Research activities, the most appropriate type of informed consent that complies with the requirements of Articles 7 and 13 of the GDPR shall be selected for each research project: broad consent; blanket consent; open consent; portable legal consent; meta-consent; dynamic informed consent.

16.1.3. Research participants may give consent orally (which must be documented, e.g. by means of an audio recording) or in writing. When an audio recording is made, the research participant shall be provided with information on the processing of personal data in accordance with Article 13

of the GDPR. For example, consent given during an interview, responding to a questionnaire, or a request to provide written responses indicates that the subject has agreed to participate in the research. In research, priority is recommended to be given to written informed consent.

16.1.4. When conducting Research in a specific company, institution, or organisation, the consent of the head of that organisation is required to carry out the Research within the organisation under their management.

16.1.5. In institutions where Research is conducted and whose representatives or wards are research participants (e.g. prisons, children's care homes, hospitals, etc.), it is important that:

16.1.5.1. the consent of the head of the institution to conduct the Research within the institution under their management and to access research participants has been obtained.

16.1.5.2. The consent (oral or written) of each person participating in the Research has been obtained; in exceptional cases, consent to participate in the Research may be given on behalf of the research participant by an authorised representative (in accordance with the legal acts governing the granting of powers of attorney) or by a person authorised to make decisions on behalf of the research participant where the participant is unable to make decisions independently (e.g. lacks legal capacity). In exceptional cases, consent to participate in the Research may also be given by another person (e.g. the head of the institution) on behalf of the research participant; however, consent for the processing of personal data shall be given by the research participant.

16.1.5.3. When conducting Research in institutions, both the researcher and the institution shall ensure the protection of personal privacy.

16.1.6. If interventional methods are applied in the Research, excluding biomedical interventional methods, and the research involves physical impact on the research participant, consent must always be given in writing or by another verifiable means.

16.1.7. In order to observe behaviour in public spaces (e.g. a retail premises, a railway station, or a higher education institution), informed consent is not required provided that no personal data are collected and that the research data do not allow the identification of specific individuals. This also does not include audio or video recordings in which individuals can be identified.

16.1.8. Consent may be specific or general in nature. The broad consent form must include the methods of data recording and archiving, the conditions for the secondary use of research data in subsequent scientific research, and information on the processing of the research participant's personal data in accordance with the requirements of Article 13 of the GDPR.

16.1.9. Where data obtained from research participants are combined with data from official registers, research participants shall be provided with comprehensive information about the registers that have been or will be used, the type of information about the research participants that has been or will be collected from those registers, as well as other information required under Articles 13 or 14 of the GDPR, as applicable. Information about data collected from state registers prior to the research participant's consent to participate in the Research shall be provided to the research participant in accordance with the time limits laid down in Article 14(3) of the GDPR.

16.1.10. Research participants have the right to withdraw from the Research at any time; however, their prior contribution (e.g. interviews, etc.) may be used in the Research. The researcher must inform research participants about the conditions governing the use of the data collected after their withdrawal from the Research. This information and the conditions for the use of the data provided by the research participant should be discussed with the individual prior to their decision to participate in the Research.

16.1.11. Passive / implied consent may be considered under exceptional circumstances, but only where: (a) the use of an alternative form of consent would result in substantial and evident shortcomings related to the quality or purpose of the Research and/or the interests of the researcher; (b) the burden on research participants is minimal and no risk is involved; (c) special efforts are made to inform research participants and/or their representatives about the scientific research and the possibility to refuse participation; (d) the refusal procedure is straightforward.

17. **Participation of Minors in Scientific Research**

17.1. The specific needs and interests of persons who have not reached the age of 18 at the time of the Research (minors) shall be protected by adults. Researchers shall have an understanding

of the development and psychology of minors in order to be able to adapt their chosen methods and the direction of the Research to the age of the research participants. Information about the Research and its consequences must be provided in an age-appropriate manner. Minors shall also be informed about the voluntary nature of participation in the Research and their right to withdraw from the Research at any time.

17.2. Where minors participate in the Research, researchers shall obtain the consent of parents or legal guardians. The researcher shall provide the parents or legal guardians giving consent with information about the Research (Annex 1 of the Procedure). Consent is given by completing and signing the informed consent form (Annex 2 of the Procedure). Minors may not participate in the Research without the consent of their parents or legal guardians, except in the circumstances specified in Clause 17.6.

17.3. It is important to regard minors as independent individuals; therefore, in addition to the official consent provided by parents or legal guardians (Annex 2 of the Procedure), it is necessary that minors themselves give their assent to participate to the extent of their capacity. A minor's verbal consent to participate in scientific research is required from the age at which the minor is capable of expressing it. An exception applies to personal data that may be obtained only with the consent of parents or legal guardians.

17.4. Minors may be included in Research only if there is no alternative way to obtain the required data and if the aim of the Research is to gain scientific insights that may be used for the benefit of minors.

17.5. When minors participate in Research, strict compliance with the principle of confidentiality is mandatory, except in situations where researchers are legally or ethically obliged to disclose confidential information to close relatives, other adults, or services responsible for the protection of children's rights (e.g. a duty to report applies if researchers become aware that a minor is being abused, sexually assaulted, or neglected). Before deciding to disclose confidential information related to a minor, the researcher shall consider all potential risks and consequences for the minor's health and life, and assess whether the disclosure of such confidential information could worsen the minor's current situation. The researcher may consult the Committee on these matters.

17.6. Researchers may refrain from requesting separate parental or guardian consent where there may be differences in values and interests between parents or legal guardians and minors. This may be considered an obstacle to collecting comprehensive scientific research data on the living conditions and behaviour of minors.

18. Research Involving Persons Belonging to Vulnerable Groups:

18.1. Researchers have a special duty to respect the interests of vulnerable groups throughout the entire Research process.

18.2. Persons belonging to vulnerable groups may be reluctant to participate in Research due to fear of adverse public attitudes towards them; therefore, such Research is permissible only in compliance with the provisions of Articles 6 and/or 9 of the GDPR.

19. **Information Provided to Research Participants**

19.1. The information to be provided to research participants depends on the nature of the data collection methods. In qualitative, quantitative, and mixed-methods scientific research, research participants must be provided with information about the scientific research.

19.2. Information about the scientific research should include the following:

19.2.1. the researcher's contact details;

19.2.2. the Research topic;

19.2.3. the method of data collection and the anticipated duration;

19.2.4. the purpose of data collection, how the data will be used subsequently, and the methods of archiving for secondary use;

19.2.5. the voluntary nature of participation;

19.2.6. information provided on the expected benefits of the Research and the potential risks to the research participant;

19.2.7. the information on the processing of the research participant's data as set out in Article 13 of the GDPR.

19.3. Research participants may request additional information about the Research. Additional information may relate, for example, to: (1) the Research itself; (2) how the confidentiality and anonymity of personal data will be ensured and where personal data will be stored after the Research; (3) how and when the Research results will be published; and (4) external sources of funding.

19.4. In research applying an experimental method, sufficient information about the experimental design shall be provided. Experimental research varies significantly across different fields; therefore, the scope and level of detail of the information provided shall always be determined and justified by the researcher.

19.5. Requests from research participants for additional information related to the Research and the personal data required from the research participant must be answered in clear and plain language, as honestly and accurately as possible.

20. **Alternative Methods of Data Collection**

20.1. Research participants may be provided with all necessary information; however, in certain cases, participation shall not be voluntary (e.g. where the Research involves the observation of military conscripts or work processes and the head of the organisation has authorised the Research).

20.2. Research participants may be provided with incomplete information (e.g. where observational data are collected from emergency services or during ride-alongs with police units, when the researcher cannot disclose that scientific research is being conducted) or with misleading information regarding the role of the researcher (e.g. where, in the course of covert research, the researcher may mislead participants when investigating cases of discrimination).

20.3. The researcher collects data for the Research without identifying themselves, while providing misleading information about the content of the Research.

20.4. When observing research participants in a public place, their consent is not required. Technical recording equipment may be used in public places, provided that the principles of privacy and data protection are observed during the use, storage, and archiving of the data.

21. **Prevention of Harm to Research Participants**

21.1. **Avoidance of Psychological Harm**

21.1.1. The avoidance of psychological harm includes respectful treatment of research participants and the ethical publication of research results in scientific publications.

21.1.2. The sensitivity of the topic and the boundaries of privacy depend primarily on the research participants themselves. Where research participants are aware, on the basis of the information provided to them, of the issues to be addressed in the Research, by giving informed consent, they express their willingness to participate in the Research and demonstrate awareness of the scope and methods of the Research. By participating in the Research, research participants regulate their own level of involvement, avoiding situations and questions that they consider harmful.

21.1.3. Where scientific research involves interaction with research participants (e.g. observation of a participant, interviews), all data relating to the participants shall be handled respectfully and in a manner that preserves their dignity.

21.1.4. The researcher is responsible for the prevention and management of any potential psychological harm to the research participant during the Research.

21.1.5. The researcher shall ensure that the principle of voluntary participation is upheld, including in cases where there is direct interaction with research participants. The researcher should always (except where objectively impossible) ensure that the research participant's participation is voluntary, in particular where there is direct interaction with research participants. Irritation, confusion, fear, or physical fatigue may constitute sufficient grounds for the researcher to suspend or terminate the Research, insofar as it relates to the topic, even if the research participant does not explicitly refuse to continue. It is particularly important to ensure that research participants participate

voluntarily when research is conducted within institutions themselves (e.g., hospitals, prisons, child protection institutions, residential care homes for the elderly, etc.).

21.2. **Avoidance of Financial and Social Harm**

21.2.1. Financial and social harm to research participants is more likely if the ethical principles relating to privacy and data protection are not observed in the Research. Guided by ethical principles, researchers must ensure the protection of confidential information and explain such protection to research participants.

21.2.2. Researchers must avoid any harm to research participants that may arise from scientific publications. However, this principle should not prevent the publication of Research results that research participants may view negatively, provided that such results have been obtained in compliance with research ethics principles. Responsibility for compliance with academic ethics principles in scientific publications lies with researchers (co-authors), collaborators, publishers, publication owners and editors, reviewers, and sponsors.

20. **Assessment of the Risk of Harm in Research**

20.1. Research involving potential risks that research participants themselves are unable to assess, as well as research that may cause harm or affect normal everyday life, shall be assessed in advance. If the researcher is aware of a risk of causing long-term psychological harm that exceeds acceptable risk levels or that the safety of the research participant may not be ensured, the researcher must disclose this to the Committee when submitting an application for the assessment of compliance with research ethics, together with the proposed risk mitigation measures. If unforeseen harm arises during the conduct of the Research, the researcher shall temporarily suspend the Research, reassess the risk of harm, inform the Committee thereof, and submit a plan outlining measures to prevent such unforeseen harm.

21. **Confidentiality and Data Protection**

21.3. Data protection is the most important aspect of privacy protection in the collection and processing of research data and in the publication of research results. In conducting Research, it is important to ensure: (1) the protection of research data and confidentiality; (2) the storage and management of research data; and (3) the quality of scientific publications. The objective of data protection is to enable the opening of research data and results while preserving the confidentiality of research participants.

21.4. The principles of privacy protection apply to publicly available material or published data that may be related to individuals and their activities in the fields of politics, business, and culture. For example, when conducting research using a biographical method, information that reveals private aspects should be agreed with the individual about whom the data are collected or with their authorised representative.

21.5. The fundamental principle governing the collection and storage of personal data is the necessity of such data for the conduct of the Research. Personal data shall be collected for specified, explicit, and legitimate purposes and shall not be further processed in a manner incompatible with those purposes.

21.6. Where research data can be reasonably analysed without direct identifiers, and there is no justification for retaining such identifiers, only data from which identifiers have been removed may be processed and stored for secondary research purposes.

21.7. Data containing identifiers may be collected and used where this is justified for the purposes of a specific Research project. Upon obtaining informed consent, data containing identifiers may also be stored for secondary Research purposes. In Research, it may be necessary to process and store identifiers in order to conduct data audits and prevent data fabrication and falsification, to investigate potential breaches of academic ethics, as well as to analyse data of historical and cultural significance. All current data may, over time, acquire historical and cultural significance; however, such significance must be assessed and justified by the researcher on a case-by-case basis.

21.8. The confidentiality of research data depends on the restrictions applied to the processing, use, and storage of the data. Research data may be used or transferred for data audit

purposes, where, in commissioned Research, the data are transferred to the client. It is particularly unacceptable to disclose information about research data or to transfer data in a manner that could influence the assessment, treatment, or position of individual research participants. Non-anonymised research data may not be transferred to the media or used for commercial purposes.

21.9. An exception to the obligation of confidentiality is the duty of every citizen to report an imminent serious crime that can still be prevented. The researcher is not required to disclose information about crimes that have already been committed, unless such disclosure helps to prevent an imminent serious crime.

22. **Storage and Publication of Research Data**

22.1. Research in the humanities and social sciences is not always replicable; however, the academic community should be provided with the opportunity, where necessary, to verify the Research findings on the basis of the Research data analysed in the Research, by making such data available in accordance with the requirements of the selected data repository and after anonymising or pseudonymising the research data. Openness is a fundamental attribute of scientific quality and is also a necessary condition for assessing the validity of scientific information.

22.2. Data that are carefully archived for secondary Research reduce the need to collect research data containing identifiers. It is particularly important to archive secondary Research data that have cultural, historical, and/or scientific value.

22.3. Where necessary, privacy protection should be ensured through anonymisation methods and by regulating access to anonymised data intended for secondary Research.

22.4. Where data from a previously conducted Research are intended to be reused for new research purposes, but it is no longer possible to obtain the informed consent of the original research participants, a research plan must be submitted detailing the nature and significance of the secondary use, including its impact on privacy. The Committee shall decide whether the reuse of the data is permissible.

22.5. If data containing identifiers are not intended for publication and cannot be anonymised, and the research participants were not asked to grant permission to store and/or make the data available, personal data and Research data should be destroyed upon completion of the Research (following the publication of the Research results). Where data have scientific value or are historically unique, the researcher may submit a request to allow the archiving of anonymised research data in a data repository/archive recommended by KK.

23. **Ensuring Privacy in Scientific Publications**

23.1. Unlike research data, scientific publications are generally publicly accessible. The factors to be taken into account when publishing scientific research are as follows:

23.1.1. The general principle is the protection of the privacy of research participants in publications. Decisions shall be made on a case-by-case basis where a person who participated in the Research is identifiable in a publication;

23.1.2. When considering whether to publish the names of research participants, due regard shall be given to the participants' authors' rights. Furthermore, with the consent of research participants who have provided information or were interviewed, their names and other basic information may be indicated in a scientific publication where the Research is based on interviews with experts. Therefore, the prior consent of research participants must be obtained for the publication of their personal data in a scientific publication or for any other form of public disclosure (e.g. at scientific or other events);

23.1.3. Research participants must not be promised complete anonymity if it cannot be guaranteed. For example, granting anonymity to research participants in scientific publications does not necessarily prevent their identification by individuals who are familiar with the activities of the community or organisation that was the subject of the Research;

23.1.4. when writing about deceased private individuals, the researcher shall act ethically. Due consideration should be given to the privacy needs expressed by the deceased person's close relatives and other immediate family members;

23.1.5. When researching organisations (e.g. institutions, associations, work communities, public bodies, etc.), the identifiability of the organisations themselves and of individual representatives shall be assessed separately on a case-by-case basis.

23.2. The results of quantitative research are presented in statistical form; however, where there is a risk of identification, it is necessary to remove identifiers or to anonymise the data.

23.3. In the case of qualitative data, prior to publishing any data excerpts and/or quotations, the risk of identification must always be assessed, including which indirect identifiers (e.g. workplace, school, place of residence, age, profession, position, etc.) are indicated, what will be coded, and what will be omitted.

23.4. Where Research involves archived materials, the identifiability of research participants depends on the conditions set by the data repository/archive in which the materials are stored.

24. **Conduct of Researchers**

24.1. When publishing Research results, researchers shall not falsify or fabricate research data, nor omit and/or conceal important data.

24.2. Researchers shall indicate the methods by which the data were collected and/or selected, as well as the methods used to validate and analyse the data.

24.3. If researchers identify significant errors in published data, they shall take measures to correct such errors by issuing corrections, amending the data, or applying other appropriate measures.

24.4. Researchers shall not present the work or parts or elements of the work or data of other researchers as their own, even where they cite another author's work or data source.

24.5. Researchers assume responsibility only for the work that they have actually (independently) carried out or to which they have contributed, where the researcher's contribution can be determined; however, where such determination is not possible, responsibility shall be assumed by all researchers. They may be identified as authors or co-authors of a work only if they meet the authorship criteria, and only in such cases may they claim ownership of that work.

24.6. Designation as the principal author or co-author of a work reflects the individual's scientific contribution rather than their status. Individuals who do not meet the authorship criteria but have contributed to the Research shall be acknowledged in the scientific publication.

24.7. The student should be the first author if the publication is based on the student's Research.

25. **Overall Validity, Interinstitutional Research, and Research Conducted in Other Institutions or Locations**

25.1. Where the KK Committee adopts a decision confirming compliance with research ethics, such a decision may be regarded as valid for other higher education and research institutions represented by the researchers involved in the Research. Where a researcher transfers from another higher education and research institution to KK, and the Research was conducted at the former institution and is continued at KK, no additional assessment of compliance with research ethics is required; however, the Research results should be attributed to the institutions at which the researcher conducted the Research. The continuation of the Research and the confirmation of its compliance with research ethics must be reported to the KK Committee by submitting a free-form notification indicating the title of the Research, the project title, number and programme (where the Research is carried out within a project), the Research supervisor and their contact details, the researchers conducting the Research, and information on the confirmation of compliance with research ethics.

25.2. Where Research is conducted by several higher education and research institutions, responsibility for obtaining confirmation of compliance with research ethics rests with the principal investigator or the Research supervisor and the institution with which they are affiliated. Where

research projects are implemented at several higher education and research institutions, it shall be deemed sufficient for the assessment of compliance with research ethics to be carried out at only one higher education and research institution, with the others being informed thereof.

25.3. In the case of interinstitutional Research, depending on the nature and context of the collaboration, assessments of compliance with research ethics for different parts of the Research may be obtained separately from different higher education and research institutions (e.g. social research at one institution and clinical research at another).

26. **Compensation in the Conduct of Research**

26.1. Any compensation or benefit offered to research participants and/or research participant communities shall be fair, justified, and proportionate.

26.2. Compensation shall not influence research participants' decision to participate in a particular Research or Research activity.

26.3. Where community resources are used, appropriate compensation shall be provided.

26.4. The researcher and the organisation in which the Research is conducted may receive compensation that does not exceed what may be considered reasonably proportionate to the nature, scope, and purpose of the Research (e.g. reimbursement of travel expenses to the Research site, such as a laboratory). When recruiting research participants, researchers generally do not offer excessive or inappropriate financial or other incentives. Where professional services (e.g. discounts on services and/or goods, training) are offered to research participants as an incentive to participate in Research, researchers shall clearly specify the nature of such services and any potential risks, obligations, and limitations associated with them.

27. **Exceptions in the Conduct of Research**

27.1. Deception may not be used in Research, except where the use of deceptive methods can be justified by the significant anticipated scientific or applied value of the Research and where no alternative effective data collection procedure is available.

27.2. The researcher should document and explain the nature of the deception and justify why it is necessary.

27.3. Where no deception is involved, research participants shall not be misled about the potential risks, inconveniences, and/or discomfort associated with participation in the Research.

27.4. The non-disclosure of information about the Research question and/or hypothesis (for the purpose of preventing influence on the research participant) shall not be considered deceptive.

27.5. All information regarding the (potential) risks or burdens of the scientific research shall be provided. Deception may be a necessary methodological tool in psychological research. However, it should be used only when necessary and shall not be employed to mislead participants about potential harm, risks, or stress.

27.6. Information may not be withheld, nor may research participants be deceived, about procedures that may reasonably cause physical or psychological harm.

27.7. Any deception or withheld information shall be explained to the research participants as early as possible, immediately after their participation and no later than upon completion of data collection. At that point, research participants shall also be informed that they have the right to withdraw their data without any negative consequences.

## CHAPTER IV
## ENSURING COMPLIANCE WITH RESEARCH ETHICS

28. The Committee for the Assessment of Compliance of Applied Research with Research Ethics, established by order of the KK Director, assesses the compliance with research ethics of Research planned to be conducted by KK researchers prior to the commencement of the Research.

29. The Committee operates in accordance with the general and special principles of compliance with research ethics set out in this Description (without being limited to them).

30. The composition, functions, and operating procedures of the Committee are established by the Committee's Rules of Procedure approved by order of the KK Director.

31. The application (Annex 3 to the Procedure) shall be submitted to the Committee by the Research supervisor. Prior to submitting the Application, the Research supervisor must conduct a research ethics self-assessment (Annex 4 to the Procedure). The results of the self-assessment indicate whether it is mandatory to submit an Application to the Committee for Approval to conduct the Research in order to assess compliance with research ethics.

32. In the case of research conducted within a student's study programme that meets the conditions set out in Clause 5.1–5.3, the Application to the Committee shall be submitted by the lecturer supervising the student's Research.

33. The Research supervisor shall submit the Research plan to the Committee for confirmation of compliance with research ethics if:

33.1. Interventional methods are applied in the Research (e.g. social experiments, participatory action research, etc.);

33.2. The Research deviates from the principle of informed consent;

33.3. The research participants are children under the age of 18, and the Research is conducted in pre-school and pre-primary education institutions, general education schools, child care institutions, healthcare institutions, etc.;

33.4. The Research indicates that research participants are exposed to exceptionally intense stimuli, and that the assessment of potential harm requires specialised expertise (e.g. relating to violence, pornography, or similar content);

33.5. The Research may cause long-term psychological harm (e.g. psychological trauma, depression, insomnia, or similar conditions) exceeding the level of risk encountered in everyday life;

33.6. the Research is associated with risks to the safety of research participants (e.g. research on domestic violence);

33.7. this is required by the research participant, the organisation financing the Research, or a cooperation partner (e.g. an international project partner, a commissioning entity in commissioned research, or similar);

33.8. A Research plan for the confirmation of compliance with research ethics must be submitted where the research participants are socially vulnerable persons and where this is required by law;

33.9. Unforeseen circumstances arise in the course of the Research (e.g. changes in the conditions for the processing of personal data, the data collection method, or similar), which affect the Research plan for which compliance with research ethics has been confirmed.

34. The Research supervisor may also submit the Research plan to the Committee for confirmation of compliance with research ethics if:

34.1. the researcher is uncertain whether the Research may cause significant psychological or physical harm or pose safety risks to research participants;

34.2. the method chosen by the researcher or the manner of publishing the Research results may give rise to other significant ethical concerns;

34.3. The Research results are intended to be published in a scientific journal that requires the submission of confirmation of compliance with research ethics.

35. The following annexes shall be submitted together with the Application:

35.1. Questionnaire for the Ethics Self-assessment of Applied Research (Annex 4);

35.2. Applied Research Description Form (Annex 5);

35.3. Information Sheet on the Conducted Research for the Research Participant (Annex 1);

35.4. Informed Consent Form (Annex 2);

35.5. Application for Consent to Conduct the Research (if applicable) (Annex 6);

35.6. Other documents (e.g. certificates confirming qualifications), where such documents are necessary for the ethical assessment of the planned Research.

36. Where several Research activities involving different groups of research participants are conducted within the implementation of a project, a single Application shall be submitted; however, the annexes shall include separate document forms intended for the different groups of research participants.

37. Where Research is conducted jointly with researchers from other Lithuanian and/or foreign institutions and another institution has obtained confirmation of compliance with research ethics, no additional assessment of compliance with research ethics is required; however, the KK Research supervisor shall submit a free-form notification regarding the ongoing Research, indicating the title of the Research, the project title, number, and programme (where the Research is carried out as part of a project), the Research supervisor and their contact details, the researchers who will conduct the Research, and information on the confirmation of compliance with research ethics.

38. Research projects initiated at a previous institution and intended to be continued at the KK shall be assessed by the Committee in accordance with the procedure set out in this Procedure.

39. The Committee provides consultation to KK researchers on the compliance of planned Research with research ethics requirements.

40. A decision on the compliance of the Research with research ethics shall be adopted within 20 working days from the submission deadline for the Application as set out in the Committee's Rules of Procedure.

41. Upon completion of the Research, the Research supervisor shall submit a free-form notification informing the Committee of the completion of the Research and of the implementation of personal data protection measures (where such data were collected and processed) in accordance with the procedures set out in the Research plan.

## CHAPTER V
## FINAL PROVISIONS

42. This Procedure shall be approved, amended, or declared invalid by a resolution of the Academic Council.

43. This Procedure shall enter into force upon its approval by a resolution of the Academic Council. It shall be published in the KK's internal information system within two working days of its approval.

44. This Procedure and other related implementation documents shall be published on the KK’s website in Lithuanian and English.

Annex 1 to the Procedure for the Assessment of Compliance of Applied Research with Research Ethics

**KAUNO KOLEGIJA**
**[NAME OF THE UNIT]**

Name and surname of the participant:

Participant's contact details (email and/or telephone number):

**INFORMATION SHEET FOR RESEARCH PARTICIPANTS**[1]

Minutes of the Meeting of the Committee for the Assessment of Compliance of Applied Research with Research Ethics *[date]*, No. *[No.]*

1. **What is the purpose of this document?**
   This document provides you with information about the Research.
2. **Why is this Research being conducted, and what is its purpose?**
   *[Please indicate the rationale for conducting this Research, as well as its main aims and objectives.]*
3. **Which research participants will be involved in this Research?**
   *[Please define the target group and the sample.]*
4. **Why have you been invited to participate in this Research?**
   You have been invited because *[please specify the age group and/or other inclusion criteria]*.
5. **How long will this Research last, and how much time will your participation require and when will it take place?**
   *[Please indicate the overall duration of the Research, the duration of the participant's involvement in the Research (e.g. duration of an interview, completion of a questionnaire, observation, or other activity), and the tentative dates of the Research]*.
6. **Where will this Research be conducted?**
   *[If the Research is international, please specify the countries involved; if the Research is conducted in Lithuania, you may indicate the regions/cities or other relevant information.]*
7. **Are you required to participate in this Research? Are you free to withdraw from the Research at any time?**
   Your participation in the Research is voluntary. Before making a decision regarding participation, you have the right to ask questions about the Research. If you agree to participate, you may withdraw from the Research at any time without providing a reason and without experiencing any negative consequences, by informing the Research supervisor of your decision. *[Please describe how the participant may do this, e.g., by submitting a written withdrawal request, completing a withdrawal form, or using another specified method.]* Within 30 days of your participation in the Research, you may also request the destruction of any information you have provided, where this is feasible. *[Please specify how the collected data will be handled up to the point of withdrawal from the Research.]*

[1] This template is based on the Guidelines for the Assessment of Compliance with Research Ethics approved by Order No. V-60 of 10 December 2020 issued by the Chief Official for Academic Ethics and Procedures of the Republic of Lithuania.

*[If minors are involved in the Research, you may use the following wording regarding consideration of the minor's wish to withdraw from the Research:*
If the minor for whom you are providing consent to participate in this Research wishes to withdraw from participation, their wish will be respected.*]*

8. **What will be the course of the Research if you agree to participate?**
*[Please describe in detail the Research steps that involve the participant and outline the main stages of the Research process. If several training or instructional sessions are required, please describe them in sequence.]*
You will be invited to participate in *[x]* sessions *at [please specify the preliminary location or platform (e.g., the survey will be conducted on the SurveyMonkey platform; observation will take place in the [name] laboratory, etc.)]. [Alternatively]* You will be asked to participate in *[x]* online sessions.
*[If applicable:]* When you arrive, the researchers will discuss the Research procedures with you and provide an opportunity to ask any questions related to the Research. You will then be asked to complete an Informed Consent Form / to provide verbal consent.
If you agree to participate in the Research, you will be interviewed / you will be asked to attend one or more follow-up sessions *[delete as applicable] at [please specify the anticipated location]*.
The interview / session is expected to last approximately *[x]* minutes / hours. *[For longer sessions: You will be offered [number] breaks of approximately [x] minutes.]* You may also request to withdraw your consent to participate in the Research or to stop the interview at any time.
*[Please provide detailed information about any follow-up meetings, including their duration and frequency.]*
*[If applicable:]* With your consent, the researchers will make an audio recording/video recording / take photographs of you *[delete as applicable],* because… *[please specify the reasons why this is necessary, e.g., the audio recording will be required in order to accurately capture your views.]*
*[Please specify where and how audio and/or video recordings and/or photographs will be stored; when and how the audio and/or video recordings and/or photographs will be destroyed; which transcription software will be used; and any other relevant information required under Article 13 of the General Data Protection Regulation (GDPR).]*

9. **Are there any risks associated with participating in the Research?**
Participation in the Research involves the following risks: *[please describe any potential risks associated with the Research; identify any possible financial, social, or other risks or inconveniences (e.g., questions on sensitive topics in a questionnaire), if applicable; also note even minimal risks (e.g., breach of confidentiality); these do not include risks related to the conduct of the Research itself].*
To minimise any potential risks, *[please describe the measures that will be taken, including that personal data will be appropriately pseudonymised[2] or anonymised].*

10. **Are there any benefits to participating in the Research?**
The benefits of participation are…
*[Alternatively:]* By participating in this Research, you will not receive any direct or personal benefits.
By participating in this Research, you will not receive any financial benefit; that is, you will not be paid for taking part in this Research.

11. **Reimbursement of Expenses and Payments**
Your reasonable expenses (e.g., travel, meals, or other costs) incurred as a result of visits to the Research *[will / will not]* be reimbursed.
*[If Research participants will be compensated for the time spent participating in the Research, please specify the amount of compensation.]*
*You will* receive *[an amount / a voucher / a gift] in return* for *[the time spent participating in the Research / reasonable travel expenses/meals / other]*.

[2] This is a method of personal data processing in which certain personal data are replaced with identifiers, so that the personal data cannot be attributed to a specific data subject without the use of additional information. However, if necessary, it is possible to restore the association of the personal data with a specific data subject.

*[Alternatively:]* You will not be paid for participating in this Research.

12. **How will the collected data be managed?**

    The information you provide during the Research constitutes Research data. Any Research data from which you can be identified is treated as personal data. *[Please specify whether personal data will be collected, e.g., name, date of birth, audio recording, etc. If so, how will they be managed?]*.

    *[If applicable, where special categories of personal data are collected:]* The data collected for the Research fall within special categories of personal data, such as data relating to your racial or ethnic origin, health, personal data revealing political opinions, religious or philosophical beliefs, trade union membership, genetic data, data concerning a natural person's sex life or sexual orientation *[please specify here any confidentiality classification or the types of commercially sensitive data being collected]*.

    Personal/confidential data will be stored *[please specify the location, security measures, and the duration for which the collected data will be retained] [the retention period depends on the policies of the information system and data repository selected by the institution/publisher] /* will not be stored.

    Other Research data (including Informed Consent Forms) will be stored for *[please specify the data retention period in years and/or the conditions determining the retention period]* after the completion of the Research/publication of the results.

    The Research data will be made openly available at *[please specify the location] and will be accessible to [please specify the target group or the general public]*.

    You have the right to withdraw your consent to the processing of personal data *[please specify the time limit up to which personal data may be withdrawn]*.

    *[If applicable:]* Your personal data will be transferred to and stored at a destination outside the European Union. *[Participants must be informed about the possibility that their personal data may be transferred to third countries (including transfers involving remote access to personal data), the appropriate or implemented safeguards, and the means by which they may obtain a copy of the data or where the data are made available for consultation.]*

    *The Researcher and/or their team, the Research Supervisor, collaborator/translator/other authorised person(s)* will have access to the Research data. Access to the data may be granted to authorised staff of Kauno Kolegija for the purposes of Research monitoring and/or auditing, as well as to the Office of the Ombudsperson for Academic Ethics and Procedures of the Republic of Lithuania when examining a potential breach of academic ethics and/or procedures.

    *[If applicable:]* We would like to obtain your consent to use direct quotations *at* any stage of the Research [with the assurance that your name will be coded (please delete if not applicable)].

    *[If applicable:]* We inform you that anonymised data will be used in future Research and that the data may be shared with other researchers (e.g., through online databases). All personal information from which you could be identified will be removed or replaced.

13. **Will the Research results and/or data be made publicly available?**

    The Research may be published *in [please specify the format, e.g., academic publications, websites, etc.]*.

14. **Who is funding the Research?**

    *[Please provide detailed information about the organisation funding the Research.]*

15. **Who should you contact if you wish to ask questions about this Research or raise any concerns?**

    If you have concerns about any aspects of this Research, please contact *[insert the name, surname, telephone number and/or email address of the Research Supervisor]*. A decision regarding your inquiry will be made, and you will be informed of it within *[x]* working days.

    If you have questions regarding your rights as a Research participant, you may contact the Kauno Kolegija Committee for the Assessment of Applied Research Compliance with Research Ethics, which reviewed and approved this Research, at Pramonės pr. 20, 50468 Kaunas, email: etika.tyrimai@kaunokolegija.lt.

16. **Protection of Personal Data**

Kauno Kolegija is the data controller (email: info@kaunokolegija.lt). Therefore, your personal data submitted for the assessment of the Research's compliance with research ethics will be processed by Kauno Kolegija in accordance with the General Data Protection Regulation, the Law of the [3]Republic of Lithuania on the Legal Protection of Personal Data, the Law of the Republic of Lithuania on Science and Studies, other national legal acts, and the internal legal acts of the KK, including but not limited to those regulating the protection of personal data.
Kauno Kolegija will process your personal data for the purposes of the Research described above.
Information about the rights regarding personal data. Data subjects have the right to:

- to know (to be informed) about the processing of their personal data;
- upon presenting an identity document to Kauno Kolegija or identifying themselves using electronic means of communication that allow proper identification, to access their personal data and information on how such data are processed; to obtain information on the sources from which and the types of personal data collected, the purposes of processing, the recipients to whom the data are or have been disclosed during at least the past one year, and to receive a copy of documents containing their personal data;
- to request the rectification or erasure of their personal data, or the restriction of data processing (other than storage), where the data are processed in violation of legal requirements;
  to object to the processing of their personal data;
- to request the transfer of the personal data obtained by Kauno Kolegija from the data subject to another data controller, or to receive such data directly in a convenient and commonly used format.
- to lodge a complaint with the State Data Protection Inspectorate;
- to withdraw the given consent, where personal data are processed on the basis of consent.

Contact details of the Data Protection Officer of Kauno Kolegija: dap@kaunokolegija.lt, address: Pramonės pr. 20, Kaunas.
A complaint regarding the processing of personal data may be submitted to Kauno Kolegija by email at info@kaunokolegija.lt or by post to Pramonės pr. 20, Kaunas; to the Data Protection Officer of Kauno Kolegija by email at dap@go.kauko.lt or by post to Pramonės pr. 20, Kaunas; to the State Data Protection Inspectorate by email at ada@ada.lt or by post to L. Sapiegos g. 17, Vilnius; or to the Office of the Ombudsperson for Academic Ethics and Procedures of the Republic of Lithuania by email at info@etikostarnyba.lt or by post to Z. Sierakausko g. 15, Vilnius.

**17. Contact Information and/or Other Information**

If you would like to discuss the Research beforehand, or if you have any questions after the Research, please contact:
Research Supervisor *[name, surname]*
Institution: *[name]*
Address: *[address]*
Research Supervisor's phone number: *[phone number]*
Research Supervisor's email address: *[email address]*

**Received**

Signature

Date

[3] Regulation (EU) 2016/679 of the European Parliament and of the Council of 27 April 2016 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data, and repealing Directive 95/14/EC (General Data Protection Regulation).

Annex 2 to the Procedure for the Assessment of Compliance of Applied Research with Research Ethics

**KAUNO KOLEGIJA**
**[NAME OF THE UNIT]**

**Participant's name and surname:**
**Participant's contact details (email, phone):**

**INFORMED CONSENT FORM FOR PARTICIPANTS**
Decision *No. [xx]* of the Committee for the Assessment of Compliance of Applied Research with Research Ethics, dated *[date]*

**Research title:**
**Research supervisor:**
**Research supervisor's unit:** *[please specify faculty, department]*
**Research supervisor's phone number:**
**Research supervisor's email:**

| | | If you agree, please indicate your consent by ticking the box | If you do not agree, please indicate this by ticking the box |
|---|---|---|---|
| 1. | I confirm that I have read and understood the information sheet for the above-mentioned Research. I have been given the opportunity to review the information, ask questions, and have them answered. | ☐ | ☐ |
| 2. | I freely and voluntarily agree to participate in the Research. | ☐ | ☐ |
| 3. | I am informed that my participation is voluntary and that I may withdraw from the Research at any time, without providing a reason and without any negative consequences or penalties. | ☐ | ☐ |
| 4. | I have been informed that the data collected during the Research may be reviewed by authorised persons not directly involved in the conduct of the Research (e.g. the Research Ethics Committee of Kauno Kolegija, the Data Protection Officer of Kauno Kolegija, the Office of the Ombudsperson for Academic Ethics and Procedures of the Republic of Lithuania, the State Data Protection Inspectorate, or a court of law). | ☐ | ☒ |
| 5. | I have been informed that this Research has been approved by the Committee for the Assessment of Compliance of Applied Research with Research Ethics of Kauno Kolegija and that the Research has received ethical approval. | ☐ | ☐ |

| | | | |
|---|---|---|---|
| 6. | I have been informed about who will have access to my personal data, how the data will be stored, and what will be done with the data after the Research has been completed. | ☐ | ☐ |
| 7. | I have been informed that the results of the Research will be made publicly available. | ☐ | ☐ |
| 8. | I have been informed whom to contact in case of questions related to the Research. | ☐ | ☐ |
| 9. | *[If applicable]* I agree to the audio recording. | ☐ | ☐ |
| 10. | *[If applicable]* I agree to the video recording. | ☐ | ☐ |
| 11. | *[If applicable]* I agree to photography. | ☐ | ☐ |
| 12. | *[If applicable]* I have been informed how audio recordings/video recordings/photographs will be used in the analysis and reporting of the Research results *[delete as applicable].* | ☐ | ☐ |
| 12.1. | *[If applicable]* I agree to the use of direct quotations attributed to me in the analysis and reporting of the Research results.<br>*[OR]* | ☐ | ☐ |
| 12.2. | *[If applicable]* I agree to my quotations being pseudonymised in the analysis and reporting of the Research results.<br>*[OR]* | ☐ | ☐ |
| 12.3. | *[If applicable]* I agree to my quotations being anonymised in the analysis and reporting of the Research results.<br>*[OR]* | ☐ | ☐ |
| 12.4. | *[If applicable]* I agree to my statements/quotations being cited only *[without indicating my personal data / with disclosure of my personal data]*. | ☐ | ☐ |
| 13. | I confirm that I have received a copy of the Informed Consent Form signed by the Research supervisor. | ☐ | ☐ |
| 14. | *[If applicable]* I agree to the data collected in this Research being shared with researchers, including those working outside the European Union, and being used in other Research studies. I understand that all data will be fully anonymised and that it will not be possible to identify me. | ☐ | ☐ |
| 15. | *[If applicable]* I agree to my personal contact information *[please specify the type of contact information and the retention period]* being stored in a secure database so that the Researchers may contact me regarding other future Research studies. | ☐ | ☐ |

Research participant (if the participant is a minor, the form is signed by one of the parents or legal guardians)

| *name* | *surname* | *basis for representation (if applicable)* | *signature* | *date of signature (DD-MM-YYYY)* |
|---|---|---|---|---|
| | | | | |

Research supervisor

| *name* | *surname* | *Position in the Research* | *signature* | *date of signature (DD-MM-YYYY)* |
|---|---|---|---|---|
| | | | | |

Annex 3 to the Procedure for the Assessment of Compliance of Applied Research with Research Ethics

**KAUNO KOLEGIJA**
**[UNIT NAME]**

**APPLICATION**
**FOR ETHICAL REVIEW OF A PLANNED RESEARCH**

- -20

In accordance with the Regulations for the Assessment of Compliance of Applied Research with Research Ethics of Kauno Kolegija, approved by Resolution No. of the Academic Council dated DD-MM-YYYY.

| | | |
|---|---|---|
| 1. | Title of the Research | |
| 2. | Project title, number and programme *[if the Research is conducted within the framework of a project]* | |
| 3. | Research supervisor | [name, surname] |
| 4. | Contact details | [phone number, email address] |
| 5. | Researchers/student researcher (if the Research is conducted by a student) | [names, surnames, units] |
| 6. | Other relevant information | |
| 7. | Annexes | Research ethics self-assessment form, ..... pages.<br>2. ....., ..... pages. |

[Research supervisor] [signature] [name and surname]

Annex 4 to the Procedure for the Assessment of Compliance of Applied Research with Research Ethics

**KAUNO KOLEGIJA**
**[NAME OF THE UNIT]**

# RESEARCH ETHICS SELF-ASSESSMENT QUESTIONNAIRE

The Research Ethics Self-Assessment Questionnaire (hereinafter referred to as the Questionnaire) shall be completed for each research project[4] planned to be conducted at Kauno Kolegija (hereinafter referred to as the KK) that involves human participants and in which personal data are collected and/or processed. The completed Questionnaire, together with the Application and the appendices specified in the Description of the Procedure for the Assessment of Compliance of Applied Research with Research Ethics at Kauno Kolegija (hereinafter referred to as the Procedure), shall be submitted to the KK Committee for the Assessment of Compliance of Applied Research with Research Ethics (hereinafter referred to as the Research.

When planning biomedical Research, it is mandatory to apply to the Lithuanian Bioethics Committee[5] or to a regional biomedical research ethics committee (Vilnius[6] or Kaunas[7]).

The questions presented in the Questionnaire are related to the planned Research. Please complete the Questionnaire carefully.

## 1. General information

| | |
|---|---|
| Title of the Research | |
| Research supervisor | |
| Academic unit, department / centre / academy | |
| Researcher(s) / student researcher (if applicable) | |
| Planned research period | |
| Contact person | |
| Contact person's email address | |

[4] The Questionnaire is not required when the Research is conducted by KK students or non-degree students; in such cases, approval must be obtained from the supervisor of the final or Research project and/or the module coordinator, *in accordance with the Rules of Procedure of the KK Committee for the Assessment of Research Compliance with Research Ethics*.

[5] Lithuanian Bioethics Committee (sam.lt).

[6] Vilnius Regional Biomedical Research Ethics Committee – Faculty of Medicine, Vilnius University (vu.lt).

[7] Kaunas Regional Biomedical Research Ethics Committee | Lithuanian University of Health Sciences (lsmuni.lt).

## 2. Research summary

*Please submit a brief summary of the Research (up to 2,000 characters including spaces), indicating the aim, objectives, participants and their expected number, as well as the methods and equipment planned for use:*

| |
|---|
| |

## 3. Research ethics self-assessment

| **Question** | **Yes** | **No** |
|---|---|---|
| The participants of the planned Research are human subjects. | ☐ | ☐ |
| Personal data will be collected and/or processed in the planned Research.[8] | ☐ | ☐ |
| 1. Does the Research involve vulnerable individuals or other participants who are unable to provide informed consent?[9] *Please specify for each group*: | | |
| • *minors (individuals who are under 18 years of age at the time of the Research)* | ☐ | ☐ |
| • *individuals with learning difficulties* | ☐ | ☐ |
| • *patients* | ☐ | ☐ |
| • *individuals receiving psychological counselling services* | ☐ | ☐ |
| • *residents of care or nursing homes* | ☐ | ☐ |
| • *individuals to be recruited via self-help groups* | ☐ | ☐ |
| • *other (please specify)*: | ☐ | ☐ |

[8] Personal data shall mean any information relating to an identified or identifiable natural person. Attention: an individual may be identified through an IP address, workplace, job position data, information obtained by linking multiple large datasets (*big data*), and other sources. (Guidelines for the Assessment of Compliance of Research with Research Ethics, etikostarnyba.lt).

[9] Some planned Research involves vulnerable participants or participants who are unable to give informed consent. Please describe the appropriate safeguards or alternative measures in the Research summary.

| | Question | Yes | No |
|---|---|---|---|
| 2. | Are the planned Research participants dependent on or subordinate to the researcher outside the Research context (*e.g., employees who are subordinate to the researcher, or students taught by the researcher whose decision to participate or not participate in the Research could affect their academic results, etc.*)?[10] | ☐ | ☐ |
| 3. | Does the Research involve the participation of individuals without their knowledge and informed consent during data collection (*e.g., observation of individuals*)? | ☐ | ☐ |
| 4. | Does the Research methodology involve providing participants with incomplete or deliberately misleading information (*actively deceiving*)? (*e.g., participants will be intentionally given incomplete or misleading information, certain information will be withheld, or they will be deceived in another way, such that they are likely to object or feel distressed when the full and accurate information about the Research is later disclosed)*. | ☐ | ☐ |
| 5. | Does the Research involve the collection and/or use of personal data[5]? | ☐ | ☐ |
| 6. | Could the Research cause physical discomfort to participants? *(If in doubt, consultation with the Lithuanian Bioethics Committee is recommended.*) | ☐ | ☐ |
| 7. | Could the Research cause long-term psychological harm to Research participants (*e.g., psychological trauma, depression, insomnia, etc.*) that exceeds the level of risk encountered in everyday life? | ☐ | ☐ |
| 8. | Could the Research pose safety risks to Research participants (*e.g., research on domestic violence*)? | ☐ | ☐ |
| 9. | Does the Research participant require approval for compliance with Research ethics? | ☐ | ☐ |
| 10. | Is it planned to offer Research participants financial or other incentives for participation in the Research (excluding reimbursement of reasonable expenses and compensation for time)? | ☐ | ☐ |
| 11. | Will video recordings, photographs, or other data capable of identifying an individual be collected and stored during the Research?[11] | ☐ | ☐ |
| 12. | Does the Research involve the use of equipment that does not have CE certification[12]? | ☐ | ☐ |
| 13. | Has an application for the assessment of this planned Research's compliance with Research ethics been submitted, or is it planned to be submitted, to the Research ethics committee/commission of another institution? | ☐ | ☐ |

**If you answered "Yes" to any of the questions 1–11:**

*Please submit* to the Committee the completed Questionnaire, the Application, and the appendices specified in the Description for the assessment of the planned Research's compliance with Research ethics.

**If you answered "No" to all of questions 1–11, however** (*please indicate the reason*):

[10] Research participants who are in dependent or unequal relationships with the Research supervisor (e.g., the supervisor's students or staff) may also be regarded as a vulnerable group. If such participants are involved in the Research, appropriate measures must be taken to protect them from any potential adverse consequences (e.g., participation in the Research will not affect the researcher's assessment of the participant). This can be achieved by ensuring the anonymity of the participants as stakeholders. If such safeguards are applied, the "NO" option should be selected. In such cases, please describe the appropriate safeguards in the Research summary.

[11] It is mandatory to ensure that the collected data are stored securely in physical form and are not accessible to individuals who are not members of the Research team or who do not have the appropriate authorisation. In addition, the data must be anonymised (where possible) and destroyed after the specified retention period. The informed consent form must clearly state the participant's consent if anonymised data are intended to be published as open data.

[12] CE marking, obtaining certification, EU requirements – Your Europe (europa.eu).

☐ you are unsure whether the Research may cause significant psychological or physical harm or pose safety risks to participants,

☐ the selected Research method or the manner of disseminating the Research results may raise other significant ethical concerns,

☐ approval of the Research's compliance with Research ethics is required by the organisation funding the research or by a cooperation partner (e.g., an international project partner, etc.),

☐ The Research results are planned to be published in a scientific journal that requires the submission of confirmation of the Research's compliance with Research ethics.

It is *recommended* to apply to the Committee with an Application for the assessment of the planned Research's compliance with Research ethics, attaching the completed Questionnaire and other appendices specified in the Description.

## 4. Annexes

Please tick (☒) the appendices that must be submitted with the Application for the assessment of the planned Research's compliance with Research ethics, if you answered the relevant questions:

**If you answered "Yes" to Question 6:**

☐ If available, please submit the recommendation of the Lithuanian Bioethics Committee.

**If you answered "Yes" to Questions 5, 6, 7 or 11:**

☐ Please provide the Participant Information Sheet and the Informed Consent Form prepared for the Research participants. Where Research involves different participant groups, individualised forms shall be provided for each participant group.

**If you answered "Yes" to Question 12:**

☐ Please submit documentation confirming the safety of the equipment.

**If you answered "Yes" to Question 13:**

☐ Please specify the details of submission or planned submission. If applicable, please also provide the approval.

**Other attachments**

☐ A Data Management Plan, if required by the Research funding institution.

☐ Any other Research-related information that you consider necessary for the KK Committee's decision-making.

Should any deviations from the Research plan approved for compliance with Research ethics occur, or should other unforeseen circumstances arise (e.g., changes in personal data processing conditions or data collection methods), I hereby undertake to submit a new application to the KK Committee.

Research supervisor:

Signature:

Date:

**KAUNO KOLEGIJA**
**[NAME OF THE UNIT]**

# RESEARCH DESCRIPTION FORM

1. **Title of the Research**

2. **Research aim**

3. **Research objectives**

4. **Rationale for the Research**

5. **Partner institutions and countries in which the Research is conducted and/or planned to be conducted**

6. **Sources of Research funding**

7. **Research methods applied in the Research**

8. **Description of participants** (please specify which participant groups or individuals are selected and why, provide the planned number of participants, and any other relevant information)

9. **Description of the Research plan and individual stages**

10. **Methods of Research data collection and analysis** (please describe how data will be collected and documented, and which analysis methods will be applied)

11. **Description of the process for inviting individuals to participate in the Research**

12. **Procedures and specifics of informing participants about the Research and obtaining informed consent to participate in the Research**

*[The participant will be personally informed about the aim of the Research and the researcher conducting the Research.] The Participant Information Sheet shall include the first name, last name and telephone number(s) of the Research supervisor, who may be contacted in case of questions, as*

*well as the email address of the Kauno Kolegija Committee for the Assessment of Compliance of Applied Research with Research Ethics. The participant will be informed that they may withdraw from the research at any time, and that their data will not be used in such a case. It will be explained that, in all cases, the Research data will be analysed only in aggregated form and that neither the data nor the results of the data analysis will make it possible to identify the Research participants. After providing full and detailed information about the Research (both orally and in writing, and leaving the participant with a copy of the Participant Information Sheet), the participant will be asked whether they consent to or decline participation in the Research. [If the participant agrees to take part in the Research, they will be asked to sign.]*

**13. Planned duration of the Research**

**14. Duration of the participant's involvement in the Research**

**15. Description of potential risks and inconveniences to participants**

**16. Ensuring participant confidentiality and protection of personal data Please specify:**

a) which personal data will be collected;

b) whether the collected personal data will be coded and, if so, how this will be done;

c) who will have access to personal data that allow the direct identification of the participant (non-coded data) and for what purpose (persons overseeing the Research, ethics committees or other supervisory authorities, researchers involved in the Research);

d) how personal data will be processed (by automated means, in paper files, etc.);

e) how, where, and for how long the personal data of participants collected during the Research will be stored, and who will be responsible for this (researcher, unit);

f) confirmation that the participant's right to access their personal data, to request correction, deletion, or restriction of the processing of their personal data will be ensured if the participant decides to withdraw from the Research. If the Research does not provide the participant with the right, upon withdrawal from the Research, to request the deletion of their collected personal data, it is necessary to explain why this right is restricted.)

**17. Procedure for documenting adverse events or outcomes observed during the Research (if applicable)**

**18. Description of the conditions for suspending or terminating the Research, and description of the storage and destruction of Research participants' personal data**

**19. Explanation of the participant's right to withdraw informed consent to participate in the Research, and description of the actions to be taken by the researchers upon receipt of a request to withdraw informed consent**

*[The participant has the right to withdraw informed consent to participate in the Research at any time, without providing reasons.]*

**20. Benefits of the Research to the participant, reimbursement of expenses incurred and compensation for time spent participating in the Research, procedures and conditions for calculating and paying compensation, the payer.**

*[No compensation will be provided for time spent or expenses incurred.]*

**21. Publication and dissemination of Research results**

*[The results will be published in X scientific articles and/or a monograph, presented at scientific conferences, and disseminated through media, etc.]*

**22. Please indicate whether documents granting permission to conduct the Research will be obtained, and from which institutions.**

*[An XXX permit will be obtained to conduct the research.]*

**23. Research supervisor's signature, date**

Annex 6 to the Procedure for the Assessment of Compliance of Applied Research with Research Ethics

**KAUNO KOLEGIJA**
**[NAME OF THE UNIT]**

_____
(Enter the name of the institution/organisation where
the Research is planned to be conducted and the surname of its head)

**APPLICATION**
**FOR CONSENT TO CONDUCT RESEARCH**
[date]
[place]

I hereby request permission to conduct Research on the topic *[insert the Research title]* at *[insert the name of the institution/organisation]*, under your management.

The aim of the Research is *[specify the aim].*
Research start date: DD-MM-YYYY
Research end date: DD-MM-YYYY
The Research will be conducted by: *[specify the researchers' surnames, positions, and institutions]*.

The Research will be conducted using [*indicate the Research methods and participant sample*]. Participant confidentiality will be ensured, as [e.g., the questionnaire is anonymous and participants' names, surnames, and other personal data will not be identifiable]. The Research results will be disseminated exclusively in aggregated form.

Following the completion of the Research, the aggregated Research data will be provided to you.

| | | |
|---|---|---|
| [Research supervisor] | [signature] | [name and surname] |

I hereby agree:

| | | |
|---|---|---|
| [Position] | [signature, date] | [name and surname] |