

APPROVED

by Order No V-60 of the Ombudsperson for Academic Ethics and Procedures of the Republic of Lithuania of 10 December 2020

(amendment by Order No V-24 of the Ombudsperson for Academic Ethics and Procedures of the Republic of Lithuania of 10 May 2021)

GUIDELINES FOR ETHICAL REVIEW

SECTION I GENERAL PROVISIONS

1. The purpose of the Guidelines for Ethical Review (Guidelines) is to help the Lithuanian academic community to review the compliance with research ethics by assuring the abidance by the principles of academic integrity established for the particular research, and to protect the interests of the research participants and animals used for research. The application of the ethical review procedure should become an indicator of research quality, when coping with the challenges and problems of research reliability, integrity, and comprehensiveness, as well as with management of collected data.

2. The Guidelines were prepared in consideration to the European Code of Conduct for Research Integrity (the European Federation of Academies of Sciences and Humanities, ALLEA, revised edition, 2018), the Guidelines of the Finnish National Board on Research Integrity (2019), the Guidelines for Research Ethics in the Social Sciences, Humanities, Law and Theology prepared by the Norwegian National Research Ethics Committees (2016), general ethical principles and research policy involving human participants and use of personal data of some of the best European universities, and the Declaration of Helsinki. The documents listed above are among the most advanced documents revealing the good practice provisions on the academic ethics in scientific research not only within the European but also within the global context. Besides, the Recommendations for Codes of Academic Ethics in Research and Higher Education Institutions of the Office of the Ombudsperson (edition of 2020), the Guidelines for Publication Ethics prepared by the Lithuanian University Rectors' Conference, and the Guidelines on Open Access to Scientific Publications and Data prepared by the Research Council of Lithuania were taken into consideration in order to integrate the Lithuanian practice in this area.

Amendment by Order No V-24 of the Ombudsperson for Academic Ethics and Procedures of the Republic of Lithuania of 10 May 2021

3. Definitions:

3.1. Institutional review board means an organisational unit that grants an ethical approval.

3.2. The concepts related to the consolidated underlying issues of protection of the children rights, child's capacity, participation in decision-making, listening to the child's opinion, response to violations of the children rights and other issues relevant for research involving children shall be defined in the Law on Fundamentals of Protection of the Rights of the Child of the Republic of Lithuania.

3.3. The concept of the socially vulnerable persons is defined in the Action Plan on Expansion of the Social Coverage for 2020–2023¹.

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

SECTION II CONTEXT

¹ Order No A1-791 of the Minister of Social Security and Labour of the Republic of Lithuania of 20 December 2019 "On Approval of the Action Plan on Expansion of the Social Coverage for 2020–2023".

4. The ethical review and approval have become an integral part of the researcher's activities in the world. When conducting the research, the community of researchers encounters challenges every time when it has to evaluate the ethical factors, therefore, the ethical review is becoming one of the tools used to plan the research and to get ready for proper compliance with ethical values and principles that assure quality of research conduct. The researcher proves the ethical approach through the following: a) active consideration of the ethical problems that may arise in the research conduct or because of the research itself; b) appropriate evaluation of possible risk caused by the research to persons, communities, and society; c) observation of any changes that may affect ethical aspects of the research.

5. The essential changes in this area are needed simply because the requirements for academic ethics in the world are growing and in order to get funding for research or to publish their results in scientific journals that have high impact factor, the researcher needs to have an ethical approval more and more frequently. This document provides general and special ethical provisions applicable for particular research that needs critical evaluation and consideration.

6. The document of such character and the authority that implements are of the national level in some European countries. For example, the Swedish Ethics Review Authority examines the applications for compliance of the research involving humans and human biological substance with research ethics; the Finnish National Board on Research Integrity operates as an appeal authority. These examples show that ethical review is a significant factor of research quality assurance, the implementation practice whereof on the national level is very diverse.

7. It is recommended for research and higher education institutions to instil the ethical review procedure because of the following reasons:

7.1. In order to assure dignity and welfare of the research participants;

7.2. In order to assure compliance with high values of academic ethics and appropriate (personal) data management;

7.3. In order to reduce the risk related to research participants, researchers and third parties;

7.4. In order to agree about common quality- and science-based criteria for research conduct;

7.5. In order to increase the benefit granted by research to the society and to raise the society's trust in the researching community.

SECTION III INSTITUTIONAL REVIEW BOARD

8. It is recommended to form an institutional review board (Board) for each research and higher education institution. The activities of this Board shall be based on the ethical principles (e.g., objectivity, responsibility, transparency). The research and higher education institution shall provide information² on the Board's members on its website (name and surname, area of competence, term of tenure). The Board's composition, operating principles and other processes shall be determined in the Regulations on the Board's Activities that would be approved by the rector/director of the research and higher education institution. The regulation related to the Board's agenda and ethical review and ethical approval should be easily accessible to the researchers on the institution's website. The main function of the Board is to evaluate compliance of the research with research ethics before the research is started. However, the Board may also foresee functions of supervision of the performed ethical review and consultations during the research conduct.

9. If necessary, it is recommended to cooperate with other authorities, depending on their competence areas (e.g., with the Lithuanian Bioethics Committee regarding biomedical research,

² More information about personal data publicising, see the methodical information of the State Data Protection Inspectorate, "Personal data publicising – what is publicised, the scope of publicising, and the purpose thereof", <https://vdai.lrv.lt/lt/naujienos/asmens-duomenu-viesinimas-kas-viesinama-kiek-viesinama-ir-kokiu-tikslu-tuo-siekiamo>

with the Office of the Equal Opportunities Ombudsperson regarding assurance of equal opportunities, with the State Data Protection Inspectorate or with the Office of the Inspector of Journalist Ethics regarding data protection, etc.), on application of operating principles and/or complex cases.

10. It is recommended for the research and higher education institutions that instil these Guidelines to assure sufficient human resources, e.g., the Board's secretary employed by the research and higher education institution at least on part-time basis should be present.

11. The competence of the Board members has to cover main disciplines of the research and higher education institutions and typical ethical issues related to the research area.

12. The Board shall decide when ethical review should be applied, while the Office of the Ombudsperson shall recommend only to implement that application in several stages, e.g.: 1) research of PhD students, research proposals; 2) research projects; 3) commissioned research; 4) other research.

13. The Board shall be formed for the period of three years. In order to safeguard the Board's activities, it is recommended to appoint its members for different tenure terms; however, the same member cannot be appointed for two successive terms. It is recommended to form the Board from the members, who could represent majority of the units of research and higher education institutions, or to make a sole list of members that would be used to appoint the members depending on the agenda's issue, and at the same time to rotate the appointed Board members randomly only for a year (or a meeting). The information about the Board members specified in Paragraph 8 herein shall be available on the website of the research and higher education institution.

14. Each employee of the research and higher education institution has the right to offer one employee satisfying the requirements set for the structure of the Board members to the Board. Upon suggestion of the stakeholders, the research and higher education institution appoints one member from the stakeholders to the Board.

15. At least six persons, who have received the majority of the votes of the employees of the research and higher education institution, shall be delegated to the Board. A chair, deputy of the chair (if appointed) and a secretary shall act as permanent members of the Board. The Board's members should have as wide academic and/or professional experience as possible so that it would be possible to assess the compliance of the research planned in the research and higher education institution with research ethics as thoroughly and properly as possible:

15.1. at least two members should be employed in the research and higher education institution, where their competence is approved in the area of appropriate methods of research data collection and analysis according to the field of research and research object; they should have 10-year experience in research activities;

15.2. at least one member should work in the area of philosophy/ethics and have 5-year experience in research activities;

15.3. at least one member should work in the administration of the research and higher education institution and have 5-year experience in research management;

15.4. at least one member should work as a data protection officer in the research and higher education institution and have 2-year experience in data protection;

15.5. at least one member should be from the stakeholders of the research and higher education institution operating there for at least 2 years.

16. The Board member has to be able to evaluate whether the proposed research is acceptable in accordance with the institutional provisions (e.g., other requirements), institutional obligations (e.g., financial and human resources) and applied provisions of professional behaviour and practice (e.g., Guidelines, code of (academic) ethics and other legal acts).

17. The Board members must be of impeccable character and sign the commitment to confidentiality that complete their tenure term by 5 years. The secret of personal data shall be stored for indefinite period. The evaluation criteria of impeccable character shall be determined and the evaluation shall be performed by the research and higher education institution. It should be noted that information related to convictions and criminal activities (e.g., confirmations about

absence of previous convictions in any form) may be collected only when such obligation is provided in laws.

18. The Board member, who encounters a conflict of interests because of the submitted research project, shall withdraw immediately when the situation is learnt (e.g., before the meeting of ethical review) and notify the chair of the Board or the deputy chair thereof in writing. Such Board member cannot take part in review of the primary or continued research project, unless the information required by the Board has to be submitted. If the chair of the Board encounters a conflict of interests, s/he shall notify thereof according to the procedure established by the institution.

19. If necessary, the Board may engage independent experts of certain field, who would provide their opinion on the application for ethical review and who would consult the Board members. The experts shall have no right to vote on the decisions.

20. If the Board members review regularly the researches related to socially vulnerable persons (e.g., children, prisoners, persons with disabilities) or persons, who are in unfavourable economic or educational situation, they should include *ad hoc* one or several persons working in the areas related to the research participants.

21. The structure and term of the Board members shall be approved by the rector/director of the research and higher education institution.

SECTION IV GENERAL PRINCIPLES OF COMPLIANCE WITH RESEARCH ETHICS

22. Regardless of the research area and/or selected methods, general principles of compliance with research ethics shall be applied for the conducted researches. These principles are needed to check, how the ethical problems are needed and how it has been prepared to solve them. The researcher shall comply with the principles of reliability, honesty, respect, and accountability.

23. The reliability principle is implemented through the following:

23.1. the research has to be conducted (conceived, revised) in such a way as to assure its quality, consistency and to increase the possibility to receive objective results;

23.2. the confirmation of ethical approval has to be provided in the research report (e.g., publication);

23.3. the transparency of research goals has to be aimed at and the suitable methods of data collection and analysis used to achieve them have to be selected;

23.4. the possible harm and benefit of the research have to be foreseen, in consideration to the interests of various research participants (groups), communities and society, and risk reducing measures.

24. The honesty principle is implemented through the following:

24.1. all the planned research stages are followed through;

24.2. the Board is notified immediately about the changed research circumstances or another unforeseen information related to the conducted research;

24.3. the information about the raised conflict of interests is disclosed to the Board;

24.4. all the responsibility is assumed for research outputs and their announcement, research consequences and impact on the affected persons.

25. The respect principle is implemented through the following:

25.1. the information is provided to research participants about personal data processing of data subject in compliance with 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 (GDPR), and sufficient information is provided to enable the persons to decide about their participation in the research (informed consent);

25.2. voluntary participation of the research participants in the research is assured;

25.3. it is made sure that the research participants know and may withdraw from the research at any time without stating a reason and without feeling any pressure to take part in the research;

25.4. the personal data provided by the research participants are stored in compliance with strict procedure of confidentiality and anonymity.

26. The accountability principle is implemented through the following:

26.1. the planned and conducted research of the research and higher education institution is registered;

26.2. the conditions are created to learn the research outputs;

26.3. the Board is informed about the encountered conflict of interest;

26.4. the persons undertake to observe the requirements related to personal data protection and to be able to prove this.

27. The principal investigator has to present the research plan to the Board for ethical approval, if:

27.1. the intervention methods are applied for research (e.g., social experiments, action research through participation, etc.);

27.2. the research deviates from the principle of informed consent;

27.3. the research participants are children under 18 years old and the research is conducted in the pre-school or pre-primary education institution, in general education school and in children's custodial institutions, personal health care institutions, etc.;

27.4. the research shows that the research participants experience especially strong irritant, while special knowledge is needed to assess the probable damage (e.g., related to violence, pornography, etc.);

27.5. the research may cause long-term psychological damage (e.g., psychological trauma, depression, insomnia, etc.) that would exceed the hazards encountered in everyday life;

27.6. the research is related to safety risk of the research participants (e.g., research on violence in family);

27.7. it is requested by the research participant, research funding organisation or a cooperation (e.g., in case of international project, commissioned research, etc) partner (party). The implementation of this provision in practice has to be described and made public on the institution's website;

27.8. the research plan for ethical approval has to be submitted if the research participants are socially vulnerable persons and it is required by legal acts;

27.9. some unforeseen circumstances occur during the research conduct (e.g., the conditions of personal data processing, data collection method, etc. change) and they affect the research plan, to which the ethical approval has been granted.

28. Other possible criteria of the research plan for ethical approval are provided in Paragraph 46 herein.

SECTION V IMPLEMENTATION OF THE ETHICAL REVIEW

29. The Board's meetings shall be convened when needed or when determined so by the research and higher education institution.

30. Upon receipt of the application (an application containing the research plan and summary, researcher's personal data (name and surname, work e-mail address, phone number (if available)/e-mail used for studies), form of the informed consent, data for research participants (e.g., questionnaire, interview description), data management plan) for ethical review, the Board shall organise the meeting within 10-15 working days. The applications submitted later shall be examined in the next meeting of the Board. The access procedure to the applications shall be particularly elaborated in the Regulations on the Board's Activities.

31. The Board's meetings have to be closed. If several research projects are considered in the same meeting, the associated persons shall be called separately.

32. The board's meetings shall be convened and conducted by the chair of the Board. If the documents for ethical review are submitted by the Board's: a) chair, the meeting shall be convened by the deputy; b) member, that member has to withdraw from the meeting and another person that satisfies the qualification requirements is assigned to substitute him/her.

33. The Board shall decide whether the research complies with research ethics in 20 working days (10–15 working days for organisation of the meeting and examination) after the application has been submitted, and the Board's chair (or secretary) shall notify about the decision following the notification procedure established Regulations on the Board's Activities.

34. If the Board identifies the shortages in the documents, it shall identify them and suggest examining them in the next meeting.

35. The Board shall be objective, impartial, and independent from the researcher or any other inappropriate influence in its activities. When the compliance with research ethics is assessed, the Lithuanian and/or foreign laws and legal acts (of the countries where the research is conducted) and the valid international norms and standards have to be taken in consideration; however, they cannot reduce or cancel any protection provided for the research participants, as indicated at the time of the documents' submission.

36. The regulation related to the ethical review procedure and the related implementation documents have to be made public on the website of the research and higher education institution in the languages, in which the website is written or in which the research activities are conducted.

SECTION VI REQUIREMENTS FOR REGISTRATION FOR RESEARCH

37. A register of the ethically approved research may be formed in the research and higher education institution. The terms of use shall be established by the research and higher education institution.

Amendment by Order No V-24 of the Ombudsperson for Academic Ethics and Procedures of the Republic of Lithuania of 10 May 2021

38. The data on research selected by the register of the ethically approved research may be publicly available on the website of the research and higher education institution only within the scope determined in the regulations of the register of the ethically approved research adopted by research and higher education institution. Besides, to promote open science, it is recommended to download the research data into the data archiving repositories according to their requirements.

39. The following data on research may be available in the publicly accessible register of the ethically approved research:

39.1. researcher's name, surname, affiliation (and/or partners) (not only the institution, but also the allocation to the group of academic society should be provided: teacher, researcher, student) and e-mail address;

39.2. name of research;

39.3. research field(s);

39.4. created and/or planned types of scientific production (e.g., article, monography, textbook, video record, etc.);

39.5. methods of research data collection;

39.6. methods of research data analysis;

39.7. funding sources;

39.8. keywords.

40. The list of publicly available data provided in Paragraph 39 herein is not exhaustive, save for the personal data³.

SECTION VII SPECIAL REQUIREMENTS FOR COMPLIANCE WITH RESEARCH ETHICS

³ The research and higher education institution has to evaluate independently, whether the regulations of the register of the ethically approved research managed by it should not be coordinated with the State Data Protection Inspectorate.

FIRST SUBSECTION BIOMEDICAL RESEARCH

41. The researcher, who is conducting biomedical research, shall act in compliance with the Law on Ethics of Biomedical Research, Regulation of the Procedure on Issue of Permits for Biomedical Research (edition of Order No V-27 of the Minister of Health of the Republic of Lithuania of 8 January 2016) and other special legal acts governing clinical research of pharmaceutical products, clinical research with medical means, etc.

42. The researchers shall refer to the Lithuanian Bioethics Committee or regional (Vilnius or Kaunas) biomedical research ethics committee regarding ethical approval.

43. The Lithuanian Bioethics Committee issues permits for biomedical research, when the biomedical research is planned for the territory assigned to the competence of more than one regional biomedical research ethics committee.

SECOND SUBSECTION RESEARCH (EXPERIMENTS) WITH ANIMALS

44. The researcher, who is conducting a research related to animals, shall act in compliance 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 on Welfare and Protection of Animals of the Republic of Lithuania, Order No B1-866 of the Director of State Food and Veterinary Service of the Republic of Lithuania of 31 October 2012 on the approval of requirements for the keeping, care and use of animals for scientific and educational purposes, and the European Convention for the Protection of Vertebrate Animals Used for Experimental and Other Scientific Purpose.

45. The State Food and Veterinary Service issues permits for scientific research and experiments related to animals.

THIRD SUBSECTION RESEARCH IN OTHER AREAS, WHERE RESEARCH METHODS OF SOCIAL SCIENCES ARE USED

46. The principal investigator may also submit a research plan for ethical approval to the Board, if:

46.1. the researcher is not sure whether his/her research may cause significant psychological or physical damage or have signs of safety hazard for research participants;

46.2. the method chosen by the researcher or the mode to publish the research outputs may cause other significant ethical problems;

46.3. it is planned to announce the research outputs in the scientific journal that has the requirement for ethical approval.

47. The list of cases when the research plan is needed provided in Paragraph 46 herein is not exhaustive.

FOURTH SUBSECTION PRINCIPLES OF RESEARCH ETHICS IN HUMANITIES AND SOCIAL SCIENCES

48. Respect of the research participants

48.1. Voluntary participation

48.1.1. The participation in research shall be voluntary and based on the informed consent.

48.1.2. The informed consent is usually defined as a free, prior and informed consent (FPIC) to take part in the research. Various types of informed consent are distinguished, e.g., broad

consent, blanket consent, open consent, portable legal consent, meta-consent, dynamic informed consent, informed consent, etc. The most suitable type of informed consent that would satisfy the requirements of GDPR Articles 7 and 13 shall be selected for each research.

48.1.3. The research participants may give their consent orally (it has to be recorded, e.g., audio record) or in writing. When the audio record is made, the research participant has to be informed about personal data protection according to GDPR Article 13, e.g., consent is given during conversation, answering to the questionnaire, or it is indicated in the request to respond in writing that the subject has agreed to be examined. It is recommended to give priority to written informed consent in the research.

48.1.4. In case of institutions, whose representatives/charges are researched (e.g., in prisons, foster homes, hospitals, etc.), it is important that each person participating in the research would give a consent. In the exceptional cases, the authorised person may give the consent to participate in the research (in accordance with the legal acts governing authorisations), or the person authorised to make decisions in the name of the research participant, who is incapable to make independent decisions (e.g., the person is (legally incapable). Another person may give consent to participate in the research instead of research participant (e.g., the institution's leadership); however, only the research participant may give consent for personal data processing. When the research is conducted in institutions, the researcher, and the institution both have to secure person's privacy.

48.1.5. If intervention methods are applied in the research or physical impact is made on the research participant, only written consent or consent in other evidentiary mode is needed.

48.1.6. In order to observe the behaviour in public space (e.g., trade place, train station or higher education institution), no informed consent is needed, unless personal data are collected and information on particular persons may be derived from the research. This also does not cover audio and video records, where the persons may be recognised. The research should not cause other obstacles, as well (e.g., to perform exhaustive observation of one person), because the obstacles are determined by the context (character of research, environment, other persons).

48.1.7. The consent may be specific or general. The form of general consent has to include the data recording and archiving forms and conditions, conditions of use of research data in the secondary research, and information about personal data processing of the research participant according to the requirements of GDPR Article 13.

48.1.8. If the data received from the research participants are verified with the data in official registers, the research participants have to receive thorough information about the data registers used, about the information that was/will be collected from these registers about the research participants, and other information indicated in GDPR Articles 13 and 14, respectively. The information about the data collected from the public register before the consent of the research participant is given shall be provided within the terms of Paragraph 3 of Article 14 of the GDPR.

Amendment by Order No V-24 of the Ombudsperson for Academic Ethics and Procedures of the Republic of Lithuania of 10 May 2021

48.1.9. The research participants have the right to withdraw from the research at any time, but this shall not mean that their early contribution (e.g., interview, etc.) shall not be used in the research. The researcher has to inform the research participants about the terms of use of collected data after the participant's withdrawal. This information and the terms of use of the data provided by the research participants have to be discussed with the person before that person makes a decision about participation in the research.

48.1.10. The passive/IMPLIED consent may be considered in exceptional cases, but only if: a) the applicable consent would cause essential or evident defects related to the research quality or purpose and/or the researcher's interests; b) the minimum burden is imposed on the research participants and there is no risk; c) special efforts are made to inform the research participants and/or their representatives about the research and their right to refuse; d) the refusal procedure is simple.

48.2. Participation of underage persons in research

48.2.1. The research about underage person (children and adolescents) is valuable and important. The specific needs and interests of the underage persons (children and adolescents)

have to be protected by adults. The children (in general sense) are developing personalities, whose needs and capacities differ in certain growth stages, so, the researchers have to know the development and psychology of children and adolescents to be able to adjust the selected methods and research fields to the age of the research participants. The information about the research and its consequences has to be provided in consideration to the specific age. The underage persons shall be also informed about voluntary participation in the research and a possibility to withdraw from the research at any time.

48.2.2. If children participate in the research, the researchers usually receive the consent of parents or custodians, who should be granted a period of at least 10 working days to express the consent (this period does not coincide with the beginning of the research), to get familiar with the information sheet about the research intended to the research participant provided by electronic communication means (Annex 1) and informed consent form (Annex 2). If the data for the research are collected without the necessary consent of the parents or custodians⁴, the parents or custodians shall have the right not to allow their child to take part in the research. However, it is important to regard the underage persons as independent persons, so, in addition to official consent of the parents or custodians, it is important that the underage persons would make the respective decision in the scope that they can. The exception is made with regard to the personal data that may be received only with consent of the parents or custodians. The children may be involved in the research only when there is no other mode to receive the needed data and if the purpose of the research is to get scientific insights or to improve the medical treatment methods (e.g., integration of persons with disabilities, etc.).

48.2.3. There is no particular (universal) age limit, until which the child is able to make (partially) independent decision to participate in the research, thus, when the child's possibilities and scope of participation in this process are evaluated, the opinion about the child's ability to formulate own views, the child's age, level of maturity and interests have to be taken into consideration. The principle of priority of the best child's interests is among the underlying principles that should be used to make any child-related decisions, in case of conflict of interests of the child and some other person, etc.

48.2.4. When children participate in research, the confidentiality principle has to be observed strictly. However, there may be situations when the researchers have a legal or ethical duty to provide the confidential information to the close relatives, other adults or agencies that safeguard protection of the children rights (e.g., the duty to notify is applied if the researchers learn about harassment, abuse, or negligent care of the child).

48.2.5. The researchers are able not to ask for the consent of the parents or custodians when the parents, custodians and underage persons may have differences in their values and interests. This may be considered as an obstacle for collection of thorough research data about the living conditions and behaviour of the underage persons.

48.3. Research involving persons from vulnerable groups

48.3.1. The researchers have a special duty to respect the interests of vulnerable groups during the research conduct. The vulnerable persons or persons in unfavourable situation are not always ready to protect their interests when communicating with the researchers. It should be remembered that the procedures of receiving the informed consent do not necessarily assure the determination of the persons to participate in the research or to protect them from unsubstantiated strain.

48.3.2. The persons within the vulnerable groups may not want to be research participants because of fear of unfavourable public attitude, so, the research may be conducted in accordance with GDPR Articles 6 and/or 9.

48.4. Information to the research participants

48.4.1. The information that has to be provided to the research participants depends on the data collection methods. In case of qualitative, quantitative, and mixed research, the information about the research has to be presented to the research participants.

⁴ The procedure of parents' notification and other conditions related to collection of the research data without the necessary consent of parents and custodians shall be established by the legal acts of the research and higher education institution.

48.4.2. The information about the research shall include at least the following items: 1) contact information of the researcher; 2) topic of the research; 3) method and expected duration of data collection; 4) purpose of data collection, their further use, archiving methods for secondary use; 5) voluntary participation mode; 6) presented information about the expected research benefit and possible risks for the research participant; and 7) information provided in GDPR Article 13 about personal data processing of the research participant.

48.4.3. The research participants may request additional information on the research. The additional information may be related to, e.g., 1) the research, 2) mode of safeguarding confidentiality and anonymity of personal data and storage of personal data after the research, 3) how and when the research outputs are published, 4) external funding sources.

48.4.4. The research, where the method of experiment is applied, must contain enough information on the experiment's plan. The experimental research in different areas differs a lot; therefore, the information's comprehensiveness shall be also determined and substantiated by the researcher.

48.4.5. The requests of the research participants for additional information related to the research and the needed data of the research participant shall be answered in simple and understandable language, as honestly and accurately as possible.

48.5. Data collection in alternative modes

48.5.1. All the needed information may be provided to the research participants; however, their participation cannot be voluntary in certain cases (e.g., the research may be related to observation of conscripts and their work processes, when the organisation's leadership has given the consent for research).

48.5.2. Insufficient information may be provided to the research participants (e.g., the observation data were collected from emergency service or while driving with the police, when the researcher cannot disclose that s/he is conducting the research), or the misleading information about the researcher's role is provided (e.g., the researcher working undercover may mislead the research participants while investigating the discrimination cases).

48.5.3. The researcher is collecting data for the research without self-identifying and providing misleading information about the research content.

48.5.4. When the research participants are observed in public space, their consent is not needed. The technical registration equipment may be used in public space if the principles of privacy and data protection are observed in the course of data use, storage and archiving.

49. Risk evaluation

49.1. The data collection, storage and consequences may cause damage to the research participants when the research data and/or results are published.

49.2. Avoidance of psychological damage

49.2.1. Avoidance of psychological damage includes respectful treatment of the research participants and ethical publishing of the research results in scientific publications.

49.2.2. The topic's sensitivity and privacy limits depend on the research participants, first of all. If the research participants know, what questions are going to be solved on the basis of the presented information, when they give the informed consent, they express the desire to participate in the research and knowledge about the research scope and methods. While participating in the research, the research participants regulate their participation and avoid the situations and questions that they consider harmful.

49.2.3. If the research involves interaction with the research participants (e.g., research participant's observation, interview), all the data about the research participants have to be reviewed respectfully, preserving their dignity.

49.2.4. The researcher has to make sure that the principle of voluntary participation is also observed in the cases of direct relation with the research participants. The researcher shall always (unless no objective possibilities are available) make sure that participation of the research participant is voluntary, especially, when the direct contact with the research participants is maintained. Annoyance, embarrassment, fear, or physical fatigue may serve as a sufficient ground for the researcher to cancel the research in the scope related to the topic, although the research

participant does not express a clear refusal to continue. It is very important to assure voluntary participation of the research participants investigated in the institutions (e.g., in hospitals, prisons, children protection institutions, homes for elderly, etc.). For example, unnecessary psychological tension may be avoided if it is tested beforehand, how long it will take for the research participants to perform the research tasks.

49.3. Avoidance of financial and social damage

49.3.1. The financial and social damage to the research participants is more probable if ethical principles related to privacy and data protection are not observed. According to the ethical principles, when the confidential information is processed and stored, it is necessary to explain to the research participants, how the protection of confidential information is ensured.

49.3.2. The scientific publications may have negative consequences to the research participants. The risk of damage is the biggest when the results are presented in non-ethically mode, e.g., when false results not substantiated by comprehensive research or systemic analysis are published. In order to avoid such cases, it is recommended to assure open access to scientific publications.

49.3.3. The researchers should avoid any damage to the research participants that could be caused by scientific publications. However, this principle should not prevent from publishing the research results that may be disliked by the research participants in any aspect. The task of the researcher is to present the information regardless of the reaction of the institutions' leadership, research participants and other persons. The research related to use of power and operation of social institutions (e.g., family, universities, hospitals, business enterprises, legal system) cannot be restricted because their results may have negative impact on the research participants. The best way to ensure the freedom of research is an accurate and systematic research conduct and substantiated and properly announced results. The researchers (co-authors), collaborators, publishers, owners of publications and editors, reviewers and supporters shall be responsible for compliance with the principles of academic ethics in scientific publications.

49.4. Evaluation of risk of damage caused by research

49.4.1. The research related to possible risk that was not taken into consideration by the research participants and the research that may cause damage and affect the ordinary life, have to be evaluated in advance. If the researcher knows about the risk of long-term mental damage exceeding the risk or that the research participant's safety will not be assured, the researcher has to state this to the Board when applying for ethical review, and to specify the modes, how to reduce the risk. If unforeseen damage is learnt during the research conduct, the researcher has to suspend the research and to re-evaluate the risk of damage, to notify the Board thereof, and to present the plan, how to avoid the unforeseen damage.

50. Confidentiality and data protection

50.1. Data protection is the most important privacy area for collection and processing of research data and publishing of research results. When the research is conducted, it is important to assure: 1) protection of research data and confidentiality; 2) storage and management of research data; 3) quality of scientific publications. The purpose of data protection is to be able to disclose the research data and results, while preserving confidentiality of the research participants at the same time.

50.2. The principles of privacy protection shall be applied to publicly available material or announced data that may be related to the persons and their activities in the political, business, and cultural areas. For example, when the research is conducted using the biographical method, the information disclosing the privacy has to be coordinated with the person, whose data are collected, or with his/her authorised person.

50.3. The main principle of personal data collection and storage is the need of personal data for research. The personal data shall be collected for the established, clearly defined, and legitimate purposes and they shall not be processed further in the mode incompatible with such purposes. If it is possible to analyse the research data validly without direct identifiers and there is no ground to store the identifiers, only the data, from which the identifiers have been removed, may be stored, and processed for secondary research.

50.4. The data containing identifiers may be collected and used when it is needed for some specific research. Upon receipt of the informed consent, the data may be also stored for secondary research containing identifiers. It may be necessary to process and store the identifiers during the research in order to carry out the data audit and to avoid the data fabrication or falsification, to investigate the allegation of academic ethics, and in case of the need to analyse the data of historical or cultural significance. All the present data may acquire historical or cultural significance in time; however, it shall be evaluated and substantiated by the researcher in each particular case.

50.5. The research data confidentiality depends in the restrictions imposed on data processing, use and storage. The research data may be used or transmitted for the purpose of data audit if they are given to the customer in case of commissioned research. The disclosure of research data or transmission of the data in such a way as to affect evaluation, treatment or situation of individual research participants is considered especially inappropriate. The non-anonymised research data cannot be transmitted to media or used for commercial purposes.

50.6. The exception of confidentiality assurance is the duty of each citizen to report the threatening severe crime that may be prevented still. The researcher is not obliged to disclose information about the already committed crimes unless such disclosure can prevent imminent severe crime.

50.7. Data protection: processing, storage, and publication

50.7.1. The personal data means any information relating to an identified or identifiable natural person. The person may be identified using the IP address, workplace, job title's data, information received by linking several big data, etc.

50.7.2. The privacy of research participants has to be respected, so the personal data have to be regarded as confidential. The personal data that may help to identify the research respondents have to be stored in such a way as to eliminate the link between the research participant and the research outputs or to protect it appropriately (e.g., to allocate the identifier, to encode). Besides, the information disclosing participation of the research participant should be also protected. It is especially important in case of vulnerable groups or sensitive information.

50.7.3. The researcher shall grant the access to all the data related to the research participant within 30 calendar days after submission of the latter's data, unless the data have been completely anonymised or linked to other data participants or shall remove all the personal data of the research participant upon the latter's request.

50.7.4. The researcher shall use the personal data only for the pre-formulated purposes that have been introduced to the research participant.

50.7.5. The researcher cannot transmit the personal data to third parties without authorisation of the research participant. The personal data may be transmitted to third parties only for the research purpose, upon receipt of the written authorisation of the research participant. Sometimes the data related to the research participant are needed for teaching purposes. The research participant shall give a respective authorisation.

Amendment by Order No V-24 of the Ombudsperson for Academic Ethics and Procedures of the Republic of Lithuania of 10 May 2021

50.7.6. The researcher shall undertake suitable technical and organisational measures to prevent unlawful access to the personal data or their processing. These measures may include use of locked cabinets, rooms, cloud computing, passwords and/or encoding, and registration of persons, who have access. The protection of the data containing identifiers has to be planned diligently, while special maintenance and restriction have to be applied for especially sensitive data. Careless data use or unprotected electronic data transmission cannot cause hazard to the privacy protection of research participants.

50.7.7. The security solutions of the data containing identifiers are especially needed to protect the vulnerable research participants (e.g., persons under psychological, social, economic, political or other impact, discriminated, prosecuted persons or persons who encounter violence) from identification and/or the related information. For example, the privacy protection of certain person may affect the registration mode of the informed consent.

50.7.8. The researcher has to decide, where the personal data containing identifiers will be stored, in which stage and in what scope the data will be destroyed, and how the research data will be stored and archived for secondary research. It is also necessary to determine, how the personal and research data will be protected electronically (e.g., backup copies, user names, processing of the right of access to data in the computers not related to the network, when needed). The anonymity of the research data has to be ensured irrevocably, unless the research participant agrees to be identified (e.g., when the experimental interview method is applied).

50.8. If the data are collected and/or stored externally:

50.8.1. When the personal data are stored not in the research and higher education institution, i.e., when the research and higher education institution contacts another research and higher education institution or commercial enterprise, it shall evaluate carefully whether the data storage and other processing comply with GDPR requirements;

50.8.2. Storage outside the European Union's Member States should be avoided. If the researcher wants to store the data in the facilities, repositories and other places operating in third countries, the researcher has to evaluate, on which ground (among the specified in Chapter V of the GDPR V, i.e., Articles 45, 46 or 49) the personal data are stored, whether additional safeguards or the permit of the State Data Protection Inspectorate are needed for that purpose, whether the agreement with the subject, to whom personal data processing would be transferred, as provided in GDPR Article 28, is present. The same shall also apply for storage of the personal data in the servers of the enterprise operating in the United States of America or third countries⁵. It should be noted additionally that the research participant has to be informed about the data storage place and possible (even little probable) consequences prior to consenting to participate in the research.

50.8.3. If necessary, it may be demanded that the researchers or the organisation providing the data processing services, and other research employees processing the data with identifiers would sign a commitment to confidentiality. The research supervisor and/or the principal investigator shall be responsible for written commitments to confidentiality. The confidentiality of the data containing identifiers shall be applied also for the persons using the data, although no written commitments to confidentiality are used. When the commitments to confidentiality are not collected, the data controller (processor) shall evaluate, how to inform the aforementioned persons about their duty to preserve secret of personal data and consequences of violation of this obligation.

50.9. If the research is publicly funded, the researcher has to safeguard preservation of the data received in the course of implementation of the research project in a digital format, as well as their transmission to the institution and/or data storage after the project's completion. After completion of the research project (publication of the research results), the personal data have to be stored at least for the period fixed by the research funding organisation. The exception of personal data storage may be applied for longitudinal research, for example. However, the identifiers have to be stored separately from the research data, where appropriate conditions should be determined for access to the data.

50.10. According to the concept of open science and international scientific recommendations (e.g., FAIR Guiding Principles for scientific data management and stewardship; <https://www.go-fair.org/fair-principles/>), the research data (anonymised, if necessary) shall be stored for at least 10 years after their publishing or for the period offered by the data repositories under the chosen license. Not published research and personal data of the research participant may be stored and destroyed in the procedure established by the research and higher education institution.

50.11. If there is no ground to store the identifiers, they have to be destroyed immediately after the respective publication, e.g., the hardcopies of identifiers have to be destroyed or the identifiers have to be deleted from the electronic storage media without delay. The identifiers that are stored for further contacts with the research participants have to be protected, provided the consent of the research participants is present (e.g., they can be recoded, divided into categories or

⁵ At the time of the Guidelines' preparation, it is not clear whether storage of personal data in the servers of enterprises and other organisations in third countries, e.g., the United States of America or China, satisfies the aforementioned requirements of the GDPR, even when the servers are located in Europe. It is because according to the valid laws, the public authorities of the third countries may demand or establish the access to the data, even though the data could be stored in Europe.

encoded otherwise), and stored separately from the analysed data, in conformity with the GDPR requirements.

50.12. The anonymised research data may be shared with other persons, if the new use or purpose of the data does not disclose the research participant's identity or does not increase the risk of disclosure (e.g., through cross links of the data). Prior to sharing the data with other persons, the research data shall be anonymised in such a way that it would not be possible to link them with some particular research participants. The identifiable personal data of the research participants may be shared only if the researcher has received an advance written informed consent of the research participant in question, where the purpose of shared data would be stated together with other information specified in GDPR Article 13 (within the applicable scope), unless the duty to provide personal data is determined in the legal acts applicable to the research and higher education institution⁶.

50.13. If the research data were collected from the official documents and registers without asking for the research participants' consent, then the identifiers and the information related to the documents containing commercial secrecy have 1) to be destroyed when they are not needed any more for the research, or 2) to be transmitted to the data owner (e.g., in case of the commissioned research, the customer is a data owner and the data shall be transmitted to the customer for the purpose of data audit).

50.14. Storage and destruction of the research data

50.14.1. The research in humanities and social sciences cannot be always replicated; however, the academic community should have an opportunity to verify the research conclusions with the analysed research data, if needed. The research data should be opened according to the requirements of the selected repository, depersonalised or pseudonymised⁷. Openness is the main feature of research quality and a necessary condition to evaluate the validity of the research information.

50.14.2. The data archived carefully for the secondary research reduce the need to collect the research data containing identifiers. It is especially important to archive the secondary research data that have cultural, historical and/or scientific value.

50.14.3. If needed, the privacy protection should be assured through depersonalisation and granting access to depersonalised data intended for secondary research.

50.14.4. If the identifiers have to be removed from the data stored for secondary use through depersonalisation, it should be done in such a way as to make it possible for secondary data users to identify individual subjects. In addition to direct identifiers (e.g., name, surname, address, personal identity code), indirect identifiers (e.g., workplace, school, place of residence, age, profession, etc.) may be removed from the archived data or they may be recorded, divided into categories, or encoded otherwise.

50.14.5. When the data of previous research are to be used repeatedly for new research, but it is impossible to get an informed consent of initial research participants, the research plan containing thorough description of the character and importance of the replicated research, including impact on privacy, has to be submitted. The Board has to decide whether a repeated use of the data is allowed.

50.14.6. If the data containing identifiers cannot be published or anonymised, and the research participants were not asked to authorise storage and/or disclosure of the data, personal and research data should be destroyed at the end of the research (when the research results are made public), unless the research and higher education institution determines otherwise. If the data have any scientific value or are unique otherwise, the researcher may apply for the permit to archive the anonymised research data in the data repository/archive recommended by the research and higher education institution.

50.15. Privacy assurance in scientific publications

⁶ Part of the information provided in GDPR Article 13 may be not presented to the person if the research participant is cognisant of it (e.g., it has been presented during previous communication).

⁷ More details are available in the recommendation of the State Data Protection Inspectorate "Depersonalisation", https://vdai.lrv.lt/uploads/vdai/documents/files/Rekomend_nuasmeninimo_metodai_2015.pdf

50.15.1. Contrary to research data, the scientific publications are usually publicly available. The factors that have to be taken into consideration when the scientific publications are published are the following:

50.15.1.1. the general principle is privacy protection of the research participants in the publication. The decisions should be made on a case-by-case basis, if the research participant is identified in the publication;

50.15.1.2. when it is considered whether to announce the names of research participants, the copyrights of the research participants have to be taken into account. Besides, upon consent of the research participants, who have presented information or who have been questioned, their names and other basic information may be provided in the scientific publication, in case the research is based on the interview with experts. Therefore, the advance consent of the research participants to publish their personal data in the scientific publication or otherwise (e.g., in scientific or other events) is needed;

Amendment by Order No V-24 of the Ombudsperson for Academic Ethics and Procedures of the Republic of Lithuania of 10 May 2021

50.15.1.3. complete anonymity cannot be promised to the research participants if it cannot be guaranteed. For example, anonymisation of the research participants in the scientific publications does not necessarily prevent their identification by the persons, who are familiar with the activities of the community or organisation that was the object of the research;

50.15.1.4. the researcher writing about dead private persons has to act ethically. The need for privacy expressed by the deceased's family and other close relatives has to be taken into consideration;

50.15.1.5. when the organisations are studied (e.g., institutions, associations, work communities, public institutions, etc.), their recognisability and that of their individual representatives should be assessed on a case-by-case basis.

50.16. The quantitative research results are presented statistically; however, in case of identification hazard, the identifiers have to be used.

50.17. In case of qualitative data, before any examples of the data and/or quotes are published, the identification risk has to be evaluated⁸: what indirect identifiers (e.g., workplace, school, place of residence, age, profession, job title, etc.) are indicated, what will be encoded or omitted.

50.18. If the research is related to the archived material, the recognisability of the research participants will depend on the conditions determined by the data repository/archive where the material is stored.

51. Behaviour of researchers

51.1. When publishing the research results, the researchers cannot falsify or fabricate them, omit and/or suppress important data.

51.2. The researchers shall indicate the methods used to collect and/or select the data, to validate and analyse the data.

51.3. If the researchers detect significant errors in the published data, they shall undertake the measures to correct the errors, by announcing about them, revising the data, or applying other appropriate measures.

51.4. The researchers shall not present the works, parts of elements of the data of other researchers as their own, even if they are quoting the work or data source of another author.

51.5. The researchers shall assume responsibility only for the work that they have performed factually (independently) or to which they have contributed if the part of the researchers' work may be identified. However, if it is impossible, all the researchers shall assume the responsibility. They may be named as work authors or co-authors only if they satisfy the authorship criteria specified in Paragraph 3 of the Guidelines for Publication Ethics, and only then they may claim authorship of the work.

⁸ More details, see the Guidelines for data controllers and data processors on the security techniques and risk evaluation of the State Data Protection Inspectorate (version 3), https://vdai.lrv.lt/uploads/vdai/documents/files/VDAI_saugumo_priemoniu_gaires-2020-06-18.pdf

51.6. The nomination as a principal author or co-author of the work shall mean scientific input of certain persons and not their status. The acknowledgement shall be expressed in the scientific publication to the persons, who have contributed to the research but who do not satisfy the authorship requirements.

51.7. The student shall be named the first author if the publication was prepared on the basis of his/her research.

52. General validity, interinstitutional research and research in other institutions or places

52.1. If the Board of the research and higher education institution makes the decision on ethical approval, this decision may be regarded as valid for other research and higher education institutions represented by the researchers of the research in question. If the researcher moves from one research and higher education institution to another and continues the research started in the previous research and higher education institution, additional ethical review shall not be needed; however, the research results shall be attributed to the institutions, where the researcher was performing the research. It is necessary to notify the new workplace about continued research and its ethical approval.

52.2. Despite of the number of research and higher education institutions performing the research, the principal investigator or research supervisor and the associated institution shall be responsible for its ethical approval. If the research projects are carried out in several research and higher education institutions, it is enough to carry out the ethical review in one research and higher education institution, while the others need to be notified thereof only, unless otherwise specified.
Amendment by Order No V-24 of the Ombudsperson for Academic Ethics and Procedures of the Republic of Lithuania of 10 May 2021

52.3. In case of interinstitutional research, depending on the character and context of cooperation, the ethical review of different research parts may be received from different research and higher education institutions (e.g., social research is performed in one institution and clinical research in another).

53. Compensations for research

53.1. Any compensation or benefit offered to the research participants and/or their communities is fair, but shall be justified and consistent.

Amendment by Order No V-24 of the Ombudsperson for Academic Ethics and Procedures of the Republic of Lithuania of 10 May 2021

53.2. The compensation cannot affect the determination of the research participants to take part in the research or its activities.

53.3. If the community's resources are used, the appropriate compensation shall be allocated.

53.4. The researcher and the organisation, where the research is conducted, shall receive a compensation that cannot exceed the amount that would be considered as reasonably proportionate to the character, scope, and purpose of the research (e.g., travel expenses to the research place (e.g., laboratory) could be paid). In attempt to employ the research participants, the researchers usually do not offer excessive or inappropriate financial or other incentives. When professional services are offered to the research participants (e.g., discounts for services and/or goods, training) as an incentive to take part in the research, the researchers shall clearly indicate the character and possible risk of such services, obligations and restrictions related to such services.

54. Exceptions applied for research

54.1. No deception is allowed in the research, unless the application of deception methods may be justified by a significant anticipated scientific or applied value of the research, and when no alternative efficient procedure of data collection is available.

54.2. The researcher should document and clarify the character of deception and justify its need.

54.3. In absence of deception, the research participants cannot be misled about possible risk, inconveniences and/or intrigues related to participation in the research.

54.4. Failure to provide information about the research question and/or hypothesis of the research in order to prevent influencing the research participant shall not be considered deceptive.

54.5. No information about (probable) risk or burden of the research can be rejected. The deception may be a necessary tool of psychological research. However, it should be used only when it is necessary, and it cannot be used to provide misleading information about possible damage, risk, or stress.

54.6. The information cannot be disclosed, or the research participants cannot be deceived about the procedures that may cause reasonably physical or mental damage.

54.7. Any deception or concealed information has to be explained to the research participants as early as possible, immediately after the participation and not later than at the end of data collection. Then the research participants shall be also informed about their right to withdraw their data without any negative consequences.

SECTION VIII FINAL PROVISIONS

55. The Office of the Ombudsperson shall consult the research and higher education institutions on the issues of these Guidelines' implementation.

[Logo]

NAME OF THE INSTITUTION

[name of the unit]

Name and surname of the research participant:

Contact details of the research participant (e-mail and/or telephone number):

Title of research

PARTICIPANT INFORMATION SHEET

Minutes No *[xx]* of the Institutional Review Board of *[date]*

1. Why is this research being conducted?

[Please state the purpose and aims of the research]

2. Why have I been invited to take part?

You have been invited because *[include age range and /or other inclusion/exclusion criteria]*.

3. Do I have to take part?

No. You can ask questions about the research before deciding whether or not to take part. If you do agree to take part, you may withdraw yourself from the study, without giving a reason, *[and without negative consequences – include if appropriate]*, by advising me/us of this decision. The deadline by which you can withdraw any information you have contributed to the research is 30 days from participation. *[Please address what will happen to the data collected until the point of withdrawal.]*

4. What will happen to me if I take part in the research?

[This section details what will be involved in your research from a participant's point of view, and in the order they will experience it. If there are multiple study visits, describe them in turn]

You will be invited to attend *[x]* sessions at *[insert location]* /OR You will be asked to complete *[x]* sessions online

[If applicable:] When you arrive, I/we will talk you through the study procedures and give you the chance to ask any questions. If you are still happy to take part, I/we will ask you to sign an informed consent form / OR give oral consent.

If you are happy to take part in the research, you will be interviewed/you will be asked to attend a single/multiple visit(s) *[delete as appropriate]* at *[add anticipated location]*.

⁹ The document template provided in this annex was formed on the basis of the document form "Template information sheet" prepared by the University of Oxford, <https://researchsupport.admin.ox.ac.uk/governance/ethics/resources/consent#collapse281101>. Upon receipt of the authorisation of the University of Oxford, the document was adapted and translated into Lithuanian. The University of Oxford that has given the authorisation shall not be liable for the translation's quality. The authorisation for adaptation and translation into Lithuanian is stored in the Office of the Ombudsperson.

The interview/session should take approximately [xx] minutes/ hours. *[For longer sessions: You will be offered [number] of regular breaks of [xx] min.]* You can also ask to pause or stop the interview at any time.

[Give details of any follow-up visits, with duration and frequencies].

[If applicable:] With your consent, I/we would like to audio record you / video record you / take photographs of you *[delete as appropriate]* because ... *[give reasons why this is necessary here, e.g., for audio recording: so, I/we can have an accurate record of your thoughts. Indicate, where and how the audio records / video records and/or photographs are going to be stored; when and how the audio records / video records and/or photographs are going to be destroyed; what transcription software is going to be used, and other important circumstances specified in GDPR Article 13.]*

5. Are there any potential risks in taking part?

The following risks are involved in taking part ... *[address any risks to research participants and pay attention even to the smallest risk, e.g., breach of confidentiality, etc.]*

To reduce any potential risks, *[say what you will do, including that personal data will be pseudonymised or anonymised¹⁰ as appropriate].*

6. Are there any benefits in taking part?

[Either:] The benefits of taking part are ...

[Or:] There will be no direct or personal benefit to you from taking part in this research.

7. [Optional] Expenses and payments

[Either:] You will receive [x amount/voucher/gift] for *[participation/reasonable travel costs/meals/other]*.

[Or:] There will be no payment for taking part in this study.

8. What happens to the data provided?

The information you provide during the study is the research data. Any research data from which you can be identified *[please list here the personal data you are collecting from research participants, e.g., name, date of birth, audio recording etc.]* is known as personal data.

[If applicable when personal data of special categories are collected:] The data collected for the research are within special categories of personal data, such as your racial or ethnic origin or data concerning health, personal data revealing political views, religious or philosophical beliefs, membership in trade unions, genetic data, data about natural person's sexual life and sexual orientation] *[Please enter here the secrecy mark and types of the data containing commercial secrecy you are collecting].*

Personal / sensitive data will be stored *[insert location, security measures and how long the data collected will be stored]* for *[the terms will depend on the information system selected by the institution / publisher and the procedure established for the data storage place]* /not stored.

Other research data (including consent forms) will be stored for *[enter the data storage period in years and/or conditions that will determine the storage period]* after the end of research/publication of research results.

¹⁰ It is a personal data processing method when certain personal data are replaced by the identifiers, thus, personal data cannot be linked to any particular data subject without using additional information. If necessary, the personal data may be restored with regard to certain data subject.

The research data will be opened [*enter the repository*] and will be available [*enter the target group or write 'everyone'*].

[*Research participant*] has the right to withdraw the given consent for personal data processing [*enter the deadline for withdrawal of consent for personal data processing*].

[*If applicable:*] Your personal data may be transferred to, and stored at, a destination outside the European Union. [*Please inform the research participants about the possibility to transfer their personal data to third countries (including the remote access to personal data), suitable or applied safeguards and the methods, how to receive their copy or where the access to the data is granted.*].

[*The researcher and/or the research team, supervisor, collaborator/translator/other authorised personnel*] will have access to the research data. Responsible members of [*name of the institution*] may be given access to data for monitoring and/or audit of the research or if the Office of the Ombudsperson for Academic Ethics and Procedures is investigating an allegation of academic ethics and/or procedures.

[*If applicable:*] I/We would like your permission to use direct quotes [and for your name to be attributed to these/anonymously/against a pseudonym] [*please delete as appropriate*] in any research stage.

[*If applicable:*] I/We would like your permission to use anonymised data in future studies, and to share data with other researchers (e.g., in online databases). All personal information that could identify you will be removed or changed.

9. Will the research be published?

The research may be published in [*enter the form, e.g., publications, websites, etc.*].

[*Note on online publication of the students' final works (only relevant if you are a student whose work will be deposited in the Lithuanian Academic Electronic Library and/or in the institution's electronic database of master theses, doctoral dissertations, and their summaries/electronic catalogue of Martynas Mažvydas National Library of Lithuania)*]:

[*Name of the institution*] is committed to the dissemination of its research to society, and, in support of this commitment, has established a register of the institution's research that is available on the institution's website [*link*], while the research material/collected data are available in [*enter the database and its link*]. Holding the archive online gives easy access for researchers to the full text of freely available theses, thereby increasing the likely impact of that research and reducing research waste.

10. [*Where the research is externally funded*]: Who is funding the research?

[*Give details of the research funding organisation.*]

11. Who do I contact if I have a concern about the study or I wish to complain?

If you have a concern about any aspect of this study, please contact [*insert principal investigator name and University tel. no./e-mail address*] or [*insert supervisor name and University tel. no./e-mail address*]. The decision regarding your query will be made and you will be informed thereof in [*xx*] working days. If you wish to make a formal complaint, please contact the Chair or the Deputy Chair of the Institutional Review Board of [*name of the institution*] who will seek to resolve the matter as soon as possible:

[*only for the applications reviewed by the institutions*] Chair of the Institutional Review Board; e-mail: [*xx*]; address: [*xx*].

[*only for the applications reviewed by the institutions*] Deputy Chair of the Institutional Review Board; e-mail: [*xx*]; address [*xx*].

12. Data Protection

[Name of the institution] is the data controller *[enter the institution's e-mail address]*, thus your personal data provided for the research will be controlled in the institution *[please enter the mode]*.

[Name of the institution] will process your personal data for the purpose of the research outlined above. The institution's research are carried out for *[entre the purpose of personal data processing]*. *[It should be noted that the purposes of personal data processing have to be clear and concrete so that it would be possible to determine the type of processing and to verify whether the particular purpose does not contradict the requirements of the legal acts. The purposes of personal data processing such as "for research" or "for the benefit of the society" are too abstract and they do not allow evaluating the related scope of the personal data.]*

Further information about your rights with respect to your personal data is available from *[shall be explained by the institution and entered here]*.

Personal data officer; e-mail address: *[xx]*; post address: *[xx]*.

The complaint about personal data processing may be filed to *[e-mail address and post address of the institution's personal data officer]* of *[the institution's name and e-mail address]*, *[e-mail address of the Office of the Ombudsperson for Academic Ethics and Procedures of the Republic of Lithuania]*, *[e-mail address of the State Data Protection Inspectorate]* and/or *[e-mail address of the Office of the Inspector of Journalist Ethics]*.

13. Further Information and/or Contact Details

If you would like to discuss the research with someone beforehand (or if you have questions afterwards), please contact:

[Name and surname of the principal investigator]

[Name of the institution]

[Address of the institution]

Researcher's telephone number: *[xx]*

Researcher's e-mail: *[xx]*

Received by

Signature

Date

*[Logo]***NAME OF THE INSTITUTION***[name of the unit]*

Name and surname of the research participant:

Contact details of the research participant (e-mail, telephone number):

Researcher's name, surname and status:

Researcher's affiliation:

Researcher's telephone number:

Researcher's e-mail:

INFORMED CONSENT'S FORMMinutes No *[xx]* of the Institutional Review Board of *[date]**[title of the project and/or research]*Description of the project and research: *[insert brief paragraph]*

		Tick if you agree	Tick if you disagree
1.	I confirm that I have read and understand the information sheet for the above project/research <i>["title"]</i> . I have had the opportunity to consider the information, ask questions and have had these answered satisfactorily.	<input type="checkbox"/>	<input type="checkbox"/>
2.	I understand that my participation is voluntary and that I am free to withdraw at any time, without giving any reason, and without any adverse consequences or penalty.	<input type="checkbox"/>	<input type="checkbox"/>
3.	I understand that research data collected during the study may be looked at by authorised people outside the research team (e.g., the Board of the research and higher education institution and/or data protection officer, Office of the Ombudsperson for Academic Ethics and Procedures of the Republic of Lithuania, State Data Inspectorate, Office of the Inspector of Journalist Ethics, court).	<input type="checkbox"/>	<input type="checkbox"/>
4.	I understand that this project has been reviewed by the institutional review board of <i>[name of the institution]</i> , and received ethical approval.	<input type="checkbox"/>	<input type="checkbox"/>
5.	I understand who will access personal data provided, how the data will be stored and what will happen to the data at the end of the project.	<input type="checkbox"/>	<input type="checkbox"/>
6.	I understand that the research results will be publicly available.	<input type="checkbox"/>	<input type="checkbox"/>
7.	I understand how to raise a concern or make a complaint.	<input type="checkbox"/>	<input type="checkbox"/>
8.	<i>[If applicable]</i> I consent to being audio recorded.	<input type="checkbox"/>	<input type="checkbox"/>
9.	<i>[If applicable]</i> I consent to being video recorded.	<input type="checkbox"/>	<input type="checkbox"/>

¹¹ The document template provided in this annex was formed on the basis of the document form "Template written consent form" prepared by the University of Oxford, <https://researchsupport.admin.ox.ac.uk/governance/ethics/resources/consent#collapse281101>. Upon receipt of the authorisation of the University of Oxford, the document was adapted and translated into Lithuanian. The University of Oxford that has given the authorisation shall not be liable for the translation's quality. The authorisation for adaptation and translation into Lithuanian is stored in the Office of the Ombudsperson.

		Tick if you agree	Tick if you disagree
10.	<i>[If applicable]</i> I consent to having my photo taken.	<input type="checkbox"/>	<input type="checkbox"/>
11.	<i>[If applicable]</i> I understand how audio recordings/videos/photos will be used in summarising research results <i>[please delete as appropriate]</i> .	<input type="checkbox"/>	<input type="checkbox"/>
11.1.	<i>[If applicable]</i> I agree to the use of direct quotes, attributed to my name, in summarising research results OR	<input type="checkbox"/>	<input type="checkbox"/>
11.2.	<i>[If applicable]</i> I agree to the use of pseudonymised quotes in summarising research results ¹² OR	<input type="checkbox"/>	<input type="checkbox"/>
11.3.	<i>[If applicable]</i> I agree to the use of anonymised quotes in summarising research results OR	<input type="checkbox"/>	<input type="checkbox"/>
11.4.	<i>[If applicable]</i> I agree to have my statements/quotes used only <i>[without stating my personal data/disclosing my personal data]</i> .	<input type="checkbox"/>	<input type="checkbox"/>
12.	I agree to take part in the study ¹³ .	<input type="checkbox"/>	<input type="checkbox"/>
<i>Optional / not compulsory</i>	I agree for research data collected in this study to be given to researchers, including those working outside of the EU, to be used in other research studies. I understand that any data will be fully anonymised so that I cannot be identified.	<input type="checkbox"/>	<input type="checkbox"/>
<i>Optional / not compulsory</i>	I agree that my personal contact details <i>[enter particular contact details and storage term]</i> can be retained in a secure database so that the researchers can contact me about future studies.	<input type="checkbox"/>	<input type="checkbox"/>

Name and surname of the research participant

Date

Signature

Name and surname of the person taking consent

Date

Signature

¹² It is a personal data processing method when certain personal data are replaced by the identifiers, thus, personal data cannot be linked to any particular data subject without using additional information. If necessary, the personal data may be restored with regard to certain data subject.

¹³ In particularly complex studies researchers may want to add an additional statement: "I hereby assign to the researcher all copyright in my contribution for use in all work stemming from this project and future projects." This should be judged on a case-by-case basis.