APPROVED Academic Councils Resolution No AT-1 of 23 January 2024

DESCRIPTION OF THE PROCEDURE FOR ASSESSING COMPLIANCE OF VILNIUS COLLEGE WITH RESEARCH ETHICS

CHAPTER I
GENERAL PROVISIONS

1. The use of a procedure for assessing compliance with research professionalism and ethics helps to ensure the quality of research, the reliability, integrity and completeness of research, and to assess the risks of managing the data gathered. The Description of the Procedure for the Assessment of Compliance with Research Ethics (hereinafter referred to as the "Description") establishes the principles of the assessment of compliance with research ethics at Vilnius College (hereinafter referred to as the "College"), the specific requirements for compliance with research ethics, the procedure for the assessment of compliance with research ethics, and the procedure for the publication of data on research studies for which compliance with research ethics has been certified.

2. The description has been prepared in accordance with the Guidelines for the Assessment of Compliance with Research Ethics approved by the Order of the Ombudsman for Academic Ethics and Procedures of the Republic of Lithuania No.V-60 of 10 December 2020 "On the Approval of the Guidelines for the Assessment of Compliance with Research Ethics", as amended by the following amendments: (Order No.V-24 of 10 December 2020 No. Order V-24 of 10 December 2020 on the amendment of Order V-60 of 10 December 2020 of the Ombudsman for Academic Ethics and Procedures of the Republic of Lithuania "On the Approval of the Guidelines for the Assessment of Compliance with Research Ethics" (Office of the Ombudsman for Academic Ethics and Procedures of the Republic of Lithuania); Order V-16 of 10 December 2022-06-06 on the amendment of Order V-60 of 10 December 2020 of the Ombudsman for Academic Ethics and Procedures of the Republic of Lithuania "On the approval of the Guidelines for the Assessment of Compliance with Research Ethics" (Office of the Ombudsman for Academic Ethics and Procedures of the Republic of Lithuania).

II CHAPTER
GENERAL PRINCIPLES FOR COMPLIANCE WITH RESEARCH ETHICS

3. The following general principles of research professionalism and ethics must guide the researcher in the conduct of research, regardless of the field of research and/or the methods chosen: reliability, integrity, respect and accountability.

4. The principle of reliability is implemented:

4.1. conducting (designing, reviewing) research in a way that ensures quality and consistency and increases the likelihood of obtaining objective results;

4.2. in the research report (e.g. a publication), with an acknowledgement of compliance with research ethics;

4.3. transparency about the objectives of the research and the choice of appropriate data collection and analysis methods to achieve them;

4.4. anticipating the potential harms and benefits of research, taking into account the interests of different subjects/groups, communities and society, and risk mitigation measures.

5. The principle of fairness is implemented:

5.1. following all the planned steps of the research;

5.2. immediately informing the Research Ethics Compliance Committee (hereinafter "the Committee") in writing of any change in the circumstances of the research or any other unforeseen

2 information relating to the research being conducted;

5.3. disclosing information to the Committee in the event of a conflict of interest;

5.4. taking full responsibility for the results of the research and its publication, and for the implications of the research and its consequences for those affected.

6. The principle of respect is implemented:

6.1. Providing subjects with information about the processing of the data subject's personal data that complies 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 95/14/EC ("General Data Protection Regulation") ("GDPR"), and with sufficient information to enable them to decide whether to take part in the research (informed consent);

6.3. ensuring the voluntary participation of subjects in research;

6.4. ensuring that subjects are aware of and can withdraw from the research at any time, without giving a reason and without feeling pressured to take part in the research;

6.4. storing personal data provided by subjects, subject to strict confidentiality and anonymity procedures.

7. The principle of accountability is implemented:

7.1. keeping a record of the College's planned and completed research;

7.2. making the results of research accessible;

7.3. informing the Committee in the event of a conflict of interest;

7.4. by being obliged and able to demonstrate compliance with requirements relating to the protection of personal data.

8. The Principal Investigator must submit an application (research plan) to the Committee for approval of compliance with research ethics if:

8.1. The research uses intervention methods (e.g. social experiments, participatory action research, etc.);

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

8.3. the subjects are under 18 years of age and the research is carried out in a pre-school or pre-primary education institution, a general education school and a childcare institution, a personal health care institution, etc.;

8.4. Research shows that subjects are exposed to exceptionally strong stimuli, and that specific knowledge (e.g. related to violence, pornography, etc.) is needed to assess potential harm;

8.5. the research may cause long-term psychological damage (e.g. psychological trauma, depression, insomnia, etc.) beyond the risks encountered in normal life;

8.6. the research is associated with risks to the safety of the subjects (e.g. research on domestic violence

studies);

8.7. to requires the subject, research research funding organisation or Partner (country) in a collaboration (e.g. international project, commissioned research, etc.). The practical implementation of this provision must be described and made publicly available on the institution's website;

8.8. An application (Annex 4) for approval of compliance with research ethics must be submitted if the subjects are socially disadvantaged and required by law;

8.9. unforeseen circumstances arise in the course of the research (e.g. changes in the conditions under which the personal data are processed, the method of data collection, etc.) that affect the research design, which has been validated for compliance with research ethics.

III CHAPTER
SPECIFIC REQUIREMENTS FOR COMPLIANCE WITH RESEARCH ETHICS SUBSECTION ONE
BIOMEDICAL RESEARCH

9. An investigator conducting biomedical research shall be guided by the Law on Ethics of Biomedical Research, the Procedure for Issuing Permits to Conduct Biomedical Research (Republic of Lithuania

V-27 o f 8 January 2016) and other special legal acts regulating clinical trials on medicinal products,

clinical trials on medical devices, etc.

10. For approval of compliance with research ethics, researchers must apply to the Lithuanian Bioethics Committee or the regional (Vilnius or Kaunas) biomedical research ethics committee.

11. The Lithuanian Bioethics Committee issues authorisations for biomedical research when biomedical research is planned to be carried out in the area covered by more than one regional biomedical research ethics committee.

SECOND SUBDIVISION
RESEARCH (EXPERIMENTS) ON ANIMALS

12. An investigator conducting research involving animals shall be guided by the d. Directive (EU) No 2010/63 of the European Parliament and of the Council on the Protection of Animals used for Scientific Purposes, the Law on Welfare and Protection of Animals of the Republic of Lithuania, the Order of the Director of the State Food and Veterinary Service of the Republic of Lithuania No B1-866 of 31 October 2012 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.

13. The State Food and Veterinary Office issues authorisations for research and testing involving animals.

THIRD SUBDIVISION
RESEARCH IN OTHER FIELDS, IF IT USES SOCIAL SCIENCE RESEARCH METHODS

14. The Principal Investigator may also apply to the Committee for approval of compliance with research ethics if:

14.1. the researcher is unsure whether the research is likely to cause significant psychological or physical harm or safety risks to subjects;

14.2. the method chosen by the researcher or the way in which the results of the research are published may raise other significant ethical issues;

14.3. the research is to be published in a scientific journal, one of the requirements of which is to provide evidence of compliance with research ethics.

15. The list of cases for the submission of an application/research plan referred to in point 14 of this Regulation is not exhaustive.

FOURTH SUBDIVISION
ETHICAL PRINCIPLES FOR RESEARCH IN THE HUMANITIES AND SOCIAL SCIENCES

16. **Respect for the subjects**

16.1. **Voluntary participation**

16.1.1. Participation in research is voluntary and based on informed consent (Annex 2).

16.1.2. Informed consent is usually defined as Free, Prior and Informed Consent (FPIC) to participate in research. There are different types of informed consent:

- broad consent;
- blanket consent;
- open consent;
- portable legal;
- meta-consent;
- dynamic informed consent, etc. Each study chooses the most appropriate type of informed consent that meets the requirements of Articles 7 and 13 of the GDPR.

16.1.3. Subjects may give their consent verbally (to be recorded, e.g. by audio recording) or in writing. In the case of an audio recording, the subject must be given information about the processing of personal data in accordance with Article 13 of the GDPR. For example, consent during an interview or a response to a questionnaire or a request to respond in writing indicates that the subject has consented to being studied. It is recommended that written informed consent is preferred in research.

16.1.4. In institutions where the research is carried out and whose representatives/guardians are being studied (e.g. prisons, orphanages, hospitals, etc.), it is important to have the consent of each person involved in the research. In exceptional cases, a person authorised by the subject (in accordance with the legislation governing the creation of powers of attorney) or a person authorised to make decisions for the subject when the subject is not capable of making decisions independently (e.g. incapacitated) may give consent to participate in the research instead of the subject. Another person (e.g. the head of an institution) may give consent to participate in the research instead of the subject, but the subject must consent to the processing of personal data. In institutional research, both the researcher and the institution must ensure the privacy of the individual.

16.1.5. If the research involves intervention methods and physical influence on the subject, consent must always be given only in writing or by other demonstrable means.

16.1.6. Monitoring behaviour in a public space (e.g. a shopping mall, a train station or a higher education institution) does not require the informed consent of the individual, unless personal data are collected and the research data can be used to derive information about specific individuals. This also excludes audio and video recordings in which individuals can be identified. Research should also not interfere in other ways (e.g. detailed observation of a single person), as the context (the nature of the research, the setting and other persons) determines what is considered interference.

16.1.7. Consent can be specific or general. The general form of consent must include forms for recording and archiving data, conditions for the use of the research data in secondary research and information on the processing of the subject's personal data in accordance with the requirements of Article 13 of GDPR.

16.1.8. Where data obtained from subjects are combined with data in official registers, subjects must be provided with details of the data registers that have been/will be used, what information about the subjects has been/will be collected from these registers, as well as any other information referred to in Articles 13 or 14 of the GDPR as appropriate. Information on data collected from public registers prior to the subject's consent to participate in the study must be provided to the subject in accordance with the time limits set out in Article 14(3) GDPR.

16.1.9. Subjects have the right to withdraw from the research at any stage, but this does not mean that their prior contributions (e.g. interviews, etc.) cannot be used in the research. The researcher must inform the subjects about the conditions for the use of the collected data after withdrawal from the research. This information and the conditions for the use of the data provided by the subject should be discussed with the individual before he/she decides to participate in the research.

16.1.10. Passive/implied consent may be considered in special circumstances, but only if: a) the applicable consent would result in substantial and obvious disadvantages in terms of the quality or purpose of the research and/or the interests of the investigator; b) there is minimal burden on the subjects and no risk; c) special efforts are made to inform the subjects and/or their representatives of the research and of the possibility of opting out; and d) the procedure for opting out is straightforward.

16.2. **Participation of minors in scientific research**

16.2.1. Research on minors (children and adolescents) is valuable and important. The specific needs and interests of minors (children and adolescents) must be protected by adults. Children (in the general sense) are developing personalities and their needs and abilities vary at specific stages of growth, so researchers need to have an understanding of child and adolescent development and psychology in order to be able to tailor their chosen methods and lines of research to the age of the subjects. Information about the research and its implications must be age-specific. Minors must also be

to inform you about voluntary participation in the research and the possibility to withdraw from the research at any time.

16.2.2. In the case of children, investigators must normally obtain parental or guardian consent, which must be given at least 10 working days (not coinciding with the start date of the trial) to consult the Participant Information Sheet (Annex 1) and the informed consent form (Annex 2) by electronic means. If data are collected for the research without the necessary consent of the parents or guardians[1] , the parents or guardians have the right to exclude the child from participation in the research. However, it is important to consider minors as independent persons and, in addition to formal parental or guardian consent, it is essential that minors themselves accept participation to the extent that they are able. An exception is made for personal data which can only be obtained with the consent of the parent or guardian. Children may only be involved in research if there is no other way of obtaining the necessary data and if the purpose of the research is to gain scientific insights or to improve methods of treatment (e.g. integration of persons with disabilities, etc.).

16.2.3. There is no specific (universal) age limit for a child's autonomous or semi-autonomous decision to participate in research, so the child's views, through the child's ability to form his or her own views, his or her age, level of maturity, and his or her own interests must be taken into account when assessing the child's capacity and extent of participation in this process. The principle of the best interests of the child is one of the fundamental principles that must guide all decisions concerning the child, in the event of a conflict between the child's interests and those of others, etc.

16.2.4. When children are involved in research, confidentiality must be strictly observed. However, there may be situations where researchers are legally or ethically obliged to disclose confidential information to next of kin, other adults, or child protection services (e.g. the duty to report applies if researchers become aware of child abuse, molestation or neglect).

16.2.5. Investigators may not seek the separate consent of parents or guardians where there may be a difference of values and interests between the parents or guardians and the minors. This may be considered as an obstacle to collecting comprehensive research data on the living conditions and behaviour of minors.

16.3. **Research on people from vulnerable groups**

16.3.1. Researchers have a special duty to respect the interests of vulnerable groups throughout the research process. Vulnerable and disadvantaged people are not always prepared to defend their interests in their interactions with researchers. It should be appreciated that informed consent procedures will not necessarily ensure individuals' decision to participate in research or protect them from undue pressure.

16.3.2. Individuals belonging to vulnerable groups may be reluctant to be subjects for fear of unfavourable public perception, and such research is therefore only possible in accordance with the provisions of Articles 6 and/or 9 of GDPR.

16.4. **Information for subjects**

16.4.1. The information to be provided to subjects depends on the nature of the data collection methods. For qualitative, quantitative and mixed research, subjects must be provided with information about the research.

16.4.2. The information about the research should include at least the following: 1) contact details of the researcher; 2) the topic of the research; 3) the method of data collection and the expected duration; 4) the purpose of the data collection, how it will be used further, and the archiving methods for secondary use; 5) the voluntary nature of the participation; and 6) the information provided on the expected benefits of the research and the possible risks to the subject;
7) the information on the processing of the subject's personal data as set out in Article 13 of the GDPR.

16.4.3. Subjects can ask for further information about the research. The additional information may relate, for example, to (1) the research, (2) how the confidentiality and anonymity of personal data will be ensured and where the personal data will be stored after the research, (3) how and when the results of the research will be published, (4) external sources of funding.

[1] The procedure for informing parents and other conditions relating to the collection of research data without the necessary consent of the parents or guardians shall be determined by the legislation of the College.

16.4.4. Scientific studies using the experimental method must provide sufficient information on the experimental design. Experimental studies vary considerably from one field to another, and the completeness of the information is always determined and justified by the investigator.

16.4.5. Requests from subjects for additional information relating to the research and the subject's personal data required must be answered in plain and understandable language, and in the most honest and accurate manner possible.

16.5. **Data collection by alternative means**

16.5.1. Subjects may be given all the information they need, but participation may not be voluntary in some cases (e.g. the research may involve observing military conscripts or work processes, where the organisation's manager has given permission for the research).

16.5.2. Subjects may be given inadequate information (e.g. surveillance data collected from an emergency room or on a ride-along with a police squad, where the investigator cannot disclose that he or she is conducting a research study) or misleading information about the investigator's role (e.g. undercover investigators may mislead subjects when investigating discriminatory cases).

16.5.3. A researcher collects data for a research study without identifying him/herself, but with misleading information about the content of the research.

16.5.4. Observation of subjects in a public place does not require their consent. Technical recording equipment may be used in a public place, provided that privacy and data protection principles are respected in the use, storage and archiving of data.

17. **Risk assessment**

17.1. Potential harm to subjects may arise from data collection, storage and the consequences of publishing research data and/or results.

17.2. **Avoiding psychological harm**

17.2.1. Avoiding psychological harm involves treating subjects with respect and publishing results ethically in scientific publications.

17.2.2. The sensitivity of the topic and the limits of privacy depend primarily on the subjects themselves. If subjects are aware of the issues that will be addressed based on the information provided to them, they have given their informed consent and are willing to participate in the research and are aware of the scope and methods of the research. By participating in research, subjects regulate their own participation by avoiding situations and questions that they consider harmful.

17.2.3. If the research involves interaction with subjects (e.g. observation of the subject, interviews), all data about the subjects must be treated with respect and dignity.

17.2.4. The researcher must make sure that the principle of voluntary participation is respected, even in cases of direct contact with the subjects. The investigator should always (unless there is no objective possibility) ensure that the subject's participation is voluntary, especially in the case of direct contact with the subjects. Annoyance, embarrassment, fear or physical fatigue may be sufficient grounds for the investigator to terminate the research as far as the subject is concerned, even if the subject does not explicitly refuse to continue. It is very important to ensure that subjects participate voluntarily in research in their own institutions (e.g. hospitals, prisons, childcare facilities, homes for the elderly, etc.). For example, unnecessary mental strain can be avoided by testing in advance how long subjects will take to complete the research tasks.

17.3. **Avoiding financial and social damage**

17.3.1. Financial and social harm to subjects is more likely if the research does not respect ethical principles related to privacy and data protection. Ethical principles for the handling and protection of confidential information require an explanation to research participants of how the protection of confidential information will be ensured.

17.3.2. Scientific publications can have harmful consequences for the subjects. The risk of harm is highest if results are presented in an unethical way, e.g. by publishing flawed results that are not based on complete data or systematic analysis. It is recommended to ensure open access to scientific publications to avoid such cases.

17.3.3. Researchers should avoid any harm to subjects that may result from scientific publications. However, this principle should not prevent the publication of research results that may not be to the satisfaction of the subjects in all respects. It is the researcher's task to provide information regardless of the

reactions of the institution's managers, subjects or others. Research on the use of power and the functioning of social institutions (e.g. families, universities, hospitals, businesses, the legal system) should not be restricted because the results may have a negative impact on subjects. The best way to ensure freedom of research is through rigorous and systematic research and the publication of valid and appropriate results. Researchers (co-authors), collaborators, publishers, owners and editors of publications, reviewers, and sponsors are responsible for ensuring that academic ethics are upheld in scientific publications.

17.4. **Research Harm Risk Assessment**

17.4.1. Research involving potential risks that cannot be assessed by the subjects themselves and research that may cause harm and affect normal life must be assessed in advance. An investigator who is aware that there is a risk of long-term psychological harm exceeding the risk, or that the subject's safety will not be ensured, must disclose this to the Committee by submitting a request for a review of research ethics, together with ways of mitigating the risk. In the event of unanticipated harm arising in the course of the research, the investigator must temporarily suspend the research and reassess the risk of harm, inform the Committee and submit a plan to avoid unanticipated harm.

18. **Confidentiality and data protection**

18.1. Data protection is a key area of privacy protection in the collection and management of research data and the publication of results. In research, it is important to ensure: the protection of research data and confidentiality; the storage and management of research data; and the quality of scientific publications. Data protection aims to be able to open up research data and results while preserving the confidentiality of subjects. In order to adequately ensure data protection in research (research data), it is recommended that researchers develop a research data management plan (Annex 3).

18.2. The Privacy Shield principles apply to publicly available material or published data that may relate to individuals and their activities in the political, business and cultural spheres. For example, in the case of research using a biographical approach, privacy disclosures should be coordinated with the person about whom the data are collected or his/her authorised representative.

18.3. The basic principle for the collection and storage of personal data is the need for personal data in the context of research. Personal data must be collected for specified, explicit and legitimate purposes and not further processed in a manner incompatible with those purposes. Where research data can reasonably be analysed without direct identifiers and there is no reason to retain identifiers, only data from which identifiers have been removed may be processed and retained for secondary research purposes.

18.4. Data with identifiers may be collected and used when it is appropriate for a specific research study. Data may also be retained for secondary research with identifiers, subject to informed consent. In research, it may be necessary to process and store identifiers in order to audit the data and prevent fabrication and falsification of data, to investigate a possible breach of academic ethics, and because of the need to analyse data that is historically and culturally significant. All current data may acquire historical and cultural significance over time, but the latter must be assessed and justified by the researcher on a case-by-case basis.

18.5. The confidentiality of research data is subject to restrictions on its handling, use and storage. Research data may be used or transferred for data auditing purposes if outsourced research is given to the sponsor. In particular, it is unacceptable to disclose information about research data or to communicate data in a way that could influence the assessment, treatment or situation of individual subjects. Non-anonymised research data must not be communicated to the media or used for commercial purposes.

18.6. An exception to confidentiality is the duty of every citizen to report an imminent serious crime that can still be prevented. An investigator is not obliged to disclose information about crimes that have already been committed, unless the disclosure of the information helps to prevent an imminent serious crime.

18.7. Data protection: processing, storage and publication

18.7.1. Personal data is any information relating to an identified or identifiable natural person. A person can be identified from an IP address, workplace, job title, information obtained by linking multiple big data, etc.

18.7.2. The privacy of subjects must be respected and personal data must be kept confidential. Personal data that can help to identify subjects must be stored in such a way that the link between the subject and the results of the research is eliminated or adequately protected (e.g. by means of an identifier,

encryption). In addition, information revealing the subject's involvement should be protected. This is particularly important in the case of vulnerable groups or sensitive information.

18.7.3. Within 30 calendar days of the subject's submission, the investigator must provide access to all data relating to the subject, if they have not already been fully anonymised or linked to other participants, or remove all personal data relating to the subject on request.

18.7.4. The researcher must use personal data only for the purposes that were formulated in advance and made known to the subject.

18.7.5. The investigator may not transfer personal data to third parties without the subject's permission. Personal data may only be transferred to third parties for research purposes and with the written permission of the subject. Sometimes data relating to the subject is necessary for training purposes. The subject must also give his/her permission for this.

18.7.6. The investigator must take appropriate technical and organisational measures to prevent unauthorised access to or processing of personal data. These measures may include the use of lockers, cabinets, cloud computing, passwords and/or encryption, as well as the registration of persons having access to the data. The protection of data with identifiers must be carefully designed and special supervision and restriction must be applied to particularly sensitive personal data. Careless storage of data or unprotected electronic transmission of data must not jeopardise the protection of subjects' privacy.

18.7.7. Security solutions for data with identifiers are particularly necessary to protect vulnerable subjects (e.g. psychologically, socially, economically, economically, politically or otherwise affected, discriminated against, prosecuted or exposed to violence) from being identified and/or having information relating to them. For example, the protection of someone's privacy may affect the way informed consent is recorded.

18.7.8. The researcher has to decide where the personal data with identifiers will be stored, at what stage and to what extent the personal data will be destroyed, and how the storage and archiving of the research data will be handled for secondary research. Procedures also need to be established for how personal and research data will be protected electronically (e.g. backups, usernames, data access rights, processing on computers outside the network if necessary). The anonymity of the research data must be guaranteed irreversibly, except in cases where the subject agrees to be identified (e.g. in the case of an expert interview method).

18.8. If the data is collected and/or stored externally:

18.8.1. Where personal data is stored outside the College, e.g. by contacting another research and study institution or commercial enterprise, the College must carefully assess whether the storage and other processing of the data complies with the requirements of GDPR;

18.8.2. Storage outside the European Union should be avoided. In order to store personal data in the infrastructures, storage facilities and elsewhere of companies operating in third countries, the investigator has to assess on which basis, among those set out in Chapter V of the GDPR (i.e. Articles 45, 46 or 49), the personal data would be stored, whether it would require additional safeguards or the permission of the State Data Protection Inspectorate, and whether it would additionally require the conclusion of the agreement set out in Article 28 of the GDPR with the entity to which the storage of the personal data would be delegated. This also applies to the storage of personal data by companies operating in the United States and third countries
on the servers[2] . In addition, it should be noted that the subject must be informed about the location of the data storage and the possible (even unlikely) consequences before agreeing to participate in the research.

18.8.3. Where appropriate, researchers or the organisation providing data processing services, other research staff handling data with identifiers may be required to sign a confidentiality undertaking. Written confidentiality undertakings are the responsibility of the study director and/or the principal investigator. The confidentiality of data containing identifiers extends to those who use the data, even if written confidentiality undertakings are not used. Where confidentiality undertakings are not collected, the controller/processor should assess how it will inform the persons concerned of their obligation to keep personal data secret and the consequences of breaching this obligation.

[2] At the time of drafting, it is unclear whether the storage of personal data on servers of third countries such as the United States, China, companies and other organisations complies with the requirements of the GDPR, even when the servers are located in Europe. This is because, under current laws, public authorities in third countries may require or determine to grant access to data even if it is stored in Europe.

18.9. In the case of publicly funded research, the researcher must ensure that the data generated during the research project is preserved in digital format and, at the end of the project, is transferred to the institution for preservation and/or made available to the repository. The personal data must be retained for a period of time specified by the research funding organisation at the end of the research project (publication of the results of the research). An exception to the retention of personal data may apply, e.g. for longitudinal studies. However, identifiers must be kept separate from the research data and access to them is subject to appropriate conditions.

18.10. In line with the concept of open science and in accordance with international scientific guidelines (e.g. the FAIR Guiding Principles for scientific data management and stewardship; https://www.go-fair.org/fair-principles/), research data (anonymised if necessary) should be retained for a period of at least 10 years from publication, or for a period offered by the repositories under the licence of your choice. Unpublished research and research subject data may be stored and destroyed in accordance with the procedures established by the College.

18.11. If there is no reason to keep the identifiers, they must be destroyed immediately after publication, e.g. paper identifiers must be destroyed immediately or the identifiers must be removed from electronic media. Identifiers that are retained for further contact with subjects and with the consent of those subjects must be secured (e.g. recoded, categorised or otherwise encrypted) and stored separately from the analysed data in accordance with the requirements of GDPR.

18.12. Anonymised research data may be shared with others, provided that the new use or purpose of the data does not reveal the identity of the subject or increase the risk of disclosure (e.g. through data cross-referencing). Before sharing data with other persons, the data shall be anonymised in such a way that the data cannot be linked to specific subjects. Identifiable personal data about subjects may only be shared if the researcher has obtained prior written informed consent from the subject, explaining the purpose of the data to be shared and, to the extent applicable, the other information referred to in Article 13 of the GDPR, unless the obligation to provide personal data is imposed by a law applicable to the College.[3] .

18.13. If research data have been collected from official documents and registers without the consent of the subjects, both identifiers and information relating to documents with commercial confidentiality must be (1) destroyed as soon as they are no longer needed for the research, or (2) handed over to the owner of the data (e.g. in the case of outsourced research, the owner is the client and the personal data are handed over to the client for the purpose of auditing data).

18.14. Storage and destruction of research data

18.14.1. Research in the humanities and social sciences is not always replicable, but the academic community should be able to verify the findings of a research study, where appropriate, from the research data analysed in the study by accessing the data in the repository of their choice

[3] Some of the information referred to in Article 13 of the GDPR may be withheld from a person if it is known to the subject (e.g. it has already been provided in a previous communication).

requirements and the personalisation or pseudonymisation of the survey data[4] . Openness is a key characteristic of scientific quality and a prerequisite for assessing the validity of scientific information.

18.14.2. Careful archiving of data for secondary research reduces the need to collect research data containing identifiers. It is particularly important to archive secondary research data of cultural, historical and/or scientific value.

18.14.3. Where appropriate, privacy protection should be ensured through depersonalisation techniques and through access to depersonalised data for secondary research.

18.14.4. If identifiers are to be removed from data stored for secondary use, the purpose of depersonalisation techniques should be such that secondary users of the data cannot identify individual subjects. In addition to direct identifiers (e.g. name, address, ID number), indirect identifiers (e.g. place of work, school, residence, age, occupation, etc.) can be removed from the archived data, or transcoded, categorised, or otherwise encoded.

18.14.5. Where data from a previous study are to be reused for new research purposes, but informed consent from the original subjects can no longer be obtained, a research plan detailing the nature and significance of the reuse, including privacy implications, should be submitted. The Committee must decide whether reuse of the data is possible.

18.14.6. If the data containing the identifiers are sensitive and cannot be anonymised, and the subjects have not been asked to give permission for the data to be stored and/or opened, the personal and research data should be destroyed at the end of the research (after publication of the results of the research), unless the College determines otherwise. If the data has scientific value or is historically unique, the researcher may request permission to archive the anonymised research data in a data repository/archive recommended by the College.

18.15. Privacy in scientific publications

18.15.1. Unlike research data, scientific publications are generally publicly available. Factors to consider when publishing scientific research include:

18.15.1.1. The general principle is to protect the privacy of subjects in the publication. Decisions have to be taken on a case-by-case basis if the publication identifies the person involved in the research;

18.15.1.2. the rights of subjects must be taken into account when assessing whether to publish subjects' names. In addition, with the consent of the subjects who provided information or were interviewed, the research publication may include their names and other basic information when the research is based on interviews with experts. This requires the prior consent of the subjects to publish their personal data in a scientific publication or to make it public in other ways (e.g. at scientific and other events);

18.15.1.3. Subjects must not be promised complete anonymity if this cannot be guaranteed. For example, granting anonymity to subjects of scientific publications does not necessarily prevent them from being identified by those who are familiar with the activities of the community or organisation that was the subject of the research;

18.15.1.4. An investigator must act ethically when writing about deceased private individuals. Due regard should be given to the expressed need for privacy expressed by the deceased's relatives and other next-of-kin;

18.15.1.5. When examining organisations (e.g. institutions, associations, labour communities, public bodies, etc.), the identifiability of the organisations themselves and of individual representatives must be assessed on a case-by-case basis.

18.16. The results of quantitative tests are reported statistically, but the use of identifiers is necessary in case of identification risks.

18.17. In the case of qualitative data, before publishing any data samples and/or quotes, the identification risk must always be assessed[5] : what indirect identifiers (e.g. place of work, school, place of residence, age, occupation, job title, etc.) will be included, what will be encoded, and what will be omitted.

[4] For more details, see the Recommendation of the State Data Protection Inspectorate "Methods of personalisation", https://vdai.lrv.lt/uploads/vdai/documents/files/Rekomend_nuasmeninimo_metodai_2015.pdf

[5] For more details, see the State Data Protection Inspectorate's Guidelines on Security Measures and Risk Assessment of Processed Personal Data for Data Controllers and Data Processors (version 3), https://vdai.lrv.lt/uploads/vdai/documents/files/VDAI_saugumo_priemoniu_gaires-2020-06-18.pdf

18.18. In the case of research involving archived material, the identifiability of subjects depends on the conditions set by the repository/archive that holds the material.

19. **Behaviour of investigators**

19.1. When publishing research results, researchers must not falsify or fabricate research data, or omit and/or suppress important data.

19.2. Researchers shall indicate the methods used to collect and/or sample the data, as well as the methods used to validate and analyse the data.

19.3. If investigators find significant errors in the published data, they must take steps to correct these errors by publishing a notice of the errors, correcting the data, or taking other appropriate measures.

19.4. Researchers do not present parts or elements of other researchers' work or data as their own, even if they cite another author's work or data source.

19.5. Investigators are only liable for the work they actually (independently) carried out or contributed to, if the investigator's share of the work is identifiable, but if it is not possible to do so, the responsibility is shared by all investigators. They can only be named as authors or co-authors of a work if they meet the criteria for authorship set out in point 3 of the Guidelines on Publication Ethics, in which case they can claim authorship of that work.

19.6. Designation as lead author or co-author of a work refers to the scientific contribution of the individuals concerned, not to their status. Those who do not meet the authorship requirements but have contributed to the research are acknowledged in the scientific publication.

19.7. The student should be the first author if the publication is based on his/her research.

20. **Joint validity, inter-institutional research and research in other institutions or locations**

20.1. If the Committee adopts a decision on the approval of compliance with research ethics, this decision may be considered valid for other research and study institutions represented by the research investigators. In the case of a transfer of an investigator from one research and teaching institution to another, where the research was carried out in the previous research and teaching institution and is continued in the new one, no further assessment of compliance with research ethics is required, but the results of the research should be attributed to the institutions where the investigator carried out the research. The continuation of the research and the confirmation of its compliance with research ethics must be reported at the new place of employment.

20.2. Regardless of the number of research institutions involved, it is the responsibility of the principal investigator or research supervisor and the institution with which he or she is affiliated to certify that the research complies with research ethics. In the case of research projects carried out in several research and study institutions, it shall be considered sufficient to carry out the assessment of compliance with research ethics in only one research and study institution and to inform the others, unless otherwise specified.

20.3. For inter-institutional research, depending on the nature and context of the collaboration, the assessment of compliance with research ethics can be obtained separately from different research institutions for different parts of the research (e.g. social research in one institution and clinical research in another).

21. **Research compensation**

21.1. Any compensation or benefits offered to research subjects and/or research communities are fair but must be justified and proportionate.

21.2. The compensation must not influence the subjects' decision to participate in a particular research study or research activity.

21.3. If community resources are used, adequate compensation must be provided.

21.4. The investigator and the organisation where the research is carried out receive compensation up to what can be considered reasonably proportionate to the nature, scope and purpose of the research (e.g. travel expenses to the place where the research is carried out (e.g. a laboratory). When attempting to recruit subjects, investigators generally do not offer excessive or inappropriate financial or other incentives. When subjects are offered professional services (e.g. discounts on services and/or goods,

In the case of services (e.g. training) as an incentive to participate in research, researchers shall make clear the nature of these services and the potential risks, obligations and limitations associated with these services.

22. **Research exemptions**

22.1. No deception may be used in research unless the use of deceptive methods can be justified

by the significant anticipated scientific or translational value of the research, and there is no alternative procedure for the efficient collection of data.

22.2. The investigator should document and explain the nature of the fraud and why it is necessary.

22.3. In the absence of fraud, subjects should not be misled about the potential risks, inconveniences and/or intrigues associated with participation in research.

22.4. Withholding information about the research question and/or hypothesis (in order to prevent the subject from being influenced) is not considered deceptive.

22.5. No information about the (potential) risks or burdens of the research is excluded. Deception may be a necessary tool in psychological research. However, it should only be used when necessary and should not be used to misinform about potential harms, risks or stress.

22.6. Information must not be withheld or subjects deceived about procedures that are reasonably likely to cause physical or mental harm.

22.7. Any deception or withheld information must be explained to the subjects as early as possible, immediately after participation and no later than the end of data collection. Subjects must also be informed at that time that they have the right to withdraw their data without adverse consequences.

IV CHAPTER
THE PROCESS OF ASSESSING COMPLIANCE WITH RESEARCH ETHICS

23. Upon receipt of the application, including the researcher's personal data (name and surname, work email address, work telephone number (if available) / study email), informed consent form (Annex 2), data for subjects (e.g. questionnaire, interview schedule), research data management plan (Annex 3), the Committee must organise a meeting within 10 working days at the latest to assess the compliance with the ethics of research. The evaluation of the applications submitted thereafter should take place at the next forthcoming meeting of the Committee.

24. Electronic copies of the applications submitted shall be sent by the Secretary of the Committee by e-mail to all members of the Committee at least 5 working days before the date of the meeting.

25. The Committee's decision may be taken without the presence of the investigator(s). The investigator(s) must be available at the workplace or by electronic means during the Committee meeting.

26. The Committee takes a final decision on the compliance of a research study with research ethics

Accept : 26.1. Within 3 working days.

26.2. In the event of comments by members of the Committee, the investigator(s) shall be given 3 working days

correct any deficiencies in the documents submitted and return the application to the Committee. The Committee shall have 3 working days to assess the quality of the corrections and take a final decision.

27. If the investigator(s) fails to amend the application within the time limit, the Committee shall propose that the application be reconsidered at a subsequent meeting.

28. The Secretary of the Committee shall inform the investigator(s) of the decision taken by the following e-mail address

by post.

V CHAPTER
PUBLICISING RESEARCH DATA

29. Research that has been approved as compliant with research ethics is made publicly available on the College's website:

29.1. the name, affiliation (and/or partners) of the researcher (not only the institution, but also the academic affiliation: lecturer, researcher, student) and email address;

29.2. Name of the research;

29.3. research area(s);

29.4. the type of scientific output produced and/or planned (e.g. article, monograph, textbook, video, etc.);

29.5. Methods of collecting research data;

29.6. Methods for analysing research data;

29.7. sources of funding;

29.8. Meaningful words.

VI CHAPTER 4 FINAL PROVISIONS

30. All procedural matters relating to the evaluation not provided for in this Regulation shall be dealt with during the meetings of the Committee.

31. This Schedule shall enter into force on the date of its approval.

32. The description shall be published on the College's website.

Discussed:
Meeting of the Committee on Compliance with Research Ethics
(Minutes of 6 December 2023, No 2)

Discussed:
Meeting of the Governance Commission (Minutes No 1 of 16-01-2024)

Description of the procedure for assessing compliance with research ethics
Annex 1

VILNIUS COLLEGE

Name of participant:

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

Name of the study

RESEARCH INFORMATION SHEET FOR THE PARTICIPANT

Minutes of the Committee on Compliance with Research Ethics of *[date]* No *[xx]*

1. **Why this study?**

[State the aims and objectives of the study]

2. **Why have I been invited to take part in this study?**

You have been invited because *[specify age group and/or other inclusion criteria]*.

3. **Do I have to participate in the study?**

No. You can ask questions about the study before deciding whether or not to participate. If you agree to take part, you may withdraw from the study at any time without giving a reason *[and without suffering any negative consequences - please specify if necessary]* by notifying me/us of your decision. You may withdraw from the study and take back any information you have shared within 30 days from the date of participation in the study. *[Please specify how the data collected will be treated until you decide to withdraw from the study]*.

4. **What will happen if I agree to take part in the study?**

[Describe in detail which steps of the study are relevant to the subject and what general steps will be followed. If several training meetings are required, describe them in turn.]

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

[If applicable:] When you arrive, I/we will discuss the procedures of the study and give you the opportunity to ask any questions you may have regarding the study. I/we will then ask you to complete an informed consent form OR give verbal consent.

If you are happy to take part in the study, you will be interviewed / I will ask you to attend one or more repeat meeting(s) *[delete as appropriate]*, *[insert intended meeting place]*.

The interview/session should last approximately *[xx]* minutes/hours. *[For longer sessions: you will be offered [number] breaks after [xx] minutes] You can also* ask to withdraw your consent to participate in the study or to stop the interview at any time.

[Please provide details of any follow-up meetings, including duration and frequency.]

[If applicable:] With your consent, I/we would like to make an audio recording/video recording/photograph of you *[delete as appropriate]* because... *[state the reasons why this is necessary, e.g. the audio recording will be necessary to enable us to accurately reconstruct your thoughts. Please indicate where and how the audio/video recordings and/or photographs will be stored; when and how the audio/video recordings and/or photographs will be destroyed; what transcription programme will be used; and any other relevant circumstances set out in Article 13 of the GDPR.]*

5. **Are there any risks to taking part in the study?**

Participation in the study carries the following risks: *[please describe the potential risks of the study, including the smallest risks, e.g. breach of confidentiality, etc.]*.

To mitigate any potential risks, *[tell us what you will do, including that the personal data will be pseudonymised*[6] *or anonymised as appropriate]*.

6. **Are there any benefits to participating in the study?**

[Or:] The benefits of participation are...

[Or:] You will not receive any direct or personal benefit from participating in this study.

7. ***[Optional]* Expenses and payments**

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

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

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

The information you provide in the course of a survey is survey data. Any research data from which you can be identified *[here, please specify the personal data you collect from participants, e.g. name, date of birth, audio recording, etc.] is treated* as personal data.

[If applicable to the collection of special categories of personal data:] The data collected for the investigation fall within the categories of special categories of personal data, such as your racial or ethnic origin, your health, personal data revealing your political opinions, religious or philosophical beliefs, trade union membership, genetic data, data concerning the sex life of a natural person and data concerning sexuality and sexual orientation of a natural person *[please indicate here the classification marking, the types of commercially sensitive data you are collecting]*.

Personal/sensitive data will be stored in *[insert location, security measures and how long the collected data will be stored] [the timeframe depends on the information system chosen by the College/publisher and the procedures established by the data repository]* / will not be kept.

Other research data (including consent forms) will be retained for *[specify the period of data retention in years and/or the conditions on which the data retention period depends]* after the research has been conducted/results published.

The survey data will be opened at *[specify location]* and made available to *[specify target group or everyone]*.

[Subject] has the right to withdraw consent to the processing of personal data *[specify by when the personal data may be withdrawn]*.

[If applicable:] Your personal data is transferred to and stored at a destination outside the European Union. *[Inform the subject of the possibility of transferring their personal data to third countries (transfer includes remote access to personal data) and the appropriate or adapted safeguards and means of obtaining a copy of the data or of having access to it.]*

[The investigator and/or his/her team, supervisor, collaborator/translator/other authorised person...] will have access to the investigation data. Responsible members of *[name of institution]* may be given access to data for monitoring and/or auditing investigations and for the purposes of the Office of the Ombudsman for Academic

[6] It is a type of processing of personal data where certain personal data are replaced by identifiers, so that personal data cannot be linked to a specific data subject without the use of additional information. However, it is possible to restore the personal data to a specific data subject if necessary.

Ethics and Procedures in the context of an investigation into a possible breach of academic ethics and/or procedures.

[If applicable:] I/we would like to obtain your consent to use direct quotes [with the undertaking that your name will be encrypted [please delete if not required] at any stage of the research.

[If applicable:] I/we would like to get your consent to use personalised data in future studies and to share your data with other researchers (e.g. in online databases). Any personal information that could identify you will be removed or replaced.

9. **Will the study be published?**

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

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

Vilnius College is committed to disseminating its research to the public, and has created a register of the institution's research, which is published on its website:

https://www.viko.lt/kolegija/mokslo-taikomoji-ir-meno-veikla/taikomuju-tyrimu-atitiktis- research-ethics/)

10. ***[Applicable if the research is externally funded]*: Who is funding the research?** *[Please provide details of the organisation funding the research.]*

11. **Who can I contact to report an investigation?**

If you have concerns about aspects of this investigation, please contact *[insert name of principal investigator and College telephone number/email address]* or *[insert name of supervisor and College telephone number/email address]*. A decision on your application will be made and you will be informed within *[xx]* working days.
If you wish to make a formal complaint, please contact *Vilnius*

the Chair or Vice-Chair of *the College's* Research Ethics Compliance Committee, who will endeavour to resolve the issue as soon as possible:

[Only for applications reviewed by the Institutions] Chair of the Committee on Compliance with Research Ethics; e-mail: *[xx]*; address: *[xx]*.

[Only for applications reviewed by the Institutions] Vice-Chair of the Committee on Conformity with Research Ethics; e-mail: *[xx]*; address: *[xx]*.

12. **Data protection**

[Name of the institution] is the data controller of *[insert the email address of the institution]* and therefore your personal data submitted for the study will be managed by *[insert which method]*.

[Name of the Authority] will process your personal data for the purposes of the above-mentioned study. The Authority's investigations are carried out by *[specify the purpose of the processing of personal data]*. *[It should be noted that the purposes of the processing of personal data must be clearly and specifically formulated in order to identify the type of processing involved and to assess whether the specific purpose is compatible with the requirements of the law. Purposes of processing of personal data such as 'for scientific research' or 'for research in the public interest' are too abstract and do not allow for an assessment of the scope of the personal data concerned.]*

Information about the rights to your personal data *[to be explained by the authorities and inserted here]*.

Personal Data Officer; e-mail address: *[xx]*; address for correspondence: *[xx]*.

A complaint regarding the processing of personal data may be submitted to *[name and email address of the institution]*, *[email address and correspondence address of the institution's personal data officer]*, *[email address of the Office of the Ombudsman for Academic Ethics and Procedures of the Republic of Lithuania]*, [*email address of the State Inspectorate for Data Protection]* and/or *[email address of the Office of the Inspector of Journalistic*

Ethics].

13. **Contact details and/or other information**

If you would like to discuss the study in advance (or if you have any questions after the study), please contact:

[Name of principal investigator]

[Name of institution] [Address of

institution]

Investigator's tel.: *[xx]*

Investigator's email: *[xx]*

Receiv

ed

Signatu

re Date

Description of the procedure for assessing compliance with research ethics
Annex 2

VILNIUS COLLEGE

Name of participant:
Participant's contact details (email, phone):

Name and status of the investigator:
Researcher affiliation:
Investigator's tel:
Investigator's email:

FORM OF INFORMED CONSENT

Minutes of the Committee on Conformity with Research Ethics of *[date]* No.
[xx] [Title of project and/or research]

Description of the project and research: *[short paragraph]*

		If you agree, please tick the box	If you disagree, tick
1.	I confirm that I have read and understand the research of the above project *["name"]* information sheet. I had the opportunity to see the information, ask questions and get answers.	□	□
2.	I am aware that my participation is voluntary and that I can withdraw from the study at any time, without giving a reason, suffering any negative consequences or receiving a fine.	□	□
3.	I am informed that the data collected during the survey may be reviewed by authorised persons outside the investigators group (e.g. the Committee and/or the Data Protection to the official, the Office of the Ombudsman for Academic Ethics and Procedures of the Republic of Lithuania, the State Data Protection Inspectorate, the Office of the Inspector of Journalists' Ethics, and the court).	□	□
4.	I am informed that a draft of this study has been reviewed by *[name of institution]* Compliance with research ethics Committee and this study was approved.	□	□
5.	I am informed about who will have access to the personal data I have provided, how the data will be stored and what will happen to it data at the end of the project.	□	□
6.	I am informed that the results of the study will be made public.	□	□
7.	I have been informed where to go for an investigation.	☐	□
8.	*[If applicable]* I agree to the audio recording.	☐	□

9. *[If applicable]* I agree to be video recorded. ☐ □

10. *[If applicable]* I consent to the taking of photographs. ☐ □

11. *[If applicable]* I am informed how the audio recordings/videos/photos will be used to summarise the results of the research *[delete as appropriate]*. □ □

[If applicable] I am informed how the audio recordings/videos/photos will be used to summarise the results of the research *[delete as appropriate]*.

11.1. *[If applicable]* I agree to the use of direct quotations in summarising the results of studies □ □ □ attributed to
me, OR

11.2. *[If applicable]* I agree to my quotes being □ □ pseudonymised[7] to summarise the research results OR

11.3. *[If applicable]* I agree that my quotes will be □ □ anonymised for the purposes of summarising the results of the research OR

11.4. *[If applicable]* I agree that my statements / quotations □ □ will be quoted only *[without giving my personal data / disclosure of my personal data]*.

12. I agree to participate in the study[8] . ☐ □ *Panepsiririvnaklotimnaai /* I agree that the data collected in this study will be made available to □ □ □ □ researchers, even those working outside the EU, and will be used in other research. I understand, that all data will be completely anonymised and that it will not be possible to identify me.

Optional / I agree to share my personal contact information □ □ *Optional*
[specify specific contact information and storage term] can be stored in a secure database so that researchers can contact me about other future research.

Participant's name, surname	Data	Signature
Name of responsible person	Data	Signature

Description of the procedure for assessing compliance with research ethics
Annex 3

(Sample Research Data Management Plan Form) RESEARCH DATA

MANAGEMENT PLAN

A research data management plan (hereafter referred to as a DMP; the research is collectively referred to as a study) is a document that describes how the data from a study should be managed throughout the conduct of the study and beyond. The DMP contains details of what data will be collected, how it will be collected, what it will be used for, etc. The DMP is one of the tools to help ensure that the management of research data is in line with the FAIR principles[9] *- research data must be discoverable, accessible, interoperable and re-usable.*

1. **General information**

1.1. Study number: *[number given automatically or by the DVP registrant]*.

1.2 Title of the study:

1.3. Principal Investigator (study leader) and members of the study team (name, institutional affiliation, email and phone): *[indicate the area(s) of responsibility of each investigator (e.g. data collection, metadata preparation, data maintenance, backup, and storage, data archiving, data opening, etc.)]*.

1.4. Investigator responsible for the DMP (name, email and phone):

1.5 Is this study part of a larger study? *[Yes / No]*
[If yes, please indicate the name of the main study and the institutions/organisations (partners) collaborating in the study (name, institutional affiliation, email and tel., responsibilities area(s)).]

1.6 Has this study been assessed for compliance with research ethics in other countries? *[Yes / No]*
[If yes, please indicate in which countries and institutions compliance with research ethics has been assessed.]

1.7 Description of the study: *[specify the purpose of the study, the relevance of the study, the study sample, the study data collection methods, methods of analysing survey data and other relevant information].*

1.8 Start of the study: _____ 1.9 Planned end of the study: _____

1.10. Source of funding for the study: *[specify funding programme and project title and number, contract for the commissioned study, etc.]*.

1.11. Version and date of the DMP:

2. **Survey data collection**

2.1 What type (e.g. qualitative, quantitative, multi-modal, etc.) and type of research data (e.g. numerical (databases), textual (documents), images, sounds, video, physiological, etc.) will be collected? Describe them in detail.

2.2 Will data from previous study(s) be used? *[Yes / No]*
[If yes, please explain what data previously collected from the study(s) will be used and how it will be used and where it will be stored. If previously collected data from the study(s) are not used, explain the reasons why.]

2.3. How will the survey data under 2.1 be collected? *[Indicate which methods and/or information programmes/systems will be used to collect the data]*.

Beltran, A. (2016). The FAIR Guiding Principles for scientific data management and stewardship. *Scientific Data*, 3(1): 160018. https://doi.org/10.1038/sdata.2016.18.

[9] Wilkinson, M. D., Dumontier, M., Aalbersberg, I. J., Appleton, G., Axton, M., Baak, A., Blomberg, N., Boiten, J. -W., da Silva Santos, L. B., Bourne, P. E., Bouwman, J., Brookes, A. J., Clark, T., Crosas, M., Dillo, I., Dumon, O., Edmunds, S., Evelo, C. T., Finkers, R., & Gonzalez-

2.4. Will the data collected from the study be suitable for re-use? *[Yes / No]*
[If yes, please specify the format of the survey data (e.g. PDF, CSV.xls, .doc, .txt, .rdf, etc.) and explain the reasons for the choice of this format (e.g. standards

used in data warehouses, information programmes/systems, etc.). If not, please explain the reasons.]

2.5 How will the survey data be stored during the collection of survey data? [Describe the structure of the survey data, the creation of versions of the survey datasets, the rules for naming the files, the structure of the folders for storing the study data, etc.]

2.6. Will personal data10 be collected? [Yes /No] [If yes, point 6 of the DPA must be completed].

3. Metadata

3.1 What metadata[10] [11] and other information about the study data (e.g. informed consent, list of subjects and information about them, etc.), the conduct and analysis of the study will you produce and document? *[Please provide definitions of variables, units of measurement and other relevant information to facilitate the re-use of the data.]*

3.2 Will you use existing metadata standards (e.g. DDI, TEI, EML, MARC, CMDI, etc.), standardised vocabularies, ontologies, etc? *[Yes / No]*
[If yes, please specify which metadata standards, vocabularies, ontologies, etc. you will use, and Please elaborate if you use different metadata standards for different types of survey data[12] . If not, please specify which type of metadata will be created and how.]

3.3 Are the metadata standards planned to be used compatible with the requirements of the data repository where the study data are planned to be stored? *[Yes / No]*

3.4 Where and in what format (e.g. *README* text file, etc.) the metadata and other relevant will information on the study data (documentation) be recorded and stored?

3.5. Will the metadata be publicly available? *[Yes / No] [If yes, please indicate where it will be made publicly available.]*

4. Analysis of survey data

4.1. How will the survey data be stored during the analysis of the survey data? *[Describe the structure of the study data, the creation of versions of the study datasets, the rules for naming files, the structure of the folders for storing the study data, etc.]*

4.2 What kind of data processing techniques will you use?

5. Storage and backup of study data

5.1 How will you ensure the implementation of the DAP? *[Describe who and how (in what way) will ensure oversight of the investigation data, etc.]*

5.2 Where will the data and *back up* copies of the study be stored during the study? *[Please specify,*
how often you plan to make copies of the survey data and where you will keep them.]

5.3 How will the investigation data be recovered in the event of an incident? *[Explain whether you plan to use an automated service to create regular backups.]*

[10] 'Personal data' means any information relating to an identified or identifiable natural person (data subject); an identifiable natural person is one who can be identified, directly or indirectly, in particular by reference to an identifier such as a name, a personal identification number, location data and an online identifier, or to one or more factors specific to the physical, physiological, genetic, mental, economic, cultural or social identity of that natural person (2016. Article 4(1) 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")).

[11] Metadata - data about the data itself: data source, size, format, etc. (Term Bank of the Republic of Lithuania, http://terminai.vlkk.lt/; source: S. Maskeliūnas. Glossary of Knowledge Technology Terms (electronic edition), 2012).

[12] For example, by research area, see. See the RDA *Metadata Standards Directory*, http://rd- alliance.github.io/metadata-directory/.

5.4 Who will have access to what data during the investigation?

6. **Personal data**[13]

6.1 Identify the authorised controller of the personal data and the contact details of the Data Protection Officer (name, email and telephone):

6.2. What personal data will you collect?

6.3 What measures will[14] take to ensure the protection of personal data?

6.4 Where will the personal data be stored during the collection of the survey data? Who will have access to which personal data during the collection of the investigation data and what access rights they will have granted?

6.5 Will personal data be destroyed? *[Yes / No]*

[If no, please indicate on what grounds (e.g. informed consent, etc.) the personal data will not be destroyed.]

7. **Post-investigation data processing**

7.1 When will the data from the study be made available for storage (e.g. after publication of the results, etc.)?

7.2 Who, by what means (e.g. by opening in a data warehouse, on request, by data transfer agreement, etc.) and what data will they have access to at the end of the investigation?

7.3. Will exclusive rights of use of the data be required? *[Yes / No]*

[If yes, please specify why and for how long, and whether data sharing will be delayed or restricted, e.g. for publication, protection of intellectual property etc.]

7.4 How long, where (e.g. in a repository, archive, etc.) and what kind of research data will you protect? For what purposes (e.g. contractual, legal or other (e.g. historical, cultural) purposes) will you keep the research data?

7.5 How other information about the research data (e.g. informed consents, subjects' and a list of information about them, etc.) will be handled (e.g. stored, destroyed, etc.) at the end of the investigation?

7.6 When and what research data will you destroy?

Description of the procedure for assessing compliance with research ethics Annex 4

VILNIUS COLLEGE

(name of the faculty - please insert) (name of the department - please insert) (job title, name and surname - please insert)

Committee on Compliance with Research Ethics

SHOP

(date)

1. The title of the research (hereinafter referred to as "the research") in Lithuanian and English.

2. Principal investigator(s) and investigator(s) (please list all investigators involved in the study and the scientific fields they represent).

3. Description of the study (up to 200 words) (specify the aim, objectives, etc.).

4. Study methodology, subjects/participants, study location (describe the study methods, instruments and who will be the subjects/participants, and where the study will be carried out; attach

[13] Personal data are processed in accordance with the provisions 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), the Law on the Legal Protection of Personal Data of the Republic of Lithuania, and the internal documents of the relevant institution regulating the protection of research data and personal data.

[14] For more details, see the Recommendation of the State Data Protection Inspectorate on 'Methods of personalisation', https://vdai.lrv.lt/uploads/vdai/documents/files/Rekomend_nuasmeninimo_metodai_2015.pdf.

the study instruments to the application).

5. If the study will use research instruments not developed by the researchers themselves, please indicate how the copyright and legality of the use of the research instruments have been ensured, the sources of the instruments and the permissions obtained to use them.

6. Milestones and timelines for the implementation of the research (please briefly indicate the milestones, start and end of the research).

7. Indicate the source(s) or sponsor(s) of the research funding (in the case of a commissioned study, attach a copy of the research commissioning agreement).

8. Will vulnerable persons be involved in the study? Vulnerable persons are those whose consent to take part in psychological research may be influenced by external circumstances or who are partially or totally unable to defend their interests:

- Persons who, because of a medical condition, cannot be considered to have the capacity to assess their own interests □ Yes □ No
- under 18 □ Yes □ No
- Students, if their participation in the study is related to their studies □ Yes □ No
- persons living in social care institutions □ Yes □ No
- soldiers during their actual military service □ Yes □ No
- staff members under the authority of the investigator in the establishments where the investigation is carried out □ Yes □ No
- Persons in prisons or other places of deprivation of liberty □ Yes □ No
- other vulnerable people or groups

If vulnerable persons will be involved in the investigation, explain how the interests of vulnerable persons will be protected.

9. Indicate whether the research may involve any risks or harms to the research participants and how these risks or harms are planned to be mitigated.

10. Please indicate whether the participation of the participants in the study will be voluntary and how it is planned to ensure such voluntary participation.

11. Please indicate whether the consent of the study participants to participate in the study will be based on informed consent? Please submit the prepared informed consent forms with your application.

12. If informed consent cannot be obtained from the research participants themselves, indicate how their safety, rights and dignity will be ensured.

13. Specify how participants will be informed that they can withdraw from the study at any time and that they can request to withdraw their data.

14. Please indicate how the participants will be informed about the possibilities to discuss aspects of the study with the investigator(s) and to contact them both during and after the study.

15. Please indicate the planned dissemination of the results of the study, whether the dissemination of the results of the study will cause harm to the subjects, and if so, how it is planned to mitigate it.

16. Indicate how the safety, dignity and rights of the participants will be ensured if, for methodological reasons, the purpose of the study cannot be disclosed to them or if the study is likely to cause discomfort.

17. Specify how the personal data of study participants will be protected, managed and kept confidential.

18. Please indicate whether the participants are to be compensated for their participation in the

study? If yes, in what way?

19. Please indicate whether compensation or rewards for participation in the study will become a decisive incentive for subjects to participate in the study? Justify the fairness and proportionality of the compensation to the level of involvement in the study.

20.If the study will involve animal testing, please indicate whether authorisation has been obtained from the State Food and Veterinary Office. A copy of the authorisation must be submitted with the application.

21. If the study or parts of the study require authorisation under the Law on Ethics of Biomedical Research of the Republic of Lithuania, please indicate whether this has been obtained. Please submit a copy of the authorisation with your application.

22. Confirm that the study will be carried out in accordance with this application and the relevant legislation. I certify (name and title of the investigator(s) or team leader(s))