

VYTAUTAS MAGNUS UNIVERSITY SENATE

DECISION ON THE ADOPTION OF PROVISIONS FOR THE ASSESSMENT OF RESEARCH CONFORMITY WITH THE FUNDAMENTAL PRINCIPLES OF RESEARCH PROFESSIONALISM AND ETHICS

March 24, 2021, No. SEN-N-17 Kaunas

In accordance with Articles 30.2 and 30.18 of the Statute of Vytautas Magnus University (hereinafter – VMU) and considering the opinion of the Scientific Committee of the Senate, the Senate sets forth the following:

to adopt the provisions for assessing the research conformity with the fundamental principles of research professionalism and ethics.

Chair

Ričardas Krikštolaitis

APPROVED by Decision No. SEN-N-17 of March 24, 2021, of Vytautas Magnus University Senate

PROVISIONS FOR ASSESSMENT OF RESEARCH CONFORMITY WITH THE FUNDAMENTAL PRINCIPLES OF RESEARCH PROFESSIONALISM AND ETHICS

CHAPTER I GENERAL PROVISIONS

1. The Provisions for Assessment of Research Conformity with the Fundamental Principles of Research Professionalism and Ethics (hereinafter – the Provisions) are intended to assist the academic community of Vytautas Magnus University (hereinafter – VMU or the University) in assessing the research conformity with the principles of professionalism and ethics set for a specific research study and to protect the interests of the research participants (persons) and the animals used in research. Adopting a procedure for assessing conformity with research professionalism and ethics helps ensure the quality, reliability, integrity, and completeness of research and assess the risks involved in managing the obtained data.

CHAPTER II FUNDAMENTAL PRINCIPLES OF CONFORMITY WITH RESEARCH PROFESSIONALISM AND ETHICS

2. The researcher must be guided by the following fundamental principles of research professionalism and ethics when conducting research, regardless of the area of science and/or the methods chosen: reliability, integrity, respect, and accountability.

3. The principle of reliability shall be implemented when:

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

3.2. achieving transparency in research objectives and choosing appropriate methods of data collection and analysis to achieve them;

3.3. anticipating the potential harms and benefits of research, taking into account the interests of the various research participants (groups), communities, society, and risk mitigation measures.

4. The principle of integrity shall be implemented when:

4.1. following all the planned stages of research;

4.2. informing immediately the evaluation committee operating in the academic unit that authorized the research permit about any change in the circumstances of the research or other unforeseen information related to the research being carried out;

4.3. disclosing information about the conflict of interest to the evaluation committee operating in the academic unit that has authorized the research;

4.4. accepting full responsibility for the research results and their publication, the consequences of the research, and the consequences for those affected.

5. The principle of respect shall be implemented when:

5.1. providing the research participants with information on the processing of personal data of the data subject in accordance with Regulation (EU) 2016/679 of the European Parliament and of the Council of 27 April 2016 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data, and repealing Directive 95/46/EC (General

Data Protection Regulation)(hereinafter – GDPR) and enough information to enable them to decide on their participation in the research (informed consent);

5.2. ensuring the voluntary research participation of research participants;

5.3. ensuring that research participants are aware and are able to withdraw from the research at any time without giving a reason and without feeling constrained on participating in the research; 5.4. protecting personal data subject to strict confidentiality and anonymity procedures provided by research participants.

6. The principle of accountability shall be implemented when:

6.1. making research results available to the academic community and the general public;

6.2. disclosing information about the conflict of interest to the evaluation committee operating in the academic unit that has authorized the research;

6.3. obliging to comply with the requirements relating to the protection of personal data and to be able to prove this;

6.4. declaring the source of funding for the conduct of the research transparently and the publication of its results.

CHAPTER III SPECIFIC REQUIREMENTS FOR CONFORMITY WITH RESEARCH PROFESSIONALISM AND ETHICS

SECTION I

PRINCIPLES OF RESEARCH PROFESSIONALISM AND ETHICS IN THE HUMANITIES AND SOCIAL SCIENCES

7. Respect to research participants;

7.1. Voluntary participation;

7.1.1. Participation in research is voluntary and based on informed consent;

7.1.2. Informed consent means free, prior and informed consent to participate in research. For specific research, the most appropriate type of informed consent that meets the requirements of GDPR Articles 7 and 13 shall be selected. The main types of informed consent are the following: 7.1.2.1. broad consent;

- 7.1.2.2. blanket consent:
- 7.1.2.3. open consent;
- 7.1.2.4. portable legal;
- 7.1.2.5. meta-consent;
- 7.1.2.6. dynamic informed consent.

7.1.3. Research participants shall give their written consent to participate in the research. When the audio recording is made, the research participant shall be provided with information about the processing of personal data in accordance with GDPR Article 13. For instance, consent during an interview or a reply to a questionnaire, or a request for a written reply, indicates that the subject has agreed to participate in the research. In the research, it is recommended that written informed consent shall be prioritized;

7.1.4. In institutions where the research is carried out, and their representatives/guardians are involved in the research (e.g., prisons, childcare homes, hospitals, etc.), it is crucial that:

7.1.4.1. to obtain the consent of the head of the institution to conduct research in the institution under his/her authority and to have access to the research participants;

7.1.4.2. to receive consent from every research participant:

7.1.4.3. in exceptional cases, a person authorized by the research participant (in accordance with the legislation governing the creation of powers of attorney) or a person authorized to make decisions for the research participant when the research participant is not able to make decisions independently (e.g., in the case of disability or the case of the participation in research of socially vulnerable persons) would give his/her consent instead.

7.1.5. When conducting the research in institutions, both the researcher and the institution shall ensure the privacy of the research participant;

7.1.6. If the research involves intervention methods and the research participant is physically influenced, consent shall always be given only in writing or by any way of proof;

7.1.7. To monitor behavior in a public space (e.g., a shopping mall, a train station, or an institution of higher education) the informed consent of the individual is not required, provided that no personal data are collected, and the research data do not allow the individual to be identified. It also excludes audio and video recordings where individuals can be identified.

7.1.8. The consent may be specific or broad. The general consent form shall include the forms and conditions for data recording and archiving, the conditions for the use of research data in secondary research, and information on the processing of the research participant's personal data in accordance with the requirements of GDPR Article 13;

7.1.9. Where data obtained from research participants are combined with data in official registers, research participants shall be provided with details of the data registers that have been/will be used, what information on research participants has been/will be collected from these registers, and any other information referred to in Articles 13 or 14 of the Regulation as appropriate. Information on data collected from public registers prior to the research participant's consent to participate in the research shall be provided to the research participant in accordance with the time limits set out in GDPR Article 14(3);

7.1.10. Research participants 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 shall inform the research participants of the conditions for using the data collected after withdrawal from the research. This information and the conditions for the use of the data provided by the research participant shall be discussed with the individual before he/she decides to participate in the research;

7.1.11. Passive/implied consent may be considered in particular circumstances under the following conditions:

7.1.11.1.The applicable consent would result in substantial and demonstrable deficiencies in the quality or purpose of the research and/or the interests of the researcher;

7.1.11.2.there are a minimal burden and no risk to study participants;

7.1.11.3.any effort has been made to inform research participants and/or their representatives about the research and the possibility of refusing to participate in it;

7.1.11.4.the withdrawal procedure is straightforward.

7.2. Participation of minors in scientific research

7.2.1. The specific needs and interests of minors¹ (children under 18) shall be protected by adults. Minors (in the general sense) are developing personalities, and their needs and abilities vary at different stages of their development. Hence, researchers need to have a good understanding of minor development and psychology in order to be able to adapt their selected methods and research approaches to the age of the research participants. Information about the

¹ Articles 13 and 14 of the Civil Code of the Republic of Lithuania distinguish between two groups of minors: under the age of 15 and between 15 and 18 years of age.

research and its implications shall be age-specific. Minors shall also be informed of their voluntary participation in the research and the possibility to withdraw from the research at any time;

7.2.2. In the presence of a minor in the research, researchers shall obtain the parents' or guardians' consent. The consent shall be given by completing and signing the Informed Participant Consent Form (see Annex 2). The researcher shall also provide the consent parent/guardian with the participant information sheet (see Annex 1). Instead of the forms set out in the Annexes, the researcher may use forms of equivalent content approved by the evaluation committee of the academic unit that authorized the study;

7.2.3. It is crucial to treat minors as independent persons and, in addition to obtaining formal consent from parents or guardians, it is essential to ensure that minors individually decide to participate in the research to the extent that they are able to;

7.2.4. A minor's consent to take part in research is required from the age at which he/she is able to express it. There is no specific (universal) age limit for a minor to make an independent or partially independent decision on whether or not to take part in research; therefore, in assessing the possibilities and scope of the minor's participation in this process, his or her views shall be taken into account through the minor's ability to formulate his or her views, age, level of maturity and interests. The principle of the best interests of the minor is one of the guiding principles to be followed in any decision related to a minor and in the event of a conflict of interests between the minor and others;

7.2.5. When minors are involved in research, the principle of confidentiality shall 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 to services that ensure the protection of the minor's rights (e.g., the duty to report applies if researchers become aware of abuse, violence against or neglect of a minor). Before deciding to disclose confidential information related to a minor, the researcher shall consider all the possible risks and consequences for the minor's health and life, and whether the disclosure of the confidential information will worsen the minor's current situation;

7.3. Research of people from vulnerable groups

7.3.1. Researchers have a special duty to respect vulnerable groups' interests (minors, prisoners, people with mental disabilities, etc.) throughout the research process. Vulnerable and disadvantaged individuals are not always prepared to defend their interests when dealing with researchers. It should be considered that procedures for obtaining informed consent do not necessarily ensure that such individuals are willing to participate in research or protect them from undue pressure;

7.3.2. Individuals belonging to vulnerable groups may be reluctant to take part in research for fear of unfavorable public attitudes towards them, which is why such research is only possible in accordance with the principles of the lawful processing of personal data and/or the requirements for the processing of special categories of personal data (the provisions of GDPR Articles 6 and/or 9);

7.3.3. The researcher shall seek the autonomous and voluntary consent of the incapacitated participant to take part in the research, i.e., the researcher shall be skilled in detecting signs of the participant's discomfort and reluctance to take part in the research, and in this case, he/she shall immediately discontinue the research. In such cases, it is also recommended to spend some time with each vulnerable or incapacitated research participant in order to establish a contact in order to facilitate the process of obtaining consent;

7.3.4. In the case of research carried out in health institutions, where the research participants are not legally incapacitated, however, due to their (mental) health condition may have difficulties in understanding the information provided during the informed consent process, it is recommended that a third party (e.g., a staff member of the institution) be present at the time of obtaining the consent of such individuals to certify with his/her signature that the researcher has adequately informed the participant and that the participant's consent to take part in the research is both informed (i.e., the person has understood the information provided to him/her) and freely given.

7.4. Information for research participants

7.4.1. The information to be provided to research participants depends on the nature of the data collection methods. For qualitative, quantitative, and mixed methods research, it is compulsory to provide participants with information about the research;

7.4.2. Information about the research should include at least the following:

7.4.2.1. the contact information of the researcher;

7.4.2.2. the topic of your research;

7.4.2.3. the method of data collection and the expected duration;

7.4.2.4. the purpose of the data collection, the way it will be used in the future, archiving methods for secondary use;

7.4.2.5. the voluntary nature of participation;

7.4.2.6. information to be provided on the expected benefits of the research and the potential risks to the research participant;

7.4.2.7. the information on the processing of the research participant's personal data set out in GDPR Article 13;

7.4.3. Research participants may request further information about the research. For instance, additional information may relate to (1) the research, (2) how the confidentiality and anonymity of the 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, and (4) external sources of funding;

7.4.4. In cases of the use of experimental research, sufficient information on the experimental design shall be provided. Experimental research varies widely from field to field, so the completeness of the information is always determined and justified by the researcher;

7.4.5. Requests from research participants for additional information related to the research and the research participant's necessary personal data shall be responded to in simple and understandable language and as fair and accurate as possible.

7.5. Data collection by alternative means

7.5.1. The researcher collects data for the research without identifying him/herself but with incomplete or coded information about the research content.

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

8. Risk assessment

8.1. The potential harm to research participants may be caused by the collection, storage, and consequences of the publication of research data and/or results.

8.2. Avoiding psychological harm

8.2.1. Avoiding psychological harm involves treating research participants with respect and publishing results ethically in scientific publications.

8.2.2. The sensitivity of the topic and the limits of privacy depend primarily on the individual participant. If research participants are aware of the issues that will be addressed based on the information provided to them, they express their willingness to take part in the research and are aware of the scope and methods of the research by giving their informed consent. By taking part in research, participants regulate their participation by avoiding situations and questions that they consider harmful.

8.2.3. During the research, the researcher is also responsible for the prevention of possible psychological harm to the research participant and for the management of situations related to unexpected psychological harm (anger, sadness, tears).

8.2.4. If the research involves interaction with research participants (e.g., participant observation, interviews), all data about research participants shall be treated with respect and dignity.

8.2.5. The researcher shall ensure that the principle of voluntary participation is respected, even when there is direct contact with the research participants. The researcher should always (unless it is not objectively possible) ensure that the participant's participation is voluntary, especially where there is a direct relation with the research participants. Frustration, embarrassment, fear, or physical fatigue may be sufficient grounds for a researcher to terminate the research as far as the subject is concerned, even if the participant does not explicitly refuse to continue. It is essential to ensure that research participants voluntarily participate when researching them in their institutions (e.g., hospitals, prisons, youth detention centers, homes for the elderly, etc.).

8.3. Avoiding financial and social impact

8.3.1. Financial and social harm to research participants is more likely if the research does not respect ethical principles related to privacy and data protection. In accordance with ethical principles, when handling and protecting confidential information, it is necessary to explain to research participants how the protection of confidential information will be ensured.

8.3.2. Scientific publications may have harmful consequences for research participants. The risk of harm is highest if the results are presented in an unethical way, e.g., by publishing false results that are not based on comprehensive data or systematic analysis.

8.3.3. Researchers should avoid any impact on research participants that may result from scientific publications. However, this principle should not prevent the publication of research results that may not be acceptable to research participants in all respects.

8.3.4. The researcher's task is to present the information as objectively and comprehensively as possible, regardless of the reactions of the institution's heads, the research participants, or other individuals.

8.4. Research harm risk assessment

8.4.1. Research involving potential risks that cannot be assessed by the research participants individually and research that may cause harm and affect everyday life shall be evaluated in advance. If the researcher knows or understands that there is a risk of long-term psychological harm or that the safety of the participant will not be ensured, he/she shall indicate this in his/her request for an assessment of compliance with the research professionalism and ethics together with the ways of mitigating risk. In the event of unforeseen harm occurring during the research, the researcher shall suspend the research and reassess the risk of harm, inform the evaluation committee in the academic unit that authorized the research, and, where possible, submit a plan to the institutional evaluation committee to prevent unforeseen harm.

9. Confidentiality and data protection

9.1. Data protection is a crucial area of privacy protection in collecting and managing research data and the publication of results. In research, it is essential to ensure: 1) the protection of

research data and confidentiality; 2) the storage and management of research data; and 3) the quality of scientific publications. Data protection aims at revealing research data and results while preserving the confidentiality of research participants.

9.2. The privacy protection principles apply to publicly available material or published data that may relate to individuals and their political, business, and cultural activities. For instance, during the research where a biographical approach is applied, privacy disclosures should be agreed with the individual about whom the data are collected or his/her proxy.

9.3. The basic principle of collecting and storing personal data is the need for personal data when conducting the research. Personal data shall be collected for specified, explicit, and legitimate purposes and not further processed in a manner incompatible with those purposes. During the research, personal data is processed in accordance with the provisions of the VMU Personal Data Processing Rules.

9.4. Where research data can reasonably be analyzed without direct identifiers, and there is no justification for keeping identifiers, only data with removed identifiers may be processed and stored for secondary research.

9.5. Data with identifiers may be collected and used when it is appropriate for particular research. With informed consent, the data may also be stored with identifiers for secondary research. In the research, it may be necessary to process and store identifiers to audit data and prevent its fabrication and falsification, investigate possible breaches of academic ethics, and analyze historically and culturally significant data. All current data may acquire historical and cultural significance over time, but the latter shall be assessed and justified by the researcher on a case-by-case basis.

9.6. The confidentiality of research data is subject to restrictions on the processing, use, and storage of the data. Research data may be used or transmitted for data audit purposes if provided to the client in outsourced research. In particular, it is not acceptable to disclose research data or to transfer data in a way that could affect the assessment, treatment, or situation of the individual research participant. Non-anonymized research data may not be transferred to the media or used for commercial purposes.

9.7. An assurance of confidentiality is the duty of every citizen to report an imminent serious crime that can still be prevented. The researcher is not obliged to disclose information about crimes already committed unless the disclosure helps prevent an imminent severe crime.

9.8. In accordance with the concept of open science and international scientific guidelines, research data (if necessary anonymized as well) shall be kept for at least ten years from the date of their publication or for a period proposed by the data repositories under the chosen license.

9.9. Storage and destruction of research data:

9.9.1. Research in the humanities and social sciences is not always repetitive; however, the academic community should be able to verify research findings from research data analyzed in the research, if necessary, by opening data according to the requirements of the selected data repository and depersonalizing or pseudonymizing the research data².

Openness is a key feature of the quality of science and is also a prerequisite for assessing scientific information's validity.

9.9.2. Data carefully archived 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.

² Detailed information is provided in the recommendations of the State Data Protection Inspectorate "Methods of Depersonalization": <u>https://vdai.lrv.lt/uploads/vdai/documents/files/Rekomend_nuasmeninimo_metodai_2015.pdf</u>

9.9.3. Where appropriate, the protection of privacy should be ensured through depersonalization methods and establishing access to depersonalized data stored for secondary research.

9.9.4. Where the data from previous research are to be re-used for new research purposes, but the informed consent of the original research participants can no longer be obtained, a research plan detailing the nature and importance of the re-use, including privacy implications, shall be provided. The evaluation committee operating in the academic unit shall decide whether re-use of the data is possible.

9.9.5. If data containing identifiers are sensitive and cannot be anonymous and research participants have not been asked for permission to store and/or open data, personal and research data should be destroyed at the end of the research (after the publication of research results). If the data have scientific value or are historically unique, the researcher may apply for permission to archive anonymized research data in a data repository/archive recommended by the University. 9.10. Ensuring privacy in scientific publications:

9.10.1. Unlike research data, scientific publications are usually publicly available. Factors to consider when publishing research are the following:

9.10.1.1. the general principle is to protect the privacy of research participants in the publication. Decisions shall be made on a case-by-case basis if the publication identifies the individual who participated in the research;

9.10.1.2. the research participants' copyright shall be considered when assessing whether to publish the research participants' names. In case the research is based on interviews with experts, the research publication may also include their names and other essential information, with the consent of the participants who provided information or were interviewed. Thus, the prior consent of the research participants to the publication of their personal data in a scientific publication or other publicity (e.g., at scientific and other events) shall be obtained;

9.10.1.3. Research participants should not be promised complete anonymity if this cannot be ensured. For instance, granting anonymity to participants in research on scientific publications does not necessarily prevent them from being identified by those who are familiar with the activities of the community or organization that was the subject of the research;

9.10.1.4. the researcher shall act ethically when writing about deceased individuals. Due account should be taken of the need for privacy expressed by the deceased's family and other close relatives;

9.10.1.5. when studying organizations (e.g., institutions, associations, work communities, public bodies, etc.), their identity and individual representatives shall be assessed on a case-by-case basis.

9.11. Quantitative research results are presented statistically, but in the case of a risk of identification, the use of identifiers or anonymization of data is required.

9.12. In the case of qualitative data, the identification risk shall continuously be assessed before any data samples and/or citations are published: what indirect identifiers (e.g., place of work, school, place of residence, age, occupation, position, etc.) are indicated, what will be encrypted and what will be skipped.

9.13. When the research deals with archived material, the research participants' identification depends on the conditions set by the data repository/archive where the data is stored.

10. Researchers' behavior

10.1. When publishing research results, researchers may not falsify and fabricate research data, as well as omit and/or conceal important data.

10.2. Researchers shall indicate methods used to collect and/or select data, as well as methods used to validate and analyze data.

10.3. If researchers identify material errors in published data, they must take measures to correct these errors by publishing the errors, correcting the data, or applying other appropriate measures.10.4. Researchers shall clearly indicate the authorship of parts or elements of other researchers' work or data, as well as when citing another author's work or data source.

10.5. Researchers shall assume responsibility only for the work they have actually (independently) performed or contributed to, provided that the part of the researcher's work can be identified, but where this is not possible, the responsibility shall be borne by all researchers. They can only be named as authors or co-authors of a work if they meet the criteria for authorship, and only then they can claim that the work belongs to them. Authorship must be attributed only to those persons who have made a substantial contribution to the concept, implementation, or interpretation of the research, i.e., who meet the following criteria:

10.5.1. approval of the final version of the work to be submitted for printing;

10.5.2. taking responsibility for the proper analysis and resolution of all issues related to the accuracy or academic integrity of the work;

10.5.3. and at least two of these criteria:

- research idea or design;
- data collection and processing;
- data analysis and interpretation;
- writing or critical rewriting/improving individual parts/chapters of the work (synthesis of literature review or part of research results).

10.6. The designation as the main author or co-author of the work implies the scientific contribution of the persons concerned, not their status. For those who do not meet the requirements for authorship, but who have contributed to the research, gratitude shall be expressed in the scientific publication.

11. Overall validity, inter-institutional research, and research in other institutions or places

11.1. If the evaluation committee operating in the academic unit of the University makes a decision on the validation of conformity with research professionalism and ethics, this decision may be considered valid for other research and study institutions represented by researchers involved in the research. If the researcher moves from one research and study institution to another, and the research was carried out in the previous research and study institution and is extended in a new institution, no additional assessment of conformity with research professionalism and ethics is required; however, the research results should be attributed to the institutions where the researcher carried out the research. The continuation of research and validation of its conformity with research professionalism and ethics shall be reported in the new workplace.

11.2. Irrespective of the fact that the research is carried out by several research and study institutions, the primary researcher or the research manager and the institution to which he/she is affiliated shall be responsible for validating the research conformity with research professionalism and ethics. If research projects are carried out in several research and study institutions, it is considered sufficient to carry out the assessment of conformity with research professionalism and ethics in only one research and study institution and to inform the other about it accordingly.

11.3. In interinstitutional research, depending on the nature and context of the collaboration, the assessment of conformity with research professionalism and ethics for different parts of the

research can be obtained separately from different research and study institutions (e.g., social research may be conducted in one institution and clinical research, in another).

12. Compensation for participation in research

12.1. The compensation or benefits offered to the research participants and/or communities of research participants for their participation in the research shall be fair.

12.2. The researcher and the organization in which the research is conducted shall receive compensation not exceeding what can be considered reasonably proportionate to the nature, scope, and purpose of the research (e.g., compensation for travel expenses to the research site (e.g., laboratory).

12.3. When research participants are offered professional services (e.g., discounts on services and/or goods, training) as an incentive to participate in the research, researchers shall clearly indicate the nature, potential risks, obligations, and limitations of these services.

13. Exemptions for research

13.1. Research methods based on fraud or deception shall not be used in the research, even where the research is intended to produce significant scientific or applied value, and it is not possible to choose an appropriate procedure for effective data collection. In this case, the researcher must use all legitimate and generally accepted data collection tools and methods to conduct the research.

13.2. Failure to provide information about the research question and/or hypothesis (in order to prevent the research participant from exerting influence) shall not be considered deceptive.

13.3. Research participants may be provided with insufficient information (e.g., observation data collected from the emergency service or while going for a drive with a police squad when the researcher cannot disclose that he/she is conducting a research) or misleading information about the role of the researcher (e.g., working in secret, the researcher may mislead the research participants when investigating discriminatory cases).

13.4. Information may not be withheld, or the research participants may not be deceived about the procedures that are reasonably likely to cause physical or psychological harm.

13.5. Any incomplete, misleading, or concealed information must be explained to the research participants as soon as possible, immediately after participation and at the latest upon completion of the collection of data. The research participants must then also be informed that they have the right to withdraw their data without negative consequences.

SECTION 2 BIOMEDICAL RESEARCH

14. The researcher conducting biomedical research shall act in compliance with the Law on Ethics of Biomedical Research, the Description of the Procedure for Issuing Approvals to Conduct Biomedical Research (the version of Order No. V-27 of January 8, 2016, of the Minister of Health of the Republic of Lithuania) and other special legal acts regulating clinical trials of medicinal products, clinical trials using medical devices, etc.

15. Researchers shall apply to the Lithuanian Bioethics Committee or the Regional (Vilnius or Kaunas) Biomedical Research Ethics Committee for validation of conformity with research professionalism and ethics.

16. The Lithuanian Bioethics Committee shall issue approvals to conduct biomedical research when biomedical research is planned to be conducted within the territory attributed to activities of more than one regional biomedical research ethics committee.

SECTION 3 ANIMAL RESEARCH (EXPERIMENTS)

17. The researcher conducting research on animals shall act in compliance with the Directive 2010/63/EU of September 22, 2010, of the European Parliament and of the Council on the protection of animals used for scientific purposes, the Law on Animal Welfare and Protection of the Republic of Lithuania, the Order No. B1-866 of October 31, 2012, of the Director of the State Food and Veterinary Service of the Republic of Lithuania on the approval of requirements for the accommodation, care, and use of animals used for scientific and educational purposes, the European Convention for the Protection of Vertebrate Animals used for Experimental and other Scientific Purposes.

18. The State Food and Veterinary Service shall issue approvals to conduct research and testing on animals.

CHAPTER IV ENSURING CONFORMITY WITH RESEARCH PROFESSIONALISM AND ETHICS

19. At Vytautas Magnus University, ensuring conformity with research professionalism and ethics shall be implemented through evaluation committees operating in academic units and consisting of at least 3 academic staff members.

20. The evaluation committees shall operate in accordance with ethical principles (including, but not limited to, objectivity, responsibility, transparency, confidentiality, integrity, equality).

21. The main function of the committees is to assess the conformity of the research to be carried out with research professionalism and ethics before the start of the research. The committees may also perform supervisory and advisory functions in the course of scientific research in relation to the assessment of the conformity with research professionalism and ethics carried out.

22. The composition, operating principles, and other operating procedures of the committees shall be laid down in the Rules of Procedure of the Committees, which shall be approved by the Rector of the University. Information about the evaluation committees operating in the academic units of the University is publicly available.

23. The primary researcher must submit to the evaluation committee his/her research plan for the validation of conformity with research professionalism and ethics if:

23.1. in his/her research, the researcher plans to use intervention methods (e.g., social experiments, participatory action research, etc.);

23.2. the research departs from the principle of informed consent;

23.3. research participants are minors and the research is carried out in a pre-school and preprimary education institution, a general education school and a care institution for minors, personal health care institutions, etc.;

23.4. the research shows that study participants experience exceptionally strong stimuli and that specific knowledge (e.g., related to violence, pornography, etc.) is needed to assess potential harm;

23.5. the research can cause long-term psychological harm (such as psychological trauma, depression, insomnia, etc.) exceeding the risks encountered in normal life;

23.6. the research involves safety risks for the research participants (e.g., research into domestic violence);

23.7. this is required by the research participant, the research funding organisation, or cooperation (e.g., international project, commissioned research, etc.) partner (party);

23.8. the research plan must be submitted for the validation of conformity with research professionalism and ethics if the participants in the research are socially vulnerable persons (minors, prisoners, persons with mental disabilities, etc.), and this is required by law. In addition, the research plan should provide answers to the following questions:

23.8.1. Whether it necessary to include socially vulnerable persons in the research;

23.8.2. If yes, whether appropriate measures are in place to protect these persons;

23.9. unforeseen circumstances arise in the course of the research (e.g., changes in the terms and conditions of the processing of personal data, data collection method, etc.) that affect the research plan, the conformity of which with research professionalism and ethics has been validated.

24. The primary researcher may also submit to the evaluation committee his/her research plan for the validation of conformity with research professionalism and ethics if:

24.1. the researcher is unsure whether his/her research is likely to cause significant psychological or physical harm or whether there are signs of security risk to the research participants;

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

24.3. the research results are planned to be published in a scientific journal one of the requirements of which is to provide validation of conformity with research professionalism and ethics.

25. In complex cases or in the case of highly important issues (including the application of operational principles) the resolution of which may have a significant impact on and consequences for the planned research, the image of the University, the reputation of the researchers, the committees may use the assistance of other institutions, taking into account their areas of competence (issues related to biomedical research may be addressed to the Lithuanian Bioethics Committee, the regional biomedical research ethics committees; issues related to ensuring equal opportunities, to the Office of the Equal Opportunities Ombudsman of the Republic of Lithuania; issues related to data protection, to the State Data Protection Inspectorate and the Office of the Inspector of Journalist Ethics, etc.).

26. The academic units of the University shall ensure that the competence of the members of the evaluation committees operating in them covers the relevant scientific disciplines of the academic unit and typical ethical issues related to the scientific field.

27. The committees shall decide independently on the cases in which the assessment of conformity with research professionalism and ethics shall be applied, but the assessment shall be necessary in the cases described in Article 23 of these Provisions.

28. The forms of the participant information sheet and the informed consent provided in the Annexes to these Provisions shall be of a recommendatory nature. The evaluation committees operating in the academic units may independently approve the forms that are more convenient and suitable for them.

29. The composition of the committee shall be approved for a maximum period of three years.

30. Members of the committees must be of good repute and sign a confidentiality commitment, which must be observed for 5 years after the expiry of their term of office. The confidentiality of personal data is protected for an indefinite period.

31. A member of the committee who has a conflict of interest with regard to the submitted research project shall, at any stage of the examination of conformity with research professionalism and ethics, withdraw from the committee immediately as soon as this becomes apparent by notifying the members of the committee involved in the assessment. A member of the committee

who is obliged to withdraw from the committee due to a conflict of interest but whose qualified opinion is required for the adoption of a decision shall continue to attend the meeting without the right to vote.

32. The committee may, where appropriate, call on the services of independent experts in the relevant field of science to provide an opinion on the assessment of the application for conformity with research professionalism and ethics and to advise the members of the committee. Experts shall not have the right to vote in decision making process.

33. The composition of the committee shall be proposed by the Council of the academic units of the University and approved by the Rector of the University.

Annex 1 to the Provisions for Assessment of Research Conformity with the Fundamental Principles of Research Professionalism and Ethics

[Logo]

VYTAUTAS MAGNUS UNIVERSITY

[Name of the academic unit]

Participant's name:

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

Research title

PARTICIPANT INFORMATION SHEET

Minutes No. [xx] of [date] of the Research Ethics Committee.

1. Why is this research being conducted?

[Please state the aims and objectives of the research]

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

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

3. Do I have to take part in the research?

Participation in the research is not compulsory. Before making a decision to take part or not, you can ask questions about the research. If you do agree to take part, you may withdraw yourself from the research at any time without giving a reason [and without negative consequences—please include if appropriate] by notifying me/us of your decision. Within 30 days of your participation in the research, you may withdraw from the research and withdraw any information you have contributed to the research. [Please specify what will happen to the data collected until the point of withdrawal from the research].

4. What will the course of the research be if I agree to take part in the research?

[Describe in detail research steps that are related to the research participant and general stages that will be followed in the research process. If there are multiple research visits, describe them in turn.]

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

[If applicable:] When you arrive, I/we will discuss the research procedures and give you the chance to ask any questions related to the research. I/we will then ask you to fill in the 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].

The interview/session should take approximately [xx] minutes/hours. [For longer sessions: You will be offered [number] breaks of [xx] minutes]. You can also ask to withdraw your consent to take part in the research or to stop the interview at any time.

[Please 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]. 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 program will be used and other relevant circumstances set out in Article 13 of the GDPR.]

5. Are there any potential risks involved in taking part in the research?

The following risks are involved in taking part in the research: [describe the potential risks of the research, as well as note the smallest risks, such as breach of confidentiality, etc.].

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

6. Are there any benefits involved in taking part in the research?

[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. [Not obligatory] 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 research.

8. How will the data collected be managed?

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

[If applicable for the collection of special categories of personal data:] The data collected for the purpose of the research fall into special categories of personal data, such as your racial or ethnic origin, health, personal data revealing political opinions, religious and philosophical beliefs, trade union membership, genetic data, data concerning a natural person's sex life and sexual orientation [please list here the types of the sensitive, trade secret data you are collecting].

Personal/sensitive data shall be stored [insert location, security measures and how long the data collected will be stored for] [time limits depend on the procedure established by the information system and data repository chosen by the institution/publisher]/will not be stored.

Other research data (including consent forms) shall be stored for [indicate the data retention period in years and/or the conditions on which the data retention period depends] after the research has been carried out/the research results have been published.

The research data will be open in [insert location] and accessible to [specify the target group or to all].

[*The research participant*] shall have the right to withdraw consent to the processing of personal data [*specify by when personal data may be withdrawn*].

[If applicable:] Your personal data may be transferred and stored at the place of destination outside the European Union. [Inform the research participant about the possibility of transferring his/her personal data to third countries (including remote access to personal data) and about the appropriate or adapted safeguards and ways in which a copy of personal data can be obtained or personal data can be accessed.]

[The researcher and/or his/her team, supervisor, co-worker/translator/other authorized person...]shall have access to the research data. Responsible members of [institution name] may be given access to data for monitoring and/or audit of the research and for the investigations of possible breaches of academic ethics and/or procedures that are carried out by the Office of the Ombudsman for Academic Ethics and Procedures of the Republic of Lithuania.

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

[*If applicable:*] I/We would like to obtain your consent to use depersonalized data in future research and to share the data with other researchers (e.g., in online databases). All personally identifiable information about you will be removed or altered.

9. Will the research be published?

The research may be published [please specify the form, e.g., publications, websites, etc.].

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

[*Name of the institution*] is committed to the dissemination of its research for the benefit of society and, in support of this commitment, has established the institutional research archive, which is published on the website of the institution [*link*], and the research material/data collected is published on [*database and link*]. Holding the archive online gives easy access for researchers to the full text of freely available doctoral dissertations, thereby increasing the likely impact of that research and reducing waste of scientific resources.

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

[Give details of the organisation funding the research]

11. Who do I contact if I have a concern about the research?

If you have a concern about any aspect of this research, please contact [insert primary researcher's name and tel. no./email address of the University] or [insert supervisor's name and tel. no./email address of the University]. I/we will, within [xx] working days, acknowledge your concern and give you an indication of how it will be dealt with. If you wish to make a formal complaint, please contact the Chair or the Deputy Chair of the Research Ethics Committee of [name of the institution] who will seek to resolve the matter as soon as possible:

[Only for applications reviewed by] the Chair of the Research Ethics Committee of [name of the institution]; email address: [xx]; address: [xx].

[Only for applications reviewed by] the Deputy Chair of the Research Ethics Committee of [name of the institution]; email address: [xx]; address: [xx].

12. Data protection

[*Name of the institution*] is the data controller [*please specify email address of the institution*], so your personal data provided for the research will be managed by the institution [*insert in what manner*].

[Name of the institution] will process your personal data for the purposes of the research outlined above. Research of the institution is carried out [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 determine the type of processing it involves and to assess whether the specific purpose is in accordance with the requirements of the law. The purposes of the processing of personal data, such as "for research" or "for research in the public interest", are too abstract and do not make it possible to assess the volume of the personal data involved.]

Information on the rights to your personal data [to be explained by the institutions and inserted here].

Personal data officer; email address: [xx]; address for correspondence: [xx].

A complaint about the processing of personal data can be submitted to [name and email address of the institution], [email address and address for correspondence of the personal data officer of the institution], [email address of the Office of the Ombudsman for Academic Ethics and Procedures of the Republic of Lithuania], [email address of the State Data Protection Inspectorate], and/or [email address of the Office of the Inspector of Journalist Ethics].

13. Contact information and/or other information

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

[Primary researcher's name] [Name of the institution] [Address of the institution] Researcher's tel. no.: [xx] Researcher's email address: [xx]

Received

Signature Date Annex 2 to the Provisions for Assessment of Research Conformity with the Fundamental Principles of Research Professionalism and Ethics

[Logo]

VYTAUTAS MAGNUS UNIVERSITY

[Name of the academic unit]

Participant's name: Participant's contact information (email, telephone number):

Researcher's name and status: Researcher's affiliation: Researcher's tel. no.: Researcher's email address:

INFORMED CONSENT FORM

Minutes No. [xx] of [date] of the Research Ethics Committee.

[Project and/or research title]

Description of	f the project and research: [a short paragraph]			
		If you agree, tick the box	If y	ou disagree, tick the box
1.	I confirm that I have been informed of and understand the inform the above project/research ["title"]. I have had the opportunity to access the information, ask questions and get answers to them.			
2.	I have been informed that my participation is voluntary and that I may withdraw from the research at any time without giving any reason, without any negative consequences or penalties.			
3.	I have been informed that the data collected during the research may be reviewed by authorized persons who do not belong to the research team (e.g., the Committee of the research and study institution and/or data protection officer, Office of the Ombudsperson for Academic Ethics and Procedures of the Republic of Lithuania, the State Data Protection Inspectorate, the Office of the Inspector of Journalist Ethics, the court).			
4.	I have been informed that the project of this research has been re <i>[name of the institution]</i> Research Ethics Committee and this research has been approved.	viewed by		
5.	I have been informed of who will have access to the personal dat I provide, how the data will be stored, and what will happen to the data at the end of the project.	a		
6.	I have been informed that the research results will be made publi	c.		
7.	I have been informed of where to apply if I have a concern about	the research.		
8.	[If applicable] I agree that an audio recording may be made.			

		t	If you agree, ick the box	If you disagree, tick the box	
9.	[If applicable] I agree that a	video recording may be made.			
10.	[If applicable]I agree that p	hotographs may be taken.			
11.		nformed of how audio recording hs will be used when summarize <i>ppropriate</i>].			
11.1.	[<i>If applicable</i>] I agree that c attributed to me may be use results, OR	lirect quotes d when summarizing the researc	ch		
11.2.	[<i>If applicable</i>] I agree that r when summarizing the resea	ny quotes may be pseudonymiz arch results, OR	ed		
11.3.	[If applicable] I agree that r summarizing the research re	ny quotes may be anonymized v sults, OR	when		
11.4.	[<i>If applicable</i>] I agree that r may be quoted only [withor my personal data].				
12. Optional/	I agree to participate in the	research.			
not obligatory	I agree that the data collected in this research would be made available to researchers, even those working outside the EU, and used in other research. I realize that all data will be completely anonymized, and there will be no way to identify me.				
Optional/ not obligatory		and retention period] may be so that researchers can contact			
Participant's	name	Date	Signature		
Responsible p	person's name	Date	Signature		