Annex 4 of Regulations of the Research Ethics Compliance Committee of the Institute of International Relations and Political Science, Vilnius University

**STANDARD APPLICATION FORM TO THE RESEARCH ETHICS COMPLIANCE COMMITTEE OF THE INSTITUTE OF INTERNATIONAL RELATIONS AND POLITICAL SCIENCE, VILNIUS UNIVERSITY[[1]](#footnote-1)**

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| 1. **Title of the research in Lithuanian and English.**   *(Please highlight changes if resubmitting)*   |  | | --- | |  | |
| 1. **Principal investigator and investigators.** Please list all investigators involved in the research and the scientific fields they represent (please find the classification of research fields [here](https://www.tspmi.vu.lt/wp-content/uploads/2024/04/Klasifikacija.docx)).   *(Please highlight changes if resubmitting)* |
| 1. **Description of the research (up to 300 words)** (*state the aim and objectives of the study, etc.).*     *(Please highlight changes if resubmitting)*   |  | | --- | |  | |
| 1. **Research methods, instruments, subjects/participants, location** *(describe the research methods and instruments, who the subjects/participants will be in the study, and where the study will be carried out; attach the research instruments to the application).*     *(Please highlight changes if resubmitting)* |
| 1. **Stages and timeline for the implementation of the research** *(briefly indicate the stages, start and end of the research).*     *(Please highlight changes if resubmitting)* |
| 1. **Indicate the (potential) sources or sponsors of the research funding (if the research is commissioned, attach a copy of the research contract).**     *(Please highlight changes if resubmitting)* |
| **7. Will vulnerable persons be involved in the study? Vulnerable persons are those whose consent to participate in this research may be influenced by external circumstances or who are partially or totally unable to defend their interests:**  **a) persons who, because of a medical condition, cannot be considered able to assess their own interests properly**  Yes  No  **b) persons under 18 years of age**  Yes  No  **c) students, if their participation in the study**  **is related to their studies**  Yes  No  **d) people living in social care institutions**  Yes  No  **e) soldiers during their active military service**  Yes  No  **f) staff members under the authority of the investigator**  **in the establishments where the research is carried out**   Yes  No  **g) people in prisons or other places of detention**  Yes  No  **h) other vulnerable persons or groups (please specify)[[2]](#footnote-2)**   Yes  No    ............................................................................................................    **If vulnerable persons will be involved in the investigation, explain how the interests of vulnerable persons will be protected.**    *(Please highlight changes if resubmitting)* |
| **8. 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.**    *(Please highlight changes if resubmitting)* |
| **9. Please indicate whether the participation in the study will be voluntary and how it is planned to ensure such voluntary participation.**    *(Please highlight changes if resubmitting)* |
| 1. **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. Informed consent may be obtained not only in written form but also, if there is a strong justification for the choice, orally by recording the verbal consent. In certain cases, consent may be given anonymously.**     *(Please highlight changes if resubmitting)* |
| 1. **If informed consent cannot be obtained from the research participants themselves, indicate how their safety, rights and dignity will be ensured.**     *(Please highlight changes if resubmitting)* |
| 1. **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.**     *(Please highlight changes if resubmitting)* |
| 1. **Please indicate how the participants will be informed about the possibility of discussing aspects of the study with the investigator(s) and contacting them both during and after the study.**     *(Please highlight changes if resubmitting)* |
| 1. **Please indicate the planned dissemination of the research results, whether the dissemination of the results of the study might cause harm to the subjects, and if so, how the potential harm is planned to be minimised.**     *(Please highlight changes if resubmitting)* |
| 1. **Specify how the participants' safety, dignity and rights 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.**     *(Please highlight changes if resubmitting)* |
| 1. **Specify how the personal data of research participants will be stored, managed and kept confidential.**     *(Please highlight changes if resubmitting)* |
| 1. **Please indicate whether the participants are to be compensated for their participation in the study. If yes, in what way? Indicate whether compensation or rewards for participation in the study will be a determining motivation for subjects to participate in the study. Please justify the fairness and proportionality of the compensation to the extent of the involvement in the study.**     *(Please highlight changes if resubmitting)* |
| 1. **Please indicate whether the planned research poses any risks or harms to the investigators who are expected to carry it out, and how potential risks or harms are to be managed or minimised.**   *(Please highlight changes if resubmitting)* |
| 1. **If the research is planned outside the European Union (EU), please indicate whether and how it will be ensured that the research does not conflict with the EU and local law.**   *(Please highlight changes if resubmitting)* |
| **20. If you are planning to use artificial intelligence (AI) tool(s) in your study, please identify what tools you are going to use and how you will inform the research participants. Assess whether and what risks the use of a particular AI tool in your study poses (whether the country of origin of the AI tool is a risk, whether your data will be subject to confidentiality, whether your data will be used to train the AI model, whether the use of the AI tool may stigmatise or discriminate against certain individuals, whether the human researcher will retain control of the AI tool, whether the use of the AI tool may lead to negative social and other consequences, etc.). What steps will you take to manage and minimise the risks?**  **For an assessment of a specific AI tool, we recommend using the Assessment List for Trustworthy Artificial Intelligence (ALTAI) available on the European Commission website** [**https://digital-strategy.ec.europa.eu/lt/node/806**](https://digital-strategy.ec.europa.eu/lt/node/806)**.**  *(Please highlight changes if resubmitting)* |
| 1. **Indicate whether/how the results of the planned research are likely to be misused or used in a way that could violate human rights or dignity or have negative social or other consequences.**   *(Please highlight changes if resubmitting)* |
| 1. **Indicate whether the planned research is likely to raise any other research ethics issues not mentioned here, and describe the means to address these issues.**   *(Please highlight changes if resubmitting)* |
| 1. **Questions to determine the need for data protection impact assessment (DPIA) in accordance with Annex 1 of the Procedures for Data Protection Impact Assessment of Vilnius University prepared by the Data Protection Officer of Vilnius University.**   **If you intend to process personal data and answer yes to one or more of the questions in the questionnaire below, your planned research will require DPIAii. If DPIA has already been carried out at the Institute for this type of research, a new DPIA will not be required. If the Committee determines that a new DPIA is necessary for your planned study, this does not mean that your planned study cannot be granted a positive conclusion on compliance with research ethics on this basis alone.**   1. **Without the subject’s consent**   Yes  No 2. **Data of people from vulnerableiii groups**  Yes  No 3. **Personal identification numbers**  Yes  No 4. **Data from a population larger than 1% of the Lithuanian population**   Yes  No   1. **Biometric or genetic data**  Yes  No 2. **Video surveillance recordings in premises or areas not under the control of Vilnius University**  Yes  No 3. **Video recordings with sound or recordings of conversations (by telephone or similar)**   Yes  No   1. **Processing of data using technologies not previously used by the investigator**  Yes  No 2. **Assessment of personal aspects of minors (ethnicity, academic performance, health, attitudes, etc.)**  Yes  No 3. **Video surveillance of employees for control purposes**  Yes  No 4. **Automated decision-making (by technological means, without any human intervention)**  Yes  No 5. **Subjects’ location data**  Yes  No 6. **Private correspondence, letters, emails, social networks**  Yes  No 7. **Transfers to third countriesiv**  Yes  No   This simplified questionnaire was prepared in accordance with the list of data processing operations subject to the requirement of a data protection impact assessment approved by March 14, 2019, order No. 1T-35 (1.12.E) of the Director of the State Data Protection Inspectorate. The final decision on the need for a formal DPIA procedure will be made by the University administration after consultation.  [i] 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 and surname, a personal identification number, location data and an online identifier, or to one or more factors specific to the natural person's physical, physiological, genetic, mental, economic, cultural or social identity.  [ii] Data Protection Impact Assessment (DPIA) is an accountability tool set out in Article 35 of the April 27 2016 Regulation (EU) 2016/679 of the European Parliament and of the European Council 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 (the "GDPR") (Article 5 of Regulation (EU) 2016/679). ) to describe the processing operation and to assess the necessity and proportionality of such processing operation, helping to manage the risks to the rights and freedoms of natural persons arising from the processing of personal data, including by assessing the risks and identifying measures to address those risks.  [iii] According to the EU Directive 2013/33/EU, vulnerable persons are defined as minors, people with disabilities, the elderly, pregnant women, single parents with minor children, victims of human trafficking, persons with serious illnesses, persons with mental disorders, and persons who have been subjected to torture, rape, or other serious forms of psychological, physical, or sexual violence. Other legal documents identify other groups of vulnerable persons. For example, see Article 6 of the Law on the Ethics of Biomedical Research of the Republic of Lithuania.  Vulnerable persons and the protection of their interests  1. Vulnerable persons whose consent to participate in biomedical research may be influenced by external circumstances or who are partially or totally unable to protect their interests are:  1) persons who, owing to their state of health, cannot be regarded as capable of making a reasonable assessment of their own interests;  2) children;  3) students, if their participation in biomedical research is related to their studies;  4) persons residing in social care institutions;  5) soldiers during their actual military service;  6) staff under the authority of the investigator in health care institutions where the biomedical research is carried out;  7) persons in custody and temporary detention.  [iv] Third countries in the context of the GDPR are countries that do not belong to the [European Union](https://european-union.europa.eu/principles-countries-history/eu-countries_en) or the [European Economic Area](https://www.europarl.europa.eu/factsheets/en/sheet/169/europos-ekonomine-erdve-eee-sveicarija-ir-europos-siaure). There is also a list of other countries for which the European Commission has adopted separate [adequacy decisions](https://commission.europa.eu/law/law-topic/data-protection/international-dimension-data-protection/adequacy-decisions_en), where no authorisation is required for the transfer of data to that country |
| 1. **I, ,** *(name, surname)* **confirm that the study will be carried out in accordance with this application and the relevant legal documents (Vilnius University Code of Academic Ethics, Guidelines for the assessment of compliance with research ethics, approved by the Ombudsman for Academic Ethics and Procedures of the Republic of Lithuania by Order No V-60 of December 10 2020, General Data Protection Regulation and other legal documents).**    Confirmed |

1. The standard application form is to be completed in a separate document and sent to the Committee by email. [↑](#footnote-ref-1)
2. Vulnerable groups: persons who, because of health problems, are considered to be unable to adequately represent their interests or give informed consent, children and other minors, people with disabilities, the elderly, pregnant women, single parents with minor children, victims of trafficking, persons with serious illness, persons with mental illness, persons who have suffered torture, rape or other forms of serious psychological, physical or sexual violence, refugees, immigrants, various minorities, students (where the investigation relates to their studies), residents of nursing or care homes, soldiers on active military service, employees under the authority of the Investigator, prisoners, detainees, persons residing in social welfare institutions, etc. There is no exhaustive list of vulnerable groups, the different legal documents list different groups. Even for a group of persons not mentioned here, the Investigator planning to investigate them must responsibly assess whether they are not considered to be vulnerable at a similar level as the groups listed here. [↑](#footnote-ref-2)