**Application for the evaluation of the study by the research ethic commetee of RTU**

***To be completed by the secretary of the ethics committee:***

|  |  |
| --- | --- |
| Application registration date | Registration nr. |
|  |  |

***To be completed by the applicant:***

1. **TITLE OF THE STUDY \***

*If an opinion in Latvian is required, add the title in Latvian as well.*

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|  |

*\** *The title can match the title of the project or be a part of the project.*

1. **LEADING RESEARCHER / SUPERVISOR**

|  |  |
| --- | --- |
| Name, Surname |  |
| Degree |  |
| Position |  |
| RTU structural unit |  |
| Phone |  |
| E-mail  |  |

1. **INVOLVED RESEARCHERS**

*Adds information about each project executor, adding additional sections as needed. Delete redundant sections.*

|  |  |
| --- | --- |
| Name, Surname |  |
| Degree |  |
| Position |  |
| RTU structural unit |  |
| Phone |  |
| E-mail  |  |

*If the researcher is outside RTU*

|  |  |
| --- | --- |
| Name, Surname  |  |
| Degree |  |
| Position |  |
| Institution |  |
| Phone |  |
| E-mail |  |

*If the researcher is a student*

|  |  |
| --- | --- |
| Name, Surname  |  |
| Study program, study year |  |
| Student card ID |  |
| Phone |  |
| E-mail |  |

1. **INFORMATION ABOUT STUDY**

*If a detailed study protocol has already been prepared for the research, this section may not be filled in, but the protocol should be added in the appendix.*

* 1. RATIONALE AND OBJECTIVE OF THE STUDY

|  |
| --- |
| **…****The objective of the project / study is**  … |

* 1. PĒTĪJUMA METODOLOĢIJA UN NORISE

|  |
| --- |
| **Type of the research (design)****Research questions…****Research methods…****Data acquisition methods…** **Data analysis methods…****Research plan…****Expected research results …**  |

* 1. DURATION OF THE STUDY

|  |  |
| --- | --- |
| Beginning date | DD.MM.GGGG |
| End date | DD.MM.GGGG |

* 1. RESEARCH SITE / S

*Information for each research site should be added, adding additional sections as needed.*

|  |  |
| --- | --- |
| Name |  |
| Address |  |

* 1. INFORMATION ABOUT RESEARCH PARTICIPANTS

|  |
| --- |
| 1. General characterization of the research participants:
2. Planned number of research participants:
3. Information on how participants will be enrolled:
4. Inclusion/exclusion criteria of research participants:
5. Other relevant information:
 |

1. **INFORMED CONSENT OF RESEARCH PARTICIPANTS**

*Are minors, persons unable to express their will, persons with limited legal capacity, potentially vulnerable persons involved in the research (mark with X)?*

|  |  |  |
| --- | --- | --- |
|  | JĀ | NĒ |
| Minors |  |  |
| Persons unable to express their will  |  |  |
| Prisoners |  |  |
| Pregnant women |  |  |
| Other (indicate) |  |  |

*Type of informed consent:*

|  |  |  |
| --- | --- | --- |
|  | JĀ | NĒ |
| Will study participants sign an informed consent form (*leave blank if not applicable*)?  |  |  |
| Will the legal representatives of the study participants sign the informed consent form (*leave blank if not applicable*)? |  |  |
| Will study participants provide informed consent to participate in the study in another way without signing an informed consent form? |  |  |

*If a written or other type of informed consent will be obtained, the methodology for obtaining consent must be indicated (who will do it, when and how the informed consent procedure will be carried out):*

|  |
| --- |
|  |

*If the informed consent of the study participants will not be obtained, the justification must be provided:*

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| --- |
|  |

1. **RESEARCH RISK AND BENEFIT ANALYSIS**

|  |  |
| --- | --- |
| What are the physical and/or psychological risks to the research participants? |  |
| What measures will be taken to reduce risks and protect research participants? |  |
| What is the expected benefit of the research to the society? |  |
| What is the expected benefit of the research to the research participants? |  |
| Does the research pose risks to the environment? If yes, describe the risks and measures to mitigate risks. |  |
| Does the study pose risks to the researchers and staff involved in the study? If yes, describe the risks and measures to mitigate risks. |  |
| Will the research use or create genetically modified organisms? If yes, describe the associated risks and measures to mitigate risks. |  |
| Does the study pose a dual-use risk (the possibility that the results of the study may be misused)? If yes, describe the risks and measures to reduce the risks. |  |
| Is there a possibility of obtaining unplanned information about a person's health, criminal activities, etc. in the research? If yes, describe the action plan for such cases. |  |
| Can the research results create risks of discrimination or stigmatization for the research participants or the groups of society they represent? If yes, describe the risks and measures to reduce the risks. |  |

1. **COLLECTION AND PROCESSING OF PERSONAL DATA**

*It is important to note that pseudonymized data is also personal data*

|  |  |
| --- | --- |
| Will personal data be collected and processed as part of the research?*If only anonymous data will be obtained and processed in the study, the next sections in Part 7 may be omitted.* |  |
| Will personal data be pseudonymized or anonymized as part of the research? If yes, the processes and methods of pseudonymization and anonymization should be described. |  |
| How long, where and how will personal data be stored?  |  |
| Who will have access to personal data as part of the study? |  |
| What will happen to personal data if a person stops participating in the study? |  |
| Provide contact information of the person, responsible for the personal data handling. |  |
| What personal data will be collected and processed during the research (questionnaires, audio, video recordings, photographs, health data, genetic data, biometric data, data revealing race, ethnicity, political opinions, religious, philosophical beliefs, trade union membership, data on a person's sex life or sexual orientation)? If yes, the types and sources of personal data should be described. |  |
| Does the study plans to monitor or track research participants (for example, by collecting geolocation data with the help of electronic devices)? If yes, the types and sources of personal data should be described. |  |
| Will the research involve secondary processing of personal data previously obtained for other purposes (for example, from patients' medical records, registers, databases, archives)? If yes, what will be the data source and legal basis for data processing? |  |

1. **BIOLOGICAL SAMPLES, TISSUES, CELLS AND CELL LINES OF HUMAN ORIGIN**

*If biological samples, tissues, cells or cell lines of human origin are used in the research, section 5 "Informed consent of research participants" must also be filled in, indicating how and what type of informed consent will be obtained from donors of biological materials.*

|  |  |
| --- | --- |
| Will the study obtain and/or use biological samples of human origin (e.g., blood, tissue, cell, saliva, exhaled air, urine, feces, hair, nail samples)? If yes, the number of planned samples, types, sources of extraction should be described |  |
| Will the study use human cell lines? If yes, describe the types of cell lines and sources of acquisition. |  |
| How long and how will the biological samples of human origin be stored? |  |
| What will happen to the biological samples obtained as part of the study if the person stops participating in the study? |  |

1. **INTERNATIONAL COOPERATION**

|  |  |
| --- | --- |
| Are cooperation partners from other countries involved in the research? If yes, name all countries involved. |  |
| I confirm that the research complies with the RTU rector's order "On not starting new cooperation with universities and other institutions of the Russian Federation and the Republic of Belarus; 07.09.2023.,01000-1.2-e/39" |  |
| Is it planned to import/export personal data from/to EU countries or countries outside the EU as part of the research? If yes, describe the planned actions. |  |
| Is it planned to import/export human biological samples or cell lines from/to EU countries or countries outside the EU as part of the research? If yes, describe the planned actions. |  |
| Does international cooperation involve other types of activities that may raise ethical issues? If yes, describe the planned actions. |  |

**APPENDIX** *(appendices should be included according to the specifics of the research. Leave in the list only those appendices that are attached to the submission).*

1. Information for research participants and informed consent form

2. Research protocol

3. Questionnaire

4. Cooperation agreement

5. In the case of clinical studies, the CV of the study leading researcher / supervisor must be attached, which includes up to 5 publications in the last 6 years

6. Other documents (specify which ones)

**By signing this application, the leading researcher / supervisor confirms that the research ethics principles and personal data protection requirements will be observed during the research.**

Please evaluate the compliance of the study with the ethical requirements of scientific research.

|  |  |
| --- | --- |
| Leading researcher / supervisor  |  |
| Signature[[1]](#footnote-1) |  |
| Date1 |  |

1. This document is signed with a secure electronic signature and contains a time stamp. [↑](#footnote-ref-1)