**APPLICATION TO The Ethics committee for research in life sciences and medicine of the University of Latvia for REVIEWING of the research study**

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

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| --- | --- |
| Registration date of the application  | Registration No |
|  |  |

*To be completed by the applicant:*

1. **Title of the research study**

*If necessary, the title should be also indicated in Latvian*

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1. **Principal investigator or Supervisor of the research study**

|  |  |
| --- | --- |
| Name, surname  |  |
| Scientific or academic title |  |
| Position  |  |
| Faculty or a scientific institute of the University of Latvia  |  |
| Phone |  |
| E-mail |  |

1. **Researchers**

|  |  |
| --- | --- |
| Name, surname |  |
| Scientific or academic title |  |
| Position  |  |
| Faculty or a scientific institute of the University of Latvia  |  |
| Title of the scientific institution *(partners from other institutions)* |  |
| E-mail  |  |

*Add information about each researcher by adding sections, if necessary*

*For student researchers:*

|  |  |
| --- | --- |
| Name, surname  |  |
| Study programme, year of study |  |
| No of the student identification card |  |
| E-mail |  |

1. **information about the research study**

*If a detailed research protocol is available for the study, Section IV of this application may be omitted by attaching research protocol.*

Background and aim of the study

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METhODOLOgy of the study

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|  |

duration of the study

|  |  |
| --- | --- |
| Starting on |  |
| Finishing on |  |

sites where the study will be performed

*Information on each research site should be added, additional sections may be added if necessary*

|  |  |
| --- | --- |
| Institution |  |
| Address |  |

INFORMation about research participants

*Indicate (1) the intended number of research participants, (2) information on how research participants will be invited to participate in the research, (3) inclusion / exclusion criteria for research participants, (4) whether it is planned to involve minors or persons unable to express their will in the research?*

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1. **innformed consent of the research participants**

type of informed consent

|  |  |  |
| --- | --- | --- |
|  | YES | NO |
| Will research participants sign the informed consent form? |  |  |
| Will legal representatives of the research participants sign the informed consent form? |  |  |
| Will research participants provide informed consent to participate in the research in another way without signing the informed consent form? |  |  |
| Will a retrospective study be carried out using data recorded in medical documents and informed consent will not be obtained in accordance with the requirements of the Section 10, Paragraph 81 of the Patients’ Rights Law? |  |  |

PROcess for obtaining the informed consent

*If written or other type of informed consent will be obtained from the research participant, please explain who, when and how will obtain the informed consent from the research participant and / or their legal representatives. If legal representatives provide consent to participate in the research, explain how the research participants (minors or persons unable to provide consent) will be informed and how their view on participation in the research will be taken into account.*

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*If the informed consent from the research participants will not be obtained, explain the reasons for this decision. If the study is to be conducted in accordance with the requirements of the Section 10, Paragraph 81 of the Patients’ Rights Law, justify why it is not possible to obtain informed consent of study participants by reasonable means.*

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1. **RISK/ benefit analysis**

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| What are the physical and / or psychological risks to the research participants? |  |
| What measures will be carried out to reduce the risks and protect the research participants? |  |
| What is the expected benefit of the research to society? |  |
| What is the expected benefit of the research for the research participants (if any)? |  |
| May the results of the research pose a risk of discrimination or stigma to the research participants or to the groups of society they represent? If yes, describe the risks and risk mitigation measures. |  |
| Does the research pose risks to the environment? If yes, describe the risks and risk mitigation measures. |  |
| Does the research pose risks to the researchers and staff involved in the research? If yes, describe the risks and risk mitigation measures. |  |
| Will genetically modified organisms be used or developed in the research? If yes, describe the risks involved and risk mitigation measures. |  |
| Does the research pose risks of dual use (the possibility that the results of the research may be misused)? If yes, describe the risks and risk mitigation measures. |  |

1. **collection and processing of PERSONAl DATa**

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| What data will be collected and processed during the study - only anonymous data or personal data?*If only anonymous data will be collected and processed during the study, the following parts in Section VII of this application do not need to be completed.* |  |
| What personal data will be collected and processed during the study?*Describe in detail the types of personal data, incl. the specific categories of data used in the study (i.e., health data, genetic data, biometric data, data revealing race, ethnicity, political views, religious, philosophical beliefs, trade union membership, data on a person's sexual life or sexual orientation).* |  |
| Will the secondary processing of personal data collected for other purposes take place during the study (e.g., the data obtained from patients’ medical records, registers, databases, archives will be processed)?*If yes, provide information on the data sources.* |  |
| Is observation or tracking of the research participants planned during the study (for example, by collecting geolocation data using electronic devices)? |  |
| Will personal data be pseudonymised or anonymised during the research?*If so, explain the pseudonymisation or anonymisation process.* |  |
| How long, where and how will personal data be stored during the study?  |  |
| Who will have access to personal data during the study? |  |
| What happens to personal data if a person stops participating in the study? |  |
| Who is the data controller for data processed in the study? |  |

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

*If biological samples, tissues, cells, or cell lines of human origin are used which are acquired from humans during the study, it is also mandatory to complete Section V "Informed consent of the research participants", by indicating how and what type of informed consent will be obtained from the donors of biological samples, tissues, or cells.*

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| Will biological samples of human origin (e.g., samples of blood, tissues, cells, saliva, exhaled air, urine, faeces, hair, nails) be used in the study? *If yes, please describe in detail the planned number, types, and sources of samples.* |  |
| Will human cell lines be used in the research? *If yes, please describe in detail the type and source of cell lines.* |  |
| How and how long will the biological samples of human origin used in the study be stored? |  |
| What will happen to the biological samples obtained during the study if the person stops participating in the research? |  |

1. **INTERNATIONAL COOPERATION**

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| Are research partners from other countries involved in the study? If yes, name all the countries involved. |  |
| Is it planned to import / export personal data from / to EU Member States or non-EU Member States during the study? If yes, please describe in detail the planned activities. |  |
| Is it planned to import / export biological samples of human origin or cell lines from / to EU Member States or non-EU Member States during the study? If yes, please describe in detail the planned activities. |  |
| Does international cooperation involve other types of activities that may raise ethical issues? If yes, please describe in detail the planned activities. |  |

**IN THE APPENDIX** *(delete if unnecessary)*

1. Information for research participants and informed consent form
2. Research protocol
3. Questionnaire
4. Other documents or research instruments *(indicate which).*

**By signing this application, the principal investigator or supervisor confirms that the principles of research ethics and the personal data protection requirements will be followed during implementation of the study.**

Please evaluate the compliance of the study with the requirements of scientific research ethics and issue the approval letter.

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| Principal investigator or supervisor |  |
| Signature |  |
| Date |  |