**Informed consent to participate in research and to the processing of personal data**

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| Name of the biomedical research participant: |  |
| Date and place of birth: |  |
| E-mail, phone: |  |

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| Title of the research project / qualification work: |  |
| Type of qualification work  (bachelor / master / dissertation): |  |
| Name of the principal investigator of the project / author of the qualification thesis: |  |
| Name of the thesis supervisor / supervisor: |  |
| Department: |  |
| Collaborating workplaces / institutions: |  |
| Project / qualification period: |  |
| Source of funding (please indicate the grant agency and project number (if available), or internal project): |  |

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| Description of biomedical research: |
| *Start by saying "I would like to invite you to participate in a research project aimed at ......"*  *Briefly describe what the project is about, what is the aim of the research.* |

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| Description of the participant's involvement in the research: |
| *Please state:*   * *what the participant will expect during the research,* * *how long it will take,* * *how many times they will be measured/sampled/surveyed,* * *a description of the technical equipment used (if any),* * *what is the content of the questionnaires (if used), what you will be using them to find out.*   *Include a disclaimer that participation in the research is voluntary, and consent may be withdrawn and the project withdrawn. Specify the point at which it is possible to withdraw from the study – this is not at any time. The option to withdraw from the research is only realistically meaningful if the participant's data can be distinguished from others (i.e. by the time it is anonymised) - in most cases it is not appropriate to offer the option to withdraw at a time when the data is being processed or even published.*  *E.g.: Participation in research is completely voluntary, and you have the right to withdraw from the research without giving any reason, and until ............... (e.g. the last measurement is completed/ the sampling is completed/ one week after the questionnaire is completed etc.), the data already collected will be used for the research to maintain continuity of results.* |

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| Contraindications for participation in this research: |
| *In particular, describe any contraindications to the methods used (e.g. epilepsy, pregnancy, cardiac weakness, spectacles) and any other exclusion criteria.* |

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| Possible disadvantages/risks of participating in research: |
| *Describe the risks associated with participation in research, e.g. side effects of the methods used, possible consequences of invasive and non-invasive examinations (blood draws, MRI, stress to maximum endurance, ...).* |

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| Procedure in case of accidental finding: |
| *Indicate what the procedure will be in the event of an incidental finding, e.g.: The examination is for the purpose of scientific research. The purpose of the examination is not to provide medical services or to determine your health status. The data collected will not be evaluated by a physician, but by a researcher. Should the researcher suspect a possible medical complication, you have the right to be informed and to consult your doctor.* |

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| Data collected on project participants: |
| *Please list clearly what specific data you will collect on participants, e.g.:*   * *basic demographic data (e.g. age, gender, occupation, school, grade, education, income, marital status),* * *health data (e.g. medical history, diagnosis),* * *questionnaire responses,* * *measured data from ...............,* * *results of blood, saliva, sweat analysis, ...............,* * *audio/video recordings,* * *contact details (e.g. e-mail, telephone).* |

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| Processing of the research participant's personal data: |
| *Describe how the personal data will be processed, in particular the pseudonymisation process, who will have access to the data and under what conditions. If you will be assigning a code to participants, do not use a login, ID number, etc., and do not include the code on the consent form (this makes subsequent anonymization difficult).*  *Eg: The data collected will be processed in a so-called pseudonymised form. At the beginning of the research you will be assigned a unique code under which all data from measurements, sampling and interviews will be stored. The file containing the name-to-code conversion (coding key) to enable data linkage will only be available to the principal investigator of the project and will be stored separately from other data.*  *If you are handling sensitive data, biological samples, etc., you may indicate where the collected data will be stored and who will have access to it, e.g.: The collected data stored under the code will be accessed by ............... (e.g. principal investigator of the project, members of the research team) and will be stored securely by ............... (indicate generally the type or location of storage, e.g. secure storage at the VSB-TUO).*  *The recordings will be transcribed into text form after acquisition and subsequently deleted, no later than ............... after their acquisition. Names and other data will be replaced by pseudonyms.*  ***This consent form will always be kept separate from other documents.*** |

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| Retention of research participant's personal data: |
| *For example:*   * *Your personal data will only be stored for the duration of the research data collection/project duration, after which the encryption key will be irreversibly deleted and the collected data will be anonymised, i.e. converted into a form that does not allow your identification.* * *Samples of biological material will be disposed of no later than ...............* * *If you consent below to the use of your personal data and samples for further research purposes, the above provisions on the storage period will not apply and we will keep the data for a period of ............... years, after which the personal data will be converted into a form that does not allow your identification and the samples will be destroyed / the processing period of the above data and samples is then not determined by calendar days, months or years, but is determined by their usefulness in the given field of research. Once the data or samples cease to be useful/useful for long-term research, they will be destroyed/disposed of.* * *Your contact information (email, phone, ...............) will only be used for the purposes of this project and will be deleted after the data collection/project is completed. /choose the appropriate option/* * *In case you give your consent below to use your contact data (e-mail, phone, ...) for invitations to participate in other research projects .............................. (fill in the name of the VSB-TUO department), then we will use this data for the duration of ............... (e.g. 2 years, 5 or 10 years).*   ***It is always advisable to state:***  *The anonymised data collected can be used in further research projects in this area.*  ***Mandatory information according to the General Data Protection Regulation (EU 2016/679, GDPR)***  *We will process your personal data on the basis of your consent for research purposes in the field of ............... (specify the field of research).*  *Administrator of personal data: VSB – Technical University of Ostrava, 17. listopadu 2172/15, 708 00 Ostrava-Poruba (hereinafter referred to as "VSB-TUO") / student's name, address of the faculty, university e-mail, phone number*  *Contact person for the processing of personal data: the Data Protection Officer Mgr. Kamila Formanová, VSB-TUO, 17. listopadu 2172/15, 708 00 Ostrava-Poruba, e-mail:* [*poverenec@vsb.cz*](mailto:poverenec@vsb.cz)  *Transfer of personal data outside the VSB-TUO: Please indicate the institution to which the personal data will be transferred (institutions within and outside the EU) and what data will be transferred.*  *Your rights in relation to the processing of personal data:*   * *to request access to, rectification or erasure of personal data concerning you, or restriction of processing,* * *lodge a complaint with a supervisory authority (the Office for Personal Data Protection,* [*www.uoou.cz*](http://www.uoou.cz)*) if you believe that the processing of personal data is in breach of the law,* * *withdraw the consent to the processing of personal data given below at any time, without any penalty or disadvantage, by notifying the contact details of the data controller. The lawfulness of data processing prior to the withdrawal of consent is not affected.*   *For more information on processing personal data and exercising your rights, please visit:* [*https://www.vsb.cz/en/university/official-notice-board/processing-of-personal-data/*](https://www.vsb.cz/en/university/official-notice-board/processing-of-personal-data/) |

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| Contact for more detailed information: |
| *E.g.: If you have any additional questions about this research, you can contact ............... with contact details for the specific researcher (name and address of the department, university email, phone number if applicable)*  ***It is always advisable to include the text below as a contact for the Ethics Committee:***  *This project has been approved by the Ethics Committee for Biomedical Research at the Faculty of Electrical Engineering and Computer Science VSB-TUO. In case of any questions, uncertainties or comments about the research process, you can contact the management of the committee at* [*eticka.komise.fei@vsb.cz*](mailto:eticka.komise.fei@vsb.cz)*.* |

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| **PARTICIPANT'S DECLARATION:**  **I, the undersigned, certify that:**   * 1. **have read** the information about the objectives and progress of the biomedical research described above (hereinafter referred to as "the research"),   2. voluntarily **agree** to my participation in this research,   3. **understand** that my unreasonable withdrawal from the research is possible only until ...............,   4. **understand** that any use and publication of the data and outputs resulting from the research does not entitle me to any remuneration or compensation, i.e. I grant all rights to use and publish the data and outputs resulting from the research free of charge.   **I also declare that:**   1. **agree** to the release of the anonymised data and outputs from the research and to their further use, 2. **agree** to the processing and storage of the personal and sensitive data provided in this informed consent for the purposes of processing the data generated by the research, for the purposes of contacting me for the processing of the data generated by the research or for the purpose of offering to participate in similar events, and for record keeping and archiving purposes; and that such personal data may be disclosed to entities authorized to control the project under which the research was conducted, 3. **am aware** of my rights concerning access to information and its protection pursuant to Sections 12 and 21 of Act No. 101/2000 Coll., on the Protection of Personal Data and on Amendments to Certain Acts, as amended, i.e. that I may request and am entitled to receive information about the processing of my personal and sensitive data, and that I may request that the University of Business and Economics correct inaccurate personal data, supplement personal data, block personal data and destroy personal data, 4. **agree / do not agree** (delete as appropriate) to the possible future use of the collected data and samples in pseudonymised form (i.e. with preservation of the possibility of identification) for further research purposes in the field of ............... *(use only if relevant and you are also above in the section "How long will personal data be stored?" you have provided information about the processing time for further research)*, 5. **agree / do not agree** (delete as appropriate) to the possible use of my contact details (e-mail, telephone, ...) for invitations to participate in other research projects *(please use only if relevant and you have also indicated above in the section "Retention of personal data of the research participant:" the period of time for which you will be able to use the contact details in this way)*.   I voluntarily grant the above permissions and consents for an indefinite period of time until revocation.  All of the foregoing shall be governed by and construed in accordance with the laws of the Czech Republic, excluding the so-called conflict of laws rules, and any disputes shall be resolved by the competent courts in the Czech Republic.  I acknowledge receipt of a signed copy of this informed consent. |
| **Biomedical Research Participant:**  In ………………………… On: ………………………… Signature: ……………………………………………………    **On behalf of the research team:** Name: ………………………………………………………………………………………….  In ………………………… On: ………………………… Signature: …………………………………………………… |

*The purpose of the informed consent form is to inform the participant about the research and what participation in the project would mean for them, as well as to obtain explicit consent to participate in the research and consent to the processing of personal data.*

*If the research is conducted independently by the student, e.g. for the purposes of a thesis, it is not VŠB-TUO research. According to the GDPR, the student is the controller of the personal data collected and is then also responsible to the data subjects (research participants) for the proper handling of their data.*

*The text of the informed consent must be addressed directly to the participant, i.e. it must be written in the 2nd person ("you will participate, you will undergo, you may ...", not "the person will participate, the proband will undergo, the participant may").*

*Use language that is understandable to the layperson and avoid technical terms or explain them simply (e.g. avoid the terms: administer the questionnaire, ...).*

*Take into account the age, education and social situation of potential participants.*

*If possible, adapt the formatting of the text so that the 'Participant Statement' section is all on one page. The informed consent document must include page numbers.*

***Replace the text in italics with your own text or delete it. This is only a recommendation of the Ethics Committee. Also, remove irrelevant fields (e.g. in the case of a project, 'Qualifying work', 'Name of the supervisor of the qualifying work', etc., and conversely in the case of a qualifying work, e.g. 'Source of funding', etc.).***

*One copy of this consent will be given to the participant and one will be kept by the research team.*

*Dear researchers, please direct your comments, uncertainties or suggestions on this model consent form or on the handling of personal data in the research project to* [*eticka.komise.fei@vsb.cz*](mailto:eticka.komise.fei@vsb.cz)*.*