**Ethical Approval Application**

**for the review of proposed research or development project**

**by the *Research Ethics Committee* of the University of Applied Sciences Vorarlberg**

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| **Proposed research or development project**  Designation:  Duration (from - to):  **Applicant** (person responsible for the project)  Name (title):  E-mail:  Telephone:  Organisational Unit:  Department:  **Requirement of an ethics approval**  Body requesting an ethics approval for the project:  Result/s of a similar, previously submitted, application for ethics approval: |

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| **Conditions**  **in the case of research and development cooperation**  organisational unit involved:  Contact person at the FH Vorarlberg:  Date of the cooperation agreement:  **in the case of a third-party funded research and development project**  Third-party funder:  Third-party funding amount:  Third-party funding quota:  **in the case of exclusively self-funded research and development project**  Own funds sum:  Release is affected by:  **in the case of R&D research by students**  Name of supervisor:  Degree programme:  Type of research work (e.g., Master's thesis, contextual studies):  The application is approved  \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  Date, Signature Supervisor |

**Applicant Statement**

The applicant acknowledges that the *Research Ethics Committee* will review the research project from an ethical standpoint. Legal issues, such as data protection or copyright, are addressed as is deemed necessary by the *Committee* for the purpose of the ethical review. In carrying out the research project, the applicant agrees to undertake all steps necessary to ensure that personal data protection is in compliance with data protection regulations, in particular the EU General Data Protection Regulation (GDPR), and the data protection laws as stipulated in the legal provisions applicable to their research field and/or specifications.

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| **Research or development project objective/s**  Description of the research purpose:  Description of the research objective/s: |

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|  | **in the case of scientific studies on or with human subjects** | |
| 1 | Research design (incl. measures, hypotheses, data collection procedures)? |  |
| 2 | Eligibility criteria for participants (incl. inclusion and exclusion criteria)? |  |
| 3 | Recruitment of research participants (incl. potential direct or societal benefits, potential direct or societal risks). Please specify. |  |
| 4 | Compensation plans (e.g., financial and/or nonmonetary). Please specify. |  |
| 5 | Total number of participants to be recruited. Please specify. |  |
| 6 | Proposed case and/or group comparisons, and/or  recruitment of vulnerable populations, please specify. |  |
| 7 | Response to participants with early withdrawal from research, please specify. |  |
| 8 | Expected/potential benefit for participants, please specify. |  |
| 9 | Risks for research participants potentially associated with participation, please specify. |  |
| 10 | Identify and document adverse effects (e.g., possible harm), please specify. |  |
| 11 | Can participants opt out? (criteria for early withdrawal from the research). |  |
| 12 | Precautionary measures for exposure and/or risk/s. Precautionary measures planned, please specify. Rationale for no precautionary measures planned, please specify. |  |
| 13 | Is insurance required? |  |
| 14 | Participant consent to publishing research findings (incl. use of participants personal data), please specify. |  |

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|  | **in the case of a product (or prototype) development** | |
| 1 | Description of the product or prototype under development. |  |
| 2 | Specify the development goal/s (incl. technology readiness level). |  |
| 3 | Who are the target groups for the product? |  |
| 4 | How could the target groups get the product? |  |
| 5 | Financial costs for the product, if commercially produced (estimated). |  |
| 6 | Size of potential target group for the product (estimated). |  |
| 7 | Response if people no longer want to use the product (data deletion etc). Please specify. |  |
| 8 | Advantages/benefits expected in use of the product (yes/no explain). |  |
| 9 | Potential risks in the use of the product?  (yes/no explain). |  |
| 10 | Procedures for detecting, recording and reporting adverse effects. Please specify. |  |
| 11 | Describe the precautionary measures in relation to the risks. |  |
| 12 | Liability issues discussed (including liability risks) (yes/no explain). |  |
| 13 | Measures to protect intellectual property (yes/no explain). |  |

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|  | **on data protection in conducting research or product application** | |
| 1 | Groups affected (children, adults, legally incapacitated persons). Please specify. |  |
| 2 | Types of data to be collected (from whom, where, how)? Please specify. |  |
| 3 | Measures taken to ensure data anonymity and confidentiality. Please specify. |  |
| 4 | Rationale for processing personal data. Please specify. |  |
| 5 | Audio/video/digital recordings of research participants, please specify. |  |
| 6 | Regulation of access to data, please specify (incl. disclosure to third parties). |  |
| 7 | Regulation of participant/s right/s to their personal data. Please specify. |  |
| 8 | Data management plan: retention of data storage and duration. Destruction of data, please specify. |  |
| 9 | Participants will be informed as to how you used their data (yes/no, please specify). |  |

**Place, date \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Signature: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

**Attachments**

- Informed consent as stipulated in § 1 para 4 of the Rules of Procedure.

- Questionnaire or interview guide, if applicable

- Declaration of earlier ethics approval in accordance with § 3 para 6 of the Rules of Procedure.