******

**Proposal to the ETH Zurich Ethics Commission**

**Project title**

|  |
| --- |
|  |

**Principal Investigator (PI)[[1]](#endnote-1)**

|  |  |  |  |
| --- | --- | --- | --- |
| **Name** | **Title** | **Group / Chair / Institute** | **University** |
|  |  |  |  |
|  |  |  |  |

**Involved Researchers**

|  |  |  |  |
| --- | --- | --- | --- |
| **Name** | **Title** | **Group / Chair / Institute / Industry** | **University** |
|  |  |  |  |
|  |  |  |  |
|  |  |  |  |
|  |  |  |  |
|  |  |  |  |

**General Information**

|  |  |
| --- | --- |
| Type of project | [ ]  Research [ ]  PhD thesis [ ]  Master thesis [ ]  Bachelor thesis [ ]  Other:  |
| Student applications (BA/MA): I, [*name*], confirm that my supervisor [*name*] reviewed this application [ ]  |
| Start[[2]](#endnote-2) | [ ]  *DD.MM.YYYY (no earlier than two months after submission, see explanatory note #2)* |
| End[[3]](#endnote-3) | *MM.YYYY* |
| Method(s) of data collection(check all that apply) | [ ]  Interviews ([ ]  in person [ ]  phone [ ]  online)[ ]  Survey ([ ]  in person [ ]  phone [ ]  online)[ ]  Focus groups ([ ]  in person [ ]  online)[ ]  (Experimental) Behavioural study ([ ]  in person [ ]  online)[ ]  Social media ([ ]  observation [ ]  intervention)[ ]  Physiological measurements [ ]  Mobile App ([ ]  incl. tracking) [ ]  Photo-/video-/audio recording [ ]  secondary analysis of personal data[ ]  Student records/data[[4]](#endnote-4) [ ]  Other methods:  |
| Number of participants | Minimum: Maximum: |
| Source(s) of funding |  |
| Liability Insurance[[5]](#endnote-5) | [ ]  ETH Zurich [ ]  Other: |
| Responsibility Kantonale Ethikkommission[[6]](#endnote-6) | [ ]  Not Clarified [ ]  Clarified (declaration enclosed)  |
| Field or lab research abroad[[7]](#endnote-7) | [ ]  No |
| [ ]  Yes | Country:Local ethics approval: [ ]  Enclosed [ ]  Handed in later[ ]  Not obtainable: *Explain why you do not intend to obtain ethical approval from the country where you conduct your research or why such an approval is not obtainable.* |
| Clinical trial abroad | [ ]  No |
| [ ]  Yes | Risk Category:Sponsor resp. Sponsor-Investigator: Responsible local institute: Local PI: Local ethics approval: [ ]  Enclosed [ ]  Handed in laterRegistration:Liability cover has been confirmed: [ ]  Yes [ ]  No |

**Proposal**

*The following parts should address the Ethics Commission in an interdisciplinary comprehensible language (running text). Literature review and technical details should be limited. Refrain from copying text from other applications and address all points where applicable (incomplete applications will be rejected for revision). All annotations (red) must be deleted before submission on* [*Etappo*](https://www.etappo.ethz.ch/index.php?act=login)*.*

**1. Abstract**

*- Study objective, method, risks for participants (lay summary, limit 250 words)*

**2. Project**

**2.1 Study Objective**

*- Indicate the research question / hypothesis / objective of the study*

*- Explain the state of research, preliminary studies, pre-tests*

*- Explain the scientific or social relevance of the project*

**2.2 Methods and Study Design**

*- Explain the method of data collection and the study design*

*- Indicate and justify any necessary or incomplete disclosure of information or deception of participants (use of deception or incomplete disclosure must be justified by its impact on the potential scientific value to the research)*

*- Describe the study site(s), procedure, and activities of the participants*

*- Mention all instruments used for data collection (questionnaires, interview questions, measuring devices, apps, etc.); refer to the relevant appendices*

**2.3 Participants**

*- State the number of participants / data sets (attach power calculations if appropriate).*

*- List all inclusion and exclusion criteria*

*- If applicable: Justification of inclusion of vulnerable participants*

**2.4 Project Schedule**

*- Project phases in tabular form with dates (the first interaction with the participants may not occur before the final approval has been obtained).*

**2.5 Project Partners and Funding**

*- Indicate the source(s) of funding*

*- If other academic institutions, external service providers, industrial partners, etc. are involved, explain their function, rights (especially to data and results) and obligations*

*- Projects with industry partners: Reference to any contracts and the role of ETH Transfer*

*- Disclose possible conflicts of interest*

**2.6 Clinical Trials Abroad** *(delete if not applicable)*

*- Explain why the study must be conducted abroad*

*- Explain how compliance with the law applicable to clinical studies conducted in Switzerland is ensured (see "Code of Conduct for Scientific Cooperation of ETH Zurich",* [*RSETHZ 416*)](https://rechtssammlung.sp.ethz.ch/Dokumente/416en.pdf?d=w67e41bec549242d5803df4e60006d676)

*- Explain how research results can be made accessible and implemented in the country where the study is conducted*

**3. Ethical Aspects**

**3.1 Informed Consent and Debriefing**

*- How are participants recruited (attach flyers / ads etc. if available)?*

*- How is the detailed study information (see below) handed out?*

*- How do participants express their informed consent to participate?*

*- Who keeps the consent forms? For how long?* [[8]](#endnote-8)

*- Explain any debriefing, e.g., in case of incomplete information or deception due to study design*

*- If some participants are illiterate, explain how informed consent is recorded (e.g., witness-consent / fingerprint / sign).*

*- Whenever possible, study results should be made available to interested participants in an appropriate form - explain how this is realised (e.g., separate and secure storage of contact data) and if not, explain why you decide not to share the results with the participants*

**3.2 Data Protection and Publication**

*- In what form are the data collected (anonymous, coded, personal data)? [[9]](#endnote-9)*

*- If personal data must be collected, for what purpose?*

*- How and where are personal data and pseudonymisation keys stored? Who has access to them?*

*- Is all data completely anonymised in accordance with ETH Law* [*Art. 36d*](https://www.fedlex.admin.ch/eli/cc/1993/210_210_210/de#art_36_d)*?*

*- How is the DPA or the GDPR implemented by third-party providers (enclose contracts)?*

*- How are results published?*

*- Are the data made accessible in an anonymous form (e.g., repository)?*

**3.3 Compensation**

*- Is any compensation or remuneration paid? Why yes/no?*

*- Does any remuneration correspond at least to the regional minimum wage (provide calculation)?*

**3.4 Risks and Countermeasures**

*- What physical and psychological risks and discomforts are to be expected for the participants?*

*- What countermeasures are foreseen?*

*- How do you deal with vulnerable persons (e.g., children, cognitively or physically impaired?*

*- Technology assessment / dual use: May the results of the project pose social or ecological risks?*

**3.5 Risk-Benefit Analysis**

*- Compare the risks related to the study with the expected social or scientific benefits and explain why the latter outweighs the former*

**4. References**

***Appendices***

***To be appended at the end of this document***

* *Appendix A: "Information sheet and consent form for participants" in the foreseen version (indicate which language this consent form will be translated to); if applicable, enclose flyer / advertisement for recruitment*
* *Appendix B-n: Instruments for data collection in final version (questionnaires, guiding questions for interviews / group discussions, etc.; as pdf, no links)*

***To be submitted as separate documents***

* *CV and publication list (short) of the PI*
* *CVs of other researchers directly responsible for the human subject research*
* *Contracts (industry, service providers, etc.)*
* *Approvals from local authorities or ethics committee*
* *Only complete applications will be reviewed*

***General information on "Information and consent form"***

* *Before individuals may participate in a study, you must obtain their informed consent, i.e., all individuals must be fully informed about the study (incl. objective, method, design, etc.), their rights and obligations, and give their documented consent to participate.*
* *Below you find a template of an information and consent form with mandatory items. Append the adapted form that will actually be presented to potential participants. In addition to a version in German or English, translations into the language of the participants must be appended.*
* *Paper form: Whenever suitable, the information and consent form should be handed out in paper form (one copy each for the participant and the investigator).*
* *Digital form: If the informed consent is obtained digitally (mail / web / app), you must explain in the proposal (sec. 3.1) how the study information is directly presented to the participants (no link) and how consent is obtained (e.g., via consent button).*
* *Use inclusive language that is easy to understand. Address participants directly. If the participants are not of age, the information and consent form must be addressed to their legal guardians and a separate version in a language suitable for children should be submitted (cf. Swissethics’* [*guidelines*](https://swissethics.ch/assets/kinder_notfall/leitfaden_pi_kinder_d.pdf)*).*
* *In case of incomplete disclosure of information or deception (cf. sec. 2.2), append the foreseen debriefing text, which should: (i) inform participants that incomplete disclosure/deception was used; (ii) specify what information was withheld or falsified; (iii) explain why it was necessary to use incomplete disclosure/deception; (iv) provide participants the opportunity to ask questions; and (v) grant the option to withdraw their data.*
* *These texts are representative of your group and ETH Zurich. Please check spelling and grammar before your submission.*

**Appendix A**

******

**Information and consent form**

***Title of the study (as on cover page)***

Participant (full name): ………………………………………………….

Conducting person (full name): ………………………………………………….

Contact project team: *Full name, affiliation, e-mail / phone*

Data Protection Officer ETH Zurich: Tomislav Mitar (tomislav.mitar@sl.ethz.ch)

We would like to ask you if you are willing to participate in our research project. Your participation is voluntary. Please read the text below carefully and ask the conducting person about anything you do not understand or would like to know.

**What is investigated and how?**

*- Objective, Method/Design (e.g., randomisation), anticipated benefit of the study*

**Who can participate?**

*- Explain in- & exclusion criteria*

**What am I supposed to do as a participant?**

*- Explain requested actions and obligations*

**What are my rights during participation?**

*Possible text:* Your participation in this study is voluntary. You may withdraw your participation at any time without specifying reasons and without any disadvantages.

**What risks and benefits can I expect?**

*- Explain all possible health /data / privacy / etc. risks*

**Will I be compensated for participating?**

*- Explain the form and level of compensation, if any*

**What data is collected from me and how is it used?**

*- Explain whether personal data such as names, place of residence or work, email address, telephone numbers, etc. are collected? What for? Are these stored separately from the other data? Who has access to them? What other (experimental) data is collected?*

*Necessary text:* Members of the ETH Zurich Ethics Commission may access the original data for examination purposes. Strict confidentiality will be observed at any time.

*- Explain the mode of publication (incl. assurance that data will only be published in anonymised form and thus no conclusions can be drawn about individuals)*

*­- Explain anonymisation: Assurance that identifying data will be deleted and all other data anonymised as soon as the purpose of the data processing allows this (cf. ETH Law Art. 36d).*

*- Where and for how long will the (anonymised) data be stored? Is the anonymised data made available in a data repository (e.g., ETH Research Collection)? For what purpose?*

*- Explanation of how any third-party providers, such as survey companies, handle personal data and why this handling complies with the DPA or the GDPR*

*- Are data or results made available exclusively to certain parties (e.g., industry partners)?*

**What are my rights to my personal data?**

*Possible text:* Before the irrevocable anonymisation of the collected data, you can request information about the personal data collected from you at any time and without giving reasons. You can also request that it be rectified, handed over to you, barred for processing or erased. To do so, please contact the person indicated above.

*- Guarantee that the applicable data protection laws (Federal Data Protection Act (FADP), if applicable the European General Data Protection Regulation (GDPR)) are complied with when collecting and processing personal data*

**Who funds this study?**

*- Disclose all sources of funding*

**How am I insured?**

*Possible text:* Adverse health effects that are directly caused by the study and can be demonstrated to be attributable to fault on the part of the project team or ETH Zurich are covered by ETH's liability insurance. You are responsible for insuring yourself against any other adverse health effects such as might occur, for instance, in connection with the trip to or from the place where the study is conducted.

**Who reviewed this study?**

This study was examined by the ETH Zurich Ethics Commission as proposal *EK-20XX-N-XX.*

**Complaints office**

The secretariat of the ETH Zurich Ethics Committee is available to help you with complaints in connection with your participation. Contact: *ethics@sl.ethz.ch* or 0041 44 632 85 72.

**Consent Form**

I, the participant, confirm by my signature that:

* I have read and understood the study information. My questions have been answered completely and to my satisfaction.
* I comply with the inclusion and exclusion criteria for participation described above. I am aware of the requirements and restrictions to be observed during the study.
* I have had enough time to decide about my participation.
* I participate in this study voluntarily and consent that my personal data be used as described above.
* I understand that I can stop participating at any moment.

I would like to be informed about the results of this study

□ Yes, Name and Phone Number or Email: ………………………………………………

□ No

*The following item may only be added if relevant:*

In the event that incidental findings result from the study that may lead to the diagnosis, treatment or prevention of existing or possible diseases, I wish

□ to be informed about the findings

□ not to be informed about the findings

|  |  |
| --- | --- |
| Full name of participant |  |
| ……………………………………………… |  |
| Place, Date | Signature participant |
| ……………………………………………… | ……………………………………………… |
| Place, Date | Signature conducting person |
| ……………………………………………… | ……………………………………………… |

***Appendix B-n: Instruments (surveys, interview questions, etc.)***

1. **Explanatory notes**

 The (co-)principal investigator (PI) must be affiliated with ETH Zurich. The PI is usually a professor or a senior scientist, or the supervising person in the case of Bachelor or Master theses (students are listed as “involved researchers”). [↑](#endnote-ref-1)
2. The start and end dates should refer to the human subject research part of the entire project. This part may only be started once the application has been reviewed by the Ethics Commission and approved by the Vice President for Research (this also applies to the recruitment of participants). The complete approval process can take up to eight weeks, which is why the requested start date should be at least eight weeks in the future (however, the project may be started once the approval is issued). Student projects are reviewed in a shortened procedure. For more information, see [“How long it takes”](https://ethz.ch/en/research/ethics-and-animal-welfare/research-ethics.html/#howlong). [↑](#endnote-ref-2)
3. Extensions can be applied for as an amendment in Etappo (tab “Amendments”; see also [“Amendments](https://ethz.ch/en/research/ethics-and-animal-welfare/research-ethics.html/#amendments)”). [↑](#endnote-ref-3)
4. Please refer to the guidelines [“Educational Research”](https://ethz.ch/en/research/ethics-and-animal-welfare/research-ethics.html/#educational). [↑](#endnote-ref-4)
5. Adverse health effects that are directly caused by participating in the study and can be demonstrated to be attributable to fault on the part of the project team or ETH Zurich are covered by ETH's liability insurance, exclusively an excess of CHF 1500 payable by the chair (cf. [“Insurance”](https://ethz.ch/en/research/ethics-and-animal-welfare/research-ethics.html/#insurance)). [↑](#endnote-ref-5)
6. *Biomedical Human Subject Research* is regulated by the Human Research Act (HRA) and corresponding ordinances (ClinO, HRO, TPA, etc.). Research involving one or more human subjects, undertaken to systematically assess the safety or performance of medical devices are deemed to be *clinical trials of medical devices,* where the HRA and the Ordinance on Clinical Trials with Medical Devices (ClinO-MD) define the corresponding requirements. Both types of research must be approved by a Kantonale Ethikkommission and, if necessary, by Swissmedic. In case of doubt, contact the responsible [Kantonale Ethikkommission](https://swissethics.ch/ethikkommissionen) or obtain a [clarification of responsibility](https://submissions.swissethics.ch/en/). If your project is approved by a Kantonale Ethikkommission, no additional review by the ETH Zurich Ethics Commission is necessary. [↑](#endnote-ref-6)
7. Whenever possible, field research abroad must also be approved by a local ethics committee (e.g., of an institute of a partner). If the research is to be conducted in a risk area, it must also be clarified with the Safety, Security, Health and Environment (SSHE) department before submitting the ethics application whether a safety concept must be submitted. [↑](#endnote-ref-7)
8. Signed consent forms and other consent records must be kept separately and securely from other data by the principal investigator for 5 years after the end of the study. [↑](#endnote-ref-8)
9. *“Anonymised data”:* Data which cannot (without disproportionate effort) be traced to a specific person (cf. Human Research Act); *“Coded Data":* Data linked to a specific person via a key (ibid.); *“Personal data”:* All data relating to an identified or identifiable person (cf. Data Protection Act). For further explanations of terms, see the [SPHN Glossary](https://sphn.ch/document/sphn-glossary/). [↑](#endnote-ref-9)