This Ethical Review Form should be completed for every research study that involves human participants or personally identifiable data. The form should be submitted and approved by your supervisor before potential participants are approached to take part in the research study.

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| Part 1: General Study Information |
| **1** | Student name and email | Your name and email |
| **2** | Supervisor name and email | Name and email of the supervisor who is responsible for the study |
| **3** | Degree Program | Which Degree Program are your following? |
| **4** | Bachelor/master  | Are you in the Bachelor or Master phase? |
| **5** | Bachelor/master end project? | Is it a Bachelor or Master end project? |
| **6** | Course name and code | Name and code of the course/project? |
| **7** | Project title  | Name of your study |
| **8** | Research location | Where will the study take place? |
| **9** | Research period (start/end date) | When will you perform the study? |
| **10** | [If Applicable] Proposal already approved by (external) Ethical Review Board: Add name, date of approval, and contact details of the ERB | Is your study part of a larger study that has been ethically reviewed before? Then describe the details of that ERB approval.  |
| **11** | Research question | What is your research question? |
| **12** | Description of the research method | What will the participants be asked to do for the study? |
| **13** | Description of the research population, in- and exclusion criteria | Describe the participants of your research. What characteristics do they have? Who is eligible and who will be excluded? |
| **14** | Number of participants | How many participants do you need to answer the research question? |
| **15** | Explain why the research is socially important.  | Why is the research important for society? Is there also any possible harm for society? |
| **16** | Describe the way participants will be recruited | How will the participants be found and contacted? |
| **17** | Provide a brief statement of the risks you expect for the participants or others involved in the research and explain. Take into consideration any personal data you may gather and privacy issues.  | Are there any risks involved for the participants or others involved in the study? Think about what participating in the study will entail for them, what type of data your will collect and how you will make sure these data will be kept safe  |

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|  |  Part 2: Checklist for Minimal Risk |
|  |  | **Yes** | **No** |
| **1** | Does the study have a medical scientific research question or claim (see definition below)*Medical/scientific research is research which is carried out with the aim of finding answers to a question in the field of illness and health (etiology, pathogenesis, signs/symptoms, diagnosis, prevention, outcome or treatment of illness), by systematically collecting and analysing data. The research is carried out with the intention of contributing to medical knowledge which can also be applied to populations outside of the direct research population.*’ | [ ]  | [ ]  |
| If yes or maybe: Your supervisor should submit the study to the ERB. You cannot get automatic ethical approval | If no: Continue with question 2 |
| **2** | Does the study involve human material (such as surgery waste material derived from non-commercial organizations such as hospitals)?  | [ ]  | [ ]  |
| If yes or maybe:This is only allowed if your supervisor has consulted with the medical coordinator. Continue with question 3 | If no:Continue with question 3 |
| **3** | Will the participants give their explicit consent – on a voluntary basis – either digitally or on paper? Or have they given consent in the past for the purpose of education or for re-use in line with the current research question? | [ ]  | [ ]  |
| If yes: Continue with question 4 | If no: Your supervisor should submit the study to the ERB. You cannot get automatic ethical approval |
| **4** | Will the study involve discussion or collection of personal data? (e.g. name, address, phone number, email address, IP address, BSN number, location data) or will the study collect and store videos, pictures, or other identifiable data of human subjects?  | [ ]  | [ ]  |
| If yes:The handling, storing and de-identification of the personal data should be discussed with your supervisor. Continue with question 5 if you met all requirements for handling personal data (see …) | If no:Continue with question 5 |

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|  | **Yes** | **No** |
| **5** | Does the study involve participants who are particularly vulnerable or unable to give informed consent? (e.g. children, people with learning difficulties, patients, people receiving counselling, people living in care or nursing homes, people recruited through self-help groups)?  | [ ]  | [ ]  |
| If yes: Your supervisor should submit the study to the ERB. You cannot get automatic ethical approval | If no: Continue with question 6 |
| **6** | May the research procedure cause harm or discomfort to the participant in any way? (e.g. causing pain or more than mild discomfort, stress, or anxiety)  | [ ]  | [ ]  |
| If yes:Your supervisor should submit the study to the ERB. You cannot get automatic ethical approval | If no:Continue with question 7 |
| **7**  | Will the participants receive any compensation for their participation? Such as a coupon or a chance to win a prize? | [ ]  | [ ]  |
| If yes:Your supervisor should submit the study to the ERB. You cannot get automatic ethical approval | If no:Continue with question 8 or 10, depending on the type of study (see red text below) |
| **The following questions 8-9 are for *observational* research (e.g. (semi-)structured interviews; focus groups; (participatory) observations). If your research is *experimental*, then skip questions 8-9 and continue with question 10** |
| **8** | Will it be necessary for participants to take part in the study without their knowledge and consent at the time? (e.g. covert observation of people)? | [ ]  | [ ]  |
| If yes: This is only allowed when observing behavior in public space. If so, continue with question 9. If you observe people in non-public space without their consent, your supervisor should submit the study to the ERB. You cannot get automatic ethical approval | If no: Continue with question 9 |
| **9** | Will participants be asked to discuss or report sexual experiences, religion, alcohol or drug use, or suicidal thoughts, or other topics that are highly personal or intimate? | [ ]  | [ ]  |
| If yes:Your supervisor should submit the study to the ERB. You cannot get automatic ethical approval | If no:Continue with part 3 |

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| **The following questions 10-13 are for *experimental* research (e.g. measurements on yourself or another person; testing a prototype/device; influencing behavior through manipulation (e.g. light or temperature). If your research is *observational*, then skip questions 10-13 and continue with part 3** |
|  |  | **Yes** | **No** |
| **10** | Is the study invasive (i.e. it affects the body such as puncturing the skin; taking blood or other body material (such as DNA) from the participant)?  | [ ]  | [ ]  |
| If yes: Your supervisor should submit the study to the ERB. You cannot get automatic ethical approval | If no:Continue with question 11 |
| **11** | Does the device have a medical purpose sucs as diagnosis, prevention, monitoring, prediction, prognosis, treatment or alleviation of disease or injury? | [ ]  | [ ]  |
| If yes or maybe: Your supervisor should submit the study to the ERB. You cannot get automatic ethical approval | If no:Continue with question 12 |
| **12** | Will the experiment involve the use of physical devices that are ‘CE’ certified for unintended use (meaning you will use existing CE certified devices for other things than they were originally intended for? | [ ]  | [ ]  |
| If yes:This is only allowed if they are completely harmless. They should have a harmless voltage of <5V and hazardous waste (fumes/gas/substances) should not be released. You should discuss with your supervisor whether you need to have the device tested for safety | If no:Continue with question 13 |
| **13** | Will the experiment involve the use of physical devices that are not ‘CE’ certified?  | [ ]  | [ ]  |
| If yes:This is only allowed if they are completely harmless. They should have a harmless voltage of <5V and hazardous waste (fumes/gas/substances) should not be released. You should discuss with your supervisor whether you need to have the device tested for safety | If no: Continue with part 3 |

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| Part 3: Enclosures and Signature |
| **1** | Enclosures (tick if applicable):[ ]  Informed consent form (link to template); [ ]  The survey the participants need to complete, or a description of other measurements (such as interview questions or a description of the prototype);[ ]  Text used to find participants (such as brochures, flyers, etc);[ ]  Approval other research ethics committee; |  |
| **2** | I hereby declare that I have completed this form truthfullySignature(s) of the student(s)Date |  |

Discuss this form with your supervisor. If any of the boxes your ticked in Part 2 suggest that your supervisor should submit your study to the ERB for ethical approval, try to change your research design in such a way that your supervisor can approve it instead. If this is not possible, ask your supervisor to submit the proposal to the ERB. It will take two to five weeks before you receive a decision from the ERB.

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| Part 4: Review by supervisor |
|  | **Yes** | **No** |
| **1** | Does the data storage adhere to all requirements of responsible data management (link toevoegen)?  | [ ]  | [ ]  |
| If yes:Continue with question 2 | If no: Discuss with your student the necessary steps to adhere to the requirements |
| **2** | Does the research proposal adhere to all requirements for automatic approval?  | [ ]  | [ ]  |
| If yes:Please skip the questions 3-6 and sign the form  | If no:Discuss with your student if any alterations can be made in order to adhere to the requirements for automatic approval. If you decide that the study cannot adhere to the requirements, then you as a supervisor need to submit the proposal to the ERB. Please answer the following additional questions (3-6) |
| **Additional questions for ERB approval** |
| **3** | Elaborate on the topics from part 2 that do not allow for automatic approval. Describe how you safeguard any potential risk for the research participant for each topic.  |  |
| **4** | Describe and justify the number of participants you need for this research, taking into account the risks and benefits |  |
| **5** | Explain if your data are completely anonymous, or whether they will be de-identified (pseudonymized or anonymized) and if so, explain how |  |
| **6** | Who will have access to the data? |  |
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| Part 5: Signature by supervisor |
|  | I hereby declare that I have completed this form truthfullySignature of the supervisorDate |  |