This Ethical Review Form should be completed for every research study that involves human participants or

personally identifiable personal data and should be submitted to ethics@tue.nl. For more information

about how this process works please click [here.](https://intranet.tue.nl/onderzoek/ethical-review/)

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| Part 1: General Study Information |
| **1** | Project title |  |
| **2** | Name of the researcher/student |  |
| **3** | Email of the researcher/student |  |
| **4** | Supervisor(s) name(s) *Additional explanation:* *Please write down the name of your direct supervisor. You can mention several supervisors if appropriate, but at least one supervisor should be mentioned.* |  |
| **5** | Supervisor(s) email address(es)*Additional explanation:* *Please give the email address of the supervisor(s) mentioned in question 4.* |  |
| **6** | Department |  |
| **7** | Are you a student and is this application for educational purposes?  | ☐ Yes, Bachelor. Course:☐ Yes, Master. Course:☐ No |
| **8** | Research location*Additional explanation: Where will the data collection take place? On campus, in a company, in public space, etc.* |  |
| **9** | Start date data collection*Additional explanation: Please state when your data collection will start. Please note that you do not have to provide information about your complete (PhD) project, but only on this particular sub-study that you are submitting for approval in this form.* |  |
| **10** | End date data collection |  |
| **11** | Does your project receive external funding (e.g., NWO, relevant for special regulations from funders)? | [ ]  Yes. Name Funder: [ ]  No |
| **12** | Which internal and external parties are involved in the study? Think about sharing data or information between TU/e and other universities, commercial companies, hospitals, etc.*Additional explanation: Describe all internal and external parties that are involved in the study or project, including:** *human participants (e.g., people being interviewed, people participating in online surveys, patients, etc.);*
* *researchers or research groups at the TU/e who participate in the study;*
* *(Researchers at) other universities/institutions that provide data/services, help analyzing the data, etc.;*
* *(commercial) partners, companies, government bodies, municipalities, consultancy firms, hospitals or care institutions that provide data (e.g., contact details of participants, data for further analysis).*

*Indicate which role each party plays: who defines the means and purposes in the study, who will supply the data (external parties?), who will process/handle the data, who will be able to access the data during and after research (only researchers at TU/e or also others)?* |  |
| **13** | Have any special agreements already been made with an external party, such as a Non-Disclosure Agreement (NDA) or a data sharing agreement? | ☐ Yes, namely: ☐ No |
| **14** | Has your proposal already been approved by an external Ethical Review Board or Medical Ethical Review Board?*Additional explanation: For example, when you are collaborating with another university and the project has been approved by their Ethical Review Board, or when you received a WMO-waiver from a Medical Ethical Review Board.* | [ ]  Yes[ ]  No |
| **15** | If yes: Please provide the name, date of approval and contact details of the ERB. Please also include the registered number for your project approval. Additionally, please send in the Ethical Review Form upon which ethical approval was granted together with this form. |  |
| **16** | Have you already performed a Data Protection Impact Assessment (DPIA) for this or a very similar project?***Please read the information below: a DPIA is not the same as a regular privacy impact assessment. More detailed questions on privacy will follow in the section below.*** *Additional explanation:* *A Data Protection Impact Assessment (DPIA) is a formal document that must be drafted under the guidelines of the General Data Protection Regulation (GDPR)* ***if you process personal data that are likely to result in high privacy risks******for participants.*** *Think of research with vulnerable people, high-risk medical research,* *The* [*Dutch DPA (Autoriteit Persoonsgegevens)*](https://autoriteitpersoonsgegevens.nl/nl/zelf-doen/data-protection-impact-assessment-dpia) *and* [*our website*](https://intranet.tue.nl/universiteit/privacy-security/faq/over-de-avg/#c79481) *provides more information about a DPIA.* | [ ]  Yes[ ]  NoIf yes: Please provide details about the DPIA here and send in the DPIA documentation together with this form. |
| **Part 2: Medical study** |
| **1** | Does the study have a medical scientific research question or claim? *Additional explanation:* *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 analyzing 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 your research contains questions about health and health related parameters (such as well-being, vitality, feelings of anxiety or stress) but your research question is not primarily medical, then you can answer ‘no’ to this question.* | ☐ Yes\*☐ No\*If yes or in doubt, please contact Susan Hommerson via s.m.hommerson@tue.nl  |
| **Part 3: Use of (medical) devices in the study** |
| **1** | Does your research include a device?*Additional explanation:* *A device is a complete piece of physical hardware that is used to compute or support computer functions within a larger system. Devices can be divided into input-, output-, storage-, internet of things-, or mobile device.* | ☐ Yes, not self-made☐ Yes, self-made☐ No |
| **2** | Please describe your device or link to an online description of the device |  |
| **3** | Will you use a device that is ‘CE’ certified for **unintended use** (meaning you will use existing CE certified devices for other things than they were originally intended for) or use a device that is not ‘CE’ certified?*Additional explanation:* *You can find more information about CE certification on https://ec.europa.eu/growth/single-market/ce-marking\_en.* | ☐ Yes☐ No |
| **4** | If yes: Do you use a device or software that has a medical purpose such as diagnosis, prevention, monitoring, prediction, prognosis, treatment or alleviation of disease or injury? | ☐ Yes, my device or software currently has a medical purpose☐ Yes, my device or software could have a medical purpose in the near future☐ No☐ I’m not sure |
| **Part 4: Information about the study** |
| **1** | What are your main research questions? *Additional explanation:* *You need to provide at least one clear research question.* |  |
| **2** | Description of the research method*Additional explanation:* *For example, interview, survey, experiment, user-test, Randomized Experiment, focus groups, pilot study, observation, etc.* |  |
| **3** | Description of the research population, in- and exclusion criteria*Additional explanation: Please describe which persons are eligible for your study. What criteria are used to select participants in your study, and what criteria are used to exclude possible participants?* *For example: We will randomly select participants from the JSF participant database with good vision and older than 18 years.* |  |
| **4** | Description of the measurements and/or stimuli/treatments *Additional explanation:* *Think about your outcome measures and the variables you will be collecting and describe them in a way such that another person understands what the participant will experience.* *For example: Participants will perform task A and see pictures from database B, and we measure validated Scale 1.* |  |
| **5** | Describe and justify the number of participants you need for this study. Also justify the number of observations you need, taking into account the risks and benefits.*Additional explanation*: *Think about if you need 3 or 30 participants for example, and why? Do they need to provide their input once, or several times, and why?* |  |
| **6** | Explain why your research is societally important. What benefits and harm to society may result from the study?*Additional explanation:* *What benefit will the results of your study have to society in general?* |  |
| **7** | Describe the way participants will be recruited*Additional explanation:* *How will you recruit participants for your study? For example, by using flyers, personal network, panels, etc.* |  |
| **8** | Provide a brief statement of the risks you expect for the participants or others involved in the study and explain. Also take into consideration any personal data you may gather and associated privacy issues.*Additional explanation:* *Risks for the participants can be anything from risk of data breach to risk of safety or well-being. Describe these possible risks and describe the way these risks are mitigated.* |  |
|  Part 5: Self-assessment checklist |
| *Note: answers in the blue boxes indicate that your research is eligible for fast-track approval* | **Yes** | **No**  |
| **1a** | Does the study involve human material? (e.g., surgery waste material derived from non-commercial organizations such as hospitals)  |  |  |
| **1b** | Will blood or other (bio)samples be obtained from participants? (e.g., hair, sweat, urine or other bodily fluids or secretions, also external imaging of the body) |  |  |
| **2** | Will the participants give their 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? |  |  |
| **3** | Are the participants, outside the context of the research, in a dependent or subordinate position to the investigator?*Additional explanation:* *Think about doing research on your own students or on your own employees. When there is a dependency or power imbalance between you and the research participants, you need to answer ‘yes’ to this question.* |  |  |
| **4** | Does the study involve participants who are particularly vulnerable or unable to give informed consent? (e.g., children (<16 years of age), people with learning difficulties, patients, people receiving counselling, people living in care or nursing homes, people recruited through self-help groups) |  |  |
| **5** | Will participating in the research be burdensome? (e.g., requiring participants to wear a device 24/7 for several weeks, to fill in questionnaires for hours, to travel long distances to a research location, to be interviewed multiple times)? |  |  |
| **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, anxiety or by administering drinks, foods, drugs, or showing explicit visual material)  |  |  |
| **7** | Will financial inducement (other than reasonable expenses and compensation for time) be offered to participants?*Additional explanation:* *For an explanation of what is considered a reasonable compensation, see the topic* [*participant fees*](https://htilabs.ieis.tue.nl/h8_participants.html#bookmark3) *from the HTI group* |  |  |
| **8a** | 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) |  |  |
| **8b** | If yes: Will you be observing people without their knowledge in public space? (e.g. on the street, at a bus-stop) |  |  |
| **9** | Will the study involve actively deceiving the participants? (e.g., will participants be deliberately falsely informed, will information be withheld from them, or will they be misled in such a way that they are likely to object or show unease when debriefed about the study) |  |  |
| **10** | Will participants be asked to discuss or report sexual experiences, religion, alcohol or drug use, suicidal thoughts, or other topics that are highly personal or intimate? *Additional explanation:* *Think about your research population. For some participants, particular topics can be considered sensitive or intimate, whereas the same topics will not be perceived as such by other participants.* |  |  |

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| **11** | Elaborate on all boxes answered outside of the blue boxes in part 5. Describe how you safeguard any potential risk for the research participant. |  |

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| Part 6: Self-assessment on privacyThe following questions (1-10) concern privacy issues, as laid down in the General Data Protection Regulation (GDPR). The Data Stewards and – if necessary – privacy team of TU/e will assess these questions. In some cases, more information is required to assess the privacy risks. If this is the case, you will be notified that the Data Stewards team will contact you.The GDPR defines ‘personal data’ as any information relating to an identified or identifiable natural person (‘data subject’). Personal data also includes data that indirectly reveals something about a natural person. Personal data can lead to the physical, physiological, genetic, mental, economic, cultural or social identity of a natural person. There are two main categories of personal data: regular personal data and special category personal data.If you are not sure whether some of these questions below should be answered with a Yes or No, please contact a Data Steward first through rdmsupport@tue.nl. |
| *Note: answers in the blue boxes indicate that your research is eligible for fast-track approval* | **Yes** | **No**  |
| **1** | Will the study involve discussion/collection/processing of **regular** personal data, or will you collect and (temporarily) store video or voice recordings for the purpose of conducting interviews?*Additional explanation: For example, name, address, phone number, email address, IP address, gender, age, video or interview recordings? If you are not sure whether your data contains personal data, please contact the Data Stewards Team (rdmsupport@tue.nl).* |  |  |
| **1A** | If yes: Please describe which regular personal data you will collect in this study? |  |
| **2** | Will the study involve discussion/collection/processing of **special category** personal data or other **sensitive data**? *Additional explanation:* *Examples of special category personal data are race, religion, health information, political views, genetic or biometric data for the unique identification of a person, sexual preference, etc. Health information concerns personal data of the physical or mental health of persons, including the provision of health care. Examples of other sensitive data is information such as communication data, financial records or credit scores, camera surveillance data, location/GPS data, internet-of-things data, employee monitoring, observing or influencing behaviour, criminal records, data of vulnerable persons (children, people with disabilities, refugees), BSN number etc. Please be aware that the use of special category personal data in research requires extra security measurements in order to safeguard the privacy of data subjects and to comply with the GDPR. Processing of this special category data is prohibited, except for specific purposes and under certain circumstances. If you need to process special category data, please consult the data stewards at rdmsupport@tue.nl.* |  |  |
| **2A** | If yes: Please describe which special-category personal data and/or sensitive data you will collect in this study? |  |
| *If you answered yes to either question 1 or 2, please answer the questions below. If you answered no to both questions, you can skip this part and continue onto part 6. Also, if an answer to any of the following questions is ‘yes’, please contact a Data Steward at rdmsupport@tue.nl* |
|  | **Yes** | **No**  |
| **3** | Will your project involve the processing of personal data on a **large scale**?*Additional explanation:* *In general, any processing that involves more than 10.000 data subjects should be considered “large scale”. However, if the data of approximately 1000 persons (or more) are involved, the data processing may still be considered large scale. In that case, besides the number of persons involved in the study, one should also assess (i) the amount of data collected from these persons taking into account the type/risk level of the personal data, (ii) the duration of the data processing, (iii) the geographic scope or extent of the processing. For example, if you would collect and process data across several European countries with 10+ socio-economic data items of 1200 individual persons for several years in a row, that is likely “large-scale processing”. Other examples of a large-scale processing activity are:** *Monitoring driving behavior of road users on Dutch highways*
* *Collecting data of Covid patients*
* *A hospital that processes patient data as part of its usual operations*
* *A transport company that processes travel information of people who travel by public transport in a certain city. For example, by tracking them through travel maps.*
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| **4** | Does this processing activity involve the use of new or innovative technologies?*Examples of a new technology: combining fingerprints and facial recognition for physical access control, the use of bodycams in public spaces, the use of new technical methods in conducting research such as AI. This question also refers to new technologies that have not been deployed by TU/e so far.* |  |  |
| **5** | Does your study involve systematic (c.q. automated) monitoring of persons?*Additional explanation:* *Consider data processing activities that have the purpose of observing, monitoring or controlling individuals, for example in circumstances where the individuals are not aware by whom their personal data is collected and how it is used. Examples of such activities are using camera systems to monitor driving behavior on highways, monitoring email inactivity or employee phone use, certain applications of machine learning and artificial intelligence.* |  |  |
| **6** | Does the study involve collaborations (with third parties) in which data are shared or exchanged in order to link or combine data?*Additional explanation:* *This may often apply in a collaboration between the university and a commercial party, contract research, etc. It is important to assess this for all data in the entire project, not just your own data.**An important consideration in this situation is whether the person whose data is involved could have expected that data from these different databases or sources of information were to be combined. For example, it is less likely for data subjects to expect that databases from different parties will be combined and the results are used for different purposes than one could reasonably expect; this may apply for example in a collaboration between the university and a commercial party.* |  |  |
| **7** | Will the study include data processing activities that prevent data subjects from exercising their rights or using a service or contract?*Additional explanation:* *Examples include processing operations carried out in public places that people cannot avoid (train station, airport, shopping mall, public university premises, etc.) or processing operations whose purpose is to allow or not allow data subjects to use a service or enter into a contract (examples: by refusing to pay a benefit, not being able to apply for a loan, etc.).* |  |  |
| **8** | Will the study process personal data to score, rank or profile persons?*Additional explanation:* *Examples: monitoring (highway) roads to give road users a “score” based on their detected driving behavior, a bank assessing its customers based on their creditworthiness, or an organization building behavioral and marketing profiles based on use of their website or navigating their website.* |  |  |
| **8** | Does your data processing include activities that involves composing “**blacklists**” – and, in particular, in relation to sensitive or special category data, such as communication data, financial records or credit scores, genetic data, biometric data, health data, camera surveillance data, location/GPS data, internet-of-things data, employee monitoring, observing or influencing behaviour, etc.*Additional explanation:* *This situation will not be a common occurrence in research, but you may indirectly be involved in this. In general, this typically concerns processing operations involving personal data relating to criminal convictions and offences, data relating to unlawful acts, data concerning unlawful or annoying behaviour or data concerning bad payment behaviour by companies or individuals are processed and shared with third parties (blacklists or warning lists, as used, for example, by insurers, hospitality companies shopping companies, telecom providers as well as blacklists relating to unlawful behavior of employees, for example in the healthcare sector or by employment agencies, etc.).* |  |  |
| **9** | Will personal data be transferred or shared outside the EU/EEA?EU data protection rules apply to the European Economic Area (EEA), which includes all EU countries and non-EU countries Iceland, Liechtenstein and Norway.*Additional explanation:* *The GDPR has drafted additional requirements for transfers data outside of the EU/EEA. Typically, additional safeguards must be implemented to protect the personal data of residents in the European Union. For example, if you collaborate with an American, Indian or Chinese university or other third party outside the EU/EEA, you must first check whether this is allowed and under which conditions this is allowed. Another typical example is storage of data on American providers of cloud (storage) services. Please contact the data stewards first to discuss this.* |  |  |
| **10** | Will any raw or anonymized personal data or any other sensitive data or research results from the project possibly be transferred to a high-risk country\*? ***\*High risk countries****: China, Russia, Iran, Turkey, and North Korea.* *If personal data or other potentially sensitive data is exchanged with one of these countries, or if part of the data processing takes place in one of these countries:* ***an advice from the Data Protection Officer, the kennisveiligheidsteam (Knowledge Security team), and the CISO (Chief Information Security Officer) is ALWAYS required.*** |  |  |

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| Part 7: Data processing, storing and archiving |
| **1a** | Is consent your legal basis for processing the personal data in your study?*Additional explanation:* *What is a legal basis? One of main principles in the GDPR is to ensure that personal data is processed lawfully, fairly, and transparently. To comply with this principle, the processing of personal data also requires that you have a valid legal basis for the personal data processing activity.**In research projects, the legal basis is often but not always consent. However, it is possible that it is not clear or not possible to establish whether to use consent as a legal basis.**Some examples where consent may not be applicable as legal basis are covert research, data collection in public spaces, secondary data analysis of existing data, data that are transferred to you by a third party, consent is not possible or would require disproportionate effort, etc. In that case, please indicate which legal basis you think that applies or (preferably) contact a data steward first.* | [ ]  Yes[ ]  No |
| **1b** | If yes: Please briefly explain how you will obtain consent from participants and send in your draft of the information letter and consent statement together with this form. You can download a suitable template [here](https://intranet.tue.nl/en/university/privacy-security/privacy/privacy-templates/consent-forms/). |  |
| **1c** | If no: Please briefly explain on which legal basis - other than consent - you will process the personal data in your study. |  |
| **2** | In which way will you collect and process the (personal) data?*Additional explanation:* *Please describe which software (e.g., LimeSurvey, Atlas Ti, Qualtrics), tools (electronic lab journals, information management systems, etc.), technologies, apps or devices (Internet-of-Things, Fitbit, etc.), techniques (monitoring, interview, survey), special data environments (e.g., Living Lab), etc. you will use to collect or process data?* |  |
| **3** | Where will the data and in particular the personal data be stored during and after completion of the study? If you have already uploaded your Data Management Plan, you can refer to your Data Management Plan.*Additional explanation:* *Please address the following:** *Where will you store your data during the study and after you have completed the study? University supported-storage facilities are SURFdrive, SURF Research Drive, Ceph, departmental drives (this includes BE Project Drive), and the TU/e instance of Microsoft OneDrive. For most personal data, the use of SURF Research Drive, departmental drives (including BE Project Drive) and SURFdrive is required.*
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| **4** | Which security measures are applied?*Additional explanation:* *Please address these questions:** *Is access to your (personal) data restricted? If yes, how (access control, password protection, etc.)?*
* *Who will have access to the data during and after completion of the study?*
* *Will you anonymize or pseudonymize the data?*
* *Is* [*Bitlocker (Windows)*](https://docs.microsoft.com/en-us/windows/security/information-protection/bitlocker/bitlocker-overview)*,* [*FileVault (Mac)*](https://support.apple.com/guide/mac-help/encrypt-mac-data-with-filevault-mh11785/mac) *or similar hard-drive encryption active on your laptop?*
* *What will you do with the data after your project has come to results? Do you need to keep all data?*
* *How long will you store the data after completion of the project, or can/will (part of) the data be destroyed?*
* *Will you or your supervisor want to keep the data for new or future research/reuse? Will you share (raw) data with others? If yes, how and how do you ensure that this is secure?*
* *If access restrictions are required during and after the study, please explain how this is arranged.*
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| Part 8: Closures and Signatures |
| **1** | Enclosures (tick if applicable):[ ]  Informed consent form; [ ]  Informed consent form for other agencies when the research is conducted at a location (such as a school);[ ]  Text used for ads (to find participants);[ ]  Text used for debriefings;[ ]  Approval other research ethics committee;[ ]  The survey the participants need to complete, or a description of other measurements;[ ]  Any other information which might be relevant for decision making by ERB;[ ]  Data Protection Impact Assessment checked by the privacy officer[ ]  Data Management Plan checked by a data steward |  |
| **2** | Signature(s)Signature(s) of researcher(s)Date: Signature research supervisor (if applicable) Date: |  |