

**Delft University of Technology**  
**HUMAN RESEARCH ETHICS**  
**CHECKLIST FOR HUMAN RESEARCH**  
**(Version January 2022)**

**IMPORTANT NOTES ON PREPARING THIS CHECKLIST**

1. An HREC application should be submitted for every research study that involves human participants (as Research Subjects) carried out by TU Delft researchers
2. Your HREC application should be submitted and approved **before** potential participants are approached to take part in your study
3. All submissions from Master's Students for their research thesis need approval from the relevant Responsible Researcher
4. The Responsible Researcher must indicate their approval of the completeness and quality of the submission by signing and dating this form OR by providing approval to the corresponding researcher via email (included as a PDF with the full HREC submission)
5. There are various aspects of human research compliance which fall outside of the remit of the HREC, but which must be in place to obtain HREC approval. These often require input from internal or external experts such as [Faculty Data Stewards](#), [Faculty HSE advisors](#), the [TU Delft Privacy Team](#) or external [Medical research partners](#).
6. You can find detailed guidance on completing your HREC application [here](#)
7. Please note that incomplete submissions (whether in terms of documentation or the information provided therein) will be returned for completion **prior to any assessment**
8. If you have any feedback on any aspect of the HREC approval tools and/or process you can leave your comments [here](#)

## I. Applicant Information

|   |  |
|---|--|
| <b>PROJECT TITLE:</b>   | <b>Designing Emotionally Expressive Behaviors for an Appearance-Constrained Robot</b>  |
| <b>Research period:</b><br><i>Over what period of time will this specific part of the research take place</i>   | <b>01-06-2024 to 01-07-2024</b>  |
| <b>Faculty:</b>   | <b>Mechanical Engineering</b>  |
| <b>Department:</b>  | <b>Cognitive Robotics</b>  |
| <b>Type of the research project:</b><br><i>(Bachelor's, Master's, DreamTeam, PhD, PostDoc, Senior Researcher, Organisational etc.)</i>  | <b>Master's thesis</b>   |
| <b>Funder of research:</b><br><i>(EU, NWO, TUD, other – in which case please elaborate)</i>   | <b>Leiden University</b>   |
| <b>Name of Corresponding Researcher:</b><br><i>(If different from the Responsible Researcher)</i>   | <b>Joost Broekens</b>  |
| <b>E-mail Corresponding Researcher:</b><br><i>(If different from the Responsible Researcher)</i>  | <b>Associate Professor</b>   |
| <b>Position of Corresponding Researcher:</b><br><i>(Masters, DreamTeam, PhD, PostDoc, Assistant/ Associate/ Full Professor)</i>   | <b><a href="mailto:d.j.broekens@liacs.leidenuniv.nl">d.j.broekens@liacs.leidenuniv.nl</a><br/><a href="mailto:joost.broekens@gmail.com">joost.broekens@gmail.com</a></b> |
| <b>Name of Responsible Researcher:</b><br><i>Note: all student work must have a named Responsible Researcher to approve, sign and submit this application</i>   | <b>Jens Kober</b>  |
| <b>E-mail of Responsible Researcher:</b><br><i>Please ensure that an institutional email address (no Gmail, Yahoo, etc.) is used for all project documentation/ communications including Informed Consent materials</i> | <b><a href="mailto:j.kober@tudelft.nl">j.kober@tudelft.nl</a></b>  |
| <b>Position of Responsible Researcher :</b><br><i>(PhD, PostDoc, Associate/ Assistant/ Full Professor)</i>  | <b>Associate Professor</b>   |

## II. Research Overview

**NOTE:** You can find more guidance on completing this checklist [here](#)

### a) Please summarise your research very briefly (100-200 words)

What are you looking into, who is involved, how many participants there will be, how they will be recruited and what are they expected to do?

*Add your text here – (please avoid jargon and abbreviations)*

The goal of this research is to investigate what features of motion, light, and sound in the behaviors of a non-humanoid, faceless robot may be perceived as emotional. To do this, a group of about 500 people will be recruited through Amazon's Mechanical Turk to respond to an online survey in which they will watch a series of videos of a robot executing certain behaviors, and will then rate any emotion qualities of the robot's behavior that may be perceived.

### b) If your application is an additional project related to an existing approved HREC submission, please provide a brief explanation including the existing relevant HREC submission number/s.

*Add your text here – (please avoid jargon and abbreviations)*

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- c) **If your application is a simple extension of, or amendment to,** an existing approved HREC submission, you can simply submit an [HREC Amendment Form](#) as a submission through LabServant.

### III. Risk Assessment and Mitigation Plan

*NOTE: You can find more guidance on completing this checklist [here](#)*

Please complete the following table in full for all points to which your answer is “yes”. Bear in mind that the vast majority of projects involving human participants as Research Subjects also involve the collection of **Personally Identifiable Information (PII)** and/or **Personally Identifiable Research Data (PIRD)** which may pose potential risks to participants as detailed in Section G: Data Processing and Privacy below.

To ensure alignment between your risk assessment, data management and what you agree with your Research Subjects you can use the last two columns in the table below to refer to specific points in your Data Management Plan (DMP) and Informed Consent Form (ICF) – **but this is not compulsory**.

It’s worth noting that **you’re much more likely to need to resubmit your application if you neglect to identify potential risks**, than if you identify a potential risk and demonstrate how you will mitigate it. If necessary, the HREC will always work with you and colleagues in the Privacy Team and Data Management Services to see how, if at all possible, your research can be conducted.

|   |     |    | <i>If YES please complete the Risk Assessment and Mitigation Plan columns below.</i>  |   | <i>Please provide the relevant reference #</i> |                                   |
|---|-----|----|---|---|--|-----------------------------------|
| ISSUE   | Yes | No | RISK ASSESSMENT – what risks could arise?<br><i>Please ensure that you list ALL of the actual risks that could potentially arise – do not simply state whether you consider any such risks are important!</i>   | MITIGATION PLAN – what mitigating steps will you take?<br><i>Please ensure that you summarise what actual mitigation measures you will take for each potential risk identified – do not simply state that you will e.g. comply with regulations.</i>  | DMP  | ICF                               |
| <b>A: Partners and collaboration</b>  |     |    |   |   |  |                                   |
| 1. Will the research be carried out in collaboration with additional organisational partners such as: <ul style="list-style-type: none"> <li>One or more collaborating research and/or commercial organisations</li> <li>Either a research, or a work experience internship provider<sup>1</sup></li> </ul> <i><sup>1</sup> If yes, please include the graduation agreement in this application</i> | ✓   |    | 1. Leiden University and TU Delft may have different ethical standards and processes for approving research involving human subjects, leading to potential conflicts or misunderstandings about the ethical conduct of the research.<br>2. The sharing of sensitive or personal data between institutions can lead to risks related to data privacy and security.<br>3. Disagreements or misunderstandings about intellectual property rights, authorship, and publication rights might arise, potentially leading to conflicts.<br>4. Collaborative projects can suffer from poor coordination and communication, leading to | 1. No personal data is collected. There is no risk of personal data being published. Furthermore, the approval process is similar between Leiden University and TU Delft.<br>2. No personal data is collected. Additionally, we will obtain informed consent from participants that clearly explains how their data will be used, stored, and shared between institutions.<br>3. Intellectual property is shared between TU Delft and Leiden<br>4. A robust project management framework has been implemented, including regular meetings, shared project management tools, and clear communication channels.<br>5. We agree that there is no financial burden across the two universities, there is no money | VI.33  | OS, ICF, Q6, Q7, Q8, Q9, Q10, Q10 |

|   |     |    | If YES please complete the Risk Assessment and Mitigation Plan columns below.   |  | Please provide the relevant reference # |     |
|---|-----|----|---|--|---|-----|
| ISSUE   | Yes | No | RISK ASSESSMENT – what risks could arise?<br><i>Please ensure that you list ALL of the actual risks that could potentially arise – do not simply state whether you consider any such risks are important!</i>   | MITIGATION PLAN – what mitigating steps will you take?<br><i>Please ensure that you summarise what actual mitigation measures you will take for each potential risk identified – do not simply state that you will e.g. comply with regulations.</i> | DMP                                     | ICF |
|   |     |    | delays, inefficiencies, or inconsistencies in research execution.<br>5. Misunderstandings or conflicts may arise regarding the allocation of funds and resources between the collaborating universities, affecting the project's progress and outcomes. | involved in the supervision of the master project.   |   |     |
| 2. Is this research dependent on a Data Transfer or Processing Agreement with a collaborating partner or third party supplier?<br><i>If yes please provide a copy of the signed DTA/DPA</i>   |     | ✓  |   |  |   |     |
| 3. Has this research been approved by another (external) research ethics committee (e.g.: HREC and/or MREC/METC)?<br><i>If yes, please provide a copy of the approval (if possible) and summarise any key points in your Risk Management section below</i>                              |     | ✓  |   |  |   |     |
| <b>B: Location</b>  |     |    |   |  |   |     |
| 4. Will the research take place in a country or countries, other than the Netherlands, within the EU?   |     | ✓  |   |  |   |     |
| 5. Will the research take place in a country or countries outside the EU?   |     | ✓  |   |  |   |     |
| 6. Will the research take place in a place/region or of higher risk – including known dangerous locations (in any country) or locations with non-democratic regimes?  |     | ✓  |   |  |   |     |
| <b>C: Participants</b>  |     |    |   |  |   |     |
| 7. Will the study involve participants who <b>may</b> be vulnerable and possibly (legally) unable to give informed consent? (e.g., children below the legal age for giving consent, people with learning difficulties, people living in care or nursing homes,).                        |     | ✓  |   |  |   |     |
| 8. Will the study involve participants who <b>may</b> be vulnerable under specific circumstances and in specific contexts, such as victims and witnesses of violence, including domestic violence; sex workers; members of minority groups, refugees, irregular migrants or dissidents? |     | ✓  |   |  |   |     |
| 9. Are the participants, outside the context of the research, in a dependent or subordinate position to the investigator (such as own children, own students or employees of either TU Delft and/or a collaborating partner organisation)?  |     | ✓  |   |  |   |     |

|   |     |    |  |   |   |                                   |
|---|-----|----|--|---|---|-----------------------------------|
|   |     |    | If YES please complete the Risk Assessment and Mitigation Plan columns below.  |   | Please provide the relevant reference # |                                   |
| ISSUE   | Yes | No | RISK ASSESSMENT – what risks could arise?<br><i>Please ensure that you list ALL of the actual risks that could potentially arise – do not simply state whether you consider any such risks are important!</i>  | MITIGATION PLAN – what mitigating steps will you take?<br><i>Please ensure that you summarise what actual mitigation measures you will take for each potential risk identified – do not simply state that you will e.g. comply with regulations.</i>  | DMP                                     | ICF                               |
| <i>It is essential that you safeguard against possible adverse consequences of this situation (such as allowing a student's failure to participate to your satisfaction to affect your evaluation of their coursework).</i>   |     |    |  |   |   |                                   |
| 10. Is there a high possibility of re-identification for your participants? (e.g., do they have a very specialist job of which there are only a small number in a given country, are they members of a small community, or employees from a partner company collaborating in the research? Or are they one of only a handful of (expert) participants in the study? |     | ✓  |  |   |   |                                   |
| <b>D: Recruiting Participants</b>   |     |    |  |   |   |                                   |
| 11. Will your participants be recruited through your own, professional, channels such as conference attendance lists, or through specific network/s such as self-help groups  |     | ✓  |  |   |   |                                   |
| 12. Will the participants be recruited or accessed in the longer term by a (legal or customary) gatekeeper? (e.g., an adult professional working with children; a community leader or family member who has this customary role – within or outside the EU; the data producer of a long-term cohort study)  |     | ✓  |  |   |   |                                   |
| 13. Will you be recruiting your participants through a crowd-sourcing service and/or involve a third party data-gathering service, such as a survey platform?   | ✓   |    | <ol style="list-style-type: none"> <li>1. There's a risk of receiving responses from bots or participants misrepresenting themselves to qualify for the study, which can compromise the authenticity and representativeness of the sample.</li> <li>2. Data collected via MTurk can vary in quality, with issues like rushed responses or participants not taking the study seriously, affecting the reliability of your results.</li> <li>3. Using third-party platforms for data collection and recruitment can lead to privacy concerns and potential data breaches, compromising participant data security.</li> <li>4. Ensuring that participants recruited through MTurk fully understand the study and provide informed consent can be challenging, especially when not interacting face-to-face.</li> <li>5. Relying on third-party platforms for critical aspects of your research makes the study</li> </ol> | <ol style="list-style-type: none"> <li>1. We will make use of Amazon Mechanical Turk's (MTurk) participant screening filters (called MTurk Masters) to verify the authenticity and quality of participants. This ensures that clearly eligibility criteria are defined and enforced.</li> <li>2. We will recruit MTurk Masters to ensure quality data. Additionally, we can include attention check questions throughout the survey to identify and exclude participants not paying attention. We will offer fair compensation to encourage serious participation.</li> <li>3. Qualtrics complies with relevant data protection regulations and offers adequate data encryption and anonymization capabilities. We will collect only the data necessary, and ensure participant data anonymization is turned on to protect their identity.</li> <li>4. A clear and concise informed consent form is included that participants must agree to before participating in the study. This form includes</li> </ol> |   | OS, ICF, Q6, Q7, Q8, Q9, Q10, Q10 |

|  |     |    | If YES please complete the Risk Assessment and Mitigation Plan columns below.  |   | Please provide the relevant reference # |     |
|--|-----|----|--|---|---|-----|
| ISSUE  | Yes | No | RISK ASSESSMENT – what risks could arise?<br><i>Please ensure that you list ALL of the actual risks that could potentially arise – do not simply state whether you consider any such risks are important!</i>  | MITIGATION PLAN – what mitigating steps will you take?<br><i>Please ensure that you summarise what actual mitigation measures you will take for each potential risk identified – do not simply state that you will e.g. comply with regulations.</i>  | DMP                                     | ICF |
|  |     |    | vulnerable to changes in their policies, outages, or discontinuation of service.   | <p>details about the study's purpose, procedures, risks, benefits, confidentiality measures, compensation, and contact information for questions. Use comprehension checks to ensure participants understand the consent information.</p> <p>5. We will stay informed about any changes in terms and conditions of the platforms we use, and have contingency plans in place for data collection and storage, considering alternative platforms or data backup strategies. We will regularly export and secure our data to protect against sudden platform changes or data loss.</p>  |   |     |
| 14. Will you be offering any financial, or other, remuneration to participants, and might this induce or bias participation? | ✓   |    | <ol style="list-style-type: none"> <li>1. Financial incentives might attract participants who are more interested in the compensation than the study itself, leading to a sample that does not accurately represent your target population.</li> <li>2. Participants may rush through the survey to complete as many tasks as possible in a short time, compromising the quality of your data.</li> <li>3. Participants may attempt to participate multiple times under different accounts to receive additional compensation.</li> <li>4. The promise of financial remuneration might be seen as coercive, particularly if participants want to participate in the study to receive needed funds because of a possible precarious economic situation.</li> <li>5. Financially motivated participation might lead to a sample that is not representative of the broader population, affecting the generalizability of our findings.</li> </ol> | <ol style="list-style-type: none"> <li>1. We will set compensation at a level that is fair and reflects the time and effort required but is not so high as to be the primary motivation for participation. This balance can help ensure that participants are motivated by interest in the study as well as financial compensation.</li> <li>2. We will implement attention checks and minimum time requirements for completing the survey to discourage rushed responses. Additionally, we will use pilot testing to establish a reasonable completion time and set minimum time requirement based on these findings.</li> <li>3. We will use Qualtrics's native capabilities to limit participation to one per individual, which consists of tracking unique identifiers (while maintaining privacy and compliance with data protection laws). It is made clear in the consent form that multiple submissions by the same person are not allowed and may result in disqualification from the study and forfeiture of compensation.</li> </ol> |   |     |

|  |     |    | If YES please complete the Risk Assessment and Mitigation Plan columns below.   |   | Please provide the relevant reference # |     |
|--|-----|----|---|---|---|-----|
| ISSUE  | Yes | No | RISK ASSESSMENT – what risks could arise?<br><i>Please ensure that you list ALL of the actual risks that could potentially arise – do not simply state whether you consider any such risks are important!</i> | MITIGATION PLAN – what mitigating steps will you take?<br><i>Please ensure that you summarise what actual mitigation measures you will take for each potential risk identified – do not simply state that you will e.g. comply with regulations.</i>  | DMP                                     | ICF |
|  |     |    |   | <p>4. We will assess the appropriateness of the compensation based on the expected demographics of the participants and the nature of the tasks involved. Ensure that the compensation is neither too low (which could be exploitative) nor too high (which could be coercive). We provide clear information in the consent form that participation is voluntary and that declining to participate will not penalize the participant in any way.</p> <p>5. We will use MTurk’s native stratified sampling techniques to ensure the sample is representative of the population of interest. The target demographic must be clearly defined and we will use MTurk’s screening to select participants who meet our criteria.</p> |   |     |
| <b>E: Subject Matter</b> <i>Research related to medical questions/health may require special attention. See also the website of the <a href="#">CCMO</a> before contacting the HREC.</i>   |     |    |   |   |   |     |
| 15. Will your research involve any of the following: <ul style="list-style-type: none"> <li>Medical research and/or clinical trials</li> <li>Invasive sampling and/or medical imaging</li> <li>Medical and <i>In Vitro Diagnostic Medical Devices</i> Research</li> </ul>  |     | ✓  |   |   |   |     |
| 16. Will drugs, placebos, or other substances (e.g., drinks, foods, food or drink constituents, dietary supplements) be administered to the study participants?<br><i>If yes see here to determine whether medical ethical approval is required</i>  |     | ✓  |   |   |   |     |
| 17. Will blood or tissue samples be obtained from participants?<br><i>If yes see here to determine whether medical ethical approval is required</i>  |     | ✓  |   |   |   |     |
| 18. Does the study risk causing psychological stress or anxiety beyond that normally encountered by the participants in their life outside research?   |     | ✓  |   |   |   |     |
| 19. Will the study involve discussion of personal sensitive data which could put participants at increased legal, financial, reputational, security or other risk? (e.g., financial data, location data, data relating to children or other vulnerable groups)<br><i>Definitions of sensitive personal data, and special cases are provided on the TUD Privacy Team website.</i> |     | ✓  |   |   |   |     |



|  |     |    | If YES please complete the Risk Assessment and Mitigation Plan columns below.   |  | Please provide the relevant reference # |     |
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| ISSUE  | Yes | No | RISK ASSESSMENT – what risks could arise?<br><i>Please ensure that you list ALL of the actual risks that could potentially arise – do not simply state whether you consider any such risks are important!</i> | MITIGATION PLAN – what mitigating steps will you take?<br><i>Please ensure that you summarise what actual mitigation measures you will take for each potential risk identified – do not simply state that you will e.g. comply with regulations.</i> | DMP                                     | ICF |
| 20. Will the study involve disclosing commercially or professionally sensitive, or confidential information? (e.g., relating to decision-making processes or business strategies which might, for example, be of interest to competitors)  |     | ✓  |   |  |   |     |
| 21. Has your study been identified by the TU Delft Privacy Team as requiring a Data Processing Impact Assessment (DPIA)? <i>If yes please attach the advice/ approval from the Privacy Team to this application</i>  |     | ✓  |   |  |   |     |
| 22. Does your research investigate causes or areas of conflict?<br><i>If yes please confirm that your fieldwork has been discussed with the appropriate safety/security advisors and approved by your Department/Faculty.</i>  |     | ✓  |   |  |   |     |
| 23. Does your research involve observing illegal activities or data processed or provided by authorities responsible for preventing, investigating, detecting or prosecuting criminal offences<br><i>If so please confirm that your work has been discussed with the appropriate legal advisors and approved by your Department/Faculty.</i> |     | ✓  |   |  |   |     |
| <b>F: Research Methods</b>   |     |    |   |  |   |     |
| 24. 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 in non-public places).  |     | ✓  |   |  |   |     |
| 25. Will the study involve actively deceiving the participants? (For example, 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).   |     | ✓  |   |  |   |     |
| 26. Is pain or more than mild discomfort likely to result from the study? And/or could your research activity cause an accident involving (non-) participants?   |     | ✓  |   |  |   |     |
| 27. Will the experiment involve the use of devices that are not 'CE' certified?<br><i>Only, if 'yes': continue with the following questions:</i>   |     | ✓  |   |  |   |     |
| • Was the device built in-house?   |     |    |   |  |   |     |
| • Was it inspected by a safety expert at TU Delft?<br><i>If yes, please provide a signed device report</i>   |     |    |   |  |   |     |
| • If it was not built in-house and not CE-certified, was it inspected by some other, qualified authority in safety and approved?<br><i>If yes, please provide records of the inspection</i>  |     |    |   |  |   |     |
| 28. Will your research involve face-to-face encounters with your participants and if so how will you assess and address Covid considerations?  |     | ✓  |   |  |   |     |

|  |     |    | If YES please complete the Risk Assessment and Mitigation Plan columns below.   |  | Please provide the relevant reference # |   |
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| ISSUE  | Yes | No | RISK ASSESSMENT – what risks could arise?<br><i>Please ensure that you list ALL of the actual risks that could potentially arise – do not simply state whether you consider any such risks are important!</i>   | MITIGATION PLAN – what mitigating steps will you take?<br><i>Please ensure that you summarise what actual mitigation measures you will take for each potential risk identified – do not simply state that you will e.g. comply with regulations.</i>   | DMP                                     | ICF   |
| 29. Will your research involve <b>either</b> :<br>a) “big data”, combined datasets, new data-gathering or new data-merging techniques which might lead to re-identification of your participants <b>and/or</b><br>b) artificial intelligence or algorithm training where, for example biased datasets could lead to biased outcomes? |     | ✓  |   |  |   |   |
| <b>G: Data Processing and Privacy</b>  |     |    |   |  |   |   |
| 30. Will the research involve collecting, processing and/or storing any directly identifiable PII (Personally Identifiable Information) including name or email address that will be used for administrative purposes only? (eg: obtaining Informed Consent or disbursing remuneration)  |     | ✓  |   |  |   |   |
| 31. Will the research involve collecting, processing and/or storing any directly or indirectly identifiable PIRD (Personally Identifiable Research Data) including videos, pictures, IP address, gender, age etc and <b>what other Personal Research Data (including personal or professional views) will you be collecting?</b>     |     | ✓  |   |  |   |   |
| 32. Will this research involve collecting data from the internet, social media and/or publicly available datasets which have been originally contributed by human participants   |     | ✓  |   |  |   |   |
| 33. Will your research findings be published in one or more forms in the public domain, as e.g., Masters thesis, journal publication, conference presentation or wider public dissemination?   | ✓   |    | <ol style="list-style-type: none"> <li>1. Publishing data could inadvertently reveal identifiable information about participants, leading to a breach of confidentiality.</li> <li>2. Readers may misinterpret the findings, especially if complex data is not clearly presented or explained.</li> <li>3. Publishing the research could expose the researchers to intellectual property theft, where others use the findings without proper attribution.</li> <li>4. Expectations or requirements for data storing and sharing could compromise participant privacy or expose proprietary data. Additionally, there might be pressure to ensure that the findings are reproducible.</li> </ol> | <ol style="list-style-type: none"> <li>1. No personal data is collected. Further, data may be anonymized by removing or altering any identifiable information. Pseudonyms will be used and no demographic information that could be used to identify participants will be published.</li> <li>2. Clarity and simplicity in the presentation of the findings must be ensured, both in the thesis and any journal publications. Limitations of the study will be Included to guide interpretation.</li> <li>3. Copyright notices will be used and publishing will be done in journals that allow retaining copyright over our work.</li> <li>4. Data will be stored and shared in a way that is consistent with the guidelines established in the DMP and in the ICF.</li> </ol> | V, VI                                   | OS,<br>ICF<br>Q6,<br>Q7,<br>Q8,<br>Q9,<br>Q10,<br>Q10 |
| 34. Will your research data be archived for re-use and/or teaching in an open, private or semi-open archive?   | ✓   |    | <ol style="list-style-type: none"> <li>1. Sensitive data could be accessed and used by unauthorized individuals, leading to privacy</li> </ol>  | <ol style="list-style-type: none"> <li>1. No personal data is collected. Furthermore, the principal investigators will implement strict access controls to ensure that data can only be</li> </ol>   |   |   |

|       |     |    | If YES please complete the Risk Assessment and Mitigation Plan columns below.   |  | Please provide the relevant reference # |     |
|-------|-----|----|---|--|---|-----|
| ISSUE | Yes | No | RISK ASSESSMENT – what risks could arise?<br><i>Please ensure that you list ALL of the actual risks that could potentially arise – do not simply state whether you consider any such risks are important!</i>   | MITIGATION PLAN – what mitigating steps will you take?<br><i>Please ensure that you summarise what actual mitigation measures you will take for each potential risk identified – do not simply state that you will e.g. comply with regulations.</i>   | DMP                                     | ICF |
|       |     |    | <p>violations and potential harm to research participants.</p> <ol style="list-style-type: none"> <li>The risk that data could be altered, corrupted, or lost over time due to technical failures or inadequate data management practices.</li> <li>Failing to comply with legal, ethical, and regulatory standards related to data sharing, especially concerning personal data protection laws.</li> <li>Even with anonymized datasets, there is a risk of re-identification, especially with large or detailed datasets.</li> <li>Long-term sustainability of the archive could be jeopardized by funding cuts, technological obsolescence, or institutional changes.</li> </ol> | <p>accessed by authorized individuals. Authorization criteria are limited to non-commercial only.</p> <ol style="list-style-type: none"> <li>We set out robust data management practices in the DMP thanks to the project storage of the TU Delft, which include regular backups, checks for integrity verification, and durable storage.</li> <li>We have reviewed and adhere to applicable laws and regulations (GDPR) in both the data collection and archiving phases. We have also ensured that the participant consent forms include permissions for data sharing and archiving in the manner planned.</li> <li>We will use Qualtrics's advanced anonymization techniques to ensure that re-identification of the participants' data is not possible.</li> <li>We will plan for long-term data storage supplied by Leiden University's funding and data storage technical infrastructure.</li> </ol> |   |     |

## H: More on Informed Consent and Data Management

**NOTE:** You can find guidance and templates for preparing your Informed Consent materials) [here](#)

Your research involves human participants as Research Subjects if you are recruiting them or actively involving or influencing, manipulating or directing them in any way in your research activities. This means you must seek informed consent and agree/ implement appropriate safeguards regardless of whether you are collecting any PIRD.

Where you are also collecting PIRD, and using Informed Consent as the legal basis for your research, you need to also make sure that your IC materials are clear on any related risks and the mitigating measures you will take – including through responsible data management.

*Got a comment on this checklist or the HREC process? You can leave your comments [here](#)*

## IV. Signature/s

***Please note that by signing this checklist list as the sole, or Responsible, researcher you are providing approval of the completeness and quality of the submission, as well as confirming alignment between GDPR, Data Management and Informed Consent requirements.***

**Name of Corresponding Researcher (if different from the Responsible Researcher) (print)**

Signature of Corresponding Researcher:



Date: 19/april/2024

**Name of Responsible Researcher (print)**

Signature (or upload consent by mail) Responsible Researcher:



Date: 25/April/2024

## V. Completing your HREC application

Please use the following list to check that you have provided all relevant documentation

**Required:**

- ☐ **Always:** This completed HREC checklist

- **Always:** A data management plan (reviewed, where necessary, by a data-steward)
- **Usually:** A complete Informed Consent form (including Participant Information) and/or Opening Statement (for online consent)

**Please also attach any of the following, if relevant to your research:**

| Document or approval                                       | Contact/s  |
|--|--|
| Full Research Ethics Application                           | After the assessment of your initial application <b>HREC will let you know if and when you need to submit additional information</b> |
| Signed, valid <a href="#">Device Report</a>                | Your <a href="#">Faculty HSE advisor</a>   |
| Ethics approval from an external Medical Committee         | TU Delft Policy Advisor, Medical (Devices) Research  |
| Ethics approval from an external Research Ethics Committee | Please append, if possible, with your submission   |
| Approved Data Transfer or Data Processing Agreement        | Your <a href="#">Faculty Data Steward</a> and/or TU <a href="#">Delft Privacy Team</a>   |
| Approved Graduation Agreement                              | Your Master's thesis supervisor  |
| Data Processing Impact Assessment (DPIA)                   | TU <a href="#">Delft Privacy Team</a>  |
| Other specific requirement                                 | Please reference/explain in your checklist and append with your submission   |