**Delft University of Technology**

**HUMAN RESEARCH ETHICS**

**COURSE/MODULE-RELATED RESEARCH
(Version: January 2022)**

|  |
| --- |
| This course-related research ethics form should be completed for every course or module that involves students in conducting research where human participants (including other students) act as Research Subjects. The purpose is to confirm that students have been familiarised with the relevant existing legal and ethical guidelines, and that the research they will conduct is considered as Minimal Risk. All applications must confirm that appropriate checks and balances are in place in the event of accidents.If you have any questions about applying for HREC approval which are not dealt with on the [Research Ethics webpages](https://www.tudelft.nl/en/about-tu-delft/strategy/integrity-policy/human-research-ethics), please contact HREC@tudelft.nl |

1. **Basic Data**

|  |  |
| --- | --- |
| **COURSE TITLE:** |  |
| **Course Code:** |  |
| **Link to Course description/materials:**  |  |
| **Start date:** *What is the start date of the course or module?* |  |
| **Duration:** *What is the duration of the course or module in a given year?* |  |
| **Valid period (if possible to say):***Over how many years will the course or module be taught in its current state?*  |  |
| **Faculty:** |  |
| **Department:** |  |
| **Level of course or module:***(Bachelor’s, Master’s)* |  |
| **Estimated number of students involved:** |  |

1. **Course/Module and Research Overview**
2. **Purpose of the research in the course or module:**

|  |  |  |
| --- | --- | --- |
|  | **Yes** | **No** |
| 1. The research will be conducted purely to teach students in methods of research design, execution and analysis and any data collected will not be stored beyond the end date of the course in a given year.
 |  |  |
| 1. The research will be conducted to teach students in methods of research design, execution and analysis but the data collected may also be conserved for future use as research data.
 |  |  |
| 1. Other – *in which case please summarise in the space below:*
 |  |  |
|  |

1. **Nature of the research**

|  |  |  |
| --- | --- | --- |
|  | **Yes** | **No** |
| 1. i) All students will conduct the same kind of research project
 |  |  |
| 1. ii) Students will select from a restricted set of research projects
 |  |  |
| 1. Students can select any kind of research project without clear restrictions
 |  |  |
| *If “yes” to iii) do the students know that their project has to be considered as Minimal Risk as standard?* |  |  |

**If you have selected b.i) or b.ii) above:**

|  |
| --- |
| *Please very briefly summarise (100-200 words) the type/s of human research that the students will conduct as part of the course. This should include what are they looking into, who is involved, how many participant will there be, how will they be recruited and what are they expected to do. For example, will the research involve (online) questionnaires, interviews, workshops, product/software testing, simulators etc.* |
|  |

**If you have selected b.iii) above:**

|  |
| --- |
| *Please* *explain how the projects will be screened, and note that projects involving more than Minimal Risk will need a separate, standard* [*HREC application*](https://www.tudelft.nl/en/about-tu-delft/strategy/integrity-policy/human-research-ethics)*.* |
|  |

1. **Risk Assessment and Mitigation**
2. **Compliance issues** – please confirm that, where the research requires it, you have sought the relevant advice from the following (or other) experts:

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Issue and/or additional required documentation** | **Contact/s** | **Yes** | **No** | **N/A** |
| Device reports, Covid protocols and other Health and Safety dimensions of the research | Your [Faculty HSE advisor](https://intranet.tudelft.nl/en/-/hse-advisor?p_l_back_url=%2Fen%2Fsearch%3Fq%3Dhse) |  |  |  |
| 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, to your submission |  |  |  |
| Approved Data Transfer or Data Processing Agreement  | Your [Faculty Data Steward](https://www.tudelft.nl/en/library/research-data-management/r/support/data-stewardship/contact) and/or TU [Delft Privacy Team](https://www.tudelft.nl/en/privacy-security/privacy/doelgroepen/researcher)  |  |  |  |
| GDPR requirements and Data Management Planning | Your [Faculty Data Steward](https://www.tudelft.nl/en/library/research-data-management/r/support/data-stewardship/contact) and/or TU [Delft Privacy Team](https://www.tudelft.nl/en/privacy-security/privacy/doelgroepen/researcher) |  |  |  |

1. **Potential risks to participants** – please complete the risk assessment table below by ticking “yes” or “no” as appropriate.

|  |  |  |
| --- | --- | --- |
|  | **Yes** | **No** |
| 1: Are there any partners or other collaborating organisations involved? |  |  |
| 2: Will the research involve using datasets provided by third parties? |  |  |
| 3: Will the research involve participants based in a country or countries other than the Netherlands? |  |  |
| 4: Will the research involve any participants who may be vulnerable and possibly unable to (legally) give Informed Consent (eg: patients, children, students in a subordinate relationship with the course tutor)? |  |  |
| 5: Is there a risk that participants might be recruited in a manner which is NOT GDPR-compliant? |  |  |
| 6: Will the research involve confidential or sensitive data OR have the potential to have a negative physical or psychological impact OR involve dangerous situations? |  |  |
| 7: Will the research involve covert observation or deception? |  |  |
| 8: Will the research involve using combined datasets, and/or learning algorithms/other AI to analyse, combine or otherwise process such data? |  |  |
| 9: Will the research involve a device which has not been CE-certified?*If so you may need to submit a signed Device Report from your Faculty HSE advisor.* |  |  |
| 10: Will the research involve face-to-face encounters (in relation to contemporary covid regulations)? |  |  |
| 11. Will the data involve collecting personal data from your participants (Research Subjects) – either Personally Identifiable Information (for administrative purposes) and/or Personally Identifiable Research Data (for analysis)? |  |  |
| 12. Is there any likelihood that you may want to publish or otherwise publicly communicate the data and/or use them in future teaching and learning? |  |  |
| 13. Do you expect any of the research conducted by students could be considered as Extensive Risk. [[1]](#footnote-1) *If “yes” then you will need to submit a normal HREC application for each such project.* |  |  |
| 14. Information to students: Will your students informed about/ referred to the guidelines for human research, including the GDPR (Informed Consent, anonymization, ‘privacy by design principle’, safe storage)?*Note: See also the TU Delft-website about the GDPR.* |  |  |

|  |
| --- |
| *If you do answer “yes” to any of the above, please consult the brief guide on* [**Human Research Ethics: completing the HREC checklist**](https://d2k0ddhflgrk1i.cloudfront.net/TUDelft/Over_TU_Delft/Strategie/Integriteitsbeleid/Research%20ethics/2_CHC-completing%20the%20HREC%20checklist_2022.pdf)*to consider the kinds of risks your Research Subjects may be exposed to, before finalising this application.*  |

1. **Mitigation measures** - Please summarise in the text box below, any measures you will take in light of your responses above

|  |
| --- |
|  |

1. Signature

|  |
| --- |
| ***Please note that by signing this checklist list as the sole, or Responsible, teacher you are providing approval of the completeness and quality of the submission, as well as confirming that, having taken any necessary expert advice, you consider the level of all of the research to be undertaken by students to be of Minimal Risk.*** |

|  |
| --- |
| **Name of Responsible teacher (print)**Signature of Responsible teacher: Date:  |

1. *Extensive risk means:*

	* *Collection or use of confidential/sensitive data*
	* *Experiments which may have a negative impact on the wellbeing of participants (pain, psychological stress or anxiety)*
	* *Involvement of children or vulnerable people*
	* *Dangerous situations*
	* *Use of deception* [↑](#footnote-ref-1)