

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

PROJECT TITLE:	Design of a low-cost laparoscope
Research period: <i>Over what period of time will this specific part of the research take place</i>	5-2026 – 6-2026
Faculty:	Mechanical Engineering
Department:	BioMechanical Design
Type of the research project: <i>(Bachelor's, Master's, DreamTeam, PhD, PostDoc, Senior Researcher, Organisational etc.)</i>	Master Thesis
Funder of research: <i>(EU, NWO, TUD, other – in which case please elaborate)</i>	TUD
Name of Corresponding Researcher: <i>(If different from the Responsible Researcher)</i>	Tijn Jeletich
E-mail Corresponding Researcher: <i>(If different from the Responsible Researcher)</i>	_____
Position of Corresponding Researcher: <i>(Masters, DreamTeam, PhD, PostDoc, Assistant/ Associate/ Full Professor)</i>	Masters student
Name of Responsible Researcher: <i>Note: all student work must have a named Responsible Researcher to approve, sign and submit this application</i>	Dr. Ir. Roos Oosting
E-mail of Responsible Researcher: <i>Please ensure that an institutional email address (no Gmail, Yahoo, etc.) is used for all project documentation/ communications including Informed Consent materials</i>	_____
Position of Responsible Researcher : <i>(PhD, PostDoc, Associate/ Assistant/ Full Professor)</i>	Assistant Professor

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?

<i>Add your text here – (please avoid jargon and abbreviations)</i>
The aim of the research is to find out what medical professionals think about the performance of the prototype low-cost laparoscope. The participants will be asked to identify several organs in a laparoscopic training doll. They will be recruited using the network of the department and of the corresponding researcher. The number of participant will be around 10.

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.

<i>Add your text here – (please avoid jargon and abbreviations)</i>
I have a previous HREC submission for the same thesis project, with ID: 6222. That submission was for interviews with medical professionals for the context study at the beginning of the project. This submission is about testing the prototype that followed from the design phase after the context study.

- 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? <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? <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
A: Partners and collaboration						
1. Will the research be carried out in collaboration with additional organisational partners such as: - One or more collaborating research and/or commercial organisations - Either a research, or a work experience internship provider¹ <i>¹ If yes, please include the graduation agreement in this application</i>		x				
2. Is this research dependent on a Data Transfer or Processing Agreement with a collaborating partner or third party supplier? <i>If yes please provide a copy of the signed DTA/DPA</i>		x				
3. Has this research been approved by another (external) research ethics committee (e.g.: HREC and/or MREC/METC)? <i>If yes, please provide a copy of the approval (if possible) and summarise any key points in your Risk Management section below</i>		x				
B: Location						

			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? <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? <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
4. Will the research take place in a country or countries, other than the Netherlands, within the EU?		x				
5. Will the research take place in a country or countries outside the EU?		x				
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?		x				
C: Participants						
7. Will the study involve participants who may 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,).		x				
8. Will the study involve participants who may 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?		x				
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)? <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>		x				
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?		x				
D: Recruiting Participants						
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	x		All participants will be recruited through my own and Dr. Oosting her network. This could introduce risk of bias.	The methods of recruitment and the limitations associated with them will be mentioned in the thesis report.		
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)		x				

			<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? <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? <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
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?		x				
14. Will you be offering any financial, or other, remuneration to participants, and might this induce or bias participation?		x				
E: Subject Matter <i>Research related to medical questions/health may require special attention. See also the website of the CCMO before contacting the HREC.</i>						
15. Will your research involve any of the following: - Medical research and/or clinical trials - Invasive sampling and/or medical imaging - Medical and <i>In Vitro Diagnostic Medical Devices</i> Research		x	Even though the research is about a medical instrument, since the research is just about usability testing of the prototype and no human (or animal) subjects are used to test on, it falls outside the scope of CCMO and WMO.			
16. Will drugs, placebos, or other substances (e.g., drinks, foods, food or drink constituents, dietary supplements) be administered to the study participants? <i>If yes see here to determine whether medical ethical approval is required</i>		x				
17. Will blood or tissue samples be obtained from participants? <i>If yes see here to determine whether medical ethical approval is required</i>		x				
18. Does the study risk causing psychological stress or anxiety beyond that normally encountered by the participants in their life outside research?		x				
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) <i>Definitions of sensitive personal data, and special cases are provided on the TUD Privacy Team website.</i>		x				
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)		x				
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>		x				
22. Does your research investigate causes or areas of conflict? <i>If yes please confirm that your fieldwork has been discussed with the appropriate safety/security advisors and approved by your Department/Faculty.</i>		x				

			If YES please complete the Risk Assessment and Mitigation Plan columns below.		Please provide the relevant reference #	
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23. Does your research involve observing illegal activities or data processed or provided by authorities responsible for preventing, investigating, detecting or prosecuting criminal offences <i>If so please confirm that your work has been discussed with the appropriate legal advisors and approved by your Department/Faculty.</i>		x				
F: Research Methods						
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).		x				
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).		x				
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?		x				
27. Will the experiment involve the use of devices that are not ‘CE’ certified? <i>Only, if ‘yes’: continue with the following questions:</i>	x			The risks are addressed in the Device Report.		
• Was the device built in-house?	x					
• Was it inspected by a safety expert at TU Delft?	x					
<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? <i>If yes, please provide records of the inspection</i>		x				
28. Will your research involve face-to-face encounters with your participants and if so how will you assess and address Covid considerations?	x					
29. Will your research involve either : a) “big data”, combined datasets, new data-gathering or new data-merging techniques which might lead to re-identification of your participants and/or b) artificial intelligence or algorithm training where, for example biased datasets could lead to biased outcomes?		x				
G: Data Processing and Privacy						
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)	x		The only PII that will be collected are participants name on the informed consent form. These forms will be stored separately from the research data and will not be published.	The consent forms with PII will be stored on the secure TU Delft Storage, which complies with GDPR requirements. This storage is only accessible for me and the supervisors.		

			<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? <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? <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
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 what other Personal Research Data (including personal or professional views) will you be collecting?		X				
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		x				
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?	x		Risk of publishing data that can be traced back to individual participants	Research data will be anonymized and will not mention participants specific job title or hospital.		
34. Will your research data be archived for re-use and/or teaching in an open, private or semi-open archive?		x				

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: Tijn Jeletich

Signature of Corresponding Researcher:



Date:

Name of Responsible Researcher: Roos Oosting

Signature (or upload consent by mail) Responsible Researcher:

Date:

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 HREC will let you know if and when you need to submit additional information
Signed, valid Device Report	Your Faculty HSE advisor
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 Faculty Data Steward and/or TU Delft Privacy Team
Approved Graduation Agreement	Your Master's thesis supervisor
Data Processing Impact Assessment (DPIA)	TU Delft Privacy Team
Other specific requirement	Please reference/explain in your checklist and append with your submission