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:	**Alternative cast for distal radius fractures**
Research period: *Over what period of time will this specific part of the research take place*	**March 2023- November 2023**
Faculty:	**3ME**
Department:	**BioMechanical Engineering**
Type of the research project: *(Bachelor's, Master's, DreamTeam, PhD, PostDoc, Senior Researcher, Organisational etc.)*	**Master's thesis**
Funder of research: *(EU, NWO, TUD, other – in which case please elaborate)*	**NA**
Name of Corresponding Researcher: *(If different from the Responsible Researcher)*	**Anne-Marijn van der Plas**
E-mail Corresponding Researcher: *(If different from the Responsible Researcher)*	**a.e.vanderplas@student.tudelft.nl**
Position of Corresponding Researcher: *(Masters, DreamTeam, PhD, PostDoc, Assistant/ Associate/ Full Professor)*	**Master student**
Name of Responsible Researcher: ***Note:** all student work must have a named Responsible Researcher to approve, sign and submit this application*	**Karin Thomassen**
E-mail of Responsible Researcher: *Please ensure that an institutional email address (**no Gmail, Yahoo, etc.**) is used for all project documentation/ communications including Informed Consent materials*	**k.e.thomassen@tudelft.nl**
Position of Responsible Researcher : *(PhD, PostDoc, Associate/ Assistant/ Full Professor)*	**PhD**

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 abbrevations)
The comfort and fitting of a design/ prototype that could be used for immobilizing distal radius fractures will be tested. Secondly, the ease of application will be tested. 10 healthy participants will join. First they will get the prototype on their arm and they have to wear it for 10 minutes while doing some simple tasks. Some measurements will be taken of their arm and hand. Then they fill in a questionnaire. After this part they will apply the product to the researcher's arm or to the arm of another participant. They will get questions through a questionnaire about this as well.

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 abbrevations)

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 alighment 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.

			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?** *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!*	**MITIGATION PLAN – what mitigating steps will you take?** *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.*	**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 provider[1] *[1] If yes, please include the graduation agreement in this application*		**x**				
2. Is this research dependent on a Data Transfer or Processing Agreement with a collaborating partner or third party supplier? *If yes please provide a copy of the signed DTA/DPA*		**x**				
3. Has this research been approved by another (external) research ethics committee (e.g.: HREC and/or MREC/METC)? *If yes, please provide a copy of the approval (if possible) and summarise any key points in your Risk Management section below*		**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?** *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!*	**MITIGATION PLAN – what mitigating steps will you take?** *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.*	**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)? *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).*		**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**				
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**				

			If YES please complete the Risk Assessment and Mitigation Plan columns below.		*Please provide the relevant reference #*	
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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 *Research related to medical questions/health may require special attention. See also the website of the CCMO before contacting the HREC.*						
15. Will your research involve any of the following: • Medical research and/or clinical trials • Invasive sampling and/or medical imaging • Medical and *In Vitro Diagnostic Medical* Devices Research		x				
16. Will drugs, placebos, or other substances (e.g., drinks, foods, food or drink constituents, dietary supplements) be administered to the study participants? *If yes see here to determine whether medical ethical approval is required*		x				
17. Will blood or tissue samples be obtained from participants? *If yes see here to determine whether medical ethical approval is required*		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) *Definitions of sensitive personal data, and special cases are provided on the TUD Privacy Team website.*		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)? *If yes please attach the advice/ approval from the Privacy Team to this application*		x				
22. Does your research investigate causes or areas of conflict? *If yes please confirm that your fieldwork has been discussed with the appropriate safety/security advisors and approved by your Department/Faculty.*		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 *If so please confirm that your work has been discussed with the appropriate legal advisors and approved by your Department/Faculty.*		**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**		The immobilization device could put pressure on the arm and hand of the patient. If applied correctly this does not cause pain or discomfort. If it is applied incorrectly there could be a chance this causes pain or discomfort to the participant	Communication with the participant will mitigate this risk. Beforehand and during the test the participant will be asked and encouraged to tell how it feels, when discomfort is experienced the device will be loosend.		
27. Will the experiment involve the use of devices that are not 'CE' certified? *Only, if 'yes': continue with the following questions:*	**x**		A not CE certified device is not checked on safety, health and environmental aspects. Risk regarding procuct safety could arise. The materials could harm the participants, the mechanism could be unsafe (fingers that could get stuck, sharp edges), the device could fall apart too easily. The device could be bad for the environment (harmful materials)	Parts and materials that will be used will be assessed on suitability for the purpose, this is done by checking other products that are used for similar purposes. Edges will be rounded to avoid harming participants. There will be made sure there are no places fingers can get stuck in a harmful way. For the environment, checking whether the same materials are used in other products will help. Furthermore, another person will be asked to check the device on safety for the participants.		
• Was the device built in-house?	**x**		*See above*			
• Was it inspected by a safety expert at TU Delft? *If yes, please provide a signed device report*	**x**					
• If it was not built in-house and not CE-certified, was it inspected by some other, qualified authority in safety and approved? *If yes, please provide records of the inspection*		**X**				

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28. Will your research involve face-to-face encounters with your participants and if so how will you assess and address Covid considerations?	**x**		Covid considerations will be addressed if regulations and advises from the Dutch government regarding this topic apply during the time of the experiment	Governmental regulations and advises will be assessed before conducting the experiment. If any apply, this will be implemented for the experiment.		
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**		Some data of the participants is needed to contact them. This is a risk if this information is leaked to other parties. If much information is obtained from the participant there are privacy risks such as identity theft, stalking and scamming.	A minimal amount of data needed is stored, only a (sur)name and something to contact this person (mostly phonenumber). This personal data is deleted after finishing the graduation project and the obtainined data is anonimised. Furthermore, the data presented in the results in anonomised. The informed consent will include information about PII to make the participants aware of the situation. Only the researcher and the supervisors have access to the names and contact details of the participant		
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**		Data about sizes of the participant need to be acquired, furthermore age and gender are noted. This could result in identification of a participant without directly stating their name. Also personal opinions on the tested device will be noted, this could also help to identify a person by the way they write. The privacy risks mentioned above also apply here.	The data will be presented as averages as much as possible without mentioning individual results. The minimum amount of data will be collected, data that is not used will be deleted after the project. Furthermore, consent of the participants is obtained and oly the researcher and supervisors can access this data.		
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**		The findings will be published in a masters thesis , which can be found online. This is publically available. The risk regarding to privacy increases as more people can access the data.	The data will be anonimised wherefore it is impossible for the public to identify the participants. Measures above also apply here. If pictures are taken, the face will not be visible		

			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?** *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!*	**MITIGATION PLAN – what mitigating steps will you take?** *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.*	**DMP**	**ICF**
34. Will your research data be archived for re-use and/or teaching in an open, private or semi-open archive?	**x**		The research could potentially be reused for other research objectives. It will not be used for teaching. The risk of archieved data is that the data can be used outside the scope of this research	The data is only available to the supervisors and not publically. Furthermore there is only non-identifyable data.		

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.

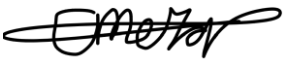
Got a comment on this checklist or the HREC process? You can leave your comments here

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)
Anne-Marijn van der Plas

Signature of Corresponding Researcher:



Date: 07-08-2023

Name of Responsible Researcher (print)

Karin Thomassen
Signature (or upload consent by mail) Responsible Researcher:

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