

Delft University of Technology

ETHICS REVIEW CHECKLIST FOR HUMAN RESEARCH

This checklist should be completed for every research study that involves human participants and should be submitted before potential participants are approached to take part in your research study.

In this checklist we will ask for additional information if need be. Please attach this as an Annex to the application.

Please upload the documents (go to [this page](#) for instructions).

Thank you and please check our [website](#) for guidelines, forms, best practices, meeting dates of the HREC, etc.

I. Basic Data

Project title:	The response of the riders body to rotational & translational motions of two wheelers rider
Name(s) of researcher(s):	George Dialynas
Research period (planning)	1 July-September 2017
E-mail contact person	g.dialynas@tudelft.nl
Faculty/Dept.	3Me/Biomechanical engineering
Position researcher(s):¹	PhD
Name of supervisor (if applicable):	Arend Schwab
Role of supervisor (if applicable):	Riender Happee

II. A) Summary Research

The research is aiming to identify the biomechanical properties of the rider's body from laboratory tests. Special test equipment has been developed; it is a bicycle mock up driven by a hexapod that generates oscillations in the range 0.5–10 Hz. The bicycle mock up is instrumented with an imu and a combination of strain gauges allowing us to measure the input motion and the response of the rider's body. The response of the rider's body will be represented in the frequency domain by means of frequency response functions: the frequency response functions will describe the motion of the rider's trunk and upper torso relative to the platform, and the mechanical impedance of the rider body. This will be described by non-parametric system identification methods. The force frequency response functions can be further used from other researchers to identify the parameters of lumped mass biomechanical models, suited to integration with the multi-body model of the bicycle.

¹ For example: student, PhD, post-doc

B) Risk assessment

III. Checklist

	Yes	No
1. Does the study involve participants who are particularly vulnerable or unable to give informed consent? (e.g., children, people with learning difficulties, patients, people receiving counselling, people living in care or nursing homes, people recruited through self-help groups).	<input type="checkbox"/>	<input checked="" type="checkbox"/>
2. Are the participants, outside the context of the research, in a dependent or subordinate position to the investigator (such as own children or own students)? ²	<input type="checkbox"/>	<input checked="" type="checkbox"/>
3. 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).	<input type="checkbox"/>	<input checked="" type="checkbox"/>
4. 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).	<input type="checkbox"/>	<input checked="" type="checkbox"/>
5. Will the study involve discussion or collection of information on sensitive topics? (e.g., sexual activity, drug use, mental health).	<input type="checkbox"/>	<input checked="" type="checkbox"/>
6. Will drugs, placebos, or other substances (e.g., drinks, foods, food or drink constituents, dietary supplements) be administered to the study participants?	<input type="checkbox"/>	<input checked="" type="checkbox"/>
7. Will blood or tissue samples be obtained from participants?	<input type="checkbox"/>	<input checked="" type="checkbox"/>
8. Is pain or more than mild discomfort likely to result from the study?	<input type="checkbox"/>	<input checked="" type="checkbox"/>
9. Does the study risk causing psychological stress or anxiety or other harm or negative consequences beyond that normally encountered by the participants in their life outside research?	<input type="checkbox"/>	<input checked="" type="checkbox"/>
10. Will financial inducement (other than reasonable expenses and compensation for time) be offered to participants?	<input type="checkbox"/>	<input checked="" type="checkbox"/>

Important:
if your answered 'yes' to any of the questions mentioned above, please submit
the full application form to HREC
(see: [HREC website](#) for forms or examples).

² **Important note concerning questions 1 and 2.** Some intended studies involve research subjects who are particularly vulnerable or unable to give informed consent. Research involving participants who are in a dependent or unequal relationship with the researcher or research supervisor (e.g., the researcher's or research supervisor's students or staff) may also be regarded as a vulnerable group. If your study involves such participants, it is essential that you safeguard against possible adverse consequences of this situation (e.g., allowing a student's failure to complete their participation to your satisfaction to affect your evaluation of their coursework). This can be achieved by ensuring that participants remain anonymous to the individuals concerned (e.g., you do not seek names of students taking part in your study). If such safeguards are in place, or the research does not involve other potentially vulnerable groups or individuals unable to give informed consent, it is appropriate to check the NO box for questions 1 and 2. Please describe corresponding safeguards in the summary field.

	Yes	No
11. Will the experiment collect and store videos, pictures, or other identifiable data of human subjects? ³	<input type="checkbox"/>	<input checked="" type="checkbox"/>
If "yes", are you sure you follow all requirements of the applicable data protection legislation? (Please provide proof by sending us a copy of the informed consent form).	<input type="checkbox"/>	<input type="checkbox"/>
12. Will the experiment involve the use of devices that are not 'CE' certified?	<input checked="" type="checkbox"/>	<input type="checkbox"/>
<i>Only If 'yes': continue with the following questions:</i>		
• Was the device built in-house?	<input checked="" type="checkbox"/>	<input type="checkbox"/>
• Was it inspected by a safety expert at TU Delft? (Please provide device report, see: HREC website)	<input type="checkbox"/>	<input checked="" type="checkbox"/>
• If it was not built in house and not CE-certified, was it inspected by some other, qualified authority in safety and approved? (Please provide records of the inspection).	<input type="checkbox"/>	<input checked="" type="checkbox"/>
13. Has or will this research be submitted to a research ethics committee other than this one? (if so, please provide details and a scan of the approval or submission if available).	<input type="checkbox"/>	<input checked="" type="checkbox"/>

IV. Enclosures (tick if applicable)

- ☐ Full proposal (if 'yes' to any of the questions 1 until 10)
- ☐ Informed consent form (if 'yes' to question 11)
- ☐ Device report (if 'yes' to question 12)
- ☐ Approval other HREC-committee (if 'yes' to question 13)
- ☐ Any other information which might be relevant for decision making by HREC

V. Signature(s)

Signature(s) of researcher(s)

Date: 12/06/2017

Signature research supervisor (if applicable)

Date: 12/06/2017

³ Note: you have to ensure that collected data is safeguarded physically and will not be accessible to anyone outside the study. Furthermore, the data has to be de-identified if possible and has to be destroyed after a scientifically appropriate period of time.

Appendix 1: Privacy and data protection

Please fill this in if you have answered 'yes' to question 11 in the checklist

- a. Are the research data made anonymous? If no, please explain.
- b. Will directly identifiable data (such as name, address, telephone number, and so on) be kept longer than 6 months? If yes, will the participants give written permission to store their information for longer than 6 months?
- c. Who will have access to the data which will be collected?
- d. Will the participants have access to their own data? If no, please explain.
- e. Will covert methods be used? (*e.g. participants are filmed without them knowing*)
- f. Will any human tissue and/or biological samples be collected? (*e.g. urine*)