

Delft University of Technology
ETHICS REVIEW CHECKLIST FOR HUMAN RESEARCH
(Version 18.06.2020)

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. This also applies for students doing their Master-thesis.

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

The data steward of your faculty can help you with any issues related to the protection of personal data. Please note that research related to medical questions/health may require special attention. See also the website of the [CCMO](#).

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 development of a guideline for the development of eHealth interventions for people with a low SES.
Name(s) of researcher(s):	Jasper Faber, Isra Al-Dhahir
Research period (planning)	01-03-21 till 01-12-21
E-mail contact person	j.s.faber@tudelft.nl
Faculty/Dept.	IDE / Industrial Design
Position researcher(s):¹	PhD
Name of supervisor (if applicable):	Valentijn Visch
Role of supervisor (if applicable):	Promotor

II. A) Summary Research

(Please very briefly (100-200 words) summarise your research, stating the question for the research, who will participate, the number of participants to be tested and the methods/devices to be used. Please avoid jargon and abbreviations).

We will develop a web-based guideline that supports professionals during the development of eHealth interventions for people with a low socioeconomic status (SES). Two studies were recently conducted to develop a better understanding of this topic: one involving people from a low SES neighbourhood (bottom-up) and one with professionals (top-down). The current study will combine results from both studies in the form of the guideline. We will employ a participatory process with professionals (N=8 -16) consisting of healthcare workers, developers, researchers, and policy officers having experience with developing eHealth interventions and/or who work with people from low SES communities. The study will consist of multiple iterations, in which we will evaluate an evolving set of prototypes of the form (online interface) and content (recommendations) through semi-structured interviews. We will use the prototypes during these interviews to

¹ For example: student, PhD, post-doc

identify the needs of the professionals during a development process and gather feedback for improvement.

B) Risk assessment & risk management

Please indicate if you expect any risks for the participants as a result of your research and, if so, describe these risks and how you will try to minimize them.

During the interviews, demographic data (age, occupation, years of experience) of the professionals will be collected through audio-recordings and transcriptions. We will ensure these sources will not contain any personal data, such as names or pictures, that could be used to identify the participants. To anonymise the recordings, we will make use of pitch changing software. The data will be stored on a project and SURF DRIVE drive throughout the course of the project. See the DMP for more details.

III. Checklist

Question	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).		X
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		X
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).		X
4. 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
5. Sensitive personal data <ul style="list-style-type: none"> Will the study involve discussion or collection of personal sensitive data (e.g., financial data, location data, data relating to children or other vulnerable groups)? Definitions of sensitive personal data, and special cases thereof are provided here. 		X
6. Will drugs, placebos, or other substances (e.g., drinks, foods, food or drink constituents, dietary supplements) be administered to the study participants?		X
7. Will blood or tissue samples be obtained from participants?		X
8. Is pain or more than mild discomfort likely to result from the study?		X
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?		X
10. Will financial inducement (other than reasonable expenses and compensation for time) be offered to participants?		X
Important: if you answered 'yes' to any of the questions mentioned above, please submit a full application to HREC (see: website for forms or examples).		
11. Will the experiment collect and store videos, pictures, or other identifiable data of human subjects? ³		X

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.

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. Also ask explicitly for consent if anonymised data will be published as open data.

Question	Yes	No
12. Will the experiment involve the use of devices that are not 'CE' certified? <i>Only, if 'yes': continue with the following questions:</i>		X
➤ Was the device built in-house?		
➤ Was it inspected by a safety expert at TU Delft? <i>(Please provide device report, see: HREC website)</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>(Please provide records of the inspection).</i>		
13. Has or will this research be submitted to a research ethics committee other than this one? <i>(if so, please provide details and a copy of the approval or submission).</i>		X

IV. Enclosures

Please, tick the checkboxes for submitted enclosures.

Required enclosures

- A data management plan reviewed by a data-steward.

Conditionally required enclosures

if you replied 'yes' to any of the questions 1 until 10:

- A full research application

If you replied 'yes' to questions 11:

- An Informed consent form

If you replied 'yes' to questions 12:

- A device report

If you replied 'yes' to questions 13:

- Submission details to the external HREC, and a copy of their approval if available.

Additional enclosures

- Any other information which you feel to be relevant for decisionmaking by the HREC.

V. Signature(s)

Signature(s) of researcher(s)

Date: 06-04-2021




Signature (or upload consent by mail) research supervisor (if applicable)

Date:

