

Ethics Review Template

Via this template you can create (or upload) your Ethics Review and request a review by the Ethical Review Board (ERB). This Ethical Review template should be completed for every research study that involves human participants or personal data.

Questions: If you have questions for the ethics committee, add them at the end of the form as a comment under "Activity".

Submit: Once you've completed the form, click "Submit". Your form will be automatically sent to the Ethics Review Board for revision.

1. Project Title*

2. Are you a?*

Bachelor student

Master student

Researcher (PhD, academic staff)

Other

3. Name of the researcher (Student or Researcher)*

4. Email of the researcher (Student or Researcher)*

5. Supervisor(s) Name(s)

5a. Supervisor(s) email address(es)

6. Department*

Select...

6a. Are you or your supervisor(s) from the HTI group?*

Yes

No

6b. How much will the total study cost?*

Below 100€

100€-1000€

More than 1000€

7. What is the purpose of this study? (select all that apply)*

Educational purposes (as part of a course)

Scientific purposes (possibly leading to a publication)

7a. For what course is this required?*

8. What are your main research questions?*

9. Has your proposal already been approved by an external Ethical Review Board?*

Yes

No

9a. External ERB, please upload your ethical approval letter here:*

Device Information

10. Does your research include a device?*

Yes

No

11. Please describe your device or link to an online description of the device*

12. Will you use a device that is 'CE' certified for unintended use (meaning you will use existing CE certified devices for other things than they were originally intended for) or use a device that is not 'CE' certified?*

Yes, my device or software currently has a medical purpose

Yes, my device or software could have a medical purpose in the near future

No

I'm not sure

13. Please explain to what extent the device was assembled according to relevant standards and provide a risk assessment*

14. Do you use a device or software that has a medical purpose such as diagnosis, prevention, monitoring, prediction, prognosis, treatment or alleviation of disease or injury?*

Yes, my device or software currently has a medical purpose

Yes, my device or software could have a medical purpose in the near future

No

I'm not sure

Population & Measurement Information

15. Please check the box that indicates the relevant study population*

Students

General healthy population

General population with specific feature, e.g., pregnancy, specifically

Patients, specifically

Other

15a. Please specify:*

16. Age category of participants*

Younger than 12 years of age

12 to 15 years old

16 to 17 years old

18 years or older

17. Description of the research method and/or measurement (select all that applies)*

(Semi-structured) interviews

Surveys

Group workshops/roundtable discussions

Diary studies

Behavioral observations

Building sensor data

Wearable device (e.g. Fitbit watch, on-skin sensors)

User testing

Pilot study

GPS tracking/location data

Living Lab

Other

17a. Please specify:*

18. Please use this box to attach any other relevant documentation (e.g. survey questionnaire, text used for ads to recruit participants, text used for debriefings, etc.)

19. Describe the procedures, measurements, and stimuli/treatments used in your study. *

20. Describe and justify the number of participants and observations for each stage of your study. *

21. Explain why your research is societally important. What benefits and harm to society may result from the study?*

22. Describe the way participants will be recruited*

Survey link posted online, e.g., social media platforms

On campus flyers

Personal network

Via a company (please write the company name in the "other" box)

Via a hospital (please write the hospital name in the "other" box)

By a Consortium Partner (please write the consortium partner name in the "other" box)

Students in a course

HTI participants database

External participant database (prolific, MTurk, etc)

Other

22a. Please specify:*

23. Will the participants give their consent – on a voluntary basis – either digitally or on paper? Or have they given consent in the past for the purpose of education or for re-use in line with the current research question?*

Yes

No

23a. Are you using the TU/e consent templates?

Yes

No

23b. Please upload here your consent template

23c. Is the public task your legal basis for processing the personal data in your study?

Yes

No

23d. Fill in the legal basis you will use here:

23. Provide a statement of the risks regarding the safety or well-being (think about stress, extreme emotions, visual or auditory discomfort) that you expect for the participants or others involved in the study and how you plan to mitigate them.*

24. Please provide a brief statement of the risks associated with the privacy and breach of data collected from the participants and how you plan to mitigate them.*

Self-assessment checklist

26. Does the study involve human material? (e.g., surgery waste material derived from non- commercial organizations such as hospitals)*

Yes

No

26a. Describe how you will safeguard any potential risk for the research participant, and how will you handle the materials (storage, access, retention).*

27. Will blood or other (bio)samples be obtained from participants? (e.g., hair, sweat, urine or other bodily fluids or secretions, also external imaging of the body)*

Yes

No

27a. Describe how you will safeguard any potential risk for the research participant, and how will you handle the samples (storage, access, retention).*

28. Are the participants, outside the context of the research, in a dependent or subordinate position to the investigator?*

Yes

No

28a. Describe how you will safeguard any potential risk for the research participant.*

29. Does the study involve participants who are particularly vulnerable or unable to give informed consent?*

Yes

No

29a. Describe how you will safeguard any potential risk for the research participant.*

30. Will participating in the research be burdensome? *

Yes

No

30a. Describe how you will safeguard any potential risk for the research participant.*

31. May the research procedure cause harm or discomfort to the participant in any way?*

Yes

No

31a. Describe how you will safeguard any potential risk for the research participant.*

32. Will financial inducement (other than reasonable expenses and compensation for time) be offered to participants?*

Yes

No

32a. How long will the intervention/interview will last?*

32b. How much will you compensate each participant?*

33. 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)*

Yes

No

33a. Will you be observing people without their knowledge in public space? (e.g. on the street, at a bus-stop)*

Yes

No

34. Will the study involve actively deceiving the participants? *

Yes

No

34a. Describe how will you safeguard any potential risk for the research participant.*

35. Will participants be asked to discuss or report sexual experiences, religion, alcohol or drug use, suicidal thoughts, or other topics that are highly personal or intimate?*

Yes

No

35a. Describe how you will safeguard any potential risk for the research participant.*