

Checklist for minimal risk for supervisors

Ethical Review Board, July 2020

Background

For research with people or with personal data, *all* TU/e employees and bachelor- and master students are obliged to request ethical approval from the Ethical Review Board in advance. The main criteria considered in the ethical review of studies with humans is whether the study participants are treated with dignity and respect, whether they participate voluntarily, whether the burden is reasonable, and whether they are adequately protected against potential risks. Special attention is paid to vulnerable groups such as children or patients and to sensitive subjects, for example gender, religion, political beliefs and alcohol and drug use.

Requirements for minimal risk

In *certain* cases, students can get automatic approval from the Ethical Review Board (ERB). Their research needs to comply with the requirements described in the document 'Ethical Review in the study guide'. These requirements are summarized below, for assisting you as a supervisor.

General

- Research with healthy adults
- No medical research
- Research with non-commercial human waste material only when supervisor has consulted the medical coordinator
- Participating in the research is completely voluntary (think about peer pressure)
- Explicit informed consent is or was obtained from participants (on paper or digitally)
- Participants are not dependent on the researcher
- Data is collected anonymously and cannot be traced back to individuals
- Participation is not burdensome (for example questionnaires that are extraordinarily long or tasks that need repeating several times)
- No harm or discomfort for the participant (such as stress, anxiety, fear, pain)
- No compensation

Observational research

- Observation only in public spaces
- No sensitive topics (such as sexual experiences, religion, alcohol and drug use, suicidal thoughts, diseases or other subjects that can be interpreted as very personal or intimate)

Experimental research

- No medical device
- Not invasive (i.e. nothing affects the body, e.g. no puncture)
- CE-certified devices are used for intended use
- Only using non-CE certified devices or CE-certified devices for unintended use if they are completely harmless (<18 V) and no hazardous waste (fumes/gas/substances) are released

Research that does not comply with the requirements for minimal risk

If the requirements for minimal risk are not met, the research design should be altered in such a way that minimal risk for the participant can be achieved. If this is not possible, you as a supervisor should submit the study to the ERB. See <https://intranet.tue.nl/ethics> for instructions.