



Regulations Ethical assessment of research by the Research Ethics Review Committee (CETOR) of the Faculty of Law

Adopted by the Faculty Board 13 April 2022

1 Objective

The Research Ethics Review Committee (*Commissie Ethische Toetsing Onderzoek Rechtsgeleerdheid* = CETOR) of the Faculty of Law aims to ensure that scientific research is conducted in an ethically responsible manner.

The Committee's task is:

- a. Conducting ethical review of proposed research;
- b. promoting ethical behavior of researchers;
- c. advising researchers on the ethical admissibility of research.

2 Composition of the CETOR

At the Faculty, the ethical review of research is the responsibility of the Scientific Research and Ethics Committee (CWB). It has set up a subcommittee for this purpose: the Research Ethics Review Committee (CETOR).

The CETOR consists of the chair of the CWB and minimally three members. These members are also members of the CWB. The chair of the CWB is ultimately responsible for the functioning of the CETOR. The secretary of the CWB also acts as secretary of the CETOR.

3 Scope of the ethical review

Academic research conducted under the responsibility of a staff member of the Faculty, which:

- involves *human subjects*; and/or
- where personal data are processed within the meaning of the GDPR such as: data containing personal data collected by the researcher himself (e.g. through interviews); where use is made of personal data previously collected (by others) (e.g. use of CBS microdata); where 'big data' analyses are used to process personal data from publicly available sources (e.g. case law databases or social media data); and/or
- involves research (or research results) that poses risks for the researchers (or their assistants and others); and/or
- where there's a real risk of malevolent use of research results

must be submitted in advance to the CETOR.

The ethical rules involved in the review are based on the research standards following from the requirements of the Netherlands Code of Conduct for Research Integrity, the General Data Protection Regulation (GDPR) and the GDPR Implementation Act.

The key points for assessment by the CETOR are, that:

- A. the human subjects will be well informed about the content of the research activities to be carried out, including how burdensome they will be, any possible inconvenience

involved and any risks associated with participation, and they will explicitly consent to this ('informed consent');

- B. the human subjects will be able to withdraw their consent and discontinue participation at any time without any consequences, which must be as easy as to give consent;
- C. the importance of the research outweighs the burden on the human subjects, the possible inconvenience and any risks associated with participation;
- D. data is collected and processed in a scientifically responsible manner by taking into account all relevant GDPR requirements;
- E. broader ethical concerns are taken into consideration;
- F. any concerns about the image of the university as an institution that upholds ethical standards are taken into consideration.

If a research project is submitted to the CETOR which in the CETOR's opinion is covered by the Medical Research (Human Subjects) Act (*Wet medisch-wetenschappelijk onderzoek met mensen*, WMO), the CETOR will state that it is not competent in this case and will refer the applicant to a Medical Research Ethics Committee (*Medisch Ethische Toetsingscommissie* = METc).

A research proposal must be submitted **before** the start of the project. The CETOR does not, except in exceptional cases, conduct a review of research that is already in progress or completed.

4 Application

The ethical review of research applies to research carried out by staff members as well as by PhD students, postdoctoral researchers, guest researchers and trainees.

There needs to be a researcher with an appointment or admission at the Faculty who is primarily responsible for the research project, the PI (primary investigator).

If more than one institution is involved in the research, researchers submit their research for assessment to the institution(s) where the contact with the human subjects takes place. Research that is carried out elsewhere on behalf of someone from the Faculty (e.g. at a school, company or institution) must also be submitted to the CETOR.

Research that is carried out in the context of education must be assessed by the supervising lecturer. If the research has high ethical risks, review by the CETOR is necessary. See point 8.

5 Procedure

The application is handled confidentially within the committee. Exchange of documents and internal reporting will take place preferably via Unishare.

If the CETOR has questions about the completed forms or requires additional information, the secretary will ask the investigator for a clarification.

The CETOR will decide whether or not a research proposal shows to a sufficient degree that the ethical rules for conducting research with human subjects will be complied with. The assessment of the research is carried out by at least two members of the CETOR. Before issuing its opinion, the Committee may either ask the applicant for further information by letter, or invite the applicant to be interviewed.

If the CETOR is of the opinion that a research project meets all the ethical criteria, the committee issues a Declaration of No Objection. If the CETOR is of the opinion that one or more ethical criteria have not been sufficiently met, it advises the researchers on the measures to be taken in order to comply with the requirements.

Rules may change as a result of social developments or experiences in the research field and the admissibility of research may therefore be called into question at any time. In exceptional cases and/or when the investigator does not adhere to the methodology and application of ethical rules approved in the application, the CETOR may (temporarily) withdraw its approval of ongoing research.

In all cases, the investigator remains responsible for the application of ethical rules, even after approval by the CETOR.

6 Timeframe for ethical review

In principle, applicants will receive a decision within one month of their application being processed. If necessary, this period may be extended to six weeks. Applicants will be informed of this well in advance. If the CETOR provides the applicant with instructions for changes to the application, the procedure may take longer.

In the event of a reasoned request by the applicant for an expedited procedure, the CETOR may grant the request and shorten the timeframe or issue a provisional approval.

The applicant receives a written response.

7 Complaints

The decision of the CETOR on approval of a research proposal is binding. If the applicant wishes to appeal a negative decision of the CETOR, he/she may submit a reasoned request for reconsideration to the Dean of the Faculty of Law.

8 Information for researchers

Detailed information on ethical guidelines for research can be found on the Faculty website. The standard forms and appendices for submitting applications to the CETOR can also be found there.

9 Annual report

The Committee reports annually to the Faculty Board on its activities.

The Regulations Ethical assessment of research by the Research Ethics Review Committee Law (CETOR) of the Faculty of Law were adopted by the Faculty Board at 9 October 2019 and amended on 13 April 2022