

Assessment framework for ethical issues

Researchers who have been appointed at the Faculty of Science are expected

- *to be aware of principles that the VSNU has established for research integrity; [\[1\]](#)*
- *to be well- informed about ethical issues that may arise within their field ;*
- *behave like a scientific professional, in accordance with the guidelines of the VSNU.*

This charter allocates the primary responsibility for integrity in scientific practice and identifying ethical issues in research proposals at the researcher. To recognize and overcome ethical issues, researchers can seek advice and support from ethics committees. This guiding principle forms the basis for the assignment of duties and responsibilities to the FNWI ethics committee (FEC). The FEC thus only advises in cases in which the researcher is in doubt whether his/her research project complies with the ethical standards applicable for the field he/she is working in.

The workflow of the committee for notification, assessment and advise on research projects of staff and students will be based on *peer review* and will respect the following principles.

1. *The FEC does not perform reviews of theoretical, experimental and applied research proposals with, in the opinion of the investigator, have no impact for the integrity of subjects and objects of research (such as humans and animals), and have no social consequences for public safety, the environment and public health.*
2. *The FEC does not examine aspects of research that are already examined under ethical legislation, such as the Medical Scientific Research Act (WMO) by a Medical Ethics Review Committee (METC), or the Animal Testing Act (WoD) by an Animal Experiments Commission (DEC) .*
3. *The FEC does not examine research proposals that fall under a sectoral ethics committee (SEC), which may be set up by one or more institutes of the faculty. [\[2\]](#)*

The following applies to all other cases.

1. *If a proposed research project may adversely affect personal or social integrity of persons or animals subject or object of the investigation, or if there can be far-reaching social consequences, the researcher or PI assesses the research proposal with the help of a checklist that can identify ethical issues.*
2. *If after this test reasonable doubts remain as to whether the research proposal is acceptable from an ethical perspective, the FEC is informed. The FEC performs a review of the proposal, following the workflow set up by the commission. [\[3\]](#)*

This testing framework applies to all research that is initiated by FNWI employees and that is carried out by staff and / or students of the faculty. Apart from *ex ante* assessments, which can be performed without interference of a research director or another official, the FEC can also perform *ex post* assessments. Reviews that are carried out ex-post always require a request from an authority. In both cases, the FEC review procedure results in an advice to the person who in charge of the researcher. In many disciplines, researchers may have to deal with different types of risk, each of which may make an inquiry desirable.

1. Risks arising from social considerations: are issues involved that are inconsistent with ethical views that live in the surrounding community?
2. Risks arising from the need of legal certainty for the researcher : can the investigation lead to prosecution, and if so, how can the risk of this be limited?

3. Risks arising from dual use and unintended use of results.

If an experiment approved by the FEC should lead to claims for compensation or damage of reputation, a researcher who has acted carefully should be guaranteed that the employer will assist him or her with (legal) advice and action. If a research project has been reviewed and approved research project, the faculty or university will take responsibility for proper handling of legal consequences, provided there is no negligence or gross negligence in the conduct of the research.

Definitions of terms that are important for ethical testing

It is important that the workflow of the FEC and other ethical committees that fall under the FNWI is based on a uniform conceptual framework. The FEC uses the following definitions. The list of definitions will be extended as soon as the need arises.

Normative concepts

Concepts by which the conduct of a researcher can be assessed on ethical grounds, such as decent, safe, careful, vulnerable, transparent, harmful or risky.

Legal concepts

Terms by which the actions of a researcher can be assessed on legal grounds, such as legitimate (within the limits of the law), violation of privacy and infringement of intellectual property.

Ethical and legal risks of research

Categories of possible adverse consequences of the research process, or disclosure of the outcomes of research, for human subjects, human objects and non-human objects with consciousness . [\[4\]](#)

Research project of an employee

A research project that is carried out in the context of employment at a research institute of the faculty.

Research project of a student

A research project that is carried out as part of the university's study program and that is supervised by an academic staff member.

Humane subjects

Persons who actively and consciously participate in research, such as clinical trial subjects.

Human objects

Persons or groups of persons who are passively subject to the investigation, i.e. the person or persons with whom something is being done during research.

External ICT objects

Data files, networks , computer systems and other ICT objects of which the organizational unit of which the researcher is a part (the institute, the school or the college) is not the right owner.

Peer review

The process of assessing research proposals by an independent committee of scientific researchers on ethical issues. The committee should include all disciplines and specialisms that are necessary for a proper assessment, such as a scientific expert, data specialist, ethicist and legal expert.

Threshold analysis

Evaluation of research proposals on ethical questions by the researcher or the principal investigator on the basis of checklists in the form of a flow chart. A threshold analysis provides an answer to the question: is the risk of ethical issues occurring during the research project so small that a more substantive review based on peer review is not necessary?

Authority

An official who leads an institute, college, school, faculty or university, i.e. a scientific director, a director of education, a dean or a rector.

Principal Investigator (PI)

A member of the permanent academic staff of a department or research institute who, on the basis of explicit consent or implicit recognition, bears final responsibility for a research project.

Assignment of the FEC

The FEC has the following operational tasks.

1. Providing a flowchart for the ethical review of research that is carried out at the faculty.
2. Reviewing research proposals from staff and students on ethical issues that are perceived by researchers and program directors (*ex ante* advice).
3. Reviewing already conducted research on ethical issues and other vulnerabilities at the request of an authority (*ex post* advice).
4. Handling appeals to advice given by sectoral ethics committees at the request of the dean.
5. Drafting checklists for the purpose of preliminary testing by research faculty.

The FEC has the following policy tasks.

1. To establish transparent procedures for submission, assessment and advice regarding research of employees and students where ethical issues may be implied.
2. To advise authorities on reducing the ethical risks of research, based on casuistry resulting from the operational task of the committee.
3. To advise authorities on adjacent areas of interest, such as training, RDM and GDPR.
4. Generating awareness for ethical issues in the academic community.

The FEC is NOT responsible for cases falling within the competence of the Data Protection Officer of the university (regarding violations of personal data) and issues in the broader fields of scientific integrity and research data management (RDM). The FEC may in certain cases check if the dealing with personal data has been correct.

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1

[1] Dutch code of conduct on scientific integrity (2018).

[2] This applies, for example, to research that falls under the Ethical Commission Information Sciences (ECIS) or the ethics committee of the QuSoft research center. The FEC handles cases that have previously been dealt with by a SEC and where the investigator or his or her supervisor has objected to the advice of the SEC.

[3] There is significant doubt if the result of the review by the investigator (s) remains above a certain limit value or *threshold*. For more information, see the following definitions.

[4] Examples of such categories are: privacy violations, violations of intellectual property's rights, violations of physical integrity and abuse of information by malicious organizations.