

**Regulations on the Establishment and Procedure
of a Committee for Ethics
at Osnabrück University of Applied Sciences
(Ethics Committee)**

adopted by the Academic Senate of Osnabrück University of Applied Sciences on
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Section 1 – Foundations

(1) The Ethics Committee works on the basis of the World Medical Association's Declaration of Helsinki, which is part of these principles (Appendix 1), as well as the Code of Ethics of the German Sociological Association (Appendix 2), and the draft of the Code of Ethics for Nursing Science Research of the German Society of Nursing Science (Appendix 3). Additional principles may be consulted by the Ethics Committee.

(2) The committee supports researchers by advising them on and evaluating ethical and data protection aspects of research projects on and with human subjects in the health, social, engineering, and agricultural sciences, without prejudice to the responsibility of the researchers for the research project and its implementation. The relevant legal provisions shall apply. The committee and its members are independent in the performance of their duties and are not bound by instructions.

Section 2 – Members of the Ethics Committee

(1) The Ethics Committee shall consist of at least eight members, including a professor of the field of medicine, a professor of health sciences, the Commissioner for Data Protection or a representative appointed by the Commissioner for Data Protection, and a legal expert. The members shall be selected on the basis of their expertise in the relevant scientific disciplines referred to in section 1 paragraph 2. The committee may consult experts in an advisory capacity. Equal representation of men and women shall be taken into account when appointing members.

(2) The members of the committee shall be appointed by the Academic Senate of Osnabrück University of Applied Sciences. At least one deputy for each member shall also be appointed.

(3) The members shall elect a chair and two deputy chairs from among their ranks. The chair shall represent the Ethics Committee internally and externally. The chair shall prepare an annual activity report for submission to the Academic Senate.

(4) The term of office of the Ethics Committee is two years. Reappointment of members/deputy members is possible.

Section 3 – Applications

(1) The committee acts at the request of researchers. Applications may be amended or withdrawn. Each application must include a description of the project in German (or English) on no more than five pages, the informed consent form, and the information letter. The application documents, including annexes, should be submitted in electronic form to ethikkommission@hs-osnabrueck.de. In the project description, the aspects of the project related to research ethics and data protection should be explained in particular.

(2) Researchers of Osnabrück University of Applied Sciences are entitled to submit applications as project leaders of research projects in the areas mentioned in section 1 paragraph 2.

(3) The application must be accompanied by a declaration stating whether and, if applicable, where applications with the same content have already been submitted before or, in the case of multicenter studies, at the same time. The Ethics Committee of Osnabrück University of Applied Sciences must be informed about participation in multicenter studies. The Ethics Committee may conduct its own review.

(4) Student research projects will be reviewed by the supervising faculty members in accordance with a screening process established by the Ethics Committee. In cases of doubt, the decision to submit an student research project to the Ethics Committee rests with the supervising faculty members.

Section 4 – Procedure

(1) Meetings of the Ethics Committee are not open to the public. Members of the committee shall be bound by confidentiality and secrecy. The same applies to any experts consulted in an advisory capacity.

(2) The committee shall normally deliberate and take decisions orally, including by electronic circulation procedure. Special meetings may be held in consultation with the chair.

(3) Committee members who are involved in the research project to be decided upon shall be excluded from the decision-making process.

(4) The committee may request additional documentation, information, or justification from the applicant. Concerns must be communicated to the applicant in writing and justified. The applicant shall be given an opportunity to respond.

(5) The committee may seek expert advice in consultation with the applicant. Experts consulted in an advisory capacity shall, like the members of the committee, be bound by confidentiality and secrecy.

(6) Minutes shall be kept of each meeting and the results shall be recorded.

Section 5 – Adoption of Resolutions

(1) Consensus shall be sought on the vote to be taken. If such consensus cannot be reached, the committee shall decide by a majority of its members. (A decision can only be taken if at least one legal expert and the Commissioner for Data Protection or a representative appointed by the Commissioner for Data Protection have participated). Voting may be conducted by electronic circulation procedure, but the Ethics Committee shall have a quorum only if at least four voting members are present at a meeting of the Ethics Committee. The committee will provide a written opinion on an application in a timely manner following a regular meeting.

(2) The committee will take the following votes on the research ethics and data protection aspects of each application:

a. Decision – approval of the application.

b. Decision – request for rework.

c. Decision – rejection of the application.

(3) The “approval of the application” decision confirms to the applicant that the Ethics Committee has provided ethical and data protection advice on their application prior to the start of the project.

(4) The decision on the ethical evaluation is valid only for the project examined and advised by the committee. It loses its validity when applied to other or similar projects.

(5) The decision shall be communicated to the applicant in writing.

(6) Any member of the committee may express a dissenting opinion in a separate vote, which shall be attached to the decision.

Section 6 – Rules of Procedure

The committee may establish rules of procedure to regulate its operating procedures; otherwise, the rules of procedure of the Academic Senate of Osnabrück University of Applied Sciences shall apply.

Section 7 – Amendment and Entry into Force

The members of the Ethics Committee shall be consulted prior to any amendment to these Regulations.

These Regulations shall enter into force on the day after their publication by Osnabrück University of Applied Sciences.