

The following regulations were adopted on February 10, 2015 by the Dean's Office of the Faculty of Psychology and Human Movement Science at the University of Hamburg and taken note of by the Faculty Council on February 11, 2015.

Last changes according to the resolution of the Faculty Council of 9.9.2015 in §2(1) and of 14.10.2015 in § 6(2).

Regulations of the Local Ethics Committee of the Faculty of Psychology and Human Movement Science of the University of Hamburg

Preamble:

The following regulations specify the procedure to be followed when the Ethics Committee is requested to evaluate a proposal.

§1 General

(1) The Local Ethics Committee ("LEC" and / or "Committee") of the Faculty of Psychology and Human Movement Science at the University of Hamburg is an independent body, which examines the ethical and legal admissibility of psychological research projects in psychology and human movement science before they are carried out, insofar as this is not regulated in other mandatory provisions. In addition, the procedure of the LEC is based on the rules of procedure of the Ethics Committee of the German Society for Psychology (Deutsche Gesellschaft für Psychologie, short: DGPs). The subject of the evaluation are usually full proposals and short proposals from the Faculty of Psychology and Human Movement Science. As a basis for its assessment, the LEC consults the ethical guidelines of the relevant professional associations, such as the ethical guidelines of the DGPs and the Professional Association of German Psychologists (Berufsverband Deutscher Psychologinnen, short: BDP) as well as the ethical principles for sports scientists.

(2) Proposals submitted to the Ethics Committee of the Faculty of Psychology and Human Movement Science of the University of Hamburg can be submitted by any scientist of the faculty. Ethical advice is also available to students of the faculty if they consider ethical consultation in the context of scientific work necessary. Decisions on the submission of proposals to the Local Ethics Committee of the Faculty of Psychology and Human Movement Science at the University of Hamburg are made by the scientific

project leader in their own responsibility, taking into account the legal provisions and official regulations.

(3) The LEC is acting on behalf of the Faculty of Psychology and Human Movement Science of the University of Hamburg. The chairperson of the commission comments on the proposals on behalf of the faculty.

(4) The commission provides assistance and advice to scientists of the Faculty of Psychology and Human Movement Science of the University of Hamburg on ethical and legal aspects of their research involving human subjects.

(5) The LEC and its members are independent in the performance of their tasks and are not bound by instructions. They are responsible only to their conscience.

(6) The responsibility of the scientist in charge of the project remains unaffected.

§2 Eligibility to submit proposals, General Procedure

(1) The review of a research project is carried out at the request of the scientist responsible for the project. Proposals may be submitted by any scientist of the Faculty of Psychology and Human Movement Science of the University of Hamburg. For a student proposal, a written confirmation of supervision by the responsible scientist or the responsible university teacher is required. Furthermore, the dean is also entitled to submit an proposal.

(2) Full proposals and short proposals can be submitted to the LEC. Full proposals usually refer to new research projects. A short proposal is possible if the study is clearly ethically unobjectionable, and/or ethics votes are already available for comparable studies.

(3) The Ethics Committee shall review the points regarding a proposal listed in §§ 3 and 4 with regard to their ethical implications, in particular, whether

1. all precautions have been taken to minimize the risk to subjects;
2. an appropriate balance between the benefits and risks of the project exists;
3. the provisions regarding the consent of the subjects, or their legal representatives, have been adequately taken into account;
4. the implementation of the project complies with the relevant legal provisions, in particular the data protection provisions.

(4) The Ethics Committee shall offer ethical process advice if required.

(5) Proposals, the evaluation of which does not fall within the professional competence of the Ethics Committee of the Faculty of Psychology and Human Movement Science of the University of Hamburg, will not be dealt with. In such cases, applicants are advised

to contact an ethics committee designated for the issue in question.

§3 Submissions of full proposals

(1) Full proposals and the documents relevant for the ethical review shall be submitted to the chairperson of the LEC electronically.

(2) Full applications to the Ethics Committee should contain information on:

1. Study author and study title;
2. Study objective and study plan of the project;
3. The type and number of subjects as well as criteria for their selection;
4. All steps of the study procedure;
5. Type and funding of the study;
6. Burdens and risks for subjects, including possible secondary effects and precautions to avert negative effects;
7. Regulations for the written and, if necessary, also oral information of the subjects about the study procedure and for their written consent to participate in the study; if forms are used, they must be attached;
8. Possibilities for the subjects to refuse or withdraw from participation;
9. In the case of minors and subjects with limited decision-making capacity (e.g., children, legally incapacitated persons): Regulation of consent to participation in the study by legal guardians and caregivers, if applicable insurance coverage provided;
10. Data registration (especially with audio and video recordings and with computer logs) and data storage in the light of data anonymization;
11. Information on whether and where a proposal has already been submitted to another ethics committee, and submission of any existing statements of ethics committees involved.

§4 Submissions of short applications

(1) The short proposal consists of a checklist issued by the LEC and completed by the applicant and, if necessary, other relevant documents determined by the LEC. The LEC ensures the further development of the checklist.

(2) The checklist shall be designed by the LEC in such a way that it indicates whether a full proposal must be submitted.

(3) The checklist and the documents relevant for the ethical review are to be submitted electronically to the chairperson of the LEC.

§5 Composition of the Local Ethics Committee

(1) The LEC consists of 8 professors, 3 representatives of the mid-level faculty, and 3 students, who represent the various fields of study at the Faculty of Psychology and Human Movement Sciences. Due to the difference in size of the two institutes, the members should be delegated to the committee in a ratio of about 2 to 1 from Psychology and the Human Movement Sciences. One member of the LEC should be from outside the department, if possible. All members of the LEC are entitled to vote unless there is a reason for exclusion according to §6(11).

(2) The chairperson of the LEC and their deputy shall be elected by the members of the LEC.

(3) The names of the members of the LEC shall be published.

(4) The members of the LEC shall be elected by the members of the Faculty Council for the term of three years (students one year).

(5) The members of the LEC may adopt rules of procedure for themselves.

§6 Review Procedure

(1) The documents relevant to the ethical review shall be submitted by the applicant to the chairperson of the LEC electronically.

(2) A full proposal shall be reviewed by at least 2 members of the LEC (at least 1 of whom shall be a professor). Different status groups (see §5 para. 1) should be represented. The reviewers are appointed by the chairperson of the LEC. Applicants cannot be reviewers.

(3) At the request of at least one member of the Commission, a meeting shall be convened.

(4) Each reviewer passes on their vote to the chairperson of the commission. The chairperson shall summarize these and their own assessment of the commission's statements in such a way that the authors of specific votes remain anonymous. These tasks of the chairperson can also be delegated in consultation with the members of the LEC to the deputy chairperson. If the votes are not compatible with each other, the chairperson shall draft a vote and submit it to the members of the committee for discussion. If even after attempts at clarification, the votes are incompatible, an oral hearing shall be scheduled to reach a decision.

(5) The chairperson may, after consultation within the commission, request votes from one or more additional experts (e.g., lawyers, data protection officers, etc.). For specific questions, representatives of affected groups (patients, persons with sensory impairments) can be included in the consultations and asked for a vote. In these cases, the experts receive the entire proposal.

- (6) As a rule, a full application must be decided in writing within one month. Short applications should be decided in writing within 10 days.
- (7) If there are substantial reservations about a full proposal, the applicant may be required to submit a revised full proposal.
- (8) If a full proposal is rejected on ethical grounds, the applicant may present counter-arguments and request a new review and statement by the commission.
- (9) Decisions of the Ethics Committee require a simple majority of the voting members. In the event of a tie, the vote of the chairperson, or alternatively the deputy chairperson, shall have the casting vote.
- (10) If a decision is reached at a properly convened oral hearing, a simple majority of the voting members present shall apply. §9 para. 2 shall apply accordingly.
- (11) If a proposal is submitted by a member of the LEC, this member shall not be entitled to vote. The voting right shall also cease temporarily if a member of the LEC is involved in the research project, is in employment or other dependent relationship with the applicant, or if there is a conflict of interest. The members of the LEC are obligated to report facts that could obstruct their voting rights. Anyone not entitled to vote in accordance with sentence 1 or 2, should, when voting on the particular application leave the meeting room.
- (12) The commission may authorize the chairperson to decide on their own in cases to be specified. Corresponding authorizations shall be decided at a meeting of the LEC. The chairperson shall inform the Commission of the decisions as soon as possible by means of a circulation procedure.
- (13) In the case of short proposals, the chairperson or a LEC member appointed by them shall decide whether a full proposal is to be submitted. If it is evident from the short proposal that there are no ethical objections, this member of the LEC can recommend a positive decision to the LEC after reviewing the short proposal. If there are doubts about the ethical harmlessness, a full proposal may be requested from any member of the LEC. If no concerns are raised by LEC members within 7 days of the recommendation, the short proposal will be granted.
- (14) Multicenter studies that have already been evaluated in another commission, may be addressed by the chairperson. The commission shall be informed by circulation. Any objections to the decision of the chairperson shall be expressed within 7 days. In such a case, the committee shall deal with the matter.
- (15) Meetings of the Ethics Committee shall not be public. Their results shall be recorded in a protocol.
- (16) All documents of the Ethics Committee (applications, notices, minutes, etc.) shall be archived in a suitable manner, either in writing or electronically, in compliance with

data protection and shall be kept for 10 years.

§7 Confidentiality of the Ethics Review

(1) The subject matter of the proceedings and reviews of the ethics committee shall be treated confidentially. The members of the committee are obliged to maintain discretion.

§8 Coming into effect

The regulations shall come into effect on the day following their adoption by the Dean's Council.

signed Prof. Dr. Brigitte Röder

Dean of the Faculty of Psychology and Human Movement at the University of
Hamburg

Hamburg, February 10, 2015