

**This is the translation into English of the "Präsidiumsrichtlinie für einen Beirat für Ethikfragen in der Forschung (Ethikbeirat) an der Leuphana Universität Lüneburg, 2012". In the event of discrepancies or differences in interpretation between the different language versions, only the official German version shall apply.**

On October 23, 2012 the presidential committee of the Leuphana University of Lüneburg approved the following presidential committee guideline for an ethics advisory board. The guideline goes into effect on the day after its publication to the university public in the Leuphana University of Lüneburg GAZETTE.

## **Presidential committee directive**

### **Advisory board for ethical issues in research (Ethical Review Board) at the Leuphana University of Lüneburg**

#### **§ 1 Preamble**

This presidential committee guideline regulates the procedures of the advisory board for ethical issues in research (ethics advisory board) at the Leuphana University of Lüneburg

#### **§ 2 Role and responsibility**

(1) The Ethical Review Board works for the presidential committee. The board delivers opinions on applications from scientists of the Leuphana University of Lüneburg.

(2) The Ethical Review Board helps and advises scientists of the Leuphana University of Lüneburg regarding ethical and legal aspects of their research, particularly research involving human subjects. The Ethical Review Board becomes involved upon request by the scientist.

(3) On request, the Ethical Review Board will express an opinion on the ethical aspects of intended research involving human subjects to be performed at the Leuphana University of Lüneburg. Such opinions are generally requested by external parties, e.g. by research institutions for third-party applications or for later publication in a professional journal. They are usually required for studies that expose the examined persons to risks or for studies in which the goals and methods are not completely revealed to the persons taking part in the study.

(4) Clinical studies involving pharmaceuticals and medical products cannot be conclusively assessed by the ethics advisory board. They will be referred to a medical ethics committee constituted under national law.

#### **§ 3 Constellation**

(1) The Ethical Review Board is comprised of at least five scientists. The members should come from different departments, with a focus on psychology. There should be at least

- Two members from the psychology department
- One member from the law department
- One member from the philosophy department
- One external expert from the medicine department

(2) The chairperson of the Ethical Review Board and his/her deputy are elected by the board members from amongst the professors.

(3) The members of the Ethical Review Board always work in an honorary capacity. External experts can be compensated.

(4) The names of the members of the Ethical Review Board are published on the Leuphana University of Lüneburg website.

(5) The members of the Ethical Review Board are appointed by the presidential committee for a term of three years.

#### **§ 4 Fundamental principles**

As the foundation for its assessment, the Ethical Review Board will consult the ethics guidelines of the "Gesellschaft für Psychologie" (DGPs, German association for psychology) as well as the "Empfehlungen zur Sicherung von Guter Epidemiologischer Praxis" (GEP, guidelines and recommendations on safeguarding good epidemiological practice). The guidelines on good scientific practice published by the DFG (German Research Foundation) also apply.

#### **§ 5 Tasks**

(1) On request, the Ethical Review Board will examine and express an opinion on the ethical aspects of intended research involving human subjects to be performed at the Leuphana University of Lüneburg.

(2) The Ethical Review Board will examine particularly whether

a. All precautions have been taken to minimize the risks and stress factors to research subjects

b. There is an adequate balance between the anticipated gain in knowledge and any risks and stress factors to the research subjects

c. The informed consent of the research subjects has been sufficiently documented

d. When a research subject is not able to grant consent, his/her vulnerability should be protected and informed consent should be obtained from his/her legal agent; also, the research subjects should be granted a way in which to signal their consent themselves

e. The intended project takes into account the relevant legal stipulations, particularly in regard to data protection

(3) Applications to the Ethical Review Board must contain information on:

a. The objective and schedule of the project

b. The type and number of research subjects as well as selection criteria

c. All steps to be taken in the course of the study

d. Risks and stress factors to the research subjects, including potential repercussions and suitable precautions to avoid negative effects

e. Provisions for providing the research subjects with information on the course of the trial and for obtaining their consent to participate in the study (include any forms that may be used)

f. Provisions for explaining to research subjects their right to refuse participation or withdraw from the study

g. For research subjects with limited decision-making ability (e.g. children, legally incompetent persons): provisions on consent granted by guardians to take part in the study and on the research subject's option to discontinue the study

h. Insurance coverage provided to the research subjects

i. Forms of data registration (particularly in regard to audio and video recordings and to computer logs) and data storage in terms of anonymizing and protecting data.

(4) The Ethical Review Board and its members act independently in carrying out their tasks and are not bound by instructions. They are responsible only to their own conscience.

(5) The opinion issued by the Ethical Review Board does not relieve the person responsible for the assessed project of his/her responsibility for execution of the studies.

## **§ 6 Application**

(1) A research project is reviewed when an application is filed by the person responsible for the project or, in the case of Ph.D. projects and student projects, by the supervisor.

(2) The applicant must give the chairperson of the Ethical Review Board all of the information required to produce the opinion.

(3) The Ethical Review Board will decide on a case-by-case basis whether to reject an application.

## **§ 7 Opinion process**

(1) The Ethical Review Board can request that the applicant orally explain the research project or provide additional documents, information or reasons.

(2) The applicant can be heard by the Ethical Review Board before the opinion is issued. He/she should be heard when he/she so requests.

(3) Members involved in the research project or whose interests are in any way affected such that apprehension of bias is possible are barred from discussion of the resolution.

(4) In agreement with the advisory board, the chairperson can request a decision from (an) additional expert(s). In this case, the complete application will be provided to the consulted expert(s).

(5) The Ethical Review Board always makes a decision after oral consideration. Written resolution after written circulation is permissible if no member objects.

(6) The Ethical Review Board appoints at least two members to submit a vote. These two votes serve as the basis for the advisory board's opinion.

(7) Ethical Review Board decisions require a simple majority of the members. When a decision is made, it is always considered a decision of the entire advisory board. The Ethical Review Board is qualified to issue opinions when at least half of the members are present.

(8) The Ethical Review Board can authorize the chairperson to decide alone in certain cases. The annex contains examples of such cases. The chairperson must then inform the Ethical Review Board of his/her decision as soon as possible.

(9) As a rule, an application should be ruled on within six weeks.

(10) The applicant(s) should receive written notification of the ethics advisory board's decision. Negative decisions, requirements and suggestions on modifying the research project should be explained in writing.

(11) Ethical Review Board meetings are not open to the public. The results should be documented in a transcript.

### **§ 8 Confidentiality and ethics review**

(1) The object of the process as well as the ethics advisory board's opinions are to be treated as confidential. (11) The members of the Ethical Review Board are bound to secrecy. The same applies to any experts consulted. Individual votes are treated as confidential.

(2) Members of the Ethical Review Board will be advised upon beginning their term of the obligation to maintain secrecy.

(3) Ethical Review Board votes, application documents, records of meetings, amendments, intermediate and final reports, correspondence, etc. will be archived for ten years.

(4) Data protection regulations should be followed in the storage of the application documents.

### **§ 9 Entry into force**

This guideline goes into effect on the day after its publication in the Leuphana University of Lüneburg GAZETTE.

Annex:

Cases which the chairperson of the Ethical Review Board decides alone

- Multicenter studies already reviewed by another committee