



## Leipzig University's Ethics Advisory Board Statutes dated 2 November 2018

### Preamble

Leipzig University meets the challenges in academia and society and its responsibility for the consequences of academic findings, especially for humankind and nature (Section 2 subsection 1 Basic Regulations). To carry out this responsibility, Leipzig University set up an Ethics Advisory Board within the Rectorate's area of responsibility for the Research Commission. Leipzig University's Ethics Advisory Board Statutes define the Ethics Advisory Board and regulates its areas of responsibility and procedures.

### Section 1 "Establishment, areas of responsibility and tasks"

- (1) Leipzig University set up an Ethics Advisory Board that advises members and affiliates of Leipzig University on the ethical aspects of research projects. The main focus is on externally funded research projects, commissioned research and development, and theses. The Ethics Advisory Board assesses ethical aspects of research involving human subjects that does not fall within the remit of the Ethics Committee in the Faculty of Medicine at Leipzig University.<sup>1</sup>
- (2) The Ethics Advisory Board has the following official title: Ethics Advisory Board at Leipzig University.
- (3) The Ethics Advisory Board operates on the basis of applicable law and academic standards. Relevant national and international recommendations are taken into account based on the current state of science and technology.
- (4) The Ethics Advisory Board examines and, if necessary, issues an opinion on ethical aspects of planned research projects involving human beings. The Ethics Advisory Board examines, in particular, whether
  - a. all necessary precautions have been taken to minimise subject risk;
  - b. there is an appropriate balance between the benefits and risks of the project;
  - c. the consent of the subjects or their legal representatives has been obtained;
  - d. aspects of data protection will be taken into account in the implementation of the project and the Data Protection Officer will be involved.

---

<sup>1</sup> Ethical aspects of **medical** research on humans are reviewed by the Ethics Committee in the Faculty of Medicine. In contrast to the Ethics Advisory Board, its mandate is clearly defined by the legislature under federal and state law. The Ethics Advisory Board is not involved in solving specific ethical problems of medical research.

- (5) The opinion issued by the Ethics Advisory Board does not release the person responsible for the research project from their responsibility for carrying out the project.
- (6) Please note that the Ethics Advisory Board at Leipzig University does not conduct a legal review of research projects.
- (7) The Ethics Advisory Board has a rules of procedure, which sets out in greater detail the procedures and processes for the performance of the tasks assigned to the Board.

## **Section 2 “Structure”**

- (1) The Ethics Advisory Board consists of five members and an appropriate number of substitutes of at least the same number. The Ethics Advisory Board’s members come from a wide range of disciplines. The members of the Board must be members of the University or retired professors, must have research experience and should be qualified to assess questions of academic ethics. In addition, a person qualified to hold judicial office, and, in cases pursuant to Section 1 subsection 4 letter d, also the data protection officer should be consulted in an advisory capacity.
- (2) Appointments to the Ethics Advisory Board should be made in such a way as to ensure that as many as possible of the individuals referred to in Section 1 can be present at each meeting.
- (3) Substitute members have the right to attend all meetings. They have the right to vote if the members they are substitutes for are not present.
- (4) The members are appointed by the Rectorate for a period of 4 years, and thereafter they may be reappointed.
- (5) The members and substitutes are notified of their appointment in writing by the Vice-Rector for Research and Young Academics. This also applies when new members are appointed during an ongoing term of office.
- (6) The Ethics Advisory Board elects a chair and vice chair from the group of individuals on the Board. The number and order of substitutes is determined by the Ethics Advisory Board prior to the election.
- (7) Any member may terminate their service on the Ethics Advisory Board at any time by giving written notice to the chair, provided that ongoing proceedings will not be unduly affected as a result. At its discretion, the Rectorate may remove members from service. Removal is also possible if there is good cause. In this case, the member must have an opportunity to present their case before they are removed. The decision must be justified in writing. A new member is then appointed for the remainder of the term of office.
- (8) In justified exceptional cases, the Ethics Advisory Board may consult outside experts (independent and experienced researchers) if its own expertise is not sufficient for a decision. These experts must be informed of their obligations of confidentiality. In justified individual cases, the experts may be invited to attend an Ethics Advisory Board meeting.
- (9) The names of the members and substitutes will be made public.

### **Section 3 “Independence, rights and duties of the Ethics Advisory Board”**

- (1) The Ethics Advisory Board and its members shall remain independent in the performance of their duties and not be bound by any instructions from superiors. They shall act to the best of their knowledge and belief. The subject matter of the procedures and the opinions made by the Ethics Advisory Board are to be kept confidential.
- (2) The persons named in Section 2 subsection 1 are obliged to maintain confidentiality. The same applies to experts, auxiliary persons and persons who support the work of the Ethics Advisory Board. They shall be informed of their duty of confidentiality before they commence their work.
- (3) Ethic Advisory Board votes, application and procedural documents, meeting minutes, amendments, interim and final reports, correspondence, and the like are kept confidential and retained.

### **Section 4 “Action taken by the Ethics Advisory Board”**

- (1) The Ethics Advisory Board takes action when it receives a written request from members and affiliates of the University. The complete application must be sent in the prescribed manner to the Ethics Advisory Board Office and should follow the instructions outlined in the Ethics Advisory Board’s *Guide for Applicants*. The application may be amended or withdrawn at any time. The application for the evaluation of a research project by the Ethics Advisory Board should contain a brief summary of the project and a detailed description of the ethically relevant aspects of the project. The application for the evaluation of a research project by the Ethics Advisory Board must include at least the following basic information:

Basic information about the project:

- a. Project objective and schedule
- b. Procedural steps
- c. Information on the processing and protection of personal data

Information on projects with human subjects:

- a. Type and number of subjects as well as the criteria for their selection
- b. Difficulties and risks for the subjects (incl. possible consequences)
- c. Regulations for informing the subjects about the procedure
- d. Regulations for obtaining consent from the subjects who will be participating in the project
- e. Possibility for the subjects to reject/terminate participation

A statement must be attached to the application that explains where and with what outcome applications of the same or similar content (if applicable) have been submitted previously or at the same time.

- (2) The chair convenes the Ethics Advisory Board and determines the time and place of the meetings. These meetings shall take place as often as the situation requires. Members of the Board shall

have at least 14 days notice, unless all members are in agreement that this period may be shorter. The chair opens, leads, and closes the Ethics Advisory Board meetings.

### **Section 5 “Meetings and issuing evaluations”**

- (1) Subject to further legal requirements, the Ethics Advisory Board establishes by resolution that it has provided advice on the respective research project with regard to safety-relevant risks. Within the scope of its competence, the Board issues an opinion on the extent to which the project can be carried out in an ethically justifiable manner – where necessary, with modifications and conditions (e.g. to minimise risks) – and makes an evaluation.
- (2) The Ethics Advisory Board constitutes a quorum when more than half of the members are present. Resolutions shall be passed by a majority of the votes of those present, unless otherwise provided hereinafter. Abstentions shall be considered as rejections. The Board may authorise the chair to decide alone in specified cases. The chair must inform the Board of the decision as soon as possible.
- (3) In principle, the Ethics Advisory Board comes to a decision after oral discussion. A written resolution passed by circulation is permissible in accordance with Section 54 subsection 3 sentence 2 of the Saxon Freedom of Higher Education Act (SächsHSFG), provided that all members agree.
- (4) The Board may require the applicant to provide an oral explanation of the research project or to submit additional documents, information or justification. If the applicant so requests, they have the right to make their case. The applicant has the right to submit a written statement at any time and to review any statements obtained by the Board. The applicant may withdraw their application until the Ethics Advisory Board makes its decision.
- (5) If there are substantial objections to an application, the applicant may be required to submit a revised application.
- (6) The Ethics Advisory Board must inform the applicant of its decision in writing. Rejections, conditions and recommendations to make changes to the research project must be justified in writing.
- (7) If an application is rejected on ethical grounds, the applicant may present counterarguments and request that the Board issue a new opinion.
- (8) The applicant must inform the chair immediately of any serious and unexpected risks that arise during the research project and that could affect the protection of the subjects specified in Section 1. In this case, the Ethics Advisory Board may revoke its approval in whole or in part or recommend changes to the research project. The applicant shall be given the opportunity to make a statement.
- (9) Ethics Advisory Board meetings are not public. The essential results must be documented.

### **Section 6 “Responsibilities held by the chair”**

- (1) The chair leads the Ethics Advisory Board meetings.
- (2) In the event the chair cannot attend, the vice chair serves in the chair’s place.

- (3) The chair reports to the Senate in an anonymous format on the Ethics Advisory Board's work.

### **Section 7 "Administration"**

- (1) The day-to-day business of the Ethics Advisory Board is conducted by the Ethics Advisory Board Office. The Office serves its members and the applicants.
- (2) The Office accepts applications on behalf of the chair, and, if the chair is not able to attend to their duties, then on behalf of the vice chair. The chair assumes the legal responsibility for the storage and security of the documents held by the Ethics Advisory Board.

### **Section 8 "Costs of the procedure and fees"**

- (1) You will not be charged any fees for consultations or to have your research project evaluated.
- (2) Serving on the Ethics Advisory Board is an official duty of the Ethics Advisory Board members employed by Leipzig University.

### **Section 9 "Grounds for exclusion and bias"**

- (1) Members who are involved in the research project in question or whose interests are affected in such a way that there is concern about bias are excluded from the discussion and decision-making process. If a member believes they should be excluded or if there are doubts as to whether the requirements of sentence 1 are met, this must be communicated to the chair. The Ethics Advisory Board decides on the exclusion. The person concerned may not participate in this decision. The same shall apply mutatis mutandis to the participation pursuant to Section 4.
- (2) The substitutes will stand in for any excluded members pursuant to Section 2 subsection 3.

### **Effective date**

The Rectorate adopts the Statutes pursuant to Section 13 subsection 5 sentence 1 of the Saxon Freedom of Higher Education Act (SächsHStFG). These shall enter into force on the day following their publication in the Official Announcements of Leipzig University.

Leipzig, 2 November 2018

The Rector