Rules of Procedure for the Research Ethics Committee at the University of Bayreuth

dated 20 August 2014

Preamble

At the University of Bayreuth, an ethics committee for the assessment of ethical and legal aspects of research on humans and animals is established by the University Governing Board within the scope of its authority according to § 2 para 3 of the University of Bayreuth's constitution. It is referred to as "the University of Bayreuth's Research Ethics Committee".

By way of advising, the Committee supports researchers and has the task of helping to assess ethical aspects of carrying out research projects on humans and animals.

The responsibility of the researcher for his/her research project remains unaffected.

§ 1 Responsibility

(1) [1]The Committee is responsible for assessing the ethical aspects of each research project carried out and supervised by members of the University of Bayreuth. [2]This applies in particular to research projects on humans and animals, including epidemiological studies, and/or to the reasonableness of the experimental conditions for the subjects of such research projects.

(2) For cooperation projects carried out by a researcher with a partner outside the University of Bayreuth, the Committee may, upon request, act in an advisory capacity.

§ 2 Membership

(1) The Committee consists of at least six appointed members and the Women's Representative of the University.

(2) [1]The Research Ethics Committee shall be made up of active professors from different subject areas. [2]The research and teaching profiles of its members should exhibit a close proximity to ethical issues and, in this respect, a distinguished academic career. [3]At least one member shall be a legal professional qualified to hold the position of judge. [4]In special cases, other researchers may be called in as special experts to advise on corresponding research projects.

(3) The members of the Research Ethics Committee are appointed by the University Governing Board for a period of three years.

(4) The Research Ethics Committee shall elect a chairperson and his/her deputy from among its members.

§ 3 Autonomy of the members and confidentiality

(1) [1]The members of the Committee shall be independent in the performance of their duties and shall not be bound by orders. [2]They shall perform their duties to the best of their knowledge and belief.

(2) [1]The members of the Committee shall be bound to confidentiality and secrecy. [2]This applies to the subject matter of the procedure, the application documents, the Committee's statements and correspondence, and the individual votes. [3]The same shall apply to the third parties called in by the Committee under the terms of § 2 para 2 sentence 4.

§ 4 The Requirement to submit a request

(1) [1]The Research Ethics Committee shall act upon a written request to be addressed to the University Governing Board. [2]Any member of the University of Bayreuth is entitled to submit a request. [3]The applicant is the researcher who carries out the research project on site and who bears direct responsibility to the test persons. [4] In the case of applicable doctoral projects, the first/primary supervisor must submit a request for the planned project in accordance with sentence 1. [5] Any changes to the project must be reported to the Research Ethics Committee without delay.

(2) The request is to be submitted in German or English.

(3) The request shall be accompanied by a statement disclosing any similar requests already submitted elsewhere.

(4) If the same request has been submitted to another ethics committee or has been rejected, the Committee may refuse to consider the request.

§ 5 Procedure

(1) As soon as the request documents have been received in full, they will be forwarded to the chairperson of the Research Ethics Committee via the Committee Office (§ 10) at the request of the University Governing Board.

(2) [1]The chairperson shall convene the Committee and chair the meeting. [2]Meeting shall be convened in writing. [3]The period of notice is governed by § 38 of the University's constitution.

(3) [1]As a rule, the Research Ethics Committee shall make decisions following oral discussion. [2]The chairman may arrange for decisions to be made in writing via circular unless a member objects to this procedure.

(4) [1]The Research Ethics Committee may consult experts in the relevant fields or obtain expert opinions if it considers that to be necessary. [2]The applicant shall be informed that an expert was consulted.

(5) The Research Ethics Committee may ask the applicant for an oral explanation of the research project and/or request additional written documents, information, or rationales.

(6) [1]The Committee may, in a simplified decision-making procedure, delegate to the chairperson the revocable task of settling certain straightforward cases that are suitable for this procedure. [2]The chairperson of the Committee shall inform the Committee of the outcome at the next meeting.

§ 6 Decision-making

(1) [1]A quorum is present for oral deliberation if all members are duly invited and at least four members are present and entitled to vote. [2]The transfer of voting rights shall be permissible in accordance with § 40 para 3 of the constitution and shall be taken into account when determining the quorum in accordance with sentence 1.

(2) [1]The Committee shall adopt its statement by having a majority of its members present and entitled to vote. [2]Abstention from voting is not permitted. [3]If votes are equally divided among its members, the chairperson shall have the casting vote.

(3) [1]The statements concerning research projects submitted are as follows:

- There are no objections to carrying out the research project.

- There are no objections to carrying out the research project if the following conditions are met.

- There are fundamental objections to carrying out the research project.

[2]Votes may be accompanied by recommendations or conditions determined by the Committee and its individual members. [3]The Committee may also combine its votes with the requirement that oral or written interim reports be submitted while the projects are being carried out. [4] It can then cast a new vote. [5]Decisions involving denial or rejection, concerns, recommendations, and conditions for modification are to be justified in writing. [6]Each member may express a dissenting opinion in a special vote attached to the statement.

(4) In the event of serious doubts about the research project or serious differences of opinion between the applicant and the Committee, the applicant must be given the opportunity to express his or her views orally or in writing before a statement is made.

(5) The applicant must be informed of the outcome of the consultation in writing by the University Governing Board, including a rationale.

§ 7 Changes to the testing plans and interim reports

(1) [1]Events which may directly or indirectly have a significant influence on the research projects or their results or their consequences must be reported immediately to the University Governing Board via the Committee Office (§ 2 para 5) together with the applicant's own assessment. [2]The University Governing Board shall inform the chairperson. [3]This person shall decide in accordance with § 5 on the further procedure or on the necessity of having the ethical-legal situation reviewed by the members of the Committee.

(2) The Committee may revoke its earlier assessment or impose further conditions at a later date, both in the event of substantial changes in the content of the project and in the event of serious or unexpected adverse events occurring or becoming known.

§ 8 Invalidity of decisions

[1]The Committee’s statement shall cease to apply if the research project is carried out with amendments not yet approved by the Committee. [2]The same shall apply if the applicant has not immediately reported serious or unexpected adverse events occurring during the implementation of the project.

§ 9 Prohibitions on involvement

Members of the Committee participating in the research project under evaluation shall be excluded from decision-making.

§ 10 Committee Office and documentation

(1) [1]The Committee Office of the Research Ethics Committee shall be the University's Office of Committee Support. [2]The University of Bayreuth provides the necessary personnel and material resources. [3]This applies, in particular, to the chairperson's expenses.

(2) [1]The Committee Office shall keep a record of procedures, including individual procedures, decisions, and minutes. [2]Procedural documents – in particular application documents, minutes of meetings, committee votes, and correspondence – shall be kept at the Committee Office for at least ten years after the end of the research project.

§ 11 Costs and reimbursement of expenses

(1) The Committee's review of requests shall be free of charge.

(2) [1]The members of the Committee work on a volunteer basis. [2]They shall be reimbursed in accordance with the provisions of the BayRKG for expenses incurred in connection with their activities in the Comittee for travel and subsistence expenses.

§ 12 Effective date

The present rules of procedure shall take effect on the day following their publication.