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**Bylaws
of the Central Ethics Committee of the Executive Board of
Freie Universität Berlin**

Section 1 Central Ethics Committee of the Executive Board of Freie Universität Berlin; Scope and Responsibilities

(1) The Executive Board of Freie Universität Berlin established a Central Ethics Committee (*Zentraler Ethik-Ausschuss*, ZEA, hereinafter referred to as “the Committee”) on April 17, 2018.

(2) The Committee is responsible for evaluating research projects at Freie Universität Berlin in all departments, central institutes, and central facilities, except for the Department of Education and Psychology.

The Ethics Committee of Charité – Universitätsmedizin Berlin is responsible for projects that involve medical research on humans or material taken from humans as well as epidemiological studies that use personal data.

The responsibilities of the State Office of Health and Social Affairs (*Landesamt für Gesundheit und Soziales*, LaGeSo), especially regarding veterinary matters, shall remain unaffected.

Section 2 Tasks and Basis for the Committee’s Activities

(1) As part of its commitment to both academic freedom and scientific responsibility, the Committee provides support in addressing and evaluating ethical issues related to research. In addition, it promotes awareness within the university of ethical concerns in research. It should be noted that questions of a purely legal nature (especially legal matters concerning data protection) do not fall within the scope of the Committee’s tasks, as these are addressed by other bodies within the university (in particular the Data Protection Officer of Freie Universität Berlin).

(2) In cases of research projects at Freie Universität Berlin (or elsewhere) that fall within the jurisdiction of other ethics committees or whenever the proper areas of responsibility are not clearly defined, the Central Ethics Committee of Freie Universität Berlin will contact the other committee involved. Both committees will then agree upon which committee shall be competent.

(3) Independent of the Committee’s counsel, researchers are ultimately responsible for their own actions.

(4) The Committee’s dealings are based on any applicable legislation, academic and scientific standards, as well as relevant professional codes and regulations. They take into account the national and international recommendations specific to individual fields of research with special attention to the opinions and positions of research associations and professional organizations. Moreover, they rely on the current state of the art in science, research, and technology.

(5) Higher-ranking laws and regulations preempt the following provisions.

Section 3 Composition of the Committee and Its Members

(1) Each academic department at Freie Universität shall nominate one member to serve on the Committee. If a department fails to nominate a member, the vice dean of research in that department serves as the department’s Committee member by default. Freie Universität’s central institutes may also nominate a Committee member.

Each department and central institute may select an alternate for the regular member nominated to serve on the Committee, who – in individual cases and on the request of the regular member – will contribute to an ethics statement or participate in a meeting of the Committee on their behalf.

Members of the Committee must be employed as full-time professors with Freie Universität as their primary employer. They should have research experience and be familiar with evaluating ethical questions related to research.

(2) Members of the Committee are appointed for an unlimited period, but are free to resign at any time without having to justify their decision.

The Executive Board of the university can remove a member of the Committee if there is due cause. The member in question has the right to a hearing. The decision must be substantiated in writing.

The respective department / central institute / central facility should nominate a new replacement member as soon as possible.

(3) The current Vice President of Research at Freie Universität serves as the chair of the Committee, whereby another member of the Committee can deputize as chair of a meeting of the Committee should the Vice President not be able to perform this role.

(4) The names of the Committee members will be made public.

Section 4 The Legal Status of the Committee and Its Members

(1) The Committee and its members act independently when carrying out their tasks and are not bound by other directives. They should act according to their best knowledge and judgment.

(2) Members are not personally liable for actions performed as part of their work for the Committee.

(3) The Committee submits an annual report of its activities to the Executive Board of the university. If necessary, the report may be redacted for privacy purposes.

Section 5 The Committee Office

The Committee's regular operations are handled by the chair. The Committee office provides the Committee with administrative support and is part of Division VI: Research.

Section 6 Initiating a Procedure

(1) Members of Freie Universität Berlin can consult with the Committee or its individual members prior to carrying out a research project in cases where third parties require an ethics review (external funding institutions and publishers often do) or if a project otherwise raises significant ethical questions. Members of Freie Universität Berlin can also consult with the Committee where they see the need for personal advice on ethical issues relating to research.

(2) A review procedure is initiated by submitting a written request to the Committee office.

The request must include:

- a description of the project as well as a short and simple summary of the project (in German or English),
- a detailed description of the project's aspects that are relevant to ethical concerns in research,
- if necessary, any requirements stipulated by third parties involved in the ethical review.

(3) The person submitting the review request (hereinafter referred to as “the applicant”) may amend or withdraw the request.

(4) The Committee may, within the scope of its authority, investigate ethical problems in research being conducted at Freie Universität Berlin, to which internal or external parties have drawn its attention. The confidentiality regulations in Section 7, paragraph 2 also apply in these cases.

Section 7 The Procedure

(1) The chair calls a meeting of the Committee at least once a semester and announces the location and time of the meeting. The chair opens, directs, and adjourns the Committee meeting.

(2) Committee meetings are not open to the public. The members of the Committee are bound by secrecy, as are any external reviewers, experts, assistants, and anyone who helps the Committee with administrative tasks.

(3) As a rule, the review procedure and deliberations are carried out through the following steps:

Two members of the Committee work together as reviewers and draft an opinion regarding the research project submitted for review and the ethical issues involved. The opinion states to what extent the reviewers see the research project as legally and ethically sound and what, if any, modifications or other conditions are necessary in order to conduct the research. One reviewer should be appointed from the department or central institute from which the review request originated; the other reviewer should come from a department that deals with closely related research topics. The opinion should be written within three weeks of receiving the original review request.

The Committee office then distributes the opinion to the other members of the Committee. The Committee members have two weeks’ time to respond to the opinion and/or to the research project.

The opinion and other responses will then be sent to the applicant. In turn, the applicant has three weeks’ time to respond. The reviewers for the case in question and the other Committee members then receive the applicant’s response for further deliberations.

(4) As necessary, the animal welfare officer and data protection officer should be included in the review process. They may submit their own statements independent of the Committee’s official opinion.

At any time during the review process, the Committee can request additional support from internal or external experts in order to ensure that they are appropriately informed about detailed aspects of special cases.

(5) The applicant can submit a written statement at any time during the review process.

(6) The Committee can also deliberate and make decisions orally in the review process.

(7) The results of Committee meetings are to be documented in the meeting minutes.

Section 8 Committee Resolutions

(1) The Committee states in its resolution that it has deliberated on the research project at hand with attention to the ethical risks involved concerning science and research.

(2) The Committee is quorate if 50 percent of its members are present. Resolutions may be passed via a written circular procedure when 50 percent of Committee members have responded to an opinion drafted by the reviewers. Committee members who are involved in the research project at hand or for

whom the project otherwise poses a potential conflict of interest are excluded from deliberations and passing resolutions on that project.

(3) The Committee should seek consensus on the decisions in resolutions. If consensus is not possible, then a majority vote suffices to pass a resolution.

(4) Every member of the Committee has the right to submit a dissenting opinion. Dissenting opinions are to be attached to the resolution.

(5) The Committee's decision including any dissenting opinions must be conveyed to the applicant. Rejections or amendments to the research project plan must be substantiated in writing.

The chair provides the applicant with a confirmation stating that the Committee has reviewed the research project.

Section 9 Fees/Payments and Compensation

(1) Research project reviews and consultations are free of charge.

(2) The time and energy devoted to Committee work belong to the regular tasks and responsibilities of Freie Universität Berlin employees. Committee members do not receive any special compensation.

Section 10 Final Provisions

(1) The Committee may stipulate additional requirements, especially pertaining to submitting review requests, in a separate document.

(2) The bylaws passed by the Committee on July 5, 2019 and ratified by an Executive Board decision on October 15, 2019 were amended by decisions passed by the Committee on July 2, 2020, February 12, 2021 and February 11, 2022, ratified by an Executive Board decision on March 9, 2021 and April 5, 2022.