

# Rules of Procedure for the Ethics Committee of the Catholic University of Eichstätt-Ingolstadt

dated July 22, 2019

On the basis of Article 5 section 3 sentence 1 of the Concordat between the Holy See and the Free State of Bavaria dated March 29, 1924 (BayRS 2220-1-WFK), the Catholic University of Eichstätt-Ingolstadt issues the following rules of procedure:

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## **Section 1 Tasks of the Ethics Committee**

(1) <sup>1</sup>The Ethics Committee of the Catholic University of Eichstätt-Ingolstadt (KU) provides support and advice for KU researchers regarding ethical and legal aspects in connection with their research involving human subjects or animals. <sup>2</sup>The responsibility of the respectively responsible researcher shall remain unaffected thereby.

(2) The Ethics Committee bases its work on relevant statutory provisions, professional regulations including scientific standards and ethical guidelines issued by professional associations as applicable for the respective research project and takes all relevant national and international recommendations into account.

(3) In particular, the Ethics Committee verifies whether

1. all measures for minimizing the risk for study participants have been taken,
2. there is an appropriate risk-benefit ratio for the project,
3. the consent of study participants or their legal representatives can be sufficiently proven.

(4) <sup>1</sup>In the performance of their tasks, the Ethics Committee and its members are independent and not bound by any instructions. <sup>2</sup>They are only subject to their personal conscience.

## **Section 2 Composition**

(1) <sup>1</sup>Each KU faculty that employs researchers who carry out empirical work shall appoint at least one researcher of the faculty as member of the Ethics Committee by resolution of the respective faculty council; as a rule, the appointed member shall be chosen from among the group of researchers who carry out empirical research. <sup>2</sup>In addition to the members appointed by the faculties, if possible, the Ethics Committee should also include a doctor and a lawyer (*Jurist/in*) who is qualified to hold the office of a judge.

(2) <sup>1</sup>All members are officially appointed by the Presidium; membership starts upon the member's appointment. <sup>2</sup>If a member of the Ethics Committee leaves the KU or notifies the Presidium of his or her membership resignation, he or she ceases to be a member of the committee. <sup>3</sup>A member may be dismissed for cause by the faculty council or the Presidium, also if he or she is the chairperson of the committee; the member has the right to be heard prior to the dismissal.

(3) <sup>1</sup>The Ethics Committee can be constituted if at least seven members have been appointed. <sup>2</sup>Additional members can be added to the Ethics Committee at any time after its constitution. <sup>3</sup>In the constitutive meeting, the members of the Ethics Committee elect a professor from among the group of members for the position of chairperson of the Ethics Committee as well as at least one deputy. <sup>4</sup>The chairperson shall represent the Ethics Committee and shall comment on applications on behalf of the KU Ethics Committee. <sup>5</sup>The vice president for research shall invite the members to the constitutive meeting and shall chair the meeting until a chairperson has been elected.

(4) For KU members, membership in the Ethics Committee is an official duty; external members sit in the committee on a voluntary basis.

(5) If required, the Ethics Committee may consult additional experts when making decisions.

(6) An office will be established for administrative support of the chairperson of the Ethics Committee.

### **Section 3 Application**

- (1) <sup>1</sup>A research project will be reviewed upon written application submitted by the project coordinator. <sup>2</sup>Applications must contain all information and documents required for an ethical statement.
- (2) <sup>1</sup>Applications shall be submitted to the committee's office using an application form as published by the Ethics Committee. <sup>2</sup>The application and all pertaining documents shall be sent to all members of the Ethics Committee by the committee's office.
- (3) In justified cases, in particular, if there are no members with relevant subject expertise, the chairperson may reject an application for review.

### **Section 4 Review procedure**

- (1) <sup>1</sup>The chairperson convenes the Ethics Committee and determines place and date for the meeting. <sup>2</sup>He or she shall convene the Ethics Committee as often as business requires. <sup>3</sup>The chairperson opens, chairs and concludes the meeting of the Ethics Committee.
- (2) The Ethics Committee prepares statements on the basis of the votes of at least three professionally qualified members who will be appointed as responsible members by the chairperson for each respective application.
- (3) Members who participate in the reviewed research project or whose interests are involved in any way that gives rise to an apprehension of bias, shall be excluded from the discussion and adoption of the resolution.
- (4) <sup>1</sup>In general, the Ethics Committee takes a decision after an oral debate. <sup>2</sup>Meetings of the Ethics Committee are non-public. <sup>3</sup>The results of the meetings shall be recorded in minutes. <sup>4</sup>Taking written resolutions by way of circulation procedure shall be permissible, provided that none of the members objects to it.
- (5) <sup>1</sup>The Ethics Committee may request that the applicant explains the research project orally or provides additional documents, information or rationale. <sup>2</sup>The applicant can be heard before the Ethics Committee issues a statement; if the applicant wishes to be heard, such right shall be granted.
- (6) If there are essential concerns with regard to an application, the Ethics Committee may request that the applicant submits a revised application.
- (7) <sup>1</sup>The decision taken by the Ethics Committee shall be communicated to the applicant in writing. <sup>2</sup>Rejection decisions, conditions and recommendations for amending the research project must be justified in writing.
- (8) If an application is rejected for ethical reasons, the applicant has the right to present arguments to the contrary and request a new statement from the Ethics Committee.
- (9) <sup>1</sup>Decisions taken by the Ethics Committee require a simple majority of the members responsible for the respective application. <sup>2</sup>If a resolution is taken, such resolution is generally deemed to be a resolution passed by the Ethics Committee as a whole.
- (10) <sup>1</sup>Multicenter studies that have already been reviewed by another committee can be dealt with by the chairperson. <sup>2</sup>The Ethics Committee must be informed of this and shall be consulted in cases of doubt.
- (11) The duration of the review procedure shall be no longer than three months.

### **Section 5 Incident reporting**

- (1) If adverse events occur during the implementation of the research project that make an ethical-legal reassessment of the research project appear necessary, the chairperson of the Ethics Committee shall be notified of such adverse events by the applicant without undue delay and an own assessment by the applicant shall be provided.
- (2) The chairperson shall decide immediately whether it is necessary that the members of the Ethics Committee reassess the ethical-legal situation.
- (3) <sup>1</sup>In case of a reassessment, the Ethics Committee may withdraw its approving assessment in

part or in full or impose additional conditions. <sup>2</sup>The applicant must be given the opportunity to comment.

(4) If the applicant fails to report the incident, such failure shall be deemed to be scientific misconduct within the meaning of the regulations on safeguarding standards of good scientific practice and dealing with allegations of scientific misconduct dated July 16, 2014, as amended from time to time.

### **Section 6 Confidentiality of ethical assessment**

(1) <sup>1</sup>The subject matter of the procedure and the statements of the Ethics Committee shall be treated confidentially. <sup>2</sup>The members of the Ethics Committee are obliged to maintain secrecy. <sup>3</sup>The same shall apply to consulted experts. <sup>4</sup>Individual votes are treated confidentially.

(2) The members of the Ethics Committee must be informed of their obligation to maintain secrecy when they join the committee.

(3) <sup>1</sup>Committee votes, application documents, minutes of the meetings, amendments, interim and final reports, correspondence etc. are archived. <sup>2</sup>Application documents shall be archived in compliance with the data protection regulations.

### **Section 7 Entry into force**

These rules of procedure enter into force on the date of their publication.

Issued on the basis of the resolution of the Senate of the Catholic University of Eichstätt-Ingolstadt dated Wednesday, June 19, 2019, and the approval of the president dated Friday, July 19, 2019.

Eichstätt/Ingolstadt, Monday, July 22, 2019

Prof. Dr. Gabriele Gien  
President

These regulations were set down in writing at the Catholic University of Eichstätt-Ingolstadt on Monday, July 22, 2019. This fact was made known to members of the Catholic University of Eichstätt-Ingolstadt on the same day. The date of publication is therefore Monday, July 22, 2019.