

## Regulations of the Research Ethics Committee (KFE) of the University of Basel

**This English translation serves information purposes only. The original German version is the legally binding document.**

Approved by the Senate on June 5, 2025

### § 1 Purpose and principles

- 1 The Research Ethics Committee is a standing committee of the Senate tasked with ensuring the implementation of research ethics principles at the University of Basel.
- 2 The Research Ethics Committee promotes, in accordance with internationally recognized standards and declarations<sup>1</sup>, the observance of the following principles with regard to research participants, researchers, directly or indirectly affected third parties, and the environment:
  - a) the principle of respect for autonomy, integrity, and privacy;
  - b) the principle of honesty and transparency;
  - c) the principle of the protection of vulnerable persons;
  - d) the principle of harm prevention and care;
  - e) the principle of justice and social responsibility;
  - f) the principle of the protection of the environment and future generations.
- 3 The members of the Research Ethics Committee take into consideration the established guidelines of the respective disciplinary cultures<sup>2</sup> and relevant laws<sup>3</sup>. They are independent in the exercise of their duties and not bound by any instructions.

### § 2 Tasks and competencies

- 1 The Research Ethics Committee advises the President's Board on research ethics issues.
- 2 The Research Ethics Committee reviews the ethical acceptability of research projects conducted at the University of Basel according to § 3.
- 3 The Research Ethics Committee has access at all times to all research projects being conducted at the University of Basel, including those that it has not reviewed.

### § 3 Ethics review of research projects

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<sup>1</sup> See the [Universal Declaration on Bioethics and Human Rights](#) (UNESCO, 2006) and the [Recommendation on the Ethics of Artificial Intelligence](#) (UNESCO, 2022, esp. Policy Area 8: Education and Research, §§101–111).

<sup>2</sup> These include [Ethics in Social Science and Humanities](#) (European Commission, 2021); the [Ethik-Kodex der Deutschen Gesellschaft für Soziologie \(DGS\) und des Berufsverbandes für Soziologie in Deutschland \(BSiD\)](#) (Deutsche Gesellschaft für Soziologie, 2025); the [Guidelines to Conflict Sensitive Research](#) (Swiss Academy of Sciences SCNAT, 2020); and the recommendations of the [Federal Ethics Committee on Non-Human Biotechnology \(ECNH\)](#).

<sup>3</sup> Especially relevant are the [Informations- und Datenschutzgesetz \(IDG\)](#) of the Canton of Basel-Stadt, the [Federal Act on Data Protection \(FADP\)](#), and the [EU General Data Protection Regulation \(GDPR\)](#).

- <sup>1</sup> Project managers (*Projektverantwortliche*) at the University of Basel can have their research projects reviewed by the Research Ethics Committee.<sup>4</sup>
- <sup>2</sup> Research projects that meet at least one of the following criteria must be submitted to and approved by the Research Ethics Committee (mandatory review criteria):
  - a) research projects involving minors, vulnerable persons, or persons lacking the capacity to consent;
  - b) research projects in which sensitive personal data<sup>5</sup> are processed<sup>6</sup>;
  - c) research projects in contexts with high risks for researchers, participants, or third parties, for example, projects in conflict zones or authoritarian or fragile contexts;
  - d) research projects involving significant risks to the environment;
  - e) research projects that fall under the “Regulations on Particularly Risky Research”<sup>7</sup>.
- <sup>3</sup> Research projects that fall within the jurisdiction of one of the following institutions are not evaluated by the Research Ethics Committee<sup>8</sup>:
  - a) projects that fall within the jurisdiction of the Ethikkommission Nordwest- und Zentralschweiz (EKNZ) according to the Human Research Act (HRA)<sup>9</sup> and the Stem Cell Research Act (StRA)<sup>10</sup>;
  - b) projects involving animals that fall within the jurisdiction of the cantonal veterinary authority of Basel-Stadt according to the Animal Welfare Act (AniWA)<sup>11</sup>;
  - c) projects involving genetic resources that fall within the jurisdiction of the Federal Office for the Environment (FOEN) according to the Nagoya Protocol<sup>12</sup>;
  - d) projects involving genetically modified organisms (GMOs) that fall within the jurisdiction of the Federal Office for the Environment (FOEN) according to the Containment Ordinance (ContainO)<sup>13</sup>, except for projects that fall under the “Regulations on Particularly Risky Research”<sup>14</sup>;
  - e) projects that are under review by an ethics committee at another university or research institution or that have already been accepted with conditions or rejected.

#### **§ 4 Ethics review procedure**

- <sup>1</sup> Ethics review applications of a research project must be submitted in good time, i.e., generally immediately after receiving approval from the funding institution and before the start of data

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<sup>4</sup> Research projects conducted by students (BA and MA) are not reviewed by the Research Ethics Committee; they are the responsibility of the supervisors.

<sup>5</sup> “Besondere Personendaten” according to § 3 of the [Informations- und Datenschutzgesetz \(IDG\)](#) of the Canton of Basel-Stadt, “sensitive personal data” according to Art. 5 of the [Federal Data Protection Act \(FADP\)](#), and “special categories of personal data” according to Art. 4 and 9 of the [EU General Data Protection Regulation \(GDPR\)](#).

<sup>6</sup> This includes in particular projects in which persons are observed or their location is tracked.

<sup>7</sup> See the [Regulations on Particularly Risky Research](#).

<sup>8</sup> The Ethics Committee of the Faculty of Psychology (EKFP) of the University of Basel will continue to evaluate the research projects of members of the Faculty of Psychology as a subcommittee on behalf of the KFE (see § 10 Transitional Provisions).

<sup>9</sup> [Federal Act on Research Involving Human Beings \(Human Research Act, HRA\)](#).

<sup>10</sup> [Federal Act on Research Involving Embryonic Stem Cells \(Stem Cell Research Act, StRA\)](#).

<sup>11</sup> [Animal Welfare Act \(AniWA\)](#).

<sup>12</sup> For more information, see the [website of the FOEN](#).

<sup>13</sup> [Ordinance on Handling Organisms in Contained Systems \(Containment Ordinance, ContainO\)](#).

<sup>14</sup> See the [Regulations on Particularly Risky Research](#).

collection. Precise instructions for submitting an application are outlined in the guidelines<sup>15</sup>. For research projects falling under the “Regulations on Particularly Risky Research”<sup>16</sup>, the provisions of those regulations apply.

- <sup>2</sup> Based on a risk-assessment concept approved by the Research Ethics Committee, the Managing Director determines the number and type of reviews to be obtained for the attention of the committee. A distinction is made between: (a) research ethics review; (b) data protection assessment.
- <sup>3</sup> The research ethics reviews are commissioned to university internal or external persons with appropriate disciplinary expertise. In particular, they are the members of the committee and the Data Protection Officer. A data protection review must be conducted if sensitive personal data are processed in a project. The deadline for preparing reviews is ten working days.
- <sup>4</sup> The Research Ethics Committee makes decisions on the submitted applications, taking the reviews into account. The committee may decide to approve applications, approve them with conditions, reject them, or dismiss them. The committee may also delegate its decision-making authority to the Managing Director in justified cases.
- <sup>5</sup> The committee’s decision must be available no later than eight weeks after the submission of the application. The Managing Director informs the researchers of the decision and, if necessary, issues the required confirmation letters to funding organizations and scientific journals.
- <sup>6</sup> The decisions of the committee are binding. Compliance with the decisions of the Research Ethics Committee is considered part of Good Scientific Practice<sup>17</sup>.
- <sup>7</sup> Should changes occur in the implementation of an evaluated research project that are relevant from the perspective of research ethics (for example, regarding the research design or research circumstances), the committee must be informed immediately.

## **§ 5 Composition of the Research Ethics Committee**

- <sup>1</sup> The Research Ethics Committee consists of thirteen members with voting right. They are composed of:
  - a) the Vice President for Research;
  - b) two members each from the Faculty of Medicine, the Faculty of Humanities and Social Sciences, and the Faculty of Science;
  - c) one member each from the Faculty of Law, the Faculty of Business and Economics, the Faculty of Theology, and the Faculty of Psychology;
  - d) two persons with expertise in research-ethics issues.
- <sup>2</sup> The composition of the committee ensures that at least six members from group I, at least two members from group II, and at least two members from group III are represented and that there is a balanced gender ratio.
- <sup>3</sup> Chairperson of the committee is the Vice President for Research.
- <sup>4</sup> Committee members are elected by the Senate for a term of four years after being nominated by the faculties. One re-election is permitted. In case of a resignation or retirement during the term, a

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<sup>15</sup> See the [KFE Website](#).

<sup>16</sup> [Regulations on Particularly Risky Research](#).

<sup>17</sup> According to the [Code of Conduct for Scientific Integrity](#) (Swiss Academies of Arts and Sciences, 2021), organizing and conducting research without the necessary approvals as well as failing to consider and accept potential harms and risks constitute forms of scientific misconduct (see Code, 5.2.11).

replacement election takes place for the remainder of the term. Members must announce their resignation from the committee three months in advance.

- 5 The Research Ethics Committee may delegate certain tasks to subcommittees. The KFE grants the subcommittee a mandate.

## **§ 6 Meetings, voting rights, and decision-making**

- 1 As a rule, three meetings are held per semester. In justified exceptional cases, an extraordinary meeting may be convened at short notice.
- 2 The committee has a quorum when two-thirds of the members with voting rights are present.
- 3 Votes may be cast for approval, rejection, or abstention. Decisions require a simple majority. The chairperson casts the deciding vote in case of a tie.
- 4 For urgent applications, decisions may be made by circular resolution. A quorum for circular decisions is reached when two-thirds of the voting members have cast a vote.
- 5 The provisions of the “Guidelines for Recusals from University Committees”<sup>18</sup> apply to committee business.
- 6 The committee may invite experts to its meetings if needed. In particular, it may consult the Data Protection Officer or the Chief Information Security Officer.

## **§ 7 Responsibilities of the Managing Director**

- 1 The Managing Director of the Research Ethics Committee reports directly to the Vice President for Research.
- 2 The tasks of the Managing Director are:
  - a) preparing and following up on committee meetings, including preparing meeting agendas, taking minutes, drafting decisions, and carrying out the correspondence with researchers and reviewers;
  - b) advising the Research Ethics Committee and researchers on matters related to research ethics and procedural questions;
  - c) assessing submitted applications from researchers and determining the review procedure and, if asked by the committee, assessing the ethical acceptability of a research project (see § 4.4);
  - d) obtaining reviews;
  - e) developing the committee strategically in collaboration with the Vice President for Research;
  - f) preparing the committee’s activity report for the Senate (every two years);
  - g) developing and ensuring training in research ethics for researchers and committee members;
  - h) knowledge management and data storage;

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<sup>18</sup> See the [Guidelines for Recusals from University Committees](#).

- i) outreach and networking, particularly with the managing directors of other ethics committees at Swiss institutions of higher education.

### **§ 8 Confidentiality**

- <sup>1</sup> Meetings of the Research Ethics Committee are not public.
- <sup>2</sup> Committee members, the Managing Director, and all consulted reviewers are obligated to maintain confidentiality toward third parties.

### **§ 9 Entry into force**

- <sup>1</sup> These regulations enter into force on 1 October 2025 upon approval by the Senate. They replace the Regulations of the Ethics Committee of the University of Basel of 30 March 2020.

### **§ 10 Transitional provisions**

- <sup>1</sup> The Ethics Committee of the Faculty of Psychology (EKFP) continues to operate within the framework of its existing regulations until a new mandate is granted by the KFE. For the granting of the new mandate, the regulations of the EKFP will be adapted to the regulations of the KFE (by the end of the spring semester 2026).