

Code:	SR/4/2026	
Ref. No.:	UTB/26/013744	
Type of document:	INTERNAL	
Category:	RECTOR'S DIRECTIVE	
Title:	Statute of the Research Ethics Committee of Tomas Bata University in Zlín	
Liability:	Tomas Bata University in Zlín	
Issue date:	9 March 2026	Version: 01
Effective from:	15 March 2026	
Issued by:	Rector	
Prepared by:	Vice-Rector for Research, Development and Creative Activities	
In cooperation with:	Legal Services, Data Protection Officer, Vice-Deans for Research, Development and Creative Activities	
Pages:	5	
Appendices:	0	
Distribution list:	TBU employees	
Signature of authorised person:	Prof. Mgr. Milan Adámek, Ph.D.	

### **Preamble**

The interests and welfare of the individual should have priority over the sole interest of science or society. (*Universal Declaration on Bioethics and Human Rights, Article 2*)

### **Article 1 Basic provisions**

- 1) This Rector's Directive establishes the Biomedical Research Ethics Committee, the Ethics Committee for Social and Artistic Research, and the Ethics Committee for Socio-Humanities and Healthcare Research at Tomas Bata University in Zlín (hereinafter referred to as the "Research Ethics Committee").
- 2) The Research Ethics Committee is an independent advisory body of the Rector for all component parts of Tomas Bata University in Zlín (hereinafter referred to as "TBU").
- 3) An opinion issued by the Research Ethics Committee constitutes an expert advisory recommendation and does not in itself guarantee the legality, safety, or ethical integrity of a research project; full responsibility for the preparation, conduct, and completion of the research in compliance with applicable legislation, internal regulations of TBU, and recognised ethical standards rests solely with the principal investigator.
- 4) This Rector's Directive further defines the basic scope of the Research Ethics Committee, the composition of the Research Ethics Committee and the duties of the members of the Research Ethics Committee.

- 5) Research involving work on human embryos and fetuses, experimental animals, research on humans and research on humans involving any physical intervention that compromises the physical integrity of the human body (e.g. tissue sampling, surgery, invasive examination of body parts) or clinical drug trials cannot be carried out at TBU without the participation of a relevant collaborating institution. In the case of research involving the above experimental procedures, it is necessary to obtain approval from the ethics committee of the collaborating institution. Approval by the ethics committee of the collaborating institution is not a substitute for approval by the Research Ethics Committee, especially in cases where the principal investigator of the project or research is an employee or student of TBU.
- 6) In its activities, the Research Ethics Committee shall respect and comply with all relevant legislation and regulations in force and applicable in the Czech Republic, in particular the Universal Declaration of Human Rights, the Geneva Declaration, the Declaration of Helsinki (including its current amendments), the International Ethical Guidelines for Biomedical Research Involving Human Participants, and the Convention on Human Rights and Biomedicine, which is in force in the Czech Republic and, as a ratified international treaty, takes precedence over statutory law. The Committee shall further observe Regulation (EU) 2016/679 of the European Parliament and of the Council on the protection of natural persons with regard to the processing of personal data (hereinafter referred to as the “GDPR”) and the relevant national legislation, in particular Act No. 110/2019 Coll., on the Processing of Personal Data, Act No. 378/2007 Coll., on Pharmaceuticals, as amended, and Act No. 375/2022 Coll., on Medical Devices and In Vitro Diagnostic Medical Devices, as amended, which constitute the current implementation of the relevant European Union legislation.
- 7) The Biomedical Research Ethics Committee deals with the ethical aspects of research conducted at TBU and involving human subjects and work with biological material of human origin in research in the field of biomedicine, medical devices, biomaterials and cosmetics. According to the international Fields of Research and Development classification (hereinafter referred to as “FORD”), this includes in particular the following groups of fields of science: No. 1.2. Computer and information sciences, 1.3. Physical sciences, 1.4. Chemical sciences, 1.6. Biological sciences, 2.2. Electrical engineering, Electronic engineering, Information engineering, 2.5. Materials engineering, 2.6. Medical engineering, 2.8. Environmental biotechnology, 2.9. Industrial biotechnology, 2.10. Nano-technology, 2.11. Other engineering and technologies, 3.4. Medical biotechnology.
- 8) The remit of the Ethics Committee for Social and Artistic Research covers the ethical aspects of research involving human participants conducted at TBU in the fields of the social sciences, humanities, and the arts. According to the international FORD classification, this includes in particular the following groups of fields of science: FORD No. 5.2 Economics and business, 5.5 Law, 5.3 Political science, 5.7 Social and economic geography, 5.8 Media and communications, 5.9 Other social sciences, 6.4 Arts (arts, history of arts, performing arts, music), 6.5 Other humanities and the arts.
- 9) The remit of the Ethics Committee for Socio-Humanities and Healthcare Research covers the ethical aspects of research conducted at TBU that involves human participants and, where relevant, work with biological material of human origin, in particular in the fields of pedagogy, philology, sociology, and non-medical healthcare disciplines, with the exception of research falling within the remit of the Biomedical Research Ethics Committee. According to the international FORD classification, this includes in particular the following groups of fields of science: No. 3.3. Health sciences, 5.1 Psychology, 5.3 Education, 5.4

Sociology, 6.1 History and archaeology, 6.2 Languages and literature, 6.3 Philosophy, ethics and religion.

- 10) The FORD classification serves only as a guiding reference and is not the sole determining criterion for the assignment of responsibilities among the individual committees. The key factor is the nature and principal focus of the research, which may lead to the designation of the competent committee irrespective of formal classification. In cases of uncertainty as to which committee the research falls under, the matter shall be decided by agreement between the Chairpersons of the committees, typically no later than 10 working days from receipt of the Research Proposal.
- 11) The Research Ethics Committee processes personal data to the extent necessary for the assessment of the ethical aspects of research. Such processing is carried out on the legal basis of the performance of a task carried out in the public interest pursuant to Article 6 Paragraph 1 Letter e) on the GDPR, and, in the case of special categories of personal data, pursuant to Article 9 Paragraph 2 Letter j) of the same Regulation.

## **Article 2**

### **Membership of the Research Ethics Committee**

- 1) The number of members of the Research Ethics Committee shall be at least five.
- 2) Membership of the Research Ethics Committee shall be by appointment.
- 3) Members of the Research Ethics Committee shall be appointed by the Rector from among the employees of TBU and other experts, subject to the prior written consent of the proposed member of the Research Ethics Committee and following consultation with the TBU Scientific Board. A permanent member without voting rights shall be a representative designated by the Vice-Rector for Research, Development and Creative Activities, who provides expert advice to the members of the Research Ethics Committee.
- 4) The Chairperson of the Research Ethics Committee shall be appointed by the Rector.
- 5) The term of office of the Research Ethics Committee shall normally be four years, but not longer than until a new Research Ethics Committee is appointed. The Rector shall appoint a new member of the Research Ethics Committee to fill a vacancy on the Research Ethics Committee in the manner as specified in Paragraph 2, but only for the remainder of the term of office of the Research Ethics Committee as a whole.
- 6) A member of the Research Ethics Committee and the Chairperson of the Research Ethics Committee shall be eligible for reappointment.
- 7) Membership of the Research Ethics Committee shall be terminated during the term of office:
  - a. by a member being dismissed after prior discussion in the Scientific Board of TBU,
  - b. by written resignation of membership delivered to the Rector,
  - c. by death.

**Article 3**  
**Responsibilities of a member of the Research Ethics Committee**

- 1) Upon becoming a member of the Research Ethics Committee, a member of the Research Ethics Committee shall:
  - a. maintain confidentiality about the content of the research projects under review and about all other facts that have been the subject of the deliberations of the Research Ethics Committee,
  - b. declare any potential conflicts of interest related to the performance of his/her duties as a member of the Research Ethics Committee,
  - c. adhere to the principle of objectivity and independence in the assessment of research projects.
- 2) A member of the Research Ethics Committee who is in any actual, potential, or perceived conflict of interest shall be obliged to notify the Chairperson of the Committee thereof in writing without undue delay and to refrain from participating in the assessment of the given project. Information regarding the conflict of interest and the recusal of the member shall be recorded in the minutes of the meeting.

**Article 4**  
**Secretary to the Research Ethics Committee**

- 1) The Secretary to the Research Ethics Committee (hereinafter referred to as the “Secretary”) shall be appointed by the Rector in agreement with the Chairperson of the Research Ethics Committee.
- 2) The Secretary shall not be a member of the Research Ethics Committee, but shall reasonably comply with the duties of a member of the Research Ethics Committee specified in Article 3.
- 3) The Secretary shall carry out administrative tasks related to the activities of the Research Ethics Committee and shall take the minutes of the meetings of the Research Ethics Committee.
- 4) The Secretary shall receive submissions to the meetings of the Research Ethics Committee and check the formal correctness thereof.

**Article 5**  
**Activities of the Research Ethics Committee**

- 1) The organisation, method of proceedings and activities of the Research Ethics Committee shall be governed by the Rules of Procedure of the Research Ethics Committee, which has been issued by the Rector as an internal regulation of TBU.
- 2) The mission of the Research Ethics Committee is to ensure that research is planned in such a manner that the health, freedom, dignity, autonomy, quality of life and safety of all persons participating in research are protected and preserved to the maximum extent possible. The

Research Ethics Committee shall pay particular attention to the protection of vulnerable or dependent research participants.

- 3) The Research Ethics Committee shall assess whether the submitted Research Proposal complies with the principles set out in international and national regulations and documents defining the ethical aspects of research.
- 4) The Research Ethics Committee is entitled to check the compliance of the research with the approved Research Proposal in the event of suspected ethical violations.
- 5) The Research Ethics Committee shall have the right to request an opinion from a TBU lawyer and the TBU Data Protection Officer (DPO). The TBU lawyer and the DPO shall be required to comply, to an appropriate extent, with the obligations of a member of the Research Ethics Committee as set out in Article 3.

### **Article 6 Transitional provisions**

- 1) Until the new Research Ethics Committees are established in accordance with this Directive, the existing Research Ethics Committees shall continue to exercise their remit within the scope of their existing competences.

### **Article 7 Final provisions**

- 1) TBU employees who have, until the effective date of this Directive, been processing operational documents related to the review of submissions considered by the TBU Ethics Committee shall be obliged to hand over all such operational documents (both in physical and electronic form) without undue delay to the Secretary to the Research Ethics Committee in an appropriate manner.
- 2) The existing TBU Research Ethics Committees shall cease to exist on the date of establishment of the new Research Ethics Committees pursuant to this Directive; until such time, their activities shall be governed by the transitional provisions.
- 3) This Directive repeals and replaces Rector's Directive No. SR/17/2023.

Document version			
Date	Version	Changed	Description of change
5 March 2026	01		Creation of document

*This English version of the internal regulation is not legally binding; it is for informational purposes only and does not have to correspond to the Czech version of the document.*