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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 Introductory provisions

- 1) This Rector's Directive establishes the Biomedical Research Ethics Committee and the Ethics Committee for Research in Humanities, Social Sciences and Health Sciences 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) 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.
- 4) 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.

- 5) In its actions, 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 Declaration of Human Rights, the Geneva Declaration, the Declaration of Helsinki, the International Ethical Guidelines for Biomedical Research Involving Human Participants, the Convention on Human Rights and Biomedicine, the Declaration on Human Rights, Regulation (EU) No. 2016/679 on the Protection of Individuals with regard to the Processing of Personal Data (ON GDPR), the Medicines Act, the Medical Devices Act, Personal Data Processing Act, Research Ethics Framework and other relevant legislation.
- 6) 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. The Ethics Committee for Research in Humanities, Social Sciences, and Health Sciences deals with the ethical aspects of research conducted at TBU and involving human subjects and, where appropriate, work with biological material of human origin in the humanities, social sciences, and non-medical health sciences, with the exception of research falling within the scope of the Biomedical Research Ethics Committee.

Article 2

Composition 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 after the prior written consent of the proposed member of the Research Ethics Committee and the opinion of the TBU Scientific Board. The TBU lawyer and the TBU Data Protection Officer (DPO) shall be guest members of the Research Ethics Committee with an advisory vote. The TBU lawyer and the DPO shall be obliged to reasonably observe the duties of a member of the Research Ethics Committee as specified in Article 3.
- 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 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.

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 organization, 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 Plan 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 Plan in the event of suspected ethical violations.

Article 6

Final provisions

TBU employees who have been processing operational documents related to the review of submissions discussed by the TBU Ethics Committee until the effective date of this Directive are obliged to hand over all such operational documents (both physical and digital part thereof) to the Secretary to the Research Ethics Committee without undue delay.

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