

MU Directive No. 5/2015

Research Ethics at MU

(in the version effective from 2/11/2015)

In accordance with Section 10, paragraph 1 of Act No. 111/1998 Coll., on Higher Education Institutions and on Modification and Amendment of Other Acts, as later amended (Higher Education Act), I issue this Directive:

Article 1

Research Ethics at MU

- (1) All research activities at Masaryk University (MU) are carried out with the intent to meet the criteria of high professional quality and socially beneficial and significant goals.
- (2) The research activities of MU employees and students are an expression of the realisation of the freedom of research while strictly observing the relevant discipline's rules and standards.
- (3) MU employees and students ensure that the research they carry out at MU is in accordance with applicable laws, internal MU standards¹ and relevant ethical standards.
- (4) The system of quality assurance and observance of ethical standards and related legal standards during research activities at MU consists mainly of:
 - a) MU Ethics Board
 - b) MU Research Ethics Committee
 - c) Ethics Committee of the MU Faculty of Medicine
 - d) ELSPAC Ethics Committee²
 - e) Expert Committee for Ensuring the Welfare of Experimental Animals
 - f) Expert Advisor for Monitoring GMO³
 - g) Research Attorney

The individual components work together to provide MU employees and students with support in addressing ethical and legal aspects of their research.

- (5) Information, guidance, best practices and contact details for those responsible for ethical and related research issues are available at <http://vyzkum.rect.muni.cz/cs/etika-vyzkumu>.

e.g. Rector's Directive 3/2010 Protection of Personal Data at MU, MU Directive No. 6/2013 on Research Data at MU.

² European Longitudinal Study of Pregnancy and Childhood

³ Genetically Modified Organisms

Article 2

Evaluation of a Research Project by the Ethics Board

- (1) Every research project⁴ within MU which involves research on a human subject (including work with biological material of human origin) and requires the approval of an ethics committee must be submitted to the MU Ethics Board in accordance with Art. 1 par. 4, letters b) to d) before starting research.
- (2) If the proposal of the research project is submitted for evaluation to the Ethics Committee of ELSPAC, it is not submitted for evaluation to the MU Research Ethics Committee or the Ethics Committee of the MU Faculty of Medicine.
- (3) The competence of the MU Research Ethics Committee and the Ethics Committee of the MU Faculty of Medicine is given by the head researcher at MU under whom the research project is submitted, unless the chairs of these committees agree otherwise.

Article 3

MU Ethics Board

- (1) The competence of the MU Ethics Board is given by Article 14 of the MU Code of Ethics. The MU Ethics Board assesses cases of violation of general moral principles or rules of the MU Code of Ethics that are beyond the organisational structure of MU or which have not been resolved at that level (research misconduct).
- (2) The MU Ethics Board of is a permanent advisory body to the Rector.

Article 4

MU Research Ethics Committee

- (1) The MU Research Ethics Committee is an independent multidisciplinary body of MU and its mission is to supervise the application and observance of the relevant ethical standards in research conducted within MU, and in particular that involving human subjects (including work with biological material of human origin).
- (2) The activities and competences of the MU Research Ethics Committee are further regulated by the Statutes of the MU Research Ethics Committee and the Rules of Procedure.

Article 5

Ethics Committee of the MU Faculty of Medicine

The Ethics Committee of the MU Faculty of Medicine supervises the application and observance of the relevant ethical standards in research conducted at the MU Faculty of Medicine and in particular that which in any way involves human subjects (including work with biological material of human origin).

⁴ A research project is any research activity at MU, e.g. projects for GACR, TACR, H2020, internal MU grants, final theses (bachelor's, diploma, dissertation, etc.).

Article 6

ELSPAC Ethics Committee

The ELSPAC Ethics Committee oversees the application of and adherence to relevant ethical standards in research conducted using ELSPAC study data.

Article 7

Expert Committee for Ensuring the Welfare of Experimental Animals

The Expert Committee for Ensuring the Welfare of Experimental Animals⁵ is established on the basis of Act No. 246/1992 Coll., on the Protection of Animals against Cruelty, and fulfils the tasks set out in Section 15g, paragraphs 4 and 5 of this Act.

Article 8

Expert Advisor for GMO Control

The expert advisor for GMO control⁶ in accordance with Act No. 78/2004 Coll., on the Use of Genetically Modified Organisms and Genetic Products, assesses the risk of the use of genetically modified organisms and genetic products, provides information and arranges documents necessary for the handling of GMOs in research conducted at MU in accordance with relevant legislation.

Article 9

The Research Attorney

- (1) Legal support for research at MU is provided by the Legal Office of the MU Rector's Office. The Research Attorney is an employee of the Legal Office of the MU Rector's Office, specialising in research-related legal issues.
- (2) The Research Attorney provides MU employees and students with consultations on the legal-ethical issues of research and supervises the application and observance of applicable legal regulations and internal standards of MU in research conducted within MU.

Article 10

Interim and Final Provisions

- (1) Until the establishment of the MU Ethics Committee for Research, the activities of all existing ethics committees operating at MU will be maintained.
- (2) This Directive is without prejudice to obligations arising from other legal regulations or internal regulations and standards of MU.
- (3) This Directive falls under the area of methodological management "Coordination and Planning of Research".
- (4) I authorise the Vice-rector for Research to interpret this Directive.
- (5) This Directive shall enter into effect on the day of its publication.

⁵ see <http://www.med.muni.cz/index.php?id=197>

⁶ see <http://www.rect.muni.cz/nso/>

Brno, 2 November 2015

Mikuláš Bek
Rector