



POLITECNICO
MILANO 1863

POLITECNICO DI MILANO

T H E R E C T O R

HAVING REGARD TO the Universal Declaration of Human Rights of 10 December 1948;
HAVING REGARD TO the European Convention for the Protection of Human Rights and Fundamental Freedoms currently in force;
HAVING REGARD TO the Charter of Fundamental Rights of the European Union (2000/C 364/01);
HAVING REGARD TO the Helsinki Declaration “Ethical Principles for Medical Research Involving Human Subjects”, as currently in force;
HAVING REGARD TO the UNESCO Universal Declaration on the Human Genome and Human Rights;
HAVING REGARD TO Recommendation no. 10 of 23 September 1983 of the Council of Europe – Committee of Ministers to Member States, concerning the protection of personal data used for scientific research and statistical purposes;
HAVING REGARD TO the Convention for the Protection of Human Rights and Dignity of the Human Being with regard to the Application of Biology and Medicine: Convention on Human Rights and Biomedicine – Oviedo, 4 April 1997;
HAVING REGARD TO Recommendation no. 5 of 13 February 1997 of the Council of Europe – Committee of Ministers to Member States, concerning the protection of health data;
HAVING REGARD TO the International Ethical Guidelines for Biomedical Research drawn up by the Council for International Organizations of Medical Sciences (CIOMS) in collaboration with the World Health Organization (WHO);
HAVING REGARD TO the Treaty establishing the European Atomic Energy Community (Euratom);
HAVING REGARD TO the Additional Protocol to the Council of Europe Convention on Human Rights and Biomedicine, concerning biomedical research (2005);
HAVING REGARD TO the current Statute of Politecnico di Milano;
HAVING REGARD to the University’s current General Regulation;
HAVING REGARD to Politecnico di Milano’s Code of Ethics and Conduct;
HAVING REGARD to Rector’s Decree no. 1133 of 14 March 2016, by which the Regulation of the Research Ethical Committee of Politecnico di Milano was issued;
HAVING RECEIVED the opinions of the Academic Senate and the Board of Governors, at their respective meetings on 22 and 30 January 2024, regarding the approval of the amendments made to the Regulation of the Research Ethical Committee of Politecnico di Milano, which have been renamed the Organisational and Operational Regulation of the Research Ethical Committee of Politecnico di Milano;
HAVING RECOGNISED, therefore, the need to issue the Organisational and Operational Regulation of the Research Ethical Committee of Politecnico di Milano, including the approved amendments;

ORDERS

Art.1

- 1) For the reasons set out in the preamble, the Regulation of the Research Ethical Committee of Politecnico di Milano is amended, including the title, as set out in the text forming an integral part of this decree.

**Organisational and Operational Regulation of the Research Ethical Committee of
Politecnico di Milano**

CONTENTS

Art.1 - Subject

Art. 2 - Duties of the Ethical Committee

Art. 3 - Composition of the Ethical Committee

Art. 4 - Operating procedures of the Ethical Committee

Art. 5 - Procedure for requesting an opinion

Art. 6 - Transitional and final provisions

Annexes

Art.1

Subject

- 1) Politecnico di Milano establishes the Research Ethical Committee, hereinafter referred to as the Ethical Committee, a body constituted and composed in accordance with criteria of expertise, interdisciplinarity and independence, as described in the following articles of this Regulation, and at the same time defines its duties.

Art.2

Duties of the Ethical Committee

- 1) The Ethical Committee operates with the aim of safeguarding, in accordance with current legislation:
 - a) the rights, dignity, integrity and well-being of individuals involved in research;
 - b) respect for every other living organism;
 - c) respect for the environment;
 - d) freedom and the advancement of science.
- 2) The Ethical Committee issues an opinion on research falling within the following categories:
 - a) research involving individuals and/or involving the collection and use of personal data, including data obtained through the use of instruments;
 - b) research involving the use, production or collection of human tissues and cells, the use of human stem cells, cells or tissues derived from human embryos, or the use of human embryos;
 - c) research in third countries (activities and/or involvement in research carried out in non-EU countries);
 - d) research that may have adverse effects on the environment or on people's health or safety;
 - e) research involving animals as research subjects;
 - f) research involving the development, implementation or use of technologies that may have a significant impact on individuals, society or the environment;
 - g) research that may have dual-use applications: the development of technologies or new knowledge that may be used, applied or exploited for military purposes;
 - h) research that develops technologies or new knowledge that could be used for unethical purposes.

Art. 3

Composition of the Ethical Committee

- 1) The Ethical Committee consists of seven members who are employed by the University or by other universities and/or national and international research institutes and organisations, and is appointed by the Academic Senate on the recommendation of the Rector. The term of office is three years and may be renewed consecutively only once. The Ethical Committee may call upon highly qualified external experts specialising in the subjects referred to in the preceding Article 2 – paragraph 2, who may attend meetings without the right to vote.
- 2) Members of the Ethical Committee are bound by a duty of confidentiality regarding matters relating to their work.
- 3) Members of the Ethical Committee who have a direct or indirect conflict of interest are required to refrain from expressing opinions or judgements and to abstain from voting.
- 4) The President, Vice-President and members of the Ethical Committee are appointed by a decree of the Rector.
- 5) The President is entrusted with the duties set out in the University's General Regulation concerning the management and organisation of the University's governing bodies.
- 6) Administrative support for the Ethical Committee is provided by the Research Office of the Research, Innovation and Corporate Relations Division at Politecnico di Milano, which acts as the technical secretariat.

Art. 4

Operating procedures of the Ethical Committee

- 1) The Research Office, in consultation with the Ethical Committee, prepares an information plan aimed at all University staff, with a view to raising awareness of the ethical implications of research activities and the administrative procedures for submitting requests for an opinion to the Ethical Committee.
- 2) The Research Office receives requests for opinions from the Ethical Committee submitted by the Scientific Directors of the departments and other units of Politecnico di Milano, as well as by the Scientific Directors and/or legal representatives of the University's spin-offs.
- 3) Once the administrative review has been completed, the Technical Secretariat forwards the documentation received to the Ethical Committee.
- 4) If necessary, the Ethical Committee may consult the Scientific Director of the research project or summon them to a hearing.
- 5) The Ethical Committee may invite the Director of the department to which the Scientific Director of the research project seeking the Committee's opinion belongs, or their delegate, to attend meetings as an observer without voting rights.
- 6) If necessary, interviews with applicants may be conducted in English. To this end, the documentation and the final opinion will be drawn up in the requested language.
- 7) For details regarding the conduct and validity of the Ethical Committee's meetings, please refer to the provisions of Articles 17 "Validity of meetings", 19 "Expression of the body's will", 20(4) "Voting procedures" and 21 "Minutes of meetings" of the University's General Regulations.

Art.5

Procedure for requesting an opinion

- 1) The Scientific Directors and/or the legal representative of a spin-off may request an opinion from the Ethical Committee in accordance with the procedures set out in this article.
- 2) The opinion of the Ethical Committee is not required if the research is subject to the opinion of another Ethical Committee by law, or because the opinion of another Ethical Committee is stipulated in the legal basis of the funding programmes or in the agreement between Politecnico di Milano and the other bodies participating in the specific activity.
- 3) It is mandatory to seek the Ethical Committee's approval before commencing the research, not least to comply with any requirements imposed at the time of publication.
- 4) The documentation to be submitted and the procedures to be followed, together with the relevant deadlines, are published alongside the Ethical Committee's meeting schedule. Applicants must notify the Technical Secretariat of the date chosen exclusively from those listed in the calendar.
- 5) For research projects involving the processing of personal data, it is mandatory to complete the 'activity analysis' form so that the necessary checks can be carried out to ensure compliance with current data protection legislation. The form, signed by the Scientific Director, along with the privacy notice, informed consent form and all other required documents, must be submitted to the data protection officer of the relevant Department, who may seek the advice of the University's Data Protection Officer/Privacy Representative (DPO), should they identify any issues or find the completed documentation to be inadequate.
- 6) The documentation must be submitted to the privacy representative and/or the DPO no later than the fifteenth working day – excluding public and religious holidays – prior to the deadline for submitting the documents to the Ethical Committee. The deadline for submitting a request for an opinion to the Ethical Committee, together with all supporting documents, is the fifteenth working day – excluding public and religious holidays – prior to the date of the Ethical Committee meeting. The Ethical Committee will issue its opinion within seven working days, excluding public and religious holidays, from the date of the meeting.

- 7) The application for an opinion must be accompanied by the following documents:
 - a) a completed and signed opinion request form;
 - b) scientific protocol, if one has already been established. If the research involves experiments that could have an impact on the health and safety of human and animal subjects, approval of the protocol by a doctor must also be provided.
 - c) document setting out the risk assessment for cases where the research project involves the use of equipment and/or devices used by human persons. This document must contain a detailed description of the potential issues that could arise from the use of the equipment in question, as well as a definition of the measures to prevent and mitigate risks.
 - d) authorisation from other bodies involved in the research, if any;
 - e) questionnaire and interview templates used for data collection;
 - f) where students or staff from outside the University are involved, a confidentiality undertaking countersigned by the Scientific Director must be attached;
 - g) all documentation submitted and approved by the privacy representative/DPO referred to in paragraph 5 above;
 - h) any other document that the Scientific Director considers relevant to the opinion.
- 8) If the DPO does not give their approval, the application cannot be submitted to the Ethical Committee.
- 9) Upon receipt of the request for an opinion and after verifying that it is complete and correct, the Technical Secretariat is responsible for informing the Scientific Director of the procedure for dealing with the request and, if a hearing is to be held, the details thereof.
- 10) The Ethical Committee may ask the Scientific Director of the research in question to provide further documentation in support of the request for an opinion.
- 11) The Ethical Committee issues a binding opinion, which will be forwarded to the applicant and to the relevant departments at the applicant's home institution.
- 12) Following the Ethical Committee's opinion, the Scientific Director is required to amend the documentation in accordance with the committee's decisions.
- 13) In the event of an unfavourable opinion, the Scientific Director or the legal representative of a spin-off may submit a new request for an opinion, after revising the project in accordance with the guidelines provided by the Ethical Committee.

Art. 6
Transitional and final provisions

- 1) This Regulation shall enter into force on the day following the date of its adoption by decree of the Rector, which shall be published on the University website: <http://www.normativa.polimi.it/>.
- 2) For any matters not expressly covered by this Regulation, reference should be made to the relevant national, EU and international legislation in force.
- 3) Requests for an opinion submitted prior to the entry into force of this Regulation will be dealt with in accordance with the provisions set out in the Regulation of the Research Ethical Committee of Politecnico di Milano, issued by Rector's Decree 1133 of 14 March 2016.

THE RECTOR
Prof. Donatella Sciuto

Digitally signed under the Digital Administration Code as amended.