



POLITECNICO
MILANO 1863

Rep. no. 1133 Prot. no. 19924

Date 14 March 2016

Title I Class 3

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POLITECNICO DI MILANO

THE RECTOR

GIVEN the Universal Declaration of Human Rights of 10 December 1948;
GIVEN the European Convention on Human Rights and Fundamental Freedoms currently in force;
GIVEN the Charter of Fundamental Rights of the European Union (2000/C 364/01);
GIVEN the Helsinki Declaration on "Ethical principles for medical research involving human subjects" currently in force;
GIVEN UNESCO's Universal Declaration on Human Genome and Human Rights;
GIVEN Recommendation no. 10 dated 23/09/1983 of the Council of Europe – Committee of Ministers to Member States, relating to the protection of personal data used for purposes of scientific research and statistics;
GIVEN 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 04 April 1997;
GIVEN Recommendation no. 10 dated 13/02/1997 of the Council of Europe – Committee of Ministers to Member States, relating to the protection of medical data;
GIVEN the international ethical guidelines on biomedical research drafted by the Council for International Organizations on Medical Sciences (CIOMS) jointly with the World Health Organization (WHO);
GIVEN the Treaty that establishes the European Atomic Energy Community (Euratom or EAEC);
GIVEN the additional Protocol to the Council of Europe's Convention on Human Rights and Biomedicine, relating to biomedical research (2005);
GIVEN the Statute of the Politecnico di Milano currently in force;
GIVEN the University Code of Ethics currently in force;
HAVING OBTAINED the favourable opinions expressed by the Academic Senate and by the Board of Directors, at the respective 15 and 23 February 2016 sessions, as regards the Regulation on establishing a Research Ethical Committee;
HAVING DETECTED a need to see to that task;

HEREBY DECREES

Art. 1

- 1) In the light of the reasons set out in the preamble, the Regulation on the establishment of the research Ethics is hereby issued.

Regulation for the Research Ethical Committee of the Politecnico di Milano

Art.1

Subject

- 1) The Research Ethical Committee, a body established and composed pursuant to criteria of competence, interdisciplinarity and independence, is set up at the Politecnico di Milano.

Art.2

Tasks of the Ethical Committee

- 1) The Committee operates with the aim of safeguarding, while duly complying with the legislation in force:
 - a) the rights, the dignity, the integrity and the well-being of the human persons involved in researches;
 - b) respect for any other living organism;
 - c) respect for the environment in all its dimensions and components;
 - d) freedom and the promotion of science
- 2) The Committee puts forward its view on research issues, that may concern, without attempting any exhaustive list, the following topics:
 - any research that involves human beings (detection of personal data or signals, equipment for surgical operations, tests and validation of new measurement and/or intervention devices, interviews, remarks, collection of biological samples, measurements of physiological parameters, information collected and used for different purposes)
 - researches that entail the use, production and collection of human tissues or cells
 - any research that involves the collection of personal data: researches about the processing of information relating to an identified or identifiable physical person. What is meant by processing is any operation that involves the collection, registration, organization, storage, elaboration, modification, extraction, consultation, utilization, communication, dissemination, blocking and erasure of personal data;
 - research with animals;
 - research in third countries;
 - possible dual use of technology: researches, technologies, information with potential objectives, use or exploitation of a military, terrorist or other such character;
 - technologies and information that might be used for non-ethical purposes.
- 3) The Committee is vested with the task of providing opinions, assessments and verifications to the scientific research coordinators, to the directly interested structures and to the governing bodies of the Politecnico di Milano, in order to ensure that the research is carried out in accordance with the ethical principles laid down by international and national legislation, and by the Ethical Committee of the Politecnico di Milano.
- 4) The decisions of the Ethical Committee are binding on the requesting party. The Committee is vested with the following tasks:
 - a) providing the ethical analysis of research proposals and the experimental protocols submitted to its scrutiny;
 - b) expressing appraisals, wherever the same are necessary to accede to requests by national, EU or international institutions;
 - c) drawing up, jointly with the Research Service, an informational plan addressed to University staff and students, in order to facilitate an ethical awareness of the implications ensuing from the research activity.
- 5) The responsibilities of the Ethical Committee shall not include the functions reserved by law to the ethical committees of other bodies, particularly hospital ones.

Art. 3

Composition of the Committee

- 1) The Committee is made up of nine members with voting rights, appointed by the Academic Senate, upon the Rector's proposal, for a three-year term, renewable on a consecutive basis once only. The members of the Committee may be selected among Full, Associate, Emeritus and Honorary Professors, and Researchers of the Politecnico di Milano, or among outside personalities of proven experience within the ethical field. They will have to include at least one bioethics expert.

- 2) Provision is made for the appointment by the Academic Senate, upon the Rector's proposal, of three alternate members, who will take over in the event of the members' impediment. Their term of office will be 3 years.
- 3) Provision might be made for consultancy services by outside experts without voting rights, if need be. In that event, the Rector shall attend to their appointment at the behest of at least two members of the Committee who are entitled to vote.
- 4) The member who has accumulated three unjustified absences shall relinquish office. His replacement shall be appointed in his stead in the same manner as described above.
- 5) The names, qualifications and CV's of members of the Ethical Committee shall be made public.
- 6) The Committee members shall have to keep the acts associated with their activity confidential until their divulgation.
- 7) The Committee members shall have to abstain from the vote and from expressing evaluations and judgments on issues potentially involving a direct or indirect conflict of interests, and generally on researches submitted to the Committee in which they are directly or indirectly involved.

Art. 4

Appointment and tasks of the Chairman

- 1) The Chairman shall be appointed by the Academic Senate, upon the Rector's proposal, among the five members with voting rights.
- 2) The Chairman shall appoint, if need be, a vice-chairman to carry out the same functions in the event of the former's impediment.
- 3) The Chairman:
 - a) Convenes, chairs and steers the sessions of the Committee;
 - b) Ensures compliance with this Regulation, its guidelines, ethical principles and the legislation in force;
 - c) ascertains, with the support of the Departments involved and the Research Service, that the decisions of the Committee are notified within the stipulated time frames;
 - d) reports on the activity carried out by the Committee to the Academic Senate and to the Rector at the behest of the Institutional Bodies themselves.

Art. 5

Operational method

- 1) The Research Service acts as technical secretariat of the Committee. It receives, as a rule 45 days prior to any possible deadlines of calls, the requests for an opinion by scientific research coordinators or by the directly involved structures, or by external bodies, and timely informs the Chairman and the Head of Department involved.
- 2) For purposes of an assessment and the formulation of an opinion, the Chairman may nominate one or more speakers, based on their competence, with the task of introducing the discussion on the project.
- 3) The Committee is entitled to question or summon the research scientific coordinator, and also, as consultants without voting rights, qualified specialists in the various disciplines.
- 4) The Committee may invite to chair the sessions, albeit without voting rights, the Head of the department to which the research scientific coordinator requesting the opinion, or his representative well-versed in the subject-matter of the assessment, is attached to.
- 5) The opinion expressed by the Committee is notified to the requesting party by the Research Service by no later than 5 days from date of resolution by the Committee.
- 6) Wherever the Committee expresses a favourable view on a project, the research scientific coordinator, if he intends pursuing it further, shall have to bring the proposal back to the attention of the Committee, after an appropriate review.
- 7) The views put forward by the Committee shall not exempt the requesting subject from his own responsibilities concerning the function discharged.
- 8) The Committee binds itself to provide an opinion on the requests received within the non-peremptory term of 45 days from date of receipt.

- 9) Sessions conducted by videoconference and electronically shall be valid. In the latter instances, the vote and/or opinion on a single issue may be transferred by any electronic means.

Art. 6

Method of voting and subsequent resolution

- 1) The sessions of the Committee are legally valid through the presence of half + 1 members who are entitled to vote.
- 2) Voting shall take place by open ballot and with a show of hands, save in the instances referred to in article 5(9) where every communication, vote or opinion may be transferred electronically.
- 3) The Chairman shall announce the result of the voting.
- 4) The final resolution, opinions and votes, as well as any other decision, including a temporary one, shall be approved by an absolute majority of members with voting rights. In the event of equal votes, the Chairman or his deputy shall cast the decisive vote.
- 5) Official minutes shall be drawn up following any consultation/session, detailing the activity undertaken, setting out reasons and any separate views expressed by single commissioners.

Art. 7

Procedure for requesting an opinion at a party's behest

- 1) The scientific research coordinator, or the Head of the relevant department, requests the opinion of the Ethical Committee, through a petition addressed to the Chairman of the Ethical Committee, c/o the Research Service, by filling out an application form.
- 2) The request is sent in electronic format jointly with the documentation necessary to the appraisal at the Comitatoetico@polimi.it address.
- 3) It is for the requesting party to attain certainty about actual receipt of the relevant petitions by the competent office.
- 4) The Committee may at any time request additional documentation from the scientific research coordinator.

Art. 8

Final provisions

- 1) This Regulation is effective on the date following the one on which the Rector's Decree is issued, and is published on the University website: <http://www.normativa.polimi.it/>.
- 2) As regards whatever is not expressly governed by this Regulation, reference should be made to the national, EU and international legislation in force.

THE RECTOR

Signed by Prof. Giovanni Azzone