

REGULATIONS OF THE ETHICS COMMITTEE FOR R&D+i ACTIVITIES AT THE UNIVERSIDAD POLITÉCNICA DE MADRID

Approved by the Governing Board of UPM on 30 March 2017, on the initiative of the Research Committee of 16 March 2017

Background

The Governing Board, at a session held on 26 January 2006, took the decision to create the R&D+i Activities Ethics Committee of the Technical University of Madrid and established operating guidelines derived from those of the Ethics Advisory Committee for Scientific and Technical Research of the Spanish Foundation for Science and Technology.

These guides have been very useful to date; however, given the growth in the number of the Committee's actions and the increased relevance of its resolutions regarding the participation of the UPM in projects and contracts of the most diverse nature, it is advisable to review the Committee's operation mode and provide it with Regulations that allows it to combine rigour in the evaluation of the ethical aspects of research with the agility of decision-making processes in research and innovation projects.

For all these reasons, the following Operating Regulations have been proposed, which follow and formalise the principles expressed by the Governing Board.

Articles

One. The R&D+i Activities Ethics Committee.

1.1. The Ethics Committee for Research, hereinafter referred to as the "Ethics Committee", is the collegiate body of the Technical University of Madrid (Universidad Politécnica de Madrid: UPM) in charge of assessing the ethical aspects of research. Proposals for research activities that involve any of the following must be submitted to the Committee for its assessment:

- use of humans or of human samples,
- obtaining and processing personal data that may affect fundamental rights,
- animal testing, the use of chemical or biological agents or radioactive substances and sources of radiation as well as genetically modified organisms,

in accordance with the provisions of current legislation, or in any other scientific field in which ethical issues arise.

1.2. In its activity, the Ethics Committee shall, at all times, comply with current legislation, with the recommendations and declarations of both national and international bodies and with internationally acknowledged scientific protocols.

1.3. The Ethics Committee will have the administrative and operational support of the Vicerector's office responsible for research matters, being independent in its operation and decisions.

Two.- Duties of the Ethics Committee

The Ethics Committee shall have the following duties:

2.1. Issue reports requested by institutions and researchers on the proposals for research activities and projects to be executed in full or in part by UPM staff, at the facilities or using equipment or data belonging to UPM, including Foundations with delegated management (understanding that entities with their own legal personality will be responsible for any infringements committed, as well as for the penalties that, where appropriate, may arise from non-compliance with the applicable legislation), or by researchers thereof, including, but not limited to, those obtained in public competitive processes, such as UPM's own R&D+i Programme, or projects contracted for with public or private entities, when the activity contained in the proposal is registered in an area that requires the evaluation of its ethical implications, such as, inter alia, the following:

- Research with Humans or Human Samples Area.
- Personal Data Privacy Area.
- Animal Testing Area.
- Research with Genetically Modified Organisms Area.
- Biological Agents Area.
- Chemical Agents Area.
- Radioactive Substances and Radiation Sources Area.
- Environmental Risks Area.

2.2. Understand the intended use of the results of the activities proposed by researchers, research groups, R&D+i University Centres and Institutes, UPM Departments and Schools.

2.3. Notify, where appropriate, the manuscripts or academic works that are to be published, provided that the activity described has been previously approved by the Committee.

2.4. Advise the Governing Board of UPM on the implementation or transposition of regional, national or community regulations that UPM is required to adopt in relation to the ethical control of R&D+i activities.

2.5. Study reports submitted by any member of the university community regarding possible irregularities in the research activity.

2.6. Serve as a communication channel with other ethics committees established in the public system or with public, regional, national and international authorities.

2.7. Any other applicable duties set forth in current legislation.

Three.- Composition of the Ethics Committee

3.1. The Ethics Committee will be made up of its president, secretary and at least two members for each of the main areas of activity. At least the eight set forth in article 2.1 will be included as areas of activity, notwithstanding the possibility of adding new areas if the progress of the activities so requires.

3.2. The Committee, represented by its Chairman, may propose the appointment of members for new areas of activity under the terms set forth in this article.

3.3. The Committee may be made up of doctors with a permanent affiliation to and full-time employment at UPM, of recognised prestige in the area of activity, who have at least two lines of research recognised by CNEAI and have not been warned or sanctioned for non-compliance with ethical duties in research. The composition of the Committee will respect the principles of equality and non-discrimination set forth in Organic Law 3/2007, of 22 March, for genuine equality between women and men. A member of the Administration and Services Staff with recognised experience in their area of activity may also be appointed.

3.4. The chairmanship of the Committee will fall to the competent Vice-rector in research matters.

3.5. The secretary of the Committee shall be the competent Deputy Vice-rector in research matters, who will have a voice but no vote.

3.6. The appointment and dismissal of Committee members is the responsibility of the Rector, on the initiative of the Governing Board.

3.7. Appointments will be for four-year terms, renewable for other four years. Every four years, at least one member of each area of activity of the Committee might be renewed.

Four.- Members of the Ethics Committee

4.1. Committee members participate on their own responsibility and with complete independence, impartiality and objectivity.

4.2. Committee members shall not be made aware of and shall not take part in the deliberation and decision making processes for matters in which they have a direct interest or by which they are directly affected, or where their independence, impartiality or objective judgement could be compromised, in accordance with the provisions of Law 40/2015, of 1 October, on the Legal Regime applicable to the Public Sector.

4.3. Committee members shall be obliged to keep secret any matters submitted to them on a confidential or restricted basis.

4.4. Committee members may not claim to represent the Committee, as that is the exclusive responsibility of its Chairman.

Five. The Chairman

5.1. The Chairman of the Committee shall:

- a) Represent the Committee.
- b) Summon the other Committee members to ordinary or extraordinary sessions and set the agenda in accordance with the provisions of these regulations.
- c) Preside over the meetings, moderate the deliberations and decide on the cancellation, continuation and conclusion thereof.
- d) Endorse the minutes and certifications of the reports, expert opinions and recommendations adopted by the Committee.
- e) Propose changes to the Regulations for their approval by the Governing Board, when appropriate.
- f) Make suggestions to the Research Commission on ethical matters or issues regarding scientific or technical research that, due to their relevance or timeliness, should be submitted to the Committee for consideration.
- g) Exercise their powers as Committee member.

5.2. In case of vacancy, absence or illness, the Chairman will be replaced by the highest ranking, most senior or oldest member, in that order.

Six.- Committee Secretary

6.1. The Secretary shall:

- a) Take part in Committee meetings with a voice but no vote.
- b) Execute the necessary summons and notifications, including calling for the Committee.
- c) Receive notifications, applications, data requests, rectifications or any other activities, writings or communications addressed to the Committee.
- d) Prepare Committee meetings.
- e) Write up and authorise the meeting minutes.
- f) Issue certifications of the reports, expert opinions and recommendations adopted by the Committee.
- g) Safekeep the minutes and other Committee documents.
- h) Prepare an annual report on Committee activities and communicate it to the members of the Governing Board.

- i) Provide administrative support to the Committee in combination with the Vicerectorate with research competencies.

6.2. In case of vacancy, absence or illness, the Secretary will be replaced by the lowest ranking, least senior and youngest member, in this order.

Seven.- Calls, Sessions and Agreements

7.1. Ordinary Committee meetings will be held twice a year. Its members will be summoned at least 7 days in advance, with a detailed agenda and information on the matters to be discussed. No member of the Committee may delegate his or her functions or be substituted at Committee meetings.

7.2. The Committee may be called on an extraordinary basis with at least 2 days' notice, on the initiative of its Chairman or at the request of a third of its members.

7.3. For the constitution of the plenary session of the Committee, at least half plus one of its members must be present. Decisions will be taken by simple majority. Proxy votes will not be accepted. The vote may be secret at the request of any of its members.

7.4. To report on any specific aspect or matter on the agenda, specialists of renowned prestige may appear before the Committee, at its request, and will be subject to the principle of confidentiality.

7.5. The Committee may meet, call and hold its meetings, adopt resolutions and send minutes both in person and remotely. In the case of meetings held remotely, its members may be in several different places, provided that electronic means - which may include the telephone and audiovisual means - provide certainty regarding the identity of the members, the content of their statements and the time when they occur, and also the interactivity and intercommunication between them in real time and the availability of the means during the session. Among others, e-mail, audio conferences and video conferences are regarded as valid means.

Eight.- Minutes

8.1. The minutes of each session will be drawn up by the Secretary stating the attendees, the meeting agenda, the time at which and the place where it is held, the progress of the deliberations, the specific statements of the members who wish them to be recorded and the content of the agreements adopted.

8.2. If there is a disagreement regarding the resolutions adopted, the members may lodge a private vote in writing within two days of the adoption of the resolution. Any particular votes lodged will be included in the text thereof.

8.3. The minutes will be approved at the following session, although the Secretary may issue a certificate of the specific resolutions that have been adopted before their approval and subject thereto.

Nine.- Commissions, presentations, working groups and external collaboration

9.1. The Committee may set up Commissions to delegate the execution of assessments for each area of activity when the number, deadlines or nature of the reports to be executed so require. These Commissions will be attended by the Chairman, the Secretary and at least two members of the area of activity or related thereto.

9.2. The Commissions will submit the reports to the Committee for their approval, by the means they deem appropriate as long as there is evidence thereof. The report shall be endorsed by a simple majority of the Committee.

9.3. On the initiative of any of its members, the Committee may agree to the constitution of subcommittees or working groups for the study or preparation of the matters on which it is to reach a decision.

9.4. On the initiative of any of its members and taking the budgetary, administrative and resource limitations established by the Research Commission into account, the Committee may request a report from, or the collaboration of, experts or external committees, individually or by creating working groups with a specific purpose.

9.5. The members of the UPM university community shall comply with the requirements of the Committee.

Ten.- Presenting assessments

10.1. The Committee may require prior notice regarding the intention to present projects that require a mandatory report from the Committee with the deadline that is set for such a purpose.

10.2. The Vice-rector's office with responsibility for research shall publish the forms for each area of action on the UPM website and shall provide the means for electronic communication of the documentation requested.

10.3. The main researcher of a project that requires a report from the Committee shall submit, before the set deadline, the assessment request forms along with the documentation of the project or research that the Committee requires for its assessment. In any event, the main researcher shall submit a copy of the application forms through the UPM General Registry in order to start the assessment process.

10.4. The Committee has the authority to request from the main researcher of a project under assessment any additional information it deems necessary to execute its duties.

Eleven.- Rating of the works subject to assessment by the Committee

11.1. The Committee will rate the activities submitted for its assessment by means of a report giving one of the following assessments:

- a) Favourable, as a result of a positive assessment of the ethical aspects of the activity.
- b) Favourable, conditional on the correction of formal defects or provision of additional documentation before a deadline. The Committee will request the main researcher to

correct the defect or provide documentation, and once this is complied with, it will issue a final favourable or unfavourable report.

- c) Unfavourable, when the Committee considers the ethical standards in research have not been met, or where it is not possible to establish their compliance with a guarantee. The issuance of an unfavourable report shall be justified.

11.2. The Committee's decisions will be notified to the relevant researcher with acknowledgement of receipt, and to the Vice-rector's office with responsibility for research. In the event that the assessment of the project suggests risks to people, the reports will additionally be transferred to the Health and Safety Committee.

11.3. An appeal may be lodged with the Rector against the decisions of the Committee within one month, according to the provisions of art. 122 of Law 39/2015, of 1 October, on the Common Administrative Procedure of Public Authorities.

11.4 Any change to the conditions approved by the Committee for carrying out the activities, or the planned use of their results, must be submitted to the Committee for a new evaluation.

Twelve.- Archives and documentation

12.1. The Committee file will be kept in the custody of its Secretary, in the Vice-rector's office with responsibility for.

12.2. The minutes, reports and any other documentation generated by the Committee in any medium shall be kept in this file. The documents shall be kept in a way that guarantees their integrity and authenticity and their accessibility by any Committee member, at least during the time for which the activities subject to evaluation have administrative, legal or technical effects.

Final Provision

This regulation shall enter into force as of its approval by the Governing Board of the UPM and its publication in the BOUPM.