

REGULATION ON THE RESEARCH ETHICS COMMITTEE OF UNIVERSIDAD SAN PABLO-CEU

(Approved by the Standing Committee of the Governing Council on 14/11/2011 and updated by the Standing Committee of the Governing Council on 27/10/2021)

STATEMENT OF PURPOSES

The regulations contained in various research funding calls require that those projects involving research with human subjects, the use of their personal data or biological samples of human origin, animal experimentation or the use of biological agents or genetically modified organisms, in addition to complying with the requirements established in each case by the legislation in force, also have the express authorisation issued by the Research Ethics Committee of the Centre where the research is to be carried out.

Beyond this obligation, Universidad San Pablo-CEU, aware of its responsibility towards society and in a way that is consistent with its humanistic Christian beliefs, has created a Research Ethics Committee, with the aim of providing a fast and effective response to cultural needs, or that the future may set, with regard to scientific research, developed in its field, with the aim of guaranteeing the respect to human beings' dignity, integrity and identity, in order to protect people's fundamental rights, the good treatment of animals used as experimental models and the environment, and to the respect of the principles and commitments made by the scientific community.

Furthermore, Universidad San Pablo-CEU wants to favour Committee's actions, introducing it as the quality criterion in those cases in which regulations in force do not require its favourable report regarding research protocols and projects, as well as expressly allowing, with their endorsement, the accreditation of research results by the most prestigious scientific societies and the most prestigious publications, which are very rigorous with the protocols followed in research and experimentation.

Article One. Field of competence.

1. The Committee shall perform its functions in general with respect to all Research Groups, Centres, Research Institutes or Centres belonging to Universidad San Pablo-CEU or in which it participates and those that are or will be attached to the same, as well as with respect to the activities of Researchers linked to any of them.
2. The studies referred to in Article 2(1) shall be submitted for a report.
3. The Vice-Rectorate for Teaching and Research may request a report on the research conventions and/or agreements held with institutions or companies that may, because of their subject matter, have ethical implications.
4. All individual research projects that are subject to the Committee's report and which obtain a favourable result shall receive the corresponding accrediting document for the purposes of dissemination and publication.

Article Second. Functions of the Committee

The Research Ethics Committee of Universidad San Pablo-CEU is responsible for the following functions:

1. To issue the reports requested by institutions and researchers on research works and projects that involve studies with human beings, the use of their personal data or biological samples of human origin, animal experimentation or the use of biological agents, chemical or genetically modified organisms, or that affect the environment, human beings, or animals.
2. To draft reports for the governing bodies of the University on ethical problems related to the matter highlighted in the previous section, that research and teaching may CAUSE. The Professor responsible for the disciplines in which trials carried out on animals alive or their tissues, shall attach to the application addressed to the Committee, all information required and necessary for their evaluation.
3. To promote the debate with university community on bioethical matters of general/common interest.
4. To disclose publicly the ethical implications of scientific advances and their applications and to offer specific information to understand their scope and potential consequences.
5. Any other functions attributed to legislation in force.

Article Three. Composition and appointments

1. The Committee is presided by the Vice-Rector for Teaching and Research and consists of working subcommittees. Each of them will consist of at least three speakers belonging to the University Professors' Senate, as well as the technicians established by regulation. In any case, the Committee will have an expert in legal matters.
2. Working Subcommittees are the following:
 - A. The Subcommittee on Biosafety and Environmental Safety, which will be attended by the Head of the Health and Occupational Risk Prevention Service.
 - B. The Subcommittee on Animal Welfare, which will be attended by a specialist on animal welfare.
 - C. The Subcommittee on Human Samples and Clinical and Human Trials, which will be attended by an expert in data protection.
 - D. The Subcommittee in Social Sciences and Humanities, which will be attended by an expert in data protection.
3. The Vice-Rector for Reaching and Research, will be in charge of the appointment and dismissal of the Committee members, as well as the appointment of whoever must exercise the functions of the Secretary, responsible for taking minutes of the sessions and issuing the corresponding certificates of the adopted agreements. For this purpose, the Vice-Rector will inform the Governing Council. Furthermore, the Committee has a Standing Committee of at least 3 members, appointed by the Vice-Rector for Teaching and Research.

4. The members of the Committee will be appointed for a two-year period, renewable for equal periods and they shall be completely independent in the performance of their duties.
5. The committee may have several advisory councils to produce non-binding reports. These boards shall be chaired by a member of the Commission and composed of experts appointed by the Commission.
6. Should it be necessary to set up further subcommittees or to terminate an existing subcommittee, the Chairperson is empowered to make the proposal and inform the Standing Committee of the Governing Council.

Article Four. General rules for its functioning

1. The functioning of the Committee will be subject to what has been set out by this Regulation.
2. The President shall convene the Committee as often as may be required for its proper functioning and the matters before it and on which it is called upon to take a decision. The members of the Committee may be notified by e-mail.
3. The Committee will normally work through Subcommittees, reserving the work in Plenary to those matters which, in the judgement of the Chairman, the members of the Committee or the requesting researcher, so require. The Subcommittees will carry out as many functions as they are entrusted by the Plenary. In any case, the Plenary may hear any case.
4. For the constitution of the Committee's Plenary, the attendance of the President or the person to whom he/she delegates and at least half of its members, shall attend. The decisions taken within the Committee and Subcommittees shall be approved by the simple majority. In the event of an even result, the President will have the quality vote.
5. The members of the Committee will be obliged by the principle of confidentiality, both for debates and reports.
6. The members of the Committee shall abstain from proceedings that affect the projects in which they participate as researchers, as well as from the rest of the cases in which a conflict of interests may arise.
7. When the Committee considers appropriate, it may ask for the opinion of external experts, who will also be subject to the principle of confidentiality.
8. The Committee is responsible for requesting from researchers a project under evaluation any additional information it deems necessary.
9. Researchers affected by the Committee's decisions shall be informed of them by the Secretary of each Subcommittee, through the technical secretary's office.
10. Before the end of each academic year, the Research Ethics Committee shall submit to the Governing Council a report on the activities carried out during the academic year.

Article Five. Submission of projects

The documentation of the projects or research requiring a report from this Committee must be submitted to its official headquarters at the University's Vice-Rectorate for Teaching and Research, enclosing, duly filled in, a copy of the relevant forms. In the event that the project is

to be submitted to a call for public funding, all the documentation must be submitted at least 15 working days before the deadline of the call for proposals.

The documentation submitted to the headquarters of the Committee shall be reviewed and kept in safe custody in accordance with the provisions of Article 7.

Article Six. Qualification of projects or research work subject to the Committee's report

The research projects or works subject to report of the Committee, once the documentation submitted has been examined, will be qualified in any of the following manners:

- a) By favourable report.
- b) By favourable report conditioned to the correction of formal defects or to the provision of additional documentation expressly requested.
- c) By pending resolution.
- d) By unfavourable report.

2. The positive evaluation of the ethical aspects involved in the research project or work will determine the issuance of the corresponding favourable report, which will be certified according to the model elaborated and approved by the Committee.

3. When the research project or work is evaluated positively, subject to the correction of any formal defect or the provision of any additional documentation accrediting compliance with the requirements for this purpose, a conditional favourable report shall be issued. In this case, the Committee shall request the rectification of such defect or the additional documentation from the person in charge of research, in accordance with the model drawn up and approved by the Committee. The strict fulfilment of the request, which shall be verified by the Secretary of each Subcommittee, with the approval of its Chairman, shall have the effects foreseen in the previous section. The decisions adopted shall be reported to the plenary session of the Committee at its immediately following meeting.

4. When the Committee observes in the submitted documentation the lack of the date whose content is relevant to evaluate positively or negatively the research project or work, he/she will classify it as pending resolution and will ask the researcher-in-charge for the pertinent explanations and clarifications. Once such clarifications or explanations have been received, the decision shall be submitted to the Committee at its immediately following meeting.

5. The issuance of the unfavourable report shall be justified in all cases.

6. All reports shall be sent with proof of receipt.

Article Seven. Archive and documentation.

1. The archives of the Committee shall be kept in the custody of the Technical Secretariat of the Committee.

In this archive, the originals of the Minutes, a copy of all reports, as well as any other documentation generated in the reporting and evaluation process shall be kept.

This archive may be consulted by any member of the Committee.

2. To facilitate archiving and documentation, all projects shall be assigned an identification register. This register shall consist of a section indicating the meeting of the Ethics Committee at which it was reported, followed by a number corresponding to the project number assessed by this Committee and an alphabetical code indicating the type of call to which the project is submitted.

Article Eight. Administrative support and dissemination

The Committee shall have administrative support for its proper functioning and sufficient means for the creation and maintenance of a website. It shall also have the right to use all the means that are suitable for the dissemination of its activity and for agile communication, which facilitates information to the university community on the issues within its remit, as well as links with other Committees with similar functions. To this end, it shall also be assigned an e-mail address.

FINAL PROVISION

This regulation shall be of application the day after its approval by the Standing Committee of the Governing Council of the University.