



REGULATION 9/2025 OF THE RESEARCH ETHICS COMMITTEE OF UNIVERSIDAD SAN PABLO- CEU

Approved by the Governing Council at its meeting on November 26, 2025

**REGULATION 9/2025 OF THE RESEARCH ETHICS COMMITTEE OF UNIVERSIDAD
SAN PABLO-CEU****STATEMENT OF REASONS**

The regulations contained in various calls for research funding require that projects involving research with human beings, 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 current legislation, also have the express authorization issued by the Research Ethics Committee of the Center where the research is to be carried out.

Beyond this obligation, Universidad San Pablo-CEU, aware of its responsibility to society and in line with its Christian humanistic aspirations, has set up a Research Ethics Committee in order to provide a swift and effective response to current and future needs with regard to scientific research carried out within its sphere, with the aim of guaranteeing respect for the dignity, integrity, and identity of human beings, in order to protect the fundamental rights of individuals, the proper treatment of animals used as experimental models and the environment, and respect for the principles and commitments assumed by the scientific community.

Likewise, Universidad San Pablo-CEU wishes to promote the work of the Committee by presenting it as a quality criterion in those cases where current regulations do not require its favorable report on research protocols and projects, thus expressly allowing, with its endorsement, the accreditation of research results before the most prestigious scientific societies and publications, which are very rigorous with the protocols followed in research and experimentation.

Article One. Scope of competence

1. The Committee shall perform its functions in general with respect to all Research Groups, Institutes, or Centers belonging to Universidad San Pablo-CEU or in which it participates, and those that are affiliated or become affiliated with it, as well as with respect to the activities of researchers linked to any of them.
2. The studies referred to in section 1 of article two shall be submitted for review.
3. The Vice-Rectorate for Teaching Staff and Research may request a report on research agreements and/or contracts entered into with institutions or companies which, due to their subject matter, may have ethical implications.
4. All individual research projects submitted to the Committee for review and receiving a favorable outcome shall receive the corresponding supporting document for the purposes of dissemination and publication.

Article 2. Functions of the Committee

The Research Ethics Committee of Universidad San Pablo-CEU has the following functions:

1. To issue reports requested by institutions and researchers on research projects or work involving studies with human beings, the use of their personal data or biological samples of human origin, animal experimentation or the use of biological agents, chemicals or genetically modified organisms, or which affect the environment, humans or animals.
2. To prepare reports for the University's governing bodies on ethical issues related to the aspects mentioned in the previous section, which may arise in research and teaching. The professor responsible for the disciplines in which practices with live animals or their tissues are carried out must attach all the information required and necessary for its assessment to the application addressed to the Committee.
3. Promote debate within the university community on bioethical issues of general interest.
4. Publicly disseminate the ethical implications of scientific advances and their applications and provide accurate information to understand their scope and possible consequences.
5. Any other functions assigned to it by current legislation.

Article Three. Composition and appointments

1. The Committee is chaired by the Vice-Rector for Teaching Staff and Research and is divided into working subcommittees, each of which is composed of at least three members from the University's faculty, as well as technical staff as determined. In all cases, the Committee shall include an expert in legal matters.
2. The working subcommittees are as follows:
 - A. **Subcommittee on Biosafety and Environmental Safety**, which will include the Head of the Health and Occupational Risk Prevention Service.
 - B. **Animal Welfare Subcommittee**, which will include an animal welfare specialist.
 - C. **Subcommittee on Human Samples and Clinical Trials and Human Trials**, which will include an expert in data protection.
 - D. **Subcommittee on Social Sciences and Humanities**, which will include an expert in data protection.
3. The appointment and dismissal of Committee members, as well as the designation of the person who will act as Secretary, responsible for taking the minutes of the meetings and issuing the corresponding certificates of the agreements adopted, is the responsibility of the Vice-Rector for Teaching Staff and Research, who will report to the Governing Council. In addition, the Committee has a Standing Committee of at least three members appointed by the Vice-Rector

for Teaching Staff and Research.

4. The members of the Committee shall be appointed for a term of two years, renewable for equal periods, and shall perform their duties with complete independence.
5. The Committee may have various advisory councils for the preparation of non-binding reports. These councils shall be chaired by a member of the Commission and composed of experts appointed by it.
6. If it becomes necessary to create other subcommittees or to dissolve any of the existing ones, the President is empowered to make the proposal and inform the Standing Committee of the Governing Council.

Article Four. General operating rules

1. The functioning of the Committee is subject to the provisions of these Regulations.
2. The Chair shall convene the Committee as often as necessary for its proper functioning and to deal with matters that it needs to consider and decide on. Notification to Committee members may be made by email.
3. The Committee shall normally work through the Subcommittees, reserving plenary work for those matters which, in the opinion of the President, the members of the Committee, or the requesting researcher, so require.

The Subcommittees shall perform whatever functions are delegated to them by the Plenary. In any case, the Plenary may take over the consideration of any matter.

4. The presence of the Chair, or the person delegated by him/her, and at least half of the members shall be required for the Committee to constitute a plenary session. Decisions within the Committee and the Subcommittees shall be taken by simple majority. In the event of a tie, the Chair shall have the casting vote.
5. The members of the Committee are bound by the principle of confidentiality, both in terms of debates and reports.
6. Committee members must abstain from proceedings affecting projects in which they participate as researchers, as well as in all other cases where a conflict of interest may arise.
7. When the Committee deems it appropriate, it may seek the opinion of external experts, who shall also be subject to the principle of confidentiality.
8. The Committee has the authority to request any additional information it deems necessary from the researchers involved in a project under evaluation.

9. The researchers affected by the Committee's decisions shall be informed of these by the Secretary of each Subcommittee, through the Technical Secretary's Office¹.
10. Before the end of each academic year, the Research Ethics Committee shall submit a report or memorandum on the activities carried out during the year to the Governing Council.

Article Five. Submission of projects

The documentation for projects or research requiring a report from this Committee must be submitted to its official headquarters at the Vice-Rectorate for Teaching Staff and Research of the University, attaching a duly completed copy of the appropriate forms. If the project is to be submitted for public funding, all documentation must be submitted at least 15 working days before the closing date of the call for proposals²

The documentation submitted to the Committee's headquarters will be reviewed and kept in accordance with the provisions of Article 7.

Article 6. Evaluation of projects or research work subject to the Committee's report

1. Once the documentation submitted has been examined, the projects or research work submitted to the Committee for review will be rated in one of the following ways:
 - a) With a favorable report.
 - b) With a favorable report conditional upon the correction of formal defects or the provision of additional documentation expressly requested.
 - c) Pending resolution.
 - d) With an unfavorable report.
2. A positive evaluation of the ethical aspects involved in the research project or work will determine the issuance of the corresponding favorable report, which will be certified according to the model developed 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 additional documentation proving compliance with the requirements for this purpose, a conditional favorable report will be issued. In this case, the

¹ In the case of studies evaluated by the Human Samples and Clinical Trials and Human Studies and Social Sciences and Humanities subcommittees, researchers will be informed via digital notification.

² The first reviews of a project take approximately two weeks, while subsequent reviews (if necessary) will require at least one additional week. Therefore, it is recommended, especially in the case of projects submitted to calls with a closing date, to submit the documentation at least one month in advance.

Committee will request the correction of such defect or the provision of supplementary documentation from the person responsible for the research, according to the model developed and approved by the Committee. Strict compliance with the request, which will be verified by the Secretary of each Subcommittee with the approval of its Chair, will have the effects set out in the previous section. The decisions taken will be reported to the Committee Plenary at its next meeting.

4. When the Committee observes in the documentation submitted the absence of data whose content is relevant to the positive or negative evaluation of the research project or work in question, it shall classify it as pending resolution and request the relevant clarifications or details from the researcher responsible. Once such clarifications or details have been received, the decision shall be submitted to the Committee at its next meeting.
5. The issuance of an unfavorable report must be justified in all cases.
6. All reports shall be sent with acknowledgment of receipt.

Article Seven. Filing and documentation

1. The Committee's archives shall be kept by the Technical Secretary's Office of the Committee³.

This archive shall contain the originals of the minutes, a copy of all reports, and any other documentation generated in the information and evaluation process. This archive may be consulted by any member of the Committee.

2. To facilitate archiving and documentation, all projects will be assigned an identification number. This number will 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 evaluated by this Committee and an alphabetical code indicating the type of call for proposals to which the project is submitted.

Article Eight. Administrative support and dissemination

The Committee shall have administrative support for its proper functioning and sufficient resources for the creation and maintenance of a website. It shall also have access to all appropriate means for the dissemination of its activities and for efficient communication, facilitating the provision of information to the university community on matters within its competence, as well as links with other committees with similar functions. To this end, it shall also be assigned an email address.

³ and by the secretaries of the various subcommittees.

REPEAL

Any other provision or regulation of equal or lower rank that conflicts with the provisions of these Regulations is hereby repealed, in particular the Regulations of the Research Ethics Committee of Universidad San Pablo-CEU, approved by the Standing Committee of the Governing Council on November 14, 2011.

FINAL PROVISION

These Regulations shall enter into force on the day following their approval by the University Governing Council.