

**LIST OF DOCUMENTS TO BE SENT TO THE TECHNICAL SCIENTIFIC SECRETARY'S OFFICE TO ASK
FOR OPINIONS FROM THE UNICAMILLUS ETHICS COMMITTEE**

The documentation must be sent via certified electronic mail (PEC) to the following address:
comitato.etico@pec.it

Useful contacts

Tel. (+39) 06 400 640

Fax (+39) 06 22 541 19 20

E-mail: comitato.etico@unicamillus.org

Head of Committee's Secretary's Office

Mrs Laura Ligi

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Documents to be presented to ask for opinions

1) Letter of Intent, addressed to the Rector of UniCamillus and the Chairperson of the Ethics Committee, containing:

- A) study/research identification data, including acronyms, if any;
- B) indication of the type of study/research;
- C) name of the study/research manager with affiliation;
- D) identification data of the promoter/funding body of the study/research.

2) Documents to be attached to the Letter of Intent:

- A) study/research protocol with date;
- B) protocol summary sheet with date and timeline;

- C) indication of the centres involved and their local contact persons in the case of a multi-centre study. If the trial takes place in public/private healthcare facilities, prior authorisation of the healthcare management is required in the case of non-routine clinical procedures;
- D) patient information forms on the type of study/research and informed consent with date, including authorisation for any subsequent use of data and/or images from the study/research for publicity purposes;
- E) personal data processing information form with date;
- F) curriculum vitae of the researcher in charge of the study/research with indication of publications relevant to the proposed study;
- G) declaration certifying that the investigator and their family members have no interest in the outcome of the study (financial disclosure);
- H) power of attorney to act on behalf of the promoter where the promoter is not the same as the applicant;
- I) proof of payment of the financial charges relating to the evaluation on the part of the UniCamillus Ethics Committee, including invoicing details;
- J) declaration that insurance coverage has been taken out to ensure financial protection for all parties participating in the study/research, including sponsors, involved entities and volunteer patients;
- K) declaration stating, where applicable, any compensation or indemnity for healthy volunteers;
- L) declaration stating that the opinion expressed by the University Ethics Committee is not a substitute for any mandatory opinions required by law.

Please note:

The Ethics Committee must be informed of the conclusion of the study/research, even when it is completed according to the indicated timetable (last follow-up of the last patient enrolled) and not only in the event of suspension, interruption or early termination.

In the event that a conflict-of-interest situation arises, or it becomes known that there are causes of conflict of interest that have not been declared by the parties concerned, it is necessary to discontinue the study/research and evaluate it again.

Economic Aspects

TYPE OF EVALUATION	AMOUNT IN EURO
Trial Evaluation with Expression of Single Opinion	€ 3,000
Trial Evaluation	€ 2,500
Evaluation of a prospective observational study	€ 2,000
Evaluation of substantive amendments	€ 1,000
Evaluation of non-substantial amendments and bioequivalence studies	€ 500

The Ethics Committee do not charge any fees for the evaluation of clinical trials, amendments or others by non-profit promoters, as per Ministerial Decree of 17 December 2004.

Requests for opinions from the Ethics Committee submitted by UniCamillus employees are not subject to any fee, except in cases where funding has been found for the research project.

Ethics Committee Invoicing Information

The amount must be paid by bank transfer to the IBAN code provided by the Administration Office following an explicit request to be sent to amministrazione@unicamillus.org