



UNICAMILLUS

ETHICS COMMITTEE REGULATIONS

Approved by the Technical Organisation Committee of 17-09-2019
Rev-1 resolution of the Technical Organisation Committee of 30-03-2023

ETHICS COMMITTEE REGULATIONS, UNICAMILLUS – SAINT CAMILLUS INTERNATIONAL UNIVERSITY OF HEALTH AND MEDICAL SCIENCES

Art. 1 Institution

The Ethics Committee is an independent body at UniCamillus – Saint Camillus International University of Health And Medical Sciences (from now on called “UniCamillus”), in accordance with current ethics committee regulations.

Art. 2 Roles in clinical trials

2.1 The roles of the Ethics Committee are as follows :

- 1) The Committee will provide opinions regarding ethical matters related to the scientific and care activities linked to UniCamillus or requested by UniCamillus in order to protect and promote the value of every human being. Actors as well as members of the Ethics Committee are entitled to request ethical opinions to the Committee. The Ethics Committee is required to issue a written opinion within a month on the requests submitted to its President.
- 2) The Committee will organize seminars and meetings in order to share information about bioethics, also for the general public.

Art. 3 Other roles

3.1 The Ethics Committee protects the rights, the health and safety of those involved in clinical trials.

The Ethics Committee protects those involved in clinical trials through the following steps:

- test
- evaluation
- approval
- monitoring
- review of clinical trial protocols

in addition to all the other steps in accordance with the current regulations.

Art.4 Structure and length

4.1 The Ethics Committee is formed by internal and external members of UniCamillus, appointed on the basis of professional, documented knowledge and experience criteria, necessary to evaluate the ethical, scientific and methodological aspects of the trial.

4.2 The Ethics Committee must be formed by at least three members, all of whom are appointed by the Principal. The members will subsequently appoint a President and a Vice-President. The members are in office for three years and can be re-elected only once.

4.3 If a member of the Committee does not attend a meeting for three times in a row, or at least 50% of the meetings in a year without justification, they will be deprived of their office by the board that appointed them.

4.4 In case of resignation, withdrawal of the office, permanent impediment or death of one or more members of the Committee, the President will ask the Principal for a substitution, in order to guarantee the functionality and continuity of the Committee.

In case of resignation, or end of office of the majority of the members, the whole Committee will be forfeited and the Principal will appoint a new one.

4.5 All the members of the Committee are bound to secrecy of the documents linked to their activity.

4.6 Where appropriate, the Committee may ask external experts in case a specific topic is not covered by any member of the Committee.

4.7 The Committee will have an internal set of rules approved by the majority of the members. In case of amendment of the regulations, the proposal must be presented during one of the Committee meetings and approved in the following meetings.

4.8 The Committee is assisted by a scientific and technical office. Its manager will operate as Secretary of the Committee.

4.9 Members of the Committee are honorary, however they receive a reimbursement of the expenses that may be substituted with an attendance fee.

Art.5 Independence of the Committee

5.1 The Independence of the Ethics Committee is guaranteed by the following features:

- presence of personnel not employed by the company where it operates;
- absence of hierarchical relations with other Ethics Committees;

- absence of hierarchical subordination of the Committee towards UniCamillus;
- absence of conflict of interest between the members and the clinical trial proposed;
- absence of economic interest between the members of the Committee and the pharmaceutical companies that require the clinical trials.

Art.6 Operation of the Committee

6.1 The Ethics Committee's meeting is convened by its President at least twice a year. Other meetings can be convened by the President or by at least half of the members of the Committee when needed. The meeting will be notified via fax or e-mail to all the members by the Secretary Office at least 5 (five) days prior to the meeting, with information about the agenda and documentation.

In case of emergency, the meeting might be notified at least 2 (two) days before the date.

6.2 Every point of the agenda is introduced by the President. It is the duty of the President to appoint a speaker that will introduce the members of the Committee to the agenda.

After the introduction, the members discuss the topic introduced. Following the discussion, the Committee votes on the subject.

6.3 The Committee can state their opinion in three different ways:

- vote in favour (-in favour; -in favour with recommendations; -in favour with request of modifications before the beginning of the trial with or without an additional evaluation by the Committee)
- vote in favour with condition in order to request a draft or an integration (the trial is sent back to the researcher and/or the sponsor, with an additional request for further information necessary for the final vote on the subject)
- opinion pending, the evaluation of the trial gets rescheduled for the next meeting
- vote not in favour

6.4 Each meeting has a written report, which is signed by the President and the Secretary.

Art.7 Incompatibility and abstaining from voting

7.1 Those members who are directly or indirectly involved in the clinical trial under examination shall abstain from voting. The Ethics Committee will detect possible incompatibilities at the

beginning of each meeting. In case one or more members are incompatible, decisions are taken by the majority of the remaining members.

Art.8 Final and postponement rules

8.1 For each matter not present in this regulation, reference is made to the current laws regarding Ethics Committees and clinical trials.

8.2 The Committee does not fulfill the tasks that are exclusive to Ethics Committees by law. Therefore, the opinions expressed by the Committee cannot substitute those established by the law on the aforementioned subject.