



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.



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;

