UNICAMILLUS

LISTS OF DOCUMENTS TO BE SUBMITTED TO THE TECHNICAL SCIENTIFIC SECRETARIAT TO REQUEST AN OPINION BY THE UNICAMILLUS ETHICS COMMITTEE

The documentation must be sent in duplicate copies: 1 electronic and 1 in paper form to the following address:

Technical Scientific Secretariat – Ethics Committee
UniCamillus – Saint Camillus International University of Health Sciences
Via di Sant'Alessandro, 8
00131 Roma
The Technical Scientific Committee assesses the completeness and the suitability of the documentation.

Contact and numbers
Tel. (+39) 06 400 640
Fax)+39) 06.22541-1920
E-mail: comitato.etico@unicamillus.org

Ethics Committee Secretariat's Head
Mrs. Laura Ligi
Tel.: 06.40064030
E-mail: laura.ligi@unicamillus.org

A) Documents to be submitted to request an Opinion regarding a Trial on a Drug:

1) Letter of intent with the identification data of the trial and the main conditions for the definition of the agreement between the parties, addressed to the Rector Magnificus of UniCamillus and to the President of the Ethics Committee
2) If the Applicant is not the Promoter of the Trial, a letter which authorizes the Applicant to act on behalf of the Promoter (authorization to the Contact Research Organization – CRO)
3) Letter of Authorization by the Italian Medicines Agency (AIFA)
4) Trial's protocol (with the "cover/first page" requested by the National Observatory on Clinical Trials, OsSC)
5) Eudract number of the trial (when applicable). Copy or summary of possible scientific advices
6) Signed protocol of the study submitted, with the documents that support it, the attachments, and the possible amendments
7) Text in Italian of the protocol of the study, containing a synopsis of the same protocol with a scheme of the diagnostic tests that will be carried out ("flowchart")
8) An appropriate recap of all the pharmacological and toxicological data available on the drug, along with a summary of the up-to-date clinical evidence with the drug; Investigational Medicinal Product Dossier (IMPD); Résumé des Caractéristiques du Produit (RCP) – for products authorized by the European Union and put to use according to AIC (Authorization for the Release on to Market by AIFA), the RCP can substitute the IMPD and the Investigator's Brochure (IB); descriptions of all the current trials ongoing with the same IMP[1]
9) studies on its viral safety (if applicable)

10) Informative letter to the patient/Informed Consent
11) Curriculum Vitae of the main experimenter
12) List of the participating centres
13) Informed consent and explication form for the subjects (patients/volunteers), written in their native language, signed and with the indication of the date
14) Declaration certifying that the experimenter and his/her relatives do not have any economic interest with respect to the outcome of the study (financial disclosure)
15) Insurance certificate in compliance with the attachment to the M.D. 7/14/2009
16) Any other document that the sponsor considers useful for understanding the study
17) Receipt of the payment of the fee due for the assessment by the UniCamillus Ethics Committee, with the data for the invoicing
18) The draft of the economic agreement to be negotiated between the Institution and the Promoter, which must include a budget scheme relative to all the expenses provided for by the protocol (if applicable)
19) The Ethics Committee must be informed in any case of the end of the study, even when it is concluded according to the chronological programme stated (last follow-up of the last patient involved), and not only in case of suspension, interruption, or anticipated conclusion
20) In case a conflict of interests develops, or if reasons for a conflict of interest, not declared by the involved parties, are known, there is the commitment to exclude the Author from the further execution of the Project.

B) Documents to be submitted to request an Opinion regarding a Trial on a Medical Devices:

1) Letter of intent with the identification data of the trial and the primary conditions for the definition of the agreement between the parties, addressed to the Rector Magnificus of UniCamillus and to the President of the Ethics Committee
2) If the Applicant is not the Promoter of the Study, a letter which authorizes the Applicant to act on behalf of the Promoter (authorization to the Contact Research Organization – CRO)
3) Technical data sheet of the medical device/s (if applicable)
4) EC trademark or letter of request to the Ministry of Health for the EC trademark for the medical device/s (if applicable)
5) Complete certificate of insurance with maximum coverage, duration, exclusion from the insurance policy
6) Signed protocol of the trial submitted, with the documents that support it, the attachments and the possible amendments
7) Text in Italian of the trial's protocol, containing a synopsis of the same protocol with a scheme of the diagnostic tests that will be carried out ("flowchart")
8) Curriculum Vitae of the main experimenter
9) Informed consent and explication form for the subjects (patients/volunteers), written in their native language, signed and with the indication of the date
10) Declaration certifying that the experimenter and his/her relatives do not have any economic interest with respect to the outcome of the study (financial disclosure)
11) Integral insurance policy for third party liability (if applicable)
12) Forms for data collection (Case Report Form – CRF)
13) List of the participating centres
14) Any other document that the sponsor considers useful for understanding the study

15) Receipt of the payment of the fee due for the examination by the UniCamillus Ethics Committee, with the data for the invoicing
16) The draft of the economic agreement to be negotiated between the Institution and the Promoter, which must include a budget scheme relative to all the expenses provided for by the protocol (if applicable)
17) The Ethics Committee must be informed in any case of the end of the study, even when it is concluded according to the chronological programme stated (last follow-up of the last patient involved), and not only in case of suspension, interruption, or anticipated conclusion
18) In case a conflict of interests develops, or if reasons for a conflict of interest, not declared by the involved parties, are known, there is the commitment to exclude the Author from the further execution of the Project.

C) Documents to be submitted to request an Opinion regarding an Observational Study

1) Letter of intent with the identification data of the study and the primary conditions for the definition of the agreement between the parties, addressed to the Rector Magnificus of UniCamillus and to the President of the Ethics Committee
2) Letter by the Experimenter in which it is described the normal clinical procedure for the pathology object of the study
3) Declaration by the Promoter on the observational nature of the study
4) If the Applicant is not the Promoter of the Study, a letter which authorizes the Applicant to act on behalf of the Promoter (authorization to the Contact Research Organization – CRO)
5) Signed protocol of the study submitted, with the documents that support it, the attachments and the possible amendments
6) Informed consent and explication form for the subjects (patients/volunteers), written in their native language, signed and with the indication of the date
7) Declaration certifying that the experimenter and his/her relatives do not have any economic interest with respect to the outcome of the study (financial disclosure)
8) Forms for data collection (Case Report Form – CRF), if applicable
9) Bibliography of the study
10) Information on the insurance policy for the risk
11) List of the participating centres
12) Any other document that the sponsor considers useful for understanding the study
13) Receipt of the payment of the fee due for the examination by the UniCamillus Ethics Committee, with the data for the invoicing
14) The draft of the economic agreement to be negotiated between the Institution and the Promoter, which must include a budget scheme relative to all the expenses provided for by the protocol (if applicable)
15) The Ethics Committee must be informed in any case of the end of the study, even when it is concluded according to the chronological programme stated (last follow-up of the last patient involved), and not only in case of suspension, interruption, or anticipated conclusion
16) In case a conflict of interests develops, or if reasons for a conflict of interest, not declared by the involved parties, are known, there is the commitment to exclude the Author from the further execution of the Project.

Financial Aspects

Assessment typology	Fee in Euro
Trial Analysis with expression of a Unique Opinion	Euro 3.000
Trial Analysis	Euro 2.500
Observational Prospective Study Analysis	Euro 2.000
Evaluation of fundamental amendments	Euro 1.000
Evaluation of non-fundamental amendments and analysis of bioequivalence studies	Euro 500

The Ethics Committee does not ask a fee for the analysis of Clinical Trials, Amendments or other requests of evaluations from promoters by the non-profit sector, as in the M.D. of December 17th 2004.
The requests of evaluations to the Ethics Committee by UniCamillus employees are not subject to a fee, apart from the case in which the research project obtained funds.

Invoicing data for the Ethics Committee's fee

The fee must be paid via a bank transfer to this IBAN:

IBAN IT 42 J 05696 03200 000013134X49

BIC/SWIFT : POSO IT 22

BANCA POPOLARE DI SONDRIO

Ag. 11 Esquilino - Via Carlo Alberto, 6/A
00185 Roma RM
Italia
Tel. +39 06 4927151

UniCamillus Bank Account
Fiscal Code 97962900581
VAT 15031161001

In the 'Reason', write: "Ethics Committee for Trial (name of the Trial) and Experimenter (name of the Experimenter)

[1] If the IMP is produced in the EU but it does not have AIC in the EU, provide a copy of the authorization to the production under art. 13 comma 1 of the legislative decree 211/2003 and the Directive 2001/20/EC; if the IMP is not produced in the EU and does not have AIC in the EU, provide the certificate of the person responsible of a Member State, which proves that the production site operates according to standards on Good Manufacturing Practices (GMP) at least equivalent to the standards on Good Manufacturing Practices that are valid in the EU; or provide a certificate that proves that every production lot underwent all the analysis, tests or relevant checks necessary to confirm its quality;