7.3. Request for authorisation of a clinical trial on a medicinal product for human use to the competent authorities and for opinion of the Ethics Committees in the European Union.

Module 1

This first module of the application form to be used to the Ethics Committee is the same as the form used in the submission to the competent authority.

To be found in 'Detailed guidance for the request for authorisation of a clinical trial on a medicinal product for human use to the competent authorities, notification of substantial amendments and declaration of the end of the trial' Annex 1.

Module 2

The second module presented below, is intended to provide detailed information on the planned trial and also on aspect that might be specific for the Member State in case of multi-centre trials. The headings provided below is intended to give guidance on aspects that might be addressed when relevant. It is not intended to be a complete listing of all elements necessary for the Ethics Committee to consider during its work, but to indicate some and give examples that might have to be considered by the Ethics Committee in some Member States.

1. EudraCT trial number Ethics Committee trial ID
2.Title of the project (This should be understandable for laypersons)
3. Summary of the project. (justification and relevance)
4. Results of pre-clinical tests or reasons for not doing pre-clinical tests
5. Primary hypothesis in this trial (if relevant, also secondary hypotheses)
Research ethical considerations (Identify and state any possible problems that might occur. Present possible gain in knowledge to be obtained in the trial and its importance, possible risks for injuries or distress for the participants. Present your own evaluation of the risk-benefit ratio).
Reason for including persons from vulnerable groups, i.e. minors, temporaily or permanently incapacitated subjects.

8. Description of the recruitment procedure (all material to be used should be appended)
Procedure at the site to provide information and obtain consent from the subjects, or parents or legal representatives if applicable (who will give the information and when, need for legal representatives, witness etc).
10. Investigational procedures and any deviations necessary from the routine treatment
Risk assessment, foreseeable risks of treatment and procedures to be used (incl. pain, discomfort, violation of integrity and means to avoid and/or take care of unforeseen / unwanted events)
12. Previous experience of the conduct of similar research procedures at this site.
13. Any foreseeable benefit for included subjects
14. Relation between subject and investigator (patient-physician, student – teacher etc)
15. Procedures of the site to check if the subject participates simultaneously in other research or if a required period has elapsed since previous participation in research (of special importance when healthy subjects are included in pharmacology trials).
16. Requirements and methods for recording health control for healthy subjects (i.e. hospital files or other national requirements)
17. Methods for searching, recording and reporting adverse effects (describe when, by whom and how, i.e. open questions and/or according to lists)
18. Procedures used to protect the privacy of recorded data, source documents and samples (if applicable).
19. Plan for treatment or care after the subject has ended the participation in the trial (who will be responsible and where)
20. Statistical consideration and reasons for the number of subjects to be included in the trial.

21. Amount and procedure for remuneration or compensation of subjects (description of amount paid, during the participation in the trial and for what, i.e. travel cost, loss of earning, pain and discomfort etc) .
22. Rules for stopping or prematurely ending the trial at the site(s) in this Member State or as a whole
23. Agreement on investigator´s access to data, publication policy etc. (if not available in the protocol)
24. Sources of funding (if not available in the protocol) and information on financial or other interests of the investigator(s).

NAME AND SIGNATURE OF APPLICANT - CO-ORDINATING INVESTIGATOR/PRINCIPAL INVESTIGATOR (and/or sponsor, if applicable)	
I hereby confirm that the information given in this application is correct and that I am of the opinion that it will be possible to conduct the trial in accordance with the protocol, national regulations and principles of Good Clinical Practice.	
Name : Surname : Address : Position: :	
Date :	Signature: