

Template No. 31: cover letter to an ECPLO for a substantial amendment

To the Chairman of the Ethics Committee

«Title» «FN» «Name»

«Institute»

«Street»

«City»

«City» «Date»

Concerns: **Request for further participation of the ECPLO for Amendment NR, dated DATE to protocol**

Study protocol NUMBER

EUDRACT NUMBER

Dear «Title» «Name»,

Please find enclosed all trial related documents necessary to apply for an ECPLO further participation opinion concerning the above mentioned trial:

- ✓ Amendment NR, dated VERSION DATE, to the protocol, signed and dated by the coordinating investigator (NUMBER OF COPIES).
- ✓ The Patient Information sheet, Informed Consent Form in LANGUAGE (Dutch and French), version NUMBER, dated VERSION DATE (NUMBER OF COPIES).
- ✓ Amendment to the "Clinical Trial Agreement" of the principal investigator, signed and dated by the investigator.
- ✓ Acknowledgement of receipt by the ECPLO.
- ✓ OTHER DOCUMENTS.

Could you please return by fax (at the following number xx/xxx xx xx) the enclosed acknowledgement of receipt within 3 days as confirmation of the valid receipt of the above mentioned documents by the ECPLO.

For practical purposes, please find enclosed an "ECPLO Review and Approval form" which you are free to use as an example or which can be used as such.

Following the review by the ECPLO, could you please inform the ECPSO on the further participation of your centre at the above mentioned clinical trial within the required timeframe, this is 25 calendar days starting from the day of receipt by the ECPSO.

Please return immediately by fax (fax number XX/XXX XX XX of the Chairman of the ECPSO) and courier to the Chairman of the ECPSO.

Thanking you in advance for your collaboration.

Sincerely yours,

« Title » « Name + coordinates coordinating Investigator »

Contact person of the ECPSO:

Chairman of the ECPSO

"Title First Name and Name"

"Institute"

"Street"

"City"

Tel: « Number »

Fax: « Number »

E-mail: « Address »