

APPLICATION
FOR SUBSTANTIAL AMENDMENT/APPROVAL OF SUBSTANTIAL
AMENDMENT BY THE ETHICS COMMITTEE AT HCS

A. This form is common for application submitted to the central executive body (hereinafter CEB) and for approval from the ethics committee at HCS.

Please indicate the relevant purpose in the box below.

APPLICATION FOR SUBSTANTIAL AMENDMENT:	
APPLICATION FOR APPROVAL OF THE ETHICS COMMITTEE AT HCS:	
NOTIFICATION FOR INFORMATION ONLY: - CENTER - ETHICS COMMITTEE AT HCS	

A1. CLINICAL TRIAL IDENTIFICATION (When the substantial amendment concerns more than one clinical trial protocol for particular investigational medicinal product, clinical trial sponsor can make summary notification to the Center and ethics committee at HCS if cover letter and application contains a list of all protocols of clinical trials related to amendment.)

Full title of the clinical trial:
Clinical trial sponsor's protocol code number, version and date:
EudraCT ¹ number (when available):

EudraCT (European Union Drug Regulating Authorities Clinical Trials) is the European Clinical Trials Database

A2. AMENDMENT IDENTIFICATION

Amendment to clinical trial protocol		If checked, specify sponsor's amendment code number, version and date
Change in initial application for conclusion/approval		If checked, specify sponsor's amendment code number, version and date

B. IDENTIFICATION OF THE CLINICAL TRIAL SPONSOR SUBMITTING THE APPLICATION**B1. Clinical trial sponsor**

Name of legal person/full name of natural person:
Full name of contact person:
Location of legal person/address of natural person:
Telephone number:
Fax number:
e-mail:

B2. Official representative of the clinical trial sponsor in Ukraine to conduct this clinical trial (if different from clinical trial sponsor)

Name of legal person/full name of natural person:
Full name of contact person:
Location of legal person/address of natural person:
Telephone number:
Fax number:
e-mail:

C. APPLICANT IDENTIFICATION (please tick the appropriate box)

C1. Application to the CEB		C2. Application to the ethics committee at HCS	
Clinical trial sponsor		Clinical trial sponsor	
Official representative of the clinical trial sponsor		Official representative of the clinical trial sponsor	

Person or organization authorized by the clinical trial sponsor to submit the application. In that case, complete below: Name of legal person/full name of natural person: Full name of contact person: Location of legal person/address of natural person: Telephone number: Fax number: e-mail:	Person or organization authorized by the clinical trial sponsor to submit the application. In that case, complete below: Name of legal person/full name of natural person: Full name of contact person: Location of legal person/address of natural person: Telephone number: Fax number: e-mail:
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D. TYPE OF AMENDMENT (please tick the appropriate box)

This amendment concerns mainly urgent safety measures already implemented	Yes	No
Reasons for the amendment:		
Amendments related to safety or well-being of trial subjects	Yes	No
Changes in interpretation of scientific documentation/value of the trial	Yes	No
Changes in composition of IMP(s)	Yes	No
Changes in conduct or management of the clinical trial	Yes	No
Change or addition of clinical trial site/principal investigator(s), coordinating investigator	Yes	No
Change of clinical trial sponsor, his official representative, applicant	Yes	No
Change in distribution of main responsibilities at conducting the clinical trial	Yes	No
If "yes", specify:		
Other change	Yes	No
If "yes", specify:		
Other case	Yes	No
If "yes", specify:		
Content of the amendment:		
Changes in information in the application form	Yes	No
Amendments to clinical trial protocol	Yes	No
Change to other documents	Yes	No
If "yes", specify:		
Other case	Yes	No

If “yes”, specify:

E. REASONS FOR AMENDMENTS (abridged form)

F. BRIEF DESCRIPTION OF AMENDMENTS

G. LIST OF DOCUMENTS ATTACHED TO THE APPLICATION FORM

Please submit only documents related to this application and/or (when applicable) make clear references to other documents already submitted. Make clear references to any changes of separate pages numeration and submit original and new texts. Tick the appropriate box(es).

	Cover letter stating the type of amendment and the reason(s)
	Summary of the proposed amendment
	List of amended documents (identification, version, date)
	Pages with original and new wording (if applicable)
	Additional information
	Revised <i>Word</i> file and copy of initial application form with amended data highlighted (when applicable)

SIGNATURE AND NAME OF THE APPLICANT

I, the undersigned, hereby confirm (on behalf of the clinical trial sponsor) that (delete which is not applicable):

the above information given in this application is correct;

the clinical trial will be conducted according to the clinical trial protocol, legislation and principles of Good Clinical Practice (GCP);

it is reasonable for the proposed amendment to be undertaken.

APPLICANT submitting the application to the CEB:	APPLICANT/INVESTIGATOR submitting the application to the ethics committee at HCS:
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Date:

Date:

Signature:

Signature:

Full name (block letters):

Full name (block letters):

*{annex in wording of the MoH Order №
523 of 12.07.2012, № 966 of 18.12.2014}*