

Annex 10
to the Procedure for Conducting Clinical Trials
of Medicinal Products and Expert Evaluation
of Materials Pertinent to Clinical Trials
(section X, chapter 1, item 1.4)

COVER LETTER

To the application to the central executive body regarding substantial amendments:

To the application for approval of the ethics committee at HCS regarding substantial amendments:

(applicant)

submits for expert evaluation/moral, ethical and legal aspects assessment the substantial amendment to:

(underline the necessary)

(full title of clinical trial)

Clinical trial protocol code number:

Investigational medicinal product (name):

Clinical trial sponsor:

Grounds for amendments to be considered as substantial:

Other important information (if any):

Applicant/investigator

(full name (block letters))

(date)

(signature)

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