|  |  |
| --- | --- |
|  | 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 assessmentthe substantial amendment to:

*(underline the necessary)*

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

(full title of clinical trial)

Clinical trial protocol code number:

Investigational medicinal product (name):

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 Ukraine Order* [*№ 523 as of 12.07.2012*](http://zakon3.rada.gov.ua/laws/show/z1235-12/paran391#n391)*,* [*№ 966 as of 18.12.2014*](http://zakon3.rada.gov.ua/laws/show/z0062-15/paran15#n15)}