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|  | Annex 11 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) |

**Application**

**for SUBSTANTIAL amendment/approval of SUBSTANTIAL amendment BY the Ethics Committee at HCS**

**А. 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
 | ******** |

**А1. Clinical trial identification** **(When the substantial amendment concerns more than one clinical trial protocol for particular investigational medicinal product, 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: |
|  |
| Sponsor’s protocol code number, version and date:  |
|  |
| EudraCT[[1]](#footnote-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 sponsor submitting the application

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| **B1. 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: |

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

**С. Applicant identification (please tick the appropriate box)**

|  |  |  |  |
| --- | --- | --- | --- |
| **С1. Application to the CEB** | **** | **С2. Application to the Ethics Committee at HCS** | **** |
| Sponsor |  | Sponsor  |  |
| Official representative of the sponsor |  | Official representative of the sponsor |  |
| Person or organization authorized by the sponsor to submit the application. In that case, complete below: |  | Person or organization authorized by the sponsor to submit the application. In that case, complete below: |  |
| Name of legal person/full name of natural person: |  | Name of legal person/full name of natural person: |  |
| Full name of contact person: |  | Full name of contact person: |  |
| Location of legal person/address of natural person: |  | Location of legal person/address of natural person: |  |
| Telephone number: |  | Telephone number: |  |
| Fax number: |  | Fax number: |  |
| e-mail: |  | e-mail: |  |

**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 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 *Word* file and copy of initial application form with amended data highlighted (when applicable)** |

##### Signature and name of the applicant

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| --- |
|  I, the undersigned, hereby confirm (on behalf of the 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: |
| Date: | Date: |
| Signature: | Signature: |
| Full name (block letters): | Full name (block letters): |

{*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)}

1. [↑](#footnote-ref-1)