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|  | Annex 7 to the Procedure for Conducting Clinical Trials of Medicinal Products and Expert Evaluation of Materials Pertinent to Clinical Trials |

## Information about health care setting and clinical trial site

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| Code number of clinical trial (hereinafter - CT) protocol: |

**1. General information about HCS and CT site:**

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| 1.1. HCS, where CT is planned: |
| 1.2. Address of HCS: |
| 1.3. Full name of HCS’s head, tel., fax, e-mail: |
| 1.4. CT site (e.g., department, unit[[1]](#footnote-1)): |
| 1.5. Full name of department’s/unit’s head, tel., fax, e-mail: |
| 1.6. Current HCS’s license for medical practice № (copy attached)2: |
| 1.7. Current central executive body accreditation certificate for HCS № (copy attached)3: |

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

 Indicate full name of department, unit

2,3 Availability is obligatory.

*If department of higher medical institution (hereinafter - HMI) is involved in CT, fill in items 1.8-1.13*

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| --- |
| 1.8. HMI: |
| 1.9. Address of HMI: |
| 1.10. Rector’s full name, tel., fax, e-mail: |
| 1.11. HMI department: |
| 1.12. Full name of department’s head, tel., fax, e-mail: |
| 1.13. Availability of agreement for cooperation between HMI and HCS, where the department is placed, and its validity period: yes; no; validity period:  |

**2. Investigational group:**

2.1. Principal investigator[[2]](#footnote-2):

|  |
| --- |
| Full name:  |
| Position: |
| Tel.:  |
| fax: |
| e-mail: |

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

 Attach principal investigator’s СV.

2.2. Investigational group members, who are to be involved for performing important functions related to CT[[3]](#footnote-3):

|  |  |
| --- | --- |
| Full name | Basic planned obligations related to CT |
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 Attach СVs of investigational group members to be involved in CT.

**3. HCS characteristics, where CT is planned:**

3.1. Treatment of patients in HCS with a condition corresponding to clinical trial protocol:

 yes; no;

*If «yes», specify:*

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| Possibility of in-patient treatment, if condition corresponds to the clinical trial protocol: yes; no; other: |
| Patient’s profile:  |
| Possibility of out-patient treatment,polyclinics availability: yes; no; other: |
| Possibility of treatment in day hospital *(if necessary)*:  yes; no; other: |
| Possibility of emergency care (resuscitation/intensive care department):  yes; no; other: |

*If «no» for the above items, specify how patients will be supervised during the whole period of the clinical trial protocol:*

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3.2. Specify availability in HCS of:

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| --- |
| Places for keeping materials related to clinical trial during CT:  yes; no; other: |
| Places for keeping investigational MP:  yes; no; other: |
| Archive for keeping materials related to CT after its completion:  yes; no; other: |

**4. Information about clinical trials in HCS at the time of filling in[[4]](#footnote-4):**

|  |  |  |  |
| --- | --- | --- | --- |
| CT protocol code (number) and phase  | Patients profile  | CT stage (phase) (planned, in-process, completed), timing | Date and number of protocol of the State Expert Center MoH Ukraine meeting, at which CT was approved  |
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 Indicate only currently active clinical trials*.*

**5. Laboratory and instrumental provision**

5.1. Indicate which laboratories will be involved in the CT:

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| --- | --- |
|  №  | Name of laboratory |
|  |  |
|  |  |

5.2. Which instrumental and diagnostic equipment will be used during CT according to CT protocol:

In HCS:

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In other institutions[[5]](#footnote-5):

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1 If the use of instrumental and diagnostic equipment in other institutions is planned, it is necessary prior to CT to make an agreement with other institution and keep it in investigator’s file.

**6. Availability of Ethics Committee in HCS (date established, Order №):**

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**7. Other information about HCS activity:**

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Principal investigator’s signature \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_

 (full name) (signature)

HCS head’s

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 (date, signature) (full name)

1. [↑](#footnote-ref-1)
2. [↑](#footnote-ref-2)
3. [↑](#footnote-ref-3)
4. [↑](#footnote-ref-4)
5. Seal

{Annex in wording of MoH Ukraine Order [№ 523 as of 12.07.2012](http://zakon4.rada.gov.ua/laws/show/z1235-12/paran388#n388)} [↑](#footnote-ref-5)