

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 (HCS) and clinical trial site

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

1. General information about HCS and CT site:

1.1. HCS, where CT is planned:
1.2. Location of HCS:
1.3. Full name of HCS's head, contact phone number, fax, e-mail:
1.4. CT site (e.g., department, unit ¹):
1.5. Full name of department's/unit's head, tel., fax, e-mail:
1.6. Enter the HCS license for medical practice number valid on the date the information is provided (copy attached) ²
<i>{Subitem 1.7 of item 1 deleted according to the MoH Order № 2197 of 30.12.2024}</i>

Indicate full title of department, unit

² Availability is obligatory.

(Note 3 of table of item 1 is deleted according to the MoH Ukraine Order № 1745 of 06.10.2023)

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

1.8. HMI:
1.9. Location 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 contract on cooperation between HMI and HCS, where the department is located, and its validity period: • yes; • no; validity period:

2. Investigational group:

2.1. Principal investigator¹:

Full name:
Position:
Contact phone number:
Fax:
e-mail:

Attach principal investigator's CV.

2.2. Investigational group members, who are to be involved in performing important functions related to CT²:

Full name	Basic planned obligations related to CT

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2

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Attach CVs 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 CT protocol:

- yes;
- no;

If «yes», specify:

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 monitored during the whole period specified in the clinical trial protocol:

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3.2. Specify availability in HCS of:

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 end: • yes; • no; • other:

4. Information about clinical trials in HCS at the time of filling in¹:

Code number of CT protocol and phase	Patients profile	CT stage (phase) (planned, ongoing, completed), planned timeline	Date and number of protocol of the State Expert Center MoH Ukraine meeting, at which CT was approved

Indicate only currently active clinical trials.

5. Laboratory and instrumental provision

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

№	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 institutions¹:

¹ If the use of instrumental and diagnostic equipment in other institutions is planned, it is necessary prior to CT to conclude a contract with other institution and keep it in investigator's file.

6. Availability of ethics committee at 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

(date, signature)

(full name)

¹ Seal

(Annex in wording of MoH Ukraine Order [№ 523 of 12.07.2012](#); as amended by the MoH Orders № 1745 of 06.10.2023, № 2197 of 30.12.2024, taking into account changes made by the MoH Order № 117 of 18.01.2025)