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|  | Annex 6  to the Procedure for Conducting Clinical Trials of Medicinal Products and Expert Evaluation of Materials Pertinent to Clinical Trials |

**Application of principal investigator**

I, ***\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_*** *(full name),* working \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ *(place of employment and position),* request permission to participate in clinical trial:\_\_\_\_\_\_**\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

*(name of clinical trial and protocol number)*

I familiarized myself with the terms of clinical trial protocol and have appropriate proficiency, possibility to involve qualified employees and/or other specialists, if necessary. Furthermore, I have the possibility to use the required facilities and equipment to conduct a clinical trial properly.

I familiarized myself with the current legal documents pertinent to clinical trials, Good clinical practice (GCP).

I confirm that clinical trial will be started only if there are contractual and legal relations between all legal and natural persons involved in clinical trial according to the legislation[[1]](#footnote-1)\*.

I undertake to give all required information pertinent to clinical trial to the Ethics Committee at HCS.

I have no conflict of interests.

I give my consent to use my personal data (full name, position, academic degree, place of work) by the MoH Ukraine representatives and the Center which may be placed at their official sites.

Principal investigator:

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

(Full name) (signature) (date)

\* The components of estimate for such clinical trials may be expenses for keeping facilities and amortization of equipment, trial-related materials, paying salary to employees, which participate in clinical trial, etc.

**Reverse side**

**Agreed with:**

1. Head of healthcare setting *(to be filled in obligatory)*

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| \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ (head’s position and name of HCS) | \_\_\_\_\_\_\_\_\_\_  (signature) | \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_(full name) | \_\_\_\_\_\_\_\_\_\_  (date) |

2. Head of higher medical institution (hereinafter - HMI) *(to be filled in if HMI involved)*

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| \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  (head’s position and name of HMI) | \_\_\_\_\_\_\_\_\_\_  (signature) | \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  (full name) | \_\_\_\_\_\_\_\_\_\_  (date) |

{Annex in wording of MoH Ukraine Order [№ 523 as of 12.07.2012](http://zakon4.rada.gov.ua/laws/show/z1235-12/paran388#n388); amended by MoH Ukraine Order № 639 as of 01.10.2015}

1. [↑](#footnote-ref-1)