

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 code number of a clinical trial protocol)

I familiarized myself with the conditions 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*.

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)*

_____	_____	_____	_____
(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)*

_____	_____	_____	_____
(head's position and name of HMI)	(signature)	(full name)	(date)

{Annex in wording of MoH Order № 523 of 12.07.2012; amended by MoH Order № 639 of 01.10.2015}