

PROCEDURE for Conducting Clinical Trials of Medicinal Products and Expert Evaluation of Materials Pertinent to Clinical Trials and Model Regulations of the Ethics Committees approved by MoH Ukraine Order of 23.09.2009 № 690, registered at the Ministry of Justice of Ukraine on 29.10.2009 under № 1010/17026 (as amended)

Annex 1: LIST OF ESSENTIAL DOCUMENTS PERTINENT TO CLINICAL TRIAL THAT ARE TO BE KEPT AT HCS, TRIAL SITE AND CLINICAL TRIAL SPONSOR

Annex 2 Requirements to informed consent*

Annex 3 COVER LETTER

Annex 4 Application form FOR CONDUCTING CLINICAL TRIAL OF MEDICINAL PRODUCT /APPROVAL OF THE ETHICS COMMITTEE AT HCS PERTINENT TO CONDUCTING CLINICAL TRIAL OF MEDICINAL PRODUCT

Annex 5 COMPLETE DOSSIER OF INVESTIGATIONAL MEDICINAL PRODUCT

Annex 6 Application of principal investigator

Annex 7 Information about health care setting (HCS) and clinical trial site

Annex 8 NOTIFICATION about the start of clinical trial in Ukraine

Annex 9 LIST OF ASPECTS OF CLINICAL TRIAL WHICH MAY BE AMENDED SUBSTANTIALLY BY CLINICAL TRIAL SPONSOR

Annex 10 COVER LETTER

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Annex 12 NOTIFICATION of the end of clinical trial

Annex 13 PERIODICAL REPORT on status of clinical trial in Ukraine

Annex 14 FORMAT of final clinical trial report

Annex 15 REQUIREMENTS to notification about suspected unexpected serious adverse reaction

Annex 16 REQUIREMENTS to development safety update report about investigational medicinal product (hereinafter - DSUR)

Model Regulations of the Ethics Committees at health care settings which conduct clinical trials