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|  | Annex 1  to the Procedure for Conducting Clinical Trials of Medicinal Products and Expert Evaluation of Materials Pertinent to Clinical Trials |

**List of main documents pertinent to Clinical TRIAL THAT are to be KEPT at health care setting (HCS), clinical trial site and sponsor**

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|  | To be stored at archive (File) OF | | | |
| investigator/HCS | | sponsor | |
| **1. Prior to clinical trial**: | | | | |
| Investigator’s brochure | Х | | | Х |
| Protocol of clinical trial and amendments to it (if any) signed by sponsor and investigator | Х | | | Х |
| Sample of case report form | Х | | | Х |
| Materials given to patients (healthy volunteers):  Informed consent (including the necessary translations);  Other written information for patient (healthy volunteer);  Advertisement about study subjects recruitment (if used) | Х  Х  Х | | | Х  Х |
| Information about financial issues of clinical trial | Х | | | Х |
| Insurance contract (insurance certificate) | Х  (copy of insurance certificate) | | | Х  (Insurance contract) |
| Signed agreement between the parties:  Investigator/health care setting and sponsor;  Investigator/health care setting and contract research organization;  Sponsor and contract research organization. | Х  Х | | | Х  Х  (if necessary)  Х |
| Dated and documented approval of the Ethics Committee at HCS pertinent to materials of clinical trial | Х | | | Х |
| Document on Staff of the Ethics Committee at HCS | Х | | | Х  (if necessary) |
| Center’s conclusion pertinent to clinical trial | Х | | | Х |
| Curriculum vitae of investigators (CV) and/or other documents which confirm their qualifications | Х | | | Х |
| Normal values/ranges for clinical/laboratory/instrumental tests/investigations envisaged in the clinical trial protocol | Х | | | Х |
| Clinical/laboratory/instrumental tests/investigations: certification or accreditation, or internal and/or external quality control of laboratory equipment, other methods of verification | Х | | | Х |
| Sample of label attached to the investigational medicinal product’s container |  | | | Х |
| Instructions for handling investigational medicinal product and the required trial-related materials (if not included in clinical trial protocol or investigator’s brochure) | Х | | | Х |
| Documents about supply of investigational medicinal product and the required trial-related materials | Х | | | Х |
| Certificate of analysis for batch of the investigational medicinal product |  | | | Х |
| Randomized code disclosing procedure for blind clinical trials | Х | | | Х |
| Randomized list |  | | | Х |
| Monitor’s report about previous visit |  | | | Х |
| Monitor’s report about starting visit | Х | | | Х |
| 1. **During the clinical trial:** | | | | |
| Updates and revisions of:  Investigator’s brochure;  Clinical trial protocol and its amendments(if any);  Case report form;  Informed consent form and written information provided to patients (healthy volunteers);  Advertisement about study subject’s recruitment (if used). | Х | | | Х |
| Dated and documented approval of the Ethics Committee at HCS of:  Amendments to clinical trial protocol;  Updates and revisions of:  Informed consent and written information provided to patients (healthy volunteers);  Advertisement about study subject’s recruitment (if used);  Results of periodical reviews of documents related to clinical trial | Х | | | Х |
| Center’s conclusions as to substantial amendments to clinical trial protocol | Х | | | Х |
| Updates of normal values/ranges for clinical/laboratory/instrumental tests/investigations envisaged in the protocol of clinical trial | Х | | | Х |
| Curriculum vitae of new principal investigator/investigator/co-investigator | Х | | | Х |
| Updates of clinical/laboratory/instrumental test/investigation procedures: certification or accreditation, or internal and/or external quality control, other verification methods | Х | | | Х |
| Documents about supply of investigational medicinal product and required trial-related materials | Х | | | Х |
| Certificates of new batches of investigational medicinal product |  | | | Х |
| Monitor’s reports |  | | | Х |
| Information on negotiations/correspondence related to clinical trial | Х | | | Х |
| Signed informed consent forms | Х | | |  |
| Source medical documents | Х | | |  |
| Completed, dated and signed case report forms of study subjects | Х  (copy) | | | Х  (original) |
| Registration of updates in case report forms | Х  (copy) | | | Х  (original) |
| Investigator's notification of sponsor about serious adverse events and related reports | Х | | | Х |
| Notifications about serious unexpected adverse reactions submitted by sponsor to the Center | Х | | | Х |
| Interim or annual reports on status of clinical trial submitted to the Center and the Ethics Committee at HCS | Х | | | Х  (if necessary) |
| Sponsor's notification of investigator about new safety data about investigational medicinal product | Х | | | Х |
| Trial subject screening log | Х | | | Х  (if necessary) |
| Trial subject identification code list | Х | | |  |
| Trial subject recruitment log | Х | | |  |
| Accounting of investigational medicinal product at clinical trial site | Х | | | Х |
| List of signature samples of principal investigator/investigators/co-investigators | Х | | | Х |
| Register of retained body fluids/tissues samples (if used) | Х | | | Х |
| **3. After completion of the clinical trial:** | | | | |
| Investigational medicinal product accounting at clinical trial site | | Х | | Х |
| Statement of disposal of unused investigational medicinal product | | Х  (if disposed at clinical trial site) | | Х |
| Final trial subject identification code list | | Х | |  |
| Document on conducted audit (if any) | |  | | Х |
| Monitor’s report about final visit | |  | | Х |
| Indicated treatment and decoding information | |  | | Х |
| Clinical trial report | | Х  (if necessary) | | Х |

{Annex 1 in wording of MoH Ukraine Order [№ 523 as of 12.07.2012](http://zakon4.rada.gov.ua/laws/show/z1235-12/paran388#n388)}