

Annex 2
to the Procedure for Conducting Clinical Trials of
Medicinal Products and Expert Evaluation of
Materials Pertinent to Clinical Trials

**Requirements
to informed consent***

The information to be given to the patient (healthy volunteer) or his legal representative/close relative in writing and orally shall specify:

that the clinical trial involves research;

the objectives of the clinical trial;

the investigational product, including potential adverse reactions, and the probability for inclusion to one of the clinical trial groups;

the clinical trial procedures;

the trial subject's rights and responsibilities;

the inconveniences to the trial subject and expected risk and benefit;

when a clinical trial is of non-therapeutic nature;

other types of treatment with or without use of medicinal products that may be prescribed to trial subject;

compensation and/or treatment which a trial subject may expect in the event of trial-related harm to his/her health, including information on an insurance contract that covers the liability of the clinical trial sponsor to third parties for possible harm to trial subjects' life and health (patients, healthy volunteers) during their participation in the clinical trial with indication of name and location of an insurance company, number and date of the contract conclusion**;

amount and conditions of the anticipated payment to the trial subject, if any (in addition to the insurance ones);

the anticipated expenses, if any, to the trial subject for participation in the clinical trial;

that the trial subject's participation in the clinical trial is voluntary and that the trial subject may refuse to participate, at any time, without explanations, without penalty or limitations of rights;

rights of representatives of the Center, the Ethics Committee and the sponsor to direct access to information of the trial subject's source medical documents for verification of clinical trial procedures and/or data and its processing, without violating the confidentiality of the trial subject;

that the trial subject or the trial subject's legal representative will be informed in a timely manner if any new information becomes available that may be relevant to the trial subject's willingness to continue participation in the clinical trial;

use of the trial subject's personal data for conducting this clinical trial in compliance with the Law of Ukraine "On protection of personal data", in particular: purpose of processing personal data, composition and contents of personal data, holder of patient's personal data, access of third persons to personal data;

persons to contact for obtaining additional information on the clinical trial and the rights of trial subjects, as well as natural and/or legal entities to contact in the event of trial-related injury to their health;

the circumstances and/or reasons under which the trial subject's participation in the trial may be terminated;

the duration of the trial subject's participation in the clinical trial;

the approximate number of trial subjects involved in the clinical trial.

The subject's information should be kept secret and processed within the framework of clinical trial in depersonalized format.

Furthermore, informed consent form shall be signed by an investigator who obtains an informed consent and a trial subject***, and in the event of participation of incapacitated trial subjects who are incapable of giving themselves an informed consent, by the legal representative/close relative.

* For the benefit of the trial subject other protocol-specific information should be added to the informed consent.

** Information about the insurance contract and the insurance company (name, address, contact person, hotline phone/fax, email, etc.) shall be entered by a principal investigator/investigator before a patient signs the informed consent in paper or electronic format based on the relevant information from the applicant for a clinical trial, or entered by the applicant into the draft informed consent to be submitted to the Center for expert evaluation.

***If children (under age 14) and minors (from 14 to 18 years old) participate in the clinical trial the informed consent of both parents should be obtained. An oral or written information about the clinical trial shall be given to children under age 14 and minors according to their capacity of understanding. A minor patient shall personally sign and date the informed consent in paper format or sign the informed consent in electronic format by electronic signature. Information on involvement of children under age 14 and minors in optional form shall be submitted to local guardianship authorities in the area of permanent residence of such persons.

In case of involvement of incapacitated trial subjects who are incapable of giving themselves an informed consent the informed consent may be obtained from their legal representative/close relative depending on the nature of a trial. The witness shall sign the informed consent if required.

{New Annex 2 is added to the Procedure according to the MoH Ukraine Order № 304 of 06.05.2014; amended by the MoH Ukraine Order № 538 від 28.03.2022; № 894 of 24.05.2024}