|  |  |
| --- | --- |
|  | APPROVEDby the Order of the Ministry of Health of Ukraine of September 23, 2009, № 690 (in wording of the MoH Ukraine Orderof 12.07.2012 №. 523) Registered at the Ministry of Justice ofUkraine on 29.10.209 under № 1011/170127 |

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

**I. General provisions**

1.1. These Model Regulations have been developed in accordance with Articles 7 and 8 of the Law of Ukraine “On Medicines” taking into account the requirements of the Directive 2001/20/EC of the European Parliament and of the Council of 4 April 2001 on the approximation of the laws, regulations and administrative provisions of the Member States relating to the implementation of good clinical practice in the conduct of clinical trials on medicinal products for human use (as amended), Good Clonical Practice rules (ICH GCP), international ethical principles for biomedical research involving human subjects, ethical code of doctor.

1.2. These Regulations set forth general requirements for evaluating ethical, moral and legal aspects of clinical trials, which may be conducted in patients (healthy volunteers), and monitoring assurance of their rights, safety and well-being while participating in clinical trials of medicinal products performed by Ethics Committees at health care settings (hereinafter – the Ethics Committee).

1.3. The Ethics Committees is an independent body which acts at health care setting where clinical trials are performed. It involves medical professionals/scientists and other specialists, community members who perform control over observance of rights, safety and well-being of the study patients (healthy volunteers), ethical, moral and legal principles of clinical trial.

1.4. The Ethics Committees approve clinical trials of medicinal products in Ukraine at place of their functioning, and perform monitoring of ethical, moral and legal principles of clinical trial at health care settings.

**II. Rights and responsibilities of Ethics Committees**

2.1. Main tasks of the Ethics Committees are as follows:

2.1.1. Protection of the rights, safety and well-being of patients (healthy volunteers), involved in clinical trials of medicinal products.

2.1.2. Protection of the rights and interests of the responsible investigators/investigators.

2.1.3. Provision of the compliance of the ethical, moral and legal principles of clinical trials in health care settings.

2.2. The Ethics Committee shall assess the ethical, moral and legal principles of clinical trials, including procedures for involving patients (healthy volunteers) in trial and getting their (their legal representatives or close relatives) informed consent.

Ethics Committees pay special attention to involving children under age 14, minors, incapacitated, critical and emergency patients in clinical trials.

Ethics Committee shall be certain that:

the responsible investigator/investigator(s)/employees participating in clinical trial do not compel trial subjects;

the patient (healthy volunteer) or legal representative/close relative is given the detailed information about essence, importance, significance and risk of clinical trial in which they participate and enough time for taking decision pertinent to participation in clinical trial;

the patient (healthy volunteer) or his legal representative/close relative is submitted the detailed answers to all issues pertinent to clinical trial;

the subjects, whose legal representative’s consent is obligatory required for participating in clinical trials, are informed within their comprehensible level about the trial, and their wish or unwillingness to take part in the proposed clinical trial is taken into account.

2.3. The decision of Ethics Committee is arranged in the form of protocol, which constitutes an endorsement of conducting the clinical trial. It should include the following information:

The full name and identification of clinical trial protocol and/or its amendments;

List of revised documents and their identification;

Full name of a person or title of organization which has submitted clinical trial materials for consideration;

Clinical trial site(s) and full name of responsible investigator/investigator(s);

Decision pertinent to approval or motivated refusal of conducting clinical trial;

Date of decision taking;

Recommendations of the Ethics Committee (if applicable);

List of members of the Ethics Committee who participated in meeting and voting;

Dated and signed decision of the head of the Ethics Committee or other authorized person.

2.4. The Ethics Committees shall control that the subject is informed about essence, importance, significance and risks for him in view of his participation in the clinical trial.

2.5. The Ethics Committees shall check all methods for informing and involving patients (healthy volunteers) in the clinical trials of medicinal products at health care settings and inform the Center about the detected violations.

2.6. The Ethics Committees shall keep documents related to clinical trial for at least three years after its completion, and then shall submit it to the archive of health-care setting.

2.7. The Ethics Committees shall submit a copy of their Regulations and information pertinent to the composition and standard operating procedures, if officially required.

2.8. The Ethics Committees have the right:

2.8.1. To request the responsible investigator/investigator to submit additional materials pertinent to clinical trial (if necessary).

2.8.2. To request the responsible investigator/investigator to submit information about all amendments and changes to be introduced to trial materials, deviations and complications, conflict situations related to rights violation, safety and well-being of study patients (healthy volunteers), ethical, moral and legal principles while conducting clinical trials at health care setting.

2.8.3. To receive reports about status of conducting clinical trial.

2.8.4. To submit written proposals to the Center about possible consideration of suspension or full stoppage of clinical trial of medicinal product in health-care setting in case of violation of rights, safety, well-being of patients (healthy volunteers), trial subjects, ethical, moral and legal principles while conducting clinical trial in health care setting.

2.8.5. To participate in conferences, symposia, workshops, schools pertinent to ethical, moral and legal aspects of conducting clinical trials.

2.8.6. To develop and submit to the Center and central executive body for health care proposals pertinent to improvement of Ethics Committees activity.

**III. Composition and operations of Ethics Committees**

3.1. The Ethics Committee should include at least five members (of whom at least one member who isn’t a scientist, one member who isn’t an employee of health care setting where the clinical trial is performed).

The Ethics Committees shall include a reasonable number of persons, who collectively have experience and skills to control rights protection, safety, well-being of patients (healthy volunteers), trial subjects, ethical, moral and legal principles while conducting clinical trial.

The Ethics Committees will include both men and women.

3.2. Composition of the Ethics Committee is drawn and approved by the Head of health-care setting.

3.3. The Ethics Committee’s head is a Chairman.

The Chairman, Deputy Chairman and Executive Secretary shall be elected at the first meeting by an open majority vote**.**

3.4. The Ethics Committees will act according to the legislation, Regulations and standard operating procedures to be approved at the meeting of Ethics Committee at HCS.

3.5. Standard operating procedures of Ethics Committees shall include:

procedure for determining the Ethics Committee’s composition;

procedure for scheduling and holding meetings, notifying the Ethics Committee’s members about the meeting, requirements to quorum;

monitoring the provision of rights protection, safety, well-being of patients (healthy volunteers), trial subjects, ethical, moral and legal principles while conducting clinical trial in the health care setting concerned;

procedure of possible interrelationships with the Ethics Committees based on consensus of opinion.

3.6. The type of Ethics Committee’s work is a meeting. The meeting shall be held at frequency determined by standard operating procedure.

3.7. A meeting is quorate when half or more of the Ethics Committee members are present.

3.8. The Ethics Committee’s decision should be taken by an open majority vote of its members present at the meeting. At equal number of votes the Chairman’s vote will be decisive.

The Ethics Committee’s decision shall be drawn up with the protocol signed by its Chairman and the Executive Secretary.

3.9. The relevant health care setting shall provide organizational and technical support for the Ethics Committee.

**K.V. Konoshevych**

**Chief,**

**Department of Pharmaceutical Sector Development,
Health Care Branch**

(Model Regulations in wording of the MoH Ukraine Order

of 12.07.2012 №. 523)