

POSITION ABOUT ETHIC COMMITTEE

Generals

1.1. Ethic committee of "Semey State Medical University" created in accordance with the order of chancellor №45 from 17.05.2006 as an independent organ with the purpose of effective participation of public, including medical, in the protection of rights and health of patients, and also examinee during realization clinical researches.

1.2. In the work the Ethic committee follows Constitution of Republic of Kazakhstan, laws of RK "About a health of citizens of RK" (2006) care, "About medicinal facilities" (2004), by Order of health of Republic of Kazakhstan Minister from February, 14 2005 № 53 "About claim of Instruction on realization of clinical researches and (or) tests of pharmacological and medicinal facilities in Republic of Kazakhstan"; By the state standard of PK "Proper clinical practice" from December, 29, 2006 № 557, and also by basic international acts – Helsin declaration of BMA "Ethic principles of medical researches with participation a man as an examinee" (2000), recommending of BO3 Committees on ethics, examining, Guidance biomedical researches (2000) on GCP (Good Clinical Practice), by the real Statute, and also universally recognized principles and norms of bioethics. .

1.3. Activity of Committee is sent to the protection of rights and dignity of man, guard and humane relation of physicians-experimenters to the laboratory animals.

1.4. An ethic committee must not have the direct personal interest in certain research (test). Regardless of researcher, customer, sponsor or medical establishment Committee criticizes the plans of researches and mechanisms of protection of human rights and his safety. All subdivisions of the Семипалатинской state medical academy, conducting researches in public, be under an obligation to co-operate with the Ethic committee.

1.5. EC must not aspire to the profit/of benefit as an aim of the activity and must not distribute the got profit/benefit between the members and founders. Nevertheless, customer/a sponsor can compensate administrative charges, here payment does not depend on that, whether documents are approved or in relation to research some other decision is accepted.

1.7. An ethic committee is an open organ. Information about his cocks, graphic arts of work, all accepted decisions is not confidential.

Basic tasks of the Ethic committee

2.1. The primary purposes of work of the Ethic committee it is been: protection of rights and interests engaged in research of examinee; protection of rights and interests of researchers. For implementation of the indicated aims Ethic

A committee decides next tasks:

2.1.1. Realization of quality ethic and legal examination of materials of clinical researches with the use of NT, medicinal facilities, food additions, medical

technique and wares of the medical setting, new methods of treatment and inspection of patients.

2.1.2. Estimation of scientific validity of realization of clinical researches and supposed efficiency and safety of the studied technologies and medicinal facilities.

2.1.3. Preparation of conclusions about expedience of realization of clinical researches of NT and medicinal facilities.

2.1.4. Regular supervision after motion of research after the receipt of permission on his realization.

2.1.5. Notification of researchers and other parties concerned about serious by-reactions or пикаж for the participants of research.

3. Plenary powers of the Ethic committee

3.1. An ethic committee carries out the expert estimation of brochure of researcher, protocol of clinical research, information for a patient and form of the informed consent, professional biography of researchers, research centers and other materials of clinical research.

3.2. An ethic committee on results examination of the presented documents and data can take away a next conclusion:

3.2.1. To approve realization of clinical researches of NT, medicinal facilities, bioactive substances, medical technique, materials and wares of the medical setting.

3.2.2. To approve realization of clinical researches with recommendations to bring in in the course of the work change and addition in materials of clinical research. In this case a conclusion is given out after an answer for the put questions.

3.2.3. To set aside a decision-making to the removal of remarks with subsequent consideration of materials of clinical research on the next meeting of Committee.

3.2.4. Not to recommend realization of clinical research.

3.3 A conclusion is given out to the declarant and directed in the Ethic committee for a decision-making about realization of clinical research.

3.4. In case of origin of disagreements of declarant with the results of examination Committee repeatedly examines materials of clinical research with participation a declarant and bringing in of independent experts.

4. Regulation and activity of the Ethic committee

4.1. A committee consists of specialists in area of medicine, socially-humanitarian sciences, including lawyers, specialists of contiguous disciplines different on sex and age.

4.2. An ethic committee is headed by Chairman

4.3. The members of Committee are elected on 5.

4.4. A committee has a plan of work, that is developed and becomes firmly established in accordance with the real Statute.

4.5. Ethic committee held session with the observance of quorum.

4.6. If necessary the Ethic committee has a right to bring over to ethic examination independent experts without a right to decision vote on condition of observance of confidentiality.

4.7. Current job performances the Ethic committee are recorded in form abstracts of record.

4.8. Regulation of work and condition of storage of documentation must provide observance of confidentiality of work of Committee.

4.9. Committee held session depending on the real volume of ethic examination and are considered competent, if on them present no less than the half of members of Committee.

4.10. Committee made decision simple most voices of members by a free vote at presence of quorum and are recorded protocols.

4.11. Protocols of meeting of the Ethic committee sign a chairman and responsible secretary.

4.12. A committee conducts and keeps necessary documentation (standard procedures, lists of members of Committee, protocols of meeting, materials of clinical researches, reports of and other) in accordance with COII EC a 011 Documentation and archiving.