



Column

**Ethics Committee Establishment at
the Yerevan State Medical University:
Present-day Urgent Challenge**

In a number of states mentality and behavior of both patients and those who agreed to take part in clinical tests have sharply changed during the last five decades. Such changes are manifested in the active role, which the patients and the participants of clinical investigation play unlike that passive one, which they played, as a rule, within the life-span of some generations.

As long as such changes proceeded, formal steps directed to provision of the rights and security for patients and clinical test participants have been undertaken. The doctrine of informed consent was worked out and implemented in a number of countries. A special attention it gained after the WW II during the work of Nuremberg tribunal, as well as in the process of working out the Nuremberg code. This code became a feedback to barbarian actions and experiments carried out by Nazi in prisoners and convicts in the name of medical science. That was reflected in the Universal Declaration of Human Rights (1948) adopted by the General Assembly of UNO.

Democracy is based on the principle of direction by approbation of the directed ones and the doctrine of informed consent became an attempt to transfer this principle to medicine and life sciences. Besides the above mentioned concepts, this doctrine requires an observation of the type of experiments, as well as potential profits and risks connected with it, it also tends to gain real informed consent of those involved into the research experiment.

However, the codes and declarations by themselves are only words on a sheet of paper. They have to obtain governmental support in

order not to remain mere statements. Thus, French National Consultation Committee on Ethics of Life and Health Sciences, Council on Bioethics under the President of the USA and similar structures in a number of states serve as a basis for guidance and consultation of policy-makers, as well as governments of their states at the national level. Some states decided to form Committees on Bioethics by approval of corresponding regulations and thus legalizing them at the governmental level and actually providing them with the constant status.

Bioethics support movement has overcome national and cultural borders, arisen the great interest in many countries. To all appearances, everybody agrees that globalization penetrates everywhere not leaving aside public health problems as well. Practically everybody agrees that public health becomes a cosmopolitan, global problem involving not only developed but developing countries as well.

Under conditions of swiftly developing public health practice and policy-realizing methods in this sphere, medical institutions as well as governmental establishments admit the importance to create more formal mechanisms, by means of which it could be possible to manage ethically complicated or difficult-to-solve problems in practice. One of such mechanisms is formation of Bioethics Committee.

Bioethics Committee is a committee, which systematically and constantly deals with ethical problems of medical sciences, life sciences and innovation policy in the sphere of public health. The members of these committees focus their efforts on principles, norms and values in the area of public health, whenever not only behavior but ethics of medical professionals and, sometimes, patients' ethics as well, demand the constant attention and even formal supervision.

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At present, all clinical experiments capable to influence the health and security of a man, as well as all trials of new medicines in human beings are regulated by the generally adopted conception of researcher's responsibility for the fulfillment of the requirements of Good Clinical Practice (GCP). The GCP rules are worked out on the basis of recommendations of the International Conference on Harmonization. These rules are adopted by corresponding regulatory bodies and pharmaceutical companies of Europe, North and South America, Japan, and other countries of the world.

12 GCP golden rules for researchers:

- Know and keep research protocol;
- Choose, train and register members of the research team;
- Register data correctly;
- Make sure that necessary equipment is available;
- Protect research participants as much as possible;
- Exactly provide and register recruitment of the research participants;
- Thoroughly take stock of the investigated preparation;
- Inform about side effects correctly and in due time;
- Make sure of the quality of laboratory research;
- Aim to the highest quality of research data;
- Inform the participants of the research;

However, ethical norms are applicable not only to the research, the participants of which are human beings.

These norms are also applied to the animals widely used with educational and research aims.

The use of animals as a model/subject in teaching process is substantiated by practical classes foreseen by the plans and curriculum in High Educational Institutions (HEI) of medical and biological profile. Their use in scientific research and experimental medical sphere greatly promotes the development of medicine. Thus,

the work with animals helps to obtain practical skills, to master invasive medical procedures and urgent surgical operations. These problems have no alternative solutions (without animals). Further process in providing health and well-being of people demands experimental work with the living models/organisms. It is of high importance to carry out students' testing to assess the level of their training for doing independent practical work in clinical conditions. Nevertheless, efforts should be continuously done to work out and implement scientifically based alternative models/subjects, additional approaches, as well as improvement of the design for investigations in animals. The right care, use and humane treatment to animals used in educational and research works require the scientific and professional approach based on the knowledge of animals' needs and special requirements of teaching programs.

Good Laboratory practice (GLP) is a rule for carrying out the work using experimental animals developed in accordance with the Principles of Helsinki Declaration, "Directory for laboratory animals maintenance and use" of the Institute of Laboratory Animal Resources (USA) in 1996, "Instructions of European Council" 86/609/EEC, "Instructions for Using the Act for animals in scientific investigations" of Great Britain. "Principles for carrying out work using experimental animals" adopted in the Russian Federation correspond to these rules.

The regulations and principles stipulated by the GLP must be followed by every investigator and person providing care (workers of vivaria, workers looking after animals, laboratory assistants and staff members of departments and research laboratories). On the whole, these principles mean:

- To work out and realize experiments taking into account what they mean for human and animal health, science development and well-being of the society;
- To use proper type of animals: necessary quality in necessary quantities;

- *To eliminate or minimize the discomfort, distress and pains that animals will experience on condition that reliable scientific results will be obtained;*
- *To use corresponding sedatives, analgesics or anesthetics;*
- *To determine terminal points of the experiment;*
- *To provide high-level care for animals, controlled and carried out by the qualified staff.*
- *To operate experimental procedures in living subjects only by the qualified personnel under the guidance of more skilful specialists.*

These principles impose a responsibility on those involved in activity that is related to using animals and should be controlled by the Ethics Committee.

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The Ethics Committee, organized at the YSMU follows the above-mentioned principles in its work.

According to the principles for carrying out scientific investigations, adopted by the Scientific-Coordination Committee, any work that is part of a research must undergo examination by Ethics Committee before being taken into consideration.

Specialists of different profile are involved in the Committee, including those who have no relation to medicine. The Committee fully realizes the imposed responsibility and duties and entirely hopes to facilitate high-quality of investigations in compliance with the requirements set forth by the international expertise.