THE LAW AND ETHICAL SUPERVISION OF SCIENTIFIC BIO-MEDICAL RESEARCH IN HUMANS IN KOSOVO

[1] Dr. Astrit M. Gashi
[1] Obstetrics and Gynecology Clinic
University Clinical Centre of Kosovo, Pristine
&
[2]Ma.sc. Ramadan Gashi
[2] Office of the Auditor General-Pristine, Kosovo

ABSTRACT

The law aims to respect and protect the dignity, identity and the fundamental rights of every individual, without distinction, towards the application procedures and other medical health procedures, including also scientific research on humans. Any health professional or citizen of Kosovo or a foreign national who wishes to carry out bio-medical scientific research in humans in the territory of Kosovo should be subject to the permit application procedure for the conduct of scientific research.
Aim: The primary objective of the research is study of Law and professional ethical Monitoring of health professionals and scientific researchers in bio-medical fields, aimed at maintaining high standards in establishing and practicing of medical profession and protection of the patients and public from bad practice of medical profession including professional and scientific research on humans in Kosovo.
Methodology: The basic method of using was: the study of literature, constitution, laws, journals and other archival documents about this issue, as well as direct views of such practices in University Clinical Centre of Kosovo

Keywords: Research in Humans, Law and Ethical supervision, Practices in Kosovo.

INTRODUCTION

The law aims to respect and protect the dignity, identity and the fundamental rights of every individual, without distinction, towards the application procedures and other medical health procedures, including also scientific research on humans. Any health professional, citizen of Kosovo or a foreign national who wishes to carry out bio-medical scientific research in humans in the territory of Kosovo should be subject to the permit application procedure for the conduct of scientific research.

The primary objective of the research is study of Law and professional ethical Monitoring of health professionals and scientific researchers in bio-medical fields, aimed at maintaining high standards in establishing and practicing of medical profession and protection of the patients and public from bad practice of medical profession including professional and scientific research on humans in Kosovo.

METHODOLOGY

The basic method of using was: the study of literature, constitution, laws, journals and other archival documents about this issue, as well as direct views of such practices in University Clinical Centre of Kosovo.

Administrative Instruction No.05/2012 Supervision of professional ethics is based in the Law on the Rights and Responsibilities of the Citizens in the Health Care No 2004/38 and Pursuant to Article 93 (paragraph 4) of the Constitution of the Republic of Kosovo, that serving for citizen of Kosovo or a foreign national who wishes to carry out bio-medical scientific research in humans in the territory of Kosovo.

The provisions of this Administrative Instruction shall apply to all institutions and all health professionals and health associates at all levels of health care, public sector, private, and public-private. Ethical and professional supervision is organized in two stages. The first stage of monitoring is represented by Ethics commissions and professional in the following level: 1). Municipal Department of Health and Social Welfare, and the Departments of health institutions in the secondary and tertiary health care in the public sector, private and public-private, and 2). The second level of monitoring is represented by the Central Board of Professional Ethics appointed by the Minister of Health.

Professional Ethics Committee in the first degree of supervision is responsible for reviewing applications and complaints from citizens against public institutions, private and public-private, primary, secondary, and tertiary health care respectively to health professionals in these institutions in case of violation of law. The committee consist of three (3) members. Whereas Board is an administrative body that aims to respect and protect the dignity, identity and the fundamental rights of every individual, without distinction, towards the application procedures and other medical health procedures. The Board has fifteen (15) members, and these members are experts with social reputation in the fields of medicine, biology, law, ethics, sociology, and representatives from associations of registered patients. Duties and competences of the Board are: 1) The Board is responsible for making decisions regarding the requirements for implementation of bio-medical scientific research. 2) The Board oversight the implementation of duties in accordance with the requirements of medical science, rules and deontological medical ethic code. 3) The Board supervises and evaluates the behaviors and activities of health professionals to ensure that they comply with best standards of medical practice and in accordance with the European Charter of Medical Ethics. 4) The board cooperates with relevant bodies to ensure progressive development of professional standards in medical services, as well as participates in planning and designing of all official programs of medical training. 5) The Board evaluates the objectives and expected results of research and experimentation in the field of bio-medical sciences that are the subject of its treatment, based on information gathered from research centers in the medical field. 6) During the Scientific research period, the carrier of the research is obliged to report regularly according to deadlines set by the Board. 7) Completed research topics should be sent to the Board together with final project results. 8) The Board formulates opinions, provides solutions and prepares draft laws depending on the problems that can arise during the course of scientific research that are subjected to their treatment or their clinical application, taking into account the protection of human rights including patient and medical researcher etc.

Procedures for applying for permission of conducting the scientific bio-medical research in humans are: Any health professional citizen of Kosovo or a foreign national who want to carry out bio-medical scientific research in humans in the territory of Kosovo should be subject to the permit application procedure for the conduct of scientific research. All physical and legal entities that makes the request for bio-medical scientific research in humans, are obliged to submit a detailed plan of scientific research for gaining the permit by the Board. Application shall be accompanied by documentation including ethical approval from the

board by corresponding faculty and other documents required under guidance provided by the Board. Board in case when it is necessary proposes the establishment of medical experts and will propose the formation of special committee for evaluation of the proposal for bio-medical research.

The criteria for issuing permission for bio-medical scientific research in humans are as follows: Request for research, general information of the applicant, copies of professional licenses of participants in research. The research project proposal which includes purpose, methodology of research, type of research, outcomes, where research is planned to be performed and evidence for adequate scientific qualifications of holder of research.

Assessment of the risk and benefits that the project will have. Form of approval for provision of samples and participation in research clients. Approval of the Ethics Committee of the corresponding Institution. The holder of the rights for bio-medical scientific research that is subject to the Board treatment is licensed health care professional with scientific title. The holder must immediately cease research study if the risk is identified, or the risk is greater than the benefits. The Board is obliged, within 60 days to accept or reject the request for issuing permits for research. The Board informs the Minister of Health, about: Purpose and research objectives, place and duration of the research, expected results and recommendations of the research project, and final results of the project. Health professionals, who have no permission to carry out bio-medical scientific research by the Board, have no right to conduct such activities in health institutions at all levels of health care to the public, private and public- private and will be subjected to appropriate legal proceedings to be initiated by the relevant institutions of justice or health or the relevant officials.

For violations of the provisions of this Administrative Instruction, Medical deontological code and legal provisions concerning medical ethics committees, can take the following measures: Verbal Notice, notice in writing, last notice for license revocation, proposes the removal of the right to practice temporarily until within one (1) year. Permanent removal of license by the Board initiated only with the final judgment when it determines that the health professional is responsible for the worst-exercise of the profession that results in permanent health damage or death of the patient.

The direct views of such practices in University Clinical Centre of Kosovo

In the field of obstetrics where authors worked, research studies of the fetus and their control constitute one of the most complex and controversial in clinical studies to human beings. Currently, the law requires scientists to make all the necessary experimental studies in animals before they begin to make the man. Each clinical study in utero should be guided by the aim to respond to the health needs of a particular fetus, and the fetus should face the lowest risk potential that may arise while fulfilling such needs. In the case of research that have nothing to do with therapy, the risk to the fetus must be "minimal". In these cases should be written approval of both mother and father, unless when it is not known who is the father, when he is not mentally fit and when the pregnancy is the result of a rape. Protocols of research to the fetus must be approved by the scientific board, who should carefully review the specific way how will the selection process and methods to be used to get written consent after being informed ago parents (or single mothers). However in Kosovo, , the principles established by state law are fundamentally important to protect the integrity of the fetus, the prospective parents, and the research itself. They also provide minimum guidance, which

should be implemented voluntarily by all institutions involved in research studies to the fetus. Research studies on therapeutic interventions, for example, (in the prevention of premature births) are allowed. Therefore it allows any type of laboratory or scientific research if it is done in order to protect or to save the life of the fetus. Legislation regarding the direct control of clinical studies and research studies to the fetus, have different logical basis. However, a Kosovar doctor is obliged to obey the law of the state, which carries out research or his experiments, therefore, recommended the recognition and enforcement in any event. A substantial legal liability is the treatment of an adult able to decide, without prior approval in writing. This doctrine is based, first, on the value that the state gives to self-determination or autonomy, and, secondly, in making rational decisions. These issues are relatively obvious when it comes to cooperate with an adult, but how can they be implemented, the word is to conduct clinical studies or medical intervention, which may directly affect the fetus, and in particular, when the difference between experimentation and therapy is often unclear? In general, medical interventions include those procedures that are performed primarily for the benefit of the patient and considered "good practices and acceptable" , while experiments include new procedures or improved, which have not yet become part of standard practice, carried out with the main purpose to test a hypothesis or to gain new knowledge. In terms of therapy, written consent of one parent usually is enough for procedures to be carried out on a child. As in the case of the fetus, if experimental therapeutic procedure endangers the health or life of the mother, only her has the right to give consent in writing, as well as she has the right to reject it, because it is her body on which to intervene, and only she - not her husband - has the right to decide whether it will be done. Written approval of a pregnant woman is a mandatory requirement by law for medical interventions with curative intent, as well as for study purpose. The patient should be informed about everything before you give her approval and must be explained at the best possible for the study procedures or medical intervention, its benefits as well as risks and fetus, other possible alternatives frequency of success and potential problems of recovery.

CONCLUSION

Any health professional or citizen of Kosovo or a foreign national who wishes to carry out bio-medical scientific research in humans in the territory of Kosovo should be subject to the permit application procedure for the conduct of scientific research. All physical and legal entities that makes the request for bio-medical scientific research in humans, are obliged to submit a detailed plan of scientific research for gaining the permit by the Board. Application shall be accompanied by documentation including ethical approval from the board by corresponding faculty and other documents required under guidance provided by the Board. Board in case when it is necessary proposes the establishment of medical experts and will propose the formation of special committee for evaluation of the proposal for bio-medical research.

Currently, the law requires scientists to make all the necessary experimental studies in animals before they begin to make the man. Each clinical study -in utero - should be guided by the aim to respond to the health needs of a particular fetus, and the fetus should face the lowest risk potential that may arise while fulfilling such needs. Protocols of research to the fetus must be approved by the scientific board, who should carefully review the specific way how will the selection process and methods to be used to get written consent after being informed ago parents (or single mothers). Written approval of a pregnant woman is a mandatory requirement by law for medical interventions with curative intent, as well as for study purpose. The patient should be informed about everything before you give her approval

and must be explained at the best possible for the study procedures or medical intervention, its benefits as well as risks and fetus, other possible alternatives frequency of success and potential problems of recovery.

REFERENCES

1. Constitution of the Republic of Kosovo
2. Law on the Rights and Responsibilities of the Citizens in the Health Care No. 2004/38
3. Annas GJ: Standard of Care: The Law of American Bioethics. New York, Oxford University Press, 1993.
4. Annas GJ, Caplan A, Elias S: Stem cell politics, ethics and medical progress. Nat Med 5:13, 1999.
5. Annas GJ, Glantz LH, Katz BH: Informed Consent to Human Experimentation, Cambridge, MA, Ballinger, 1977.
6. Friedman JM: The federal fetal experimentation regulations: an establishment clause analysis. Minn Law Rev 61:961, 1977.
7. Brock EA: Fetal research: what price progress? Detroit Coll Law Rev 3:403,1979.
8. Annas GJ, Densberger JE: Competence to refuse medical treatment: autonomy vs. paternalism. Toledo Law Rev 15:561,1984.
9. Annas GJ, Glantz LH, Katz BH: The Rights of Doctors, Nurses and Allied Health Professionals. Cambridge, MA, Ballinger, 1981.
10. Danforth v. Planned Parenthood, 428 U.S. 52 (1976)
11. Elias S, Annas GJ: Prespectives on fetal surgery. Am J Obstet Gynecol 145:807, 1983.
12. Annas GJ: Waste and longing: the legal status of placental-blood baking. N Engl J Med 340:1521, 1999.