

## LEGAL ASPECTS OF REGULATION ON BIOMEDICAL SCIENTIFIC RESEARCHES

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### SUMMARY:

The existence of numerous new relationships created upon the improvement of modern medico biological researches emphasized, during the last decades, the need of improvement of several normative regulators which are to assure the following of certain ethical and legal principles. Different scientific societies have been issuing ethical codes and regulations, in order to regulate their activities. The appliance of these codes is assured by certain committees and commissions, which come up with expert opinions according to the level up to which certain research complies with the ethical and legal principles prescribed in specific legal regulation on European and national level.

In Bulgaria, there are created committees in ethics of scientific research in the field of medicine, among which are: National Council of Bioethics to the Ministry of Education and Science, National Ethic Committee and ethic committee of transplantations to the Ministry of Health, Bioethics Committee to the Institute of Neurobiology to the Bulgarian Academy of Sciences, Committee of ethics in scientific research activity to the Medical University in Pleven and Committee of ethic in scientific researches to the Medical University in Sofia. The activity of these committees, commissions and councils is regulated by acts such as the Universal Declaration of Human Rights, WMA Declaration of Helsinki regarding ethical principles for medical research involving human subjects, the European convention on bioethics as well as all legally binding European legal instruments related to ethics in scientific researches, as well as article 203 of the Bulgarian Healthcare Act, Regulation No 14 issued by the Ministry of Health on the terms and orders for conduct of clinical trials of drugs on humans and the regulations in other international and national documents in the field of ethics in scientific research and scientific publications.

Subject of expert evaluation are clinical and non-clinical biomedical scientific researches on human beings, scientific researches using personal biomedical data, human tissue, animals particular- genetically modified animals and microorganisms. The range of interest also include all ethical problems regarding protection of public interests and the researched objects from dishonest activities of

researchers in production, announcement, offering and publication of results of scientific researches.

**Key words:** Biomedical research, Ethics, Framework programmes, Funding, Legislation.

The existence of numerous new relations, based on the development of modern biomedical research in recent decades, emerged the need of legal regulations development ensuring compliance with certain ethical and legal principles. Ethical codes and regulations were created by different scientific communities for regulating their activities. The appliance of these regulations is provided by relevant Commissions and Committees providing expert opinions on matters of weather a conduction of research or study is in accordance to ethical and legal principles functioning on national and international level.

Ethical problems emerging in medical research activities are directly linked to bioethical issues.

Medical science is facing philosophical issues ever since defying its scope and the approach to its examination. Various matters have to be considered, such as questions regarding man's nature, the relation between man and nature and the society in general, interaction between form and content, phenomenon and essence, external and internal, and so on and so forth.

Medicine, as any other science, is developing based on research. Without research, cannot be achieved progress in matters of prevention, diagnosis and treatment. Biomedical research contributes to better understanding of etiology and pathogenesis of the disease.

Over the past three decades an intensive discussion is going on about the role of bioethics in contemporary theory and practice. It is regarded as a systematic and rational reflection (such as moral reasoning, discussion and justification) on various moral, ethical, legal and social problems caused by rapid development of medicine and other natural sciences.

Planning and conducting research or experiment of theoretical or practical importance, have to fulfill four main "technocratic" requirements:

- academic - to increase scientific knowledge;

- technological - to improve methods and/or techniques used;
- practical - to screen new drugs or to create new methods for treatment or diagnosis, or to resolve major issues determining quality of life;
- economic - to evaluate, as positive, the attitude efficiency/cost in innovations.

In many cases, compliance with these requirements may lead to collision with some basic bio-ethical principles. When disagreements with accepted bio-ethical principles are present, conflicts may occur on different basis:

- professional - in genomic-based effects on organisms or in production and use of genomic-modified plants or animals;
- egal - in euthanasia or therapeutic cloning;
- moral - in organ donation and transplantation of human stem cells;
- religious - in abortion or reproductive cloning.

In biomedical research field, a main difference should be considered, between medical testing where the aim is therapy and diagnosis as well as prognosis, and medical research, where the goal of is strictly scientific, without direct link to the person being tested.

The appliance of results from research involving human subject is important for further scientific knowledge. In accordance to that, the World Medical Association has prepared recommendations, to guide each physician in conducting biomedical research.

Emergence of new cases, driven by modern technology, posing an ethic challenge, has led to creation of various ethic codes, written by scientific communities for regulating their activities. For their compliance, except scientific community's opinion, the position of media and legal system, ethical committees give expert opinion on whether one study or another contradicts the rules of relevant legal acts.

The UK Medical research council, in order to improve scientific research activity, has published instructions for conduction, by research teams and institutions, as it requires units to create their own instructions, taking into consideration the specifics of different local conditions, as well as to include standards set by the Council. These instructions create a framework under which scientists are responsible for carrying out their scientific work.

In Bulgaria, various committees on ethics in medical research are functioning. Some of them include: National Council on Bioethics, to the Ministry of education, youth and science; Ethical Commission on transplantation; Commission on Bioethics, to the Institute of Neurobiology, part of Bulgarian academy of sciences; Commission on Bioethics on scientific research activity, to the Medical University – Pleven and Commission on Ethics in scientific research, to Medical University - Sofia.

The activities of these Committees, Commissions and Councils are undertaken according to various international and national documents, including the Universal Declaration of Human Rights; The World Medical Association's Declaration of Helsinki, which is statement of ethical principles for medical research involving human subjects; The European Convention on Bioethics, as well as all legal instruments regarding ethics of scientific research, such as article 203 of the Bulgarian Health Act and Regulation No 14, issued by the Bulgarian Ministry of Health, regulating terms and conditions of drug clinical trials conducted on humans.

The expert evaluation include clinical and non-clinical biomedical scientific research on human subjects, scientific research related to use of personal biomedical information, human tissue, animals, in particular - genetically modified animals and microorganisms.

EU legislation achievements consists of large number of decisions taken by the Council and the Commission, mainly in two areas:

- Framework programmes on European Union's activities in research and technological development, and
- Third countries agreements on cooperation in science and technology.

'Framework programmes (FPs) have been the main financial tools through which the European Union supports research and development activities covering almost all scientific disciplines. FPs are proposed by the European Commission and adopted by Council and the European Parliament following a co-decision procedure.

The procedure of awarding research funds out of the EU budget is clearly defined in terms of content and time, this procedure being referred to as Research Framework Programme (RFP). All measures of the Community in the field of Research and Technological Development (RTD) are integrated in this framework programme. Since the first framework programme for research, technology and development was introduced in 1984, the European Union has played a leading role in the planning and implementation of multidisciplinary research and cooperation measures in Europe.

Framework Programmes have been implemented since 1984 and cover a period of five years with the last year of one FP and the first year of the following FP overlapping.

The Framework Programme came about at the start of the 1980s, with a view to putting a little order into an increasing profusion of activities by placing them, as the name suggests, in a single 'framework'. This was done while putting in place, as the name also suggests, a medium-term 'programme', with a budget covering several years, rather than just one. Up until now, total of Seven Framework Programmes have been started.

It has often been stated that the European Union's Framework Programme only covers a very limited part of the

funding for research in Europe. The First Framework Programme represented a tiny fraction of the total public funding for research in Europe at that time, and the Seventh only accounts for 5% of this total in Europe today. In a country like France, European financing accounts for half of the 'incentive' credits, while many research departments at British universities are heavily dependent on funding from the Union in order to function. In countries like Spain, Portugal or Greece, the Framework Programme plays a role that is just as important as national funding, in terms of global funding for research.

The Second Framework Programme for Research and Technological Development acted from 1987 to 1991. The third FP ended in 1994 and the fourth one acted until 1998.

The Fifth Framework Programme (FP5) has two distinct parts: the Fifth European Community Framework Programme - covering Research, Technological Development and Demonstration activities and the Fifth Euratom Framework Programme - covering research and training activities in the nuclear sector. FP5 has a multi-theme structure, consisting of seven Specific Programmes, of which four are Thematic Programmes - Quality of Life and management of living resources (Quality of Life), User-friendly information society (IST), Competitive and sustainable growth (GROWTH, Energy, environment and sustainable development (EESD) and three are Horizontal Programmes. The last three programmes underpin and complement the Thematic Programmes by responding to common needs across all research areas: Confirming the international role of Community research (INCO 2), Promotion of innovation and encouragement of SME participation (Innovation/SMEs) and Improving the human research potential and the socio-economic knowledge base (Improving).

FP5 was conceived to help solve problems and respond to major socio-economic challenges the EU is facing. It focuses on a number of objectives and areas combining technological, industrial, economic, social and cultural aspects. This approach is reinforced by the Key Action concept. Key actions deal with concrete problems through multi-disciplinary approaches involving all the interested parties.

The 6th Framework Programme for Research and Technological Development, which was in force from 2002 to 2006, has now been superseded by the 7th FP, for the period 2007 to 2013. As its name implies, the 6th FP was the overall framework for the EU's activities in the field of science, research and innovation in the 2002-2006 period. Its principal objective was to contribute to the creation of a genuine European Research Area (ERA) by fostering more integration and coordination in Europe's previously fragmented research sector. Its main activities included support cooperation in the field of research, promote mobility and coordination, as well as harness research and

innovation in the service of other EU policies.

The framework programme envisages the introduction of two new instruments: networks of excellence and integrated projects. The aim of networks of excellence progressively to integrate the activities of partners networked through "virtual" centers of excellence. Integrated projects are substantial projects aimed at constituting a critical mass in research activities focusing on clearly defined scientific and technological objectives.

As regards research and innovation, the Programme's objective aimed to stimulate technological innovation, the utilisation of research results, transfer of knowledge and technologies and the setting up of technology businesses throughout Europe, particularly in the less developed regions.

The Seventh Framework Programme will be operating for total of seven years – until end of 2013. Its overall budget is EUR 53.2 million. In relation to the previous programme, this means 30% annual increase. FP7 presents strong elements of continuity with its predecessor, mainly as regards the themes which are covered in the Cooperation programme. The themes identified for this programme correspond to major fields in the progress of knowledge and technology, where research must be supported and strengthened to address European social, economic, environmental and industrial challenges.

On national level, for the first time, ethical, legal and social aspects of clinical research are being discussed by the first ad hoc created ethical Committee, as part of the Second EU's Framework Programme covering the time from 1987 to 1991. While conducting the Third FP, the role of ethics is related to the introduction of specific medical ethics studies and evaluating the consequences for society and people by entering and applying biotechnologies. Fourth Framework Programme launches bio-ethical research in medicine and biology.

Ethical legal and social aspects in EU research activities emerged when the European Parliament asked questions about a small pilot programme on the human genome ("predictive medicine") at the start of the 2nd Framework Programme. As a result, the first 'ad hoc' ethics committee was created to consider the "Ethical Legal and Social Aspects" of research.

In the Framework Programmes that followed, ethical legal and social aspects were given increasing attention.

The 3rd Framework Programme (1990-1994) required specific research on medical ethics and studies to assess the impacts of biotechnology.

The 4th Framework Programme (1994-1998) marked the beginning of bioethical research in the Life Sciences<sup>4</sup> and ethical review of project proposals raising sensitive issues

The 5th Framework Programme (1998-2002) was the

first Framework Programme to place a special emphasis on the ethical dimensions of the Community research and to extend the ethical requirements to all specific programmes<sup>5</sup>.

The 6th Framework Programme (2002-2006) is going much further. The European Commission has undertaken to ensure that the ethical, legal, social, and wider cultural aspects are taken into account at the earliest possible stage of Community-funded research in the life sciences and biotechnology.

The integration and participation of social scientists, experts in ethics and stakeholders into research projects is promoted. The ethical and social debate becomes an active part of the research and development process, involving the general public to the greatest extent possible.

With the implementation of the Seventh Framework Programme (FP7), the European Commission has established a new network of National Contact Points (NCPs). As under FP6, the network of National Contact Points is the main structure to provide guidance, practical information and assistance on all aspects of participation in the Seventh Framework Programme.

The Seventh Framework Programme (FP7) is the main instrument for the European Union to fund and promote European research and technological development for the period of 2007 - 2013. The programme has a budget of 53.2 billion euros over 7 years.

Topics of interest for several funded projects were identified as priorities among which: human experimentation in food research, consumer science and the cultural meaning of food, communication of scientific information /results,, as well as establishment of bio banks, gene banks, use of genetic information.

The decision of the European Parliament and the Council concerning FP7 states that research activities supported by the Framework Programme should respect fundamental ethical principles, including those reflected in the Charter of Fundamental Rights of the European Union and take into account opinions of the European Group on Ethics in Science and New Technologies (EGE).

Article 15 of the FP7 Rules for Participation states that any proposal which contravenes fundamental ethical principles or which does not fulfill the conditions set out in the specific programme, the work programme or in the call for proposals shall not be selected and may be excluded from the evaluation, selection and award procedures at any time.

Applications for EU-funded research activities may, if appropriate, include specific tasks or a specific work package that explicitly addresses ethical concerns (in terms of the research, its conduct and outcomes) and outlines how ethical issues raised by the proposed research will be handled.

It is likely that most of the principles of the Charter of Fundamental Rights of the European Union will be

relevant to the approach adopted by Information and Communication Technology (ICT) researchers. These principles cover dignity, freedom, equality, solidarity, citizens' rights and justice.

Proposals must comply with Article 8 of the European Human Rights Convention<sup>6</sup>. In particular, given the pervasive and ubiquitous nature of ICT and the many opportunities it offers, researchers should consider the sensitive implications of their proposals for privacy and autonomy.

However, researchers should recognize that new dangers associated with the process of ICT research can exist. They should carry out a prior assessment of risk and identification of precautionary actions proportional to the potential risk/harm.

Researchers should comply with national legislation, European Union legislation, respect international conventions and declarations and take into account the Opinions of the European Group on Ethics.

The right to privacy and data protection is a fundamental right and therefore applicable to ICT research.

Researchers must be aware that volunteers have the right to remain anonymous. Researchers must comply with Data Protection legislation in the Member State where the research will be carried out regarding ICT research data that relates to volunteers.

Informed consent is required whenever ICT research involves volunteers in interviews, behavioral observation, invasive and non-invasive experimentation, and accessing personal data records. The purpose of informed consent is to empower the individual to make a voluntary informed decision about whether or not to participate in the research based on knowledge of the purpose, procedures and outcomes of the research.

Before consent is sought, information must be given specifying the alternatives, risks, and benefits for those involved in a way they understand. When such information has been given, free and informed consent must be obtained. Depending on the nature of the research, different consent procedures may be used. Special consideration must be given when volunteers have reduced autonomy or are vulnerable.

Personal health data must be treated as 'sensitive personal data'. ICT researchers using it have a duty of confidentiality equivalent to the professional duty of medical secrecy. Therefore:

- The use of personal health data in ICT research for the purposes from which society as a whole benefits must be justified in the context of the personal rights.
- The security of ICT in healthcare is an ethical imperative to ensure the respect for human rights and freedoms of the individual, in particular the confidentiality of data and the reliability of ICT systems used in medical care.

- Proposers should be particularly aware when ICT is linked to sensitive medical areas such as the use of genetic material.

- Proposers should access established general medical and genetics ethical guidance when formulating their proposals.

The ICT 2011-2012 working programme defines the priorities for calls for proposals that will result in projects to be launched in that period of time. These projects will start having impacts on markets in 5-10 years, on average.

Societal challenges such as the ageing population, sustainable health and social care, inclusion, education and security will also govern policies and drive economic and societal development for the decades to come. ICT plays a major role in providing responses to such challenges.

Projects will focus exclusively on analyzing multi-parametric data in the context of Personal Health Systems used for prevention or remote management of clearly targeted diseases or co-morbidities. Multi-parametric data may include physiological measurements, genetic data, medical images, laboratory examinations and other

measurements related to a person's activity, lifestyle and surrounding environment. The developed systems will process and interpret such data for accurate alerting and signaling of risks and for supporting healthcare professionals in their decision making.

This may be either by correlating the multi-parametric data with established biomedical knowledge to derive clinically relevant indicators and/or creating new medical knowledge for diagnosing worsening of conditions and prompting early intervention. Projects may use patient data already available in databases or from other research projects or pilots. Creation of new patient data with the use of previously developed and tested monitoring systems is also possible. Adaptation of existing monitoring systems is eligible, but the development of new monitoring systems is not in scope.

Projects will pay attention to security and protection of patient data. Validation will aim to demonstrate, with quantitative indicators, the effectiveness and the medical and economic benefits.

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