Health & Research Journal

Vol 9, No 2 (2023)

Volume 9 Issue 2 April - June 2023

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doi: 10.12681/healthresj.31998

To cite this article:

Masoura, P., Skitsou, A., Laizinou, A.-N., & Charalambous, G. (2023). Research's policies on health: fundamental texts of the European Union and Greece. *Health & Research Journal*, *9*(2), 71–78. https://doi.org/10.12681/healthresj.31998

HEALTH AND RESEARCH JOURNAL
E-ISSN:2459-3192

(2023), Volume 9, Issue 2

SPECIAL ARTICLE

Research's policies on health: fundamental texts of the European Union and Greece

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Abstract

The research on health has to offer new data which are based on empirical facts. That fact doesn't make the research immoral or without limits. The purpose of this study is the survey of the existing knowledge about the scientific research on the health's field and the promotion of the major institutional legislation that set the boundaries of the research as well as of the problems that arise from it. We noticed a lack of published articles about the European policies around research on health. We present new data and we ended up to conclusions which for the first time are been published in this domain. Main aim is to expand the policies that the European Union follows on the field of health's scientific research that come up through studying relevant legislation.

We studied the main international and European institutional and legislative articles as well as Greek domestic law through Google scholar and the website (of) World Medical Association , through the Greece's National printing house , the Greek parliament, the European council and the European's Commission's site that sets the boundaries of the scientific study on the health's field and we proceed on a historical flashback so we would be able to explain the need of the creation of these legislative texts. The research took place in December of 2017 and it got repeated in March-April of 2021. The medical research was originally aiming the improvement of the human life. In the legislative texts which try to put restrictions in the ways of the scientific research's conduction, there are some gaps. New forms of scientific research create some questions considering the subject's safety. In conclusion several concerns came up which demand to be answered with insight and creative thought.

Key words: Scientific research, legislation, limits, restrictions.

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Cite as: Masoura, P., Skitsou, A., Laizinou, A-N., Charalambous, G. (2023). Research's policies on health: fundamental texts of the European Union and Greece. Health and Research Journal,9(2),71-78. https://ejournals.epublishing.ekt.gr/index.php/HealthResJ

INTRODUCTION

Scientific study according to Paraskevopoulos[1] is the study that has as its purpose the promotion of knowledge and that is distinguished for its originality. On the health's field we could say that research is the study which aims the promotion of knowledge for the improvement and the advancement of the health and the precaution. The research on health has to offer new data that are based on empirical facts. The scientific research has to be characterized by strict rules which aim the human right's protection and human's decency. Furthermore, it has to respect the animals' rights. For all the above reasons there is a special institutional framework that sets restrictions on the scientific research. Despite that frame which is applied there are often conflictions on a moral level, which can't be solved inclusively by legal science.

International Level

On international level there are two fundamental law regulations that tried to put boundaries on the scientific research on humans. The Code of Nuremberg and the Declaration of Helsinki. The Code of Nuremberg got applied and acceptable by the Judges at the trial of Nuremberg that took place from 9-12-1946 to 20-8-1947.[2] The Code of Nuremberg is made of ten rules. The principal of consent, the principal of the freely interruption of the participation in the study, the protection of the subjects from pain, disability and death, the calibration between danger and profit, the conductors of the experiment has to be properly educated, the aim of the experiment has to be for the best interest of the social total and an alternative method not to be available , to be based on experiments that were conducted on animals, the suitable precautions to be taken so the subject of the experiment to be protected, the subject to be able at any time to terminate the experiment, the experimental physician has to terminate the experiment when he understands that there is a possibility for the subjects to die or become disable except in those experiments where the experimental physician is at the same time a subject (5th principal of the Code). There is dispute considering what right has the experimental physician to put himself through an experiment that knows a priori that it is going to cause him injuries. It is a moral issue which rises, about how much wanted is a self-causing injury with the excuse of the general profit. According our opinion neither the conductor himself has the right to cause damage, disability or even death to himself during an experiment. The Greek law system (A2§1, A-5§2 The constitution of Greece)[3] as well as the international and European provisions of the article 3 of Universal Declaration of Human Rights[4] and the articles 2 and 5 of the European Convention on Human Rights[5] protects the right in life not just as an individual right but as a human good of supreme value which none has the right to insult. The cause of this protection comes from the nature of the good of life and from the weakness of physical death choice. Those two facts, that no one can self-create life naturally and no one can choose his natural death it creates the certainty that neither life but especially death is not a natural creation of people. For that reason, since neither life or death are a human creation, a human can't have the right to cause damage on his own existence. As it turns out from the above ten rules the Nuremberg's Code presents some gaps which can be an object of exploitation. For that reason, the scientists understood soon enough that it has to be modified. That way the universal medical community proceed to the Helsinki's Declaration in 1964.[6]

The Declaration of Helsinki describes analytically the moral standards which should be followed during the medical researches. It hasn't an application as strong as a law but it is a code of moral values which should be followed during experiments on human beings. It establishes the obligation of a doctor to keep safe the health of people, particularly those in a susceptible group and to always take the consent of the human beings taking under consideration its state (legal or moral), at the same time the declaration proceeds to the confirmation that the medical progress is based on the medical research and experiments. For the first time there is a dialogue for the decency and the privacy- secrecy of a human being. It's being presented for the first time the concept of a research's protocol and the concept of the animal's and the environment's protection. Finally, it is presented the distinction between a treating and a non-treating research.

European Union- Greek law

European Union

Convention of Oviedo

In the European Union at 4-4-1997 it was signed an agreement for the human rights and the biomedicine. This agreement got ratified and put into power with the law 2619/1998 (Greek Government Gazette A΄132 19/6/98)[7] and became an inseparable part of the Greek domestic law and it is more powerful than any other opposite law according to the article 28 of the Constitution. It is about the calling contract Convention of Oviedo (4-4-1997). According to the agreement above, the interests of people will stand over the social interest or science (article 2). Special provisions are taken for the consent of a person in surgeries and special protective measures are enacted for minors, the disable, etc. The general provisions of the Oviedo's agreement are compatible with these of the Helsinki's declaration. The articles 13-14 are considered an innovation because they define when it is allowed to intervene in the human gene and forbites the prochoice of the child's sex with an only exception of a serious heritable disease, that can and has to be avoided.

Inherited diseases are considered both physical and mental diseases. Eugenic practice as a field of application includes the development of genetics and diagnostics with the help of genetic engineering and genetic tests where they can diagnose an abnormality in the individual's genetic material (DNA). [8] According to the above articles (13-14) the choice of gender is allowed for children in cases where in this way a hereditary disease will be prevented and avoided. From the above, it can be seen that the operation on the sex of the child will be done during pregnancy without specifying whether the choice is made with pre-implantation diagnosis, i.e. whether during assisted reproduction only embryos are implanted with a gender that will not cause any hereditary disease or if through prior intervention in the material it is possible to "construct" gender. A question arises in the first case with what happens to the embryos of the other sex. Are they driven to destruction? In such a case, a weighty ethical issue arises, that of creating eugenics as opposed to the destruction of a protected human being or a potentially human being according to the relevant theories. According to Katsimigas & Kaba (2010)[9] there are three cases of considering the fetus. The first is that the fetus is an integral part of the female body, the second is that the fetus exists as a human being, i.e. it is human nature under protection, and the third is that the fetus is potentially a human being. The second theory appears to be more logical since the fetus actually settles from the moment of its conception in a protected environment (that of the uterus) which environment protects it from external risks even from risks experienced by its mother (e.g. a fall or an injury). This fact that the fetus is protected from external factors gives the impression that its existence could be isolated from that of its mother and not considered an integral part of the female body but a self-sufficient human being with its own rights. This is also followed by legal science since it protects the value of the human fetus after a few weeks of pregnancy (abortion ban). It must therefore be ethically and legally investigated whether the human rights of a subject with human DNA exist from the moment of creation. The answer for any average reasonable person may be different for everyone and can be divided into acceptance of DNA manipulation or sex selection on the grounds of improving human life through the absence of disease, or rejection of manipulation and sex selection based on complete freedom of the natural evolution of human nature in an environment stripped of human intervention so that the will of nature can prevail.

European's Union policy for protecting the animals during the experiments

The existing active fundamental rules in the European union can be found in the law 2015 of 21.2/27.2.92 "ratification of the European contract for the protection of the vertebrate animals which are being used for experimental or other scientific purposes". This law ratified the European Convention for the Protection of Vertebrate Animals Used for Experimental or Other Scientific Purposes. In the contract above it is been considered two data which are used for its institutionalization. That the animals suffer and have memory. For that reason, there are some positive criteria that are bounding the frame of the animal use for the health's and safety's improvement of the human species. These criteria are the contribution of knowledge or the result's achievement which are going to help both the humans and the animals. Special care is being taken so the experiments can be replaced with other methods that will cause less side effects. De-

spite the fact that the contract has as its aim to protect the animals, at no point does this protection appear. In particular in the article 11 of the law there is a reference that by the end of the procedure it is decided if the animal has to be kept alive or to be euthanized with a non-brutal way. It is possible for an animal to keep suffering and be in pain or agony even after the general restoration of its health. Then that animal has to be euthanized ("does not remain in life" according to the covert reporting of the law who using this particular phrase covers the crime of killing an animal).

Furthermore, for the animals' protection which are used for experimental purposes used to be applied the Presidential Decree 160/1991 (Greek Government Gazette A΄ 64/3.5.1991) which imbodied the instruction Directive 86/609/EEC in the domestic law. The above Directive 86/609/EEC since the 1.1.2013 has been canceled due to the article 62 of the Directive 2010/63/EU of the European Parliament and the Council (L 276), which has been transferred at the domestic law with the Presidential Decree 56/2013) (Greek Government Gazette A΄106/30-04-2013).[7]

The policies that the European Union follows in the field of clinical trials on medical products for human use

With the MD G5a/59676 (Greek Government Gazette B΄ 4131/22.12.2016) the provisions were made for the implementation of regulation EU n.536/2014 of the European Parliament and of the Council of 16 April 2014 on clinical trials of medicinal products for human use, and repealing Directive 2001/20 /EC. With this instruction the concept of a good clinical trial was defined as "the good clinical trial is a total of international recognizable quality demands of moral and scientific character, that must be followed by the planning, the conduction, the registration and the publishing of the clinical trial in which the participants are humans". The guideline above was put in action in the E.U. for the clinical tests and the administration of medicines to humans and in Greece has put into action with the MD DYG3/89292/2003 (Greek Government Gazette B΄ 1973/31.12.2003) Harmonization of Greek legislation with the corresponding community according to the Directive 2001/20 /EC "for the approach of the legislative, regulative and administrative provisions of the member states considering the application of the right clinical practice in the studies of medical products for human use".

The new Regulation (EU) 536/2014 defines that all the conditions for the conduction of a clinical trial such as the consent of the subject, informing people or of its spokesman for the consent, the conduction of the trial with less pain, fear, the conduction of the clinical tests to happen with respect of the subject's dignity and of its personal data, to be conducted by a qualified scientist etc.

The European Union proceed to signing the contract of the human rights and the biomedicine, and that wasn't by chance. It wanted to protect the human rights and to establish boundaries in the research with main purpose of banning the attempts to violate human rights in the name of science. The memories of Europe after the second World War's ending are still fresh. "The judgment by the war crimes tribunal at Nuremberg laid down 10 standards to which physicians must conform when carrying out experiments on human subjects in a new code that is now accepted worldwide."[10]

After it was found that in the name of "scientific research" on the health's field were done all of the above crimes against life, bodily and mentally independence, dignity and human race in general, a decision was taken to define some rules which would lead the moral and legal limits of the scientific research on humans.[11]

Greek law

As the article 16§1 of the Constitution, research and science has to be free and the state is responsible for their development and growth. The Greek field of the general research area develops at a steady pace in the last years but it stills presents some particular difficulties. According to the recital article of law 4386/2016 (Greek Government Gazette A΄83/ 11-5-2016) "the present orders are an emergency and transitional legislative intervention on the area of research and technology. This intervention is necessary to handle not only the major guidance issues of the researching system but also the serious functioning problems, that were created from the voting of the law 4310/2014.[7]

In the same time that intervention was necessary to fix the double meanings and the fundamental gaps and to support everything that has been produced until now on the knowledge and

culture area. In parallel, the new measures aim the direct response to the consequences of memorandum policies[12] which have create serious problems on the research web of the country and on the human recourses, especially they have lead a big number of young scientists in mandatory immigration" [13] From all of the above it has been created a new reflection on the scientific research area, due to the restrictions that are applied on research due to the international economic crisis and the application of the memorandum at Greece.

Moral issues

Nowadays still are found new forms of research which probably need more scientific discussion.

Analyzing the real data from above that came up during the 2nd World War in relation to these new forms of research, the scientific research causes several moral and ethical issues which consider the measure where the research can reach in the health's field in relation to the promotion of the public interest and social good.

As a small example the main moral issues in research is the protection of the personal data, the consent, the use of animals in experiments, the research on human stem cells.[14]

Personal data

The personal data are being protected by the Greek legal order with the laws 2472/1997 (Greek Government Gazette A'50 10.4.1997) and 3471/2006 (Greek Government Gazette A 133/28.06.2006), as they were modified to be activated after the application from the E.U. of the General Data Protection Regulation 2016/679.[15] Sensitive data, are defined by the law 2472/1997 (Greek Government Gazette A'50 10.4.1997) as the data that consider the racial origins, the politic beliefs, the religious or philosophical beliefs, the participation in a trade union, the health, the social care and the love life, anything that has to do with criminal prosecutions or convictions as well as the participation to clubs with people belonging to any category above. The matter of the personal data was firstly mentioned when the contract between the umbilical cord blood bank and the health business group (National Bioethics Committee of the Hellenic Republic, 2017) were interrupted. With the committee's decision it brought up the delicate issue of the protection of that matter and the personal data of the child and the parents.[16]

Without the subject's consent the processing by the responsible principals of processing of its data it is forbidden. As consent it is considered the clear and full understanding and the explicit statement of the person-subject, who after their information decided to become a subject to the experiment. Exceptions can be made especially for the scientific research as well as for statist reasons but with a specific procedure. The consent on the scientific research considers the reassurance of the human's willing to participate in the research either under the form of a clinical research or under the form of a clinical study. For the consent to be given from a natural person, that person has to have legal practice ability. Legal practice for all the legal practices according to the article 127 (Civil Code) have the adults, that is people who are over 18 years old. On the contrary incapable for legal practice (128 C.C) are everyone who are under the age of 10 years and everyone who are under total guardianship. In the following articles of the Civil Code there is an escalation of the age or the ability which defines for what legal practices a person is capable of. In the scientific research those people categories are being represented by a special representer and it is taken under serious care/consideration when it is about people who belong in sensitive social groups.

Recently the E.U. applied the General Regulation for the data protection (GDPR - 2016/679) that embodied in the Hellenic order with the law 4624/2019 (Greek Government Gazette A΄137/29-8-2019).[7] It is applied a special derogation with the article 22, that allows the processing of special personal data categories since it is necessary among others for reasons of precautioning medicine, medical diagnosis, public interest on the field of public health such as serious borderline threats against health's under the condition that all the necessary and special measures to protect the subject's interest.

A practical issue of personal data protection was raised during the period of the COVID-19 pandemic where the above article 22 para. c of Law 4624/2019 (Greek Government Gazette A΄137/29-8-2019) had to be applied in accordance with which allows the processing of special categories of personal data by public and private bodies for reasons of public interest in the field of public health, such as serious cross-border threats to health. Dealing with an urgent and unpredictable situation, such

as a pandemic, is considered a matter of public interest in the field of public health. The protection of personal a case relaxes, prior to the protection of the public interest and primarily the protection of human life. This fact gives rise to knowledge from mainly public services, such as the various health structures, personal data such as the circle of our contacts, sensitive data such as for example vaccination or not, a fact which also led to rivalry between groups (vaccinated and non-vaccinated) due to different perceptions on the subject. In this case, the knowledge of social and personal contacts was not particularly dangerous for citizens' personal data because the specific virus is transmitted to general population groups in which reporting their illness will not cause a breach of personal data.

The ECDC report on monkeypox is relevant. (2022)[17]

Laboratory animals

A special subject's category is the animals that are being used in experiments. Above analyzed the legal framework which regulates the use and livelihoods, and the subsequent development of the test animal. Applying special standards of the buildings in where the animals will stay etc. The phrases that are being used in the laws above Presidential Decree 160/1991) (Greek Government Gazette A΄ 64/3.5.1991), Law 2015/1992 (Greek Government Gazette A΄30/1992) create the certainty that the animal during an experiment may die, become disabled or hurt and anesthesia is not carried out in every case of experiment. (Article 8 of the Directive 86/609/EEC - Presidential Decree 160/1991 (Greek Government Gazette A΄ 64/3.5.1991). The question if the animal has a smaller value than a human has and for what reason, comes up. It is deemed appropriate to reduce the animal use in clinical trials through the theory of 3Rs principle.[18]

For each R there is one principle on the ethical use of animals in experiments:

Reduction refers to the methods applied which allow the use of less animals in a protocol. Refinement means to apply methods which minimize or eliminate animal suffering, such as: using anesthesia in a procedure analgesic to relieve animal pain while recovering, using non- invasive techniques, providing comfortable and safe housing environment and training the animals in order to cooperate during procedure. The major objective in scientific animal use is replacement. It refers to substituting animals with other models, like invertebrates, cell cultures, organs, cellular fractions and microorganisms. A protocol conducted without any use of animals would ideally be the expected replacement.[19]

Stem cells

The stem cells are found in every state of the embryonic development. They can be Embryonic stem cells (ESCs) are the most commonly used pluripotent stem cells. Initially there was, and still is, great ethical conflict on therapies using ESCs, based on the discovery by scientists, in 1998, that it was possible to remove ESCs from human embryos. A number of diseases, even some considered incurable, seemed to be effectively treated by stem cell therapy. The issue raised was that the embryo (which would potentially become a human) was destroyed during the isolation of ESCs in the scientific lab.[20]

The National Bioethical Committee of the Hellenic Democracy had a meeting in 2001 to answer issues considering the use of the stem cells in biomedical research. It decided that the use of the stem cells that came up form an abortion is allowed, since the abortion is legally allowed in the Hellenic legal order so is the isolation of the stem cells. Only one member voted saying that the value of a person exists from the moment of the fertilization and that abortion is morally devilish.

Specifically, the decision of the National Bioethics Commission of Greece's Democracy said: "Most members of the Commission recognize that, although abortion is natural to raise some ethical concerns to some degree, it is enshrined in modern law. Therefore, as long as the isolation of stem cells from an embryo does not raise ethical dilemmas of a different order, there is no reason to rule it out in advance. Although according to the opinion of a committee's member… the value of a "person" (as a being of soul and body) exists from the moment of the egg's fertilization. Thus, in this view not only the isolation of the embryo's stem cells can't be accepted but the abortion itself it is morally flawed. So, by that point of view, the only acceptable stem cells' source is the somatic stem cells from an adult or even an underaged person (if it is about his own treatment) under the condition to not get used for reproductive cloning or embryogenesis (embryo creation for therapeutic purposes) and since the standards of the certificated researching labs have been defined and the

conditions of the research's conduction".[21]

There is a question, considering the opinion of the Committee's member in which the value of a person exists since the time of the fertilization, if it is moral to delete a future life with the parallel isolation of stem cells for the healing of another. With what guide do we define which life has value?

CONCLUSIONS

The medical research begun with purpose the improvement of the human life. In the process it has been used (thankfully minimals) with the wrong means by the wrong people to achieve wrong aims. For that reason, it has been put a wed of restrictions in the scientific research after the 2nd World War due to the illegal and denounced used methods. So, in an international as in a European level it has been applied rules that define those restrictions. The moral and ethical issues in medical research have been created due to the development of the technology and the new means that the biomedical field uses. New questions come up and issues which has to be answered with insight and creative thought.

Declaration of conflicting interests

The authors declared no potential conflicts of interest with respect to the research, authorship, and/or publication of this article.

Funding

No funding

The authors received no financial support for the research, authorship, and/or publication of this article.

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