



The effects of criminal damage and damage caused by research on third parties

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ABSTRACT

Objective: Biomedical research and the health sciences are a key element to improve the quality and life expectancy of the citizens and to improve their well-being, which has substantially changed, both methodologically as well as conceptually in the last years. **Methodology:** The appearance of new analytic tools has led to great discoveries which allow us to foster reasonable hopes on the treatment and even the cure in a not very distant future of pathologies which are not capable of being dealt with at present. The incidence of serious misconduct in research, which will be referred, is the clear evidence of attention the widespread to the issue of ethics in research. In fact, ((protection of human subjects in biomedical research)) is prime mover in initiating and maintaining attention to the issue of ethics in research. **Results:** The purpose of this research is to try to examined the criminal aspects of this phase of the research (research on humans), Ie criminal liability arising from injury or damage to in the investigation of third parties, patients and participants will be entered explored, and on the one hand look at the criminalization and dos and don'ts that pursuant to the rules of international conventions in this field and in order to dealt with protect the rights of the subjects. **Conclusion:** The respective results of the experiments and research, can be very beneficial for mankind the growth and development of the science of genetics and biotechnological provide route to prevention and treatment of diseases.

1. Introduction

Furthermore, these new scientific advances question the organisation that biomedical research had been based until now, that this new context requires a multidisciplinary approach, an approximation of the basic researcher to the clinical and coordination and work in networks, as necessary guarantees for the obtaining of a quality research. Spain, which already participates in a decided manner in the generation of biomedical knowledge, is not foreign to the interest raised by these researches and the debate it arises (Barbara, 2004). In this sense, the public administrations are decisively supporting biomedical research and are providing important economic and human resources and the necessary infrastructures to foster such end. Both the General Administration of the State, when exercising its jurisdiction of the fostering and general coordination of scientific and technical research as established in article 149.1.15 of the Constitution, as well as the administrations of the autonomous communities, which in their statutes have unanimously stated their jurisdiction to foster research, are establishing structures for biomedical research in networks open to the participation and collaboration with private enterprises, with different entities of research, universities and their own centres of the National Health System, in order to take advantage in an efficient manner of the available resources and to obtain results from the contributions of the different research groups, that can be applied to the improvement of the health of their citizens. In this manner, there is compliance in the field of biomedical research with the mandate established in article 44.2 of the Spanish Constitution that entrust the public powers to promote science and scientific and technical research for the general welfare (Chow et al., 2004). This law is set within this context and, on the one hand, responds to the challenges that are posed by biomedical research and tries to take advantage of its results for the collective health and well-being, while on the other, promotes and stimulates the coordinated action of the public powers and of the public and private entities and institutions dedicated to research, which are provided with better instruments to comply with their task (Imami, 1995). Furthermore and in order to achieve these objectives, the Law establishes regulations in areas that were not regulated up to the present, that have been so in a fragmented

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manner or that were foreign to the changes that have happened in the last years, such as genetic analysis, research with human biological samples, in particular of an embryonic nature, or biobanks (Jourdan, 1994).

The discussion of the rights and duties of human is also relevant and if in the meantime someone violated the law else intentionally and harm him the penal law entering in the arena. This raises the question as to how these tests can be done on humans? And codify what regulations are necessary to protect the rights of patients and participants in the research process? and finally in log injury to the basics and what conditions can the researcher or research team once the criminal responsibility? (Larijani et al., 2005).

Recent Q or the criminal liability arising from injury or damage in the investigation of third parties, patients and participants will be entered is the main issues in medical law here are other issues that must be addressed such as informed consent of subjects and patient and whether the informed consent of subjects can considered any kind of modal test on the subjects or not? If yes can be attributed to the fact that the criminal responsibility of the researcher or research team will also void? (Mohaghegh, 1995).

1.1 Purposes

1. Readout, transparent and revealing the subject's rights, examining the legal shortcomings and gaps in relation to the subject, according to documents and international treaties and laws of the leading countries in this field (Montazeri, 2009).

2. Review and transparent and clarify implementation guaranteed of the subject rights is implied in concrete of the law

3. Providing suggestions and solutions to create guarantees for the rights of patients and research subjects and protect them from domestic and international institutions.

1.2 Hypothesis

1. The object of this Law, with full respect towards human dignity and identity and the inherent rights of a person, is the regulation of biomedical research, and in particular: a. Researches related with human health that imply invasive procedures. b. The donation and use of human oocytes, sperm, pre-embryos, embryos and fetuses or of their cells, tissues or organs for biomedical research purposes and its possible clinical applications. c. The handling of biological samples. d. The storage and movement of biological samples. e. Bio banks. f. The Spanish Committee on Bioethics and other entities with competence on biomedical research matters. g. The mechanisms for fostering and promotion, planning, evaluation and coordination of biomedical research. 2. Likewise and exclusively within the health ambit, this Law regulates the undertaking of genetic analysis and the processing of genetic data of a personal nature. 3. The biomedical research to which this Law makes reference to includes basic and clinical research, with the exception of clinical trials with medication and sanitary products, which shall be regulated by its specific regulation. a. The implantation of organs, tissues or cells of any origin shall be regulated by that established in Law 30/1979 of 27 October, on the Extraction and Transplantation of Organs and other applicable legislation, and are excluded from the scope of application of this Law (Oxford Encyclopedic English Dictionary, 1996).

Using the capacity of legal jurisprudence and Islamic Republic of Iran with regard to the legislative experience of other countries in this area, need to incorporate of appropriate criminal and policies and determining imprisonment penalties, act the criminalization.

2. Materials and methods

Initially referred to various sources pay the place and features of subject then, the data are analyzed, evaluated and conclusions. Since it is based on a methodological approach in the humanities and social sciences to undertake this two task and basic mission are statement - descriptive and prescriptive; This study also attempts to explain and describe the relationship and interaction between biomedicine and Criminal Law and Criminology (explanatory-descriptive aspect), how Criminal support of biomedical research to evaluate the framework and practices that are appropriate to meet this goal, provided (normative function).

2.1 Chapter I: criminal liability arising from biomedical research and for actions research

2.1.1 Section I: Principles of criminal responsibility and biomedical research institutes First speech: Opponents of criminal liability for biomedical research institutes

In 1999 in America, a young 18 year old named Jesse Gelsinger suffers from a mild illness hereditary liver, hope her recovery and provide scientific data that may be more severe than in the treatment of babies born with the disease useful, participated in the study of gene therapy voluntarily. . After receiving the dose of virus designed to deliver healthy genes into cells of the liver, he died. He had signed the informed consent form that lacks important information that should be told. Such that the monkeys were tested before, died at the treatment and also the two people who have received treatment before he have been suffered severe side effects. However, in some areas of biomedical research against criminalization and argue offenses that occur in these areas should not be criminalized (Pouresmaeili, 2010).

America's among the countries that oppose criminalized of biomedical research. So the punishment for crimes that have taken place in biomedical research are not considered in America or just be contented to financial penalties. Opponents of criminalization of biomedical research in this country for two reasons cited for their claim:

- 1- Researchers social status often are physicians.
- 2- 2. The social benefits arising from biomedical research.

1. The free will of persons that may participate in biomedical research or that could provide their biological samples shall be respected. Their previous express and written consent must be provided once the adequate information has been provided. The information provided shall be written and shall encompass the nature, importance, implications and risks of the research in the terms provided for in this Law. People with disabilities shall be provided

this information in accessible manners and formats that are appropriate to their needs. If the subject of research is unable to write, the consent may be granted through any means admitted by law that allows the stating of a record of his or her will. 2. When a person is legally disabled or is a minor, their consent shall be granted through representation, provided that there are no other alternatives to the research. The conveyance of the consent through representation shall be proportionate to the research to be undertaken and shall be done in accordance with the respect of the dignity of a person and for the benefit of their health. The disabled and minors shall participate, in so far as it is possible and in accordance to their age and capacities, in the decision making process throughout the research. 3. Those persons who participate in biomedical research shall be able to revoke their consent at any moment, notwithstanding the limitations provided in this Law. Those persons or entities that have received this consent shall have available those measures that are necessary for the effective exercise of this right. 4. The lack of consent or the revocation of consent that has been previously granted shall not entail any damages in the health care assistance of the subject. 5. Every person has the right to be informed of his or her genetic data and other data of a personal nature that are obtained in the course of a biomedical research, in accordance to the terms that he or she assented. The same right is recognized to the person who has provided, with the aforementioned purpose, biological samples or when other biological materials are obtained from these (Shein et al., 2004).

2.2 first speech: Reasons of fans of criminal responsibility of biomedical research institutions

Today, the prevailing legal does not accept theory of criminal liability of legal persons and believe that justice fact and criminology fact these individuals should be considered. Legal persons have legal fact and cannot be ignored their existence in the criminal law area.

Proponents of the criminal responsibility of research institutions believe that since the offenses committed by such entities directly associated with the physical and psychological safety. And its consequences can be far more dangerous to the cause of the offenses committed by individuals, Therefore, they cannot be realized only by the people within the firm, they will be exempt from criminal liability (Shojapurian, 1984).

2.3 first topic: necessary schemes for biomedical research

A) the ethics of research design

In most clinical trials has been accepted randomized and placebo-controlled selection problem, However, there are certain points in each of these cases that should be considered and in some cases other methods designed to achieve.

2.3.1 Randomly selecting

Randomly selecting is one of the important means of eliminating discrimination in medical research. Random selection or any other method to specify the type of treatment they receive, if the method creating unnecessary risks for the individual, it is considered unethical. Among them is that if a randomly selected lead to a person will receive the treatment they need, be denied. A material that is highly acceptable; If the results of A treatment and B treatment or A with placebo to medical professionals have not determined that has significant difference can be used random selection. In this case is said the clinical balance.

2.3.2 Confidentiality of Research

at The research that findings may be make a problem by legal or social for the participants, Should be more careful with obtained information be confidential. Give participants the confidence to creating more incentives for participation and continue their cooperation and to share real information as well as risks of psychological and behavioral causes less for them (Wada, 2000).

2.3.3 Selection of study subjects

The selection subject should be used carefully do not use to those in boarding institutions such as welfare (elderly or groups that they can answer questions about immorality of deliberate choices they make. This is especially the case for children, pregnant women and fetuses, prisoners and a mental patient is emphasized (Stuart, 2009).

3. Discussion and results

3.1 Ethical principles in conducting research

In a large of study of ethical issues, such as the Agreement on the study results during the study and research of executive responsibility.

3.1.1 The information threshold and agreement

The threshold is the person who asked him to sign the agreement, Must have sufficient capacity to make a decision and let him be given the choice, decide.so must provide sufficient information must be understandable to him. After two steps of threshold and data was performed, Those who have agreed to participate in the study by signing a consent decision will express.

3.1.2 The responsibility of conducting research

It is very important that about responsible implementation of the study, the sampling method to the method of data entry and analysis, and report them to be used accurately enough. Pay particular attention to the above furthermore, in terms of scientific research assures, will cause unwanted risk not threatened subjects. The responsible for investigator is people who are helping him at the research familiar with all of the above and the administrative and managerial responsibilities of research to teach and to monitor its effective implementation.

3.2 first issue: the criminal liability of doctors and their toy breaks in biomedicine

3.2.1 First speech: the nature of responsibility in biomedicine research

There are two views in case of medical Liability. The first approach is based on enforcement of the physician-researcher responsibility and another approach, which is attributed to the contract idea of commitment and dedication to the conclusion, derived from the same perspective.

3.3 The enforcement of researcher responsible

in France law has long been considered the responsibility of the physician enforcement. In 1833, the French Supreme Court, ruled that the responsibility of the physician to the French Civil Code Articles 1382 and 1383, adapted, so the responsibility of the physician, is inevitable. Until 1936, the Supreme Court expressed a different view about the responsibility of the physician, the courts of France, the Medical Responsibility exercise regulations governing of the enforced duties. The injured party must prove that the doctor's fault. Court of France in 1936, with the approval of the terms, the contract physician's responsibility.

3.4 The contractual responsibility of the researcher

There is a good deal and establish causality condition is fulfilled contractual liability. So a lack of commitment arising out of any contract means a contract committing an error. Whether this is caused by the intentional or the result of an error. In any case, the fundamental element of contractual liability is breach of warranty which recognized by each party in a contractual relationship. indeed, contractual liability, obligation to compensate for damages resulting from non-performance of the contract is discussed in the contract Section. But civil liability of non-contractual is arising from crime and tort, the obligation to compensate for damages caused by the illegal incident that occurred outside of the contract.

3.5 Section II: The nature of the researcher commitment

Being committed perspective of practitioner also at the Imami has many fans. Sani martyr believes that even if the doctor has sufficient knowledge and skills to treat the patient's and did not commit a fault in the event of death or bodily injury to any person, is guaranteed. Many Arab lawyers believe that doctors commitment is a commitment by Instrument physicians who, by paying attention and effort, all the means necessary for the treatment to work, the result is not achieved, may not be his responsibility. socially also know responsible physicians about the loss of something he has done in the context of its time, he takes the initiative and stops the science from boundaries of conventional and harmless. Morally, how can answer punishment for Charity to bad, and of human that all his efforts and knowledge is applied at the treatment, the damage was?

3.6 Section III: Elements of criminal liability researcher

Regulations of Regional Committee for Medical Research Ethics is particular system that biomedical research anchors and researchers in the field are required to follow in case of violation of the fault committed and the punishment will be.

3.7 Second speech: Toys exemption from criminal responsibility in biomedical research

Section I: Necessary sufficiency of biomedical research

Section II: Rule duct E.

Section III: lack of legal

Section IV: the satisfaction of participants in medical research

(A): The concept of legal consent

volition, however, is the foundation for any legal action but when volition be effective that the consent is to create a legal action, calculate profits and losses of the arrangements volition be developed. Whenever a person see his interest select volition or choose to stay. But what is needed to calculate the benefit and disadvantage, namely is freedom of the volition. Who acts under pressure of foreign or domestic of physical or spiritual, he volition legally valid will. A basic condition for the effectiveness of the volition is "consent" volition. Thus, according to Article 199 of the Civil Code says "consent obtained as a result of mistake or duress, caused a deal of influence is" no legal effect.

(B) consent forms

Satisfaction is on both explicit and implicit. If you volition be using the word or text that is traditionally used for this purpose is explicit and implicit. In other words, implicit or explicit consent is expressed by action. Refer the patient to a physician to treat, go to the dentist for tooth extractions, etc are examples of implied consent. Patient satisfaction offered pre-treatment or post-treatment. French lawyers believe that man is the only creature that has a lien on his body. And hence, the physician must obtain the patient's explicit consent.

(C) the validity of consent

Consent must be informed. It is clear that if an unwanted consent or the uncertainty is still the effect is not reduced. If you are aware of the issue, in the absence of consent, a person's health or life is jeopardized, Many patients did not consent to undergo major surgery. Financial incentives do not ineffective satisfied. Even if the psychological and social pressures (for example, removing a kidney for transplantation into a relative) will consent is still consent not to be ineffective.

(D) domain satisfaction

obtain consent from the patient when is necessary that avoid causing hardship. According to Article 43 of the French medical ethics, doctors who treat someone mature and incapable, it should try to obtain consent, notify his legal representative. In an emergency or when the legal representative is not access to care physician is required to do. So if a patient is not unable to consent or there is not sufficient time should be allowed to consent to the consent of any other person who drew. If postpone action lead to damage and harm to the patient, the doctor is allowed to act without consent.

4. Conclusion

Meant- medical of new advances, without extensive application experience on the nature and man have not been possible. Basically " developmental biology of humans especially science of genetics and his ability to treat disease by manipulating the function of organs, tissues, organs, and he is not possible unless the possibility of an extensive empirical research and scientific experiments on humans exist. Verify and confirm the proposed hypotheses in the field of bio-technology, testing is required either directly performed on humans or the components are separated from his body. The respective results of the experiments and research, can be very beneficial for mankind the growth and development of the science of genetics and biotechnological provide route to prevention and treatment of diseases. On the other hand there is also the possibility of a very solemn and serious that this research and testing, destructive effects are permanent and serious impact on the physical and mental human subjects.

One of the guiding principles and approach in relation to the issue of experimentation on human subjects is respect for human high dignity. Because some of the experiences and research on man can bring the effects of permanent and serious physical and mental health, therefore, it is necessary experience and research done on humans in the context until the principle of human dignity has not entered any damage.

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