Biomedical research from the perspective of criminal law

Zohreh Parsaeian,
Department of law, Central Tehran Branch, Islamic Azad University, Tehran, Iran.
Mahmoud Abbasi (corresponding author),
Associate of Shahid Beheshti Medical Sciences University and president of the Center for Medical Law and Ethics

Abstract
Rapid and significant advances in medical knowledge and discovered new ways to prevent, diagnose and treat is indebted Scientific Research. However, the fact that before therapy including a new drug use of new technologies in society as a common method used, It is necessary to test the various stages of clinical trials (research on humans) to be spent, this is a new legal questions and challenges in the valley of support for Bioethics and protect the rights and dignity of patients and subject is face the human. 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.

Keywords: Biomedicine, bioethics, criminal liability, and exemption toys from criminal liability

Introduction:
With the development of medical research in fields such as human and animal research need to special meditations in this area. 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. The expansion of health services and the development and application of new methods and development of research on the other hand, regarding of clear boundaries at two areas and lack of research on patient costs and maintain it according to clear principles of medical ethics and research is necessary to expand. The purpose of speaking on ethics isn't create new obstacles in the way of research, but also ethics, self-help and ensure continuity of service to the people and neglecting it can
interrupt the continuity of the research. Medical advances in the diagnosis, treatment and prevention associated with new ethical problems that the necessity of perspectives and practical application of ethics in research is indispensable. In fact, the practice is not only a medical indication, ethics in research is the medical standards for service delivery. But scholars and scientists in every community are role model and source and in distraction or guiding people can play a major role.

**Statement the problem**
Rapid and dramatic advances in medical science over the past half century and discovered new ways to prevent, diagnose and treat is indebted Scientific Research. Biomedical research to protect and promote the health and community underpin the medical advances. That before therapy including a new drug use of new technologies in society as a common method used, It is necessary to test the various stages of clinical trials to be spent. These steps include research in the laboratory and outside the lab. Research outside the laboratory are divided to pre-clinical studies (animal) and clinical (human). It is clear that new methods of treatment and research are not free from harm and in most innocuous conduct research on animals, is not guaranteed to be safe for humans. The most modern methods of treatment outcome should be tested and assessment on humans. Clinical stages of human are used as subjects in research and facing the human, new legal questions and challenges that in this study, we try to explain it from the perspective of criminal justice and criminology. Human as subjects in experiments done on him has legal lab has been assignments to be tested on humans. Thus the study of law opens in the realm of science. 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? 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?
Materials and Methods
The research method used in this study is the analytical method. Thus, initially referred to various sources of 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).

The main method of data collection study is the library, and will attempt to take advantage of online resources to increase the richness of the discussion.

Research 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.
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.

Hypothesis research
Two main hypotheses have been considered:
1. In terms of the impact on ethical aspects of biomedical research and the legal requirements of the law morality and also due to enumerated adverse effects for some subjects in biomedical research, based on the principle of harm, and on the necessity of supporting the criminal realm biomedical research demonstrated. Today, the need for responsibility in biomedical research question is not, however, regarding the nature, scope and strategy of proving seen the differences.
2. 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.
First topic: Concept of biomedical research that and Principles
medical science as one of the oldest human knowledge is constantly being
developed and improved. Discover new ways to prevent and treat and
managing a variety of medicines and diagnostic tools and medical devices,
including the development. But the question the experts in the field that how
and what way of biomedical efficacy of new phenomena of health and care or
diagnosis set humans. The answer to measure the profit or loss on a new
medical discovery is the only way to use human subjects in biomedical
experiments. So now it is one of the most important medical ethics and medical
law, medical research agenda on human beings.

Speech I: Concept of biomedical research
The disagreements among scholars in the field of biomedical research can be
seen, But these differences to the extent that the nature and principles exist
that do not, It was felt necessary to examine these issues in a separate
discussion, accordingly, in the first speech of this issue in the context of
biomedical research and examine the principles which we will in second
speech.

Section I: Concept of biomedical research
R word refers to a set of activities designed to develop or contribute to
generalizable knowledge that is possible, are designed. Generalization of
knowledge consists of theories, principles, or data collection that the
knowledge based on is created and accepted, observation and inference and
confirmed by the scientific method. Biomedical is conditions belongs to the
range of medical science that is relevant to human biology. In other words,
those medical issues that directly "linked with human biology and leading to
changes in the structure of human biology called biomedical.

Typology of biomedical research
Biomedical research between the two modes of treatment and non-treatment
research have been distinguished. criteria of this assessment is based on
objective to be followed in the study. Experience shows that only scientific
search or experience that can be used to improve a patient's. The significance
of this difference is that, judging by the experience of therapy with little
problem is not encountered, If a judgment about an experience strictly "science
is much more difficult. There is a wide variety of biomedical research. If these
investigations division from various aspects. The most segmentation is often
regarded at international instruments differentiation of biomedical research is
primarily aimed at "the diagnosis or treatment of a disease with research of their aim is quite" science and straight "not conducted for the purpose of diagnosis or treatment. Biomedical research shared from medical and clinical research or non-clinical and scientific research.

**Speech II: Principles of biomedical research**

**Necessary to protect human dignity**

The term in its broadest sense implies a certain quality to it that human carriers. The sense of dignity has lateral aspects and is acquisition and declining. However, when dignity is attributed to human the meaning denying of the cross privileges on the sanctity of every human have it. The sense of dignity, ie, not obtained or not lost. The most important principle of medical ethics is the obligation to respect the human dignity and human rights is the Universal Declaration of Human Rights and even the Human Genome and Human Rights and Bioethics is also manifested. Universal Declaration of Human Rights in 1948 emphasized the dignity and worth of the human person for all peoples and all nations. Perhaps what distinguishes international instruments relating to biomedicine is the main role assigned to human dignity and a sense of common measures adopted within the framework of human rights surprising is that human dignity is one of the few shared values of philosophical pluralism world.

**Internal approach**

**Tehran Declaration:**

The first National Committee of Ethics in medical research in 1998 in Iran was established under the chairmanship of the Minister of Health and Medical Education and one year after the regional committee of ethics in medical research at medical universities and research centers opened and currently are working. Although the statements of international and Islamic typically do not contradict together. But given the condition of our nation and the Islamic perspective, national Center for Ethics in Medical Research program has implemented legislation in response to these needs. Thus, working group composed of the number of researchers of Ethics Research Center and History and Medicine in collaboration with consultants, Experiences of health professionals at national and international level examined in this area. Ethics Research Center and the History of Medicine formulated regulations of 26 originally.

**The six principles of ethics guiding at research**

This directive published by the policy of Ministry of Health and Medical Education Research Center Ethics and History of Medicine of Medical Tehran
University in 2006, The aim of preparing them, providing ethical guidelines in six areas of emerging research in medical and biological sciences that is motivating ethical and legal issues.
The six ethics guide includes moral instructions in "genetic research", "research on specific groups", "animal research", "research on gametes and embryos", "Organ and tissue transplantation research" and "clinical Trials".

The second topic: the concept of criminal responsibility and principles

First speech: the concept of criminal responsibility and its kinds

None of the Criminal Code, whether past or present, the legal nature and definition of criminal responsibility is not clearly, And lawyers in this field have presented various definitions for it. However, the nature of the legal definition of criminal responsibility is not clearly.

Section I: The Concept of Criminal Responsibility

Criminal responsibility requiring a person in responding to the consequences of adverse events is criminal or offense. From the perspective of a criminal offense or any violation of Penal Code only and does not in itself lead to criminal liability but to know crime commit, punishment and responsible from morally reprehensible socially and we need to:

First, "criminal behavior or the criminal phenomenon that stem from a conscious desire and determination.

Secondly, "criminal act that is fulfilled outside with the thought and commit intention and desire to a indicate bad faith or the result of committed by his mistake or error.

Thirdly, "according to criminal justice for Know the crimes committed responsible in addition to the determination and criminal guilt and ill between the crime and its agent must be capable of assignment It is deserving to be punished and the purpose of the assignment feature is that the judicial authorities have ascertained that the subject of the crime of physical and mental development and willpower are important.

Section II: Types of criminal responsibility

1. The potential criminal responsibility, potential responsibility is an abstract concept. Competence and ability to bear the consequences behavior is criminal and responsibility in this sense refers to "a particular trait in a particular person or situation". Abstract and potential concept of criminal liability in a criminal capacity is obvious. According to some lawyers only prerequisite is required for criminal liability. For the assignment of the way to make it real and take
responsibility for the consequences of his crime matters that the state has committed (subject) will be accrued at the time of committing the act.

2. Potential criminal liability: is a real and objective sense. Imposing consequences of behavior, crime, committed on a person's. Responsibility in this sense is not a single trait or state vested with the person, but is something distinct and overseeing coercive imposition of penal consequences. Potential criminal liability for past and relying on punishment, subsequent offense arises. The concept of potential criminal liability is found potential criminal liability sentence must intellect or supposed, because the consequences of criminal behavior imposed on a person except in a state that does not have the capacity to bear the consequences are unthinkable.

Speech II: Principles of Criminal Responsibility
Sometimes, traditions, customs and culture of a society dictates that men do or leave in terms of it would say common logic. In this case the logic is not Aristotelian or old logic, so the methodology or methodology is not meant that there is now a science, but the common logic, the same logic that makes men different from between good bad and the ugly and the beautiful, bright words, what common sense dictates that the average person.

The second topic: the concept of criminal responsibility and principles
Section I: rationale responsibility
Sometimes, traditions, customs and culture of a society dictates that men do or leave in terms of it would say common logic. In this case the logic is not Aristotelian or old logic, so the methodology or methodology is not meant that there is now a science, but the common logic, the same logic that makes men different from between good bad and the ugly and the beautiful, bright words, what common sense dictates that the average person.

Section II: the moral responsibility
Within the territory of customary logic, merely "a given society at a time counts acceptable or unacceptable feasible, while the moral and ethical norms and rules (in many cases), a wider scope and acceptable in the sight of more communities. Some may argue that rational ethical is standard to recognize rational good and evil of actions and include plenty of human and social values that it accepts all communities.

Section III: The psychological basis of liability
Another foundation that criminal liability is based on is that the offender is blameworthy mental. If the criminal through the psychological sciences, considered to be a non-responsible, responsible him is non-rational and did not meet any of the objectives of the legislation. In the old days people are insane, like the wise men had criminal responsibility. Even if they had not committed a
crime, punishable by flogging until the devil out of their body. For the first time in the West in the late eighteenth century AD, the two psychiatrists called by (Pinel) and ((Isquirl) offered fresh ideas in this area the result of their studies on the fate of crazy was impact and it included in the French Penal Code of 1810. This law, first clearly stated no responsibility of madness, so that before in Europe, both in antiquity and in the not too distant era, insane, is responsible.

Section IV: the social responsibility principles

The topic of social responsibility as one of the fundamental principles of criminal responsibility, Experience relatively "long, especially since the advent of positive school of the social responsibility made clear and independently, is more marked.

Section V: The legal basis for liability

In most overwhelming legal system, criminal liability and punishment is based on the assumption of legal liability; means the criminal law knew responsible and deserving of punishment every adult, sane, and that under normal circumstances the offense will be committed. Rule known as "ignorance of the law shall not be responsible", in the circumstances has been accepted both in common law and Islamic law. In Iran this rule has been approved by lawyers and the Supreme Court. By voted one of the branches of The Supreme Court "ignorance and the accused plight led to practical impunity by law" is prohibit and punish perpetrators have not."

Chapter II: criminal liability arising from biomedical research and for actions research

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 Jlsinger 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.

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- The social benefits arising from biomedical research

Second 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.

Second 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.

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. 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.

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.

B: 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.

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.

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.

Second issue: the criminal liability of doctors and their toy breaks in biomedicine
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.
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.

(B) 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.

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?
Section III: Elements of criminal liability researcher
Regulations of Regional Committee for Medical Research Ethics is a 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.

Second speech: Toys exemption from criminal responsibility in biomedical research

Section I: Necessary sufficiency of biomedical research
Section II: Rule of thumb 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.

**Conclusion:**

Ment- 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.
References

Article 2 General provisions, draft international declaration on human genetic date, 8 October 2003

Abbasi, Mahmoud, A collection of documents and declarations of international cultural and Bioethics, p 84


Fact Sheet, what is Biomedical Research, California Biomedical Research Association, Website: www.ca-biomed.org p 1


Montazeri, M. given legal protection of genetic information from the 2009 season, a medical law, third year, No. XI, p. 43.


Stuart, M. C, utilitarianism, (2009), the man translated, printed, Tehran, spreading straw.