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Civil Liability Arising from Health and Medical Research

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ABSTRACT

Background: In, health in addition to promoting medical knowledge, it aims to diagnose or treat diseases. According to ethical and legal principles, the damage to the patient in the process of health research must be fully compensated.

Methods: In this research, the issued verdicts and the existing judicial procedures in legal cases in judicial and quasi-judicial authorities were analyzed in order to formulate the necessary legal theories with regard to the jurisprudential and legal basis of civil liability of researchers and scientific centers. To achieve results, it has been tried to avoid any violation of human rights without hindering the process of scientific research.

Results: The basis of this view is moral and legal commitment of society to compensate for injuries caused by research, because ultimately, it is society that benefits from the results of medical and scientific research. As a result, it is better to provide legal support for the need to insure patients in medical research and to allocate special funds for damages resulting from medical research.

Conclusion: There are drawbacks to filing a civil liability lawsuit for injuries caused by medical research; this is because it either leads to incomplete compensation or is an obstacle to medical research and medical researchers. Assuming the sole responsibility of research centers to create such liability insurance, legislators should enact comprehensive laws to resolve the existing ambiguities regarding the claim for injuries.

Keywords: Medical Liability, Civil Liability, Compensation, Medical Research, Obligation

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Introduction

In recent years, the increasing pace of medical knowledge is due to the research done on living organisms, humans and their environment. Without successful medical research, existing techniques and methods will not be easily improved. However, while research results may be very useful, a number of ethical and legal challenges have been raised. One of the most important issues in this regard is civil liability for injuries to subjects from research. In examining this issue, other issues should be considered, including the need to obtain the patient's informed consent to conduct research and the amount of necessary information that should be given to these individuals before conducting medical research.

The importance of conducting medical research and the need for new healthcare methods on patients is undeniable. This is because in some cases, there is no definitive treatment to cure the disease and the only way is to use new treatments. Determining the legal framework governing this type of treatment is one of the essential issues in medical law today, and the present article intends to answer some of the questions that arise from performing these treatments. One of the aims of this research is to explain the legal principles governing medical research, the violation of which will lead to civil liability of physicians and researchers. In other words, in case of injury to the patient, in what cases and with what matters, damages can be claimed. Moreover, according to Iranian laws, what are the principles and legal documents of a doctor's civil liability in health and medical research?

1- Conceptualization of the subject

Currently, medical research on human beings is one of the most important and complex topics in medical law; so, the explanation of civil liability in these cases requires a precise understanding of the concepts and terms used.

1-1. Civil liability

In general, civil liability is the obligation of a person to pay for the damage caused to another person, whether the loss is due to the action of the responsible individual or those related to him or the objects and property owned or seized. Be him (1). In other words, whenever a person is obliged to compensate for the damage to another person, he has a civil liability against him, whether this liability arises from the contract or not. As a result, civil liability is divided into two important categories: contractual liability and coercive liability, also called civil liability in a specific sense. Contractual liability is the result of non-commitment to the contract; this liability is the result of violation of the provisions of a private contract (2).

Coercive liability or civil liability in the specific sense is when a person is harmed as a result of a breach of legal duty. In coercive liability, there is no contract between the two parties, and one party intentionally or erroneously harms the other due to his act or omission. The root of this type of liability is not the agreement with the injured party, but the violation of the obligations that exist for all people (3). For example, a driver who crashes into a pedestrian due to speeding has violated his legal duty not to harm others. This responsibility is not the pact between him and the victim, but the violation of the legal obligations that exist for everyone.

1-2. Biomedical research

Biomedicine includes a range of medical sciences related to human biology. In other words, those medical topics that are directly related to human biology and lead to changes in the human biological structure are called biomedicine. Therefore, biomedical research refers to those studies that are either performed directly on humans or their results affect human biological life. A clear example of biomedical research is the research done on human beings, or in some way related to individual's freedom, personality and human existence.

The most important division in biomedical research is the distinction between biomedical research that primarily aims to diagnose or treat the disease and the research whose purpose is

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completely scientific and is not directly aimed at diagnosing or treating a disease.Biomedical research is therefore divided into therapeutic research and scientific research. This distinction was made in the initial version of the 1964 Helsinki Declaration, but in the 2000 version, this distinction was removed after much debate and concern by supporters of the study participants (4). Nevertheless, the legal distinction between medical research and scientific (non-therapeutic) research is essential for any discussion of the legal challenges of biomedical research (5). Because the legal obligations imposed on researchers vary according to each type of biomedical research, and the patient is the direct beneficiary of the research, there is less legal protection regarding the amount of information. It is necessary to obtain consent while there are many restrictions in scientific research in this regard, and the researcher is obliged to fully inform the subject of all information and risks related to the research (6).

1-3. Health research

Health research aims to diagnose or treat the subject's disease in addition to promoting knowledge of health and medical sciences. The subject is the patient himself, and since all the available treatments have been ineffective for him, an attempt is made to treat him experimentally by performing unusual methods or treatments, perhaps with a new study. There is a possibility of his treatment. For example, testing the effects of a new drug to treat hepatitis and comparing it to other standard therapies is a therapeutic research (7). This research is also called medical research combined with medical care or clinical research.

In scientific biomedical research the subject participates in the research that aims only to promote human knowledge and is not treat him (8). In other words, they are not directly intended to diagnose or treat the disease. In such research, the patient is not self-tested and does not benefit directly; he/she participates in the research only to discover and invent new drugs or treatments (9). This type of biomedical research is also called non-medical research.

Until now, important claims in the field of health and medical research were considered by the public. Jesse Glesinger died in 1999 as a result of gene therapy at the University of Pennsylvania Children's Hospital (10). In another case study in 2001, 13 patients admitted to the University of Oklahoma Health Center filed a suit in federal court for damages they allegedly suffered as a result of participating in a medical investigation. In 2003, a patient with psoriasis in North Carolina filed a lawsuit against his physician for injuries he sustained because of participating in medical research (10).

It is a fact that participating in medical research sometimes leads to injury, physical disability or even death for the patient, but this fact should not and cannot overlook the benefits and necessity of using new methods of treatment. For this reason, in the last few decades, there have been extensive debates by medical researchers, lawyers, and thinkers in other fields of ethics and technology on the need to form a national structure and program to compensate for the human subject (7). The basis of this proposal is moral commitment of society to pay for research-related injuries and damages; this is because, ultimately, it is society as a whole that benefits from the results of medical research (7).

2- Fundamentals of civil liability resulting from health and medical research

The principles of civil liability resulting from health and medical research include ethical, legal, and jurisprudential principles which are explained and interpreted below.

2-1. Legal basis

By studying the historical evolution of the principles of responsibility, four main theories can be deduced: fault theory, risk creation theory, mixed theory, and right guarantee theory. Fault and risk creation theories are of special importance. Although the theories of risk creation or responsibility without error are historically ahead of the theory of fault and were common in European law until eighteenth century, with Industrial Revolution, their attraction was lost and

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fault-based liability become more prevalent.

The theory of fault is based on the perpetrator's mistake in causing damage and is accepted in Article 1 of the Civil Liability Law as a principle in Iranian law; the causal relationship between the perpetrator's mistake and the perpetrator must be established and the burden of proof is on the claimant. However, in risk creation, any activity in society is the source of creating a risky environment from which everyone who benefits from it must also compensate for the damage caused by it. Therefore, fault is not one of the pillars of this type of responsibility. Later, the theory of guarantee of right was introduced, which considered the creation of liability in each of the theories of fault and risk creation wrong; it suggested that the right for protection be guaranteed by compensation. This theory, like other theories, could not be considered a unique basis of civil liability and create a just system.

Although with the advancement of new sciences and technologies and the complexity of social life, the solution of all legal problems of society cannot be sought in specific theories; but, it should be noted the new approach of legal thinkers and legislators in developed countries based on theories of risk-taking or error-free liability might cause harm to individuals, especially in the field of biomedical research, in governments, public institutions, or insurance companies. In the current case law of developed countries, medical liability is based more on the theory of risk creation or liability without error (11).

2-2. Jurisprudential principles

In the Islamic legal system, liability is based on the rule of no harm, stating that the shari'ah leaves no harm uncompensated, even if the cause of the harm is not the culprit. In examining the principles of responsibility in the Islamic legal system, in addition to the no-harm rule, the rules of loss and causation should also be studied.

One of the rules that are effective in modifying or supplementing the Shari'a scripts and many sub-rules have been deduced from it is the rule of no harm or the rule of negation of harm. Although many religious texts have been cited by jurists as evidence of this rule, but without a doubt, the ugliness of harm and goodness is prevented from it, and as a result, the prohibition of harm is one of the rulings that reason, regardless of religious texts or jurisprudential evidences. It is independent of reason and in other words, this rule is one of the general rules based on fairness.

Another well-known jurisprudential rule that jurists have relied on for guarantee is the rule of waste. The meaning of the rule is that whoever loses, seizes or exploits another's property without his permission is a guarantor against the owner of the property. The basis of this rule is the rule of reason and the construction of rational people and many verses and hadiths. All jurists agree on this rule and not only there is no disagreement about it, but it can be said that it is common to all Muslim sects (12).

If a person does not waste money directly but lays the groundwork for wasting it, it is called waste, and he/she is responsible for the losses incurred in this way. Therefore, whenever a person does something that leads to the loss of property, it is called waste. But, when the ground is provided for the loss of property, it is called mitigation; for example, if someone digs a well and another one falls into it and breaks his leg, the person digging the well is the guarantor for the cause (13). The proof and documentation of the rule of tasbib is narrations and consensus. According to the application of these narrations, the perpetrator, intentionally or unintentionally, is the guarantor of course, it is necessary to attribute damage to the causal act (14).

2-3. Ethical principles

One of the most important principles of civil liability resulting from medical research is medical ethics. Covenants of ethics in medical research can be invoked in claims for damages resulting from medical research, given that these covenants have legal value and validity. In other words, in case of violation of the rules, the observance of physicians and researchers is legally required, not just their recommendation.

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Regarding Helsinki Declaration, it should be noted that its validity is legally weak and limited; it states the rules or ideals of professional ethics for medical practitioners. In the introduction of the statement, it is emphasized that the envisaged standards are merely guidelines for physicians around the world; this is because physicians are not exempt from the moral, civil, and criminal responsibilities of their own countries (6). This statement provides limited assistance and support to individuals and patients harmed by a group of physicians who violate the rules and ethics of the profession.

Nevertheless, Helsinki Declaration had had a major impact on the creation of many national and international treaties governing research, especially research on human issues. But research shows that, when the Declaration of Helsinki has resorted to legal solutions, it is severely restricted by the constitutional laws and trial regulations of other countries. US courts have relied on Helsinki Declaration in some cases; for example, Pfizer pharmaceuticals have been charged with conducting medical tests on a new and untested Trojan antibiotic that killed 11 children and seriously injured other disabled and deaf children. Moreover, in the International Covenant on Civil and Political Rights, this statement has been used as a guide for international legal principles regarding medical examinations (6).

Overall, the Helsinki Declaration, like other international moral conventions, lacks any means of punishing violators. Looking at the perspective of those who have been victims of violations of the rules, it can be seen that the statement has legal authority and the right to judge in resolving disputes, but lacks executive guarantee (6).

Contrary to Helsinki Declaration, which lacks sufficient legal value, national treaties for the protection of human subjects are mandatory in medical science research, both in Iran and in European countries, and violation of these rules will result in the liability of the physician and the researcher. The basis of the legal validity of these covenants at the national level can be summarized in the fact that these covenants, according to their provisions, are professional rules for medical experts and in line with the legal principles of liability. Non-observance of the rules is considered a kind of fault and leads to liability of the offender. Another reason for the legal validity of these covenants is the origin of these covenants from human rights rules. In other words, these covenants are the result of the application of human rights principles in biomedical research.

3- Legal aspects of civil liability resulting from health and medical research

After clarifying the concepts, history, and principles of the discussion, it is time to examine the civil liability arising from medical research in terms of substance and form. In the following, the authors first examined the nature of such responsibilities, and then, analyzed the aspects of civil liability litigation in medical research. Finally, the burden of proof and the issue formally were discussed.

3-1. Physician's civil liability in health research

Until the late 1980s, most countries did not have a specific set of laws regarding physician's liability in health or non-medical research, and these issues were largely governed by general or medical liability laws (15), As a result of the wide-ranging debates discussed in various conferences, many countries have adopted laws on medical research and compensation (16). Unfortunately, in Iran, no action has been taken to pass comprehensive laws in this regard, and civil liabilities arising from medical research are addressed under the general rules of civil liability and special rules of physicians' liability mentioned in the Penal Code.

Before discussing civil liability, it is necessary to discuss the nature of civil liability in this type of health research. Because the choice of any of these principles, in principle, the citation rules have a definite effect on this responsibility. Civil liability in health research in fact raises the same issues as physician's liability. That is, if there is an explicit or implicit contract and a combination of conditions, the responsibility in these cases is contractual; otherwise, the responsibility resulting from medical research will be coercive. In the

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following, examine both cases will be examined.

3-1-1. Contractual responsibility

If there is a contractual relationship between patient and physician, the physician may be held liable for breach of contract. In legal systems where medical contracts constitute a specific type of contract and have their own effects and conditions, the quality of medical contract is important, and different rules of liability can be applied. The patient-physician relationship in medical research is often a contract in which the physician undertakes to use his or her skill effectively to treat the patient using a specific and uncertain treatment method. In this contract, the doctor does not guarantee his/her success and does not consider himself/ herself responsible for the failure. In Iranian laws, medical contracts are not subject to special rules and are examined under the same general rules of contracts. Therefore, the contractual liability in these cases can be invoked if the physician does not fulfill one of the contractual obligations, as a result of this violation, the patient will be harmed.

3-1-2. Coercive responsibility

The discussion of coercive liability is important because in the law of some countries, including Iran, even if there is a contract, it is possible to invoke the rules of coercive liability (2). In addition, in the absence of a contract or its annulment in medical research, the only way to claim damages is to invoke the rules of coercive liability. Also in the law of some countries such as France and Germany, the time limit for filing a lawsuit and the passage of time vary according to the contractual or coercive liability (15). In most legal systems, a specific medical malpractice can be both a breach of contract and a fault in a coercive liability lawsuit. But an exception to this rule can be found in the French legal system, where it is impossible to combine contractual and coercive liability, and if there is a contract, the injured party cannot invoke the rules of coercive liability (15). But what is common to all legal systems is that the claimant must first determine the basis for the lawsuit. In the Iranian legal system, invoking the rules of coercive liability in the presence of a contract is possible only if it does not upset the contractual balance desired by the parties (2).

German law also applies certain provisions to the liability of physicians. In some cases, doctors have not been held accountable and the government has been held liable as their employer. In addition, under German law, compensation for non-pecuniary damage or bodily injury is possible only under the rules of coercive liability (Articles 253 and 847 of the German Civil Code).

3-2. The aspects of physician civil liability in health research

Regarding the direction and origin of civil liability in health research, a distinction is made between the two. The first case is the damages that have been inflicted on the subject during the medical research due to the incompetence of the physician and non-observance of professional criteria and the second case is the damages inflicted on the patient in medical research without obtaining informed consent.

Given that health research poses risks, it is common to test it on animals first; there is a possibility of success or failure, or even the death of the patient. Now the question arises whether the doctor has the right to risk his patient's life to perform an experiment?

In these cases, what is certain is that physicians cannot be allowed to run new tests on patients. In addition, the conditions that legally exempt the doctor from liability must be within medical research. The conditions include legal permission, patient satisfaction and legitimate purpose reflected in the physician's practice in health research. In other words, the patient must know about the dangers of innovative treatment, express his / her consent, and the physician's goal must be treating patient. The doctor should not just conduct the research to satisfy his/her scientific lust, even if it is a service to medicine or Society. When the physician's action is not based on the patient's desire to recover and treat, even the consent of the patent is pointless.

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The "intent to treat" condition allows the use of a new dangerous treatment that is necessary ; so, where the patient can be treated with normal and existing medical devices, the doctor cannot proceed to new treatment (17).

Another condition that does not lead to the physician's responsibility in medical research is lack of skills. In other words, medical research should be based on scientific principles and the correct method, and the attending physician should have the necessary degree to allow him to conduct such research. There needs to be a balance between the harms of disease exposure to new treatment. Therefore, if the physician uses a dangerous new method in the treatment of a simple disease, it is considered a fault and the physician is responsible, even if he intends to treat the patient (15).

Therefore, in cases where the patient is not in danger and his disease is not life-threatening, the doctor cannot use dangerous medical research in which the possibility of irreparable damage is high. However, in cases where there is a possibility of certain death or severe bodily injuries such as paralysis, etc., the doctor can try any kind of treatment, no matter how dangerous it isto save the patient's life. Of course, it should be noted that such a case is also permissible due to the necessity and intention of healing the patient.

According to what has been said, if the physician conducts medical research on the patient without his express and clear consent, or with his consent, but not with the intention of healing and treating the disease, and just for the scientific virtue and theoretical and academic issues, like what is done in some public hospitals by some doctors and medical students on patients, the civil responsibility falls on the doctor.The aspects of physician's responsibility in medical research and new methods of treatment can be examined under the following two headings:

3-3-2-1. Unlawful treatment (malpractice, unlawful treatment)

In some cases, civil liability arising from health research is examined for medical error. Responsibility in these cases is sometimes due to lack of sufficient skills and knowledge in conducting medical research and sometimes due to not taking a specific therapeutic action. Avoiding some medical procedures may also be considered a medical error, if these measures are deemed necessary in accordance with medical practice or law in treatment or research. The criterion for determining the level of skill should be determined according to medical knowledge of the time and place of medical research.

Another criterion that must be observed in health research and its violation causes the physician to be responsible is the ethical principle in medical research, which is foreseen in the treaties of ethics:

1. Physicians can integrate research and medical care to the extent that the research can be justified by its potential therapeutic, diagnostic and follow-up values. When research and medical care are integrated, additional standards should be used to support the patients under study.

2. The benefits, risks, pressures, and effects of a new method should be weighed against the best conventional prevention, diagnosis, and treatment methods. This does not rule out the use of placebos or the lack of treatment in studies where there is no proven method of prevention, diagnosis or treatment.

3. At the end of each study, each patient should ensure access to the best and most effective methods of prevention, diagnosis, and treatment in the study.

4. The physician should fully inform the patient of which aspect of care is relevant to the research. The patient's refusal to participate in the study should in no way interfere with the physician-patient relationship.

5. In the treatment of a patient, when there are no proven methods of prevention, diagnosis and treatment, the doctor, after obtaining the consent (after giving sufficient information to the patient), can use unproven methods. Treatment is free if, in his view, these methods can save life, improve health, and reduce suffering. In all cases, new information should be recorded, and if necessary, published if the feasibility study of the efficacy and

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safety of these methods is determined as the purpose of the study. Other relevant strategies must be followed as well.

3-2-2. Treatment without the patient's informed consent

The physician's responsibility in health research concerns patient's dissatisfaction. Satisfaction must be conscious, but it is clear that if satisfaction is based on doubt and hesitation, it still does not diminish its effect. Because if the patient's health or life is not in danger, many patients would not give their consent for surgery (18).

However, it should not be denied that awareness is a precondition for satisfaction. People cannot be satisfied with things they are not aware of. Therefore, consent without knowledge is not legally valid. Many of the laws of consent also include awareness (19). Article 1 of the Nuremberg Declaration is the first document that defines informed consent, and all subsequent compliments are taken from this definition: "The voluntary consent of the person being tested is absolutely essential. This means that the test subject must be legally competent to consent and without the intervention of any pressure, deception, or reluctance and coercion, whether in the early stages or in the later stages, easily decide (20).

Article 37 of the French Code of Medical Ethics states that physicians are required to state their prescription clearly and to ensure that the patient and those around him or her are able to understand it. They also need to do their best to make sure the patient receives the best treatment. The importance of obtaining informed consent in French law is such that under Article 223 8 8 of the French Penal Code, if the physician does not inform the patient of all aspects of the examination and medical investigation, he/she will be sentenced to three years of imprisonment and a fine of three hundred thousand francs (21).

According to US federal regulations, one of the essential elements of informed consent is that "a research more risky than usual should be explained whether or not there is compensation, and provide medical treatment in the event of injury" (22).

According to the existing laws, especially paragraph (c) of Article 158 of the Islamic Penal Code and the principles of medical ethics, the patient's informed consent is a necessary condition for any medical action. Therefore, the physician should inform the patient of his or her health status and explain to his or her risks and possible side effects that may arise from treatment or surgery. The nature of the information requirement depends on the type and nature of the physician's intervention, especially when the intervention is surgery or a major test. The physician is required to inform the patient of the risks that are normally foreseeable. Therefore, it is legally necessary to give the necessary information to the patient (19).

There are three criteria for the amount of information a physician must provide to a patient for informed consent. The first one is the medical standard, which is the accepted custom among physicians. The second one is the information should be enough for a reasonable and normal person to make an informed decision. The third criterion is a personal criterion; the mood, behavior, actions and thoughts of the patient. In therapeutic and non-therapeutic research, since the principle of ethics in research is based on the support of the patient, personal criterion on the amount of information required to obtain consent must be acknowledged. Because this criterion is more in the interests of the patient than other criteria. According to US federal law, information provided to the subject or his / her legal guardian must be in a statement that can be understood by him / her or his / her guardian; in other words, in US law, the required information criterion is personal (22). The medical criterion is in the interest of physicians and research institutes, and a typical criterion, due to the lack of a clear definition, leads to multiple interpretations, which in most cases are in the interest of physicians. As a result, the only criterion for the amount of information needed to obtain consent in order to protect the rights of the subject is the personal criterion. In other words, the amount of information necessary to obtain informed and legal consent from the patient and the subject is

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determined according to the characteristics of each person. Patients should be fully aware of the status and effects of research and participate in research with full awareness of the consequences of their satisfaction.

3-3. The burden of proof in civil liability arising from health research

Obviously, the success of liability lawsuits against physicians depends to a large extent on who is responsible for proving the lawsuit. Two assumptions should be considered separately; the first one is that in order to file a liability lawsuit, the physician's mistake is in the process of medical research, and the second one is that in order to file a liability lawsuit, the patient does not obtain informed consent to conduct the research.

3-3-1. File a lawsuit based on medical error

In general, in medical liability claims based on medical error, the patient who must provide evidence that the physician committed the error and that the damages were caused by the physician's fault or lack of accepted medical practice. But according to the laws of some countries, the courts tend to consider the liability of physicians as liability with the presumption of fault or even liability without fault (23). As a result, in these cases, if the patient can only prove that the damage was typically the result of a new treatment, the courts can rule based on the presumption of guilt that the causal relationship between the medical error and the damage is presumed. The only difference between liability and the presumption of fault and absolute liability is that in the first type, the physician can prove his innocence and irresponsibility, but in the second type, the proof of innocence has no effect on the physician's liability.

Also, in cases where a lawsuit is filed against the head of the research team or the director of the research institute and the lawsuit is based on the responsibility of the employer, the responsibility is considered to be on others and there is no need to prove their guilt; Only the damage caused by the actions of the staff of the institute and the subordinates of the head of the research team must be proved.

Despite these arguments, the difficulty of proving a physician's guilt in medical research is one of the disadvantages of civil liability claims. For this reason, the US Presidential Committee has recommended the researchers and research institutes in the United States to use the basis of no-fault liability to pay for the damages to the subject to prevent injustice (24). According to the fault-free system, the expert in each case determines the damages to be compensated and only pays attention to whether the damage was caused by participating in the research or caused by personal error. The focus is on the causal relationship between the investigation and the injury. In this case, the subject cannot claim only the injuries caused by his latent disease. Moreover, if the patient is injured due to not following the instructions of the doctor or researcher in taking the drug, he cannot have any claims (22).

3-3-2. Filing a lawsuit based on lack of informed consent

In most legal systems, it is the physician who must prove that he or she has obtained the patient's informed consent (10). This is because consent is necessary to justify the treatment and to authorize the principle of operation. The physician can also prove that the patient's informed consent was not required if the case was an emergency and it was not possible to obtain consent due to the need to save the patient's life and the need for immediate action, or if the patient has validly deprived herself/himself of the right to information and knowledge about treatment aspects. However, with regard to new methods of treatment and research, it is very unlikely that courts confirm the waiver of the patient's right to have the necessary information. In France, however, from the date of the judgment of the Court of Appeal on 29 May 1951, patient must prove that treatment was carried out without his consent (15). However, this ruling does not seem correct in the case of medical research, because the duty of physicians to obtain consent based on providing sufficient information and full knowledge of the patient is a legal and

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certain duty in such cases; based on this duty, proving consent is the responsibility of doctors.

In addition, the basis of the ruling of the Court of Appeals is that it is often the patient who goes to the doctor for treatment and the patient is generally satisfied with the treatment. If the patient, contrary to appearances, is dissatisfied, he should prove it. However, this basis is not applicable to medical research and scientific research, because in principle, people do not go to the doctor to participate in medical research and do not volunteer, but it is the doctor who offers medical research to the patient. As a result, he/she has to prove the patient's consent to participate in the research, because in principle, individuals do not expose themselves to the risks of medical research.

Since civil liability litigation is a very long, difficult, and costly process, researchers and research institutes should take steps to reduce litigation. In other words, as in some countries, the insurance plan to compensate the subject for research-related injuries should be defined or the treatment of these injuries should be provided by the same institution conducting the research; this is done to reduce the likelihood of filing a civil liability lawsuit (22).

Conclusion

With the expansion and multiplicity of health and medical education centers in Iran, and especially the extensive activities of clinics and teaching hospitals and medical universities in the field of treatment and medical research, there is always a fear that the human rights of patients will be neglected, whether in laboratory and medical research.

Given the ethical and legal principles under discussion, it is easy to understand that the damage done to the subject in the process of medical research must be fully compensated. The basis of this view is the moral commitment of society to pay for damages in research-related injuries, because ultimately, it is society as a whole that benefits from the results of medical research and scientific research.

Regarding the covenants of ethics in medical research, it can be said that they are not just a set of ethical precepts, but rules and regulations that have a legal basis and are binding, and in case of violation of these rules, the doctor and researcher is responsible for compensating patients for all damages.

The followings concern the effect of satisfaction on civil: the conditions of permission to occupy the souls of others exist only with the permission and consent of the person. Therefore, research and any other medical action performed on the patient has no civil liability only if it is legally legitimate and performed with the permission and consent of the patient or his guardian without error. In the absence of any of the above conditions, the physician will be liable against the treatment.

Finally, filing a civil liability lawsuit for damages resulting from health research has its drawbacks, because it either leads to incomplete compensation for the damage or is an obstacle for medical research. In order to prevent these problems, it is better to emphasize the necessity of patients' insurance in medical research and to provide the ground for this by insurance companies. It is also better, like in other countries, for government funds to provide compensation for damages resulting from medical research so as not to interfere with the rights of patients and subjects and not to impede the advancement of medical knowledge.

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Conflicts of interest

The authors declared no conflicts of interest.

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Filing a civil liability lawsuit regarding the damages caused by medical research has problems, because it either leads to the complete non-compensation of the damages, or it is considered an obstacle for medical research and medical science researchers. As a result, in order to avoid these problems, it is better to emphasize the

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necessity of insurance for patients in medical research and to provide the basis for this by the insurance companies. Also, like in other countries, it is better to provide state funds for compensation for damages caused by medical research, so that the rights of patients and subjects are not disturbed, and there is no obstacle to the progress of medical knowledge.

Ethical considerations

The conditions for taking possession of others' souls exist only in the case of a person's permission and consent. Therefore, the research operation and any other medical action that is performed on the patient, only if it is legally legitimate and is done with the permission and consent of the patient or his guardian without fault, it has no civil liability. In the absence of any of the mentioned conditions, the doctor will be the guarantor against self-treatment and the act of committing

Authors' contributions

J. R; participated in the writing and designing of the study, and first draft of the manuscript. All authors contributed to the preparation of the final manuscript and jointly approved the final version for submission.

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Subtitle

1. Biomedical researches
2. Therapeutic researches
3. Scientific studies
4. In the field of medical research, a distinction must be made between clinical research in which the goal is primarily to treat the patient, and non-clinical research which is scientific and has no therapeutic goal for the patient (Helsinki Declaration 1964).
5. Clinical studies
6. Non-therapeutic studies
7. Psoriasis disease
8. Article 1 of the Civil Liability Law, passed in 1339, and provides: "It is responsible for compensating the damage caused by its action."
9. Verse 194 of Surah Al-Baqarah: "So whoever transgresses against you, transgress against him as he attacked you."
10. Among the narrations cited to prove the rule of Tasbib are: "Everything that harms the way of the Muslims, its owner is liable for what happens to it." And it was narrated that "everyone who digs in something other than his property has a guarantee."
11. P. fizer, Abdullahi Upfizer INC, 2002 WL 31082G56 (SD NY, SEPTEMBER 17, 2002
12. Covenant on Civil and Political Rights (ICCPR)
13. Article 158- In addition to the cases mentioned in the previous articles, committing behavior that is considered a crime according to the law is not punishable in the following cases: ... C- Any type of legitimate surgical or medical operation that is performed with the consent of the person or her parents or guardians or legal representatives and in compliance with technical and scientific standards and government systems. In urgent cases, consent is not necessary.
14. President's commission for the study of ethical problems in medicine and biomedical and behavioral research

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