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Is the current regulation on research on living beings in Mexico sufficient to guarantee the rights of research subjects?

La regulación vigente en investigación en seres vivos en México, ¿es suficiente para garantizar los derechos de los sujetos de investigación?

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Abstract:

This paper examines the regulation of research involving human subjects in Mexico. It reviews the principles of bioethics, their origin and background, as well as their role in protecting the dignity and rights of participants. The analysis focuses on the General Health Law, the Regulation of the General Health Law on Health Research, and the Official Mexican Standard NOM-012-SSA3-2012, which establish the essential elements for conducting research projects. The study concludes that, although Mexico has a regulatory framework, ongoing biotechnological advances highlight the need for its updating.

Keywords:

Bioethics, Research on human subjects, legislation, research ethics.

Resumen:

Este trabajo analiza la regulación de la investigación en seres humanos en México. Se revisan los principios de la bioética, su origen y antecedentes, así como su papel en la protección de la dignidad y los derechos de los participantes. El estudio se centra en la Ley General de Salud, el Reglamento de la Ley General de Salud en Materia de Investigación para la Salud y la Norma Oficial Mexicana NOM-012-SSA3-2012, que establece los criterios para la ejecución de proyectos de investigación para la salud en seres humanos., donde se establecen los elementos esenciales para la realización de proyectos de investigación. Se concluye que México cuenta con un marco regulatorio, aunque los avances biotecnológicos hacen necesaria su actualización.

Palabras Clave:

Bioética, Investigación en seres humanos, legislación, ética en la investigación..

INTRODUCTION

Currently, research on human beings generates many discoveries about diseases, such as their diagnosis, treatment and prevention; but it must always be taken into account that the research subjects are human beings with rights. Even if they agree to participate in experiments, they should not be dehumanized, since thanks to them many genetic problems can be avoided or learned to treat them. The advances made have allowed previously incurable diseases to be treated today and improvements to be identified to achieve a better quality of life. However, these advances must always be regulated.

There are certain ethical principles (1) that must be taken into account when conducting research on human beings, which have international support and precedent. The first of these is respect for autonomy, which recognizes people's capacity to make decisions; this principle is materialized through the process of informed consent. Another of these principles is that of beneficence and non-maleficence, which requires ensuring scientific relevance, the competence of researchers and the protection of participants. As for the principle of justice, it is implied that research responds to the needs of a specific population and that the distribution of burdens and benefits is equitable among research subjects, in order to ensure that it is science, and not vulnerability, that determines participation. Finally, the principle of responsibility, developed by the German philosopher Hans Jonas, requires considering, in the face of the dizzying advance of technology – especially in the field of biomedicine – its implications for future generations.

Therefore, this article analyzes whether the current regulation in Mexico on research on human beings is sufficient to guarantee that it is carried out without compromising the human rights of the research subjects.

Historical background of research on human beings

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Among the most relevant antecedents of experimentation on human beings, we must consider the experiments carried out during World War II by the Nazi regime, with prisoners of concentration or war camps; These included the performance of procedures without consent, extreme temperatures and exposure to diseases, implying that since that time rights were needed for the protection of the subjects who are under the experiments (7).

As a result of the above, the Nuremberg Code emerged, which was created from the Nuremberg trials, which took place in 1947 to try Nazi doctors who committed crimes against humanity for their experiments on concentration camp prisoners. M. Ferrer Colomer and L. M. Pastor García mention that from these basic ethical principles were established for research on human beings, the most important of which are informed consent, the absence of coercion, benefit to society, avoidance of harm, moderate risk, preparation and protection, qualified researchers, freedom to abandon and the scientific justification of the study. (7)

Another important precedent is the Tuskegee Study, whose relevance is that its lack of ethics was widely known, which led to significant changes in medical research where informed consent, respect for participants and transparency were highlighted. The study, carried out between 1932 and 1972, aimed to investigate the progression of syphilis in African-American men who were not told that they were being infected with this disease nor were they provided with the corresponding treatment, since penicillin was already available at the time. This was a study in which the rights of the participants were violated in various ways, being proven that the consent of the participants in the study is needed and that they must be informed about what is being done in the research, also guaranteeing dignified treatment. (8)

Another important precedent is the Declaration of Helsinki adopted by the World Medical Association in 1964; It establishes ethical principles for medical research on human subjects, including the need to obtain informed consent, the protection of the health of participants, not taking advantage of vulnerable groups, being transparent with the publication of results and supervision by ethics committees. (9)

For its part, the Belmont Report is an essential document for ethics when conducting research on human subjects. This was developed in 1978 by the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research of the United States, through which some key principles were created such as respect for the subjects of these investigations, beneficence where the people in charge have to maximize all the benefits to be obtained and not take advantage of vulnerable groups. (10)

This background account for the violations of the rights of the people who serve as subjects in the investigations, who have been in several cases against their will participating in them. In other cases, they take advantage of people's vulnerability and do not give them the correct and complete information that allows them to make a decision with responsibility and the knowledge of what it entails.

Bioethics

As a result of the above, bioethics emerges as a discipline. Several authors (2) point out that the term "bioethics" was introduced in English by Van Rensselaer Potter in 1970. Potter defined it as a discipline that combines biological knowledge with human value systems. He understood it as a new cultural paradigm that articulates scientific facts (especially in the life sciences) with values, that is, a bridge between science and the humanities. The author stressed that the priority should be life and health.

Principles of Bioethics

(5)Bioethics can be considered a normative instrument that advises public authorities in the drafting of laws to fill legal gaps derived from rapid scientific and technological progress, as well as from inequality in the distribution of resources for health. These principles are fundamental in research on human beings because they seek to safeguard their dignity.

This manifestation can be observed through the principles which are a very important basis in bioethics and consequently in research on Human Beings because they seek the safeguarding of their dignity as persons. For example, in the principle of beneficence and non-maleficence (1), the benefit of the research is often not direct for the participating subject, but for third parties or for humanity in general; in other cases, those who suffer from a disease participate with the expectation of receiving an innovative treatment.

Another of these principles is Autonomy (1) in which the subject who is going to participate in a research is going to decide what is going to happen to his body or his biological records, he has the right to accept or refuse to participate taking into account his customs and traditions or how far to go.

In the case of justice (1) it implies treating all participants equally, without taking advantage of their vulnerability. An example is the Tuskegee Study(6), on untreated syphilis in 1940, in which 400 people of African descent participated, who did not know that they were being given placebos and were not allowed to treat other diseases because this could interfere with the study. In addition, when these individuals died, they took advantage of their vulnerability and by expressing their desire to carry out their funeral rites and offered them payment of these with the aim of being able to perform autopsies on the corpses

of the deceased and thus finish their experiments. This case shows how the lack of justice in the distribution of benefits violates fundamental rights.

Finally, confidentiality (1) is key to protecting the personal data and privacy of research subjects.

Regulations in Mexico on Research on Human Beings

In Mexico, research on human beings is regulated, mainly by the General Health Law (12). In Article 41 Bis, section I mentions the existence of a Hospital Bioethics Committee, responsible for dealing with problems arising from the medical care referred to in Article 33 of the same law. This committee also assists in decision-making on bioethical problems that arise in medical practice and promotes the development of ethical guidelines and guidelines for medical care and teaching.

Section II establishes that for the existence of establishments where research on human beings is carried out, the committee will evaluate and determine the research protocols, issuing recommendations and developing guidelines. These committees will be subject to current legislation and the criteria established by the National Bioethics Committee. The committee must be made up of interdisciplinary staff: doctors from different specialties, psychologists, nurses, social workers, sociologists, anthropologists and jurists, as well as representatives of the users of the services, guaranteeing a gender balance.

Article 166 Bis (12) establishes that, in cases of medical emergency in which there is no family member or legal representative, the decision on the medical procedure will be made by a specialist doctor or by the Bioethics Committee.

There are certain mechanisms in place to ensure that people understand what their participation in research entails; one of them is informed consent, which the American College of Physicians (3) defined as

> explaining to an attentive and mentally competent patient the nature of his or her illness, as well as balancing the effects of the disease and the risk of the recommended diagnostic and therapeutic procedures, and then requesting his or her approval to undergo these procedures. The presentation of information must be understandable and unbiased, the patient's collaboration must be achieved without coercion, and the physician must not take advantage of his or her potential psychological dominance over the patient.

Informed consent must meet certain requirements:

- Competence: the subjects must be of legal age; In the case of minors, their legal guardians are responsible.
- Clear and precise information: it must be communicated in an understandable way, avoiding medical technicalities.
  Comprehension: it is not enough to inform; it must be ensured that the person understands the risks and benefits, considering that the emotions of the moment can affect understanding.
- Freedom to decide: there should be no coercion or pressure from third parties.

In many developed countries, informed consent is a legal requirement for any procedure involving human subjects. In Mexico, it is regulated in the General Health Law, as well as in its Regulations on Health Research (12), in articles 20 and 22. It establishes that informed consent must be in writing, include an explanation of justification, objectives, procedures, risks, benefits, alternatives, possibility of withdrawal at any time, availability of medical treatment and compensation. The document must be prepared by the researcher and approved by the corresponding ethics committee, indicating the names of two witnesses, their address and relationship with the research subject, with one copy remaining in the possession of the subject.

Likewise, the Official Mexican Standard NOM-012-SSA3-2012 (14) contains specific criteria for the execution of research projects on human beings, including provisions on informed consent and confidentiality of information.

Additional concepts on informed consent are found in (4):

- Article 6 of the Universal Declaration on Bioethics and Human Rights (UN, 2005): All medical interventions must be carried out with prior free and informed consent, based on adequate information; Consent must be able to be revoked at any time without prejudice to the individual.
- Article 5 of the European Bioethics Convention (15): any health intervention requires free and informed consent.
- Article 3(a) of the Charter of Fundamental Rights of the European Union (16): in medicine and biology, the free and informed consent of the individual shall be respected, in accordance with the law.
- Article 5 of UNESCO's Universal Declaration of Bioethics (17): the autonomy of the individual to make decisions and assume responsibility is respected, respecting the autonomy of others.
- Article 2 of the Patient Autonomy Law (18): all health action requires prior consent, obtained after adequate information and, where appropriate, in writing.

Similarly, research on human beings is legislated in the Regulations of the General Health Law (13) on health research, starting with Article 13, which emphasizes that every human

being who participates as a subject in research must receive respect for their dignity and protection of their rights. The same article establishes that research must be based on scientific and ethical principles that justify it, be based on previous documented experience, and only be carried out when the knowledge cannot be obtained by another suitable method. Likewise, foreseeable risks must prevail over expected benefits. It is essential to have the informed consent of the subject or his or her legal representative, that the research is conducted by health professionals, that there is a favorable opinion from the corresponding ethics committees, that the research is only carried out with the authorization of the head of the health institution, and that it is immediately suspended in case of risk to the subject. The institution responsible for the investigation must guarantee medical care when it is directly related to the case.

Article 16 refers to the protection of the privacy of the participating individual. Article 17 classifies the risks of research as: without risk, when no physiological, psychological or social variable is altered; minimal risk, in which common routine physical or psychological examination procedures are performed; and greater than minimum risk, when there is a significant probability that the subject will suffer harm.

Chapter II regulates community-based research, allowing it only when the expected benefit is reasonable and small-scale studies have not produced conclusive results. In these cases, the principal investigator must obtain approval from health and civil authorities, in addition to the letter of consent; For vulnerable communities, the Research Ethics Committee must also approve it.

Chapter III focuses on minors or incapacitated persons, with differentiated requirements according to age and capacity for emancipation. To research on minors, the research must have previously been carried out on adults, except for specific age conditions. The consent of the person exercising parental authority is required and, when mental capacity and psychological state allow it, the acceptance of the subject. Risk research with direct benefit to the child is admissible only if the benefit justifies the risk; risk without direct benefit are permissible when the risk is minimal or, if greater, offers a high probability of understanding, preventing or alleviating a serious health problem.

Chapter IV deals with research on women of childbearing age, pregnant women, during childbirth, puerperium or breastfeeding. Steps should be taken to ensure that the participant is not pregnant prior to acceptance and to minimize the likelihood of pregnancy during the study. Informed consent from the participant and, where applicable, her spouse is required. Research on pregnant women will be permitted only to improve the health of the mother or increase the viability of the fetus, and researchers have no authority over the termination of pregnancy; Only the ethics committee can modify the method. During the postpartum period, the investigation should not interfere with the health of the mother or the newborn. During breastfeeding, the mother should not be at risk, she cannot breastfeed her child and a letter of informed consent is required. Fetuses may only be studied guaranteeing the health of mother and fetus; Newborns will only participate when their birth is confirmed. In assisted fertilization research, these will only be allowed to solve sterility problems that cannot be addressed in any other way.

Chapter V regulates research on subordinate groups, such as students, laboratory and hospital workers, members of the armed forces, prisoners, and other special groups. In these cases, the representatives of the group must ensure that the participation does not affect their school, work or military situation, that the results are not used against them, and that the responsible institution guarantees the necessary treatment and care.

Research with organs, tissues and their derivatives is governed by the provisions of Chapter VI.

This research is also regulated by NOM-012-SSA3-2012 (14), which establishes criteria for the execution of research projects on human beings. This standard defines the minimum elements that researchers must meet, the requirements for the authorization of projects or protocols, the delivery of research advances, the establishments where projects can be carried out and their conditions. In addition, it regulates the research, ethics, and biosafety committees, including their formation, registration, and operation. The responsibility of the principal investigator is emphasized, who must plan and develop the project, and guarantee the safety of the research subject, including the possibility of withdrawing consent at any time and ensuring that there is no harm arising from the research. Finally, the standard ensures consistency with international laws, such as the World Medical Association's Declaration of Helsinki on Ethical Principles in Medical Research and the Istanbul Protocol for the investigation and documentation of torture and other cruel, inhuman or degrading treatment or punishment.

Conclusion

Research on human beingsaims, both in Mexico and in the world, to improve the treatments of certain diseases, their prevention and understand their causes; however, to carry them out, a process must be followed that guarantees respect for Human Rights.

Based on what has been read and researched, research on human beings involves the participation of living individuals with the purpose of generating knowledge or collecting data that contribute to medical advances.

In order for them to be carried out in our country, protocols established in the General Health Law, the Regulations of the General Health Law on Health Research and the Official Mexican Standard NOM-012-SSA3-2012, which detail the procedures and steps necessary to carry out research on human beings, must be followed.

Analyzing what has been researched in this document, research on human beings has been carried out for years, but previously the rights and dignity of the subjects were not considered, so protocols and documents were established that define the necessary requirements for their performance and ensure that the rights of the participants are not violated.

From my point of view, an essential requirement is informed consent, which allows us to understand the terms of acceptance. Over time, this has evolved and, in Mexico, the basic requirements are consistent in all cases, although there are special provisions for minors, pregnant women or newborns, in which ethics committees also intervene.

Focusing on this, Mexico has legislation in force on these investigations; although perhaps not so extensive, it is enough. However, in the future it will be necessary to update it, given that science and technology are advancing rapidly, to avoid legal loopholes that can be used unethically.

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