

## Health research in vulnerable groups in Mexico La investigación para la salud en grupos vulnerables en México

Santiago Emmanuel Vite Barrera <sup>a</sup>

---

### Abstract:

Health research on human beings has medical, legal, and bioethical implications. Because of its nature and reach, it has legal regulations, particularly in Health Law. Consequently, it has medical and bioethical implications, causing diverse principles from medical organizations, including international organizations, in declarations that constitute ethical principles of medical discipline and can be observed in terms of *lex artis*. One of the modalities of health research is carried out in vulnerable groups. The term vulnerability is suited to those groups from the population whose condition of age, sex, social status, and ethnic origin is found in conditions of danger, leading to trouble incorporating the development and access to better well-being conditions. Based on its bioethical and legal transcendence, there are a minimum of three principles to know: respect, charity, and justice. The provisions regulated in the research on vulnerable groups are not discriminatory in any sense instead, they look for the protection of their rights.

### Keywords:

*Bioethics, Vulnerable Groups, Research in human beings, Implications*

---

### Resumen:

La investigación para la salud en seres humanos tiene implicaciones médicas, jurídicas y bioéticas. En virtud de su naturaleza y alcance, tiene una regulación jurídica especial, particularmente en las normas del Derecho Sanitario. Al tener implicaciones médicas y bioéticas, consecuentemente se han pronunciado diversos principios por parte de las organizaciones médicas, incluso de organismos internacionales, plasmados en Declaraciones; constituyen principios éticos de la disciplina médica y que habrán de observarse en términos de la *lex artis*. Una de las modalidades de la investigación para la salud es aquella que se realiza en los grupos vulnerables. El término de vulnerabilidad es aplicable a los grupos de la población que por su condición de edad, sexo, estado civil y origen étnico se encuentran en condición de riesgo que les impide incorporarse al desarrollo y acceder a mejores condiciones de bienestar. Dada su trascendencia bioética y jurídica, se han fijado al menos tres principios, a saber, *respeto, beneficencia y justicia*. Las disposiciones que rigen la investigación en grupos vulnerables, en ningún caso son discriminatorias, sino por el contrario, pretenden proteger sus derechos

### Palabras Clave:

*Bioética. Grupos vulnerables. Investigación en seres humanos. Legislación*

---

### INTRODUCTION

Health research on human beings has medical, juridical, and bioethical implications.

It constitutes one of the purposes of our guarantee established in Article 4 of the constitution - the right to health protection, in terms of numeral 2 of General Health Law:

*Article 2. Right for health protection has the following purposes:*

*...VII. The development of education, and scientific and technological research for health.*

Regarding its nature and reach, it has a special legal regulation, particularly on health law standards. However, as was mentioned before, having medical and bioethical implications causes diverse principles which can attribute ethical aspects from medical organizations, including international organizations, reflected in statements. It is relevant to clarify that if any of these documents are not part of the national legal

---

<sup>a</sup> Corresponding author: Autonomous University of Hidalgo State, Institute of Health Science, <https://orcid.org/0009-0001-7375-7157>, Email: [sviteb@uaeh.edu.mx](mailto:sviteb@uaeh.edu.mx)

order,<sup>1</sup> They constitute ethical principles of medical disciplines and could be observed in terms of *lex artis*.

Health research involves diverse sectors of society within vulnerable groups.

Any person who participates as a subject of an investigation on human beings must be protected and respected for possessions like dignity, life, and integrity. Nevertheless, when they belong to vulnerable groups, broad protection is required, so the position exposes higher risks about the mentioned possessions. Therefore, a brief reference to bioethical and regulatory aspects will be done as part of this research.

## VULNERABLE GROUPS AND BIOETHICAL PRINCIPLES

One of the modalities of health research focuses on vulnerable groups. According to Tomas and Garrido (2001), there are human beings characterized by being vulnerable to experimenting by biological or legal title, especially fetuses, children, pregnant women, the elderly, people with mental disabilities, terminal patients, hospitalized patients with penitentiary or charitable institutions, and the homeless. Keep affirming that it is a form of “scientific colonization”. When patients from poor countries are not submitted for experimentation it is not authorized in rich countries. To protect these groups, there will be an analysis to see if it is related to therapeutic research or not.

On the other hand, the term vulnerability is suitable for groups whose conditions of age, sex, social status, and ethical origin impede them from being part of the development and accessing better well-being conditions. Because of its bioethical and legal transcendence, there are a minimum of three principles to know, respect, charity, and justice.

- Respect:  
It is also known as autonomy, which indicates a person with a certain course of action based on his outlined plans and projects. (Beaucham & Childress 2019). That implies if the person has access to be part of the research can decide in a voluntary and informed way. It derives from the fundamental right to liberty.
- Charity:  
It will always be the person's benefit's final purposes being followed by health personnel. It has three actions: a) Prevent damage, b) Counteract the damage, and c) Do good or foster good. Medical ethics has been showing the principle *primum non nocere*<sup>2</sup>.  
As for the matter at hand, Double Effect Theory needs to be summed up that it is licit to take a risk, neither loved nor used as means, when the benefit looked, is higher. In these terms, it has been claimed: “Do not

damage unless that damage is intrinsically related to the benefit to be reached” (Veatch, 1989).

- Justice:  
It implies equal treatment concerning the circumstances in which the person finds himself. The greater abundance, the more equitable treatment is when it is in the same situation. In other words, different aspects such as age, health state, and sex will be considered as long as they are not used to discriminate. On the contrary, to consider these circumstances to have equal treatment.

From this point, the special protection given to vulnerable groups in no case means discrimination is followed by proper treatment and equality. Addressing the mental states, some of them have mental disabilities, or under these special circumstances such as pregnant women, people, or minors deprived of freedom, it is necessary to consider the rights that may arise with that.

Based on the before mentioned, there are not only legal provisions in a strict way but also principles emitted in different documents of an international character. Therefore, Nuremberg Code<sup>3</sup> establishes that experimentation on human beings must be performed within reasonable and defined limits, being justified since they provide beneficial results to humanity and can not be obtained from other methods or means of study.

The Declarations from Helsinki and Tokyo – Helsinki II mention that in medical research, the well-being of human beings will prevail over interest in science and society. Additionally, it obliges us to comply with the ethical rules and to give special protection to vulnerable groups. Moreover, for the person's consent, it will be observed that there is no dependence on the researcher or against their will, in light of another physician asking for permission, as well as the cases in which a legal representative or legal tutor expressed consent.

Furthermore, Operational Guidelines for Ethics Committees evaluate Biomedical Research of the World Health Organization (WHO) providing research ethical committees must be established according to national regulations, values, and principles of the community they serve, that means when referring to vulnerable groups, physical and moral areas will be safeguarded.

## MEXICAN REGULATORY FRAMEWORK

The international aforementioned documents from ethical and bioethical principles for health research must be compulsorily observed as follows:

The General Health Law would regulate the right for health protection organized in its Fifth Title of health research. In

<sup>1</sup> In a strict sense, based on Article 133 from the Constitution.

<sup>2</sup> Do not harm first.

<sup>3</sup> Considered the first international code of ethics for research on subjects, it arose as a result of the atrocities committed by Nazi medical researchers.

particular, Article 100 mentions the principles for research on human beings, among others adjusting to scientific and ethical principles justifying medical research and balancing risks, and benefits. So informed consent is obtained and carried out by professionals of health and responsibility is taken by them due to possible risks. The regulation for health research also considers the obligation to approve protocols by ethics, research, and biosecurity commissions. In this case, guaranteeing the person's privacy.

In terms of Regulation<sup>4</sup>, this research understands development actions which are:

- To the knowledge of biological and psychological processes in human beings;
- To the knowledge of links among the causes of disease, medical practice, and social structure;
- To prevent and control health problems;
- To knowledge and evaluation of harmful effects of the environment on health;
- To the study techniques and methods that are recommended or used for the provision of health services, and
- To the input production for health.

Under risk assumed in the studies of research, the numeral 17 is classified into three types:

*Research with no risk, Research with minimal risk, and Research with greater than minimal risk.*

In addition, it is relevant to mention that Mexican Official Standard NOM-012-SSA3-2012 establishes the criteria to implement the projects for health research on human beings and National Guidelines for the Integration and Functioning of Research Ethics Committees (National Bioethics Commission).

## INFORMED CONSENT AND VULNERABLE GROUPS

One of the legitimate principles of research on human beings is informed consent which gives the person under investigation, or in case legal representation. Once the person has been informed clearly and completely about the justification and objectives of research, risks and expected benefits, the availability of treatment or compensation that could come from damage caused directly due to research, and the possibility of withdrawing from the study<sup>5</sup>. This consent will be given in writing and checked by the Research Ethical Committee.

In case of existing dependence, descent, or subordination of the individual towards the researcher and not allowed free expression of consent, this will be gathered by other research team members.

Concerning vulnerable groups, consent contains special formalities.

To the assumptions of research with minors or disabled people, consent will be granted to exercise parental rights<sup>6</sup> or legal representation; if the mental capacity and psychological state of the minor or disabled allows it. It will be asked for his acceptance to participate in the study. In the case of pregnant women, during labor, postpartum, and breastfeeding, whether living or dead birth, in which embryos or fetuses are used, and which requires informed consent from the woman or her spouse or cohabitant<sup>7</sup>.

To research communities, besides consent from each one of the participants, it will obtain authorization from health authorities or other civils of the community. If the members of the community can not comprehend the implications of participating in the study, the Research Ethical Committee can authorize informed consent through other members with moral authority in the community.<sup>8</sup>

Following the Regulations, research on vulnerable groups will be done in communities with minors or disabled people, women of fertile age, pregnant women, during labor, postpartum, and breastfeeding, newborns, while using embryos or fetuses, and while performing assisted fertilization. Applicable provisions will be briefly checked:

### A) Communities research:

Regarding consent, it has already been mentioned the way to obtain it. This research will always develop for the expected benefit of the community, being reasonably assured, so the results shown have not reported conclusive results. Similarly, protective measures for the individuals will be implemented, participating the minimum of them to be representative.

The ethical rules of research involving human beings will be applied to communities within relevant aspects.

### Research with minors or disabled people:

This type of research is found to especially regulate the articles 34 to 39 regulation cited. The consent will be gathered in the exposed terms. Those over 16 years of age who are emancipated are excluded. Among other criteria, the study will be justified when it refers to age-related conditions or mental conditions.

Provided that there is a distinction within the research of risk with and without direct benefit to the minor or the disabled. In the first case, it will be justified because of the benefit received by the people and it will be the same or greater than the existing alternatives for diagnosis or treatment.

<sup>4</sup> Article 2.

<sup>5</sup> Article 21 of the Regulations of the General Health Law on health research.

<sup>6</sup> If two people exercise parental rights, consent from both will be obtained. Article 36 of the aforementioned Regulations.

<sup>7</sup> Article 43 from the same Regulations.

<sup>8</sup> Article 30 from the Regulations.

In the second case of not having a direct benefit, the following guidelines will be observed:

On one hand, if there is minimal risk, research will provide a reasonable experience of the medical, psychological, social, or educational state of the minor or disabled one or represent a high probability of obtaining general knowledge about the condition. On the other hand, if there is a greater risk than minimal risk, it will function to prevent or relieve a health problem for minors or disabled ones. In case the foreseen risk increases, the researcher must discontinue the study when it can affect the biological, psychological, or social well-being of the participants.

B) Research on women of fertile age, pregnant women, during labor, postpartum, or breastfeeding:

In the case of studies with women of fertile age with greater risk than the minimal one, it will verify there is no pregnancy or the possibility of pregnancy will decrease.

Referring to the research on pregnant women, when the study is necessary for this condition, it will be justified. If it is intended to look for general knowledge about pregnancy, it will not be admissible for the research if it represents a higher risk than the minimum one for the woman and for the product from its conception. Concerning obtaining a therapeutic benefit related to pregnancy, the research will be allowed if it has the objective to improve women's health with minimum risk for the embryo or fetus or if it is looked to increase the feasibility of the product from conception, meaning a minimum risk for the researcher woman.

The researcher does not have the authority to decide to terminate the pregnancy or participate in decision-making about the feasibility of the fetus. If it is necessary to modify the method or to end the pregnancy for research, the Ethics Committee could authorize it whenever the risk would be minimal for the mother and there is no risk to the survival of the fetus. It is not permissible for monetary stimuli of other nature to terminate the pregnancy.

For research during labor, consent could be revoked by the patient at any moment. About postpartum, the study could be done when it does not interfere with the mother's health and the newborn's. While breastfeeding, research will not cause harm to the

minor, or if the mother decides not to breastfeed him, the feeding method will be assured.

Regarding studies with fetuses, the methods and techniques must guarantee maximum safety for the baby and the mother. In this type of research, and the ones that use embryos, deceased, dead born, fetal matter, organs, tissues, and cells removed from those, rules for disposal of the human body will be observed. The newborns can only be subjects of research when the living or dead born has been certified. Unless it looks to increase the probability of feasibility until the fetal stage and the study does not cause termination of vital duties.

Concerning research for assisted fertilization, it could only be performed when it is a solution for the couple's infertility problems, and it could not be solved in another way.

A) Research on subordinated groups<sup>9</sup>. For purposes of the mentioned Regulation, subordinated groups are students, workers of laboratories or hospitals, employees, members of the armed forces, inmates in prisons or social readaptation centers, or other groups of the population whose consent can be influenced by any authority. The virtue of the vulnerability of these groups, The Ethics Committee, a member of the group must participate, who can represent the moral, cultural, and social values of this population to monitor the non-acceptance of the subjects of the study, not injure rights due to the condition, and the results will not be used to their detriment.

Based on the mentioned, legal standards, especially those of health law, seek to provide higher protection to people involved in research work and whose members belong to a vulnerable group.

An unavoidable aspect is the inclusion of a Research Ethical Committee in charge of evaluating the research protocol from the group representative that could be seen as affected by being in this situation.

To ensure the principle of justice, it requires an election and correct incorporation of the participants, which means that fully justified, without its state of vulnerability impeding deserved access to the people, or they are exposed to unnecessary risks.

By doing so, it can be appreciated that there is a reasonable and proportional distinction without being discriminatory thus far from pretending to annul or undermine their freedoms. It offers the legal protection that vulnerable groups deserve.

---

<sup>9</sup> Articles 57 and 58 are applicable from Regulations.

## **CONCLUSIONS**

Based on the previously mentioned, the provisions regulated on the research on vulnerable groups are not discriminatory. In contrast, they pretend to protect the rights in any situation found and can emerge “different rights” that obligate a special regulation.

"The norms created by the legislator, an organ of the State made up of one or more men, for the governed, human beings who constitute the State society, cannot under any circumstances be unjust, arbitrary or absurd mandates, which attempt against the physical and spiritual integrity of the human beings to whom they are addressed. Every rule of Positive Law must have a content that is followed the nature of men, and that provides for him the appropriate conditions for his preservation and development and for the achievement of the lawful ends he proposes, whatever his natural stage, pre-embryo, fetus, child, youth, adult, elderly or dying".

The purpose of the legal norm is to guarantee protection in the light of justice.

## **REFERENCES**

- Beauchamp, Tom L. & Childress, James F. (2019), Principles of Biomedical Ethics, 8th ed.
- León Rábago, D. (1998). Bioethics for the Law. University of Guanajuato.
- National guide for the integration and operation of Research Ethics Committees. (2016). National Bioethics Commission. Retrieved May 21, 2023, from [https://www.conbioetica-mexico.salud.gob.mx/descargas/pdf/registrocomites/Guia\\_CEI\\_pagina\\_da\\_con\\_forros.pdf](https://www.conbioetica-mexico.salud.gob.mx/descargas/pdf/registrocomites/Guia_CEI_pagina_da_con_forros.pdf)
- Operational Guidelines for Ethics Committees Evaluating Biomedical Research, World Health Organization, 2000.
- Tomás and Garrido, G. M. (2001). Manual de Bioética. Ariel.
- Veatch, R. M. (1989). Cross-cultural perspectives in medical ethics: readings. In Jones and Bartlett eBooks. <http://ci.nii.ac.jp/ncid/BA10546558>.