Legal Norms for Scientific Ethical Review Committees*

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Introduction

In the context of globalization, in which the progress of science has involved its application on human beings, and the international scientific exchange that transcends boundaries has become outstanding, it is indispensable to get closer to law science, with the purpose of protecting societies from possible abuses and to enhance values, without depending on any individual preference. Nowadays, no positivism can be sustained any positivism that tries to explain the essence of Law in the willingness of authority, without the legitimate connection to the reality of the common good which is a morally primordial idea([1]).

That is why it is relevant to safeguard the dignity of a human being, identifying the person as an entity composed of different aspects which cannot be treated as objects. According to this perspective, we find ourselves before rights designated as, "third generation," which comprises humanity in its totality and not fixed social categories, projecting human dignity as a unique and unconditional value that is recognized by every individual for the exclusive reason of being a human, independent of any quality accessory.

Without any doubt, the objective of legal norms in research, is to propose a current, objective and coherent theory about the relation between Law and research involving human beings.

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Background

The history of research involving human beings like a scientific practice which tries to prove in subjects probable hypothesis, with the potential to produce advancements in the field of science, which traces back to the XIX century, not only considering that in past centuries there was no basic knowledge and methodological design to give it a scientific value; moreover, where the subjects of these experiments were mainly slaves being condemned to death, jailed or moribund.

Once a real scientific methodology was established in the year of 1865 with the publication of the book *Introduction to The Study of Experimental Medicine* of the french Claude Bernard([2]), scientific hypothesis and research projects began to be formulated for proof. At the time of producing these types of studies, human beings became a subject necessary for the investigation, questioning the prejudices of the time period, which condemns the experimentation on human beings since it generates too many expectations for the sake of scientific benefits which could be generated([3]).

In this context, a scientific logic capable of establishing its own principles for the sake of its ends was created, detecting that one cannot only know the reality of the human being, but also to modify, for good or for bad, by assuming a position in which the development of science will weigh a cost, even guaranteeing the cost on human beings for considering science like a benefit to humanity.

As stated previously, society was in need of adopting diverse measures, mainly in response to the actions committed by the medical investigators in nazi Germany, generating the Nuremburg Codes, the document that analyzes and classifies the conclusions derived from the trial on professionals that experimented with prisoners. In 1948, the General Assembly of the United Nations, promulgated the Universal

Declaration on Human Rights[2]; in 1964, the World Medical Association adopted the Declaration of Helsinki[3], introducing the risk-benefits notion for subjects as well as the review of investigations by an independent ethics committee (from researchers); in 1966, the General Assembly of the United Nations implemented an International Pact on Civil and Political Rights[4], ratified in article 7°, no one can be submitted to medical or scientific experiments without his/her free consent, attempting to protect human beings as subjects in scientific experiments. In 1966, through the International Pact on Economic, Social and Cultural Rights[5], it established a compromise from the States to respect the indispensable freedom for scientific research and creative activity, and, at the end of the 70's, a special consideration was given to the circumstances of developing countries, with respect to the applicability, particularly, of the Nuremburg Code and the Declaration of Helsinki, giving entrance to the elaboration in 1982, of the international norms CIOMS(Council for International Organizations of Medical Sciences), [6] published in 1991 (epidemiology) and 1993([4]), respectively.

The previous international norms are the main documents, with the intention of a to guarantee the protection of persons, while recognizing the need of research involving human beings. Nevertheless, most lack coercive power, remaining as catalogues of good intentions more than effective results, in which each state evaluates its situation and is entitled to endorse those principles necessary to guarantee the dignity and physical and psychological security of its inhabitants.

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[2] United Nations General Assembly , 12/10/1948.
[3] World Medical Association. Ethical principles for medical research involving human beings. Adopted by the 18th World Medical Assembly, Helsinki, Finland June 1964, amended by the 29th World Medical Assembly, Tokyo, Japan, October 1975. 35th World Medical Assembly, Venece, Italy, October 1983. 41th World Medical Assembly, Hong Kong, September 1989. 48th General Assembly, Somerset West, South Africa, October 1996. And the 52nd General Assembly, Edinburgh, Scotland, October 2000.
[4] United Nations General Assembly, New York, 1966.
[5] United Nations General Assembly, Resolution 2200 A, New York. 12/16/1966.
[6] Prepared by the Council for International Organizations for the Medical Sciences (CIOMS) in collaboration with the World Medical Association, Geneva (epidemiology) 1982, (biomedical research) 1993, Review 2002.

Ethical and Legal Responsibilities

The scientific practice with human beings produces concrete effects that have a joint ethical and legal responsibility, as a result of the actions carried out consciously and freely by the investigator.

The term “responsibility” derives from the Latin word *respondere*, to be obligated, the relation of causality existing between the act and its author; thus, the capacity to respond for ones acts. In a more concrete sense, responsibility is translated by the rise of an obligation or deserving a punishment in a determined or decisive case, as a result of the execution of a specific act; in another case, it can be understood as the obligation that a person has to rectify the damages produced or the harmed caused on a third party, as established by a norm, an original convention, or stipulated by a contract or derived from certain occurrences([5]).

It is necessary to distinguish between ethical and legal responsibility; the first one adheres to the consequences necessary for the freedom of will that entails the settlement of oneself debts, that is to respond to ones own acts before ones own conscience in relation with ones own morality.

Science itself does not recognize its limits, the researcher is therefore subjugated to ethical responsibilities and to make distinctions between good and bad; moreover this responsibility should respond to the social demand of guiding the conduct of those who intervene or interfere with human life.

In this respect, Diego Garcia, in his book “Medical Profession, Investigation and Health Justice”,([6]) establishes that moral conscience is nothing but the judgment of ones reasoning on the morality of our own actions. Despite, the above mentioned, the human being alone, is responsible when he/she has the sufficient moral knowledge to approve or disapprove his/her conduct, and will is not affected by a powerful impulse or

by suspense, in the same way as the different types of mental disturbances that reduce or nullify the responsibility. In this sense, it is the investigator's duty to process their critical analysis on their fundamental conceptions and submit them to a verification which concords with his/her actions, without ambiguity.

Ethical principles have been compiled in codes and professional oaths. The most widely known in western medicine is the Hippocratic Oath, of whose its main ethical aspect mentions that the doctor must always act in the best interests of the patient, based on two components, "First do no harm to patients…" and "I will act for the benefit of the patient…". Nevertheless, this oath adheres to a paternalistic vision in which the patient and his/her capacity play a small role for participating in the decision making.

On the other hand, the legal responsibility demands the subjugation of the facts and actions committed by a human to confess his accounts, which brings the duty to make amends in the case of committing a fault. In general terms the elements of responsibility are: the existing types of conduct and anti-legality, if a voluntary or involuntary action or omission that produces harm, as an argument for legal responsibility,. The involuntary character of the action does not annul the duty to respond, since although the subject did not want to commit certain acts, or even willingly would not have foreseen its consequences, this situation does not exempt the reparations of the harmed produced. On the other hand, the antilegality, can have two facets: that of which can be from an illicit act, or from failing to fulfill a contract ([7]).

Responsibility in research implies an obligation of conduct with the capacity to amend and satisfy the consequences of ones acts, omissions and voluntary and involuntary faults within certain limits, established in his/her professional practice. If during the course of an investigation, the researcher causes a harm or damage to a subject, reparations should be made independently based on the sanctions that he is

accredited to. Such responsibility has its assumptions in the general principle of responsibility, according which any fact or act done discriminatingly, intentionally and deliberately, generate obligations for his/her author in proportion with the harm provoked to another person.

Furthermore, in some cases the investigators avoid the ethical responsibility, due to their lack of coercive power and they are more worried in protecting themselves of possible legal processes against them, than safeguarding the dignity, health and even life of research subjects.

Norms for research

It is understood that nothing can be justified in the field of law if the human being is not the protagonist and addressee, without disregarding the social dimension; in this context it should be understood that society and State are subordinated to achieve individual and collective goals. In sum, persons perspectives, society, and authority figures, attend to achieve the common good through sanctions that seek to give a natural and necessary response to the non-fulfillment of the prescribed duty in the norm. With respect to the sanctions, we must add that the notion of right is conceived as an established human order in a fixed place and time in society, that functions predominantly externally thanks to the State's disposal coercive action ([8]).

A legal system can be made up of complex normative bodies that receives its unity by belonging one State and, generally, it is expressed in a document known as the Constitution; hence it is stated that in these systems, norms are still incomplete, as unfinished work, supported simply not only by legislation and the jurisprudence, but also by its underlying maintenance that crystallizes in the major and minor general rational principles for social conduct and also in the principles of the national rights that

are specified in the field of their legal norms. Thus, the judicial system is not simply a system of structures and orderly networks; it is also a system of solutions, content, values and ideals.

Derived from the previous section, the State transforms itself in the guarantor of physical integrity, protects the dignity of persons, goes against social discrimination and looks for equality of opportunities, among other rights, and for that it has no other remedy than to transform the essence, truth, and values of society into positive norms.

But, norms must intervene in the field of research with the final goal of securing the social dominion over production, dissemination, and use of research involving human beings, for which the majority of countries have resorted to norms of four types:

a) The codes for professional ethics;

b) The rules imposed in certain associations

c) The rules of conduct established by certain institutions, and

d) The orientations given by ethical review committees

In this respect, there has been two critics established, the first consists in that these regulations are inefficient, since they are devoid of any coercion power and they can be easily molded, and therefore, do not allow the attainment of the objective sought; the second corresponds to the classification given to them as antidemocratic, because it is imposed by defined professional sectors which do not represent the interest of the social body as a whole, since they are not proposals withdrawn from a public debate ([9]).

From our standpoint, these norms do not result inefficient, since even though they lack mandatory character they serve as a preventive mechanism, which demonstrate how to fulfill the principles adequately in a participative and consensual

mode by the involved sectors in the construction of the norm, although strictly from a judicial positive perspective they are fragile and in some cases, devoid coercion power.

Current State of Norms in Latin American Countries

Currently the legal systems in Latin American Countries are based, in most cases, at the constitutional level, with the recognition of the dignity of the human being and the right to health, which is of major importance since the constitution is the supreme norm in the judicial system, as well as in international treaties ratified by the States. There lies the source of legitimacy for an ordered system of norms by establishing authority faculties or the expansion of rights to particulars.

The judicial system should demonstrate its function through the unity and coherence of its norms, for which the immediate stratum under the constitution must be constituted by laws, understood by an organic body of judicial precepts that frequently revolve around the same field.

The regulatory faculty corresponds to the Executive Power, since the functions of rules is to facilitate and make possible the execution of the law; the rules develop and make more precise the precepts contained in the laws, but they cannot contradict or exceed their range.

Technical norms are subjected to the principle of supremacy of the law, with the function of specifying and standardizing the technical function of the ethical review committees. It should be insisted in the judicial instrumental character disposed by the ethical review committee. What is expected is to open not only the space for ethical reflection but also, in a very particular way, to observe resolutions by the members of the committee.

We also found that the distinct legislations in Latin America apply scientific and ethical principles that guide the medical practice to cover the legislative lack of foresight that cause the common denominated gaps in the law, for which the existing Codes of Professional Ethics in all countries are of crucial significance.

The concern of this subject in Latin American countries is not minor, due to the fact that our reality is different from developed countries. It must be taken into account the particular demands of our local cultures that support a pluralist culture, accepting the preexistence of distinct ethical discourses, for which the adaptations to the practices of each state on a legal and legitimate framework must be assumed by the ethical review committees.

Here we show in table 1 the current situation of the judicial systems of six Latin American countries that count with ethical review committees.

Table 1.

	CHILE	MÉXICO	COSTA RICA	COLOMBIA	VENEZUELA	PERÚ

Constitution	Article 19 The constitution guarantees to all people: ***1.*** The right to life and to physical and psychological integrity of the person... **9. The right to the protection of health. The State protects the space open and equal access to promotion, protection, and recovery of health and rehabilitation of the individual. It is also the duty of the State to coordinate and control actions related to health…**	Art. 1º Any discrimination is prohibited… that attempts against human dignity or has as objective to annul or undermined the rights and liberties of persons. Art. 4º Every individual has the right to the protection of health...	Art 21 Human life is inviolable Art. 50 The State will procure the greatest well being for all inhabitants of the country… Any person has the right to a healthy and ecologically equilibrated environment… The State will guarantee, protect and preserve this right.	Article 13 ... The State will promote the conditions for equality to be a reality and effective and will adopt measures in favor of discriminated or marginal groups. The state will protect particularly, those individuals that due to their economic, physical, and mental conditions, are found to be in a vulnerable position, and will sanction the abuses or mistreatment committed against them. Article 27 The State guarantees the liberties of teachings, learning, research, and chair. Article 49… It is guaranteed to all persons the services of promotion, protection and recovery of health.	Article 46 Any person has the right to have his/her physical , psychical and moral integrity respected. in consequence:… 3. No person will be subjected to scientific experiments or to medical or laboratory texts without his/her free consent, except when his/her life is in danger or for other circumstances that the law determines. Article 83 Health is a fundamental social fundamental right, obligation of the State, which will be guaranteed as part of the right to life. The State will promote and develop policies oriented to enhance the quality of life, the well being of the community and the access to services.	Article 2º Any person has the right to: 1. Life, personal identity moral, physical and psychological integrity and to its free development and well being. The human conceived is subject of rights in all that is in favor. Article 7 Any person has the right to the protection of his/her health, that of the family and of the community, as well as he/she has the duty to contribute to its promotion and defense. The disabled person, in order to take care of oneself due to a physical or mental deficiency, has the right to the respect of his/her dignity and to legal systems of protection, attention, readjustment and security.
Law	Health Code Decreed with Law Enforcement No. 275 Article 102 No pharmaceutical or cosmetic product can be commercialized or distributed in the country without being processed by prior registry in the Institute of Public Health.	General Health Law Article 3 Based on the terms of this law, it is a matter on general health the following: Fraction IX. The coordination of research on health and its control in human beings; Article 98. In the Health institutions, under the responsibility of the directors or respective heads and in agreement with applicable dispositions, it will be constituted: … an ethical review committee…	General Health Law Article 26 Under no circumstances will it be allowed any therapeutic or scientific clinical research hazardous to the health of human beings. Article 64 The professionals in health sciences that intervene in experimental scientific research Involving human beings as subjects should register in the Ministry of Health, declaring the	Law 10 of 1990 It reorganizes the National Health System and dictates other juridical resolutions. Article 8°. The administration of the National Health System will be in charge of the Ministry of Health who consequently will formulate policies and enact all scientific and administrative mandated norms… a) For scientific norms: All guidelines of scientific and technological character for the organization and provisions of health services;	La w on Medical Drugs Article 72 The clinical trials should be done in conditions that respect the fundamental rights of persons and the ethical postulates related in biomedical research In which human beings are affected, in accordance with the contents of the Helsinki Declaration on research involving human beings and the successive postulates that update the matter Article 73 … It should be approved by the director of the institute	General Health Law of Peru Law 26842 Article 28º The experimental investigation involving human beings should be restricted to special legislation on the matter and to ethical postulates contained in the Helsinki Declaration and successive declarations that update the referred postulates.

			nature and objectives of the research and the establishment where it will be carried out		in which the research is carried out.	
Regulation	Supreme Decree 42 Systematic Regulation of Health Services Article 19... A committee of Ethical, Scientific Evaluation will be destined to inform on the research to be accomplish, involving patients in public or private hospitals placed within its competent territory, utilizing drugs not registered in the country.	Regulation of the General Health Law on the subject of Research Article 109… The Ethical Review Committee has attributed the function to emit a technical opinion on ethical aspects of the research proposed, by evaluating the risks, benefits, and the consent in the protocols and its binding parties, in order to guarantee the well-being and rights of the subject of research	Decree Nº 31078-S Regulation for Research Involving Human Beings Article 1º The research on health involving human beings will be developed according to the following principles: ... d) No public or private authority could authorize any investigation without the approval of the respective scientific ethical review committee duly accredited and authorized by CONIS when it corresponds.	Resolution Nº 008430 by which scientific, technical, and administrative norms for research on health are established Article 2 The institutions carrying out investigations involving human beings should have a scientific ethical review committee, with the responsibility to resolve all issues related to the topic.		Supreme Decree Nº 013-2002 – SA Regulation by the Health Ministry Article 34º National Health Institute To fulfill its mission, it must achieve the following general and functional, objectives a) To develop and disseminate the scientific and technological research on health.
Technical Norm	Technical Norm N° 57 Regulation of Clinical trials execution which use pharmaceutical products on human beings		Operational Guidelines for Ethical Review Committees which evaluate biomedical research by the World Health Organization, and respective revisions			

Conclusions

The international norms reflect a useful concern to warn researchers, but they are not sufficient if States do not assume the responsibility of adopting and adapting the principles in their own norms. All of this to abandon the character of being a recommendation or advice, in order to become a normative with the character of a law.

It is undeniable that research involving human beings develops within a context in which opinions from different sectors of society acquire relevance. It corresponds to the state to demand all members of the scientific community, the assistance necessary, as actions or omissions, directed towards the common good, in order to elaborate norms of juridical character and in that way to fulfill its objective.

In the field of research, the norms should consider public policies from each State, rooted on scientific and ethical principles from which to identify and reconcile the inner actions of a particular society. This should allow, in one hand, not to become remnants of the advancements in research and on the other hand, that results become applicable for the benefit of society.

Consequently it is necessary to take the necessary measures to respect the principle of human dignity, with the goal to avoid the negative repercussions in society and to guarantee the application of science and technology for the benefit of humanity.

On the other hand, research must continue giving useful information to comprehend and solve the problems of health/disease suffered by humanity, to predict the course of diseases and to design strategies that bestow the possibility to eradicate them completely.

It is necessary, to recognize that the law has become remnant before the scientific advancements. It runs the risk of being overwhelmed by reality, for which the legislator must always be aware, anticipating the biggest social problems, since to the contrary, one can only react lawfully when there has been harmed done to human beings participating in research.

[1] Soto Sobreyra and Silva I. *Teoría de la Norma Jurídica.* México: Editorial Porrúa. 1997, p. 11.
[2] Bernard C. *Introducción al estudio de la medicina experimental*, presentación y notas de Juama Pí-Sunyer. España: Editorial Fontanella; 1976.
[3] Pelayo González-Torre. *Bioética y Experimentación con Humanos.* España: Editorial Comares: 2002; 1-5.
[4] Lolas F. *Bioética y Medicina.* Santiago de Chile. Editorial Biblioteca Americana; 2002: 74-90.
[5] Fernández Ruiz, Jorge. *El Aspecto Civil de la Responsabilidad Profesional*. La Responsabilidad Profesional del Médico y los Derechos Humanos. México: Editorial Comisión Nacional de Derechos Humanos; 1995; 19.
[6] Gracia D., *Profesión Médica, Investigación y Justicia Sanitaria.* Bogotá: Editorial El Buho; 1998: 42.
[7] Muñoz de Alba Medrano M.. El Médico y su Responsabilidad Profesional. En: *La Responsabilidad Profesional del Médico y los Derechos Humanos.* México: Editorial Comisión Nacional de Derechos Humanos; 1995: 109.
[8] Soto Sobreyra y Silva, Ignacio. *Op. Cit.* 87.
[9] De Oliveira Leite, Eduardo. *El Derecho y la Bioética: Estado Actual de las Cuestiones en Brasil.* Acta Bioética. Derecho y Bioética No. 2. Chile: Programa Regional de Bioética de la Organización Panamericana de la Salud/Organización Mundial de la Salud, OPS/OMS; 2002; 163-281.