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.
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(3), 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\textsuperscript{2}; in 1964, the World Medical Association adopted the Declaration of Helsinki\textsuperscript{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\textsuperscript{4}, ratified in article 7\textdegree{}, 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\textsuperscript{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 Nuremberg 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),\textsuperscript{6} published in 1991 (epidemiology) and 1993\textsuperscript{(*)}, 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.

\textsuperscript{2} United Nations General Assembly, 12/10/1948.
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 one’s 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 one’s own acts before one’s own conscience in relation with one’s 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.

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<th>CHILE</th>
<th>MÉXICO</th>
<th>COSTA RICA</th>
<th>COLOMBIA</th>
<th>VENEZUELA</th>
<th>PERÚ</th>
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### Constitution

**Article 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...

**Article 10** Any individual has the right to a healthy and ecologically equilibrated environment...

The State will guarantee, protect and preserve this right.

**Article 27** The State guarantees the liberties of teachings, learning, research, and chair.

Art. 49... It is guaranteed to all persons the services of promotion, protection and recovery of health.

### 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 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 health and psychological integrity of persons.

### Law 10 of 1990

**Article 10** 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 technical character for the organization and provisions of health services;

### Law 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 to 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 declarations that update the referred postulates.

### General Health Law of Peru

**Article 28** 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 subsequent declarations that update the referred postulates.
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.