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SUMMARY

scientific with beings Experiments humans have marked history. In certain periods, as an example we can mention the Second World War, where Nazis subjected their prisoners to terrible experiments, they are a reference to cruelty and disregard for life. Among other moments throughout the historical period where human beings were used as guinea pigs. Currently, science does seek new knowledge that requires an experimental phase, but is carried out according to regulations that concern what can or cannot be accomplished, as the State seeks to protect the dignity of the human person and guarantee the physical integrity of each person. This area increasingly needs attention regarding the methods applied and Bioethics and Biolaw have been playing an important role. Encompassing improvements to the wellbeing of human beings must also comply with the law.

Key words: Scientific experimentation. Bioethics. Biolaw. Dignity of human person.

ABSTRACT

Scientific experiments with human beings have marked the history of mankind. In certain periods, as an example we can mention the Second World War, where nazirs subjected their prisoners to terrible experiments, they are a reference of cruelty and neglect of life. Among other moments during the historical period where human beings were used as guinea pigs. Nowadays, science does seek new knowledge that requires an experimental phase but is carried out according to a regulation that concerns what may or may not be carried out, as the State seeks to protect the dignity of the human person and guarantee the physical integrity of each one. This area is increasingly in need of attention as to the methods applied and Bioethics and Biological Rights have been playing an important role. Covering improvements for human well-being is necessary and complying with the law as well. Keywords: scientific experimentation. Bioethics. Bioright. Human dignity.

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1. INTRODUCTION

The search for scientific answers and challenges has permeated our current times, seeking evidence to improve life, in terms of physical and emotional well-being (PEREIRA, 2009)

As a major milestone in history, we can mention the Second World War, where Nazis used the prison of their prisoners for various research studies that they were forced to undergo, that is, a tragedy for humanity. And other historical situations that caused and continue to cause great commotion due to such disregard for human beings themselves. (RANGEL, 2012)

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Each person is free to choose, within legal limits, what they believe will be best, having the right to their own decisions. In the same sense, article 13 of the Brazilian Civil Code deals with physical integrity, and that within its limits it is protected by the State.

In Brazil, resolution 466 of 1996 regulates clinical research carried out with human beings, but leaves gaps when the advancement of technology includes nanoscale materials in existing formulations to combat diseases, mainly in the field of oncology. (MARRA, 2016).

However, although the law presents assistance as the right of the person being researched, it does not stipulate in detail how this assistance should take place nor for how long it should continue. This gap becomes a problem as it does not complement the regulated law, as participating individuals will be exposed to unknown technologies, and due to greater knowledge of the consequences and reactions obtained in previous clinical trials with the medicine to be tested, researchers will not they can predict the reactions that each individual may present, even after the research is successful (MARRA, 2016).

Scientific research adds advances, brings discoveries, making them necessary so that human beings are increasingly able to find answers and solutions to these problems. (PEREIRA, 2009).

Analyzing that scientific experiments and experimental phases must continue to be regulated according to the resolution, periodically and as described: each thematic area of investigation and each modality of research, in addition to respecting the principles





emanating from this text, must comply with sectoral requirements and specific regulations. This guarantees the physical integrity of those who submit, having this state control, so that inhumane experiments do not occur and so that this area is of scientific scope and not of personal interests.

2 ETHICAL AND LEGAL LIMITS

The physical personality rights are: physical integrity, protection of safety, bodily health, use of the body, use of disposable or regenerable parts, image, use of the voice, right to the corpse and its separate parts. In this sense, any act that undermines its preservation, such as health, individual safety, torture or cruel punishments, is prohibited. Thus, from these illicit situations, physical integrity in medical treatments and surgical interventions is extremely important. (MALU, 2020).

Scientific experimentation with human beings is prohibited if carried out in a disoriented manner, as they require bioethical principles to be observed, with written, free and informed consent regarding the risks they may run as a result of seeking benefits, and this is why To prevent crimes from occurring in the name of scientific development, as already mentioned, several Ethics Committees were created around the world, so that people are protected from unlimited researchers (MALU, 2020).

And it is for these reasons that there are currently several legal documents that designate how actions must be carried out so that human life is protected. In this way, health, dignity, freedom, well-being and rights involved in this research are protected, so that scientific research is in no way carried out that does not follow bioethical principles (MALU, 2020).

According to Barboza (2009) in Brazil, in relation to civil liability for medical activities, there is still a lot to be explored. Therefore, currently this responsibility is more linked to medical error, while it is extremely important that this responsibility is incisive, regarding other activities carried out in the biomedical field, which can generate harmful effects, which is the carrying out of research involving human beings. And in relation to civil liability, it is directly linked to the consent form, these are very complex issues. Research par excellence is a risky field, and accountability when





if it involves human beings, it should only admit research that observes constitutional principles, and the ethical principles that authorize it (BARBOZA, 2009)

Research carried out with human beings must have a different approach, taking into account increased vulnerability and certain cases of people who were already vulnerable and sick. Therefore, it is an integral risk and must be imposed directly on who should be responsible for applying this research (BARBOZA, 2009)

Research with human beings must necessarily meet ethical and scientific requirements, respecting the principle of human dignity, respecting their autonomy and vulnerability. There is always free and informed consent, either by themselves or by legal representatives, from individuals or groups that participate in research. (BARBOZA, 2009)

Risks are present in this research, therefore, it is extremely important that for this to happen, there are objectives outlined, such as offering a great possibility of generating understanding, preventing or alleviating a problem that affects those who are undergoing it and other individuals; the risk taken must justify the benefit sought; that the benefit is greater or at least equivalent to that of other methods already tried to prevent, diagnose or treat. Knowing that if there is any damage, it may occur immediately or in the long term, and may also compromise only that individual or the community. (BARBOZA, 2009)

Regarding responsibility, both the researcher and the sponsor must be responsible and provide full assistance for complications and damages resulting from risks taken. And these must be compensated, and it is clarified that in no way will the person being researched waive their right to compensation for the damages incurred. Even with the consent form, it is prohibited for it to contain clauses that remove the responsibility of researchers and sponsors and for the researched to in any way give up their legal rights, including the right to compensation, in the case of damages (BARBOZA, 2009).

2.1 BIOLAW AND BIOETHICS

The study of Biolaw and bioethics emerged with the evolution of technology and science, with the great advances in scientific research that are part of social reality, these developments have brought and still bring benefits, but also risks (MALU, 2020).





The contemporary issues that are most evident in bioethics are: a) The right to life from its inception, and there are civil and criminal laws that make this guarantee and aim to protect life in dignity for humanity; b) The relationship between personality rights and human rights with biolaw; c) The right to genetic heritage, therapy, the development of research. Therefore, it is necessary that there is consensus and integration between the scientific community and the laws, as it is extremely important that the dignity of the human person is respected, and also that the quality of human life is maintained as a priority in any studies. (MALU, 2020).

Second, Malu (2020) it is necessary to establish a universal moral standard, as this biotechnological progress has impacted the traditional ways of acting of health professionals, revamping medical ethics and with this a current and specific study: bioethics. And this studies the morality of human conduct in the field of life sciences, bringing a standardization of socially congruent conduct.

There are themes whose foundations are based on bioethics, such as: clinical bioethics (doctor-patient relationship), the origin and end of life: abortion, euthanasia, dysthanasia, transplants, informed consent and social bioethics (health policies). Topics of great relevance today. (MALU, 2020).

Biotechnological research aims at scientific development as its main focus, including the cure of various diseases and therapeutic treatments, so that all research with human beings must be based on the principles of bioethics and biolaw, in search of autonomy, beneficence, justice and other principles. These main changes came mainly from the 20th century, with paradigmatic transformations originating from technological development and customs (MALU, 2020).

Integrations between human beings can generate selfish behavior, where people are only used by others to satisfy their objectives and achieve expected perspectives. But there is a sense of humanity that is co-responsibility and an ethical presence. Therefore, Bioethics is part of the responsibility of human beings, their duties towards each other, and these towards society (GOLDIM, 2009).

According to Goldim (2009) there is something called a sense of humanity, which is inherent and fundamental in relation to bioethics, which is thinking in a supportive way, having an attitude with integrity towards others and towards society. This is also a shared and interdisciplinary vision, on debates and any issues that involve life and living.





Bioethics is directly linked to social movements and the development of science, and also to the thinking that changes with historical evolution. As for biolaw, it is responsible for regulating the activities that are explored by biotechnology, through the introduction of bioethics, which make their advances at an extremely fast speed, changing even everyday life (MALU, 2020).

Ethical and operational limits must be well aligned and precise so that experiments and research can advance according to parameters of dignity, without compromising future species, ensuring that individual interests are disseminated to the community, so that it cannot there is subjection of man by man (MALU, 2020).

And even though the evolutionary process of the human being is in great progress, Regardless of its discoveries, human life must always be respected, taking into account that there are many scientific discoveries that can be made in practice, but not everything that is scientifically possible is also ethically permissible. And this is how the importance of bioethical discussions, of biolaw in its regulation, is shown in relation to what biotechnology creates (MALU, 2020).

According to Barboza (2009), regarding disrespect for the patient's autonomy, for bioethics, there will be a violation of an ethical duty, in the field of morality and social disapproval, and in some situations the implication of disciplinary and administrative measures may occur for the doctor.

As for biolaw, in addition to these consequences for bioethics, the medical researcher will be violating the researched person's right, not fulfilling his duty, and will then be made to answer for his civil liability, and depending on what happened, he could be held administratively and even criminally responsible. (BARBOZA, 2009). Emphasizing that any research without the free consent of the researched person constitutes an illegal act, failing to comply with the essential duty of care. In this case, the researcher will be responsible for any damage that may be caused, and his guilt will then be presumed. Thus, the free and informed consent form aims to make this research a lawful act, and establish limits of this lawfulness (BARBOZA, 2009)





2.2 PRINCIPLE OF HUMAN DIGNITY

The dignity of the human person is a principle that has already been highlighted in several constitutional sections. Standing out first in the 1934 Constitution, in its art. 115. Then the 1946 Constitution, in its art. 145. And in the 1967 text, it is found in its art. 157, II. The 1988 Constitution adhered to a compilation of fundamental rights and guarantees, both individual and collective, preserving and promoting the dignity of the human person. (MALU, 2020).

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According to Malu (2020), the dignity of the human person does reach the biotic principle of autonomy, which ensures the conscious freedom to choose and make decisions. And it is extremely important for society to debate the issue of ethical procedural limits, especially when linked to technological research with human life, taking into account normative instruments of protection and respect for human life. Together with the drafting of a specific law, to moderate and limit the intervention of science on life.

The basis for the foundation of biolaw and biotechnology is exactly on the principle mentioned here, especially because there are still many uncertainties linked to economic and cultural interests. For example, the search for discovery to bring a cure to hereditary diseases recently became evident, where many are already controlled, or may even have the chance of a cure (MALU, 2020).

If there is a confrontation between medical-scientific activity that is opposing some fundamental right of the human person, what must stand out is the principle of human dignity. Thus, it is in fact that no research in its scientific freedom can put human safety and dignity at risk (MALU, 2020).

Second, Adorno (2009) there must be a balance between the freedom and dignity of the human person and this is one of the main objectives of bioethics. So much so that most major arguments are linked to these two principles, which are associated with a real or apparent conflict. It is necessary to also emphasize human freedom in this bioethical context, thus taking into account harmonization with the principle of human dignity.

Freedom is a characteristic of the human being, man is destined and entitled to decide for himself, make choices, all based on his reason, each case is analyzed and thus the decision on how to behave. Therefore, everyone has knowledge about their





biological capabilities and needs such as sexual instinct or the biological function of hunger, and having knowledge, you can thus make your choices, and can even move away from your instinctive desire. Therefore, it is not programmed for all instinctive activities, ignoring how it works and carrying them out inevitably. (ADORNO, 2009)

Decisions are not only linked to the education he received, his genes and his instincts, but rather, it is he himself who causes his way of acting, he is the one who decides, and this is the capacity for self-determination which, together with intelligence, is a of the most incredible capabilities of the human being (ADORNO, 2009)

This capacity for self-determination does not imply that the content of the action is irrational or arbitrary. Thus, freedom to act does not mean that people can act in any way, do whatever they want, or in any way they want, especially when two actions and conduct will be harmful to themselves or even harmful to other people. (ADORNO, 2009)

In bioethics, the freedom expressed by the person is called autonomy, which in this context is usually the knowledge of the ability to make decisions about which treatment they want or not to undergo. And valuing this autonomy in relation to the patient is extremely important for ethics. Therefore, there can only be a biomedical intervention if the patient is informed of the risks, consequences, their nature and purposes, thus giving their free consent. (ADORNO, 2009)

2.3 EXPERIMENTS BENEFITS AND HARMFUL

Research is a very important activity representing society, it is linked to biotechnology, it is the study of technique and knowledge of life, encompassing biosafety and bioethics (VETTORATO, 2019). The issue under debate is the availability of human life, which is the target of severe criticism in all segments of society. The right to life is linked to the principle of human dignity of the person, therefore, the right to life will be the right to a dignified life. (VETTORATO, 2019)

Research is a systematic study that investigates reality, or seeks to discover facts that relate to any sphere of knowledge, and in addition to producing scientific knowledge, it is important to improve promotion, prevention, and also health care, contributing to the functioning of health services (GUERRIERO,





2010). All research must respect the resolutions of the National Health Council on Ethics in research with human beings. Generally, tests of both new medicines and procedures are studies carried out by pharmaceutical laboratories that always aim to make these discoveries, then carrying out the procedures. (GUERRIERO, 2010). It is important to make it clear that there is a big difference between researching just one assistance. They are different situations, but they can happen at the same time. In assistance, the main objective is the treatment of a disease, prevention or even guidance on how to have a healthy life. In research, it is different, there is a relationship between the participant and the researcher who will collect data to be analyzed and to produce knowledge. Thus, the relationships in the situations presented are different, as the situation changes from the moment the professional becomes a researcher. (GUERRIERO, 2010).

Research always seeks knowledge that should be of great use for better health care for people. And there is research that brings the possibility of direct benefits to those who participate, and other research may be useful to the community, without offering immediate benefit to the participant. Emphasizing that a person should only participate in the research if they have no doubts and have fully understood what is intended, possible risks and benefits. (GUERRIERO, 2010).

Thus, if the patient needs a legal representative to participate in the research, they will have to have their authorization, but even so, it is necessary to understand what will be done, it must be clarified in an accessible way to the person being researched. , even if it is in a language suitable for your ability to understand. Thus, all principles must be met and respected, such as autonomy, beneficence, non-maleficence and justice. In this way, research will be advances that bring extremely important benefits to humanity (GUERRIERO, 2010).

FINAL CONSIDERATIONS

It is necessary to defend improvements in quality of life, always being the basis, the fundamental principles. Therefore, the limitations are to guarantee and ensure humanity from risks to its physical integrity and all other principles. Therefore, if these advances are used correctly and in a completely conscious way, they will certainly help humidity even in its survival.





It is very important that the topic continues to be debated, analyzed and revised, because, with humanity's advances, new demands will emerge and an analysis of them will be necessary, which, if they are to be met, must be done in an effective but safe way. , respecting all necessary and required parameters. Discoveries, innovations, exchanges of experiences must be made, so that other researchers understand new methods and effective ways. In the same way that greater clarification for society is necessary, so that people really understand these discoveries and the purpose of each research is clear.

Emphasizing that free consent is essential, extremely important, so that only then can research be carried out. The best way to ensure that there are no possible problems regarding the agreement of those being researched is to clarify everything thoroughly, clarifying doubts and checking possible causes of damage, consequences or improvements.

On the part of researchers, it is understandable that the limitations imposed can even place limits on the very sense of research, of creativity, but, in the same way, this is completely necessary, and all rights must be protected.

Research cannot simply be carried out for one's own enjoyment, only for unique and non-utilitarian knowledge. But, they must have a sense of bringing innovations followed by improvements in life, well-being, advances in science, health, and human life. Scientific experiments with human beings must be the hope of better living conditions, they must bring hope for solutions, advances and scientific achievements for the benefit of humanity.

And all of this can be achieved through research with human beings that is always in accordance with and based on the laws that govern them, always seeking to be in agreement with the principles, and going hand in hand with biolaw and bioethics that emerged with evolution. technology and sciences that are currently part of social reality.

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