Analysis of criminal dignity and the lack of criminal protection in relation to research involving human beings

Talita Ferreira Alves Machado [1], *Claudio Cohen* [2], *Reinaldo Ayer de Oliveira* [3]

Abstract

The evolution of humanity encourages the development of technologies, especially in regard to research involving human beings. In this context lies the protection of people from the risks of research. The article analyzes the criminal dignity and the lack of criminal protection in relation to research involving human beings. It notes serious situations that demonstrate the need for this protection and the lack of instruments that guarantee the imperativeness of documents about this subject. It states that Criminal Law is the most effective way to protect life and physical integrity. The article says the consent form is necessary, but it doesn't avoid the criminal responsibility.

Key words: Criminal dignity. Lack of criminal protection. Research involving human beings.

Resumo

Análise da dignidade penal e carência de tutela penal nas pesquisas envolvendo seres humanos

A evolução da humanidade estimula o desenvolvimento das tecnologias, notadamente no que tange às pesquisas envolvendo seres humanos. Nesse âmbito reside a proteção das pessoas ante os riscos das pesquisas. Este artigo analisa a dignidade penal e carência de tutela penal nas pesquisas envolvendo seres humanos. Nele é constatada a existência de situações graves que demonstram a necessidade desta tutela e a carência de instrumentos aptos a garantir a imperatividade de documentos que regulam a matéria. O artigo afirma que o Direito Penal é o meio estatal mais eficaz para a tutela da vida e integridade física. Salienta que a existência de termo de consentimento para a realização dessas pesquisas é necessária, mas não afasta, contudo, a responsabilidade penal eventualmente existente.

Palavras-chave: Dignidade penal. Carência de tutela penal. Pesquisas envolvendo seres humanos.

Resumen

Análisis de la dignidad criminal y la falta de protección penal en relación con la investigación en seres humanos

La evolución de la humanidad estimula el desarrollo de tecnologías, especialmente en lo que respecta a la investigación involucrando seres humanos. Ahí se encuentra la protección de las personas ante los riesgos de las investigaciones. Este artículo examina la dignidad criminal y la falta de tutela penal en las investigaciones involucrando seres humanos. En el artículo se constata graves situaciones que demuestran la necesidad de esta tutela y la falta de instrumentos capaces de garantizar la exigencia de los documentos que rigen la materia. El artículo afirma que el Derecho Penal es el medio estatal más efectivo a la protección de la vida e integridad física. Señala que es necesaria la existencia del consentimiento para llevar a cabo este tipo de investigación, pero no descarta, sin embargo, la responsabilidad penal que puede existir.

Palabras-clave: Dignidad criminal. Falta de protección penal. Investigación en seres humanos.

1. Master Student talita.alves@hotmail.com **2.** Lecturer ccohen@usp.br **3.** Doctor rayer@usp.br – University of São Paulo (USP), São Paulo/SP, Brazil.

Correspondence
Talita Ferreira Alves Machado – Ipiranga Avenue 84, apt 902 República ZIP CODE 01046-010. São Paulo/SP, Brazil.

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We live in a risk society, which definitely does not mean that current risks are greater than those of the past. Although today there is more security, the feeling of danger is higher. This is due to the characteristics of these hazards, which currently are largely produced by humans and, in theory, controlled by the Criminal Law.

In this context, technological advances often create new dangers, which could generate, or otherwise, harmful effects that bring impact to the Criminal Law. Another important aspect concerns the extent, size and power of the damage brought by new technologies. Under such scenario, it is certain that the criminal policy cannot wait for the implement of the risk to act in the same way that the Criminal Law cannot await the outcome and only then act.

Risk Society

Because of the dynamic evolution of society and technology, the legislator's job has become very complex, which means it has to use techniques which avoid the immediate obsolescence of criminal types and at the same time, the advances of "risk society": *The risk society, the new paradigm of the late industrial era, due to the excesses committed by an evolution 'at all costs' (...) that have been causing a Pandora of risks which may be defined as invisible, immeasurable, potentially unlimited (both spatially and temporally as, yet, the circle of affected), incapable of constituting the object of insurance, blurring boundaries both physical (read geographic) and cultural – triggering a kind of equality in difference between those who share with us the adventure of life provoked, and have a tendency to cause feelings of insecurity, uncertainty and fear in people and organizations* [1].

Because of this complexity that pervades the legislative activity, the political burden of determining the boundaries between which deserves and which does not deserve the protection of the Criminal Law has been in charge of the Judicial Power. This power, although it is not – in fact – prepared for this, eventually determines the word and defines the political decision about the risk, which happens through mechanisms such as Direct Action of Generic Unconstitutionality, Direct Action of Supplier Unconstitutionality of Omission, Declaratory Action of Constitutionality, and Petition for Breach of Fundamental Precept and binding precedents.

These mechanisms are instruments by which the Judicial Power determines, in certain cases, the word on the *risk*, notably by the judicialization of policies and the expansion of the powers of magistrates. Indeed, the relevant and accelerated economic, political and scientific transformations require a change in attitude of the Judiciary. This new social organization also impacts the dogmas of Criminal Law, which cannot fit into society, in the face of new developments which arise every day. It is in this context which makes the discussion of criminal dignity and lack of criminal protection in researches involving human beings possible – research which may result in situations marked by considerable risk of impact to the society.

Research involving human beings

Thou workest in such a way that you use humanity, whether to your own person or to the person of any other, always and simultaneously as an end and never simply as a means (Kant) [2]. About the theme, it is worth mentioning which is meant by a research involving humans *that which, individually or collectively, involves humans either directly or indirectly, in whole or partially, including the management of information and materials* [3].

The Resolution 1, from the National Health Council (CNS), repealed by Resolution 196/96, considered in its Article 7, as risk of the research, the probability of an individual suffer some injury as an early or late consequence of the study. For this regulation purposes, the surveys were classified into three categories: research without risks, with minimal risk, and with a risk greater than the minimal [4]. The CNS Resolution 196/96, which repealed the previous one, institutes about the risks considering the item V in which all the researches involving human beings involve risk. An eventual injury may be immediate or delayed, affecting the subject or the collectivity [5].

The evolution of humanity stimulates the need to develop and improve technologies, notably in regard to research involving human beings, whether in order to prevent or to treat/cure of diseases. The desire for a longer life with better quality encourages such research. As Oliveira Filho and Angels clarify:

In order for those wishes to become viable it is necessary to know ever more deeply the complex machine that is the human body, develop new pharmaceuticals, medicines, vaccines and therapies to fight diseases, uncover the 'fountain of youth' by methods of deceleration – or perhaps interruption – of cell degeneration, among other possibilities and chal-

lenges. The achievement of these goals depends on several factors related to scientific research, among which (...) the experimentation in human beings [6].

The Constitution itself, in Article 218, provides: *The State shall promote and encourage the development of science, research and technological expertise* [7]. The paragraphs of this article specify norms for promotion, encouragement and funding of the research activity.

The research is, therefore, encouraged and, often, even funded by the State, and it is necessary, however, to bear in mind that one *should find a less artificial and anachronistic preservation and protection of life (...) to accompany without any fear revolutions that we gave cause* [8]. Thus, the object of protection in that context must be indistinguishable, i.e. regardless of sex, age, color, race, origin, social status, ability to understand and self-determination. And therein lays the issue of experimentation involving human beings and protecting people about the risks of the research.

Bioethics, in this context, reflects on the ethics of research involving humans. The relevance of research involving human beings is unquestionable because they constitute mechanism which search options for prevention and treatment for the benefit of mankind. So, it can involve whether observation or physical, chemical and psychological intervention, as well as using records which contain information about specific individuals.

Indeed, the current stage of development of medicine can be attributed in large part to research involving human beings, because these have allowed more accurate diagnosis, more appropriate therapies and greater expectancy and quality of life to people. As the CNS Resolution 196/96 explained itself, researches involving humans always imply risk, and most times, they are invasive. One should therefore consider the need to protect the dignity of the research subject and ensure their rights.

The variation of ethical standards adopted in these researches arouses attention to a more detailed study of the topic. The screen in point aims to analyze the criminal dignity and lack of criminal protection concerning researches involving human beings.

Criminal dignity, legal asset and criminalization criteria

Criminal dignity represents the analysis of the need or absence of criminal protection, in a given situation. More than that, by virtue of the subsidiarity principle of the Criminal Law, it means the analysis of the lack or its absence of criminal protection in the hypothesis. In this regard, Alice Bianchini says:

The Criminal Law works for the protection of fundamental values to human life in society. This, however, does not mean that at every opportunity in which a conduct offends such values there is a need to resort to it. It can also happen that the good does not require criminal protection throughout its length. The issues surrounding this problem constitutes part of the legitimacy of criminalizing analysis, which goes through a series of checks to reach a final conclusion on the matter [9].

The same author states that, firstly, it is required to analyze, on the hypothesis, the worthiness of the criminal protection, which emerges from the combination of the dignity of the legal asset and offensiveness of the conduct. Secondly, it is required to evaluate the need for such protection, so that the more important the asset is and more harmful its conduct which is intended to be interdicted by means of the Criminal Law, more necessary its intervention will be and less certain will be required whether other means could sufficiently protect the well.

It should be noted, in this regard, the existence of criteria to define how and when to create criminal law. They are the crime selection criteria and possible penalties, in which the legislator must be guided to make the incriminating provisions, to ensure the protection of individual freedoms and the democratic regime. It should also be taken into account the need to respect the human condition and the rationality of the criminal system, defined by Ripollés as *the ability to develop, within this social control, a legislative decision that meets the relevant data from social and legal reality on which it focuses* [10]. The analysis of these criteria of criminalization reveals the difficulty of the legislator to work with the legal assets.

There are many theories about what the legal asset would be and, it may be said, in sum, that legal asset is the *expression of the person's or of the community's interest in maintenance or integrity of a certain state, object or asset in itself socially relevant and therefore legally recognized as valuable* [9]. Under a last analysis, it is the value protected by a certain criminalization. Thus, without any legal asset to justify it, the conduct typified should be decriminalized or, if there is still no criminal type, there will be no reason to create it.

This analysis reveals, thus, the existence or not of criminal dignity, in the species treated, i.e. the existence or not of worthiness and lack of criminal protection.

It is worth mentioning that, with respect to the criteria of criminalization, it can only be criminalized the conduct which injures legal asset provided in the Constitution, which assumes the value of fundamental right. It is important to emphasize, the conduct *may* be criminalized and *should not*. It will be only be when it is established that there is a need for and lack of criminal protection. This analysis falls to the legislator, who should read the Constitution as an instrument which *authorizes* criminalizations and does not require them. This avoids that we work in a simply reactive way to legislating. In this sense, *the Constitution influences the matter to be criminalized, however it does not determine the first one* [9].

In legislative task, therefore, when it is created the criminal types it should be borne in mind both the worthlessness of action as the worthlessness of the result, emphasizing that there will be only typed before harmful or hazardous results to the legal asset. Considering the essentiality of legal assets already approached and the intolerable offenses of which we want to protect, it is justifiable to the debate about the need for development of a criminal law which provides for research involving humans. Moreover, in these cases, in order to prevent abuse, the penalty, possibly, would be *the only and last resource to protect the legal asset* [2].

Normative History

As we know, the first document that attempted to regulate researches involving human beings was the *Nuremberg Code*. The mass extermination of Jews and other ethnic minorities in concentration camps turned out to be genocide, dismaying the world. Among the ways to annihilate humans in these fields, the clinical experiences were identified. Held in the name of science and the development of a military power, these studies, carried out by Nazi doctors, also shocked the international community.

The knowledge of these facts sensitized the people and it became apparent the ambivalence of science and technology in relation to aspects of ethics and morality. It was understood then that scientific progress is not synonymous with human progress. For this understanding, the fact that the atrocities committed in the Nazi researches, which were held in inhumane conditions thoroughly and especially in people who have not given their consent, were condemned by the Nuremberg Court in 1947.

From this judgment came the *Nuremberg Code*, which deals fundamentally with defining standards of experimentation on humans. From these norms, the most prominent ones are the free and informed consent of the research subject; experimentation in animal preceding experimentation in humans, absence of risk; qualification of the experimenter; interruption of the experiment at any time of the tests. Certainly, based on the professional ethical responsibility, this code instituted the mandatory informed consent of the individual who participates as a research subject.

Concurrently, in 1948, the *Universal Declaration of Human Rights*, conceived as rights of the individual or person, reaffirms the dignity of the human person: his imprescriptible freedom to dispose from himself (of his existence, of his body). The human rights consecrate within the democratic society, the principle of individual autonomy against all abusive protective and powers. The philosophical basis of these human rights will become progressively an inspiration for part of the discussions on ethics and bioethics.

The *Nuremberg Code* and the *Universal Declaration of Human Rights* have changed the history of relations between researchers and research subjects, introducing rules which consecrated individual rights and autonomy. It is detailed in them how the human person must be respected when he is a subject of a research procedure. And, emphasizing the respect to his decision, according to his ability and self-determination. The expression of his consent is a decision which now predominates in statements and standards of human research.

The Declaration of Helsinki also advances to establish core standards in the field of ethics in biomedical research. Informed consent reinforces the concept of human autonomy and expands the responsibilities of the researcher. The Declaration advances because it defines that the interest of research subjects should prevail over the interests of science and society; points out the difficulties of informed consent in specific situations of dependency and disability and establishes ethics committees, independent, for evaluation of research protocols [11]: *a specific person or population may be the object of research to unravel diseases that afflict them or to uncover the reasons why it is less susceptible or not affected by certain disease that affects other human beings* [6].

Necessity and lack of criminal protection

It is worth mentioning that there have been situations in the History serious enough to demonstrate the possible need for criminal protection regarding researches involving human beings and even demonstrating the lack of that protection. In this context, it just cannot be expected the occurrence of an event with a repercussion of gigantic proportions so that Criminal Law can act, which does not mean that it should be created a law with open types to the extent of not translating the activity rate that is expected from types of criminal cases.

Thus, by all the reasons already given, it is believed, indeed, in need for a debate about the possibility of drafting criminal legislation regarding the conducts which involve the researches in human beings. Moreover, although – as already mentioned before – the Federal Constitution encourages researches, guarantee standards inserted in it eventually become ineffective in the face of the excessive delegation of power which the legislator gives to administrative bodies [2].

About Education and Medical Research, the Code of Medical Ethics (CEM), approved by Resolution 1931 CFM, from 17 September 2009, in its Chapter XII it is determined that it is prohibited to the doctor *participate in any kind of experimentation involving human beings for military, political, ethnic, or other eugenic purposes or others which act against human dignity (article 99), as well as fail to obtain approval of protocol to carry out research on human beings, according to the current legislation (article 100).* Furthermore, the physician must *obtain from the patient or his legal representative the term of free and informed consent to carry out research involving human beings, after appropriate explanations about the nature and consequences of the research (article 101)* – the sole paragraph extends this warranty to minors.

Besides these fundamental aspects to ensure ethics in researches, the article 102 of CEM provides for the use of *correct therapy, when its use is released in the country, and the sole paragraph which defines the use of experimental therapy is allowed if it is accepted by the competent bodies and with the consent from the patient or his legal representative*. The subsequent articles of 103-110 also point fundamental aspects to maintain ethical standards of the professional researcher [12].

It appears from the reading of the instruments above the following objectives: 1) protection of human dignity, 2) safeguarding of the research subject, and 3) emphasis of the importance of consent and, 4) absence of conflicts of interests and motives eminently profitable in researches involving humans. The article 99, for example, prohibits the accomplishment of researches involving human beings which act against human dignity. Thus, the legal asset protected by this standard is the very dignity of the human person, whose breach occurs in hypothesis in which researches have purposes not linked to the common benefit of mankind.

The article 100, in turn, conveys the prohibition to conduct researches previously not approved, allowing us to conclude that, when a specific ruling for directing research involving human beings is absent, it is possible that it deviates from altruistic interests which should guide it, which is prohibited by the CEM. The article 104 prohibits the medical doctor to fail to be professionally and scientifically independent regarding the funders of the research. Thus, it forbids the medical doctor to act motivated by profit interests. The following article seeks to avoid the conflict of interests between the research subject and researcher, because it impedes the course of the study when there is direct or indirect relationship of dependency or subordination between those people. The article 106 seeks to prevent the research subject to be misled by the researcher, through the use of placebo and, finally, the article 109 emphasizes the importance to avoid the conflicts of interest, even in potential.

Indeed, the objectives which can be deducted from the prohibitions imposed to physicians by CEM are of high relevance. In addition, it is necessary to mention the control held by ANVISA regarding the providing of authorization to conduct a clinical research with medicines and health products. It is considered to make the exception, however, that the prediction of penalties proportional to the seriousness of any violations that may be committed do not exist, whether in the prohibitions described in the CEM, or when ANVISA carries out the control.

Resolution 196/96 and supplementary resolutions from CNS, along with CEM, are a set of standards which deal with research involving humans, regulating its application in the country. It is interesting to note that the guidelines outlined by them, when they regulate the researches, could provide a basis for the formulation of criminal types which protect humans in the researches that they were subject.

Despite the existence of these regulations *there is a lack of imperative tools that ensure the en-*

forceability of such documents [6], since, despite the harmfulness which may result from certain researches, the penalties provided for possible violations may not be able to prevent further and more abuses. In that sense, it can be mentioned as an example the section II of Chapter XIV (General Provisions) of CEM, which provides: *Medical doctors who commit serious breaches of conduct misconduct provided in this Code and whose continual professional practice constitutes a risk of irreparable harm to the patient or society may have their professional practice suspended upon specific administrative procedure* [12].

The suspension of professional practice, depending on the gravity of the situation does not meet the proportionality which should guide the establishment of sanctions. The question which must be asked on this scenario is: *may ethical codes obligate scientists to place the interests of human beings as guinea pigs above those of society and science?* [8] Considering this respect, it is asked whether the State, acting in a coercive way, could ensure that researches involving human beings were carried out respecting the human person as an purpose in itself and not as an instrument? In that sense, it is worth noting that only on occurrence of harmfulness or potentiality for its occurrence is that the actions of the Criminal Law would be justified.

Thus, we speak of the impossibility from criminalization of ethical or moral conducts which are arisen from a value system of the individual himself or certain subcultures – the State must, therefore, tolerate them and respect them. Alongside, there is the duty to criminalize behaviors that interfere or expose to real danger essential assets to a qualified individual's existence in society. It is the principle of harmfulness, which ensures that criminal penalties will only be used when a behavior injures the rights of others[9].

In that sense, it can be mentioned as an example a fact occurred *in the early 1980s, when the head of the Indian community Ucluelet authorized the use of samples of his blood for arthritis research, whose objective was assess the genetic aspects associated with rheumatic diseases. The geneticist responsible collected blood from 900 other Indians. At the end of the decade, the geneticist moved to another country (from Canada to the United States), taking with him all the blood samples. Since this moving, the Indians remained unanswered about what had been done with the biological material stored. In 2000, they discovered that the researcher had used this same biological material for other studies in different parts of the world, without requesting new consent. Currently, the researcher is director of the Institute of Biological Anthropology, University of Oxford, England. The tribal council met in late 2000 to request the return of the samples to prevent further unintended uses* [13].

In the situation described it can be observed that, although there has been occurred disrespect to the authorization initially granted for the research, since this was extended to other members of the tribe, in addition to biological material has been used for other studies other than that stated at first, there was no injury to those people who participated in the research, which was able to justify the intervention of the Criminal Law. Thus, the example above cannot be regarded as decent and worthy of protection criminal.

It should be noted that, in this debate, social and human values which require pronouncements about its relevance, so it seems necessary the existence of legal regulations. On the one hand, there is the fear due to possible threats to life, physical integrity and dignity of the human person, on the other hand, there is the outcry for the benefits which researches involving human beings can bring. In the midst of these two extremes, the Law cannot stand as a mere regulatory institution of social conflicts, impeding the scientific development, nor it can remain silent – leaving issues relevant to mankind, which demand combination of knowledge and efforts to be better understood, up only to scientific ethics [14].

The role of the Criminal Law in this area should be discussed, considering that the matter affects the needs of the whole system, i.e. it transcends the conflict among the people directly involved in these studies, being socially harmful from the perspective of general interests. Such conflict has generalization capability, so that, when the Criminal Law does not act, the disruptive effects which may be generated will certainly be more severe than those ones observed to this day, especially before the lack of proper accountability of those who cause damage in the context discussed.

Given this finding, it is important to check which has been done in this scenario. So, if there is penal legislation, for example, about the transplant, it is certain that there was criminal dignity to sustain this activity. Thus, why would be no criminal dignity regarding researches involving humans, if the legal asset protected, in both situations, covers the life, integrity and dignity?

It is not that is believed that the fact is a fundamental right (in the species, right to life, right

to integrity and right to dignity) implies protection required by Criminal Law. Neither that, in order to a fundamental right is recognized as such, it has to be held protected criminally. The question is really about proportionality and reasonability before the circumstances of notable necessity and lack of criminal protection regarding researches involving human beings.

The creation of criminal types, therefore, seems appropriate to meeting the expectations set out herein. The observance of legality and specificity would bring security expected of Criminal Law. Furthermore, the intervention of the Criminal Law in this area would be justified also because of the existence of a pharmaceutical industry with intentions eminently profitable.

It is not forgotten, moreover, that human dignity, physical integrity and life are legal assets of considerable importance, which make Criminal Law to be the most effective state mean for their protection, justifying the criminalization of certain behaviors. And it is just on typing of the conduits which are usually spoken on the principle of integrity, by which the legislator should just criminalize certain behavior only after ensuring empirically about its usefulness and effectiveness to the extent of protection which is proposed to. In the case under review, in which is present the integrity of the protection, because ...

... In other countries (...) it was resorted to the most serious of all formal social controls, i.e. to the Criminal Law, by understanding that the extra-criminal legal systems have proved insufficient and inadequate in protecting the legal assets of the highest constitutional hierarchy, threatened by biotechnology[14].

Criminal law, in this case, shall be translated into a way to avoid certain practices indicating a maximum penalty for them. Only with the characterization of conducts is that it will become possible the State intervention, therefore. The criminal types to be created must reflect the social consensus, formed from an interdisciplinary discussion, which is able to elucidate the consequences of research involving humans.

It is worth mentioning that this protection should not be done hastily, just as a reaction to media opinion, but elaborated in detail, considering that, as known, the Criminal Law is the last *ratio*. Which must be borne in mind is that proportionality must be present in the formulation of these types. Thus, it should be put on a scale, on one hand, what is intended to be prohibited, under threat of penalty, and the on the other hand, the actual effectiveness of the criminal action. The criterion to be used, then, must be based on the severity of the fact that seeks to prevent, according to the ability of Criminal Law to modify its performance.

Criminal protection alongside the existing legislation

As it is known, some behaviors related to researches involving humans which could be criminalized, they subsume to types already provided for in the Criminal Code, such as the bodily injury (article 129, CP) and homicide (article 121, CP). However, the specificity of the situation discussed herein is an argument which justifies the creation of a specific law on the theme.

Moreover, only in the publication of research results is that the problems held during its realization usually appear. Factors such as these certainly converge to haze many of the potentially criminal behaviors committed during the performance of research involving humans. It is also important to note that the industry behind the researches involving humans is magnificent and often violates ethical rules established for the work it performs. Thus, the context in which the researches are developed is the factor of which can be extracted the lack of criminal protection in this regard.

In order to exemplify and also justify the specific protection in certain contexts, it can be mentioned the known Maria da Penha Law [15]. Despite the criminal conducts committed against women already encounter criminal answer in the legal system in force, the law was created before the need to define which would be the domestic and family violence against women, and to establish mechanisms to prevent and reduce such violence, besides setting instances, mechanisms and policies to assist victims.

It also happened to the law of transplants, concerning some of the crimes which it describes. Although they can be subsumed under the existing criminal types, the specificity of the context in which the behavior is practiced justified the creation of a specific criminal type.

The peculiarity of the context in which the research is performed, besides justifying the development of criminal law on the subject, it also allows the development of other criminal types, in addition to those existing in the current legal system, which are able to encompass any criminal conduct practiced in this mean – i.e. the criminal dignity and lack

of criminal protection in species exist without any harm to which is provided for in the Criminal Code and special criminal laws.

It must also recognize that the creation of specific criminal law could inhibit the practice of criminal conducts in researches involving humans, given the preventive function which the punishment takes, alongside the retributive function which it is also common (article 59, CP) . Thus, the development of criminal law about researches involving human beings would permit to define which criminal conducts committed against the research subjects, or against any other potential victim, as, for example, the collectivity, and establish mechanisms to enable the prevention and reduction of these practices, as well as to outline the forms of assistance to the victims.

Free and informed consent

In this discussion, we must also give approach to the important issue of consent. The CNS Resolution 196/96 defines consent as *approval of the research subject and/or his legal representative, without defects (simulation, fraud or error), dependency, subordination or intimidation, after a complete and detailed explanation about the nature of the research, its aims, methods, provided benefits, potential risks and discomfort that it can cause, set forth in a consent form, authorizing their voluntary participation in the experiment* [5].

CNS Resolutions 251/97 and 340/04 also deal with consent in researches involving humans. The first one deals with the consent of patients with reduced capacity or not developed as well as psychiatric patients. The second addresses situations of researches involving human genetics. Thus, it mentions the minimum term of informed consent in such cases.

The consent term must be written according to the guidelines established by Resolution 196/96 and, sequentially, be approved by the committees of the institutions in which the research is carried out. Only then it will be applied to the research subject, allowing it to begin.

According to Goldim, informed consent is the moral right of patients, which generates moral obligations for physicians. It consists of three basic elements: competence or capacity (ability to think and act), information (give awareness on the risks, benefits, discomforts and economic implications of assistive or experimental procedures, aiming that people make decisions duly informed) and consent (voluntary choice made by the individual, free from coercion from the physician, researcher, other healthcare professionals, family, friends or society itself).

The author stresses that consent should be seen as a process and not as an event, and there will be violation of this process when appropriate information misses or when it fails to obtain consent [16].

Anyway, the term of consent aims to protect the research subject. His prediction of the resolutions mentioned above allows the establishment of guidelines for the activities of agents involved in the research, which are the institution, the investigator, the sponsor etc. The suitability of the consent term to the guidelines outlined in the resolutions mentioned above is crucial, since the right information of the research subject about the procedure which he will be submitted is the basis for making an autonomous decision.

In this sense, not only information, but above all, clarification should be present. That is, the information provided must be adapted to the cultural and intellectual level of the research subject in order to enable a proper understanding of the consent term. It is clear, therefore, that the consent term represents moral right of the patients – in this case, of the research subjects. Thus, it should be perfect regarding the elements which integrate it and which were mentioned above.

Consent, criminal classification and availability of assets

At this point, it should be made a proviso about the theme involving consent and criminal classification. This is actually the problem that involves the consent of the victim in fact typical of the practice, which can be configured by three hypotheses.

The first deals with the issue of consent as exclusion of typicality. This is the case, for example, of the practice of carnal knowledge with the consent of the person, an undoubtedly atypical event. If there is no consent, however, or if it is supplied by whomever is unable to do so, it will be configured the crime as provided for in article 213 of the Criminal Code, namely rape.

In the second hypothesis, the consent is seen as integral element of criminal type. In this sense, it can be mentioned the provocation of abortion with the consent of the pregnant woman, criminal type set forth in article 124 of the Criminal Code.

Finally, there is the case where the consent figures as a cause of illegality exclusion – i.e. though typical, the fact is not anti-law. It is interesting to know, however, about the validity of consent, to have the legal interests involved in this discussion.

In this regard, Aníbal Bruno teaches that *to function as a cause of illegal exclusion, the consent must result from a legally valid will. He who consents must be able to will with legal effectiveness, and the consent should express their real intention, to be voluntary, which is not obtained by violence or essential error. There can only be granted validly the holder of the legal asset, who can legitimately afford it*[17]. The possibility to dispose of the legal assets only exists, therefore, in case of available assets, assets on which the private interest prevails.

In such cases, the consent is able to delete the anti-legality of conduct. Thus, it can be consented, for example, when certain material asset is damaged because it is an available asset. When it is dealt with unavailable assets, however, the solution is another, since the collective interest prevails, overseen by the State, even though the victim consents to the offense.

In the present analysis, the life and physical integrity are covered, unavailable assets, which may be violated when researches involving human beings are carried out. It cannot be consented, for example, physical injuries to his own body. Likewise, one cannot consent to his own death. Of course, exceptions, such as the possibility to consent to the donation of an organ in life – kidney, for example – exist. Thus, the crime is not typified as bodily injury, because the consent removes the anti-legality of the conduct in kind.

However, which is discussed here is the possibility that the consent, given at the time of signing the free and informed consent, removes the anti-legality of an eventual conduct, criminally typed to protect the unavailable assets referred above – life and physical integrity – and perhaps violated in researches involving humans. Indeed, the life and physical integrity of people cannot be subject to the free provision, with pure limit. And they are constitutionally protected and tied to the dignity of the human person.

The legal acts by which a person puts his life at the disposal or submits himself to severe danger are not valid. Although it is scientific experimentation, the public order and morality should be considered in order to prevent the occurrence of abuses. Thus, it is important to recognize that the physical integrity must be preserved, considering that it integrates the attributes of the human person.

Thus, even if there is a consent term which expresses agreement with possible practices to achieve the legal assets already mentioned, this cannot invalidate any criminal liability in kind, as explained before. The provisions of article 13 of the Civil Code corroborate with this understanding: *Except for medical requirement, the act of disposal of the body is closed, when it imports permanent diminution of physical integrity or contradicts good morals*[18].

It seems that the existence of the term of free and informed consent would not be able to avoid the anti-legality of the conduct, therefore, with no guarantee that the criminal liability of the investigator or any other agent involved in the research – determined in the extent of their guilt, pursuant to Article 29 of the Criminal Code – would be removed. In cases there would breach to the process of obtaining consent, it is believed that the hypothesis is the provision of a cause of increased penalty for the types established, to be applied in the third stage of sentencing, and, thus, it can overcome the maximum limit of the penalty base.

The criminal dignity, therefore, seems to be present regardless of whether or not the consent term exists. The conducts to be criminalized should be similar to those practiced by scientists and not mere practices which diverge with our reality and it should be noted that the construction of criminal types has to be rigorous, in order not to hinder the development of biotechnology in the country.

Final considerations

Throughout this work we developed an argument according to which there is lack of dignity and criminal protection in human researches. Thus, it was asserted that there was ever in the history of mankind serious situations enough to demonstrate the need for such protection and the lack of suitable instruments to guarantee the urgency of documents which regulate this matter, in the example of the Code of Medical Ethics.

It was seen that only the State, coercively, can ensure the development of biomedicine in order to respect the human person as an end in himself, and the creation criminal types, in accordance with the principles of legality and specificity, would bring the safety expected from Criminal Law. It was stressed also that the life, physical integrity and dignity of the human person, due to the importance they have,

make the Criminal Law to be, in these cases of hypotheses of researches involving humans, the most effective state mean to their protection.

We also discoursed on the suitability of the criminal protection concerning this matter, especially given the experience of other countries, where only the creation of criminal types proved to be able to handle the matter. It was also said that the existence of a consent term to carry out such researches is needed, not removing, however, the eventual and existent criminal liability, since the life and physical integrity must be preserved, with any subjection to free disposal.

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Authors' participation
Talita Ferreira participated in the conception, analysis and writing of the article. Claudio Cohen participated in the critical revision of the article. Reinaldo Ayer participated in the analysis and critical revision of the article.