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Research Ethics Committees

Comités de Ética en Investigación

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Abstract:

Research Ethics Committees are governing entities whose purpose is to evaluate and rule, approving or disapproving future research protocols. Furthermore, they contribute to authorities in monitoring compliance with health legislation. As well as they constitute a guarantee of respect to the people involved as part of the subjects of research and legitimate those who develop this procedure. They are compulsory for all the premises in which research involves human beings.

Keywords:

Research Ethics Committees,The subjects of research,Legislation

Resumen:

Los comités de ética en investigación son órganos colegiados cuyo objeto principal es evaluar y dictaminar, aprobando o no aprobando, los protocolos de investigación que vayan a realizarse en seres humanos; asimismo, coadyuvan con las autoridades en la vigilancia del cumplimiento de la legislación sanitaria. Constituyen una garantía del respeto a las personas que participan como sujetos de investigación y legitiman a quienes desarrollan ese procedimiento. Son de carácter obligatorio para todos los establecimientos en donde se efectúe investigación en seres humanos.

Palabras Clave*:*

Comités de Ética en Investigación. Investigación en seres humanos. Legislación

INTRODUCTION

Technological advances in health sciences have developed rapidly in the last few years. It is not undoubtful the benefits given to humanity since it contributes to improving the quality of life in patients with chronic diseases, increasing life expectancy, among others. However, especially to clinical research on human beings shows inherent risks that could affect properties of great value to humans such as life, dignity, and personal integrity.

Unfortunately, there are some cases in which these types of research are carried out without guaranteeing the minimum of respect to people, letting out some of the principles that govern research in human beings.

This article will shortly mention some background aspects that mark a turning point in history as abuses were done to diverse groups of people.

Considering human beings, Kantian thinking is an end in itself, and it is never a means. Because of that, it is required to establish controls so that research studies on human beings do not exceed the allowed risk, and by doing so, practices imply unnecessary damage to those subjects of experimentation.

Since the publication of the Belmont Report (Beaucham & Childress 2019) ethical rules and orientations have been created to protect human beings during experimentation, for example, charity, autonomy, and justice[1].

[1] Afterward it was added the principle of non-maleficence.

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Monitoring and Application of these principles are insured to protect the legal assets of those who participate in the research study.

In this way, Research Ethical Committees (REC) constitute an appropriate way for such purpose, giving them faculty to approve or disapprove research protocols on human beings based on ethics and jurisdiction.
In Mexico, health legislation imposes compulsion, those protocols to be forced to be evaluated by committees, and those must be constituted within each sector that facilities the development of these studies.

HISTORICAL BACKGROUND

With the purpose of an explanation of the emergence of these committees, some historical background will be mentioned.

From 1932 to 1972 Tuskegee Syphilis Study was led to verify the evolution of a not-treated syphilitic population composed of 400 Afroamerican men of humble social status with other one not syphilitic (Vailhen, D. R., Moutel, G., & Hervé, C. 2008). This consisted of determining the evolution of syphilis and comparing the longevity of a sick population not treated with a healthy population. Neither was a diagnostic given to patients , nor were they informed about an available treatment from the commercialization of penicillin. Their consent was given in exchange for medical examinations and free blood tests (Vailhen, D. R., Moutel, G., & Hervé, C. 2008).

Another case was the study of hepatitis carried out by Willoubrook in New York (Vailhen, D. R., Moutel, G., & Hervé, C. 2008). In 1950, in a public institution for children with mental disabilities hepatitis virus was inserted into various healthy children to its efficacy taken from an injected vaccine the same as the virus. Nonetheless, the result obtained was used to identify both variants of hepatitis A and hepatitis B. Although it was questionable since the consent given by the parents was a condition of the immediate entrance to the institution, in case of not doing it, they were sent to a long waiting list.

REGULATORY FRAMEWORK

The regulatory framework governs activities done by REC and is formed by legal, ethical, national, and international sources. It is also worth mentioning that medical ethics is compulsory for the development of the investigation in human beings to be recognized as legal provisions.

At the international level, the following documents are highlighted (Cancino Marentes, M. E., Gascón Cervantes, A., Manrique de Lara Ramírez, A., & Medina Arellano, M. D. J. (2019):

- Nuremberg Code, 1947.
- Declaration of Helsinki, WMA, 1964 (last amended 2013).
- Belmont Report, National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research, NIH USA, 1979.
- Universal Declaration on Human Rights of Future Generations, UNESCO, 1994.
- Good Clinical Practice Guideline (GCP), ICH E6 (R2) 1996 (last amended 2016).
- Statement on the Responsibilities of the Present Generations Towards Future Generations. UNESCO, 1997.
- Convention for the Protection of Human Rights and Dignity of the Human Being concerning the Application of Biology and Medicine "Oviedo Convention" Council of Europe, 1997.
- Operational Guidelines for Ethics Committees Evaluating Biomedical Research, WHO, 2000.
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- International Ethical Guidelines for Health-Related Research Involving Human Subjects, CIOMS, 2002 (last amended 2016).
- International Declaration on Human Genetic Data, UNESCO, 2003.
- Universal Declaration on Bioethics and Human Rights, UNESCO, 2005.
- International Ethical Guidelines for Epidemiological Studies, CIOMS, 2009.
- Guidelines and operational guidance for the ethical review of health research involving human subjects. WHO, 2011.
- Guidelines for members of the Research Ethics Committees. Steering Committee on Bioethics of the Council of Europe, 2012.

During the sanitary emergency caused by COVID-19, the Inter-American Court of Human Rights issued Resolution 4/2020 Rights for people suffering from COVID-19, which explained that in all research involving human subjects, free consent could be obtained previously. Also, participants are informed to safeguard their data, which could be shared with the previous authorization of their owner, with public health institutions and other groups of researchers for future studies. (Resolution 4/2020 Human Rights of People with COVID-19, 2020)

Moreover, Pan American Health Organization cast a document “Orientation and Strategies to hasten revision and ethical monitoring of research related to COVID-19” to regulate this activity while the crisis of public health, allowing the speed revision without prejudice and respect for human rights (Orientation and Strategies to hasten revision and ethical monitoring of research related to COVID-19, April 7, 2020,n.d).

The most significant national rules are the following:

- Political Constitution of the United Mexican States.
- General Health Law.
- Law on Biosafety of Genetically Modified Organisms.
- Regulation of the General Law of Health in matters of health research.
- Regulations of the Federal Commission for the Protection against Sanitary Risks.
- Decree created the decentralized body called the National Bioethics Commission.
- Agreements with General Dispositions are broadcasted to the Integration and Operating of REC, the establishment of Unit Cares, which must count on them, and conformity with the established criteria by the National Commission of Bioethics.
- The agreement amends and adds to the one that issues the General Provisions for the Integration and Operation of Research Ethics Committees and establishes the hospital units that must have them, per the criteria established by the National Bioethics Commission, published on October 31, 2012.
- Official Mexican Standard NOM-012-SSA3-2012 clarifies the criteria for implementing health research projects involving human beings.
- Guide for submission of new or initial protocols (Federal Commission for the Protection against Sanitary Risks).
- National Guide to Integration and Operation of Research Ethical Committees (National Commission for Bioethics).

BELMONT REPORT.

It is considered relevant to mention of Belmont Report since it is one of the most relevant documents to conduct the work of review committees for research projects involving human beings.

Particularly in the case of Tuskegee, in April 1979, the National Commission for the Protection of Human Subjects in Biomedical Research and the Behavior of the United States issued the report "Ethical Principles and Guidelines for the Protection of human subjects in Research known as Belmont Report, due to the reunion in Conference Center of the same name (Morales, n.d).

In this report, the basic ethical principles were identified as general trials taking as a reference the particularity of ethical requirements and evaluations of human actions such as respect for people, charity, and justice (Belmont Report Principles and Ethical Guides for protection involving human subjects of research, 1979):

A) Principle of respect for people: it mainly refers to two aspects, people must be treated as autonomous agents, and those who are less autonomous have the right to protection.
First of all, every human being must be respected as an autonomous person, recognizing his capacity to decide and be informed of any intervention that applies to his integrity. That means, in general, anyone must be respected his liberty of deliberation and decision based on the values constructed as a parameter of behavior in the light of the imposed rules by society and the legal system.

Nevertheless, a person can make a free and authentic decision and must be informed promptly, clearly, sufficiently, and accurately about the activities to do. Considering the beforementioned, it is recognized the right to give informed consent. This is one of the fundamental requirements to participate in research studies involving human beings, and it was a greater omission in the cases described as background.

Second of all, the other aspect focuses on protecting people who cannot exercise their autonomies due to a legal incapacity or caused by their health situation. For example, underage or those who suffer a mental incapacity. Because of that, the limitation of their autonomy makes these people vulnerable, so they must be tutored to avoid damage to their integrity.

This guardianship must be in charge of their parents, tutors, and other legal representatives who will protect them anytime. In some situations, it will be necessary to prevent participation in those studies that constitute a high risk for their integrity. In terms of the prohibition of researching them. In some cases, autonomy is limited because belonging to a subordinate group is necessary to approve the research study from any guardian from this collectivity that could be affected.

This principle is generally known as the principle of autonomy, and its objective is to guarantee respect for the person's dignity.

B) Charity: This principle seeks to guarantee the benefit of the person involved in all the acts of research on human beings. Not only is respect needed to respect autonomy, but also be sure not to pretend to cause damage to the person. The same report points to two

general rules as complementary actions from the actions: a) Not to cause harm, and
b) Increase the benefits and decrease eventual damage as far as possible.

Hence, this principle entails the right not to cause harm, thus the *principle of non-maleficence* has been incorporated according to the principle of medical ethics *primum non-nocere* to those that govern research on human beings (Belmont Report Principles and Ethical Guides for protection of research involving human beings,1979).

From this principle, it also must be considered that not all research is free of risks, so it is imperative to balance risk-benefit to justify in which cases can assume that eventuality.

In other words, every concrete case must be valued if the benefit sought is higher, if the risk can be controlled, or if it is another than the well pursued, which could justify the intervention, recognizing the called *allowed risk*. In such cases, it is unavoidable that the person be informed about these possible risks to feel free to decide, ensuring the principle of respect for the person.

On the contrary, when the risk is higher than the expected benefit, it will not allow the development of the research since it could cause higher harm to the person, even if he is permitted to participate a limit to this autonomy is the framework that protects human dignity.

This principle is also of great utility in the justification of research involving people with limited autonomy with the awareness that the benefit pursued could only be obtained with their participation of them. Based on the foregoing, it is important to identify the scope of the principle of respect for people, especially for those with limited autonomy.

The Report mentions that Claude Bernard extended the Hippocratic principle of "no cause harm" to the field of search, stating that no one should hurt another person, independently from the benefits that could be derived for others
https://www.conbioetica-mexico.salud.gob.mx/descargas/pdf/normatividad/normatinternacional/10._INTL_Informe_Belmont.pdf).
Witdoubtting, there is a connection with the principle of autonomy.

C) Justice: About the Report, this principle emerges from the concept of justice as "give to each one what it belongs" implies equality in the distribution. So a question is raised Who should receive the research benefits, and who should carry the burdens? It can be said that it would be unfair to deny the benefits to those who have the right to receive it or impose an obligation on a person who does not have the responsibility to support it. For that distribution of burdens and benefits, the report points to five formulations:

   a) To each person an equal proportion;b) to each person based on his individual needs;c) to each person corresponding to the individual effort ; d)to each person relative to his role in society, and e) to each person according to his merit (Belmont Report Principles and Ethical Guides for protection of research involving human beings,1979)

   A clear example of why this principle must be respected in the case of Tuskegee, in which it was not given access to antibiotic treatment men to cure syphilis, and also it was imposed an unfair burden to support the natural evolution of the disease without the corresponded medical treatment.

To apply these principles to the development of research involving human beings, the Report mentions the responsibility of considering indispensable requirements of informed consent, the balance between risk-benefit, and the selection of the subjects involved in the research.

A) Informed consent: As mentioned in the principle of respecting a person, informed consent is a means to warrant free decision, and this information must be provided to the subject to decide if he participates or not in the study. The Report refers to informed consent must be integrated into three elements:
information, understanding, and wilfulness (Belmont Report Principles and Ethical Guides for protection of research involving human beings,1979):

   While informing, it must be provided the procedure of research, purposes, eventual risks, and expected benefits, alternating procedures and the human right to ask all the possible questions, and to revoke his consent any moment, without liability on your part.

Referring to health research, it is possible that revealing certain information could jeopardize the outcome of the Research (Belmont Report Principles and Ethical Guides for Protection of Research involving human beings,1979):

a. Understanding refers to taking into consideration the capacity of comprehension from the person involved at the moment that information is given. Not only must it be sufficient, but also must it be understandable to those who participate in Research and consider the context in which it takes place.

   If there is a limitation of understanding, it must attend to the guardian of this person to guarantee his protection, saying limitation is not always absolute, so that it will be taken into account its degree, as well as listening to the person's opinion on the research.
b. Concerning wilfulness, the person who will participate in the research must express his consent free of coercion and deception. This freedom could be violated when information is false or inaccurate, being imperative in its veracity

B) Valuation risk-benefit: In most cases, research on human beings has risks of implementation. Therefore, as an exercise of the principle of charity, it is an essential responsibility to balance the eventual risks against the expected ones to define the extent of each one justifying and assume the first ones because of lower results pretended to achieve. This Report foresees the assumed risks and considers the following:

   a. Inhuman treatment will not be morally acceptable.
   b. The risks must be reduced to the minimum required.
   c. In case research shows a high risk, review committees should be emphatic in the justification of the research project.
   d. If the research is developed with vulnerable people, it must mention the need to include them due to a lack of other options.
   e. Risks and benefits must be comprised of the documents that show the consent of the participants in the research.

C) Selecting subjects: It is linked with the principle of justice. Based on that, an election of the participants in the research project will be considered. In its dimension, justice concerns not only supplying greater benefits to certain people but also being equal to those who accepted to be part of the study. Additionally, not to select people who are seen unfairly as "undesirable" to part of the search. For instance, the social justice dimension demands to give the reason for selecting determined vulnerable groups because of age or belonging to the subordinated population.

D) If it is not a unique guide, this report is of great relevance to analysis, deliberation, and resolution that committees in charge of the revision of research studies on human beings.

WHAT IS A RESEARCH ETHICS COMMITTEE?

On one hand, the Latin American Dictionary of Bioethics (Tealdi, 2008) defines it as a multidisciplined and independent group of health professionals, as well as, other areas of knowledge, and members of the community whose main objective is to contribute to dignity, rights, security, and well-being of the actual and potential participants of the research. Ensuring that the benefits and burdens of the research will be equal among groups and the status of society.In addition to safeguarding relevance and scientific correction from the protocol of research that is taken into consideration.

On the other hand, the National Bioethics Commission (National Guide to Integration and Functioning of Research Ethics Committees,2016), REC has as its objective to check research protocols on human beings and safeguard the dignity, rights, and security of those people involved in the process, emphasizing their protection as a space for deliberation, in which discussion and reflection are developed, within an environment of freedom and tolerance.

An interpretation of numeral 4.4 of the Mexican Official Standard NOM-012-SSA3-2012 establishes the criteria for the implementation of research projects for the health of human beings and mentions that these committees are a set of professionals that are in charge of revising, approving, and monitoring that the projects and research protocols are done according to ethical principles that rule the research.

From those definitions, it can be warned that these committees have as their main function, revision, in the light of ethical principles, research protocols on health developed on human beings to rule if it is approved or declined implementation to protect possessions of great value such as life, dignity, and personal integrity. For this reason, its resolutions are linked to those who develop research, thus its approval will depend on its implementation, on the contrary, it would be illicit research.

General Health Law, Article 41 Bis claims that all medical unit's care in which research activities take place on human beings must have a Research Ethics Committee that will be responsible for evaluating, and ruling research protocols on

human beings, formulating ethical recommendations, as well as preparing guidelines, and institutional ethical guides to the health research, being given monitoring to the recommendations. Similarly, numeral 99 of the Regulations to the General Health Law in the matter of health research disposed of in health institutions that health research involving human beings must constitute a research ethics committee.

In this regard obeys the unavoidable task of pronouncing whether or not, it fulfills the disposed requirements emitted by legal standard and safeguard the properties of the people already mentioned.

National Guide for Integration and Implementation of Research Ethics Committees (2016) characterizes these committees as being:

- Autonomous: they are independent of any professional, institutional, or marketing political influences, among others.
- Institutional: they belong to an institution to get medical attention, health institutions, or higher education from the public, social, or private sectors of the National Health System[2], where research on human beings is done.
- Multidisciplinary: they converge all the knowledge from different disciplines, specialists on scientific, and methodological issues, and good clinical practices must be included. At least one member must have knowledge related to research bioethics, and ethics. It is advisable for the participation of nursing personnel social work staff, lawyers, among others, and also a guardian of the affected core, or user of health services. If necessary, we must consider the possibility of inviting expert people from specific areas.
- Plurals: they recognize and encourage diversity, and intend to reach agreements among diverse positions, within a discussion that has the minimum shared.
- Advisory: they assess the governing body and look for determining values of social ethics, and serve as organs of the first instance to issue opinions or recommendations of a general character.

Based on the previous characteristics, these committees are seen as spaces in which research protocols will be objectively, impartially, and professionally checked and ruled considering respect and tolerance.

The REI will be formed by (the National Guide for Integration, and Functioning of Research Ethics Committees, 2016):

A) President.
B) Board members (minimum of four, from which the Secretary is).
C) Representatives of the involved core or users of health service.

According to Article 58 of The General Health Law and its Regulations in a matter of health research when research is applied with subordinate groups, the representatives of the involved core, or users of health services that participate in REC will monitor authorization, rejection, or decision of not continuing with the study neither affecting their situations of subordination nor using results to affect them, so compensation will be paid if there were damage caused while researching. It is warned their participation within REC.

As for the matter at hand, during the sessions of REC, specialists, and experts could be invited to enrich decision-making.
The position within REC is honorary, as a result, it is advisable to consider it as a distinction to value the performance inside the facility.
National Guide establishes it as an entry requirement.

(NATIONAL GUIDE):

- Have personal and professional references which validate ethical behaviour and employment references from the community or organization.
- Document his professional experience in the research field or research ethics.
- Have some academic training, coaching, or experience related to bioethics, research ethics, and good clinical practices.
- Be committed to taking continuous training regarding bioethics and research ethics ▪Be respectful, tolerant, open-minded, flexible, cautious, honest, and with conciliating behaviour.
- not have conflicts of interest with the functions assigned within REC.

These requirements do not apply to the representative of the involved core or the users of health services.

To maintain authentic independence among related committees with health research, the President of REC could not govern the Research Committee or Biosecurity Committee. Besides, the members of REC must freely discuss any conflict of interest that could affect an impartial and objective resolution.
The integration of multidisciplinary allows anyone to have a study from different perspectives fortifying its analysis for a complete and integral declaration. Since evaluation from the correction of methodological design to all the aspects that could infer the human rights caused by their participation in the study.

[2] Article 5 of General Health Law points out that the National Health System is conformed by dependences, and entities of Public Administration, either federal, or local, and individual and legal people from the social, and private sectors that provide health services. As well as the mechanisms of coordination of decision-making, and whose objective is to fulfil the right to the protection of health.

As a consequence, REC must have health registration with the Federal Commission for the Protection against Sanitary Risks.

Concerning the National Guide, the National Commission of Bioethics identifies three functions from REC:

A) Solving function: It analyzes and supervises research protocols to rule, from an ethical point of view approbation or declination to be executed. In case of the integrity of a person is in danger, a disruption of the study can be asked.
B) Control and Monitoring function: It gives continuity to the resolutions, and monitoring of research development, supervising the fulfilment of applicable law.
C) Educative Function: It encourages continuous training in bioethics and research ethics among the members and health personnel. Members are indeed demanded to know the minimum of about the subjects checked so that it is recommended that during the first sessions, there is a training. The advisory function is of greater help for the directors of the facility to count on specialized counselling for ethical implications related to research in general situations.

These committees represent an idoneous way to verify that clinical research involving human beings observed regulatory requirements which govern that activity, not only from its approbation but also during its implementation. Having the power of monitoring until the end of the study.
This criterion is a source of legal standards, especially to health law and Biolaw every time they emerge from the analysis to the light of ethical and legal principles leading to safeguarding people's life, dignity, and integrity.

CONCLUSIONS

To conclude, research ethics committees are a means of control to guarantee that studies involving human beings represent a benefit for the person and not cause unnecessary and excessive dangers.
Furthermore, they contribute to health surveillance, and have the faculty to verify the fulfillment of legal provisions that regulate research on human beings.
Because of that, its integration must be multidisciplinary to have a broad and objective vision while providing resolution since it depends if a study is carried out or not.
In Mexico, they are obligatory for all the projects executed by human beings.

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