National Guidelines
For the
Organization and Operation
Of
Hospital Bioethics Committees
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One of the duties of the National Commission of Bioethics is to encourage both public and private health institutions to organize and operate hospital bioethics committees as well as research ethics committees. Therefore, it is important to establish and disseminate the criteria to be taken into consideration by these committees so they may carry out their activities, and support the training of their members. The main objective of this document is to propose uniform criteria for their integration and operation.

These guidelines have been elaborated based on the current national and international rules and the country’s pre-existing practices. These guidelines will be revised and updated as new situations or problems arise.

This working paper has been elaborated to offer a conceptual framework through which to initiate a constructive dialogue between the National Commission of Bioethics and hospital bioethics committees, in order to establish a continuous updating process regarding the fundamental bioethics issues to be taken into consideration in clinical activities, education, research and professional relationships. This document is part of a series that includes the National Guide for the Integration and Operation of Research Ethics Committees.

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I. THE NATIONAL COMMISSION OF BIOETHICS

The National Commission of Bioethics (CNB) is an Independent Body that falls under the scope of the Ministry of Health. It has technical and operational autonomy. The aim of the CNB is to promote the creation of a bioethical culture in Mexico, encourage attitudes that include multidisciplinary and multisectorial reflection, deliberation and discussion regarding issues about human health, and develop ethical rules for health care, health research and education.\(^2\)

The CNB’s mission is to promote a bioethical culture, within a secular state, that involves deliberation about ethical dilemmas. This deliberation is based on sound information, within a framework of plurality, multidiscipline and tolerance, in order to maintain a well-founded, reasoned and reasonable dialogue regarding the issues at hand and find ethical minimums to maintain a plural coexistence within the diversity.

The CNB responds to the needs of a pluralistic and democratic Mexican society, searching for ways in which distinct groups and social actors can communicate, dialogue, agree and negotiate, as well as ways to establish a connection between them and the State, to analyze and discuss the ethical, legal and social problems that have emerged since the establishment of human rights and the spectacular contemporary advances in science and technology, among other factors.

The reason why it is so important for bioethics to support social practices is that it focuses on the reflection of vital processes, meaningful laws can be established in a clearer and more pluralistic manner; respect for human rights is encouraged; the environment is protected; medical treatment and health research focus on the collective well-being and respond to the needs of the general population, particularly the more vulnerable groups; more autonomy is given to patients in the decision-making process, among others.

The CNB would like professionals to incorporate a democratic vision of the health field into their regular activities wherein inter-subjective agreements of Mexican society, morally plural, are the platforms from which to launch law initiatives. Moreover, one of the CNB’s goals is to invite different social sectors to debate, in an orderly fashion, about the distinct aspects that shape bioethical problems; identify and systematize the ethical components present within the disagreements and controversies in order to favor sustained, rational, reasoned and plural agreements; and create spaces for analysis and understanding in order to offer agreements that ensure a tolerant and respectful coexistence of differences for the well-being of society.

1. Historical background of the National Commission of Bioethics

The National Commission of Bioethics was established in 1992 through the initiative of Dr. Manuel Velasco Suárez. The current phase of the National Commission of Bioethics begins on September 7, 2005 when, by Presidential Decree, it becomes a more Independent Body (deconcentrated) pertaining to the Ministry of Health.\(^3\) The following table shows the historical evolution of the National Commission of Bioethics.

\(^2\) Article 1. Decree by which the Independent Body known as the National Bioethical Commission is created. Diario Oficial de la Federación, September 7, 2005.

Historical Evolution of the National Commission of Bioethics

The General Health Council establishes the Bioethics Study Group and it becomes a Collegiate Body headed by Dr. Manuel Velasco Suárez. 1989

The National Commission of Bioethics is created at the Antiguo Claustro de San Pablo. 1992

Internal Policies of the CNB are established. 1993

Publication of the Presidencial Agreement that makes the CNB a permanent body. 2000


After the death of Dr. Velasco Suárez, Dr. Fernando Cano Valle is appointed Executive Secretary of the CNB. 2002

Publication of the Bioethics Code for Health Professionals. 2002

Initiative for the creation of Bioethics Commissions in Federal Entities. 2003

The CONAGEN disappears and the CNB takes over the ethical aspects of the human genome. 2004

The CNB becomes an independent body with technical and operational autonomy. Dr. Guillermo Soberón Acevedo is appointed Chairman of the Board. 2005
Duties of the National Commission of Bioethics  

Article 2 of the Presidencial Decree of September 7, 2005 indicates the scope of the CNB’s duties to fulfill its mission and objectives. It is the following:

I. Establish public health policies associated with bioethics.

II. Act as a national advisory body regarding specific bioethical issues.

III. Identify and systematize the elements inherent to bioethics, in order to offer pertinent information about them to institutions, social groups or any other interested sector.

IV. Foster the implementation of the right to health protection within the area of health research, as well as in the quality of health care.

V. Propitiate debates on bioethics with the participation of different sectors of society.

VI. Encourage bioethics education, particularly in health care and health research.

VII. Promote the creation of state bioethics commissions.

VIII. Promote the integration and operation of hospital bioethics committees and research ethics committees, in public and private health institutions, with the powers granted to them by the applicable legal dispositions, and support training for members of these committees.

IX. Establish and disseminate the criteria to be taken into consideration by hospital bioethics committees and research ethics committees in order to carry out their activities.

X. Organize and participate in research and teaching activities that are inherent to its objectives.

XI. Express an opinion on the health research protocols that are submitted to its consideration.

XII. Endorse any collaboration agreements necessary to achieve its goals.

XIII. Foster communication with universities, higher learning institutions, academic and civil society groups that are connected to bioethics.

XIV. Procure the observance of bioethics criteria, at the inter-sectorial level, in health related issues regarding food, water, the environment and education, among others.

XV. Other attributes assigned to it by the Ministry of Health.

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4 Decree by which the Independent Body known as the National Commission of Bioethics is created. Diario Oficial de la Federación, September 7, 2005.
II. CONCEPT AND PRINCIPLES OF BIOETHICS

The term *bioethics* was first used by Van Rensselaer Potter as a proposal for a new discipline that would serve as a bridge between two cultures: the scientific, regarding life and the environment, and the humanistic, centered on ethics.\(^5\)

Although there is no single way to define bioethics, the Encyclopedia of Bioethics defines it as “the systematic study of life sciences and health care, examined in the light of values and moral principles”.\(^6\) In the third edition of the encyclopedia, this definition is expanded upon: “The systematic study of the dimension of morals—including moral vision, decisions, behavior and policies—, of life sciences and health care, employing a variety of ethical methodologies within a multidisciplinary context”.\(^7\)

Bioethics has evolved into an international movement that includes traditional aspects of medical ethics, environmental ethics, debates on the rights of future generations, sustainable development, etc.\(^8\) Bioethics is an instance of practical judgement that is implemented in concrete circumstances and to which a practical finality is assigned through different forms of institutionalization.\(^9\) Bioethics is conceived as an interdisciplinarity field of specialists and as a social and cultural movement of citizens. It is an area of knowledge that refers to the morality of the new forms of being born, dying, healing and caretaking.\(^10\)

The CNB conceives bioethics to be the following types of disciplines:\(^11\)

- **Secular.** Finds ways for individuals from diverse religious affiliations or atheists to reach rational agreements. It is tolerant.
- **Plural.** Recognizes and promotes diversity and tries to reach reasonable agreements between differing positions through debates that depart from shared minimums. It recognizes plurality not only as a fact but also as a value.
- **Autonomous.** It is beyond political, religious and economic influence. It recognizes the ability of human beings to self-regulate.
- **Rational, philosophical and discursive.** Ethical reality is not known *a priori* but through reflection about the consequences of decisions.
- **Universal.** Valid for everyone, anywhere. Decisions must surpass moral conventionalisms since the goal is to make responsible decisions through inter subjective agreements but based on minimum objective agreements, such as human rights.
- **Interdisciplinary.** Includes philosophical, scientific, social, anthropological, psychological, technical and legal aspects, health care and health research.
- **Mediator.** Promotes reasoned and rational mechanisms to reach difficult decisions and resolve conflicts.
- **Regulatory or procedural.** Provides support for protocols, procedures and collegiate bodies.
- **Applied.** Reflects on and questions real, everyday and concrete problems.

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\(^5\) Potter V.R (1970). *Bioethics, the science of survival*. Perspectives in Biology and Medicine, 14:127-153


\(^10\) Ibid

Therefore, bioethics cannot be reduced to merely classic medical deontology. It does not offer a series of simplistic recipes, or rigid preestablished values or formulas that clearly indicate what is right and what is wrong. Bioethics, because of its dynamic nature, is not a series of commandments or absolute prohibitions, or a series of subjective and relative affirmations.

Bioethics has become a multidisciplinary space for reflection to successfully tackle the complex problems that arise in the specific area of health care, and has progressively widened its scope to the study of natural, technological and social factors that could have important repercussions on human health and the biosphere. In spite of being such a new discipline and in constant development, it has become a fundamental tool for advisory committees and organisms that are required to elaborate reports; develop training programs for professionals in biomedicine; and identify the ethical aspects of research protocols involving human subjects. In order to function properly, committees dedicated to making ethical evaluations should have members who are familiar with the basic aspects of debate and moral reasoning.

In this sense, it is important to remember that ethics does not solely consist in a mechanical application of imported moral principles or rules based on nothing more than a previous code, but in a rational justification through debate of the best courses of action among several alternatives. The quality of the deliberative process is a fundamental aspect, since only within the framework of a multidisciplinary and pluralistic dialogue can minimum guarantees be found to identify the relevant aspects that must be taken into consideration, so that the practical action in particular circumstances responds to the values in question.

This cannot happen by simply applying widely accepted general principles. It is important to realize that values are the condensed product of experiences and circumstances that for generations have shaped everything good, desirable and important for a wide variety of human groups. Having gone through multiple drafts that vary the order of their importance, these general principles are now the foundation upon which codes for moral rules are articulated, sometimes with great detail and much complexity. Moral codes can serve as references for institutions, groups and entire societies, impregnating essential socialization processes and behavioral guidelines.

Open and pluralistic societies have had to mediate efficient procedures to confront the conflicts of interpretation regarding the extent, pertinence and priority of moral principles in particular circumstances and in complex cases.

Moral principles serve as guides or rules but they often come into conflict and each one can be pondered in different ways depending on their particular context. They cannot be considered precise rules since their purpose is to serve as guides and depend on the circumstances. Their alleged validity a priori can be seriously affected by the details of a given case in which they may conflict with equally important principles. Consequently, the role of moral principles is to guide. They cannot be applied mechanically but rather mediated through reflection and debate with a sensibility to details and applicable circumstances. It is during deliberation that criteria can be identified and applied to principles that often compete in order to make sure that in the end, the action selected promotes the values that provide content to the principles. It is not simply about “doing the right thing” just because a widely accepted rule or principle is apparently taken into account. It is about guaranteeing that “the result is good”, by taking into consideration the circumstances and relevant details of the situation wherein certain principles must be applied.
Principles can be a source of support during an argument directed towards identifying the most reasonable course of action, either within the framework of a reflection that is strictly individual (self regulation) or in specialized institutional surroundings (social self regulation). In both frameworks, practical actions should respond to certain values. Principles may be compelling at the beginning, but not with the same intensity, because the complexity of the contexts wherein they could be applied requires the identification of application criteria that is sometimes quite complicated. Those who bestow an absolute character to moral principles (deontological approach) consider them valid in spite of the circumstances and develop styles of moral debate based on deductive rigidity. From those standpoints, it is hard, if not impossible, to tackle cases in which some of these principles collide.

It is unlikely that research ethics committees or hospital bioethics committees are able to express pluralistic reflections regarding exclusively deontological proposals. Their members usually consider principles to be relative or binding *prima facie*, that is to say, that they should always be taken into consideration, unless particular circumstances prevent some of them from being applied at the same time. Then application criteria is developed to safeguard the values inherent to the principles in collision, trying to ensure that the resulting rules or proposals are consistent with the relative importance of the values to be protected. Undoubtedly, the fact that moral principles often compete against each other necessitates the development of environments and application criteria that is reasoned and reasonable, attending to an ever-complex reality that does not allow itself be caught in the simplifying formulations of moral principles.

Within bioethics, the principalistic trend is one of the theoretic approximations directly related to the development of the discipline. In its midst are the most widely known principles that have been revisited in most of the ethical and regulatory documents. Among these, the most famous is the Belmont Report, elaborated by the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research (1978).\(^\text{12}\) Said report expressed the principles of respect for individuals, beneficence and justice. Subsequently, these principles were expanded and applied to biomedical ethics by Beauchamp and Childress. They are the following:\(^\text{13}\)

1. **Respect for Autonomy.** Refers to the need to respect, in both actions and attitudes, the capacity and the right of individuals to decide between options that to the best of their knowledge are better for them among different possibilities other than those they are made aware of, according to their values, beliefs and life plans. They are decisions about their bodies and their health, both in the case of medical interventions and research.

   This principle upholds the need for informed consent\(^\text{14}\) and the right to refuse medical intervention or participating in a clinical relationship or research.

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\(^{14}\) The principle of autonomy has certain limitations in every country. Among others, the patient’s own competence may be one of them, depending on the nature of the decision.

Article 10.- Non observance of the law discredits a claim of disuse, custom or practice to the contrary.

Article 11.- Laws that establish an exception to the general rules, are not applicable to any case that is not expressly specified within the laws themselves.

Within this context it is illegal to resign to the right to the conservation of life or health protection.
It does not refer to non-interference in the decisions of others. It entails the obligation to create and maintain the conditions for autonomous decisions while helping to dispel fear and other situations that destroy or interfere with autonomous actions. From this principle we derive the duty to protect those who are unable to protect themselves.

2. **Beneficence.** This principle considers the need to evaluate the advantages and disadvantages, risks and benefits of the proposed treatments or research procedures, in order to maximize the benefits and minimize the risks. It has a positive dimension that implies the unyielding duty to carry out specific actions aimed at procuring the well-being of individuals, defend their rights, prevent harm, eliminate conditions that generate risk, discomfort and pain, among others.

3. **Non-Maleficence.** No harm or pain should be inflicted. This principle requires the avoidance of physical or emotional damage and harm during procedures or interventions.

4. **Justice.** It is the principle through which the distribution of benefits, risks and costs of health care or research are to be carried out in a fair manner. That is to say, that they are to be distributed equitably among all groups within a society, taking into account age, sex, economic and cultural status, and ethnical considerations. Moreover, it states that all patients in similar situations should be treated the same way and should have the same access to the best diagnostic and therapeutic methods.
III. REGULATIONS

Health activities are regulated by current standards at national and international levels that are based on ethical rules that provide a structure for analysis and decision-making. These rules stress the need for health professionals to protect the dignity, rights, safety and wellbeing of patients. They also establish guidelines to evaluate and balance the benefits and risks of interventions with an emphasis on maximizing the benefits over the risks.

1. Current International Regulations

1.1 The Belmont Report

In 1972, news about a study carried out in Southern United States known as the Tuskegee Experiment was published. In this study, the course of latent syphilis was researched in over 400 poor and illiterate black men. All 400 individuals who participated in the study were denied treatment for their disease, even after the specific antibiotics to combat it were discovered in the 40’s. In 1972, when the manner in which this study was carried out was made public, the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research was established. The Commission worked for four years and in 1978 it published a final report known as the Belmont Report: Ethical principles and guidelines for the protection of human research subjects. The report contains the principles of respect for individuals, beneficence and justice.

1.2 Convention for the Protection of Human Rights and Dignity of Human Beings in Relation to the Application of Biology and Medicine (Bioethics Convention of Asturias or Convention of Oviedo).

This Convention governs the member countries of the Council of Europe in the European Community. It is a referential framework that can be applied to countries other than those who are members of the European Community because the Council of Europe has several observers among its members, including Mexico. These observers, like the member countries, are able to sign and ratify protocols. During the past two years the CNB (represented by its current executive director) has regularly attended the sessions of the Bioethics Steering Committee of the Council of Europe and is negotiating a ratification of the Convention of Oviedo with the corresponding institutions. This is an initiative that was adopted by our country since 2002.

This Convention centers on biomedicine and Human Rights and establishes the protection of dignity and human rights in the application of medicine and biology, a ban on human cloning, equal access to health benefits, protection of individuals who are incapable of expressing or giving their consent, the right to a living will, protection of privacy and the right to information, among other topics.

1.3 Documents issued by UNESCO

UNESCO is the organ that specializes in economic and social issues for the United Nations. It has issued documents that are of interest and relevance to the development and universalization of bioethics. Among the relevant documents we have the Universal Declaration on the Human Genome and Human Rights,\(^{18}\) the International Declaration on Human Genetic Data\(^{19}\) the Declaration on the Responsibilities of The Present Generations Towards Future Generations\(^{20}\) and the Universal Declaration on Bioethics and Human Rights.\(^{21}\) Mexico has played an important role on the International Bioethics Committee (IBC) and the Inter Governmental Committee, both pertaining to UNESCO. The National Commission of Bioethics participated in the latter (represented by its actual Executive Director) as a regular member and representing Mexico, exactly when the Universal Declaration on Bioethics and Human Rights was drawn up. All the aforementioned Declarations have been endorsed by UNESCO’s supreme organ, the General Conference (United Nations Charter, Article 57). It refers to international documents containing human rights issues and reflects an expanded and modernized update of said documents. The four declarations can be considered and analyzed as a single group. The character of these declarations as a source of international law is of a relatively obligatory and imperative force.\(^{22}\) These declarations have collected the consensus of member states regarding the protection of human beings who participate in biomedical research, health care, design of public policies and the preservation of dignity and human rights.

The aim of the Universal Declaration on Bioethics and Human Rights is to provide a universal framework of principles and procedures to guide States in the formulation of their legislation and policies. Moreover, it aims to guide the actions of individuals, groups, communities, institutions and corporations, public and private, in the field of bioethics and human rights under the following principles:

- Human dignity and human rights.
- Benefits and avoiding harmful effects.
- Autonomy and individual responsibility.
- Equality, justice and equity.
- Access to quality health care and essential medicines.
- Protection of participants in research projects.

In order to implement them, the Declaration considers that:

- States should adopt all appropriate dispositions, both legislative and administrative or of any other kind, to apply, through laws or regulations, the principles formulated in the Declaration.
- Establish independent pluridisciplinary and plural ethics committees.

\(^{20}\) http://www.unesco.org/cpp/sp/declaraciones/generaciones.htm

\(^{22}\) Gross Espiell, Héctor. Las declaraciones de la UNESCO en materia de bioética, genética y generaciones futuras. Su importancia y su incidencia en el desarrollo del derecho internacional. www.juridicas.unam.mx
• Bioethics Committees should monitor the duties and rights of involved parties, propitiate the resolution of conflicts, evaluate research projects, participate in bioethics training and dissemination, seek distributive justice and contribute with regulations.

Moreover, UNESCO has published the following guides for the establishment of bioethics committees:

• **Guide Number 1 Creation of bioethics committees.**

  This Guide, published by UNESCO in 2005, offers a number of suggestions after having reviewed the experiences of several Member States that have already established bioethics committees at the national (commissions), regional and local levels, in schools and professional associations, hospitals and human research. The purpose of this Guide is to contribute ideas for the establishment of bioethics committees at national level all the way down to hospitals and research on human beings. This Guide emphasizes that among the different goals of bioethics committees, these should include the establishment of health and scientific policies to benefit citizens, solid professional health practices for patients, improvement of health care focused on the wellbeing of patients and the protection of human research participants. It includes a list of recommended reading material to increase knowledge about the subject. As its name indicates, it is a guide and its suggestions are general and not intended to be applied in a literal sense. It indicates that each country, each institution, should implement the integration and operation of their own bioethics committees according to their particular circumstances and needs.

• **Guide Number 2 Operation of bioethics committees: procedures and policies.**

  This Guide, also published by UNESCO in 2005, offers bioethics committee members a series of policies and procedures that may be of use to them in the performance of their duties. These policies focus on respect for the dignity of human beings and the practice of equity and justice. This Guide considers that hospital bioethics committees are the most significant bioethical answer to education, the resolution of problems and the development of policies aimed at the protection of individuals. Therefore it considers answers to problems such as which individuals the committees should help, who should serve on these committees, what issues should be discussed, what is the scope of their authority, among others. The Guide concludes by stating that if answers to these questions are not defined in a timely fashion, bioethics committees are doomed to fail.

• **Guide Number 3 Training Bioethics Committees.**

  This Guide, published in 2008, seeks to help members of the four different types of bioethics committees obtain the necessary knowledge regarding the complex and versatile field of bioethics. It offers examples and information about useful training resources. The contents include a variety of concepts, problems and dilemmas in the field of bioethics that may be helpful to bioethics committee members. This Guide offers information about materials that may help to achieve more intensive training in this field. It is probably more useful for committee members to receive information about materials that are readily available on line at no cost. This procedure is highly recommended so that bioethics committees can focus more on the interests at hand and dedicate more time and effort to training its members, by selecting and tackling specific issues according to prevailing circumstances.
Article 23 of the Universal Declaration on Bioethics and Human Rights regarding education, training and information on bioethics, is closely related to this guide. The article states that: “every State should endeavor to protect and foster bioethics education and training at every level, as well as to encourage bioethics information and knowledge dissemination programs. The aim of this Guide, as well as Guides 1 and 2, is to provide guidance to the members of bioethics committees.

2. National Regulations

2.1 Mexico’s Political Constitution

The Federal Constitution, in its dogmatic section from Articles 1 to 29, establishes guarantees or the fundamental rights of the Mexican people. With respect to the present Guide, Article 4, paragraph 3, establishes the right to health protection. This right is explained and developed in the General Health Law, in the regulations resulting from said law and through official Mexican regulations issued by the Ministry of Health.

2.2 Organic Law of the Federal Public Administration

Article 39 of the Organic Law of the Federal Public Administration indicates that the Ministry of Health is an integral part of the Central Administration and as such has the power to head the Health Sector. Said article establishes the Ministry of Health’s authority to plan, develop, establish, evaluate and monitor the implementation of the right to health protection.

2.3 Internal rules of the Ministry of Health

Article 2, section XI bis of this rule, states that the National Commission of Bioethics is an independent body pertaining to the Ministry of Health. The goals and duties of the CNB are determined in the Decree by which the Independent Body known as the National Commission of Bioethics is created, published in the Diario Oficial de la Federación September 7, 2005. Said Decree is mentioned further on.

2.4 Decree by which the Independent Body known as the National Commission of Bioethics is created

The Decree establishes the goals and duties of the National Commission of Bioethics, which are mentioned at the beginning of this Guide.

http://www.constitucion.gob.mx/
http://www.ordenjuridico.gob.mx/Federal/PE/PR/Leyes/29121976(1).pdf
http://www.cnb-mexico.salud.gob.mx/interior/normatividad/normanac.html
2.5 The General Health Law: 27

The General Health Law establishes the right to health protection. In the case of health care, Title Three of the Law establishes certain dispositions wherein it is understood that health services are those actions carried out to benefit individuals and society in general, directed towards protecting, promoting and restoring the health of individuals and the community. It establishes that health services are classified into health care, public health and welfare wherein quantitative and qualitative health services are guaranteed, especially to vulnerable groups. This Law emphasizes that health care includes prevention, healing and rehabilitation, as well as emergency medical treatment.

2.6 Rules of the General Health Law in Relation to Health Care Services 28

This rule shapes Title Three of the General Health Law. It emphasizes that health services are a set of actions carried out to benefit individuals within society whose purpose is to protect, promote and restore health. It classifies health services as health care, public health, and social welfare. It defines health care as a group of services provided to individuals to protect, promote and restore their health. Moreover, it considers that health care services represent the way to preserve and protect the health of individuals, through prevention, healing and rehabilitation.

2.7 Rules of the Federal Commission for Protection Against Health Risks. 29

The Federal Commission for Protection Against Health Risks (COFEPRIS) is the health authority in charge of carrying out duties regarding the regulation, control and promotion of health, conferred by the General Health Law, its regulations and applicable legal dispositions. These duties, according to Article 3 of the Law, encompass:

- Health establishments where human organs, tissues, cells and their components are stored and blood banks
- Medicines, herbal remedies and other health products
- Food and food supplements
- Substances that are toxic or health hazards
- Essential chemicals, precursor chemicals, narcotics or psychotropic drugs
- Biotechnological products
- Sources of ionized radiation for medical use.
- Harmful effects on human health from environmental factors
- In general, the health conditions that must be met by procedures, products, methods, installations, services or activities related to the aforementioned materials.
- Issue, extend or revoke health permits within its realm of competence, and authorize the regulation, control and promotion of health according to what is established in or derive from the Law and its regulations, from official Mexican laws, the present regulations and other applicable laws.
- Apply research, evaluation and monitoring strategies regarding health risks together or in collaboration with other competent authorities.

http://www.cnb-mexico.salud.gob.mx/interior/normatividad/normanac.html
• Impose administrative sanctions for non-compliance with the Law, regulations or other applicable rules, and determine safety measures, as well as preventive and corrective measures, within its realm of competence.

• Implement the corresponding health controls, regulations and promotions to prevent and reduce health risks to the community from exposure to chemical, physical and biological factors.

2.8 Commitment to transparency between doctors, health care institutions and the pharmaceutical industry.  

This commitment was issued by the General Health Council of the Office of the President of the Republic to establish a consensual framework of principles and actions directed toward the promotion of an ethical relationship between the pharmaceutical industry, doctors and health institutions thereby contributing to the development of a transparent relationship that will benefit patients, the medical profession, pharmaceutical research and development, and health in general. Said document defines the principal directives for interaction between doctors and the pharmaceutical industry, in both the private and public sectors. It includes such topics as the promotion and dissemination of information regarding authorized medicines, training and updates for doctors sponsored by the pharmaceutical industry, studies and clinical research, as well as the appropriate use of medicines and respect for medical prescriptions. It contains the following premises:

• Individuals are the center of health care. This partnership between the pharmaceutical industry and doctors should revolve around the safety, efficient treatment and financial protection of patients.

• Cooperation between the medical profession and the pharmaceutical industry has been and still is essential at every phase of the development, appropriate use and prescription of medicines.

• The relationship between these two groups must be based on ethical principles, a humanistic approach to patient care, veracity and scientific support, professional independence, transparency and collaboration.

• The fact that doctors are free to prescribe medicine entails a great deal of responsibility and competence, meaning that the implementation of therapeutic or diagnostic methods must be preceded by a thoughtful consideration of their scientific validity, efficiency and suitability for specific patients, including careful thought about the cost-benefit to patients.

2.12 Agreement that establishes the guidelines to be observed in public health facilities, to regulate their relationship with manufacturers and distributors of medicines and other health products, derived from the promotion of products or academic, research or scientific activities.

This Agreement, issued by the Ministry of Health, contemplates in Article 1 that all public health facilities that in any way or manner receive support or financing from representatives of manufacturers and distributors of medicines and other health products, must establish internal rules that regulate and make said relationship transparent with regards to the provision of health services, and will moreover report to the Ministry of Health on how the latter is being implemented.

31 Diario Oficial de la Federación, August 12, 2008.
2.13 Federal Law of Transparency and Access to Public Information.\textsuperscript{32}

This Law establishes in Article 1 that its purpose is to provide whatever it takes to guarantee that all individuals are able to gain access to information in the possession of government branches, autonomous constitutional organs or those with legal autonomy, and any other federal government offices. Article 6 states that the interpretation of this Law and its Rules, must favor the principle of maximum publicity and accessibility to information in the possession of the obligated agencies mentioned above. According to Article 7, with the exception of confidential or reserved information anticipated in this Law, the obligated agencies must make the information available to the public.

With respect to the development and elaboration of research protocols in federal public health facilities, it is important for information provided by the entitled parties to the obligated parties to be considered confidential, as well as personal information requiring the consent of individuals for its dissemination, distribution or commercialization.\textsuperscript{33} It is important to note that information found in public registers or public records will not be deemed confidential, for example the COFEPRIS register. Finally, according to Article 19 of the aforementioned Law, when private citizens give information to the obligated parties they must indicate which documents contain confidential information, reserved or commercially reserved information, as long as they have the right to said reserved information, according to applicable provisions. When there is a request for access to a document that contains confidential information, the obligated parties may not provide it unless they obtain the express consent of the entitled party.

2.14 Official Mexican Rule NOM-168-SSA1-1998, of Clinical Files.\textsuperscript{34}

This Rule is the instrument through which to regulate clinical files and foster the development of a culture of quality by allowing its use in distinct areas, such as: medical, legal, education, research, evaluation, administration and statistics. The present disposition is aimed at systematizing, homogenizing and modernizing the management of clinical files that contain records of essential technical elements for the rational study of and solution to patient’s health problems through prevention, healing and rehabilitation. This Official Mexican Rule establishes the scientific, technological and administrative criteria essential for the elaboration, integration, utilization and filing of clinical files. It is adhered to throughout the nation and its provisions are obligatory for health care providers in the public, social and private sectors, including doctor's offices.

2.15 Bioethics Code for Health Professionals\textsuperscript{35}

The Bioethics Code for Health Professionals was issued by the National Commission of Bioethics in 2002. It represents a behavioral guide for professional practices, to resolve differences in the provision of health services to the sick and their families, as well as between individuals and professionals who intervene in life events, particularly those related to medicine and health. Through this instrument, the National Commission of Bioethics establishes itself as a conduit for the observance of the constitutional right to health protection by establishing the generic aspects of ethical behavior in the provision of health services.

\begin{itemize}
\item \textsuperscript{32} http://portal.funcionpublica.gob.mx:8080/wb3/wb/SFP/leyftaipg
\item \textsuperscript{33} Article 18 of the Law in question.
\item \textsuperscript{34} http://cnb-mexico.salud.gob.mx/descargas/pdf/normatividad/normatinacional/5._NAL._NOM._Expediente_Clinico.pdf
\item \textsuperscript{35} http://cnb-mexico.salud.gob.mx/descargas/pdf/normatividad/normatinacional/1._NAL._Cxdigo_de_Bioxtica_del_Personal_de_Salud.pdf
\end{itemize}
2.16 Charter of the General Rights of Doctors

The Charter for the General Rights of Doctors was elaborated by the National Commission of Medical Arbitration (CONAMED). This charter enumerates the basic principles on which the practice of health care professionals is sustained and constitutes prerogatives already contemplated in judicial resolutions that are in general use. These rights are not intended to conflict with those of patients, since they are both linked to a series of universal values consistent with a profoundly humanistic professional activity: medicine.

The Decalogue for the rights of doctors is as follows:

1. Practice their profession freely and without any type of pressure.
2. Work in appropriate and safe facilities that guarantee their professional practice.
3. Have at their disposal the resources their professional practice requires.
5. Receive respectful treatment from patients and their families, as well as from their staff.
6. Have access to continuous medical education and to equal opportunities for professional development.
7. Have access to research and education in their professional field.
8. Create alliances to promote their professional interests.
9. Safeguard their professional prestige.
10. Receive remuneration for services rendered.

2.17 Charter of the General Rights of Patients

The Charter for the General Rights of Patients was elaborated by the National Commission of Medical Arbitration (CONAMED), in 2001. Emphasis is made on the importance of the respect for the rights of patients regarding their dignity and autonomy, guaranteeing the confidentiality of the information generated within the doctor-patient relationship and medical treatment that minimizes multiple waiting periods.

The Decalogue for the rights of patients is as follows:

2. Be treated with dignity and respect.
3. Receive sufficient, clear, opportune, and truthful information.
5. Give or refuse valid informed consent.
7. Be able to obtain a second opinion.
9. Have a clinical file.
10. Be heard when unhappy about received medical treatment.

IV. HOSPITAL BIOETHICS COMMITTEES (CHB)

Medical practice entails the ethical principle of service and respect for human beings, particularly patients, by safeguarding their dignity, human rights and their free will.

All medical treatment by health professionals and technicians is carried out in a dynamic and changing scenario. On the one hand, this scenario is a consequence of the diversity of characteristics inherent to the medical staff and the patient, and on the other, the development of technology used in the health care process. That is why the result and impact of these actions not only depend on the level of knowledge and discernment of the health professionals, but also on the application of technology and the conditions of the environment where said technology is being used as well as the circumstances of the doctor-patient relationship. Therefore, in the relationship between the health professional and the patient there are factors that are intrinsic to professional and technical practices, as well as external factors.

The purpose of medicine, according to the Hastings Center is to:

- Prevent disease
- Promote health
- Alleviate pain and suffering
- Tend to and care for individuals with incurable diseases
- Prevent unnecessary and premature death
- Help to die with dignity

To ensure that this is achieved, it is important to have general guidelines, rules and guides that support competent medical practice by health care professionals thereby protecting the physical, moral and psychological integrity of the patient.

Hospital Bioethics Committees (CHBs) are considered spaces for analysis, for reflection and study that have been established to assist health professionals and their patients and/or families. Therefore, the CHB are where conflicts that arise during the health care or training process are systematically analyzed. The context of decision-making with regards to the health of a person has gradually become more complex. The types of decisions that health professionals must make are changing drastically. A wide range of possibilities creates situations that generate ethical dilemmas. The fact that patients now are recognized as having the same moral authority and capable as their health professional to make decisions about their bodies, in spite of being sick, increases the complexity of the decision-making process. That is why different points of view between patients (and/or their families) and the health professionals occur more frequently.

The definition of what is good and advisable for the patient is no longer limited to technical aspects, which are under the exclusive power and obligation of health professionals. Quality of life and benefits are also determined according to the life plans and/or values of the patients. Therefore, they may not necessarily coincide with the values of the health professionals and that is where ethical conflicts may arise. This is when the CHB becomes a mediator of sorts in charge of advising the interested parties who request it.

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Hospital bioethics committees are:

- A guide and support for the decision-making process of doctors when there is a conflict of values.
- A group of individuals who will make sure that everybody’s values are taken into consideration by everyone involved in the clinical relationship.
- A public guarantee
- Are an element to promote interdisciplinary and multisectorial education.
- The institutional expression of bioethics in health institutions.

It is important to understand that the CHB is a space for deliberation and education wherein debates are carried out in a free and tolerant environment. As collegiate groups anchored to a social role, they accompany the physician, all the members of the health team, and the patients and/or family members. They support and interpret distinct existing guidelines regarding the diversity of experiences and perspectives, to resolve, in the most prudent and adequate manner, the ethical dilemmas submitted to them.

The CHB must advise, educate and promote the creation of institutional protocols but may never substitute the responsibility of the doctors to their patients.

Based on what has been expressed in earlier paragraphs, the need has arisen to elaborate the project of a decree to amend and reform several dispositions within the General Health Law. It contemplates that public and private health care facilities, depending on their level of complexity and size, should establish a hospital bioethics committee for the resolution of problems or disagreements. These committees would be responsible for the analysis, discussion and support of decision-making regarding the bioethical dilemmas that arise in clinical practice. The project consist of the following:

Article 41 Bis. Health care establishments from the public, social or private sectors of the national health system, aside from those mentioned in articles 98 and 316 of the present Law, and according to their degree of complexity and level of resolution, will have the following committees:

I. A hospital bioethics committee that will be responsible for the analysis, discussion and support of decision-making relative to bioethical problems or dilemmas that may be present in clinical practice, medical attention, or health education, as well as promote the elaboration of guidelines and institutional ethics guides for health care and education. Moreover, it will promote permanent bioethics training for its members and the establishment’s staff, and

II. In the case of medical establishments that carry out research on human subjects, an ethics committee that will be responsible for the evaluation and ruling on research protocols involving human beings, formulation of the corresponding ethical recommendations, as well as the elaboration of guidelines and institutional guides for health research, and monitor their recommendations.
Hospital bioethics committees and research ethics committees should be subjected to current legislation and the criteria established by the National Commission of Bioethics. They should be interdisciplinary and be formed by medical professionals from distinct specialities and by individuals from the following professions: psychology, nursing, social work, sociology, anthropology, philosophy or law, who have had training in bioethics. It is essential that representatives from the affected nucleus or health service consumers also be present to round out the established number of members, who may or may not be attached to the health unit or establishment, while maintaining a gender balance.

The duties of the Hospital Bioethics Committees do not interfere with the duties of the National Commission of Medical Arbitrage (CONAMED) because the activities of the committees are defined as preventive whereas the duties of CONAMED are to rectify and reconcile.

1. Objetives and duties of Hospital Bioethics Committees

1.1. Objetives

Contribute to decision-making that is prudent, reasonable, rational and well-founded regarding ethical dilemmas that arise in clinical practice, medical treatment and education within hospitals; thereby helping to safeguard the dignity, rights, safety and well-being of all the present or potential participants in the clinical relationship.

Act on behalf of the participants in the clinical relationship and the involved communities, taking into consideration the laws, national regulations and those of the institutions where medical treatment is being given.

Make sure that fair access to services and resources are contemplated in the institutional protocols for medical attention.

1.2. Duties

The main duties of the hospital bioethics committees established within health institutions will be the following:

- Be responsible for the analysis, discussion and support of decision-making regarding bioethical problems or dilemmas that arise in clinical practice, medical treatment or medical education of the health institution itself.

- Analyze from an ethical standpoint the bioethical problems or dilemmas in a manner that is transparent, independent, competent, opportune and qualitative, without any political, institutional, professional or commercial pressure or influence.

- Issue the ethical recommendations that may apply.
• Establish self-evaluation mechanisms for the committee so it is able to measure its impact in its distinct areas of competence.  

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• Elaborate guidelines and institutional ethical guides for the practical aspects of medical education within the institution.

• Promote permanent bioethics training for committee members, health establishment staff, patients and their families.

• Provide advice to institutional authorities regarding the subject of clinical bioethics although it is not part of their duties to endorse decisions that were made before being submitted to the committee for consideration by the medical professional, the patient or the patient’s family directly involved in the case.

• Make sure that the current legislation and criteria established by the National Commission of Bioethics are present during committee meetings.

The specific objectives of hospital bioethics committees are the following:

1. Consultation

Consultation of clinical cases that present a bioethical dilemma represents one of the main duties of the CHB.  

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Consultation of clinical cases that present a bioethical dilemma represents one of the main duties of the CHB.  

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http://www.biomedcentral.com/1472-6939/2/1

Its main objective is to resolve conflicts and thereby contribute to improve the quality of health care. Part of this activity could include the analysis of cases that transcend public opinion, through mass media, as a way to prevent future analogue situations. The consultative activities may culminate in the creation of institutional protocols.

Hospital Bioethics Committees are advisory organs that do not make decisions but limit themselves to giving advice, guidance or opinions as a way to support the medical team in order to increase the patient’s well being. The CHB, in general, can only intervene when asked to do so by one of the interested parties: the medical staff, the patient, his or her family or legal representative. The CHB may play a proactive role in the detection of situations that could generate bioethical conflict. The CHB, once it receives the submitted doubts or questions, listens to the opinions of medical experts and the interested parties. The Committee then analyses the information and issues a recommendation.

The consultative activities of the CHB must include, among its objectives, the ability to provide the tools, knowledge and abilities that allow the hospital community to identify ethical problems, foster practices and behaviors that are ethically correct and implement measures that help prevent future ethical problems.

39 This is a very important and complex aspect, but it must be included. The following article should be consulted: Evaluation of Heathcare Ethics Committees: The experience o fan HEC in Spain. DE Hernando Robles Pablo. HEC Forum. Sep.1999;11, 3; Health Module. p:263-276. This in turn contains more references.


http://www.biomedcentral.com/1472-6939/2/1

2. Guidance

Guidance is of great relevance to the CHB. This activity allows them to anticipate possible conflicts that may arise during medical treatment through guideline protocols. These protocols need to take into consideration the institution’s socio-economic and cultural contexts and be consistent with the historical moment and current legal framework.

Guidance (Procedural) contemplates the following cases: 42

a. Decision-making protocols in the clinical field that contemplate conflicts of values such as: informed consent procedures, rejection of treatment, decision-making for minors, among others.

b. Help establish dialogue and informed consent procedures with the clinical areas.

c. Evaluate the capacity and willingness of donors in the case of transplants between living donors.

3. Education

The CHB’s duties regarding education include a series of activities that will help committee members and the institutional community to incorporate information, knowledge and behaviors to identify and resolve ethical conflicts.

The formation of CHB members is not automatic. Committee members go through a stage of self-formation, through different training methods. 43 This is because of the multidisciplinary composition of the members. It is important that they all acquire the ability for rational thought and deliberation, and that at least one member have formal training in clinical bioethics.

Subsequently, or at the same time, training should begin for the hospital staff with conferences, courses, audiovisuals and other activities that contemplate reviewing clinical cases where ethical conflicts have been presented.

At a later stage, the CHB could have an outreach program toward the community, patients and their families so they are aware of the committee’s activities and know that they can apply for advice if they need to. In order to do this, a physical space for information can be created (bulletin boards, leaflets, etc.) or a virtual space (institutional web site) where articles, newsletters and relevant facts about the subject are transmitted; or talks in the waiting rooms, among other alternatives.

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43 The President of the CHB and other members must engage in theoretical training and begin an exercise regarding the analysis of retrospective cases.
Therefore, education is carried out on three levels:

a. Inside the Committee.

b. Inside the institutional community.

c. Towards the external community of the institution.

This duty may be carried out inside the committee, through:

- Sessions wherein basic bibliographic reviews are carried out regarding bioethical aspects.

- Periodic revision of the guidelines.

- Gradual and constant training of CHB members to teach them about concepts, principles, values and basic tools to improve the performance of their duties.

- Attendance to and organization of academic seminars about bioethics.

- Have sessions where clinical cases with bioethical implications are analyzed and discussed.

- Sessions to exchange knowledge and work tools with Hospital Bioethics Committees from similar institutions.

These resources will help members congregate and share what they have learned. This will help create a common language and facilitate communication and development of the rest of their duties.

**2. Composition of the Hospital Bioethics Committees**

Hospital Bioethics Committees are institutional organs with a flexible structure. They must be multidisciplinary, multisectorial and plural. They must include medical professionals from different specialities and individuals from the following professions: psychology, nursing, social work, sociology, anthropology, philosophy, specialists with formal training in bioethics, lawyers with knowledge of the health field, representatives of the affected nucleus or health care consumers, civil society, etc. It is important that they all have an honest professional career; a high percentage of individuals with solid knowledge and experience should also be members. They may belong to the institution itself or come from other medical institutions. There should also be a high percentage of external members in order to obtain unbiased opinions. Administrative staff, directors or individuals who occupy important positions at the institution should not serve on the committee.

The reason why committees should be multidisciplinary is so that arguments can be introduced from different points of view. These arguments from different origins provide a wide variety of suggestions and alternatives for the resolution of the ethical problems submitted to their consideration. For example:
Health professionals can clarify the clinical aspects of the case, such as the diagnosis, prognosis and alternative treatments. This must be the first step, without fail, before any ethical analysis can be undertaken.

Bioethics experts would be familiar with the methodology of bioethical analysis and charged with guiding the reflection and consideration of the conflicting ethical values.

Lawyers are able to define the current legal framework under which the case should be analyzed and the legal aspects that should be considered.

Representatives of the patient’s religious beliefs (if the case warrants it) are charged with analyzing the moral aspects related to their beliefs and helping members to understand the religious values inherent to that specific case.

Representatives from the community are charged with analyzing the clinical case from the point of view of the consumer, who is neither an expert in health care nor any other areas of professional expertise within the committee.

They all play important roles, since the contents of the conclusions are a task that involves every committee member. The conclusions must focused on obtaining universal results, not just results that cover the needs of a certain group.

The amount of members on committees will be decided by the institutions that create them. The number of members for a hospital bioethics committee should vary from six to twenty, although it can fluctuate between eight and twelve. A balance of age and gender must be maintained.

Being part of a hospital bioethics committee implies a serious commitment. To select members, certain characteristics are taken into account, such as:

- Personal backgrounds that reflect honesty and commitment (references from their peers, job positions, from the community and/or the organization they belong to).
- Review their professional experience in their particular field or the degree of commitment to their jobs, in the case of individuals who do not have a long career.
- Preferably, have a degree of formation or training in clinical bioethics.
- Ability to represent the interests of health care service consumers.
- Be interested and be willing to develop the ability to listen to others with respect and make rational and reasonable arguments.
- Be committed to gradually be trained in bioethics knowledge.
- Commit to remaining on the committee for the duration of the period established by the committee and fulfill their duties.
- Admit to and be open about any conflicts of interest should any arise.
• Flexibility, reflection, prudence and honesty

• Members must sign a confidentiality agreement concerning the meetings in which clinical cases and related issues are discussed.

• Pledge that the information they are privy to will not be put to misuse.

• Undertake to care for the interests of individuals who participate in health care and the work that being a member of the committee entails.

Every committee, especially recently established ones should, during the first two years, have at least one member complete an elemental bioethics course. The following year, at least an intermediate level course; and the following year, at least an advanced level course.

In the case of recently created committees, and when the right members cannot be found within the institution, the head officer, together with the president of the designated committee, will be able to apply for support and advice from committees at an immediately superior level within the institution itself or from other institutions, as long as the aforementioned requirements are met.

Health Services that do not have their own CHB should contact an institution within the same geographical area that has a CHB and if that is not possible, it should contact the National Commission of Bioethics and be assigned an ad hoc Committee to adequately review the bioethical problem in question.

2.1. Administrative Process

The Hospital Bioethics Committee should be established through a formal act and endorsed by the respective Health Authority. This formal act should be ratified by a legal administrative act that legalizes its establishment and stipulates its characteristics and duties.

Operational costs of the CHB should be financed by its institutional authorities. This should not cause a conflict of interest between the source of financing and the duties of the Committee.

It is important for committee members to receive support from the institution’s authorities, at least in the following ways:

• Time off to participate in the ordinary and extraordinary sessions of the committee.

• Recognition (academic, for example) for their participation in the committee.

• Support for continuous bioethics training, both within the institution and elsewhere.

• A fixed physical space for the headquarters of the hospital bioethics committee.

• Provide secretarial support since a record must exist of the consultations made by the committee.

• Provide the necessary materials to adequately carry out their duties.

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44 Institutional, Regional or National Health Director of the district, region or country.
45 It refers to an administrative resolution, a decree or a public act.
• Training of committee members is of vital importance therefore institutional support towards such activities is highly recommended.

In the case of community or patient representatives, depending on the case, payment should be considered for transportation costs and perhaps additional financial compensation if their participation causes economic loss from having to miss work.

Hospital Bioethics Committees should publicly indicate the operational procedures that determine the authority upon which the committee is established, their duties and tasks, the qualifications of its members, the terms and conditions of appointments, the offices, the structure of the secretariat, internal procedures and quorum requirements. Hospital Bioethics Committees should act according to their written operational procedures.

2.2. Selection Process:

In the case of a recently created committee, the Director General of the health institution may appoint the Committee President. This President will have the authority to appoint the rest of the committee members, only on this occasion, since the committee is just beginning its activities. Therefore, the President may appoint the secretary and the members. The duration of this first committee will be three years.

At the end of the first three-year period, the committee members will put forward a shortlist of candidates to designate a person to the position of President. Moreover, at the end of the three years, the committee members themselves will propose candidates for the renewal of the remaining members. The candidates may be members of the committee or members of the health staff of the institutions or non-governmental organizations. In any case, the characteristics of the required profile for committee members should be taken into consideration. The renovation of the committee, once the first three-year period has ended, should be carried out through an open summons to the entire institutional community.

The committee must establish the process through which it will select its new members. The selection must include curricular evaluation, personal interviews and the aspects considered necessary for a proper integration and operation of the committee. The Director of the health institution will issue the official appointment to the selected committee members. It is important to maintain a balance between highly experienced individuals and individuals with less experience to avoid creating committees that only contain veterans and experts.

Established committees should implement a process of continuity regarding committee members. This means taking advantage of the accumulated experience and training. In this case, the new positions would be ratified by the Director of the Institution, according to the terms listed in the previous paragraph. However, appointments are not expected to be of a permanent nature. A gradual substitution of members should be considered to make sure that new members begin to acquire knowledge and experience from the older members.
The CHB may ask for support from another CHB or from other specialists to help solve relevant points of specific cases that are submitted to them. That is to say, they may seek advice from another committee or have external advisors when they lack the necessary specialists for the topic being analyzed. These members, if they are external advisors, will participate in the deliberations and final decision and are equally obliged to maintain confidentiality regarding the information they are privy to. If only technical support is required from another professional, that professional should not participate in the deliberations.

2.3. Terms of the appointment

The terms of the appointment of committee members must include the following:

- Duration of the appointment
- Policies for the renewal of the appointment
- Procedure for disqualification
- Procedure for resignation
- Procedure for substitution

2.4. Conditions of the appointment

A declaration regarding the conditions of the appointment must be drawn up and must include the following:

- Members must accept their incorporation into the Committee in writing wherein they fully pledge to perform their duties.
- Members must be willing to give their complete name, profession and affiliation.
- They must sign a confidentiality agreement regarding the meetings where deliberations are carried out on issues, petitions and information about those involved in the cases submitted to the committee.
- They must pledge that no improper use will be made of the information by incorporating it into their academic works or exploiting their advisory duties to obtain co-authorships.

Conflicts of interest must be avoided when appointments are made. In case of an inevitable conflict of interest, there must be strict transparency regarding said conflict.

The entire administrative staff of the CHB must sign a similar confidentiality agreement.

2.5. Positions

The committee must establish clearly defined posts in order to function correctly. Definition and declarations for the following positions are required: president, secretary, members and specialists who will eventually be consulted in specific cases. The requirements must be incorporated to maintain each appointment, terms and conditions, and the duties and responsibilities of each member. The following will be considered minimum requirements:
2.5.1. President of the Committee

2.5.1.1. Authority and responsibilities

- Preside the sessions of the hospital bioethics committee.
- Make sure quorum is obtained according to established terms and representative numbers.
- Carry out deliberation in order to submit a recommendation.
- Convene ordinary sessions according to the criteria established in the guidelines of the committee.
- Convene extraordinary sessions according to the criteria established in the guidelines of the committee.
- Authorize the agenda for ordinary and extraordinary sessions.
- Sign the corresponding minutes of meetings.
- Coordinate the activities of the committee.
- Monitor the detection of eventual conflicts of interest.
- Be responsible for the renovation process and appointment of members according to the methods established in the formation of the committee.
- Be responsible for providing information regarding the activities of the committee to the Director General of the health institution.
- Facilitate access to pertinent documentation and coordinate continuous training activities for the members.
- Perform all functions related to the afore-mentioned activities.

2.5.1.2. Requirements for the selection

- Aside from the requirements listed in the paragraph that corresponds to member requirements, the committee president cannot occupy the position of general director, medical director, academic director or any other executive position within the institution.
- Must be a member of the institution who works in the area of health care.
2.5.2. Secretary of the Committee

The secretary must comply with the prerequisites mentioned in the paragraph about member requirements.

2.5.2.1. Authority and responsibilities

- Negotiate the elaboration of all documents required for the committee to carry out its activities.

- Observe the correct undertaking of the agenda, including the necessary support documents.

- Review and accept the issues being proposed to the committee for deliberation. In each case, care must be taken that proper and sufficient information is available in order to adequately analyze the issues to be considered.

- Notify the agenda for the next meeting and give each Committee member the documentation regarding the issues to be discussed at the upcoming meeting. The documentation must be sent 7 days in advance at the very least. Except in the case of emergencies, when an advisor will be designated to present the case to the committee for retrospective analysis as soon as possible.

- Take minutes of each session and number them in chronological order and keep them in a sequential file. The minutes of each ordinary or extraordinary session will be numbered in chronological order and be signed by the members of the CHB who attended each corresponding session.

- Formalize and distribute copies of the respective acts to members of the Committee.

- Send a copy of the recommendation issued by the committee to the applicant. Said copy must be presented in the form of an official letter.

- Maintain the CHB archives up to date.

- Register the agreements and verify their fulfillment.

- Maintain the database up to date regarding issues submitted to the consideration of the CHB.

- Protect the documentation inherent to the operation of the committee.

- Coordinate the elaboration of reports, rulings and recommendations requested from the committee, according to proper guidelines.

- Sign the minutes of the sessions wherein he or she was present.
2.5.3. Technical secretary of the Committee

The secretary must comply with the prerequisites mentioned in the paragraph about member requirements.

2.5.4. Committee Members

Members must comply with the prerequisites mentioned in the paragraph about member requirements.

During the selection of members, staff should be chosen from the institution itself as well as from other institutions. A community representative or patient representative should preferably not be the only external member on the committee.

2.5.4.1. Duties of the members

- Analyse the agenda and documents regarding the issues to be discussed.
- Participate in deliberations and express opinions.
- Keep track of agreements and identify issues that could be used in future deliberation by the CHB.
- Participate in the selection of committee members.
- Participate in training activities, updates regarding bioethics and other tasks pertaining to the committee within the institutional community.
- Participate in bioethics education and dissemination and in the tasks pertaining to the committee within the institutional community.
- Inform the committee about delays, irregularities and any other problems related to agreements.
- Sign the minutes of the meetings they may have attended.
- Carry out any other activities entrusted to them by the President or the committee itself.

2.5.5. Independent consultants

These consultants may be ethical or legal specialists, regarding diseases or specific methodologies or can be representatives of the community, patients or special interest groups. Independent consultants may participate in the sessions in person or can send in their comments. In any case, they only have the right to a voice but not a vote. They cannot participate in the deliberations, unless they are specifically invited to do so because of their ethical expertise, or help is asked from another committee, as we mentioned earlier.
2.5.5.1. Duties and authority of independent consultants

• Help the Committee evaluate bioethical problems or dilemmas when it is asked of them.
• Sign confidentiality agreements about information in the cases in which they participate as well as the committee sessions where they were present.
• Consultants who attend sessions to provide or clarify information regarding the subject at hand will have the right to a voice but not to a vote. They will not participate in the deliberations.

3. Requirements for a quorum

Hospital Bioethics Committees must establish specific requirements for a quorum to review and approve a petition. These requirements must include:

• The minimum amount of members required to complete a quorum must be more than 50% of the members.
• The quorum is not only about the number of members. It is important to take into consideration the distribution of the capabilities of said members. No quorum can consist in the exclusive participation of members of a single profession or of the same sex. A quorum must include at least one member of a primary area of expertise that is non scientific and at least one member who does not belong to the institution where the case is being presented as well as one representative of the community or the patients.
• If a member of the CHB has a conflict of interest with the case submitted to the committee, he or she must disqualify him or herself from that particular deliberation and cannot be counted on to complete the quorum.

The president and secretary must be present as one of the minimum requirements of a quorum. Without their presence committee sessions cannot begin.

4. Duties of the Hospital Bioethics Committees

The CHB must present an annual report to the direction of the Institution and to the National Commission of Bioethics about the number of bioethics problems or dilemmas they have evaluated and pertinent follow up information.

4.1 Session requirements:

The CHB will periodically carry out ordinary sessions, according to the needs and workload. Ordinary sessions should be held at least once a month. If there were no cases to study, closed cases may be used to to train and update the members.

• The programmed dates for the sessions will be announced beforehand to the institutional health staff. The schedule for the entire year should be made known in January.
• If necessary, extraordinary sessions may be convened by the Committee President or a majority of the members.

• Meetings will be held when at least the President or the Committee Secretary and more than half the members are present, as long as the requirements specified in the paragraph about quorum are covered.

• Decisions will be made only after exhaustive discussion and analysis regarding the clinical and ethical aspects of the case. The distinct courses of action that result from the deliberations must be presented, specifying which options are considered to be the best. In the work of the CHB, the aim is not to reach a consensus; the important part is the discussion, therefore, when there are discrepancies in the votes, it is important to point out that they exist and what reasons they are based on. In this case, the alternatives submitted by all the participants must be presented to the consultant so that he may evaluate them and decide how to act. This must be consigned and be reflected in the minutes of the committee.

• The agenda and documents for each session must be delivered at least seven days before the meeting. In the case of extraordinary sessions, they must be delivered three days before the meeting, if possible. This is so that members of the CHB have enough time, before the meetings, to review the most relevant documents, except in the case of patient emergencies.

• They must elaborate minutes of the meetings and establish a procedure for their approval.

• The physician, patient and/or family member who requested the CHB intervention, must be invited to speak before the committee about the specific aspects of the problem. Generally, however, they may not be present during deliberations.

• Independent consultants may be invited to meetings, subject to the confidentiality agreements applicable to the rest of the CHB members.

Every member must read the petition and the documents containing the problems to be evaluated by the CHB. The relevant ethical aspects will be identified. Doubts or elements that are unclear will be presented and then the ethical aspects that need to be addressed will be identified or those that have not been adequately considered by those involved in the clinical relationship. First, the meeting will be opened for discussion so that every member can submit his or her arguments and doubts can be cleared up regarding the clinical and socio-demographic aspects; and then the debate and deliberations will follow.

4.2 Expedite Evaluations

The CHB can make expedite evaluations (clinical situations that require a quick answer), in emergency situations, without going through a formal review by the committee in a regular meeting. Expedite evaluations will be carried out by those appointed to the “emergency committee” or consultants who represent the rest of the members because of their knowledge and experience in both the clinical and bioethical aspects. Those in charge of expedite evaluations in emergency situations must convene either an ordinary or extraordinary session, depending on the circumstances, to expound or renew, as the case may be, the issued recommendations.
4.3 Petitions

It is important to establish mechanisms for both the petitions and prior inspection of documents. This is to make sure that all the necessary documents are present for the committee to correctly evaluate the problem or dilemma submitted to its consideration. This will enable the committee to optimize its performance. It can also help avoid an evaluation that might lead to inadequate recommendations or be misunderstood and generate confusion and lack of confidence in the committee’s recommendations.

Documents should be delivered to the CHB secretary’s office. Delivery will be registered with seal and date of reception stamped or registered in a logbook and on the letter containing the petition. When the complete documents are received, a receipt will be issued, signed and sealed by the person who receives it and the person delivering it.

Individuals who request the Committee’s intervention should deliver the pertinent documents to the office of the Hospital Bioethics Committee, at least 10 to 7 working days before the next CHB meeting.

The petition must be accompanied by a letter addressed to the president of the CHB requesting the intervention of the committee.

It is important to avoid turning the relationship between the CHB and the health professionals or the patients and their families into a bureaucracy, but simple procedures should be established in order to carry out the work in an orderly fashion and keep a record of each consultation.

4.4. Decision-making

4.4.1 During the decision-making process the following points should be taken into consideration:

When issuing their recommendations, members of the committee must analyze the issues from different angles as outlined in the deliberative method.

Recommendations must comply with the following minimum requirements:

- Issue date and place of the recommendation.
- Explain the ethical conflict, or motive of the consultation and the name of the petitioner.
- Decisions can only be reached if the established quorum is present.
- Members who have a conflict of interest may not be present during the sessions.
  - It is important to have all the necessary documents and enough time to review them.
- Recommendations must be based on solid and well-founded arguments.
- They must contain the signatures of all committee members.
• Recommendations must be sent in writing to the petitioner in a period that does not exceed seven days as a general rule, although this will depend on the characteristics of the case and the type of conflict.

The recommendations issued by the committee, due to its advisory capacity, are not binding. In other words, they cannot be enforced. Petitioners are not obliged to follow the recommendations of the committee.

In spite of this, resolutions from hospital bioethics committees are an important tool for the creation of procedures on how to manage situations regarding bioethics within a hospital environment and these rulings can be used as a reference source. This is particularly important when the contributions refer to issues that have not been legislated or even legislation whose regulations are deficient or obsolete.

The confidentiality of the information and the privacy of the patient and petitioner must be respected.

Both the recommendations and the final decisions of the CHB must appear in the minutes of the committee and in the case of issues that were not agreed upon; there is lack of consensus regarding the decision of whether or not to include them in the clinical file of the patient. The main tendency is not to.

Communication of the Decision

Communication of the recommendation must include at least the following:

• The problem presented to the Committee.

• The reviewed documents.

• Name of the petitioner.

• Issue date and place of the recommendation.

• Name of the committee that issued the recommendation.

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46 There is no consensus on whether to include the consultation and recommendations of the committee in the patient’s clinical file. In both the literature on the subject and the international experience, there are marked differences of opinion, although criteria for not including them prevail because in general there is not enough culture to manage this information correctly and there is a risk that the committee’s duty may be interpreted erroneously (that it controls or is responsible for the decision, when the responsible party is in fact the consultant). Moreover, if recommendations are not included, they are less likely to become an element that could eventually be used against a member of the medical team. It is also not clear whether it is a medical action or an inter consultation as such, and should therefore be recorded in the clinical file according to the terms of the clinical file, since consultations to the CHB are ethical, voluntary, their recommendations are not binding and their decisions do not always reach a consensus. That is why the literature states that it is not easy to use a mechanism for a case by case evaluation if there is doubt about whether the recommendations were used as a self evaluation mechanism of the committee; the use of other indirect mechanisms related to other aspects of the committee’s work is suggested. Moreover, an indirect mechanism for the analysis of specific cases has been suggested: crossing the information about what was done to the patient with the recommendations issued by the committee, but asking for the information a posteriori, without having to resort to the clinical history and with the explicit request to monitor the work of the committee and for self evaluation purposes only.

Another argument in favor of including the consultation and recommendations, is the issue of transparency; at a given moment, the doctor could include a note stating that due to the complexity of the case, he or she consulted a bioethics committee or that the family did, and therefore a mention could exist, but it would not respect confidentiality between the committee and the consultant. It is a delicate situation that deserves careful study regarding the advantages and disadvantages and then we should develop our own national experience.
• A clear declaration of the recommendation(s).

• Date and signature of the president or secretary of the CHB.

5. Archives

The archives (sources of printed, magnetic or electronic material) must be kept in the office of the CHB. They should include at least:

• Regulations of the CHB.

• Procedural Manual of the CHB.

• Operation manuals, manuals, national rules, international rules, technical documents, applicable regulations.

• Names and current curricula of CHB members.

• Schedule of CHB sessions.

• Records of CHB meetings, listed in sequence, by year. One copy of all the material sent by petitioner.

• Reports of recommendations made by the CHB.

• Received correspondence.

• Correspondence sent by the CHB.

• Evaluated cases, with all the analyzed documents.

• Correspondence from the Director of the Institution (Official letters, notes, confidential mail)

All the papers and communications of a CHB must be dated, numbered and filed according to written procedures. A definition is required regarding access and recuperation procedures (including authorized personnel) to the different documents, files and archives.

It is the responsibility of the CHB to keep case files for 5 years from the date of their resolution. After the 5-year period is over they must be transferred to archives of the health institution. Evidence of this will be left in the pertinent database.

6. Limitations of Hospital Bioethics Committee duties

The duties of the CHB are not designed to replace the doctor-patient relationship, nor the decisions and responsibilities inherent to said relationship.
The CHB must not be directly involved in decisions related to the treatment of patients, unless it is invited to do so. These committees cannot replace the duties of professionals with regards to clinical decision-making. It will only intervene when said professionals perceive a conflict of values and require the advice of the CHB to complete their analysis.

The CHB must define its duties clearly and must abstain from involving itself in decisions that pertain to tending physicians. Other areas of the hospital are authorized to review the appropriateness of certain medical decisions related to medical treatment, such as the committees of morbidity-mortality, infections, etc. A CHB is not authorized to define or sanction medical negligence either.

It is important to keep these committees from becoming bureaucratic. Therefore the necessary mechanisms must be established so that each institution may adjust their duties according to specific needs.

Within a hospital environment, there are different problems involving different individuals. Therefore, it is important to emphasize that the CHB is not meant to involve itself in labor, administrative and legal issues or disputes. These cases must be turned over to the corresponding authorities or departments.

ANNEX 1. DELIBERATIVE METHOD

Bioethics travel unique paths during the decision-making process. It is another of the discipline’s contributions.

In keeping with its own principles and in order to reach inter-subjective types of agreements, bioethics adopt the deliberative method as an alternative to finding solutions to ethical problems that arise within a society.

The most outstanding feature of the deliberative process is that it is not an emotional process; it is an intellectual process with a practical objective: decision-making. The deliberative process can help find a solution that is agreeable to the majority. The aim is to reflect on the factors involved in a certain decision, taking into account not only medical reasons but also personal values.

Deliberation is a process in which the factors that intervene in a situation are pondered in order to find the best solution or one that causes the least harm, ethically speaking. It is about knowing how to jointly search for an alternative that best satisfies the expectations of the interested party and the option that most respects his or her values or goals.

During deliberation, attempts are made to find more than one viable and prudent solution. These may not only be different, but even opposites. In order to reach a prudent and reasonable decision, it is necessary to encompass as many different perspectives as possible while the problem is being analyzed, by respecting the plurality of the members of a CHB and accepting that to listen to the arguments of others is enriching and leads to greater knowledge, since no single individual possesses the whole truth. He who listens believes he may learn something, he who knows he does not know everything.
Bioethical deliberation does not attempt to solve conflicts through a vote without dialogue. It does not consist of evaluating problems from the subjective position of the interested and involved parties (or by committee members), because a sum of subjectivities does not add up to inter-subjectivity. Bioethical deliberation attempts to unravel the principles and values of social ethics (civical ethics, the ethics of citizens) and from that position evaluate the concrete issue set before a CHB.

Decisions are reached using logical debate. However, in the area of morality, logical procedures are not enough, because moral judgements may also entail qualitative arguments that influence the final decision. Deliberation tries to analyse the dilemmas in all their complexities. It ponders the principles and values at stake, but also the circumstances and the consequences of the case in point. That way possible courses of action can gradually be identified.

In order to deliberate it is necessary to develop certain abilities and capabilities:

- Clearly express the arguments that support one’s own position.
- Willingness to approach those who think differently.
- Ability to listen to and understand the point of view of others.
- Ability to negotiate.

Deliberation is an art form and requires training. When decision-making involves the regulation of unfamiliar or unknown topics, moral uncertainty may arise.

There are two different levels in decision-making.

- Facts and cases on which specific moral decisions are made. At this level the context determines the result of a decision since it involves a well-defined situation.
- Specific rules and regulations applicable to certain types of cases or situations.
- General principles. At this level one would find international agreements: declarations, conventions, codes, etc.
- Theories and belief systems (cosmovisions, religions, philosophies or scientific theories).

Each case requires an understanding of the motive of the discussion and a visualization of this motive from distinct perspectives. Different possibilities must be presented and the possible consequences of the decision must be pondered. It is important to consider that the more general the level of a decision, the greater its social impact and inherent responsibility.

Within the deliberative method several suppositions may present themselves:

- The opinion may be uncertain but not irrational.
- Different opinions may coexist regarding the same problem.
Different perceptions of reality may exist.

Perception may guide the course of action.

Deliberation may not wear out the reality.

There may be unknown information.

No one has the absolute moral truth.

The perspectives of those involved in the moral problems should be taken into consideration.

The deliberation process is important because it broadens the points of view of those involved, which represents individual and collective moral growth. This method is not only about reaching a conclusion; the process itself is important.

It is about a collaborative effort to reach agreements and find solutions, not to create irreconcilable positions or impose points of view.

The deliberative method is based on founded, reasoned and rational debate.

All opinions are equally valid if they are correctly sustained.

The deliberative process for decision-making requires two parts:

A. Satisfy the required conditions for deliberation.

   a) Participation of all those who are affected. Decisions are not to be reached solely by experts. Those who are affected, with the advice of experts, will have the power to make decisions.

   b) Participation should be free and without coercion, having been informed beforehand.

   c) All participants should be considered valid speakers, that is to say, that their arguments must be taken into consideration.

   d) Listen carefully to others and understand their reasons. We can thereby adjust and modify our own.

   e) Communication must be clear and truthful.

   f) Collaboration, even in cases when there is disagreement.

B. Application of the analysis method in cases dealing with bioethical issues and decision-making. The following is a detailed list:

   I. Analyze the facts
a) Presentation of the case. If clinical and ethical sessions are to be successful, a complete clinical history of the patient is essential. First the medical aspects must be analyzed. It is important to know what diagnostic and therapeutic procedures have been carried out and what other alternatives are available, as well as the patient’s opinion about these procedures.

b) Analysis of the values and principles of the affected parties. In this case it is important to evaluate the competence of the invididual or his or her legal representatives. It is equally important to know the opinion of the patient, the family and the medical staff, as well as the scale of values and how they could impact on the decision.

c) Analysis of socio-economic problems. Review cultural and economic characteristics of the family structure. Evaluate their access to health services, material resources, etc.

d) Review of the current legislation regarding these issues.

II. Identify Conflicts

These vary from one case to the next, even when the illnesses are the same, because the conflicts are caused by interaction between the different aspects of each specific patient’s life. By carefully analyzing the medical facts, values and principles, the socio-economic situation and current legislations, among others, the conflicts can be clearly identified.

III. Identification of bioethical problems, that is to say, the principles or values at stake.

Amongst these there are 4 universally known bioethical principals to be taken into consideration (beneficence, non maleficence, justice and autonomy). It is worth mentioning that these are not the only principles. Other values, for example, could be life, quality of life, responsibility, respect, dignity, patient confidentiality, and any other value that is presented as such by the patient and the petitioner.

IV. Identification of probable courses of action.

a) Frequently, the experience of professionals or national and international scientific bibliography can be useful for similar cases.

b) Consider the qualifications of the doctor and the material and economic resources of the institution.

c) Consider the socio-cultural situation and economic resources of the patient and/or his or her family.

d) Evaluate the foreseeable outcomes of the probable courses of action.
e) Identify whether exceptions are being made to certain values, and if so justify them adequately.\textsuperscript{47}

V. Analysis of the ideal course of action.

a) Choose the most adequate option.

b) Analysis of arguments in favor.

c) Analysis of arguments against.

d) If the chosen course of action is harmful to a principle, then explain why this option implies a choice of doing the “least harm”.

e) If a principle or value has been harmed, an explanation must be given as to why this course of action is the one that most respects the individual.

VI. Final decision

a) The decision is only valid for the particular case being analyzed.

b) The aim of the deliberative process is to issue a recommendation and it will be the patient, his or her legal representative, his or her family or the physician in charge who will ultimately decide, that is to say, whoever consulted the committee.

Ethical judgements must be:

- Consistent with cultural surroundings, belief systems or the level of knowledge wherein they are expressed.

- Balanced between general and specific judgements (according to specific levels) and between ideals and strong principles.

- Founded.

- Inclusive.

- Thoughtful and prudent.

Sometimes, certain elements can stand in the way of deliberation:

a) Lack of an experience of joint work in the deliberative process (respect for plurality, democracy, freedom and legality).

b) Absence of conditions necessary for careful reflection and insufficient knowledge to carry it out. The circumstances are inadequate.

c) Psychological obstacles: subconsciously we all want to be right and be right all the time.

\textsuperscript{47} Such as cases where the autonomy of the patient cannot be respected because he or she is requesting a decision that is harmful (contraindicated).
It is important to always take into consideration that the deliberative process starts at the beginning of the doctor-patient relationship. It is wrong to think that it only starts when a decision has to be made.

Finally, it is important to teach the deliberative method to health staff and inform the patients about their scope and limitations. The participation of society is important so that it can learn to exchange ideas and grow, morally and ethically.

Although the aforementioned procedure is the one recommended by the National Commission of Bioethics, other outlines have been used in other fields and they are all valid as long as they contain a methodology for analysis, respond to plurality, principles of ethics and the regulations upheld by the Mexican State.

ANNEX 2. INFORMED CONSENT

Informed consent is a tangible expression of respect for the autonomy of individuals in the field of health care and health research. Informed consent is not a document; it is a continuous and gradual process between the health staff and the patient and is implemented in a document.

Through informed consent the health staff informs a competent patient, in sufficient amounts of quality and quantity, about the nature of the illness and the diagnostic or therapeutic procedure to be used, the risks and benefits that these entail and the availability of possible alternatives. The written document is only proof that the health staff has informed the patient and that the patient has understood the information. Therefore, informed consent is the manifestation of a responsible and bioethical attitude of the medical staff or health researchers that elevates the quality of the services and guarantees respect for individuals' dignity and autonomy.

Since the values or goals of each individual vary, the best election may not always make the health of an individual a priority, but rather his or her wellbeing, according to the values or goals of each individual. Therefore, the doctor is not the only one who gets to decide on the best alternative.

Informed consent consists of 2 parts:

1. The right to information

   The information must be clear, truthful, sufficient, timely and objective regarding everything about the medical process, mainly the diagnosis, treatment and prognosis of the patient’s illness. Before any procedure is carried out, the patient must also be adequately informed about the risks, benefits (physical or emotional) and the duration of the procedure, as well as other alternatives, if they exist.

   The information process includes verifying that the patient has understood the information he or she has been given, prompting the individual to ask questions and answer said questions and even give advice when asked to do so.
2. Freedom of choice

Freedom of choice consists in giving or denying consent to the proposed diagnostic or therapeutic procedures after having been adequately informed.

It is important to respect the autonomy of the participants, evaluate their mental capacity and establish the necessary conditions for them to exercise their right to decide. In the case of patients who are incapable of giving their consent, their assent must be obtained.

Consent requires the following elements:

A. Consent must be voluntary. It must be given without coercion, improper influence, incentive or intimidation. The benefits should not be exaggerated nor should the risks be minimized. A prudent amount of time should be set for the patient to decide without undue pressure, whenever possible.

B. Enough information should be offered regarding the illness, prognosis, therapeutic procedure, risks and benefits, as well as the alternatives available in a particular case. The information should be given orally and in person, using simple language, according to the patient’s level of understanding. The health staff should make sure the patient or responsible family members understand the information and should even urge them to ask questions and give simple answers. The level of education and socio-cultural background of participants should be taken into account so that appropriate language is used. This aspect is particularly important in Indigenous populations, where the distinct cosmovisions must be taken into consideration.

C. Information must be given to a competent person (legally competent in both age and mental capacity). In the case of individuals who are not competent because of limited states of consciousness (coma or brain death), limitations in reasoning (children, gravely ill patients, the elderly or those who suffer dementia) and limitations in intelligence (mental deficiencies), it is necessary to obtain authorization from a legal representative. However, whenever possible, it is preferable to obtain the patient’s consent. It is important to make sure that the legal representative or family member is seeking to benefit the patient and has the capacity and required competence to make this decision. Therefore, it is important to consult the hospital bioethics committee whenever doubts or discrepancies regarding moral opinions arise between the health staff and the legal representative with respect to what is best for the patient.

D. Consent must be expressed and confirmed in writing through a signed form, in the case of a procedure that involves a more than minimal risk of harm.\textsuperscript{48} Said consent must contain truthful, clear and complete information about the procedure to be undergone by the patient and its possible complications. In the case of illiterate patients, they must set their fingerprint on the document and choose a witness to sign testifying to this consent. It is elaborated in duplicate: the original for the file and the copy for the patient. The aim of this document is for the patient to take it home, review it and comment with whomever they think best, in case they have any doubts, and as a guarantee that the procedure is in fact carried out.

\textsuperscript{48} It is important to point out that when there is no indication of a need for written informed consent, this does not mean that it should not be asked for anyway, and under the same understanding that consent means a constant exchange of information communication between a patient and the health staff.
E. The Official Mexican Regulation (NOMSSA1-168) establishes the obligatory scientific, technological and administrative criteria for the elaboration, integration, use and filing of the clinical file. Informed consent must be a part of the clinical file.\textsuperscript{49}

Situations for which written informed consent are required, according to the Official Mexican Regulations for Clinical Files, are the following:

- Hospitalization of psychiatric patients through legal warrants, emergencies, because they are a threat to their families, or suicide risks, etc.
- Surgical procedures
- Procedures to control fertility
- Participation in research protocols
- Diagnostic or therapeutic procedures that entail physical, emotional or moral risks
- Invasive procedures
- Procedures that produce physical or emotional pain
- Procedures that are socially invasive or provoke exclusion or stigmatization.

In the case of emergencies when there is no opportunity to speak to the family, and it is impossible to obtain authorization from the patient, the doctor may invoke his “therapeutic privilege”, until the patient is stabilized, at which time he should inform the patient or the immediate family. This procedure should be well documented in the clinical file. The obligatory nature of informed consent is directly proportional to the risk of the intended procedure. The greater the risk, the greater need for authorization.

No procedure should be carried out against the wishes of a mentally competent patient, even when authorized by the family. This and the evaluation of the patient's mental capacity should be annexed, in writing, in the patient's clinical file.

\textsuperscript{49} According to the Official Mexican Regulation NOM-168-SSA1-168 regarding Clinical Files, informed consent must be part of the clinical file. Informed consent should have the following minimum requirements:

Name of the institution to which the establishment pertains, such as: Name, legal name of the establishment; Title of the document; Place and date of issue; Authorized Act; Indication of the risks and benefits expected from the authorized medical procedure; Authorization for the medical staff to attend to contingencies and emergencies derived from the authorized act, taking into account the principle of prescriptive freedom; and full name and signature of witnesses.

The minimum events that require an informed letter of consent are the following:

- 10.1.1.2.1. Hospitalization;
- 10.1.1.2.2. Major surgery;
- 10.1.1.2.3. Procedures that require general anesthesia;
- 10.1.1.2.4. Salpingoclasia and vasectomy;
- 10.1.1.2.5. Transplants;
- 10.1.1.2.6. Clinical research on human beings;
- 10.1.1.2.7. Hospital necropsy;
- 10.1.1.2.8. Diagnostic and therapeutic procedures considered high risk by the attending physician.
- 10.1.1.2.9. Any procedure that entails mutilation.
- 10.1.1.3. The health staff may obtain informed letters of consent for reasons other than those listed in the previous paragraph when they deem it necessary, without the obligatory use of printed forms.
In our country there is clear documentation regarding the obligatory nature of informed consent, such as:

- General Health Law
- State Health Laws.
- Rules of the IMSS Medical Services.
- Official Mexican Regulations
- National Commission for the Certification of Health Establishments
- Charter of the Right of Patients (CONAMED)