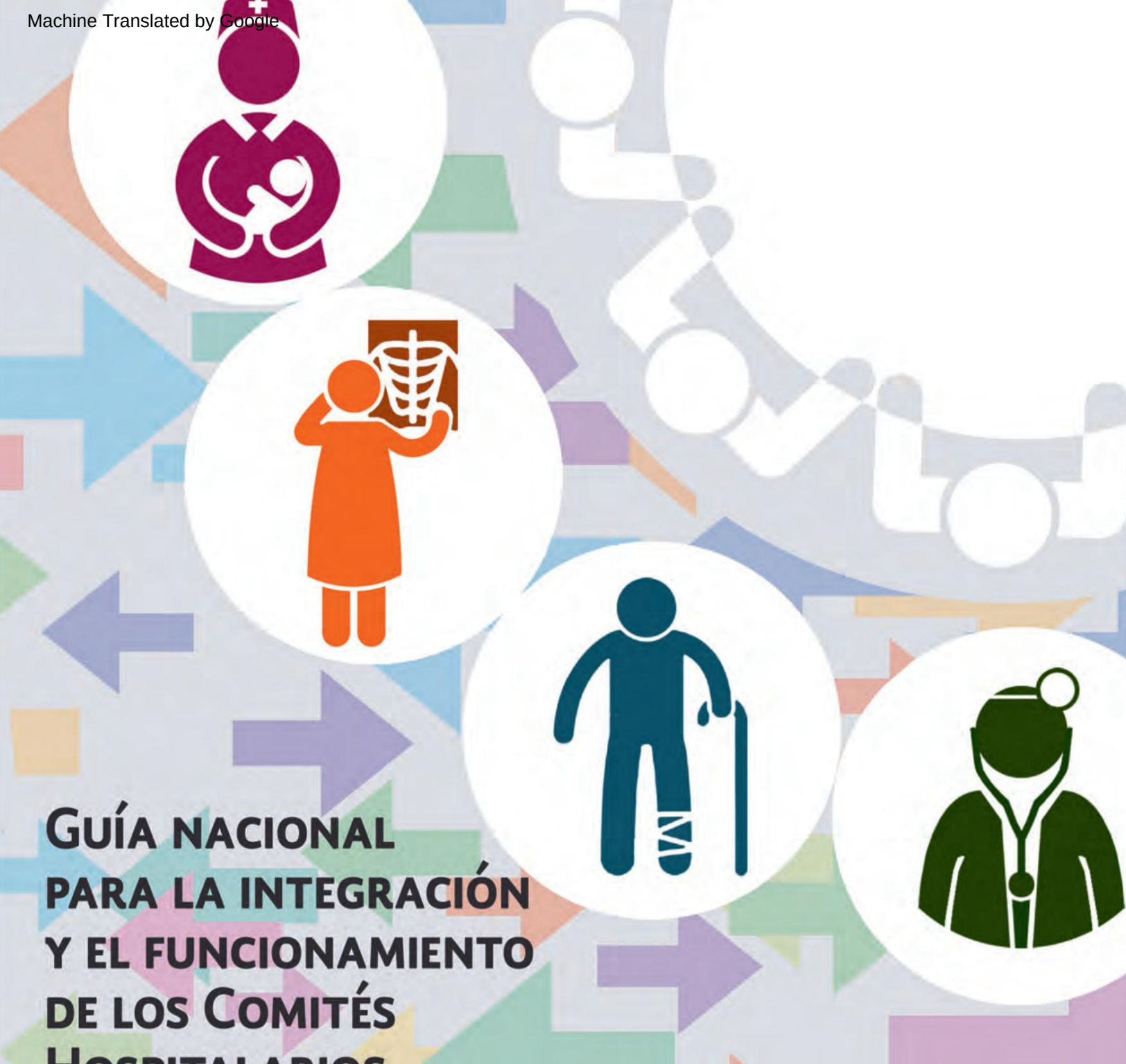

Guía nacional para la integración y el funcionamiento de los Comités Hospitalarios de Bioética

Comisión Nacional de Bioética

National Bioethics Commission

SALUD
SECRETARÍA DE SALUD

CONBIOÉTICA
Comisión Nacional de Bioética

National Bioethics Commission

National Guide for the Integration and Operation of Hospital Bioethics Committees

SALUD
SECRETARÍA DE SALUD

CONBIOÉTICA
Comisión Nacional de Bioética

National Guide for Integration and Operation
of the Hospital Bioethics Committees
Fifth edition 2015

Calzada Arenal No. 134, corner with Xochimaltzin, Arenal Tepepan
neighborhood, Tlalpan district, CP 14610. Phone: 5487 2760
http://conbioetica-mexico.salud.gob.mx

ISBN: 978-607-460-516-7
Responsible editor: Manuel H Ruiz de Chávez
Editorial coordination: Emma Verastegui Aviles and David Alejandro Lopez Vibaldo
Proofreading and correction: Alma Rosa Macedo de la Concha
Update (fifth edition): Raul Hector Rodriguez Otero, Erika Salinas de la Torre and Gustavo Olaiz Barragán
Cover design: Mario Patricio Silva Schütte

Printed and made in Mexico

Index

Attachments

Presentation

Bioethics is an essential support for the resolution of dilemmas that may arise in any health care process, as well as in the interaction of health personnel, patients, family members and society in general. The practice of medicine can sometimes go beyond the strictly clinical scope, which is why it is necessary to form interdisciplinary groups that can evaluate cases and solution perspectives from different points of view and provide advice.

The Decree that adds Article 41 Bis and reforms Article 98 of the General Health Law - published in the Official Gazette of the Federation on December 14, 2011 - introduces the obligation to have Hospital Bioethics Committees (CHB) in health care establishments in the public, social or private sector of the national health system; likewise, these committees are established as an instance of analysis, discussion and support in decision-making with respect to bioethical dilemmas that arise in clinical practice and medical care, as well as in teaching.

The National Bioethics Commission, in accordance with its mandate, promotes the creation of Hospital Bioethics Committees and Research Ethics Committees in public and private health institutions, establishing, through national guidelines, the criteria that these collegiate bodies must consider for the development of their activities and the training of their members.

The National Guide for the Integration and Operation of Hospital Bioethics Committees offers a conceptual framework that can foster dialogue between CONBIOÉTICA and the Committees, with the aim of implementing a process of continuous updating on issues related to clinical activities, health teaching and professional development, among others.

Institutional ethical guidelines and guides are established to address the practical aspects of medical teaching and promote training in bioethics for its members, health facility staff, patients and family members, in addition to offering a mechanism for self-assessment and diagnosis.

This new edition presents general guidelines, based on current national and international regulations and the practices prevailing in the country, in terms of health care and research on human beings.

It offers different analysis mechanisms and tools to address, study and issue the necessary recommendations on cases that arise in the daily practice of medicine, promoting respect for the dignity of users and their rights, in addition to building a bridge to promote their participation in aspects that affect the quality of health services.

Manuel Ruiz H of Chavez
President of the Council
National Bioethics Commission

Marco conceptual

The term *bioethics,* developed by Fritz Jahr as a bioethical imperative, first defined the ethics of human relations with animals and nature. Van Rensselaer Potter incorporated it into contemporary academic discourse and general culture in the article *Bioethics, the science of survival,* published in 1970 and in his book *Bioethics: bridge to the future.* 1

For the National Bioethics Commission, bioethics is the branch of applied ethics that reflects, deliberates and makes normative and public policy proposals to regulate and resolve conflicts in social life, especially in the life sciences, as well as in medical practice and research that affect life on the planet, both now and in future generations. This notion of bioethics, formulated with the support and endorsement of the Council of the Commission, derives from two fundamental aspects: the need to have a conceptual approach - since there is no universal definition - and the importance of transferring it to the operational field and putting it into practice.

By integrating the perspectives of different types of knowledge, it provides us with analytical frameworks and theoretical tools to address the complex reality of human beings. Bioethics is not limited to the field of clinical practice, but rather includes the preservation of life in all its forms and offers us the possibility of addressing the issue of health in an integrated manner. This is why bioethical reflection is essential to achieve conditions of justice, equity and respect for human rights in all areas of health, from basic research to the development of infrastructure and public policies. This approach is fundamental in public debates on issues involving scientific and technological developments, as well as their repercussions on all dimensions of life, which is why it has been included in national and international dialogue to guide decision-making in the public space.

Bioethics, without being a code of precepts, integrates analytical activity and is based on philosophical principles and scientific criteria, in order to guide practice in the different areas of health and research, promoting the safeguarding of dignity and human rights. To ensure ethical treatment in health care, a series of minimum ethical principles have been established that must be followed by doctors and health personnel. These principles are present in international regulations, which are the declarations issued by the United Nations Educational, Scientific and Cultural Organization (UNESCO), among which the following stand out: the Universal Declaration on the Human Genome and Human Rights (1997),2 the Declaration on the Responsibilities of Current Generations Towards Future Generations (1997);3 the International Declaration on the Rights of Persons with Disabilities (1997);4 the Declaration on the Rights of Persons with Disabilities (1997);5 the Declaration on the Rights of Persons with Disabilities (1997);6 the Declaration on the Rights of Persons with Disabilities (1997);7 the Declaration on the Rights of Persons with Disabilities (1997);8 the Declaration on the Rights of Persons with Disabilities (1997);9 the Declaration on the Rights of Persons with Disabilities (1997);10 the Declaration on the Rights of Persons with Disabilities (1997);11 the Declaration on the Rights of Persons with Disabilities (1997);12 the Declaration on the Rights of Persons with Disabilities (1997);13 the Declaration on the Rights of Persons with Disabilities (1997);14 the Declaration on the Rights of Persons with Disabilities (1997);15 the Declaration on the Rights of Persons with Disabilities (1997);16 the Declaration on the Rights of Persons with Disabilities (1997);17 the Declaration on the Rights of Persons with Disabilities (1997);18 the Declaration on the Rights of Persons with Disabilities (1997);19 the Declaration on the Rights of Persons with Disabilities (1997);20 the Declaration on the Rights of Persons with Disabilities (1997);2

1 *Cfr.* Juliana González, coord., *Bioethics Perspectives* (Mexico: Fondo de Cultura Económica, 2008).

2 United Nations Educational, Scientific and Cultural Organization, *Universal Declaration on the Human Genome and Human Rights* (Paris: UNESCO, 11 November 1997) http://unesdoc.unesco.org/images/0012/001229/122990So.pdf (Accessed 11 December 2015).

3 United Nations Educational, Scientific and Cultural Organization, *Declaration on the Responsibilities of Present Generations towards Future Generations* (Paris: UNESCO, 12 November 1997) http://www.unesco.org/cpp/sp/statements/generations.htm (Accessed on: December 11, 2015).

on Human Genetic Data (2003),4 and the Universal Declaration on Bioethics and Human Rights (2005).5

The case of the Convention on the Protection of Human Rights and Dignity of the Human Being in the Application of Biology and Medicine of the Council of Europe (1997)6, known as the Oviedo Convention, deserves special consideration, as it is the only instrument in the world adopted by 29 countries of the European continent that has the hierarchy of an international treaty7. Although our country has a solid regulatory framework, by adhering to the treaty, national legislation and public policies will be strengthened in various areas of biomedicine.

These instruments highlight various commitments, such as the protection of human rights; respect for the dignity and privacy of individuals; avoiding all forms of discrimination; equity in quality health care and conducting research on human beings while ensuring their integrity and well-being.

In order to comply with these obligations, national ethics/bioethics commissions or committees have emerged in various countries. These bodies advise political representatives and governments, promote democratic and public debate, as well as the analysis and development of public policies in complex ethical fields. Their function is not strictly normative; these commissions promote analysis and dialogue on bioethical issues, with the aim of exploring possible solutions and formulating recommendations.

In 1992, the Mexican State created the National Bioethics Commission through the Ministry of Health, and in 2005, by Presidential Decree, granted it the status of a decentralized body, granting it the power to assist in safeguarding dignity and respect for human rights in medical care and health research. Currently, the institutional infrastructure in bioethics is made up of the National Bioethics Commission, the State Bioethics Commissions, the Hospital Bioethics Committees and the Research Ethics Committees.

Through these organizations, bioethics is brought into the field of public and governmental action to support the formulation and evaluation of public policies. Likewise, federal and state legislatures are increasingly speaking out in favor of regulation on issues related to the subject. In addition, this is complemented by the participation of higher education institutions and non-governmental organizations. Thus, the repercussions of the institutionalization of bioethics transcend the different orders of social life.

4 United Nations Educational, Scientific and Cultural Organization, *International Declaration on Human Genetic Data* (Paris: UNESCO, 16 October 2003) http://portal.unesco.org/en/ev.php-URL_ID=17720&URL_DO=DO_TOPIC&URL_SECTION=201.html (Accessed: December 11, 2015).

5 United Nations Educational, Scientific and Cultural Organization, *Universal Declaration on Bioethics and Human Rights* (Paris: UNESCO, October 19, 2005) http://portal.unesco.org/es/ev.php-URL_ID=31058&URL_DO=DO_TOPIC&URL_SECTION=201.html (Accessed December 11, 2015).

6 Council of Europe, *Convention for the Protection of Human Rights and Dignity of the Human Being in the Face of the Application of Biology and Medicine* (Oviedo: Council of Europe, April 4, 1997) https://rm.coe.int/CoERMPublicCommonSearchServices/DisplayDCTMContent?documentId=090000168007cf98 (Accessed: December 11, 2015).

7 *Cfr.* Manuel H Ruiz de Chávez, Sandra Carrizosa, Karla Sánchez, Anna Cadena, *Convention on Human Rights and Biomedicina. Propositive analysis for Mexico's accession* (Mexico: Fontamara/National Bioethics Commission, 2015).

Bioethics in hospital practice

Since the origins of medicine, the doctor-patient relationship has been interpreted in various ways according to the historical contexts in which it occurs. Thus, the development of scientific and technological knowledge that occurred from the second half of the twentieth century transformed the practice of medicine, and it is currently carried out in a complex scenario in which sometimes what is technically possible could be ethically questionable.8 Under this paradigm, factors such as the exercise of patient autonomy, the equitable distribution of resources, the use of available technology, among others, are weighting elements within medical practice that have given rise to new ethical conflicts, since the values of all the individuals involved and the possible differences of criteria are considered within the decisions.9

Bioethics in hospital practice must identify, analyse and resolve ethical problems that arise in patient care. In the book *Clinical Ethics* by Jonsen, Siegler and Winslade10, two important points to bear in mind are pointed out: on the one hand, the doctor-patient relationship and, on the other, the need to reach a decision. Making decisions is always difficult because the values that support them are subjective and may come into conflict when considering them.
Thus, within medicine, the discipline of bioethics, understood as practical ethics, attempts to resolve the problems that arise in medical care using a wide variety of methods, the exposition of which goes beyond the limits of this guide,11 but which are stated schematically (See Annex 3).

Importance of Hospital Bioethics Committees

Hospital Bioethics Committees emerged in the second half of the 20th century with the purpose of implementing formal mechanisms aimed at resolving dilemmas that arise in the practice of medicine.12 In 1975, the need for multidisciplinary committees to guide decision-making on ethically complex issues was first stated.13

The CHBs have been created to open a space for analysis, reflection and study of the elements that form part of a medical care process. They must be conceived as bodies that represent a collegiate body, with professional competence, high scientific and technical solidity, objectivity, impartiality and rectitude of their actions. The CHBs must promote respect for Human Rights; the recognition of the dignity of individuals; promote the education of health personnel; foster respect for the autonomy of patients through informed consent, among other actions that tend to improve the quality of health care.

8 *Cfr.* Alberto Lifshitz, “The Doctor-Patient Relationship at the Dawn of the 21st Century,” in *The Current Practice of Medicine* (Mexico: Siglo XXI) Editors, 2000), 39.

9 *Cfr.* Miguel Sánchez-González, Benjamín Herreros, “Bioethics in clinical practice”, *Medical Journal of the Mexican Social Security Institute,* Vol. 53 (1; 2015): 66-73.

10 Albert Jonsen, Mark Siegler, William Winslade, *Clinical ethics: a practical approach to ethical decisions in clinical medicine,* 7ma. Edition (New York: McGraw-Hill, 2010).

11 *Cfr.* Kevin W. Wildes, *Moral Acquaintances. Methodology in Bioethics* (Notre Dame: University of Notre Dame Press, 2000).

12 *Cfr.* Anne Slowther, Carol Johnston, Jane Goodall, Tony Hope, “Development of clinical ethics committees”, *British Medical Journal (Clinical Research Ed),* No. 7445 Vol. 328 (Apr 17; 2004): 950-952.

13 *Cfr.* Karen Teel, “The physician’s dilemma: A doctor’s view: What the law should be.” *Baylor Law Review,* Vol. 27 (1; 1975): 6-9.

As a historical reference to point out the importance of Hospital Bioethics Committees or clinical ethics, the case of Karen Ann Quinlan is paradigmatic.14 The ethical dilemmas that arise at the beginning and end of life are topics of frequent consultation and deliberation within the CHB, as well as aspects related to neuroethics, the commercialization of the human body, access to high-cost medications and prenatal diagnosis, among others.15

Regulations

CONBIOÉTICA has promoted the creation and modification of health regulations to strengthen the national legal framework in this area, incorporating and observing respect for human rights recognized in current regulations.

This section sets out in general terms the regulatory instruments that refer to clinical practice, medical care and health education, and that establish the regulation and operation of the Hospital Bioethics Committees.16

National legal framework

ÿ **Political Constitution of the United Mexican States17**

The Constitution establishes the human rights recognized for every person in the national territory, as well as the guarantees for these rights. The right to health protection is recognized in article 4, paragraph 4. This right is explained and developed by the General Health Law, the regulations emanating from it and the official Mexican standards issued by the Ministry of Health. In addition, it should be noted that the Magna Carta itself recognizes the human rights contained in the international treaties to which Mexico is a party.

ÿ **Organic Law of the Federal Public Administration18**

Article 26 identifies the Ministry of Health as part of the centralized administration. Article 39 establishes the powers of the Ministry of Health to plan, develop, establish, evaluate and monitor the implementation of the right to health protection.

14 *Cfr.* Elizabeth Heitman, “Institutional Ethics Committees: Local Perspectives on Ethical Issues in Medicine”, *Society’s Choices: Social and Ethical Decision Making in Biomedicine,* Eds. Ruth Ellen, Elizabeth Meyer, Harvey Fineberg (USA: Institute of Medicine, 1995), http://www.ncbi.nlm.nih.gov/books/NBK231970/#_ncbi_dlg_citbx_NBK231970 (Fecha de consulta: 11 de diciembre de 2015).

15 *Cfr.* Jim Thornton, Richard Lafford, “Clinical ethics committee”, *British Medical Journal (Clinical Research Ed.)* 311, No. 7006 (Sep 9; 1995): 667–9 http://www.ncbi.nlm.nih.gov/pmc/articles/PMC2551433/pdf/bmj00609-0035.pdf (Fecha de consulta: 11 de dic-iembre de 2015) & Thaddeus Mason Pope, “Legal Briefing: Healthcare Ethics Committees,” *The Journal of Clinical Ethics* 22, no. 1 (Spring; 2011): 74-93 http://www.thaddeuspope.com/images/Pope_-_JCE_22_1_HEC_FINAL.pdf (Fecha de consulta: 11 de dic-iembre de 2015).

16 Considering that national regulations may undergo several changes that concern research on human beings, it is suggested that the most recent information be consulted on the following electronic pages: http://www.diputados.gob.mx/LeyesBiblio/index.htm (Consultation date: December 11, 2015) or http://www.ordenjuridico.gob.mx/ (Consultation date: December 11, 2015).

17 *Cfr.* Political Constitution of the United Mexican States (Mexico: Official Gazette of the Federation, Reform published on July 7 (2014). http://www.diputados.gob.mx/LeyesBiblio/htm/1.htm (Consulted on: December 11, 2015).

18 *Cfr.* Organic Law of the Federal Public Administration (Mexico: Official Gazette of the Federation, last reform published on December 17, 2015). http://www.diputados.gob.mx/LeyesBiblio/ref/loapf.htm (Accessed December 11, 2015).

ÿ **General Health Law19**

This Law develops the principles of the right to health protection in various areas. Title Three establishes the provisions relating to the provision of health services, defining them as those actions carried out for the benefit of the individual and society in general, aimed at protecting, promoting and restoring the health of the person and the community. It classifies health services into medical care, public health and social assistance, in which the quantitative and qualitative extension of health services must be guaranteed, preferably to vulnerable groups. In addition, it emphasizes that medical care includes preventive, curative, rehabilitative and palliative activities. Special mention should be made of the addition of Title Eight Bis, which establishes the criteria for providing palliative care to terminally ill patients. This Title includes articles 166 Bis to 166 Bis-21, and it contemplates the rights of terminally ill patients, as well as the powers and obligations of health institutions and medical and health personnel in this area.

ÿ **Federal Law on Transparency and Access to Public Government Information20**

Its purpose is to provide the necessary actions to guarantee the access of all persons to the information held by the Powers of the Union, the autonomous constitutional bodies or those with legal autonomy, and any other federal entity. In addition, it establishes the guarantees so that the personal data that public bodies have in their records are adequately protected. This law indicates the parameters to know under what circumstances the data should be considered reserved or confidential.

ÿ **Federal Law on the Protection of Personal Data Held by Private Parties21**

This law aims to protect personal data held by individuals, in order to regulate their legitimate, controlled and informed treatment, in order to guarantee privacy and the right to informational self-determination of individuals. In light of the above, private sector institutions that provide health services must take into account the provisions of this law so that the personal data to which they have access are adequately protected. In addition, they must comply with the provisions of the General Health Law and its Regulations on the Provision of Medical Care Services.

19 *Cfr.* General Health Law (Mexico: Official Gazette of the Federation, Reform published on March 17, 2015). http://www.diputados.gob.mx/LeyesBiblio/ref/lgs/LGS_orig_07feb84_ima.pdf (Consulted on: December 11, 2015).

20 *Cfr.* Federal Law on Transparency and Access to Public Government Information (Mexico: Official Gazette of the Federation, Reform published on July 14, 2014). http://www.diputados.gob.mx/LeyesBiblio/pdf/244_140714.pdf (Accessed December 11, 2015).

21 *Cfr.* Federal Law on the Protection of Personal Data Held by Private Parties (Mexico: Official Gazette of the Federation, Reform published on July 5, 2010). http://www.diputados.gob.mx/LeyesBiblio/pdf/LFPDPPP.pdf (Accessed December 11, 2015).

ÿ **Regulations of the Federal Law on Transparency** and **Access to Public Information Gubernamental** 22

Its purpose is to regulate the provisions of the Federal Law on Transparency and Access to Public Government Information in relation to the Federal Executive Branch, its agencies and entities and, in general, any other body that forms part of the Federal Public Administration.

ÿ **Regulations of the Federal Law on the Protection of Personal Data Held by the Particulares23**

Its purpose is to regulate the provisions of the Federal Law on the Protection of Personal Data Held by Private Parties. It will apply to the processing of personal data held on physical or electronic media, which make it possible to access personal data according to certain criteria, regardless of the form or method of its creation, type of media, processing, storage and organization.

ÿ **Regulations of the General Health Law on the Provision of Health Care Services Medical Education24**

It develops the content of the General Health Law regarding the requirements of health service providers to provide quality medical care, indicating the parameters that must be met in the treatment of patients. It considers that health care services represent a means for the conservation and protection of people's health, involving prevention, healing and rehabilitation activities.

ÿ **Regulations of the General Health Law on Transplants25**

Its purpose is to regulate the disposal of organs, tissues and cells, with the exception of blood, blood components and progenitor or stem cells, for transplant purposes. Its provisions are of public order, social interest and mandatory application throughout the national territory. It states that both the internal committee for donation and the internal committee for transplants must have a representative from the Hospital Bioethics Committee.

ÿ **Decree creating the decentralized body called the National Bioethics Commission26**

22 *Cfr.* Official Gazette of the Federation (Mexico: Constitutional Government of the United Mexican States, June 11, 2003). http://www.diputados.gob.mx/LeyesBiblio/regley/Reg_LFTAIPG.pdf (Consulted on: December 11, 2015).

23 *Cfr.* Official Gazette of the Federation (Mexico: Constitutional Government of the United Mexican States, December 21, 2011). http://www.diputados.gob.mx/LeyesBiblio/regley/Reg_LFPDPPP.pdf (Accessed December 11, 2015).

24 *Cfr.* Regulations of the General Health Law on the Provision of Medical Care Services (Mexico: Official Gazette of the Federation, March 24, 2014). http://www.salud.gob.mx/unidades/cdi/nom/compi/rlgsmpsam.html (Accessed December 11, 2015).

25 *Cfr.* Official Gazette of the Federation (Mexico: Constitutional Government of the United Mexican States, March 20, 2014). http://www.diputados.gob.mx/LeyesBiblio/regley/Reg_LGS_MT.pdf (Consulted on: December 11, 2015).

26 *Cfr.* Official Gazette of the Federation (Mexico: Constitutional Government of the United Mexican States, September 7, 2005). http://www.conbioetica-mexico.salud.gob.mx/descargas/pdf/normatividad/normatinacional/6._NAL._Decreto_CNB.pdf (Consulted on: December 11, 2015).

ÿ **Agreement issuing the General Provisions for the Integration and Operation of Hospital Bioethics Committees and establishing the hospital units that must have them, in accordance with the criteria established by the National Bioethics Commission27**

The purpose of this legal regulation is to indicate the criteria for the integration and operation of the Committees that assist in decision-making on bioethical dilemmas that arise in medical care or in teaching in the health area, and its provisions are mandatory for the establishments referred to in articles 69 and 70 of the Regulations of the General Health Law on the Provision of Medical Care Services.

ÿ **Agreement that establishes the guidelines that must be observed in public establishments that provide health care services to regulate their relationship with manufacturers and distributors of medicines and other health supplies, derived from the promotion of products or the performance of academic, research or scientific activities28**

ÿ **Agreement by which the General Health Council Declares the Obligation of the Comprehensive Palliative Care Management Schemes, as well as the processes outlined in the Comprehensive Palliative Care Management Guide29**

ÿ **Mexican Official Standard NOM-011-SSA3-2014, Criteria for the care of terminally ill patients through palliative care30**

ÿ **Mexican Official Standard NOM-004-SSA3-2012, for clinical records31** Establishes the mandatory scientific, ethical, technological and administrative criteria for the preparation, integration, use, management, archiving, conservation, ownership, title and confidentiality of clinical records. It is generally observed throughout the national territory and its provisions are mandatory for healthcare service providers in the public, social and private sectors, including clinics.

ÿ **Mexican Official Standard NOM-024-SSA3-201232**

It establishes the functional objectives and functionalities that the Electronic Medical Record Systems products must observe to guarantee interoperability, proce-

27 *Cfr.* Official Gazette of the Federation (Mexico: Constitutional Government of the United Mexican States, October 31, 2012). http://www.conbioetica-mexico.salud.gob.mx/descargas/pdf/normatividad/normatinacional/AcuerdoCHB.pdf (Consulted on: December 11, 2015).

28 *Cfr.* Official Gazette of the Federation (Mexico: Constitutional Government of the United Mexican States, August 12, 2008). http://www.dof.gob.mx/nota_detalle.php?codigo=5056216&fecha=12/08/2008 (Accessed December 11, 2015).

29 *Cfr.* Official Gazette of the Federation (Mexico: Constitutional Government of the United Mexican States, December 26, 2014). http://www.dof.gob.mx/nota_detalle.php%3Fcodigo%3D5377407%26fecha%3D26/12/2014 (Consulted on: December 11, 2015).

30 Official Gazette of the Federation (Mexico: Constitutional Government of the United Mexican States, December 9, 2014). http://dof.gob.mx/nota_detalle.php?codigo=5375019&fecha=09/12/2014 (Consultation date: December 11, 2015).

31 Official Gazette of the Federation (Mexico: Constitutional Government of the United Mexican States, October 15, 2012). http://dof.gob.mx/nota_detalle.php?codigo=5272787&fecha=15/10/2012 (Consultation date: December 11, 2015).

32 Official Gazette of the Federation (Mexico: Constitutional Government of the United Mexican States, September 8, 2010). http://www.dof.gob.mx/normasOficiales/4151/salud/salud.htm (Consultation date: December 11, 2015).

processing, interpretation, confidentiality, security and use of standards and catalogues of information in electronic health records.

ÿ **Code of Bioethics for Health Personnel33**
The Code of Bioethics for Health Personnel was issued by the National Bioethics Commission in 2002. It represents a guide to conduct in professional practice and its purpose is to resolve the differences that arise in the provision of services to patients and their families, as well as between health personnel and professionals who intervene in life events related to medicine and health.

Through this instrument, the National Bioethics Commission seeks to facilitate compliance with the constitutional right to health protection by establishing the generic aspects of ethical conduct in the provision of health services.

ÿ **Charter of General Rights of Physicians34.**

ÿ **General Charter of Rights of Patients35**
It was developed by CONAMED in 2001. This decalogue highlights the importance of respecting the rights of patients, respect for their dignity and autonomy, as well as the need to guarantee the confidentiality of the information generated in the doctor-patient relationship.

International framework

The international framework of Human Rights constitutes the basis on which the functioning and integration of Hospital Bioethics Committees is defined. This normative body is made up of declarations, treaties, guides, recommendations, among others, and although many of these instruments are not binding, they serve as criteria to guide medical care according to ethical principles. Some of the main instruments in this area are:

ÿ Nuremberg Code.36
ÿ Declaration of Helsinki.37
ÿ Universal Declaration on the Human Genome and Human Rights.38
ÿ Universal Declaration of Human Rights of Future Generations.39

33 National Bioethics Commission (Mexico: Ministry of Health, 2002). http://www.salud.gob.mx/unidades/cdi/documentos/DOC-SAL7470.html (Accessed December 11, 2015).

34 National Commission for Medical Arbitration (Mexico: Ministry of Health, 2003). http://www.conbioetica-mexico.salud.gob.mx/descar-gas/pdf/normatividad/normatinacional/3._NAL._Derechos_de_los_Mxdicos.pdf (Accessed December 11, 2015).

35 National Commission for Medical Arbitration (Mexico: Ministry of Health, 2001). http://www.conbioetica-mexico.salud.gob.mx/descar-gas/pdf/normatividad/normatinacional/4.NAL_Derechos_de_los_Pacientes.pdf (Accessed December 11, 2015).

36 Nuremberg Code (Nuremberg: Nuremberg Trials, August 20, 1947). http://www.conbioetica-mexico.salud.gob.mx/downloads/pdf/normatividad/normatinternacional/2.INTL._Cod_Nuremberg.pdf (Consulted on: 11 December 2015).

37 World Medical Association, *Declaration of Helsinki,* 2013.

38 United Nations Educational, Scientific and Cultural Organization, *Universal Declaration on the Human Genome and the Human Rights,* 1997.

39 United Nations Educational, Scientific and Cultural Organization, *Universal Declaration of the Human Rights of Future Generations* (Paris: UNESCO, February 26, 1994) http://gestor.pradpi.org/download.php?id_doc=658. (Accessed December 11, 2015).

- ÿ Convention for the Protection of Human Rights and Dignity of the Human Being in the Application of Biology and Medicine (Oviedo Convention).40
- ÿ International Declaration on Human Genetic Data.41
- ÿ Universal Declaration on Bioethics and Human Rights.42
- ÿ International Health Regulations, issued by the World Health Organization.43
- ÿ Code of Ethics of the World Medical Association.44
- ÿ Guidelines, prepared by UNESCO, for the Creation of Bioethics Committees", 2005;45 for the Operation of Bioethics Committees: procedures and policies", 2006;46 for the Training of Bioethics Committees", 2007. 47
- ÿ Guías elaboradas por la Organización Mundial de la Salud OMS: Ethics, access and safe-ty in tissue and organ transplantation: Issues of global concern, 2003;48 Basic principles for treatment and psychosocial support of drug dependent people living with HIV/AIDS, 2006;49 y Guidance on Ethics of Tuberculosis Prevention, care and control, 2012.50

Hospital Bioethics Committees

Hospital Bioethics Committees are spaces for reflection, analysis, guidance and education about the dilemmas that arise in medical care. They are formed as interdisciplinary and plural bodies, which in no case can replace the responsibility of doctors towards patients or impose their decisions, but rather their character is solely consultative.51

40 Council of Europe, *Convention on the Protection of Human Rights and Dignity of the Human Being in the Face of Applications of of Biology and Medicine,* 1997.

41 United Nations Educational, Scientific and Cultural Organization, *International Declaration on Genetic Data Humans,* 2003.

42 United Nations Educational, Scientific and Cultural Organization, *Universal Declaration on Bioethics and Human Rights, hands,* 2005.

43 World Health Organization, *International Health Regulations* 2nd Ed. (Geneva: WHO, 2008). www.who.int/ihr/IHR_2005_ es.pdf?ua=1 (Accessed: December 11, 2015).

44 World Medical Association, *Handbook of Medical Ethics* 3rd Ed (France: World Medical Association, 2015). http://www.wma.net/ es/30publications/30ethicsmanual/pdf/ethics_manual_es.pdf (Accessed: 11 December 2015).

45 United Nations Educational, Scientific and Cultural Organization, *Guide No. 1 Creation of bioethics committees* (France: UNESCO, 2005). http:// www.unesco.org.uy/shs/fileadmin/templates/shs/archivos/guia1.pdf (Accessed December 11, 2015).

46 United Nations Educational, Scientific and Cultural Organization, *Guide No. 2: Functioning of Bioethics Committees: Procedures and Policies* (France: UNESCO, 2006). http://www.unesco.org.uy/shs/fileadmin/templates/shs/archivos/guia2.pdf (Accessed December 11, 2015).

47 United Nations Educational, Scientific and Cultural Organization, *Guide No. 3 Training of bioethics committees* (France: UNESCO, 2007). http://www.unesco.org.uy/shs/fileadmin/templates/shs/archivos/guia3.pdf (Accessed December 11, 2015).

48 World Health Organization, *Ethics, access and safety in tissue and organ transplantation: Issues of global concern* (Madrid: WHO, 2004). http:// www.who.int/transplantation/en/Madrid_Report.pdf (Accessed December 11, 2015).

49 Organización Mundial de la Salud, *Basic principles for treatment and psychosocial support of drug dependent people living with HIV/ AIDS* (France: WHO, 2006). http://www.who.int/substance_abuse/publications/basic_principles_drug_hiv.pdf (Accessed 11 December 2015).

50 World Health Organization, *Guidance on Ethics of Tuberculosis Prevention, Care and Control* (Switzerland: WHO, 2010). http://whq-libdoc.who.int/publications/2010/9789241500531_eng.pdf (Accessed December 11, 2015).

51 Mark Siegler, "Ethics committees: decision by bureaucracy", *Hastings Center Report* 3, Vol. 16 (Jun; 1986): 22-24.

Goals

The main objectives of the Hospital Bioethics Committees are:

ÿ Advise health personnel and users regarding bioethical problems and dilemmas that arise in the provision of health care services and health education, from a secular and scientific perspective.

ÿ Serve as a forum for reflection on bioethical problems and cases. ÿ
Promote the participation of the population in the debate on bioethical problems.

Functions

The performance of the CHB includes the following functions:

Advisory function

The advisory function is carried out at the explicit request of the professional and technical health care staff, the patient, family members or legal representatives. In exercising this function, the Committee will receive the questions presented, may resort to the opinion of experts, will analyze the case from various methodologies that allow an objective view, promoting reasoning and justification for each case, and will formulate recommendations.

The opinions of the Committees shall be reasoned and the decisions of the persons involved, i.e. the doctor, the patient or the family, must always be respected. The role of the CHBs shall not be to issue binding judgments, but to assist the parties involved in a conflict.

The Committees generally intervene:

ÿ When a problematic situation arises arising from the process of caring for a patient or a person providing the care service and a risk to physical, moral or psychological integrity is observed; ÿ In decision-making processes that may
imply a greater risk to the patient's health or death; ÿ In situations of vulnerability in the treatment of any person involved
in the health care process; ÿ When guidance is required on very expensive and/or dubious treatments; and ÿ In
cases of patients not competent to make decisions, among others.

It is important to mention that, although the advisory function is the paradigmatic activity of the CHB, as its scope of action expands, it must provide the hospital community with instruments to identify bioethical dilemmas and promote the implementation of preventive measures for future cases.

Guiding function

It allows anticipating potential conflicts of interest that arise in medical care, through procedures consistent with social, economic and cultural conditions, as well as with the historical moment and the current legal framework, for example, through the establishment of

dialogue and informed consent processes with clinical areas, to promote an appropriate relationship between health personnel and patients. This should be flexible and reviewed periodically to be modified if necessary.

The exercise of the guiding function includes the following aspects: 1. Establishes decision-making procedures in the clinical field that consider value conflicts, such as the refusal of treatment and the lack of capacity to give consent,52 as in the case of minors, people with mental disabilities or temporary loss of consciousness; 2. Establishes processes of dialogue and informed consent with the clinical areas to promote an appropriate relationship between health personnel and patients; and 3. Performs the analysis of the bioethical aspects involved in the donation and transplantation of organs and tissues, from living donors or obtained by cadaveric donation.

It is possible to propose some policies in hospitals so that, in the event of facing a bioethical dilemma, timely care is provided regarding not resuscitating, disconnecting the devices that provide life support, determining the content and relevance of informed consent, distributing medical resources and equipment and indicating therapies in cases of family discord, among others.
others.

Educational function

It includes a set of activities that help members of the institutional community to incorporate information, knowledge and conduct consistent with the bioethical aspects developed and defined by the Committee. The group that makes up the Committee goes through a training stage,53 as does the hospital staff, through conferences, workshops, courses, audiovisual materials and other activities. Subsequently, the CHB promotes bioethical knowledge among patients and family members to sensitize them in the debate on bioethical problems.

Limitations on the functions of Hospital Bioethics Committees

To prevent the functions of a Hospital Bioethics Committee from being confused with those of other types of committees, it is important to point out what its limitations are:

- ÿ They do not replace the functions of professionals in clinical decision-making; they will only intervene at their request when a conflict is identified in the exercise of health care and advice is required for its analysis, and therefore they must refrain from getting involved in decisions that concern the treating physician and the patient.
- ÿ It is not their area of competence to analyse or sanction medical negligence. ÿ It is not their responsibility to deal with matters or problems of a labour, administrative or legal nature.
- ÿ They should not be understood as activist or political groups
- ÿ It is not the responsibility of the CHB to review research protocols.

52 United Nations Educational, Scientific and Cultural Organization, “Article 6 - Consent”, in *Universal Declaration of Human Rights on Bioethics and Human Rights,* 2005.
53 The CHB Chair and other members should undergo theoretical training and initiate a retrospective case analysis exercise.

Integration

Committees must be multidisciplinary and plural, and made up of medical personnel from different specialties and other members of the health team, experts in bioethics, professionals from non-medical areas, lawyers with knowledge of health matters and representatives of the affected group. They may or may not belong to the institution itself and must have prior training in bioethics, or receive it during the following six months of joining the Committee. Administrative personnel, directors of institutions or people who occupy management positions in the institution should not be included in order to promote an environment of equity.

The purpose of the multidisciplinary integration of the Committee is to carry out the argumentation from various perspectives to favor the resolution of ethical dilemmas, for example: 1. Health professionals clarify the clinical data of the case, such as diagnosis, prognosis and treatment alternatives, this should be considered as the previous step to any bioethical analysis; 2. The bioethics expert leads the reflection and weighing of the conflicting values and principles, according to the methodology of bioethical analysis; 3. The lawyer defines the current legal framework and the legal aspects to be considered under which the case will be analyzed; and 4. Citizen representatives make considerations as users of health services.

The Committee shall be composed of a President and Members (minimum four) and, in the performance of its functions, shall be assisted by a Secretary, appointed from among the members by its President. Gender balance must be sought and at least one member not attached to the establishment must be included.

Selection and requirements of members

Belonging to a Hospital Bioethics Committee represents a distinction, so the requirements for designating each position must be observed, as well as the terms, conditions, tasks and responsibilities of each one. The Committee must establish in its operating rules the process by which the members will be chosen.

This selection should consider the following characteristics:

- ÿ Have a background that demonstrates honesty and commitment (references from peers, jobs, community and/or the organization to which they belong).
- ÿ Document professional experience.
- ÿ Have some training or qualification in clinical bioethics, preferably.
- ÿ Make a commitment to continuously train in bioethical knowledge, from a secular and scientific perspective.
- ÿ Be interested and willing to develop respectful listening skills, argue rationally and reasonably. Be tolerant, thoughtful, prudent and honest.
- ÿ Represent the interests of the community that uses health care services.
- ÿ Maintain the commitment to remain during the period established by the Committee itself and carry out its tasks.
- ÿ Admit and make transparent conflicts of interest, if they exist.
- ÿ Commit to the care of participants in health care.
- ÿ Must not be a member of the hospital's governing body.

Skills

Competencies are understood as the set of knowledge and skills combined with human attitudes that allow medical practice, appropriate to the social context in which it is developed.54

In bioethics there is a set of knowledge that constitutes the body of the discipline and the basic framework that makes the acquisition of skills possible. The person with bioethical skills must be able to act on the ethical conflicts that arise in the provision of health services, to critically analyze them and make decisions that are ethically consistent. Knowing the theory of bioethics without knowing how to apply it critically to analyze a clinical case is not very useful; knowing and knowing how to do are complementary aspects.55

Professional skills

ÿ Identify the bioethical aspects of the dilemmas that arise.

ÿ Deliberate and issue recommendations for decision-making related to a bioethical dilemma.

Specific skills

ÿ Communicate and collaborate effectively within CHBs.

ÿ Identify, respect and appropriately consider patients' beliefs and perspectives. ÿ Use relevant health legislation.

ÿ Know the clinical context related to CHB.

ÿ Analyze bioethical issues and recurring concepts in CHB.

ÿ Access and use relevant ethics literature, policies, guidelines and standards.

Transversal skills

ÿ Critically analyze bioethical dilemmas.

ÿ Use different methodologies to address bioethical dilemmas.

ÿ Understand the most representative ethical foundations and bioethical positions.

ÿ Deliberate respectfully and competently in the committee to which you belong.

ÿ Ability to engage in respectful dialogue and accept the strongest arguments.

ÿ Know the national and international regulations on bioethics.

ÿ Practice effective and efficient decision making.

Designation

The head of the establishment will issue the letter of appointment to the official position to all members. In the case of a newly created Committee, the head of the establishment must appoint the President as well as the rest of the members. It is recommended that the management period of this first Committee be three years. It is advisable to consider a gradual replacement of the members to ensure that the new ones acquire knowledge and experience from their peers, as a way of

54 Leonard Mertens, *Labour Competence: Systems, Emergence and Models* (Montevideo: Cinterfor/ILO, 1996), 27-39.

55 Azucena Couceiro, “Teaching Bioethics and Competency-Based Curricula,” *Journal of Health Sciences Education* 11 (2; 2008): 69-76. http://scielo.isciii.es/pdf/edu/v11n2/colaboracion3.pdf (Accessed December 11, 2015).

a staggered replacement, which must be contemplated and specified in the Committee's internal regulations.

New members must be proposed by the Committee and ratified by the director or head of the establishment, paying special attention to potential members from outside the institution.
Any update to the Committee's composition must be recorded in the corresponding minutes of the session, notifying the National Bioethics Commission through official emails published on its website.

The letter of appointment granted to members must include the following minimum requirements:

- ÿ Name and position.
- ÿ Duration of the assignment.
- ÿ Confidentiality clause and the honorary nature of the member.
- ÿ Signature of the owner of the establishment.

These letters may also explicitly state the commitment of the Committee members to safeguard the interests of patients or users of the services, as well as the acceptance and compliance with the Committee's operating policies and provisions.

External consultants and the representative of health service users must have a special commitment to confidentiality, protection and use of information, in relation to their participation in the Committee's work sessions. These commitments must be expressed in the corresponding confidentiality letters, duly signed by the actors.

It is recommended that the participation of the representative of the users of health services be for a period of 1 to 2 years and preferably alternated by gender so that the citizen perspective can be contributed; he or she should not belong to any group that could generate conflicts of interest and hinder the functioning of the Committee.

The procedures for the appointment of members that must be included in the Committee's internal regulations are:

- ÿ Replacement procedure.
- ÿ Policy for renewal.
- ÿ Resignation procedure.
- ÿ Procedure for revocation of office.

Functions of the members

President

- ÿ Convene and chair sessions in accordance with the criteria established in the Committee guidelines and the needs of the establishment.

- ÿ Create and update the internal regulations as well as other normative and administrative documents of the Committee.
- ÿ Promote the Committee's ongoing training activities in bioethics.
- ÿ Notify the applicant and the corresponding authorities of the recommendations issued by the Committee.

- ÿ Coordinate the preparation of activity reports and facilitate access to the Committee's documentation to the head of the institution and the National Bioethics Commission.

Vocal Secretary

- ÿ Receive requests submitted to be discussed at Committee sessions.
- ÿ Organize the logistics of the Committee's work sessions.
- ÿ Record the minutes of the sessions and follow up on the agreements reached, as well as the resolutions issued by the Committee for each of the case requests submitted for consultation.

- ÿ Coordinate the integration of the annual program of activities that includes educational, consultative, and monitoring actions, with contributions from the members.
- ÿ Keep the Committee's files up to date by recording activities and corresponding documentation.

Vowels

- ÿ Participate in the analysis and deliberation of cases for the issuance of resolutions agreed upon by the Committee and to comply with its functions and objectives.
- ÿ Follow up on the agreements reached and identify issues that could be the subject of deliberation by the Committee, in order to take advantage of experiences in case analysis.
- ÿ Intervene in the benefit of the functioning of the Committee, making contributions to its administrative and regulatory functioning.
- ÿ Collaborate in training activities, updating in bioethics, and other actions, for the staff and population in the area of influence of the establishment.

The representatives of the users of health services, in addition to performing their duties in general like the rest of the members, must consider the importance of their role in the community by disseminating bioethics.

External consultants Advise

the Committee on bioethics, for the evaluation of bioethical problems or dilemmas, either personally in the sessions or by sending their technical comments.
Maintain confidentiality regarding the information to which access was obtained.

Expert consultants may be invited to sessions - subject to special confidentiality agreements - to provide information or help clarify ethical, religious, legal, medical and specialty issues, among others. They must provide their suggestions and opinions based on the discipline by which they were called to provide information to the case under analysis; however, they may not participate in the issuance of recommendations and must maintain confidentiality regarding the cases advised.

Installation

The Hospital Bioethics Committee must be established by means of an Installation Act, in a formal act with the respective authority. The Installation Act will specify the following data:

- ÿ Name or corporate name of the institution to which the Committee belongs.
- ÿ Address of the Committee, as well as the institution to which it belongs.
- ÿ Purpose of the Committee.
- ÿ Characteristics and functions of the Committee.
- ÿ Integration of the Committee.
- ÿ Powers of the Committee members.
- ÿ Method of financing the Committee's operating expenses.
- ÿ Place, date and time of installation.
- ÿ Legal basis containing the powers of the holder for the constitution of the Co-moth.
- ÿ Declaration by the owner of the establishment that the Committee is being established under his or her responsibility.
- ÿ Autograph signature of the person responsible for the establishment.

The objectives, functions and characteristics of the Committee, as well as the powers of its members and its financing method will be attached to the installation minutes. From the time of its installation, they will have sixty calendar days to issue their operating rules. The forms for the registration of the Hospital Bioethics Committee can be downloaded from the electronic page of the National Bioethics Commission.56

Operability

In the newly created Committees and during the first six months, members must undergo ongoing training in bioethics.

In the case of establishments that do not have a CHB because they do not comply with the criteria issued by CONBIOÉTICA and that identify a bioethical dilemma in their medical practice, they may request support and advice from the Committees registered with CONBIOÉTICA at the next higher level of care in their own institution. If this is not possible, they must contact the State Bioethics Commission or the National Bioethics Commission to request the assignment of a registered and competent Committee to review the bioethical dilemma in question.

The Committee shall establish its own rules of operation, which shall specify the functions of its members, as well as the internal mechanisms and procedures for operating its sessions. The Committee shall promote, with the head of the hospital, the dissemination, development and implementation of institutional bioethical guidelines and guides for medical care and teaching. It shall also promote the ongoing bioethical education of its members and hospital staff.

56 National Bioethics Commission, *Procedure for registration of Hospital Bioethics Committees (CHB),* http://www.conbioetica-mexico.salud.gob.mx/interior/registrocomites/Registro_CHB.html (Accessed December 11, 2015).

The National Bioethics Commission, with the support of the State Bioethics Commissions, may at any time request information from hospitals regarding the composition and operation of the Committees. The CHB must submit an annual report to the management of the institution and to the State Bioethics Commission, and if it does not have one, to the corresponding State Health Secretariat, which in turn will inform the National Bioethics Commission about the number of bioethical problems or dilemmas evaluated, the results of the evaluation and the relevant follow-up data.

Support for the Hospital Bioethics Committee

It is important that the members of the Committee receive support from the authorities of the institution, at least in the following areas:

- ÿ Time to participate in the Committee's regular and extraordinary sessions. ÿ Academic or work-related recognition for performance on the Committee.
- ÿ Support for ongoing bioethical training activities, inside and outside the institution. tion.
- ÿ Fixed physical space for the headquarters of the Hospital Bioethics Committee.
- ÿ Administrative assistance, since a formal record of queries made to the Committee is required.
- ÿ Material support for its performance and a bioethics library.
- ÿ Training of members.
- ÿ Compensation for transportation expenses - in the case of the community representative or the patients, depending on the case - and any additional compensation, if their participation would entail significant economic losses due to neglecting, postponing or suspending any remunerated activity.

- ÿ The operating expenses of the CHB must be financed by the authorities of the institution. This should not translate into conflicts of interest between the source of funding and the functions of the Committee.

Requests for intervention by the Hospital Bioethics Committee

Requests may be made by healthcare personnel, the patient or his/her family member, guardian or legal representative, as well as by those involved in the case being treated.

The Committee must establish a physical location within the hospital where requests for intervention are received, as well as establish mechanisms for reviewing the documentation necessary to adequately analyze the problem or dilemma that has been presented for consideration.
This procedure will allow you to optimize your work, avoiding an analysis that may lead to inappropriate recommendations or that may be misinterpreted, which may generate confusion and undermine confidence in the work of the committee. The president must call a meeting of the Committee.

Requests for intervention will be registered and must also be accompanied by a letter of request. It is advisable to facilitate the relationship between the CHB and health personnel or patients and their families so that simple procedures can be established that allow for organized work and allow for the maintenance of a file of the consultations carried out.

The Committee will issue rejections when the request for intervention does not correspond to its functions, in accordance with the procedure established in the internal regulations, for example, when the case does not contain a bioethical dilemma and involves administrative, labor, disciplinary or legal aspects, among others.

Sessions

The Committee shall meet regularly at least six times a year and in extraordinary sessions at any time, at the request of its Chairman, or when requested by the majority of its members. The Committee shall meet regularly and periodically according to the needs and workloads of the hospital.

Ordinary The

dates scheduled for the sessions will be announced through an annual calendar distributed to health personnel in advance. The sessions will be held when at least 50% plus 1 of the members are present, which must include the President and the Secretary of the Committee.

The debate is opened to the plenary session so that all members can present their arguments and clarify any doubts about the clinical aspects, giving rise to the start of the analysis of the clinical case with a bioethical dilemma and deliberation at a later stage.

The various courses of action that emerge from the deliberation should be presented, specifying which are considered the best. In the work of the Committees, the objective is to reach consensus, therefore, when there are dissenting opinions, it is important to point them out with the reasons.

The recommendations issued by the CHB must be included in the Committee's minutes and must be issued in writing to the consultant, so that he may decide how to act.

Extraordinary

sessions are those that need to be held outside of the regular schedule and that require a quick response. They will be organized taking into account the needs of the establishment, without the need to undergo formal review at a regular meeting. To be carried out, they will require the attendance of at least three members of the Committee, who will be appointed by the rest of the board based on their knowledge and clinical and bioethical experience.

The Committee shall establish the mechanism for convening and issuing recommendations within its internal regulations. The recommendations issued shall be reported to the Committee plenary at the next ordinary session.

Minutes

Minutes shall be drawn up for each of the Committee's sessions, and shall include the following information: 1. Date, time and place where the session is held; 2. Purpose of the meeting; 3. Name and signature of each of the members who attended; 4. Certificate of compliance with the resolution of the issues discussed at the meeting; 5. Agreements and recommendations reached by consensus based on cases with bioethical dilemmas.

Quorum

CHBs must establish specific *quorum* requirements for reviewing and deciding on an application. These requirements must include: the minimum number of members required, the attendance of the Committee Chair, and the attendance of half plus one of its members.

The *quorum* is not limited to the number of members; it is necessary to take into account the distribution of their skills. It cannot be constituted with the exclusive participation of members of the same profession or the same sex. If one of the persons who make up the Committee has a conflict of interest in relation to the case under consideration, he or she must declare himself or herself disqualified from that particular deliberation and may not participate in it.

Issuance of recommendations

The resolutions issued by the Committee are the result of the analysis and deliberation of the members present at the session and must be communicated by means of an official letter addressed to the applicant who presented the case.

Recommendations issued by the Committee should not be incorporated into the clinical record. Communication of the recommendation should include at least the following:

- ÿ Problem raised to the Committee.
- ÿ Documents reviewed.
- ÿ Name of the applicant.
- ÿ Date and place of the recommendation issued.
- ÿ Name and registration code of the Committee that issued the recommendation.
- ÿ Statement of the recommendation(s) issued. ÿ Date and signature of the CHB chair or secretary.

The recommendations issued are not binding, that is, the consultants cannot be forced to act in accordance with the Committee's recommendations; likewise, its members will not have any responsibility for the decision that the affected person (health personnel, patient or their relatives) chooses. The confidentiality commitment regarding the information submitted about the case will be respected, as well as the privacy of the patient and the applicant.

Information and archives The safekeeping of the archives will be the responsibility of the Chairman of the Committee in office. All documentation and communications of the CHB must be dated, numbered and archived in accordance with written procedures and applicable regulations. A definition of the access and retrieval procedure (including authorized persons) for the different documents, files and archives is required.

The classification of the information contained in the Committees' archives, for the purposes of access to public government information, must be carried out in accordance with the provisions of the applicable regulations. The protection and access to the Committee's information will be carried out in accordance with the provisions of the Federal Law on Transparency and Access to Public Government Information and its correlatives in the federal entities and in the Federal Law on the Protection of Personal Data.

in Possession of Private Parties, as appropriate, as well as in other provisions applicable to the matter.

It is the responsibility of the CHB to keep the files of the cases raised for five years from the date of their resolution. After the execution period has elapsed, they will be transferred to the institution's concentration archive.

The files (printed, magnetic or electronic data sources) that will be kept in the office of the Hospital Bioethics Committee must include at least:

- ÿ Minutes of the Committee's Installation.
- ÿ CHB internal regulations. ÿ CHB organisation and procedure manuals. ÿ Operational guides, national standards, international standards, technical documents and applicable regulatory texts.
- ÿ Identification list and updated curriculum of CHB members.
- ÿ Appointment of Committee members (copy).
- ÿ Programming of CHB sessions.
- ÿ Minutes of CHB meetings, listed consecutively by year.
- ÿ Evaluated cases, with all documentation analyzed and their respective recommendations, as well as follow-up reports, if required.
- ÿ Correspondence related to CHB.

Conflict of interest

The United States Institute of Medicine defined conflict of interest as *"circumstances that create a risk that a professional's judgment or actions with respect to a primary interest may be unduly influenced by a secondary interest."*57 The United Nations *defines it as "any circumstance or situation in which the professional judgment or the integrity of an individual's or an institution's actions with respect to a primary interest is unduly affected by a secondary interest, which may be financial or personal, such as professional or academic recognition, concessions or privileges to third parties."*58

The primary interest includes the promotion and protection of the welfare of patients, and where appropriate the quality of medical education. The secondary interest may be financial, which need not be substantial and which is often influenced without the physician being aware of it. Personal conflicts of interest are more difficult to recognize and document; professional and personal recognition and concessions or privileges to friends, family, students and colleagues also represent conflicts of interest. The third point is the risk that in certain circumstances professional judgment is unduly influenced by the secondary interest. 59

57 Cfr. Bernard Lo, Marilyn Field, (eds.), *Conflict of interest in medical research, education, and practice* (Washington, D.C.: Institute of Medicine/The National Academies Press, 2009).

58 United Nations, *Ethics Advice and Guidance/ Conflicts of Interest,* http://www.un.org/ethics/conflictofinterest.shtml (Accessed December 11, 2015).

59 Dennis Thompson, "Understanding financial conflicts of interest", *The New England Journal of Medicine* 8 Vol.329 (Aug 19; 1993): 573-576.

The possibility of facing conflicts of interest arises in different environments and disciplines, involving people or institutions. They can be intangible, such as those involving academic activities, or tangible, such as those related to economic interests.60 One aspect that has been the subject of attention worldwide for some years has to do with the interaction of doctors with the pharmaceutical industry. In Mexico, from the medical perspective,61 and from the pharmaceutical industry,62 there are recommendations to make these relationships transparent and avoid conflicts of interest.

Registry of Hospital Bioethics Committees

Establishments that must have a Hospital Bioethics Committee CHBs must request registration with the National Bioethics Commission, in accordance with the provisions of the First Provision of the Agreement issuing the *General Provisions for the Integration and Operation of Hospital Bioethics Committees* and establishing the hospital units that must have them.

According to the criteria established by the National Bioethics Commission, the establishments referred to in articles 69 and 70 of the Regulations of the General Health Law, in the Matter of Provision of Medical Care Services, must be part of a CHB. The purpose of the Registry is to compile information inherent to the integration and operation of the Committee for statistical and monitoring purposes.

Procedure

The documents to carry out the Registration process must be submitted electronically through the CONBIOÉTICA portal:

- ÿ Registration Request.
- ÿ Self-assessment format.
- ÿ Installation Certificate.
- ÿ Letters of appointment of the members.
- ÿ Document proving the legal status of the establishment.

The registration application contains the identification data of the Committee, such as: name and address of the establishment to which it belongs, date of installation, name and position of the members, contact information, email to receive notifications, as well as name and autograph signature of the applicant.

60 World Medical Association, *WMA Statement on Conflicts of Interest* (Moscow: 201st Session of the WMA Council, Revised October 2015). http://www.wma.net/en/30publications/10policies/i3/ (Accessed 11 December 2015).

61 National Academy of Medicine of Mexico, “Committee on Ethics and Transparency of Physicians with the Pharmaceutical Industry (CETRE-MI),” *Gaceta Médica de México* Vol. 151 (May-Jun; 2015): 293.

62 Pharmaceutical Industry Ethics and Transparency Council, *Code of Ethics and Transparency of the Pharmaceutical Industry* http://www.cetifarma.org.mx/codigos-y-documentos/quienes-somos/codigo-de-etica-y-transparencia (Consulted on: December 11, 2015).

The Self-Assessment Form is a diagnostic document that allows the Committee to identify the elements it has at the time of registration and contains the basic elements of its integration and operation.

The Installation Act establishes the functions and characteristics of the CHB, its integration and the identification data of the establishment where it is installed. It indicates that its constitution is under the responsibility of the owner of the establishment.

The Letters of Position Designation must be issued by the head of the establishment with his/her autograph signature, and contain the following elements:

- ÿ Name and position.
- ÿ Duration of the assignment.
- ÿ Confidentiality clause and the honorary nature of the member.
- ÿ Signature of the owner of the establishment.

The document that certifies the legal personality of the establishment must be: 1. For public institutions: Decree or agreement of creation published in the gazette, federal or state official journal. The supplementary document may be the internal regulations or organization manual of the establishment; and 2. For private institutions: Constitutive deed of the establishment, which is the public instrument granted before a notary public, through which the creation of a commercial company, civil association or civil society is recorded.

The corporate purpose must specify that it carries out one of the activities provided for in articles 69 and 70 of the Regulations of the General Health Law on the Provision of Medical Care Services.

Documents must be submitted for processing during business hours from Monday to Friday from 9:00 a.m. to 6:00 p.m. If any of the requirements are missing, they will be requested to be completed electronically within a period of fifteen business days, with the understanding that failure to do so will result in the application being deemed not submitted. In the event that the documents submitted do not meet the requirements, the applicant will be notified of the decision within a period of no more than ten days and the reason for rejection will be included.

Documents must not contain abbreviations, deletions or amendments. The names of members must not contain titles or abbreviations. The information provided for registration will be auditable by the appropriate authorities.

Registration Certificate Once the requirements have been met, the National Bioethics Commission will issue a Registration Certificate within fifteen business days. The certificate will contain the registration code and validity.

Validity of registration The validity period will be three years, after which time it may be renewed. The director or owner of the establishment must submit the application in the month prior to its expiration.

Completion of these procedures does not require payment of any fee.

Renewal of registration

The application for renewal of the registration must be requested within 30 business days prior to the expiration of the validity, for which the following must be submitted:

- ÿ Renewal application in the format previously established by the National Commission of Bioethics.
- ÿ Certificates of appointment of each of the members of the Committee.
- ÿ Simple copies of the professional certificates of the Committee members. In the case of representatives of users of health services who do not have a profession, they will be excluded from this obligation.
- ÿ Certificates of bioethics training for each of the Committee members, including representatives of users of health services.

Control and monitoring of Hospital Bioethics Committees

The integration and operation of the CHB are elements of analysis that allow establishing the level of quality of the services they provide, which is why it is important to maintain a control and monitoring system to identify areas of opportunity to ensure the optimal performance of their activities. In this sense, CONBIOÉTICA and/or the State Bioethics Commissions may request information from the establishment or institution so that the CHB participates in the control and monitoring system.

The control and monitoring program for Hospital Bioethics Committees will be carried out by CONBIOÉTICA with the participation of the corresponding State Bioethics Commission. The evaluation elements that have been established for this purpose are those stated in this Guide, in the requirements referred to in the sections on formation, installation and operation.

SALUD
SECRETARÍA DE SALUD

SOLICITUD DE REGISTRO DE COMITE
HOSPITALARIOS DE BIOETICA

CONBIOÉTICA
Comisión Nacional de Bioética

No. de Folio.

NOTA: Anexo instructivo de llenado del formato.

1. DATOS DEL ESTABLECIMIENTO			
Nombre del Establecimiento			
Nombre del representante legal			
DOMICILIO DEL ESTABLECIMIENTO			
Calle, Número y Colonia	Calle	Número	Colonia
Delegación o Municipio		Ciudad	
Entidad Federativa		Código Postal	
Correo electrónico		Teléfono	

2. INTEGRACION Y FUNCIONAMIENTO DEL COMITE			
Fecha de instalación	Día / Mes / Año		
Nombre del Presidente del Comité	Nombre(s)	Apellido Paterno	Apellido Materno
Nombre del Secretario del Comité	Nombre(s)	Apellido Paterno	Apellido Materno
	Correo electrónico		

CARGO	INTEGRANTES		
	Nombre(s)	Apellido Paterno	Apellido Materno

3. MARK WITH AN (X) THE ACCOMPANYING DOCUMENTS		
Committee Registration	☐	Installation Act
	☐	Certificates of appointment of each of the members
	☐	Self-assessment form

I declare under penalty of perjury that the information provided is correct and I undertake to provide, upon request of the National Bioethics Commission, any information, data or documents that may be required.		
4. PLACE		
5. DATE	Day / We / Year	
6. NAME AND SIGNATURE OF THE APPLICANT		

INFORMATION

National Bioethics Commission Calzada Arenal No. 134, 4th floor Col. Arenal Tepepan Tlalpan Delegation, CP 14610, Mexico City
Tel. 5487 2760 Ext. 59474
Website: http://www.conbioetica-mexico.salud.gob.mx/

LEGAL BASIS

Article 88 of the Regulations of the General Health Law on the Provision of Medical Care Services and Seventh Provision of the Agreement issuing the General Provisions for the Integration and Operation of Hospital Bioethics Committees and establishing the hospital units that must have them, in accordance with the criteria established by the National Bioethics Commission.

FILLING INSTRUCTIONS

This format must not contain abbreviations, deletions or amendments.

1. Enter the details of the corresponding establishment, legal representative, address, telephone number and email address where you will receive all types of notifications and notices.
2. Provide the committee details: installation date, name of the person responsible for the committee, name of the interlocutor with email address staff and other members.
3. Mark the documents that accompany the application, which must be submitted in a simple copy or in an electronic file.
4. Enter the place where the request was issued.
5. Note the date the application was issued.
6. Write the full name of the applicant, starting with the paternal and maternal surname and first name(s), as well as your signature.

SALUD
SECRETARÍA DE SALUD

CONBIOÉTICA
Comisión Nacional de Bioética

SELF-EVALUATION FORMAT

The Self-Assessment form is a diagnostic form that serves to determine the elements that the committee has at the time of registration.

CHB DATA			
Institution to which it belongs (e.g. SSA, IMSS, among others)			
Name of the establishment			
Address of the establishment	Street	Number	Cologne
	Postal Code	City	Federal entity
Health License Number			
CHB Phone	(- area code--)		
Name of the president			
Email			

SELF-EVALUATION ELEMENTS	BUT	
1. Confidentiality letters		
2. The integration complies with not including personnel from the governing body of the institution		
3. In its composition it is multidisciplinary		
4. Integration includes a representative of health service users		
5. Internal regulations		
6. Annual session program		
7. Annual training program		
8. Physical work area		
9. Administrative support for committee functions		
10. Procedure for requesting intervention by the committee for the analysis of clinical cases		
11. Procedure for monitoring recommendations issued by the committee		

Logo y nombre de la institución

Modelo de la Carta de designación del Presidente del Comité Hospitalario de Bioética

México, D.F., a (día) de (mes) del (año).

Asunto: Designación del Presidente del Comité Hospitalario de Bioética del (Establecimiento).

C. (nombre del Director (a)) por medio del presente documento y en función de las atribuciones que me confiere el cargo de Director (a) del (de la) (institución) se nombra al C. de profesión como Presidente del Comité Hospitalario de Bioética del (de la) (institución).

El cargo tendrá una duración de (número) de años y estará sujeto a los procedimientos internos reglamentados por el mismo Comité para efectos de renovación, sustitución, renuncia y/o descalificación del cargo.

Se anexa a la presente carta de designación de cargo, la declaración del C. _____ quien se compromete a cumplir con las funciones y obligaciones inherentes al cargo, incluyendo la aceptación del acuerdo de confidencialidad de confidencialidad, en la que se compromete a no hacer mal uso de la información a la que tenga acceso y en apego a la legislación aplicable. La integración al comité es de carácter honorífico.

La importante actitud ciudadana de aceptar el cargo de la Presidencia del Comité Hospitalario de Bioética de nuestra institución honra y demanda realizar las acciones para promover el desarrollo de la cultura bioética que nuestra sociedad demanda y merece la gratitud sincera en esta encomiable empresa social que el día de hoy Usted inicia.

Atentamente,

C. _____

Director (a) del (de la) (institución)

C.c.p
C.c.p
C.c.p

Logo y nombre de la institución

Modelo de la Carta de designación del Vocal Secretario del Comité Hospitalario de Bioética

México, D.F., a __(día) _de (mes) _del (año) _.

Asunto: Designación de cargo oficial del Vocal Secretario del Comité Hospitalario de Bioética del (Establecimiento).

C.__ (Nombre del Director de la institución) __, por medio del presente documento y en función de las atribuciones que me confiere el cargo de Director (a) del (de la) (institución) designo al C._____ de profesión _____ como Vocal Secretario del Comité Hospitalario de Bioética del (de la__ (institución) _____.

El cargo tendrá una duración de____ (número) ____ de años y estará sujeto a los procedimientos internos reglamentados por el mismo Comité para efectos de renovación, sustitución, renuncia y/o descalificación del cargo.

Se anexa a la presente carta de designación de cargo, la declaración del C._____ quien se compromete a cumplir con las funciones y obligaciones inherentes al cargo, incluyendo la aceptación del acuerdo de confidencialidad, en la que se compromete a no hacer mal uso de la información a la que tenga acceso y en apego a la legislación aplicable. La integración al comité es de carácter honorífico.

La importante actitud ciudadana de aceptar el cargo de Vocal Secretario del Comité Hospitalario de Bioética de nuestra institución honra y demanda realizar las acciones para promover el desarrollo de la cultura bioética que nuestra sociedad demanda y merece la gratitud sincera en esta encomiable empresa social que el día de hoy Usted inicia.

Atentamente,

C._____

Director (a) del (de la) (institución)

C.c.p
C.c.p
C.c.p

Logo y nombre de la institución

Modelo de la Carta de designación del Vocal del Comité Hospitalario de Bioética

México, D.F., a (día) de (mes) del (año).

Asunto: Designación de cargo oficial del Vocal del Comité Hospitalario de Bioética del __(Establecimiento)_____.

C.__ (Nombre del Director de la institución) __, por medio del presente documento y en función de las atribuciones que me confiere el cargo de Director (a) del (de la) (institución) designo al C._____ de profesión _____ como Vocal del Comité Hospitalario de Bioética del (de la__ (institución) _____.

El cargo tendrá una duración de___ (número) ___ de años y estará sujeto a los procedimientos internos reglamentados por el mismo Comité para efectos de renovación, sustitución, renuncia y/o descalificación del cargo.

Se anexa a la presente carta de designación de cargo, la declaración del C._____ quien se compromete a cumplir con las funciones y obligaciones inherentes al cargo, incluyendo la aceptación del acuerdo de confidencialidad, en la que se compromete a no hacer mal uso de la información a la que tenga acceso y en apego a la legislación aplicable. La integración al comité es de carácter honorífico.

La importante actitud ciudadana de aceptar el cargo de Vocal del Comité Hospitalario de Bioética de nuestra institución honra y demanda realizar las acciones para promover el desarrollo de la cultura bioética que nuestra sociedad demanda y merece la gratitud sincera en esta encomiable empresa social que el día de hoy Usted inicia.
Atentamente,

C._____
Director (a) del (de la) (institución)

C.c.p
C.c.p
C.c.p

Logo y nombre de la institución

Modelo del Acta de instalación del Comité Hospitalario de Bioética

Siendo las _____ horas del día _____ de _____ del _____, se reunieron los servidores públicos C. _____ y C.(opcional), con la finalidad de instalar el Comité Hospitalario de Bioética, en Institución con dirección en _____.

Fundamento legal

El Artículo 41 Bis de la Ley General de Salud, en el cual se establece la obligatoriedad de crear Comités Hospitalarios de Bioética en las instituciones del sector público, social o privado del Sistema Nacional de Salud.

El Acuerdo por el que se emiten las Disposiciones Generales para la Integración y Funcionamiento de los Comités de Hospitalarios de Bioética y se establecen las unidades hospitalarias que deben de contar con ellos, de conformidad con los criterios establecidos por la Comisión Nacional de Bioética.

La Guía nacional para la integración y funcionamiento de los Comités Hospitalarios de Bioética, en donde se establecen las especificaciones y procedimientos para la instalación, integración, conformación y funcionamiento de los CHB.

Artículo 88 del Reglamento de la Ley General de Salud en Materia de Prestación de Servicios de Atención Médica.

Integración del Comité Hospitalario de Bioética

El Comité Hospitalario de Bioética de la (institución) se integra de la siguiente manera:

Organigrama funcional
Presidente (1)
Vocal Secretario (1)
Vocales (mínimo 3)

Objetivos del Comité Hospitalario de Bioética

Los Objetivos de los Comités Hospitalarios de Bioética son:

a) Asesorar al personal de salud, usuarios y a la población en general en relación con los problemas y dilemas bioéticos, surgidos en la prestación de servicio de atención médica y docencia en salud desde una perspectiva laica y científica.

b) Fomentar la conciencia y participación de la población del ámbito de influencia del establecimiento de salud, con respecto en los avances de las ciencias básicas y conductuales, para contribuir a la sensibilización de sociedad en el debate de los problemas bioéticos.

c) Servir de foro para la reflexión de problemas y casos bioéticos para deliberar en los establecimientos de salud y en los ámbitos educativos locales.

Funciones del Comité Hospitalario de Bioética

Las funciones de los Comités Hospitalarios de Bioética son:

a) Actuar el interés de los participantes en la prestación de servicios hospitalarios y de las comunidades involucradas, en consideración con los fundamentos y principios bioéticos desde una perspectiva laica y científica y en conformidad con las regulaciones nacionales y de los hospitales.

b) Emitir alternativas de solución a los dilemas bioéticos que se pongan a su consideración, con base en análisis sistemáticos, propiciando la toma de decisiones razonadas y fundamentadas, contribuyendo así a salvaguardar la dignidad, los derechos, la seguridad y el bienestar de los participantes en la prestación de servicios de atención médica y docencia en el área de la salud.

c) Desarrollar acciones que ayuden a los miembros del Comité y al personal de salud del hospital a incorporar información, conocimiento y conductas para la identificación y posible resolución de dilemas bioéticos y así promover la educación bioética permanente de éstos.

d) Contribuir a la prevención de conflictos de interés que puedan surgir en la atención médica, a través de procedimientos orientadores; considerando el contexto social, económico, cultural y la congruencia con el momento histórico y el marco jurídico vigente.

e) Conformar y proporcionar informes periódicos de las actividades realizadas, con apego a la normatividad, a las instancias que correspondan para ser utilizados en la prospectiva de sus acciones.

Declaraciones

1. El C. _____, director o titular de la institución de salud denominada _____ manifiesta tener facultades para crear el Comité Hospitalario de Bioética, de conformidad con lo dispuesto a la normatividad aplicable.

2. El C. _____, director o titular de la institución de salud, manifiesta que bajo su responsabilidad se constituye el Comité Hospitalario de Bioética.

Cierre del acta

Habiéndose leído el contenido de este instrumento el C._____ director o titular de la institución de salud así como los integrantes del Comité Hospitalario de Bioética firman la presente acta de instalación.

Nombre, cargo y firma de cada uno de los integrantes del Comité Hospitalario de Bioética.

Presidente	Vocal Secretario
Vocal	Vocal
Vocal	Vocal
Vocal	Vocal

_____

Director o titular de la institución de salud

Attachments

Annex 1

Procedure for Registration of Hospital Bioethics Committees The owner of the health establishment must request registration of the CHB before the National Bioethics Commission, in accordance with the General Provisions for the Integration and Operation of Hospital Bioethics Committees and the Reforms to the Regulations of the General Health Law on the Provision of Medical Care Services: Art. 88.63

Instructions for registration of the Hospital Bioethics Committee

The CHB Registration process is only carried out electronically, so it is required that the documents be sent to the email chb.conbioetica@salud.gob.mx64, the requested documents son:

- ÿ Registration application.
- ÿ Self-assessment.
- ÿ Appointment letters. ÿ Installation certificate. ÿ
- Document proving legal personality.

In the event of omissions or errors in the content of any of the documents, CONBIOÉTICA will require the applicant to correct the omissions within fifteen business days from the date on which he/she was notified, noting that failure to do so will result in the application being deemed not to have been submitted.

Once the requirements have been met, the National Bioethics Commission will issue a certificate of registration within a maximum of fifteen business days; the validity of the registration is three years.

These procedures do not require payment of any fee and the hours for receiving documents will be on business days from Monday to Friday from 9:00 a.m. to 6:00 p.m.

To facilitate the work of the CHB, models of the requested documents can be downloaded from the institutional portal: www.conbioetica-mexico.salud.gob.mx

63 National Bioethics Commission, *Procedure for registration of Hospital Bioethics Committees (CHB),* http://www.conbioetica-mexico.salud.gob.mx/interior/registrocomites/Registro_CHB.html (Accessed December 11, 2015).
64 With copy to chb.conbioetica@gmail.com

Annex 2
doctor-patient relationship

The recognition that the patient is a person with the power to make decisions about his or her body and health has triggered a paradigm shift. Previously, a paternalistic view prevailed, but from 1969, with the first code of the rights of patients, the will and, above all, the autonomy of patients to decide about their own body was recognized.

The Medical Act65 has the following characteristics:66

- ÿ Professionalism: It can only be carried out by duly trained and accredited health personnel.
- ÿ Standardized execution: In terms of the *lex artis ad hoc,* health personnel may only perform actions that are expressly valid in light of generally accepted medical literature.
- ÿ Lawful purpose: The medical act is legitimate when it is carried out in accordance with the law, the *lex artis ad hoc* and the consent of the patient or his legal representative has been duly obtained.
- ÿ Non-formal: It does not require the formal contracting of services. Notwithstanding the above, the documentation of the medical act is mandatory in the clinical record, in terms of the provisions of the Regulations of the General Health Law, regarding the provision of medical care services and in the Mexican official standard NOM-004-SSA3-2012, of the clinical record NOM-024-SSA3-2012.

The doctor-patient relationship has been radically reformulated. Previously, the doctor acted and the patient complied, but today the patient's right to decide on the course of treatment is recognized,67 as well as the ethical and legal obligation of the doctor to provide the patient with all relevant information about his or her illness and treatment options.68

There are various types of doctor-patient relationships that can be classified as follows:69

- ÿ Paternalistic. The doctor decides for the patient.
- ÿ Informative. The decision depends exclusively on the patient.
- ÿ Interpretive. Interprets and ensures that the information provided is understood by the patient and attempts to assume what the patient's values are.

65 Set of actions that the user or patient receives in health services, which have as their objective the recovery of the patient and are performed by a health professional.
66 Ibero-American Association of Health Law, “Madrid Declaration”, *CONAMED Magazine* 4 Vol. 9 (October-December; 2004): 34-35.
67 Pablo Arango, “The doctor-patient relationship. An ideal for the 21st century,” *Medicas UIS* 1, Vol. 25 (January-April; 2012): 63-69.
68 Institut Borja de Bioética, *Foundations of bioethics: bioethical acts of the care relationship in a situation of fragility,* http://www.bioetica-debat.org/modules/news/article.php?storyid=55 (Accessed December 11, 2015).
69 Ezekiel Emanuel, Linda Emanuel, “Four models of the physician-patient relationship”, *The Journal of the American Medical Association* 16 Vol. 267 (Apr 22; 1992): 2221-2226.

- ÿ Deliberative. Through dialogue, the patient analyses the different values related to health, their importance and their indications for treatment.

These models are not unique and should be applied according to the circumstances and type of patient.

Annex 3

Case analysis and the deliberative process for decision making

Bioethics is a practical discipline that provides a structured approach to help health personnel identify, analyze and resolve ethical issues in clinical medicine.70 An ethical-clinical problem can be defined as the difficulty in making decisions regarding a patient, in the resolution of which it is necessary to refer to values or principles that specify what should be done as opposed to what can simply be done or is frequently done.

For this reason, in the deliberation of cases, an orderly pattern is required that facilitates the discussion and understanding of the ethical dilemma. Below are some specific methodologies, which, although not univocal, since the reflective exercise is rather ponderative, constitute a guide for the debate and orientation for health personnel.

The different methodologies or procedures for making ethical decisions could be classified into two large groups: those that establish a priori the ethical principles that must be respected (principlist or deontologist) and others that consider that the ethical judgment must be established a posteriori once the consequences that can be predicted as probable or certain have been evaluated (consequentialist or teleologist).

Over the last thirty years, various authors have developed different methodologies, some principlist and others consequentialist, for bioethical decision-making in healthcare practice. In 1979, T. L. Beauchamp and J. F. Hildress, inspired by the ethical principles of the Belmont Report, published their work Principles of Biomedical Ethics,71 which represents the first ethical theory of bioethics. Its methodological proposal is recognized as “principlist” because it attempts to resolve ethical problems in the biomedical field by adhering to the principles of autonomy, beneficence, non-maleficence and justice.

The casuistic method proposed by AR Jonsen, M. Siegler and W. J. Winslade72 is one of the first critics of principlism. The starting point of this method is not to begin by establishing great principles, but to study the specific cases that healthcare practice poses. For these authors, bioethics is "a discipline that provides a structured approach to identify, analyze and resolve ethical issues that arise in the field of clinical medicine."

The work of Diego Gracia73 and his methodological proposal introduce a hierarchy between the four “canonical” principles, based on the one hand on a reference system prior to the principles and, on the other hand, on the different degree or force of obligation existing between these principles. This author justifies the need to combine the principlist and consequentialist currents that occur in all ethical action, since he considers it an error to base ethical decisions in a dichotomous manner, since duties cannot be separated from consequences. Therefore, in the deliberation process, both moments are successive.

70 Howard Brody, *Ethical decisions in medicine* (Boston: Little Brown, 1981).
71 Tom Beauchamp, James Childress, *Principles of Biomedical Ethics,* 5th Edition (New York: Oxford University Press, 2009).
72 Albert Jonsen, Mark Siegler, William Winslade, *Clinical ethics,* 2010.
73 Diego Gracia, *Decision-making procedures in clinical ethics* (Madrid: Eudema; 1991).

In his work published in 1988,74 P. Thomasma considered it inappropriate to apply general ethical theories to all cases of bioethical dilemmas without considering the factors that may allow a choice between the various ethical principles at stake. For him, these factors are of two types: “facts” (clinical data) and “values” (of the doctor, the patient and society). Thus, his methodology aims to coherently articulate the facts and values within the clinical relationship established between the health professional and the patient.

It is advisable that the case analysis be carried out considering the following common points of study:

- ÿ Clinical data: diagnosis; therapeutic alternatives with benefits and risks; survival prognosis, based on evidence; and physical, psychological, spiritual and economic costs, among others.
- ÿ Social background.
- ÿ The patient's wishes regarding his or her treatment or family members.
- ÿ Conflicting values or doubts of those requesting review of the case.
- ÿ Resolution alternatives.
- ÿ Consequences of the alternatives.
- ÿ Principles involved in each alternative.
- ÿ Recommendation.
- ÿ Basis for the recommendation.

74 Edmund Pellegrino, David Thomasma, *For the patient’s good: the restoration of beneficence in health care* (New York: Oxford University Press, 1988).

Annex 4
Informed consent

Informed consent is the tangible expression of respect for the autonomy of individuals in the field of medical care and health research. It is a continuous and gradual process that takes place between health personnel and the patient and is consolidated in a document.

Through informed consent, health personnel inform the competent patient in sufficient quality and quantity about the nature of the disease and the diagnostic and/or therapeutic procedure that is proposed to be used, the risks and benefits that it entails, as well as possible alternatives.

The written document is only proof that the health personnel have informed and that the patient has fully understood the information. Therefore, informed consent is the manifestation of the responsible and bioethical attitude of medical or health research personnel, which raises the quality of services and guarantees respect for the dignity and autonomy of people.

In informed consent:

- ÿ It must be ensured that clear, truthful, sufficient, timely and objective information is provided regarding the care, diagnosis or therapeutic process; the risks, benefits (physical or emotional) and the duration thereof, as well as other alternatives, if any.

- ÿ Information should be given orally and personally, using non-technical language and appropriate to the individual's abilities. Health personnel should ensure that the patient or the responsible family members have understood the information provided and should encourage them to ask questions in order to provide the appropriate answers in an understandable manner. The educational level and socio-cultural background of the participants should be taken into account and appropriate language should be used.
- ÿ This aspect is important since the various cultural forms must be considered.
  The information must be given to a competent person (legally competent in age and mental capacity). It is important to mention that at any time during the process the patient may freely withdraw his or her consent.
- ÿ It is voluntary, the patient has the freedom of choice to accept or refuse without coercion, undue influence, incentive or intimidation to give or not consent to the doctors, about the proposed diagnostic or therapeutic procedures, after having been informed. A reasonable period of time must be considered for the patient, family or legal representative to make the decision.

- ÿ It is important to privilege the autonomy of patients, creating the necessary conditions for them to exercise their right to decide. In the case of patients with legal incapacity to give consent, their consent must be obtained.

Informed consent letter requirements

The minimum requirements that the informed consent letter must contain are the following:75

- ÿ Name of the institution to which the hospital belongs.
- ÿ Name, reason or corporate name of the hospital.
- ÿ Title of the document.
- ÿ Place and date of issue.
- ÿ Procedure or treatment to be applied and explanation of the same (it is important to ensure that the patient understands the procedure, the risks, benefits and available alternatives).

- ÿ Act that is authorized.
- ÿ Indication of the expected risks and benefits of the authorized medical act.
- ÿ Authorization to health personnel to deal with contingencies and emergencies arising from the authorized act, in accordance with the principle of prescriptive freedom.
- ÿ Full name and signature of the patient who is granting the authorization, if his/her state of health allows it. If his/her state of health does not allow him/her to sign and give his/her consent, the full name and signature of the closest family member who is present, the guardian or the legal representative must be entered, provided that there is prior indication to this effect by the treating physician.

- ÿ Full name and signature of the physician who provides the information and obtains consent for the specific act that was granted; if applicable, the data of the treating physician will be recorded.

- ÿ Full name and signature of two witnesses.

In addition, the following points can be considered:

- ÿ Benefits of the intervention or treatment such as: What improvement is expected to be obtained?, the criteria that have guided the professional in suggesting the procedure and the data of the intervention that are considered relevant or important.
- ÿ Possible discomfort from the procedure and its consequences.
- ÿ Risks, understood as those risks that are usually expected under normal conditions according to experience and the current state of science.
- ÿ Patient's statement of being satisfied with the information.

The document must be printed and written clearly, without abbreviations, amendments or deletions. In addition, the regulations of the General Health Law on the Provision of Medical Care Services indicate that in the medical-surgical procedures necessary to arrive at a diagnosis or to treat the condition in question, the informed consent of the patient must be obtained. NOM -004-SSA3-2012 Of the clinical record, it states at least the following processes:76

75 Mexican Official Standard NOM-004-SSA3-2012, Of the clinical record, *Sections 10.1 to 10.1.1.10* (October 15, 2012).
76 Official Gazette of the Federation (October 15, 2012).

ÿ Hospital admission.
ÿ Major surgical procedures.
ÿ Procedures that require general or regional anesthesia.
ÿ Salpingoplasty and vasectomy.
ÿ Organ, tissue and transplant donation.
ÿ Clinical research on humans.
ÿ Hospital autopsy.
ÿ Diagnostic and therapeutic procedures considered by the physician as high risk.

ÿ Amputation, mutilation or organic removal that produces permanent modification of the person.

Because people's values or objectives vary, the best choice is not always the one that prioritizes health, but rather the maximum well-being according to the values or objectives of each person. Therefore, it is important to have the advice of a Hospital Bioethics Committee that guides the competent exercise of health professionals when there is a discrepancy between health personnel and the legal representative, regarding the best decision for the patient.

In the case of persons who are legally unable to give consent, it will be necessary to obtain the authorization of a legal representative. Whenever possible, the patient's consent should be obtained. It is important to ensure that the patient's legal representative or family member is seeking the patient's best interest and has the capacity and competence required to make the decision.

Consent must be expressed and verified in writing using a signed form when it is a high-risk procedure. This must contain true, clear and complete information about the procedure the patient is going to undergo and its possible complications. Illiterate patients must print their fingerprint on the document and appoint a witness to sign, attesting to their consent. An original is prepared for the patient's file and a copy is given to the patient. The purpose of this document is for the patient to take home, review and discuss with whomever they consider appropriate, in case any doubts arise and as a guarantee that the procedure they were informed would be carried out.

Confidentiality

The patient's right to confidentiality is protected by various national and international legal provisions, highlighting section 5.7 of the Mexican Official Standard NOM-024-SSA3-2012, of the Clinical Record:77

Mentally competent adult patients may not share their personal information with other people, even close family members, in which case physicians and health care personnel shall have the obligation to respect the patient's wishes. Medical personnel shall not discuss any patient's medical information in public places or permit the disclosure of patient information in an inappropriate manner.

77 Mexican Official Standard NOM-004-SSA3-2012, From the clinical record (October 15, 2012).

Confidentiality may be waived in some circumstances, however, the implications of breaching confidentiality must be considered. Circumstances in which this obligation may be waived include:

- ÿ The possibility of harming third parties.
- ÿ Due to legal circumstances where reporting to health authorities is required (in cases where there is a risk to public health, due to the risk of an epidemic).
- ÿ Medical information about minors should not be hidden from their parents.

In medical practice there are cases that require special considerations depending on age, type of disease or life expectancy.

Annex 5

End of life and palliative care

At the end of life, there are challenges in the comprehensive management of patients that are frequently accompanied by ethical dilemmas involving all members of the health team.

Palliative care is an approach aimed at improving the quality of life and symptom management of patients, both adults and children, who suffer from chronic, incurable diseases, and their families. Its essence is to offer a comprehensive and multidisciplinary approach to provide prevention and relief from pain, suffering and other physical, psychosocial and spiritual problems associated with their illness.78

Palliative care is based on a philosophy that affirms life and considers death as a natural process, without seeking to influence the moment of its occurrence; support systems are offered so that patients can live as actively as possible until the moment of death and so that families can cope with the patient's illness and also their own grief. They can be administered from the initial stages of the disease, together with other treatments that aim to.79

The World Health Organization (WHO) recognizes that more than 40 million people in the world need palliative care each year and this number is expected to continue to increase.80 However, due to various political, legislative, educational, psychological, social, cultural and economic factors, palliative care is only provided to a small fraction of people who require it.81

Communication with patients and families

One of the most difficult aspects of dealing with patients in palliative care is undoubtedly information. During this period, discussions about complex decisions that must be faced by the patient and his or her family are frequent. Health personnel also sometimes find it difficult to provide bad news, discuss the relevance of continuing with treatments for the disease, talk about the prognosis, offer the option of palliative treatment, artificial nutrition or hydration, the use of expensive medications, and do-not-resuscitate orders. The way of providing information to the patient and family must be individualized.

78 Human Rights Watch, *Caring when cure is not possible. Ensuring the right to palliative care in Mexico,* https://www.hrw.org/es/report/2014/10/28/cuidar-cuando-no-es-posible-cuar/ensuring-the-right-to-palliative-care-en (Accessed December 11, 2015).

79 World Health Organization, *WHO definition of palliative care,* http://www.who.int/cancer/palliative/definition/en/# (Date of (accessed: December 11, 2015).

80 World Health Organization, *Strengthening palliative care as part of comprehensive treatment throughout life* (Geneva: 67th World Health Assembly, 24 May 2014). http://apps.who.int/medicinedocs/documents/s21454en/s21454es.pdf (Accessed: December 11, 2015).

81 Worldwide Palliative Care Alliance, *Global Atlas of Palliative Care at the End of Life* (Londres: WPCA/OMS, 2014). http://www.the-whpca.org/resources/global-atlas-on-end-of-life-care (Accessed 11 December 2015).

Points to consider before starting the conversation with the patient and family:

ÿ Review the patient's clinical progress over the past six months and analyze laboratory and imaging studies. The patient's age and associated diseases.

ÿ Find a suitable place to talk. Information should be provided in a private location and avoid interruptions.

ÿ Do not give important or sensitive information over the phone, except when face-to-face discussions are difficult due to geographical reasons.

ÿ Analyze the possibilities of improvement with different treatment options, the percentage of improvement that could be expected with treatment, and how long the response will last.

ÿ What side effects and toxicities are expected.

ÿ The balance between potential benefits and risks.

ÿ It is important to have enough time to be able to answer the questions of the patient and their family.

ÿ The presence of a family member with the patient should be suggested.

ÿ Avoid being impersonal, try to be warm.

ÿ Start the conversation by mentioning the need to talk about the disease.

ÿ Ensure that they have understood the information provided (for example, “Tell me what you know about your illness at this time”)

ÿ Ask the patient about his or her expectations (for example, what do you think will happen with your illness in the future? What is important to you?)

ÿ Provide medical information if necessary.

ÿ Never say there is nothing else to do.

ÿ Patients interpret this as meaning that there is no treatment for any of their symptoms, they feel abandoned. It can be said that there is no treatment for the disease, emphasizing that symptom management will continue.

ÿ When talking about the forecast, explain the difficulty in providing it.

ÿ Never give precise dates or times.

ÿ You have to be realistic, listen to the personal aspects that are important to the patient

ÿ Talk about family relationships and aspects that need to be addressed.

ÿ Prepare to answer questions regarding death.

ÿ Reaffirm the continuity of treatment.

ÿ Discuss medical care.

ÿ Ask about your wishes to receive hydration, transfusions and antibiotics, among others. others.

ÿ Explain the benefits and risks (or reluctance) of any intervention.

ÿ Discuss do not resuscitate orders.

ÿ Start the conversation in a prudent manner, for example, “we need to talk about a topic that we discuss with patients who are admitted to the hospital.”

Therapeutic Obstinacy

Dystanasia or therapeutic obstinacy is the unnecessary or futile prolongation of treatments.
For the American Medical Association, futile treatments are those that do not have a reasonable chance of benefiting the patient. It is important to have good communication with patients and to inform them in a clear and simple manner about the characteristics of the disease, the prognosis and the objectives of possible treatments.82

Ideally, discussions about prognosis and therapy goals should be dynamic processes in which information is provided at regular intervals according to the evolution of the disease. It is important to bear in mind that the concept of futility can be perceived differently and patients or their families may request disproportionate treatments. In these cases, the intervention of Hospital Bioethics Committees is valuable.83

Quality of death

Improving quality of life is an acceptable goal for health teams that care for patients with chronic, life-threatening diseases and the elderly. However, although death is one of the few events that we can be certain will happen to us, in most countries (even the richest ones), there are no health policies that contemplate end-of-life care for a good quality of death. The *Economist Intelligence Unit* has published for the second time a Quality of Death Index that considers the availability of health services and access to palliative care, the human resources allocated, the costs of care and the level of community participation.84

The quality of death in Mexico

Even though the General Health Law was reformed by adding a special title of palliative care for terminally ill patients, and there is legislation in some states regarding advance directives, the conditions for care of these patients require a different approach, in order to reduce costs and improve the quality of care, as well as to educate the public debate around the topic.85 Many doctors, patients and family members in Mexico still perceive palliative care services as a defeat and synonymous with suffering and death.

The determining factors in the quality of death of Mexicans are the lack of access to opioids and the excessive regulations for prescribing them. In this regard, it is worth mentioning that, in response to the recommendations of the WHO and the recent demands of groups such as Human Rights Watch, *Tómatelo a Pecho* and the Mexican Foundation for Health, the federal government has taken decisive measures to implement these services - which were offered almost exclusively in large hospitals.

82 Ammy Sullivan, Matthew Lakoma, Robin Matsuyama, et. al. “Diagnosing and discussing imminent death in the hospital: a secondary analysis of physician interviews”, *Journal of Palliative Medicine* 4, Vol. 10 (Aug; 2007): 882-893.
83 Eric Chow, et, al. “Patients with advanced cancer: a survey of the understanding of their illness and expectations from palliative radio-therapy for symptomatic metastases”, *Clinical Oncology* 3, Vol. 13 (2001): 204-208.
84 Human Rights Watch, *Caring when healing is not possible…* https://www.hrw.org/en/report/2014/10/28/caring-when-healing-is-not-possible ble-cure/ensuring-the-right-to-palliative-care-in (Consultation date: December 11, 2015).
85 The Economist Intelligence Unit/Lien Foundation, *The 2015 Quality of Death Index* (London/New York/Hong Kong/Geneva: The Economist Insights, 2015). http://www.economistinsights.com/healthcare/analysis/quality-death-index-2015/ world (Accessed 11 December 2015).

specialized hospitals and in federal entities with greater economic development, which include everything from structural reforms to guarantee access to these medications to the integration of palliative care subjects into the country's health education programs.

Advance directive

Advance directive can be defined as a process by which a person plans the health care and treatments that he or she wishes to receive or reject in the future, particularly for the time when he or she is no longer capable of making decisions for himself or herself.

The General Health Law refers to the advance directive in section X, of article 166 Bis 3 and article 166 Bis 4, as follows:

Article 166 Bis-3. Terminally ill patients have the following rights:

- ÿ Section X. Designate a family member, legal representative or a person of their trust, in case that, as the disease progresses, they are unable to express their will, to do so on their behalf.
- ÿ Article 166 Bis 4. Any adult, in full use of his or her mental faculties, may, at any time and regardless of his or her state of health, express his or her will in writing before two witnesses, to receive or not to receive any treatment, in the event that he or she should suffer from an illness and be in a terminal situation and is unable to express such will. This document may be revoked at any time.

An increasing number of states also have legislation on advance directives. To date, the following states have an advance directive law: Aguascalientes, Coahuila, Colima, Chihuahua, Federal District, State of Mexico, Guanajuato, Guerrero, Hidalgo, Michoacán, Nayarit, San Luis Potosí, and Oaxaca.

In the case of the Federal District, the Advance Directive Law aims to establish and regulate the rules, requirements and forms of realization of the will of any person with capacity to exercise it, regarding the refusal to undergo means, treatments and/or medical procedures that seek to unnecessarily prolong his or her life, protecting at all times the dignity of the person, when for medical, fortuitous or force majeure reasons, it is impossible to maintain his or her life in a natural way.

This law establishes the legal procedure for a person to prepare his or her advance will in a document with legal validity. The will must be recorded in writing in the so-called Advance Will Document, which can be granted by any person at any time. There are two ways to subscribe to the Advance Will Law: 1. Advance Will Document, which is granted before a notary by persons over 18 years of age, with the capacity to exercise their rights and in full use of their mental faculties, and who may or may not have a terminal illness. 2.
The Advance Directive form is issued in Public and Private Hospitals in the Federal District to patients who suffer from a terminal illness. It is signed by the terminally ill patient or his/her representative (in the case of minors and persons without decision-making capacity), before the medical staff of the hospital where the person is located.

Annex 6

Establishments that must have a Hospital Bioethics Committee in accordance with the General Health Law.86

In accordance with the provisions of the First Provision of the Agreement issuing the "General Provisions for the Integration and Operation of Hospital Bioethics Committees and establishing the hospital units that must have them, in accordance with the criteria established by the National Bioethics Commission", a Hospital Bioethics Committee must be established in those establishments referred to in articles 69 and 70 of the Regulations of the General Health Law on the Provision of Medical Care Services:

Article 69.- For the purposes of this Regulation, a hospital is understood to be any public, social or private establishment, regardless of its name, whose purpose is to care for patients who are admitted for diagnosis, treatment or rehabilitation. It may also treat outpatients and carry out activities for the training and development of health personnel and research.

Article 70.- Hospitals will be classified according to their degree of complexity and resolution power as follows:

I. General Hospital: This is the second or third level establishment for patient care in the four basic specialties of medicine: General Surgery, Gynecology and Obstetrics, Internal Medicine, Pediatrics and other complementary and support specialties derived from them, which provide emergency services, outpatient consultations and hospitalization.

The hospitalization area will have beds for General Surgery, Gynecology-obstetrics, Internal Medicine and Pediatrics in general hospitals, where care will be provided in the different branch specialties.

In addition, it must carry out prevention, treatment and rehabilitation activities for users, as well as training and development of personnel for health and scientific research;

II. Specialty Hospital: This is a second and third level establishment for patient care, of one or more medical, surgical or medical-surgical specialties, that provides emergency services, outpatient consultation, hospitalization and that must carry out prevention, cure, rehabilitation, training and development activities for health personnel, as well as scientific research.

III. Institute: cited This is a third-level establishment, primarily intended for scientific research, training and development of health personnel. It may provide emergency services, outpatient consultations and hospitalization to people who have a specific disease, a system condition or diseases that affect a certain age group.

86 Official Gazette of the Federation (October 31, 2012).

Annex 7

Hospital Bioethics Committees as a requirement for Certification and Accreditation of health facilities

Hospital Bioethics Committees are a support and guide for decision-making when bioethical dilemmas arise. Their functions include:

a. Resolve problems arising from medical care.
b. Analyze, discuss and support decision-making regarding bioethical problems that arise in clinical practice or in teaching in the health area.
c. Promote the development of ethical guidelines and guides for medical care and teaching.
tip.

Among the standards for the *Certification of Healthcare Establishments of hospitals,* in the area of Government, Leadership and Management, is having a Hospital Bioethics Committee in Standard GLD.6.2. The establishment's framework for ethical management supports ethical decision-making regarding medical care.87

Starting in 2012, public hospitals that do not have a prior Certification must first pass the *Accreditation as providers of health services* to beneficiaries of the Social Health Protection System.

87 General Health Council, *Standards for certifying hospitals 2015* (Mexico: Ministry of Health/General Health Council). neral, 2015).

Annex 8

Conscientious objection

Conscientious objection is a subjective conflict between a legal mandate and an ethical or religious norm that prohibits compliance. As ethical pluralism in our society grows, so does the number of conflict situations in the health field between what the law prescribes, what patients want, and what the doctor does.

Conscientious objection, which has been defined as:

"The individual decision taken by a health professional to stop performing a medical act scientifically and legally approved according to the *ars* medica, claiming that it violates his freedom of thought, conscience or religion (moral principles and religious beliefs). This can only be acceptable as a strategy of resistance as long as it does not generate a greater harm than the one it is supposed to correct; in other words, when it does not violate the right to health of the patient who has requested the medical act that is intended to be objected to."88

In this regard, the Universal Declaration of Human Rights in its article 18 establishes the following:

"Everyone has the right to freedom of thought, conscience and religion; this right includes freedom to change his religion or belief and freedom, either individually or in community with others and in public or private, to manifest his religion or belief in teaching, practice, worship and observance."89

Likewise, the American Convention on Human Rights recognizes in its Article 12, freedom of conscience and religion, stating that:

1. Everyone has the right to freedom of conscience and religion. This right includes freedom to maintain or change one's religion or belief, and freedom, either individually or in community with others and in public or in private, to profess and spread one's religion or belief.
2. No one may be subjected to restrictive measures which may impair his freedom to maintain his religion or beliefs or to change his religion or beliefs.
3. Freedom to manifest one's religion and beliefs is subject only to such limitations as are prescribed by law and are necessary to protect public safety, order, health, or morals, or the rights and freedoms of others.90

88 College of Bioethics, *Conscientious Objection,* http://colegiodebioetica.org.mx/wp/links-laterales/postura-del-colegio-de-bioeti-ca-ante-la-objecion-de-conciencia-en-la-atencion-medica/objecion-de-conciencia/ (Consultation date: December 11, 2015).

89 United Nations, *Universal Declaration of Human Rights* (Geneva: UN General Assembly 217 A (III), December 10, 1948).

90 Organization of American States, *American Convention on Human Rights (Pact of San José)* (San José: OAS, 22 November 1969).

It should be noted that the Committees are not legal-administrative bodies, so they do not issue binding pronouncements; their function is limited to guiding decision-making and the resolution will be issued by the corresponding bodies.

Glossary

Assent

The process of inclusion and promotion of the autonomy of a minor in decision-making on issues that concern him or her.

Bioethics

The branch of applied ethics that reflects, deliberates and makes normative and public policy proposals to regulate and resolve conflicts in social life, especially in the life sciences, as well as in medical practice and research that affect life on the planet, both currently and in future generations. CONBIOÉTICA Council.

Community

A group of people who share characteristics or interests.

Confidentiality

The obligation not to communicate information about an individual in order to protect his or her preferences and rights.

Conflict of interest

These are circumstances in which professional judgment in relation to a primary interest - such as the well-being of the patient in the case of the doctor - is influenced by a secondary interest, such as financial benefit or professional recognition.

Dilemma

The juxtaposition of two theses, such that if one is considered true, the other will necessarily be false.

Privacy

Protection against third party intrusion into a person's thoughts or assets.
end.

Vulnerability

Condition of the human being, which refers to his capacity to be hurt. Social vulnerability expresses the economic and social inequalities between different population groups.

Suggested readings

ÿ Beauchamp, Tom; James Childress. Principles of Biomedical Ethics (5th Edition). New York: Oxford University Press, 2009.

ÿ Calipari, Maurizio. *Healing and being healed: between patient abandonment and therapeutic obstinacy.* Buenos Aires: Educa, 2007.

ÿ Calipari, Maurizio. “The principle of proportionality in therapy: foundations and applica-tions criteria”. *NeuroRehabilitation* 4 Vol. 19 (2004): 391-397. ÿ Fletcher, John; et al.

Introduction to clinical ethics. Frederick, Maryland: University Publi-shing Group, 1995.

ÿ Gómez-Lobo, Alfonso. *Human Goods: Ethics of Natural Law.* Santiago, Chile: Medi-terráneo, 2006.

ÿ Gracia, Diego. *Decision-making procedures in clinical ethics.* Madrid: Eudema, 1991.

ÿ Gracia, Diego. *Foundations and teaching of bioethics.* Bogotá: Editorial El Búho, 1998.

ÿ Heitman, Elizabeth. “Institutional Ethics Committees: Local Perspectives on Ethical Issues in Medicine”. En *Society’s Choices: Social and Ethical Decision Making in Biomedicine,* edi-tado por Ruth Ellen, Elizabeth Meyer, Harvey Fineberg. USA: Institute of Medicine, 1995.

ÿ Jonsen, Albert; Mark Siegler; William Winslade. *Clinical ethics: a practical approach to ethical decisions in clinical medicine* (7th. Edition). New York: McGraw-Hill, 2010.

ÿ Koepsell, David; Manuel H Ruiz de Chávez. *Research ethics. Scientific integrity.* Mexico: National Council of Science and Technology/National Bioethics Commission, 2015.

ÿ Lavados, Manuel; Alejandro Serani. Clinical Ethics: Fundamentals and Applications. Santiago de Chile: Catholic University of Chile, 1993

ÿ Lifshitz, Alberto. “The doctor-patient relationship at the dawn of the 21st century”. In *The current practice of medicine,* coordinated by Octavio Rivero, Miguel Tanimoto. Mexico: Siglo XXI Editores, 2000.

ÿ Lo, Bernard; Steven *Schroeder.* “Frequency of ethical dilemmas in a medical inpatient ser-vice”. *Archives of Internal Medicine* 8 Vol. 141 (Jul; 1981): 1062-1064.

ÿ Pellegrino, Edmund; David Thomasma. *For the patient´s good. The restoration of benefi-cence in health care.* New York: Oxford University Press, 1988.

ÿ Pope, Thaddeus Mason. “Legal briefing: healthcare ethics committees”. *The Journal of Clinical Ethics* 22, no. 1 (Spring; 2011): 74-93. ÿ Sgreccia, Elio.

Manual de bioética. México: Diana, 1996. ÿ Slowther, Anne; Carol

Johnston; Jane Goodall; Tony Hope, “Development of clinical ethics committees”, *British Medical Journal (Clinical Research Ed)* No. 7445, Vol. 328 (Apr 17; 2004): 950-952.

ÿ Tealdi, Juan Carlos. “The Georgetown Principles: A Critical Analysis”. In *Epistemo-logical Statute of Bioethics,* coordinated by Volnei Garrafa, Miguel Kottow, Alya Saada. Mexico: UNESCO/UNAM, 2005.

ÿ Teel, Karen. “The physician’s dilemma: A doctor’s view: What the law should be”. *Baylor Law Review* Vol. 27 (1; 1975): 6-9.

ÿ Valdez-Martínez, Edith; Miguel Bedolla. "Clinical ethics committees in Mexico: their development in the IMSS". *Medical Journal of the Mexican Institute of Social Security* 3 Vol. 45 (May-Jun; 2007): 265-268.

ÿ Valdez-Martínez Edith; Alberto Lifshitz; José Medesigo; Miguel Bedolla. “Clinical ethics committees in Mexico: the ambiguous border between healthcare ethics and ethics in clinical research”. *Pan American Journal of Public Health* 2 Vol. 4 (Aug; 2008):85–90.

Places of interest

ÿ World Medical Association ÿ http://

www.wma.net/en/10home/index.html ÿ CDC Associate Director for
Science ÿ http://www.cdc.gov/od/science/ ÿ CIOMS

ÿ http://www.cioms.ch/ ÿ World Health Organization
ÿ http://

www.who.int/en/ ÿ PAHO/PAHO/

WHO Regional Program on Bioethics ÿ http://

www.paho.org/HQ/index.php?

option=com_content&view=article&i-d=5582%3A2011-regional-program-

on-bioethics&catid=3347%3Abioethics&Itemi-d=4124&lang=en

ÿ The Nuffield Council on Bioethics ÿ http://

nuffieldbioethics.org/ ÿ UN Universal

Declaration of Human Rights ÿ http://www.un.org/en/universal-

declaration-human-rights/ ÿ US National Bioethics Advisory Commission ÿ http://

bioethics.gov/ ÿ US Office of Human Research ÿ http://

www.hhs.gov/ohrp/ ÿ Operational
Guidelines for Ethics Committees Reviewing

Biomedical Research http:// apps.who.int/

iris/bitstream/10665/66641/1/TDR_PRD_ETHICS_2000.1_eng.pdf ÿ UNESCO Universal Declaration on Bioethics and Human Rights ÿ http://portal.unesco.org/es/ev.php-URL_ID=31058&URL_DO=DO_TOPIC&URL_SEC-

TION=201.html

ÿ Information brochure for Hospital Bioethics Committees ÿ http://www.conbioetica-

mexico.salud.gob.mx/opencms/opencms/sites/cnb/descar-gas/pdf/registrocomites/Folleto_CHB.pdf ÿ Ministry of Health ÿ http://www.gob.mx/salud ÿ National Bioethics Commission ÿ http://
www.conbioetica-

mexico.salud.gob.mx/ ÿ Library of the
National Bioethics Commission - Friends of

CONBIOÉTICA ÿ http://amigosconbioetica.salud.gob.mx/

Directory

Secretary of Health Dr. Mercedes Juan Lopez

National Bioethics Commission

Chairman of the Board Dr. Manuel H Ruiz de Chavez

Deputy General Director Ms. America Nelly Perez Manjarrez

Director of the Center for Bioethical Knowledge Anthrop. David Alejandro López Vibaldo

Director of Operations Dr. Emma Verastegui Avilés

Director of Planning and Academic Development Mr. Raúl Jiménez Piña

Director of Administration and Finance Mr. Alfredo Reyna Ángel

http://conbioetica-mexico.salud.gob.mx Calzada Arenal No. 134, corner with Xochimaltzin, Col. Arenal Tepepan, Tlalpan District, CP 14610. Phone: 5487 2760

The National Guide for the Integration and Operation of
Hospital Bioethics Committees was completed
in December 2015 at Edamsa Impresiones SA de CV, Av.
Hidalgo 111, Col. Fracc. San Nicolás
Tolentino CP 09850, Iztapalapa, Mexico City.
The edition consists of five thousand copies plus surplus for replenishment.
The editing was carried out by David Alejandro López Vibaldo, Alma Rosa Macedo
de la Concha, Mario Patricio Silva Schütte and Alfonso Heredia
Arriaga.

ISBN 978-607-460-516-7

9 786074 605167