National Guidelines for the Integration and Operation of the Hospital Bioethics Committees (HBC)

Conceptualization of the Hospital Bioethics Committee

Hospital Bioethics Committees are open spaces to reflection, discussion and education, in an atmosphere of freedom and tolerance, which systematically analyze the conflicts of values and ethical principles that may arise during the process of health care and education in the health area. They are formed as autonomous, institutional, interdisciplinary, pluralistic and consultative bodies. Committees can be regarded as a guide and a support for decision-making when bioethical dilemmas arise, making sure that they take into account the values and bioethical principles of all those involved in the clinical setting. They are a government guarantee and an element to promote interdisciplinary education and education in many sectors. They represent the institutional expression of bioethics in health institutions. The Hospital Bioethics Committees should advise, educate and promote the creation of institutional procedures, and under no circumstances, they will substitute the responsibility of doctors on their patients.

Objectives
The Hospital Bioethics Committees' objectives are:

a. To advise health-care personnel, patients and general public about bioethical problems and dilemmas arising from the provision of health care services and education in the health area.

b. To increase awareness and participation of the population in the influence field of the health establishment, regarding the advances in basic and behavioral sciences in order to contribute to public awareness for the discussion of bioethical issues.

c. To serve as a forum for reflection, focused on the multiplicity of problems and bioethical cases, in order to discuss about the health facilities and about local educational fields.

Roles
The roles of the Hospital Bioethics Committees are:

a. To work for the interest of the participants in the provision of hospital services and the communities involved, taking into account the grounds and principles of bioethics, in compliance with national and hospitals regulations.
b. To give alternative solutions to bioethical dilemmas that are brought to its consideration based on systematic analysis, leading to reasonable and founded decision-making, in order to help safeguarding the dignity, the rights, the safety and the welfare of the participants health care services provision and during the educational process in the health area.

c. To develop actions to help the Committee members and hospital staff to incorporate information, knowledge and behaviors to identify and possibly solve bioethical dilemmas; therefore, to promote a permanent bioethics education for its members and the staff.

d. To contribute to the prevention of conflicts of interest that may arise in health-care, through establishing guidance procedures that consider the social, economic and cultural context, which are consistent with the historical and the current legal framework.

e. To form and provide periodic reports in accordance with the regulations of the performed activities to the appropriate instances to be used in their future actions.

General functions

Advisory function: The examination of clinical cases that a bioethical dilemma has is one of the main functions of the Hospital Bioethics Committees (HBC). The main objective is the solution of bioethical problems in order to contribute to the improvement of health care quality. The advisory activity can lead to the creation of institutional action protocols, as a way of preventing future similar situations. The CHB advisory activity should have among its objectives to provide the hospital staff with tools, knowledge and skills that allow them to identify bioethical problems, promote practices and correct behaviors, and to implement measures to prevent future ethical problems.

The Hospital Bioethics Committees are advisory organs, not responsible of the decision making, but limited to advising, orienting or giving opinions (just for support) to the health-care team in order to achieve the patient’s maximum benefit. In general, they can only intervene when it is requested by any of the parties concerned: the patient, their family, their legal representatives or health-care staff. The CHB appeals, if necessary, to the opinions of experts in medical practice and the various people involved, then analyzes the information received and makes recommendations.
Guiding function: These activities allow to anticipate conflicts that may arise in medical attention through guiding action procedures. These protocols should consider the institution’s socio-economic and cultural context and they should be consistent with the existing legal framework.

The CHB can take a proactive role in the detection of situations that may create a bioethical conflict. The guiding function includes the following subjects:

- It establishes procedures for decision-making in clinical fields that include value conflicts, such as: treatment refusal, decision-making for people without the capacity to express their consent\(^1\), such as minors, mentally handicapped people, people who suffer temporal loss of consciousness state, among others.

- It establishes dialogue processes and expressed consent with clinical areas, to promote a good relationship between health-care personnel and patients.

- It performs analysis on bioethical issues related to organ and tissue donation and transplantation from living and dead donors, for example: capacity and voluntary assessment of donors.

Educational function: The educational work is done in three levels:

- **Inside the Committee:** It can be done through periodic reviews of regulatory documents, review sessions of literature on bioethical issues, gradual and continuous training of the members of the Committee, attendance and organization of academic seminars on bioethics, conduction of sessions in which they could analyze and deliberate clinical cases with bioethical implications, and sharing sessions of knowledge and work tools with Hospital Bioethics Committees of other establishments and institutions. These activities will help socialize and share what was learnt, as well as to create a common language and to facilitate communication and development. The training of the members of the CHB should be continuous. It involves an educational and development process of the group. Those without formal training in bioethics should receive it within the first six months after joining the Committee. It encompasses a set of activities that will help the Committee members and the institution to incorporate information, knowledge and behaviors for the identification and resolution of bioethical conflicts. Due to the multidisciplinary composition of the members, it is necessary that everybody acquires rational basic skills and deliberation skills.
To the hospital personnel: The Committee should develop an educational program on bioethics for the establishment staff, through conferences, seminars, courses, audiovisuals, and other activities that take into account the review of clinical cases presenting bioethical dilemmas.

To the general population: In a further consolidation stage, the Committee must promote its objectives, functions and activities for patients, families, the establishment and the community, so that patients can seek advice if necessary.

To do this, it is appropriate to create an information space on physical media (bulletin boards, brochures, etc.) or virtual media (website) in which relevant information in bioethics is conveyed.

Restrictions on the functions of the Hospital Bioethics Committees

- They are not intended to replace the doctor-patient relationship, nor the decisions and responsibilities of each of the actors in this relationship.

- They do not substitute the roles of professionals in making clinical decisions, they only intervene, whenever it is requested, when a conflict in the practice of medical attention is identified and when advisory is required for its analysis; therefore, they should refrain from getting involved in decisions that are responsibility of the physician.

- They should not be directly involved in decisions related to the patient treatment, unless it is requested.

- It is not their responsibility to analyze or sanction medical malpractice.

- It is not their responsibility to deal with issues or problems related to employment, administration or legal issues.

Integration

The Committees should be multidisciplinary and plural. They should be composed by medical staff from different specialties, paramedics, members of various non-medical professions, specialists trained in bioethics, lawyers with expertise in health, representatives of the affected group, or users of health services and civil society, among others. It is necessary for them to have an honest professional career. The Committee should have a high percentage of members with sound knowledge and experience in their disciplines.
They can come from the same institution or from another. Administrative staff, the directors of the institutions or people occupying management positions at the institution should not be included. The purpose of the multidisciplinary integration of the Committee is to be able to introduce within the discussion some of the arguments derived from different points of view. These arguments favor the issuance of suggestions and alternatives for resolving the ethical problems that are brought into consideration. For example:

- Health professionals clarify the clinical data of the case, as the diagnosis, prognosis and treatment options. This should be considered as the previous steps to all the bioethical analysis.

- The expert on bioethics carries out a reflection and weighting of the values and principles in conflict, according to the methodology of the bioethical analysis.

- The lawyer defines the legal framework and legal issues to consider under which the case will be analyzed.

- The representative or minister of church affairs will analyze the aspects that are related to their beliefs and will help on the understanding of the implied religious values.

- The citizen representatives make considerations from the standpoint of the general population, as users of the health-care services.

The Committee will be set up by a President and vocals (a minimum of four) The Committees, carrying out their duties, will be assisted by a secretary appointed by the President from among the vocals. Requirements should be added in order to designate each position, terms, conditions, duties and the responsibilities of each of them. Gender balance should be assured, including at least one member that is not assigned to that establishment.

**Members’ requirements:** Belonging to a Hospital Bioethics Committee represents an honorable commitment; therefore, the selection of its members should consider the following characteristics:

1. To have background that shows honesty and commitment (peers references, job positions, and of the community and/or organization to which it belongs).

2. Documenting professional experience in their performing field or commitment in their work.
III. To have any formation or training, preferably, on clinical bioethics.

IV. To have the commitment to gradually and continuously be trained on bioethical knowledge.

V. To have interest and be willing to develop the skills of respectful listening, rational and reasonable argumentation. To be tolerant, reflexive, cautious and honest.

VI. To represent the interests of the user community of the health care services, with the required capacity.

VII. To have the commitment to work for the period established by the Committee and perform his/her tasks.

VIII. To admit and disclose transparently the conflict of interest, if any.

IX. To have commitment to look after the medical attention of the participants.

Selection: The Committee shall establish its operational rules, the process by which the members will be elected. The selection of members should include curriculum assessment, a personal interview and the aspects that are considered necessary for the integration and operation of the Committee. The president of the Committee shall not: Be the director, the medical director, the educational director or any other officer of the institution.

At the end of the first three years management and for the appointment of the new president, members of the Committee will present a short list of three candidates for his/her selection, according to the procedure detailed in the operational rules. Furthermore, and hereof, members shall nominate candidates for the renewal of the members. External advisors or specialists may be professional in ethical aspects, religious services, legal fields, medical aspects or specific methodologies. They may be representatives of the public, patients or groups of interest. Independent specialists that attend meetings to provide information or clarify matters to be discussed shall be entitled to speak but not to vote.

Committees can seek support from other CHB or other specialists to get recommendations for cases that may occur. In case those are external advisors, they will participate in the deliberation and final decision and are also obliged to keep confidentiality of the information to which they had access.

Appointment: The principal officer of the establishment shall issue the document that appoints the official position for elected members of the Committee. In the case of a newly
established Committee, the principal officer of the establishment shall appoint the President. The appointed President shall have the power to appoint the other members, and their positions will be confirmed by the principal officer of the establishment. The period of the first Committee is three years long.

It is convenient to consider a gradual replacement to ensure that new members are acquiring knowledge and experience. The staggered replacement will be established in the agreement that specifies the current creation of the Committee. Conflicts of interest when making the position appointments shall be avoided. In case of the existence any unavoidable conflict, transparency must be severe in relation to the conflict. The appointment consistency awarded to members shall include at least the following requirements:

I. Full name of the appointed person and positions held.

II. Time length of the assignment

In addition, the record of each of the members of the Committee shall include the following documentation accepted and signed:

I. Commitment to seek for the interests of the participants in the research.

II. Confidentiality, protection and good use of the information commitment.

III. Acceptance and compliance with policies and operational regulations of the Committee.

IV. Expressed appointment that the incorporation to the Committee shall be of honorary nature.

V. Policies clause and management of conflicts of interest.

In the case of external advisors, they shall also sign confidentiality, protection and use of the information agreement, as well as a non-conflict of interest agreement regarding their participation in the meetings of the CHB.

**Requirements for the Positions Appointment**

I. Time length of the appointment

II. Appointment renewal policy
III. Disqualification procedure

IV. Waiver procedure

V. Replacement procedure

Roles of the members

President

I. Convene, organize and HOLD meetings in accordance with the established criteria in the guidelines of the Committee.

II. Implement mechanisms for the prevention and detection of conflicts of interest within the Committee.

III. Implement the appointment and members renewing process in compliance with the internal rules of the Committee.

IV. Promote continuous training activities inside and outside the Committee, which involve the population of the area of influence.

V. Report the recommendations and alternative solutions issued by the Committee to the corresponding authorities.

VI. Conduct the registration of the Hospital Bioethics Committee before the State Bioethics Commission and the National Bioethics Commission and other appropriate institutions.

VII. Coordinate the elaboration of activities reports and facilitate the access to the Committee's documentation to the principal officer of the institution and the instances that require it.

VIII. Perform other duties related to the previously listed.

Secretary Vocal:

I. Summon the vocals, at the express request of the President, to the meetings of the Committee.
II. Prepare and provide the working agendas of meetings and submit the necessary documentation to the members of the Committee in advance, except for expedited sessions.

III. Coordinate the preparation of the documents and ruling and operational instruments for the integration and activities development of the Committee.

IV. Record the minutes of the meetings, gather the participants’ signature for the ratification and distribution to where it proceeds.

V. Receive the subjects that are to be discussed in the meetings of the Committee and check that the information is appropriate and sufficient in order to add it in the work agendas.

VI. Integrate the annual activities program, which includes advisory actions, training and monitoring, by requesting input from the Committee members.

VII. Collaborate in the training, updating and dissemination of bioethical knowledge among the personnel of the establishment.

VIII. Coordinate the preparation of the requested reports, findings and recommendations to the Committee.

IX. Keep the files of the Committee updated, by recording activities and adding evidential documentation.

X. Integrate and submit to the adequate instances the findings and alternative solutions issued by the Committee in a timely manner.

XI. Perform any other functions as may be assigned by the President.

Vocals

I. Participate in the analysis and discussion of cases with bioethical dilemmas, to issue resolutions by consensus of the Committee in order to meet its functions and objectives.

II. Follow up the reached agreements and identify subjects that may be the reason of a Committee’s deliberation, to take the most from the experiences of the case analysis.
III. Intervene in benefit of the functioning of the Committee, by contributing to its organization and operation.

IV. Collaborate in training, update of bioethical knowledge, and other activities, for staff and for the population of the area of influence of the establishment.

V. Perform any other function as may be assigned by the President.

External Advisors

I. Advise the Committee, in terms of bioethics, for the assessment of problems or bioethical dilemmas, either in person during meetings or by sending technical comments.

II. Participate with honesty and be oblivious to conflicts of interest in the sessions, into which he/she is expressly summoned.

III. Collaborate with the analysis process of the case, either in person at the meetings or by sending technical comments, without participating in the issuance of resolutions.

IV. Keep confidentiality of the information that was accessed and not participate in the deliberation of the case.

V. Implementation

The Hospital Bioethics Committee shall be constituted by an implementation agreement, at a formal event with the support of the respective authorities. The implementation agreement shall specify the following requirements:

I. Corporate name of the institution to which the Committee belongs.

II. Address of the Committee and the institution to which it belongs.

III. Objective of the Committee.

IV. Characteristics and functions of the Committee

V. Integration of the Committee.

VI. Attributions of the members of the Committee.
VII. Funding form for the operation expenses of the Committee.

VIII. Place, date and time of implementation.

IX. Legal basis containing the same powers of the principal officer in order to constitute the Committee.

X. Statement of the principal officer of the establishment that under his/her responsibility the Committee was established.

XI. Hand-written signature of the principal officer, who is responsible for the establishment.

The objectives, functions and qualities of the Committee, as well as the faculties of the members and its funding form shall be annexed to the installation agreement. The Committees shall have sixty calendar days, from its installation, to issue its rules of operation.

Operating capacity

In the newly established Committees and during the first six months, at least one member should be trained on bioethics, with the goal that all members receive ongoing training. In the case of newly established Committees, and when within the institution it is no possible to gather the right people, the respective principal officer with the appointed President of the Committee, may seek support and advice from the Committees constituted in the immediate higher level of medical attention, of their own institution or from other institutions of the sector, provided they meet the above requirements. Establishments that do not have a CHB, should contact the closest institution to their geographic area that has a CHB and, if not possible, contact the National Bioethics Commission for the allocation of an appropriate Committee in order to evaluate the bioethical problem in question.

The Committee shall establish its operational rules, specifying the duties of its members, as well as the mechanisms and internal operating procedures in sessions. The Committee shall promote, with the principal officer of the hospital, the preparation and implementation of guidelines and institutional bioethical guides for health-care and medical education. Furthermore, it will promote permanent bioethical education for its members and hospital staff.

The National Bioethics Commission, through the State Bioethics Commissions, may request, at all times to hospitals any information regarding the composition and functioning of the Committees. The CHB shall submit an annual report to the management department.
of the institution and to the State Bioethics Commission, if it does not exists, to the Local Secretary of Health, who shall report to the National Bioethics Commission about the number of problems or bioethical dilemmas evaluated, the results of the evaluation and the monitoring of relevant data.

**Support for the members**

It is important that the activities of the members of the Committee are supported by the authorities of the institution and it is slightly considered to observe the following:

I. Time to participate in regular and special sessions of the Committee.

II. Academic or work acknowledgements due to their performance within the Committee.

III. Support for ongoing training activities on bioethics, inside and outside the institution.

IV. Fixed physical space for the headquarters of the Hospital Bioethics Committee.

V. Administrative support, as it requires a formal record of queries made to the Committee

VI. Necessary support to request the material for a proper performance.

VII. Training of members. The access to these activities is highly recommended.

VIII. In case the participation of a representative of the community or any patient will involve a significant economic loss, depending on the case, the transportation-costs shall be refunded and an additional reward shall be given, if the representative is overlooking, deferring or suspending any paid activity.

IX. CHB operating expenses have to be funded by the authorities of the institution. This should not result in conflicts of interest between the funding source and the functions of the Committee.

**Request for the Intervention of the Committee**

Mechanisms should be established, both request for intervention of the Committee, as well as a previous review of the submitted documentation. This review is intended to verify that it has all the necessary documentation to enable the Committee to properly analyze the
problem or dilemma that has been submitted for its consideration. This procedure will enable to arrange and optimize the work of the collegiate body, preventing an analysis that may lead to unsuitable or misinterpreted recommendations, which create confusion and reduce the confidence in the collegiate work of the Committee.

The President may call the Committee into session, by a written request, in which the reason for its intervention is explained.

Applications can be made by the medical staff, the patient or family member, guardian or legal representative, as well as by anyone, who is involved in the case.

The person who requests the intervention of the Committee must submit the corresponding documentation to the case in the office of the Hospital Bioethics Committee, between ten and seven business days prior to the next meeting of the CHB. The reception of the documents will be carried out in the secretary's office of the CHB. The record will be done in a notebook of correspondence, with a stamp and date of receipt, as well as in the letter of request. The receipt of complete documentation will be held on a form, which will be signed and stamped by the person that receives it and submits it. It is recommended to facilitate the relationship between the CHB and health-care personnel or patients and their families; therefore, simple procedures shall be established to enable work in an organized way and to keep up-to-date the inquiry file of the Committee.

**Sessions**

The Committee shall meet in an ordinary way, at least six times a year and extraordinarily at any time the President requests it, or when requested by the majority of its members.

**Ordinary:** The Committee shall periodically carry out ordinary sessions according to the needs and workloads of the establishment. It is recommended that the ordinary sessions are held at least once a month. The scheduled dates for the sessions will be announced to health staff in advance. The yearly calendar must be published in January. The sessions will take place when at least the President or the secretary of the Committee and half of the members attend, in order to cover all the requirements specified in section quorum.

Decisions will be made after a thorough discussion and the analysis of clinical and ethical aspects of the case in question. Various courses of action should be presented. These spring up from the discussion, then the courses of action considered as the best ones shall be specified. In the work of the Committees, the objective is to reach consensus, so when there are divergent points of view, it is important to point them out as well as their groundings. In this case, all the alternatives proposed by the patient should be presented, so he can assess them and decide how to act. The aforementioned should be written and reflected in the Committee's minutes. The agenda and corresponding papers for each session will be given at least seven days before the meeting.
The doctor, the patient and/or family who has requested the intervention of the Committee, should be invited to comment on the specific aspects of the problem. As a general rule, they cannot stay for the deliberation. Independent advisors may be invited to meetings, and they will be subject to confidentiality agreements that are applicable to other members. Everyone should read the application and documentation related to the problems presented.

Relevant ethical problems shall be identified. Questions or unclear elements shall be presented and ethical issues, considered as relevant, shall be identified to be addressed, as well as those ethical issues that are not adequately considered by the participants in the clinical setting. The discussion is open to all members, so that in the first place they raise their arguments and clarify doubts about the clinical and socio-demographic aspects, and secondly so that debate and deliberation can be carried out.

**Extraordinary:** These are all those sessions that are required to be held out of the regular schedule. These meetings will be organized taking into account the needs of the establishment, in the short and medium term; however, they require seventy-five percent of the members of the Committee. The procedures to carry out extraordinary sessions should follow the same requirements as the regular sessions, emphasizing the summons mechanism. Some examples of reasons for extraordinary sessions are the replacement of members and appointment of the President, among others. When required, at the request of the President or of the majority of members, it will be summoned into extraordinary sessions.

In the case of extraordinary sessions, the agenda and documents for each meeting will be presented within three days of notice, if possible. The aforementioned has the objective that the Committee members have sufficient time prior to the meeting to review the most important documents, as long as these are not emergency patients.

** Expedited:** The Committee may conduct expedited sessions in clinical situations requiring rapid response in emergency cases without having to go through the formal review of a regular meeting. These meetings will be made by those who were appointed as "emergency Committee" or "advisor" by the rest of the members, by virtue of their knowledge and experience in both clinic and in bioethics. The recommendations issued in expedited assessments should be fully informed in a regular or special meeting, as applicable.

**Minutes:** A minute report is prepared for each of the sessions that the Committee holds, with the following minimum requirements: The date, time and venue where the meeting is held, the purpose of the meeting, the name and signature of each of the members that attended, pursuant to the recommendations that are reached by consensus during the meeting.
**Quorum:** Hospital Bioethics Committees should establish specific quorum requirements for reviewing and deciding on an application. These requirements shall include the minimum number of members required, the assistance of the President of the Committee 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 consideration the skills distribution of the members. It cannot be established with the exclusive participation of members of the same profession or the same sex. It shall include at least one member of a primary area of expertise, which should not be scientific, and at least one independent member of the institution, where the case problem was presented. If one of the members of the Committee has a conflict of interest in connection with the presented case, he should be disqualified for that particular discussion and may not be considered.

**Conflict of interest**

A conflict of interest is a situation that occurs when a person is influenced in his/her professional judgment by an intention or a different purpose than that required to be complied, according to the responsibility that he/she performs, with adherence to fairness and responsibility principles. To avoid these conflicts, operating expenses of the Committee shall be funded by the establishment, without implying a conflict of interest in its functions. The Committee shall avoid any conflict of interest in the discussion of bioethical dilemmas.

**Decision making**

In decisions making it should be deemed to be taken as a minimum the following requirements:

I. Place and date of the issuance of the recommendation.

II. Describe the bioethical problem, i.e., the advisory reason and the reason of the person that requires advice.

III. To make decisions when an established quorum exists.

IV. Dispense during the session with members who may have a conflict of interest.

It is necessary to have all the documentation, and enough time to check it. The members of the Committee shall analyze the subjects applying different methodologies. Subsequently, the deliberative process advances to the phase of critical exchange of ideas, the recognition of moral principles and values that are in conflict, in order to understand the dynamics of the dilemma and issue consensus recommendations with substantiated arguments. The purpose of the deliberative process is to issue a recommendation and it will be the patient, his legal representative, family or physician who makes the decisions in each case.

The decisions made by the Hospital Bioethics Committee serve to create procedures for handling bioethical dilemmas encountered in medical care, in the hospital field, and these recommendations
may be useful to provide a reference source. The methodologies and the deliberative process are described in the addendum of the Guide.

**Issuance of the recommendations**

The resolutions issued by the Committee shall be based on the consensus of the members present at the corresponding analysis and deliberation session. They will be issued by an office and directed to the applicant who filed the case. The issued recommendations are suggestive, not binding. Patients cannot be compelled to perform with the same determination of the Committee and its members shall not have any responsibility for the decision that the plaintiff (patient or family) choose, whereas the members, by the exercise of their function within the Committee, shall not be affected on their work. The confidentiality agreement about the treated case information will be respected, as well as the privacy of the patient and the applicant.

**Decisions Communication**

The applicant shall be given notice within a period not exceeding seven working days, as a general rule; however, it depends on the characteristics of the case and the conflict analyzed and it should have the signatures of the Committee members, who are involved in the process. The recommendations made by the Committee should be introduced into the clinical record. The communication of the recommendations should include at least the following:

- Problem presented to the Committee
- Reviewed documents
- Name of the applicant
- Date and place of the issued recommendation
- Name and registry code of the Committee that issued the recommendation.
- Statement(s) of issued recommendation(s).
- Date and signature of the President of CHB secretary.

**Registration of the Hospital Bioethics Committee**

The CHB must apply for registration before the National Bioethics Commission, in accordance with the General Provisions for Integration and Operation of Hospital Bioethics Committees. It should have as its objective the creation of the database with the inherent information for the integration and operation of a Committee, with monitoring, compliance, regulatory and statistical purposes.

**Paperwork:** The application for registration must be submitted electronically through the website of the Commission, in the specified format, which contains the identification data of the Committee, name and address of the establishment to which it belongs, implementation date, name and job
positions of the members, contact details, E-mail address to receive notifications, and the name and signature of the person responsible for the Committee. The information shall be audited by the corresponding instances.

Registration includes a previous self-assessment of the prepared form for this purpose, which should contain the basic elements of integration and operation. The application shall be sent electronically, with the following elements:

I. Implementation date of the Committee
II. Name and job position of the members
III. Name of the liaison members
IV. Address
V. E-mail
VI. Date and place of the registration application
VII. Name and signature of the responsible for the Committee. This shall also be attached electronically.

VIII. Implementation agreement.
IX. Proof of appointment of each member of the Committee.
X. Required self-assessment form.

In case there are omissions of requirements, it will be required to be completed electronically within ten working days, assuming that in failing to do so, the application will be deemed as not presented.

In the event that the application for registration and documents submitted do not meet the requirements for registration, the resolution will be notified to the applicant within a period not exceeding ten days, including the reason for its rejection. The application will be entered for processing in a schedule from nine to eighteen hours from Monday to Friday.

Record: Once the requirements are met, the National Bioethics Commission will issue a registration certificate in a maximum of ten working days. In case of any of the requirements omission, the Commission will require the applicant electronically to remediate such omissions within a period of twenty working days from the date of the notification, knowing that in the absence of doing so, the application will be deemed as not presented, containing the following: registration key and validity of registration.

Registration validity: The validity will endure three years, once met this period the information of the Committee shall be updated. The Committee shall make the application electronically the previous month to the registration’s expiration, which must be attached to
the application and self-assessment format. The completion of these procedures does not require the payment of rights.

**Control and monitoring**

The integration and operation of CHB are elements of analysis that allow them to establish the quality levels of the services provided by a Committee, so it is important to maintain a control and monitoring system to identify areas of improvement and opportunity, which must be adequate to ensure better performance of their activities. In this regard, the National Bioethics Committee and/or the State Bioethics Commissions can inquire the establishment or institution so that the CHB participates in such control and monitoring system, when required. The control and monitoring program for Hospital Bioethics Committees will be established by the National Bioethics Commission, according to the correspondent State Bioethics Commission. Assessment items that have been established for this purpose, are those set out in this Guide, in the requirements referred to conformation, installation and operation paragraphs.

**Information and files**

It shall be responsibility of the President of the Committee on duty, the storage of the aforementioned files. All documentation and communications from CHB should be dated, numbered and filed, according to written procedures and applicable regulations. A definition of the access and recovery procedure (including authorized persons) to the different documents, records and files is required.

The classification of the information contained in the file of the information of the Committees for the purpose of government information access, shall be made according to what is prescribed in the applicable regulations. The storage and access of the information of the Committee will be as stipulated in the Federal Law of Transparency and Access to the Public Government Information and the federal entities, as well as in the Federal Law on Protection of Personal Data in Possession of Individuals, as applicable, and other applicable provisions in field.

It is the commitment of the CHB to keep the files for cases raised during five years from their resolution. After the implementation period is completed these will be transferred to the concentrating file in the institution. It shall be recorded in the corresponding database. The files (printed data sources, magnetic or electronic) that will be preserved in the office of the Hospital Bioethics Committee shall include at least:

- Act of installation of the Committee
- Internal regulations of CHB
- Operation guidelines, national regulations, international regulations, technical documents and applicable regulation texts.
- Identification list and updated resume of the members of CHB
- Appointment of Committee members (copy).
- Programming of the sessions of CHB.
- Minutes of the meetings of CHB numbered correlatively per year.
- Evaluated cases with all the analyzed documentation and its correspondent advise, as well as monitoring reports if applicable.
- Correspondence related to CHB.

**Addendum: Methodologies of analysis for clinical cases containing bioethical dilemmas**

**Analysis of clinical bioethics cases**

Clinical bioethics is a practical discipline that provides a structured approach to help physicians to identify, analyze and solve ethical issues in clinical medicine. The practice of clinical medicine requires knowledge on ethical issues such as informed consent, professional communication in a doctor-patient relationship, confidentiality, care at the end of life, pain relief, and patient rights. In medicine, the physician's work in terms of diagnosis of the disease, providing management advice and treatment, is inserted in a moral context. Moral values such as mutual respect, honesty, integrity and compassion, are a commitment in the physician-patient relationship, and sometimes, it could be morally problematic; physicians and patients may disagree about the values or options in relation or hierarchy of values. That's when ethical issues arise, even when the perplexity is high and emotions are present, doctors and nurses, patients and families can work constructively to identify, analyze and solve bioethical issues arising in clinical medicine.

The purpose of writing this topic is providing an approach that facilitates it to think about the complexity of problems that health personnel face. We believe it is important for those involved in developing the ability to analyze the cases they face, instead of just having a book to "seek answers". The chapter is intended not only for physicians who care for patients, but also for others whose work requires an awareness and sensitivity to ethical issues in clinical care, such as hospital administrators, hospital attorneys, members of
institutional Ethics Committees, social work, quality reviewers and managers of health plans. In the complex world of modern health care, all these people are responsible for maintaining the ethics that are at the heart of quality care.

Many books on ethics of health care are organized around moral principles, such as respect for autonomy, beneficence, non-maleficence and justice, and the cases are analyzed in the light of those principles. While we appreciate the importance of the principles, we believe that the doctor, who is presenting a case, needs the method which is better adapted to realities of clinical practice and reasoning. Clinical situations are complex, because they often involve a wide range of medical data, a multitude of circumstances and a variety of values, often, decisions must be made quickly. Clinicians need a simple way to organize facts and case values in an orderly pattern that facilitates discussion and resolution of the ethical problem. Here are some suggested methods of analysis and the deliberative process for making decisions is described.

**Analysis Methods for the decision making**

**Principlist Method**

Stated by *Beauchamp* and *Childress* in 1979, has been subject of criticism. It states that in order to make proper decisions in the field of health care practice, the principles of non-maleficence, beneficence, autonomy and justice shall be respected. However, problems arise when these principles are in conflict. There are always problems, but they do not always generate conflicts.

Some of these principles have been taken considering a more consequentialist analysis that deontologist posing as *prima facie* principles, it is to say, the moral ideal that should be set in the performance, which in practice is conditioned by *actual duties* or the duties set in real problems, being able to skip the guidelines set by the principles according to concrete circumstances. Basically the analysis is performed according to the principles of non-maleficence, justice, autonomy and beneficence:

- First, the absence of malice, clinical assessment for the indication or indications to medically intervene.

- Second, from justice this refers to contextual features, ensuring a fair distribution of resources in the management of services and health resources.

- Third, from autonomy, being the latest discovery in health relationships and probably the one that poses the most problems. The respect for autonomy of the affected person involves the following factors to consider: capacity, information and
voluntariness.

- Fourth, from the beneficence or life quality, which is inevitably linked to the patient’s preferences, and also their general content includes health practice which is the most comprehensive understanding of goodness, assisting and curing diseases, promoting and maintaining health, relieving pain and suffering, preventing premature death and to ensure a peaceful death (Hasting Center).

Deliberate and analyze all the content on the previous steps, it is the methodology that arises, argued for the primacy of one or another aspect, based on the data presented in each case. However, in particular cases, the order of analysis process can be random or in the most convenient order.

**Method of analysis of clinical ethics cases Jonsen**

In a collaborative effort, three specialists in clinical ethics (a philosopher: Jonsen, a physician: Siegler, and a lawyer: Winslade) developed a method in order to work in difficult cases. They identified four "themes" basic and intrinsic to each clinical encounter. Focusing in our discussion around these four themes, this provides us a way of organizing the facts for the particular case.

- **Medical Indications:** All medical encounters include a diagnosis review and treatments options.

- **Patients’ preferences:** All clinical encounters occur because a patient attends the physician with a complaint. The patient’s evaluation is essential for the encounter.

- **Quality of Life:** The purpose of all clinical encounters is to improve or, at least try to guide the life quality of the patient.

- **Contextual Characteristics:** All medical encounters occur in a broader context beyond the physician and the patient, it is important to include the family, legal issues, hospital policies, and insurance companies, and so on.

These four areas are present in all cases. In the interest of coherence, the order of issues review remains the same; however, no topic is more important than the others.

Each of these will be evaluated from the perspective of the facts related to the case we are concerned with. Once the details of a case have been outlined according to these four themes, there are a number of questions that the clinician should make:
- What is this about?
- Where is the conflict?
- What is this case about?
- Is this similar to other cases?
- What do we know about other similar cases?
- Is there a clear precedent? If so, we call this, a paradigmatic case.

A paradigmatic case is one in which the facts of the case are clear, and a professional consensus has been reached and/or a public agreement about the resolution of such case has also been reached.

- Is this case similar to the paradigmatic one?
- How is this different?
- Is there similarity of significant ethical differences?

The resolution in any particular case will depend of the facts of such case. After its analysis, health personnel can clearly think about this and determine the best available action course.

**Decision-making of Diego Gracia**

Diego Gracia, academic of the Royal National Academy of Medicine of Madrid, Medicine History professor and director of the Masters in Bioethics of the Complutenese University in Madrid, proposes the analysis procedure of the following moral problems:

**First evaluation (Reference system)**

- See if the act can be universal.
- See if it complies with the principle of treating everyone with the same consideration and respect.

**Moral principles (Correction and goodness)**

- Level I of "Correction": Principles of Justice and Non-maleficence. Objective correction. Contrasting the problem with the content of these two principles.
Level II of "Goodness": Principles of Autonomy and Charity.
Subjective goodness. Analyze whether the decision is consistent with the individuals’ values and their group: "Authenticity".

- Evaluate the subject’s autonomy.

Consequences (Minor consequence)

- Objective consequences (from Level 1).
- Subjective consequences (from Level 2).
- Ordinary/Extraordinary.

Final decision-making

Decision-making of Thomasma

Thomasma, in the article published in 1984 in the Journal of Bioethics, considered the application of general ethics theories to all cases as inappropriate, without addressing all factors that may allow a selection among various ethical principles within the concern. According to him, these factors are divided into two types: the "facts" (clinical data) and the "values" (of physician, patient and society). What this Thomasma’s principle pretends is to articulate in a coherent way the facts and values in the clinical relation that is established between a health professional and the patient. After some modifications, the Thomasma’s procedure since 1990 is the following:

- Describing all the case facts. Investigating each medical fact not present in the case; but significant for its solution.
- Describing the relevant values of physicians, the clients and members of the family, the rest of health professionals and society. (It will not be an exhaustive list).
- Determining the main threatened value.
- Determining the possible actions courses which can protect in that concrete case, the highest number of possible values.
- Selecting an action course.
- Defending such action course from the fundamental values.
This procedure has subsequent modifications, by Pellegrino, as by Kieffer (in the concrete field of Biology). Viafora, member of Lanza Foundation of Padua, Strong, member of Tennessee University and in Memphis, Engelhardt, Mccullough and Hans-Martin Sass.

**Galveston Procedure**

The decision making of Texas’ University in Galveston is a procedure that has been adopted by the Humanities and the Internal Medicine Program within the same Institution. The work center of Winslade, philosopher, jurist who became an expert in bioethics.

**Indications for medical intervention**

- Specific medical facts.
- Therapeutic options, possible side effects and expected consequences.
- Are there special circumstances considering ethical problems?

**Patient preferences**

- Patient most important preferences.
- Patient’s capacity to choose.
- Practice of informed consent.

**Life Quality**

- Definitions about life quality in a concrete case.
- Moment in which considerations about life quality are presented for such type of patients.
- Forms of finding a solution for life quality issues.

**Non-clinic factors**

- Contrasting clinical and non-clinical factors.
- Defining the significant factors in the case.
Should these significant factors influence in clinical decisions?

The deliberative process for decision-making

Bioethics has its own ways to approach the decision making. This is one of the other contributions of the discipline. Consistent with its own principles and in order to achieve inter-subjective agreements, bioethics attaches to the deliberative method as an alternative to approximate the resolution of ethical issues that are presented in society. The most important feature of the deliberative process is that it is not an emotional, but an intellectual process, which has a practical purpose: to make decisions. The deliberative process can help you making a decision through a larger consensus. The aim is to reflect the factors involved in the decision making considering not only medical reasons, but personal values.

Deliberation is the process of considering the factors involved in a situation in order to find an optimal solution or the least harmful in ethical terms. This is about seeking together the alternative that meets the expectations of the individual and the option that respects their values or objectives. Deliberation seeks to support more than one viable and reasonable solution. These solutions can be not only different, but opposite. In order to make a reasonable and prudent decision it is necessary to have as many different perspectives when analyzing a problem, respecting the plurality of CHB members, accepting that it is rewarding to hear other people arguments and thus, increasing knowledge because no person has the whole and absolute truth. People that think they can learn something and know they do not know it all, listen to the ones they can learn from.

The bioethical deliberation does not try to solve conflicts through a vote without dialogue. It does not consist in evaluating the problems from the subjective positions of the interested and involved person (or by members of the Committees), because a sum of subjectivity does not result in inter-subjectivity. The aim of the bioethical deliberation is to unravel the principles and values of civic social ethics and evaluate, from them, the concrete matter to considerate a CHB. The decisions made are discussed through the use of logic. However, in the field of morality, logical procedures are not enough because in moral judgment they may be qualitative arguments that influence the final decision. The deliberation seeks to analyze the dilemmas in all their complexity; that is to say, to analyze the principles and the values involved, but also the circumstances and consequences of the case.

This is the way the possible action fields can be identified. In order to deliberate, certain capacities and skills must be developed.

- Clear expression of arguments supporting the same decision.
• Willingness of approach with those who think differently.

• Ability to listen and understand other people’s point of view.

• Ability to negotiate.

• Ability to deliberate, as in any art, it requires training. When the decision-making involves topics regulation in which there are no previous experiences, moral uncertainty increases.

The facts and cases in which individual moral judgments are established (in this level context is crucial to establish a judgment because it is a well-defined situation) rules and special rules applicable to a certain class of cases or situations, the general principles (at this level would be international agreements: declarations, conventions and codes, among others, etc.), and the theories and beliefs systems and worldviews, religions, philosophies and scientific theories.

Each case requires an understanding of the reason for the discussion and visualizes it from different perspectives. Different actions must be considered and the possible consequences for such decision must be discussed. It is vital to consider that the impact and its inherent responsibility will be greater while the decision-making is taken at a more general level.

Annex 1
Reforms to the General Health Law: Decree of Addition to Article 41 Bis

On December 14, 2011, the Decree of the addition of Article 41 Bis and the reform of Article 98 of the General Health Law was published in the Official Journal of the Federation; which states the obligation of establishments for public sector health care, private, social or national health system, to have Hospital Bioethics Committees (CHB, by its acronym in Spanish) and, in the case of conducting human research, Research Ethics Committees (REC). The Decree determines that the Secretariat of Health, through the National Bioethics Commission (CONBIOÉTICA) shall issue the necessary provisions for the integration and operation of the Hospital Bioethics Committees and the characteristics of hospitals that should have them.

Article 41 Bis: Establishments of the public, private or social health care sector, of the national health system, in addition to those mentioned in Articles 98 and 316 of this Law, and according to their degree of complexity and level of resolution, will have the following committees:

I. A Hospital Bioethics Committee for the resolution of problems resulting from medical care referred in Article 33 of the present Law, as well as for the analysis, discussion and medical support for the decision-making process on bioethical issues, that arise in clinical practice or in the teaching implemented in the health area; as well as promoting the development of guidelines and institutional ethical standards for medical
care and education. Also, this will promote bioethics education of its members and facility staff permanently.

II. In the case of health care facilities that carry out research activities in humans, an Research Ethics Committee will be responsible for evaluating and regulating research protocols in humans, making ethical recommendations that apply, as well as elaborating guidelines and institutional ethical standards for health research complying with its recommendations.

Hospital Bioethics and Research Ethics Committees will be subject to current legislation and the criteria established by the National Bioethics Committee. These will be interdisciplinary and must be set up by medical staff from different specialties and also professionals from different areas such as psychology, nursing, social work, sociology, anthropology, philosophy or law that have a training on bioethics; being essential to have representatives for the affected core or users of health services, reaching the agreed number of its members, keeping gender balance, who may be or not attached to a health unit or establishment.

Annex 2
General provisions of Hospital Bioethics Committee

Since the publication of the aforementioned Decree, the National Bioethics Commission developed several actions:

- In December 2011, the State Health Secretaries made public the Decree which adds the Article 41 Bis and reforms the Article 98 of the General Health Law, which was spread at the same time in the website of the National Bioethics Commission. CONBIOÉTICA subsequently developed working papers of the General Provisions for Integration and Operation of Hospital Bioethics Committee of Bioethics and Ethics Research and it’s adherence to the legal process for the approval of General Provisions, the documents were sent to the of Legal Affairs and Human Rights of the Secretariat of Health.

- A worldwide electronic consultation was performed to collect information about the opinions on work documents to people from different institutions in the public and private sector, as well as academic and research bodies.

- As a final document we obtained, the “Agreement issuing General Provisions for Integration and Operation of Hospital Bioethics Committees” and hospital units were established to incorporate the Committees; according to the criteria set by the Bioethics National Commission, assisting in the decision making on the bioethics dilemmas raised in medical care or in teaching health.

- Regulations must be mandatory for the establishments referred in the Articles 69 and 70 of the Regulations of the General Health Law in terms of Medical Care
Annex 3
Informed consent and assent

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

Through informed consent, health personnel informs with sufficient quality and quantity to the competent patient, the nature of the disease and the diagnostic procedure and/or therapy that they pretend to use, the risks and benefits it entails and the possible alternatives. The written document only supports that the health personnel has reported, and the patient has fully understood the information. Therefore, the informed consent is the manifestation of responsible and bioethical attitude of medical personnel or health research, which increases the quality of services and ensures respect for the dignity and autonomy of individuals. The informed consent differs with assent because the latter is the acceptance of a person who is incapable of being previously informed about the diagnosis, treatment options, benefits, scope, risks and consequences, in order to receive such treatment or to participate in a research. This highlights the goodwill of the incapable person. Since the values or objectives of individuals vary, the best choice is not always the one that prioritizes health, but the one that prioritizes the maximum welfare in accordance to the objectives and values of everyone. The Informed consent consists of two parts:

- Right to information: the information must be clear, accurate, sufficient, timely, and objective about everything related to the process of care, primarily of diagnosis, treatment and prognosis of the condition of the person. Before performing any procedure the patient should be properly informed about the risks, benefits (physical or emotional) and the duration, as well as other alternatives, if any.

- Freedom of choice: consists in giving or withholding consent to physicians, about the proposed diagnostic or therapeutic procedures, after being properly informed. It is important to privilege the autonomy of the participants, evaluate their competency and create conditions for exercising their right to decide. In patients unable to consent, their assent must be obtained. Consent requires the following elements:

- Being a volunteer: Accepting without coercion, without wrongful influence, inducement or intimidation. Benefits should not be exaggerated nor must the risks be minimized. A sufficient time should be considered so the patient makes the decision and not be pressed for time, whenever possible.

- To provide sufficient information: About the disease, the prognosis, the therapeutic procedure, the risks and benefits, as well the available alternatives for
the particular. The information must be oral and personal, with a non-technical language and proper for the patient.

- The information process: Healthcare personnel should ensure that the patient or responsible relatives have understood the provided information and should encourage to ask questions and be able to answer them in an understandable way. You should consider the education level and socio-cultural background of the participants and try to use appropriate language.

This is important because different cultures should be considered. The information should be given to a competent person (legally competent in age and mental capacity).

In the case of incapable persons due to consciousness limitations (coma or brain death), and limitations of reasoning (children, severe disease, elderly people or elderly patients with dementia) and limitations of intelligence (mentally handicapped), it is necessary to get the authorization of a legal representative. However, whenever possible, it is desirable to have the patient's consent. It is important to ensure that the legal representative of the patient or family member is looking after the patient’s benefit, and that has the ability and competence required to make the decision.

For this purpose, the counseling of the Hospital Bioethics Committee is important, if there is doubt or moral opinions discrepancy between health personnel and the legal representative related to the best decision for the patient. The consent must be expressed and written in a signed form, when it is a high-risk procedure. This must hold true with clear and complete information about the procedure to which the patient is undergoing and its possible complications. Illiterate patients must stamp their fingerprint on the document and designate a witness to sign, attesting to their consent. An original document is written for the record with a copy for the patient. The purpose of this document is that the patient can take it home, review and comment it with whom he considers appropriate, in case questions arise and as support for the procedure that will be performed.

The Official Mexican Standard (NOMSSA1-168) establishes the scientific, technological and administrative mandatory criteria in the development, integration, use and storage of the medical records. The informed consent will be part of the clinical record. The situations in which informed consent is required in writing, according to the Official Mexican Standard regarding the clinical record, are the following:

- Hospitalization for psychiatric patients due to legal mandate, urgency, danger of people living with the patient and suicide risk, among others.
- Surgery.
- Procedures for fertility control.
- Participation in research protocols.
- Diagnostic or therapeutic procedures involving physical emotional or moral risks.
- Invasive procedures.
- Procedures producing physical or emotional pain.
- Socially invasive procedures producing exclusion and stigmatization.

In emergency cases where there is no opportunity to talk to family members, and it is not possible to obtain the patient’s authorization, the doctor can act through the therapeutic privilege until the patient is stabilized, and then inform the patient or his/her relatives. This procedure must be well grounded in the clinical record and the informed consent should be sought as mandatory. The patient has the right to refuse and withdraw his/her consent at any time (diagnosis, treatment or research); therefore no procedure should be conducted against the will of the competent patient. This fact and the assessment of the ability of the patient must be written in the file. In our country there are specific regulations about the mandatory nature of the informed consent:

- General Health Law.
- Regulation of the General Health Law, on the matter of Research for Health.
- State Health Laws.
- Regulation of Medical Services of the Mexican Social Security Institute (IMSS, by its acronym in Spanish)
- Official Mexican Standards
- National Commission for the Certification of Health Establishments.