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MEDICAL ETHICS

# What are medical ethics, research ethics and clinical bioethics committees?

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Ethics, Medical, Bioethics, Ethics Committees, Research, Health Education, Pediatrics.

## Abstract

**Introduction:** Health professionals, in their daily practice, from time to time, face ethical dilemmas and doubts about the functions of committees and commissions governed by ethics and bioethics. It is imperative to clarify the attributions of these instances, in order to contribute to the practice of care and medical research. **Objectives:** This document aims to address in a practical way the characteristics and peculiarities of the Medical Ethics Committees, Research Ethics Committees and Clinical Bioethics, clarifying the functioning, the attributions, the objectives and the responsibilities of each of them. **Discussion:** The Medical Ethics Committees monitor the ethical problems of the hospital, based on the verification of medical facts that have occurred and promoting preventive attitudes. Research Ethics Committees ensure the dignity, rights, safety and well-being of scientific research participants, and support the needs of researchers, promoting the discussion of ethical and legal aspects of research involving human beings. The Clinical Bioethics Commissions or Committees discuss and deliberate on the various conflicting aspects that involve activities related to mans life. **Conclusion:** Ethics, considered a human construction, is taken care of in the scope of these commissions, guaranteeing the proper conduct of the processes, with protection and trust between the individuals involved.

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*"Life is short,*
*science is enduring,*
*the opportunity is cunning,*
*experimentation is dangerous,*
*judgment is difficult."*
**Hipócrates (Aforisma I.1)**

## INTRODUCTION

Many health professionals, even those with years of experience, ask "What is a Research Ethics Committee for?", "Clinical Bioethics Committee, discuss what?", "We already have a Medical Ethics Committee, so that other ?". Even though all these committees and commissions are governed by ethics and bioethics, each one has its attributions, objectives and responsibilities.

The purpose of this document is to practically approach the characteristics and particularities of each of these committees/commissions, from the perspective of ethics and bioethics.

## MEDICAL ETHICS COMMISSION

The Medical Ethics Committee of a hospital represents the Regional Council of Medicine (CRM) in this institution, being subordinate and linked to it . It is composed of physicians from the clinical staff elected for this purpose. It accompanies the institution's ethical problems, providing the verification of medical facts that have occurred, or even suspected, as well as extending to preventive attitudes in areas of greater risk of occurrence. It has , therefore, investigative, educational and supervisory functions of the ethical performance of medicine. The Medical Ethics Committees incorporate Resolution No. 1481/1997 of the Federal Council of Medicine (CFM) into their Rules of Procedure, which establishes guidelines for the Internal Rules of Clinical Staff and subsequent Resolutions with textual changes[1-4].

Its attributions are: to supervise the exercise of medical activity, ensuring that the doctor's working conditions, as well as his freedom, initiative and quality of care offered to patients, are in accordance with the ethical and legal precepts that guide the profession; establish preliminary internal procedures through formal or ex officio denunciation; collaborate with the Regional Council of Medicine in the task of educating, discussing, disseminating and guiding professionals on topics related to medical ethics; act preventively, raising the awareness of the clinical staff of the institution where he works regarding the legal norms that govern their ethical behavior; guide the patient of the health institution on issues related to Medical Ethics; act effectively in the fight against the illegal practice of medicine; promote debates on topics of medical ethics, including them in the regular activity of the clinical staff of the health institution[4].

According to CFM Resolution No. 2152/2016 , the Medical Ethics Committees must have autonomy in relation to the administrative and directive activity of the institution where they operate, and the technical director is responsible for providing the conditions for their operation, sufficient time and materiality necessary for the development of the works. Their actions are restricted to the clinical staff of the institution to which their registration is linked. Physicians involved in the facts to be investigated, summoned in the internal investigations that deliberately refuse to provide clarifications to the Medical Ethics Committee, will be subject to an administrative procedure within the scope of the respective Regional Council of Medicine, as recommended by art. 17 of the Code of Medical Ethics[4].

The elections of Medical Ethics Committees take place in accordance with CFM Resolution 2152/2016, which highlights the obligation for hospital institutions that have a number equal to or greater than 31 doctors in their clinical staff. They must be composed of 1 (one) President, 1 (one) Secretary and other effective and alternate members. The President and Secretary will be elected from among the effective members, at the first meeting of the Commission[4].

## ETHICS COMMITTEE IN RESEARCH IN HUMAN BEINGS

The practice of scientific research requires the ethical action of the researcher and a conscious and free action of the participant, who must have guaranteed the full exercise of their rights. The researcher-participant relationship is continually built in the research process, and there must be constant concern about possible harm to the participant. In this way, scientific production must have the purpose of promoting benefits for the human being, for the community in which it is inserted and for society, enabling the promotion of a dignified quality of life based on respect for civil, social, cultural rights and the an ecologically balanced environment[5].

The Research Ethics Committee (CEP) is formed by a group of people who voluntarily dedicate part of their time to ensure the dignity, rights, safety and well-being of participants in scientific research, as well as to support the interests of and needs of researchers, exercising an advisory and, in particular, educational role, promoting the discussion of ethical aspects and requirements established by regulatory agencies and legislation in research involving human beings.

For its performance, the CEP must be authorized by the National Commission for Ethics and Research (CONEP), which regulates research ethics in Brazil. CONEP is one of the commissions of the National Health Council (CNS). The CEP-CONEP System is organized through ordinances and resolutions on research in human beings.

Currently, all research must be submitted to the Plataforma Brasil system, a national and unified database of research involving human beings for the entire CEP/CONEP system. This system allows surveys to be monitored at their different stages - from submission to final approval by CEP and CONEP, in a shared environment where all those involved have access to information, reducing the processing time of projects throughout the CEP system. /CONEP. It also allows society to access public data on all approved research[6].

CNS Resolution 466/2012, in force, revokes previous resolutions and determines guidelines and regulatory norms for research involving human beings. This Resolution incorporates the references of bioethics - autonomy, non-maleficence, beneficence, justice and equity - from the perspective of the individual and collectivities, affirming the dignity and freedom of the human being. It aims to ensure the rights and duties that concern research participants, the scientific community and the State (item I). References to documents such as the Nuremberg Code, the Declaration of Human Rights, the International Covenant on Economic, Social and Cultural Rights, the Covenant on Civil and Political Rights, the Universal Declaration on the Human Genome, the Universal Declaration on Human Genetic Data and the Universal Declaration on Bioethics and Human Rights[7].

Some modifications that Resolution 466/2012 established in relation to CNS Resolution 196/96 include[8]:

a) New terms and definitions, such as: **"Research Participant"; "Free and informed consent"; "Comprehensive assistance"; "Immediate assistance"; "Research Benefit"** (item II);
b) As for the Ethical aspects of the Research, it assures all participants at the end of the study, on the part of the sponsor, **free and indefinite access** to the best prophylactic, diagnostic and therapeutic methods that have been shown to be effective. Access will also be guaranteed in the interval between the end of the individual participation and the end of the study, and in this case, this guarantee may be given through an extension study, according to a duly justified analysis of the participant's attending physician. It also guarantees, for women who declare themselves expressly exempt from the risk of pregnancy, either for not engaging in sexual practices or for exercising them in a non-reproductive way **, the right to participate in research without the mandatory use of contraceptives** (item III.3.d) ;
c) New Free and Informed Consent Process, understood as **all the steps to be necessarily observed so that the person invited to participate in a research can express himself, autonomously, consciously, free and informed** (Item IV);
d) As for the Risks and Benefits, it guides that "all research involving human beings involves risk in different types and degrees. **The greater and more evident the risks, the greater the care to minimize them and the protection offered by the CEP/CONEP System to participants. Possibilities of immediate or subsequent damages, at the individual or collective level, must be analyzed. Risk analysis is an essential component of ethical analysis, resulting in the monitoring plan that must be offered by the CEP/CONEP System in each specific case** ." And that research whose benefits to its participants are exclusively indirect are admissible, provided that the physical, psychic, moral, intellectual, social, cultural **or spiritual dimensions of** these are considered (Item V)
e) New attributions of the CEP that include evaluating research protocols involving human beings, **with priority on topics of public relevance and strategic interest in the SUS priority agenda, based on epidemiological indicators, issuing an opinion, duly justified, always oriented, among others, by the principles of impersonality, transparency, reasonableness, proportionality and efficiency, within the deadlines established in the operational standard, avoiding redundancies that result in delays in the analysis** (Item VIII);
f) As for the attributions of the National Research Ethics Commission (CONEP), it establishes new determinations for specific Thematic Areas (Item IX); among other resolutions.

Officially, CNS Resolution 466/2012 explains:

> The CEPs are interdisciplinary and independent collegiate bodies, of public relevance, of a consultative, deliberative and educational nature, created to defend the interests of research participants in their integrity and dignity and to contribute to the development of research within ethical standards[7].

From a practical point of view, the CEP has the function of analyzing research projects regarding their ethical aspects and issuing the opinion, with guidelines to the researchers of the necessary adjustments for their final approval. The CEP/CONEP system analyzes: 1) Free and informed consent: guaranteeing freedom of voluntary choice. Language accessible to lay people; 2) Assurance to the patient of adequate treatment; 3) The competence of the researcher and team to carry out the study; 4) The infrastructure of the study site; 5) Protection of the researcher against adverse publicity and legal action; 6) Protection of the institution's reputation. The Research Ethics Committee also evaluates methodological aspects of the project, since these are directly related to the ethical aspects of the research. However, many teaching and research institutions have methodological and collegiate advisory committees that analyze the methodological aspects before sending the project to the CEP, following the rigor of good research practices.

A fundamental aspect of research ethics is obtaining the Free and Informed Consent Form. It is a document provided to the person invited to participate in the research, or to his/her legal representative, so that he/she is informed about the research and can voluntarily choose to participate or not in the study. It must have an explanatory character, free from simulation, fraud, error or intimidation, addressing all issues related to the study that may be related to the research participant's decision making, such as: the nature of the research, justifications, objectives, methods, procedures, potential risks and benefits and identification of the researchers involved. It is a document that aims to protect the participant, the researcher and the institution, and must be written in the form of an invitation, always addressed directly to the participant and in accessible language, according to the person's degree of understanding (without technical terms). Its application requires a process of dialogue and mutual trust in which the participant has the opportunity to clarify their doubts and time to make an autonomous decision.

In cases of research involving children, the Free and Informed Assent Term must be requested, starting from the age at which they understand the reason for their participation in a research and how it takes place, that is, 5 years old[7]. The text of this document should be very simple and direct, depending on the age and level of understanding of the child/adolescent, explain the objectives and procedures that the child will go through, ask if the child wants to participate and inform that if he/she does not want to participate or wants to stop participating, she can withdraw from the research without being in any way punished for it. It is interesting to use graphic resources such as drawings, characters, illustrative stories, for better understanding.

Some research, according to CNS regulations, must be forwarded for consideration by CONEP, namely: 1. human genetics (sending abroad of genetic material or any human biological material to obtain genetic material; storage of biological material or human genetic data abroad and in the country; alterations in the genetic structure of human cells for in vivo use; research in the area of human reproduction genetics ( reprogenetics ); research in behavioral genetics; and research in which the irreversible dissociation of data from participants of search); 2. human reproduction (assisted reproduction; manipulation of gametes, pre-embryos, embryos and fetus; and fetal medicine, when involving invasive procedures); 3. therapeutic equipment and devices, whether new or not registered in the country; 4. new invasive therapeutic procedures; 5. studies with indigenous populations; 6. Research projects involving genetically modified organisms (GMO), embryonic stem cells and organisms that represent high collective risk, including organisms related to them, in the areas of: experimentation, construction, cultivation, manipulation, transport, transfer, import, export, storage, release into the environment and disposal; 7. protocols for setting up and operating biobanks for research purposes; 8. Research with coordination and/or sponsorship originated outside Brazil, except those with co-sponsorship of the Brazilian Government; and 9. projects that, at the discretion of the CEP and duly justified, are deemed worthy of analysis by CONEP[7].

As of 2016, Resolution 510/2016 , provided for the rules applicable to research in Human and Social Sciences whose methodological procedures involve the use of data directly obtained from the participants or identifiable information or that may entail greater risks than the existing ones in everyday life. Research in these areas has ethical specificities and uses their own methodologies, given their particularities [5] .

In its article 1, sole paragraph, it determines that the following will not be registered or evaluated by the CEP/CONEP system: I – public opinion polls with unidentified participants; II – research that uses publicly accessible information, pursuant to Law No. 12,527, of November 18, 2011; III – research that uses information in the public domain; IV - census survey; V - research with databases, whose information is aggregated, without the possibility of individual identification; and VI - research carried out exclusively with scientific texts to review the scientific literature; VII - research aimed at theoretical deepening of situations that emerge spontaneously and contingently in professional practice, as long as they do not reveal data that can identify the subject; and VIII – activity carried out with the exclusive purpose of education, teaching or training, without the purpose of scientific research, of undergraduate students, of technical courses, or of professionals in specialization[5].

In addition, within the educational scope, the CEP conducts lectures and orientation courses for researchers regarding the requirements for the elaboration of research projects involving human beings and, also, guides the researcher about the Brazil Platform and the posting of their research project.

The CEP must be constituted to act independently from political, institutional, professional and commercial influences. It must be made up of specialists from different areas of knowledge, of a multiprofessional and intersectoral nature, favoring a balance between age and sex and including people who represent the interests and concerns of the community.

CEP members are required to know the conditions for appointment, duration and policy for renewing their mandate; the absence of conflict of interests in the process of nomination and appointment of members (when unavoidable, these interests must be explained); availability to disclose your full name, profession and institutional affiliation; the maintenance of confidentiality regarding the meetings at which the projects are deliberated, the protocols submitted for consideration, the information on the research participants and other related matters, and the initial and continuous training throughout its mandate, in relation to the ethical and scientific aspects of biomedical research [7] .

Alves (2016)[9] highlighted weaknesses in the work of health professionals, resulting from deficient professional training in the area of humanities and pointed out needs for a better understanding of research in children and adolescents.

## CLINICAL BIOETHICS COMMITTEE OR COMMITTEE

Loch and Gauer (2010) define the Clinical Bioethics Committee as an independent space, based in hospitals, clinics, research institutes or laboratories, where professionals from different areas of knowledge meet to discuss and work on the various components of related activity sectors. with human life and health [10] .

According to CFM Recommendation No. 8/2015, article 1, the Bioethics Committee is an autonomous, consultative and educational multi-professional collegiate that works in hospitals and healthcare institutions, with the aim of assisting in the reflection and solution of related issues. to morals and bioethics that arise in patient care. This resolution recommends the creation, functioning and participation of physicians in Bioethics Committees. To the technical and clinical director of the clinical staff of hospitals, to the technical directors of other health institutions and to the presidents of professional medical entities that contribute, within the scope of their competence, to the creation, operation and maintenance of a Bioethics Committee in your institution,

according to relevance, pertinence and number of existing professionals [11].

The main objective of Clinical Bioethics is to reflect and deliberate on the different aspects involved in ethical conflicts, most of which are complex, which arise in clinical practice, with the aim of helping decision-making [12].

According to the Center for Bioethics of the Regional Council of Medicine of São Paulo (CREMESP) [13], in the Constitution Model for Hospital Bioethics Commissions, this has the following purposes:

- Prepare opinions on problems of a bioethical nature that arise in clinical contexts;
- Reflect on ethical dilemmas arising from scientific and technological progress, formulate recommendations and contribute to educational and dissemination actions, thus promoting awareness of health professionals as well as the community.
- Address and emphasize issues related to the humanization of medical treatment in the hospital.

In Section I, article 12, on the Competences of the Bioethics Commission [13], it establishes:

I - The analysis, issuance of opinions, promotion of educational and dissemination actions on bioethical problems, especially those referring to:

- Beginning and end of human life;
- Procedures related to health actions and services;
- Patient rights and duties;
- Rights and duties of the health professional;
- Terminally ill patients and euthanasia
- Transplants of organs, tissues and parts of the human body;
- Prophylactic diagnostic, therapeutic and rehabilitation resources;
- Assisted reproduction;
- Patient's record;
- Cloning;

II - Ensure compliance with national and international standards on bioethics;

III - Advise on the issuance of technical standards and instructions to discipline the relationship between health professionals and patients.

IV - Do not issue opinions of a deontological nature suggesting the competence of the Hospital's Medical Ethics Committee for such procedures.

According to CFM Recommendation No. 8/2015, in article 1, §4, the Bioethics Committees are not responsible for: a) Imposing decisions. b) Assume the responsibility of the consultant. c) Issuing value judgments about professional practices. d) Exercise control over professional practices. e) Carry out expertise[11].

In the pediatric area, the bioethical questions are varied and cover particular aspects since the doctor/patient relationship extends to guardians and/or family members. Among the conflicts, the most frequent are those in which the physician is faced with children with complex malformations that are incompatible with life, communication of reserved prognoses, refusal to accept blood transfusions in some religious beliefs, repeated cardiorespiratory resuscitation maneuvers in terminally ill patients. , unnecessary interventions, discontinuation of futile treatment, palliative care, approaching drug-dependent adolescents or those who have attempted suicide, mental disorders that prevent socialization, discharge at the request of family members of very seriously ill patients, organ donation, genetic selection to obtain specific phenotypes or for organ donation, and unavailability of a place in a pediatric or neonatal ICU. The performance of a Hospital Bioethics Committee (CBH) represents, in cases like these, an invaluable instrument for the best decision to be taken for the benefit of the patient[14].

The Health Unit is responsible for structuring a clinical bioethics commission, according to demand. There is no national legislation or even guideline that deals with its creation, even with the increase of bioethical dilemmas and doubts in patient care, on the part of health teams. Thus, there is a need to publicize such topics at events, as well as education and training of professionals[15].

A first aspect to note is that, for the successful implementation of Clinical Bioethics Commissions or Committees, there is a need for a clear definition of their functions and attributions, their composition and their limits of action. A second aspect is the understanding, in practice, by health professionals and teams of the role of the Clinical Bioethics Committee, which basically has three focuses: educational, consultative and normative, always with the objective of improving team care. , family and patient[16].

The implementation initiative starts, in most cases, from the need to discuss cultural, social, diagnostic or therapeutic aspects, based on professional ethics and current legislation, where health professionals can discuss in a safe environment, with the objective of sharing doubts, dilemmas, anxieties and responsibilities about the best care to be offered.

The Committee will be able to start the activities with discussions of bioethical and legislative theoretical content and thus, verify its needs for composition. Some committees have only health professionals, others have already evolved to look beyond health, with theologians, anthropologists, lawyers, administrators. In choosing the names of the Bioethics Committee, a maximum number of 50% of professionals from the same functional category of the Hospital staff must be respected. Based on its advisory role, the Bioethics Committee assists health professionals in conflict situations, favoring an ethical, balanced and appropriate clinical practice to the demands that arise.

In summary, the Clinical Bioethics Committee differs from other ethics committees that also work in health institutions, such as the Ethics and Medical Deontology Committees and the Nursing Committees, aimed at observing the fulfillment of the professional duties of doctors and nurses. It also differs from Research Ethics Committees, which aim to

analyze the ethical adequacy of research projects involving human beings.

## FINAL CONSIDERATIONS

Ethics is considered a human construction, therefore social, cultural and historical. In all areas of these commissions, it is essential to guarantee the ethical conduct of the processes, guaranteeing protection and trust between the individuals involved, maintaining confidentiality, secrecy and privacy.

Confidentiality aims to safeguard the information given in confidence and to protect against its unauthorized disclosure. Professional secrecy aims to prevent publicity about facts known during the exercise of their profession and whose disclosure would damage the reputation, credit, moral or economic interest of clients and their families, being guaranteed in articles of the Federal Constitution of 1988 and in the Code Brazilian Civil Law - Law 010406/2002. Privacy guarantees the participant's right to maintain control over their choices and personal information and to protect their privacy, their image and their personal data, being a guarantee that these life choices will not be unduly invaded by public, state or public control. non-state, and by social disapproval based on the characteristics or results of the research (access limitation ) [5] . Respect for these ethical guidelines guarantees professionals the proper exercise of their activity, whether from the point of view of professional care and interpersonal activities, clinical research or the dilemmas faced during their practice.

*"It acts in such a way that the effects of their action are compatible with the permanence of authentic human life on Earth and are not destructive to the possibility of future life".*
**Hans Jonas ("The Responsibility Principle" - 1979)**

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