Research Ethics Committees*

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Introduction

Ethics committees represent a "way of doing bioethics" useful in plural and democratic societies. Although there are different types of ethics committees –clinical ethics committees, national ethics committees or *ad hoc* –, I will focus my analysis on research ethics committees in biomedical research with human beings. I will examine the international legal framework of research ethics committees – from a bioethical perspective – in order to define them and identify their functions. In addition, I will provide some practical data as a member of two research ethics committees.[1] Lastly, I will analyze the possible instrumentalization of research ethics committees to draw some conclusions and make proposals.

States must articulate legal regulations to define the conditions for exercising freedom of research such that other recognized rights are not undermined. Likewise, coordinated action is necessary to develop international legal regulations based on principles, rights and guarantees. A framework to guide the development of regulations to allow the same level of protection for individuals involved in research, regardless of the places where the research is carried out, with their different economic and social situations. This is not an easy task. The legal system does not provide a response to all the problems and dilemmas that research and scientific and technological innovation generate[2]. In societies in which pluralism is a legally recognized value[3], there can be different, equally valid ways of dealing with the same problem. The law cannot respond to rapidly changing research and innovation. Advances in scientific knowledge and its applications persistently question the limits established by legal regulations and ethical guidelines. The use, then, of multidisciplinary research ethics committees must be explored in order to solve these problems, and to make decisions of profound

[1]Bioethics Committee at the University of Barcelona (since 2011 up to present) and Research Ethics Committee at Hospital Clínic de Barcelona (since 2012 to present).

[2]Stefano Rodottà, *La vita e le regole. Tra diritto e non diritto* (Feltrenelli 2009).

[3]Article 12. Declaration on Bioethics and Human Rights, UNESCO (2005); and Maria Casado, *Bioética, Derecho y Sociedad* (Trotta 2015); Javier de Lucas, "Dignidad, pluralism y democracia" in Maria Casado (coord.), Sobre la Dignidad y los Principios: Análisis de la Declaración Universal sobre Bioética y Derechos Humanos de la UNESCO (Aranzadi Thomson Reuters 2009). Ethics and Clinical Research.

importance for individuals and social groups in societies potentially in conflict. This is the reason why research ethics committees have become a significant part of the research system; without their involvement, the development of biomedical research is inconceivable.

The analysis of the conditions established in legal regulations for the protection of human rights in biomedical research, leads to a focus on research ethics committees. Committees that the international legal regulations considered as cornerstones in bioethics establish as the most appropriate mechanisms to ensure the protection of the rights of persons involved in such activity.

1. Bioethics and Ethics Committees in Biomedical Research

The origin of bioethics is linked to the creation of multidisciplinary and independent research ethics committees, to respond to the need to review and monitor research projects that involve human participation. Consider, for example, clinical trials for the development of medicinal products for human use, genetic or observational studies. These committees must weigh up the research freedom of the researcher – the main impetus for the advancement of knowledge, and its subsequent application – with other implied rights, such as autonomy, physical or mental integrity, the free development of the personality and the privacy of patients and healthy volunteers who participate. It is well-known that the first research ethics committees were established to avoid the abuse of participants, which took the form, for example, of not asking for their consent, not providing them with adequate information, not informing them about the consequences of their participation, and placing them in situations of completely disproportionate risk in relation to potential benefits.[4]

Ethics committees in biomedical research are, in my opinion, "a way of doing bioethics". They make a move from theory to action[5] in research where bioethics has been and is the main protagonist, largely due to the spread of the so called principles in bioethics of autonomy, beneficence, and justice, imported from the US research and health care setting.[6] Thus, international regulations establish that research ethics committees must analyze, along with methodological aspects, the ethical, legal and even social issues involved in the research projects.[7]

We start here from a conception of bioethics that takes as reference the legal and ethical minimum represented in internationally recognized human rights, in order to reflect on

[4] Henry K. Beecher, "Ethics and Clinical Research" (1966) N Engl J Med 274, 1354-1360

[5] Itziar de Lecuona, "Ethics Committees:The Challenges Facing Bioethics in the 21st Century" 3, 2 (2011) ABR 164-169.

[6] "The Belmont Report" Office of the Secretary Ethical Principles and Guidelines for the Protection of Human Subjects of ResearchThe National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research U.S.A, April 18, 1979.

[7] European Convention on Biomedicine and Human Rights, Council of Europe (1997).

scientific and technological progress and the consequences of its applications, especially for human beings. This reflection can also be extended to other living beings and to the environment. This ethical reflection has legal-political consequences, and must also consider cultural and local specificities.[8] Thus, the challenge for research ethics committees in biomedical research is to be able to integrate these different perspectives in the exercise of their functions.

The creation of research ethics committees has accompanied bioethics since its beginnings, with the ultimate goal of guaranteeing that the interests of science and society do not prevail over those of the individual.[9] Annas notes that ethics committees were born in part from the fear of the legal responsibility of medical institutions and from societal rejection of certain abusive situations, which necessarily led to regulations that have fostered the development of bioethics since the 1970s.[10] The Declarations and Reports considered milestones in bioethics, such as the World Medical Association's Declaration of Helsinki[11] and the Belmont Report, are about ethics in biomedical research. Their purpose is to establish ethical guidelines for proper conduct in research that does not undermine the rights of the subjects involved and does not impede the advancement of knowledge. It is in these documents where we find the first references to the need to establish research ethics committees that review specific requirements before, during and after research conducted with human beings. The history of biomedical research has been written through the public disclosure of incidents in which human beings, especially those most vulnerable, such as prisoners, the disabled and even minors, have been damaged, apparently for the purpose of research.[12] These episodes have acted as a catalyst for the development of ethical guidelines such as the Declaration of Helsinki, which make it possible to carry out biomedical research through the exercise of scientific freedom in a way that is compatible with respect for the individuals involved and their rights. With this purpose, research ethics committees signed on to and were consolidated into the original version and further revisions of the Declaration of Helsinki from 1964 until the last revision carried out in Fortaleza, in 2013 that states the following[13]:

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[8] Gilbert Hottois, *Le paradigme bioéthique: une éthique pour la technoscience* (De Boeck Université 1990); María Casado (Comp.), *Estudios de Bioética y Derecho* (Tirant lo Blanch 2000).

[9] Art. 2. European Convention on Biomedicine and Human Rights, Council of Europe (1997).

[10] George J. Annas, "At law: Ethics committees: from ethical comfort to ethical cover" (1991) 21 *The Hastings Center Report*.

[11] Declaration of Helsinki: Ethical Principles for Medical Research Involving Human Subjects, World Medical Association (1964).

[12] Baruch A. Brody, *The ethics of biomedical research: An international perspective* (Oxford University Press 1998).

[13] Research Ethics Committees: 23 Declaration of Helsinki: Ethical Principles for Medical Research Involving Human Subjects, World Medical Association (WMA) Adopted by the 18th WMA General Assembly, Helsinki, Finland, June 1964 and amended by the:29th WMA General Assembly, Tokyo, Japan, October 1975 35th WMA General Assembly, Venice, Italy, October 1983 41st WMA General Assembly, Hong Kong, September 1989 48th WMA General Assembly, Somerset West, Republic of South Africa, October 1996 52nd WMA General Assembly, Edinburgh, Scotland, October 2000 53rd

> "The research protocol must be submitted for consideration, comment, guidance and approval to the concerned research ethics committee before the study begins. This committee must be transparent in its functioning, must be independent of the researcher, the sponsor and any other undue influence and must be duly qualified. It must take into consideration the laws and regulations of the country or countries in which the research is to be performed as well as applicable international norms and standards but these must not be allowed to reduce or eliminate any of the protections for research subjects set forth in this Declaration. The committee must have the right to monitor ongoing studies. The researcher must provide monitoring information to the committee, especially information about any serious adverse events. No amendment to the protocol may be made without consideration and approval by the committee. After the end of the study, the researchers must submit a final report to the committee containing a summary of the study's findings and conclusions".

The creation and implementation of ethics or bioethics committees has become *"*the way of doing bioethics", promoted by international governmental organizations, such as UNESCO[14], and non-governmental organizations, such as the World Medical Association. Likewise, states have considered it necessary to regulate the conditions for the creation and functioning of these committees. Consequently, research ethics committees have taken on a prominent place in biomedical research, such that the mandatory and favorable opinion of a research ethics committee is necessary for the responsible authority to approve research being conducted that involves the participation of human beings -or in which biological samples of human origin or personal data are used-. Although the contribution of research ethics committees from an ethical, legal and social perspective is an open question, they represent the most agile mechanisms to operate with agility and flexibility in the spaces created by biomedicine in today's complex societies.

2. International legal regulation of research ethics committees from a bioethics perspective

Biomedical research aims to contribute to the increase in generalizable knowledge, as well as to improve the health, well-being and quality of life of individuals.[15] Biomedical research is necessary to test and verify the effectiveness and safety of new methods of

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WMA General Assembly, Washington DC, USA, October 2002 (Note of Clarification added) 55th WMA General Assembly, Tokyo, Japan, October 2004 (Note of Clarification added) 59th WMA General Assembly, Seoul, Republic of Korea, October 2008 64th WMA General Assembly, Fortaleza, Brazil, October 2013

[14] UNESCO *"*Assisting Bioethics Committees", (http://www.unesco.org/new/en/social-and-human-sciences/themes/bioethics/assisting-bioethics-committees) accessed 15 september 2016

[15] The Council for International Organizations of Medical Sciences CIOMS International Ethical Guidelines for Biomedical Research Involving Human Subjects (2003) Preamble "The term "research" refers to a class of activity designed to develop or contribute to generalizable knowledge. Generalizable knowledge consists of theories, principles or relationships, or the accumulation of information on which they are based, that can be corroborated by accepted scientific methods of observation and inference. In the present context "research" includes both medical and behavioural studies pertaining to human health. Usually "research" is modified by the adjective "biomedical" to indicate its relation to health.

diagnosis, prevention and treatment in humans. Beyond pure research interests, biomedical research generates knowledge and power, as well as economic profits for states and private initiatives. In a market society[16] there are different interests and purely mercantile practices exist in which those involved in research may be unprotected if the necessary precautions are not instituted. In this section we analyze the response provided by the international legal framework considered to be a reference in bioethics for regulating ethics committees in biomedical research with human subjects. The *Convention on Human Rights and Biomedicine* of the Council of Europe of 1997 and its *Additional Protocol on Biomedical Research* of 2005, and the *Universal Declaration on Bioethics and Human Rights* of UNESCO of 2005.

The *Convention on Human Rights and Biomedicine* was the first legally binding international legal on the protection of human rights with respect to applications of biology and medicine. In relation to scientific research, the *Convention* establishes that "the research project has been approved by the competent body after independent examination of its scientific merit, including assessment of the importance of the aim of the research, and multidisciplinary review of its ethical acceptability"; art 16.iii). It also establishes that the state authority responsible for authorizing research will delegate decision making to a multidisciplinary group of persons including professionals and lay persons. The contributions of the 2005 *Additional Protocol to the Convention on Human Rights and Biomedicine, concerning Biomedical Research*, which further developed the previsions contained in the Convention on Human Rights and Biomedicine of the Council of Europe related to biomedical research, should also be considered. The features of the *Protocol* regarding the definition of research ethics committees in biomedical research –independence and multidisciplinarity– are introduced in establishing the evaluative and ethical monitoring of biomedical research that said authorities must carry out. The *Protocol* mandates, first of all, that states must assure conditions that allow real independence, establishing that ethics committee cannot be the object of any type of improper external influence (art.10.1) that could lead to a biased conclusion. Secondly, a mandate is addressed to each of the member of an ethics committee in biomedical research: They must make a declaration of interests, understood in a broad sense, whose purpose is "to declare all those circumstances which could lead to a conflict of interest" (art 10.2). In addition, it establishes that members faced with a conflict of interest related to a research project under evaluation cannot participate in said evaluation.

In relation to multidisciplinarity, the analysis of the ethical acceptability of a research proposal should be carried out by professionals with different types of experience and knowledge (art. 9.2), as well as by individuals who are not experts on the subject. The *Protocol* does not, however, establish the number of members or the profile of the individuals that must form part of the committee. It requires that committees include "different types of knowledge and experiences and different points of view", and it

[16] Michael Sandel, *What Money can´t buy. The Moral Limits of Markets* (Penguin 2003).

emphasizes that there should be lay members, so that the interests and concerns of the community are represented.

It seems that the presence of lay or community members in ethics committees generates trust in the system established to control biomedical research. In the *Explanatory Report to the Additional Protocol*[17] the term, "layperson" refers to individuals who have no experience in biomedical research and who are not health care professionals. The participation of persons who are not experts in research, but who have expertise in other areas, does not disqualify them from issuing valid opinions. It is also considered necessary for committees to have balanced representation in regard to gender and cultural perspective. Also considered in the Protocol is the ad hoc participation of experts to issue an opinion on a specific research project under consideration related to their area of knowledge, so that they can contribute to making a proper assessment to protect the rights of individuals, their safety and wellbeing. This form of participation is very important given the highly specialized nature of scientific knowledge today. To conclude, and in relation to multidisciplinarity in the composition of research ethics committees, should consider the possibility of patients' organizations being consulted on specific issues.

Research ethics committees must issue a reasoned judgment after the multidisciplinary assessment of the methodological and ethical aspects of the research, in which it justifies the conclusions it has reached, whether positive or negative (art. 9.3) and presents them in a manner that is clear and understandable for both specialists and non-specialists. In addition, the *Protocol* states that the judgment must be made available to potential participants in the research project evaluated.

UNESCO's *Universal Declaration on Bioethics and Human Rights*, adopted by acclamation by the international community in 2005, and addressing "ethical issues related to medicine, life sciences and associated technologies as applied to human beings, taking into account their social, legal and environmental dimensions" (art.1.1), makes the following sound contributions:1) It defines ethics committees in general terms as independent, multidisciplinary and pluralist bodies; 2) it places ethics committees in a strategic position in the area of applying the principles it upholds, which, among others, include autonomy and individual responsibility (art. 5) and respect for cultural diversity and pluralism (art.12); 3) it establishes a typology of ethics committees, including among them committees in biomedical research, and assigns them the function of evaluating the ethical, legal and scientific problems of research projects related to human beings (art. 19). The *Declaration* states that these committees must also evaluate relevant social factors, which implies that the context in which the research is carried out is also an object of analysis for ethics committees examining biomedical research projects (art. 19); 4) the Declaration indicates that states should

[17] *Explanatory Report to Additional Protocol on Biomedical Research* of 2005 (http://www.coe.int/en/web/conventions/full-list/-/conventions/treaty/195) accessed 15 september 2016.

encourage the creation of these bodies to address biomedicine either through policies or regulations (art. 22.2.); 5) the Declaration assigns them the functions of promoting social debate and raising awareness around bioethical issues (art. 19) which are considered part of the discipline of bioethics, and allowing ethics committees to pass from theory to action; 6) Research ethics committees should evaluate the integrity, honesty and the professionalism of the researchers that direct and participate in the projects undergoing evaluation (art. 18) and apply the principle of transparency in decision making. In this regard, research ethics committees must analyze projects and monitor them from beginning to end – including possible publication of the results in scientific journals – in order to avoid, for example, scientific fraud as well as to detect research misconduct; 7) the *Declaration* states that transnational research in health should respond to the needs of the host countries and alleviate urgent health problems worldwide. The principles established should be applied and transnational research, which takes place in different states at the same time, should be ethically evaluated by the research ethics committee in the country where the funding comes from in addition to the country or countries where the research is going to be carried out (art. 21). In this transnational framework it is possible that practices can occur related to, for example, trafficking in samples, organs and tissue or to the undesired or illegal use of data and parts of the human body. Research ethics committees must detect these situations, including the trend toward the commodification of the human body and its parts.[18] The exercise of biomedical research, which can cause harm to human subjects, poses an unavoidable challenge: to protect their rights, safety and wellbeing. Thus, the creation of research ethics committees becomes necessary. It acquires a universal dimension, as biomedical research is today transnational.

In sum, research ethics committees must evaluate: the design of the study; the competence and qualifications of the researcher; the procedure foreseen for obtaining informed consent from individuals; and the risk benefit ratio, crucial for evaluating if the rights of the participants or individuals involved will be disproportionately affected.

3. The instrumentalization of Research Ethics Committees

Are ethics committees in biomedical research independent and impartial? From the perspective of protecting human rights the possibility of interference in ethics committees in the area of biomedical research is an issue of concern. In theory, research ethics committees ensure the protection of participants in research projects. Thus, they guarantee the safety of the public. But in practice, they can respond to certain interests, which have nothing to do with that goal.

[18]Elena G. Sevillano, "My tumor is sold abroad" (El País, 25 July 2016) http://archyworldys.com/my-tumor-is-sold-abroad/ accessed 15 september 2016

For Lysaught,[19] when bioethics emerged in the 1970s its aim was to strengthen the establishment and development of biomedical research. Its tasks included creating ethics infrastructures – ethics and bioethics committees – as well as obtaining social approval for research. However, bioethics may have already made the subtle move from the rhetoric of defending the freedom and autonomy of the individual to converting the person into a "docile body" in the interest of industry or the state, as a form of control and management of individuals, and especially their bodies, as power is manifested through them. Not only should we speak of "docile bodies", but also of "docile states", as occurs with research in so-called developing or underdeveloped countries. From this perspective, although biomedical research involving the participation of human beings is considered necessary, it must be done through an equitable sharing of the costs and benefits among those who will bear the disadvantages and who will presumably enjoy the benefits, and satisfy their needs or expectations of health. It is for this reason that the principle of justice has taken on a major role in biomedical research, especially when it comes to research carried out in developing countries that is sponsored by industrialized countries.

Biomedical research is synonymous with progress and power for certain agents – the state, industry, institutions – with diverse scientific, economic and social interests. The development of diagnostic, preventive and therapeutic methods, as well as new types of health interventions that may be beneficial for individuals is carried out through research protocols that must be reviewed and approved by independent research ethics committees, as established by the legal regulations previously discussed. Bioethical reflection in advance of the development of the necessary legal norms to regulate research can be seen as a bioethics at the service of a politics that strengthens the development of the biomedical industry and research, in contrast to a process of bioethical reflection that leads to genuine social debate. According to Lysaught, it strengthens the interests of private enterprise with state participation – with its resulting economic benefits – and does so under the discourse of the interest and wellbeing of the person and the protection of his/her rights. The result, for this author, is a strengthening of public and private structures of biomedical research through the establishment of docile subjects, enabling the development of a powerful new economic structure based on biomedical research, of which the pharmaceutical industry lobby is an example. A bioethics that is considered above other humanitarian or social considerations would be at the service of a politics that pursues the development of the biomedical industry and its financial gain.

From this critical perspective, the trend toward the marginalization of research ethics committees in the area of clinical trials is of concern, as the *European Group on Ethics* has stated.[20] In the European context, research ethics committees that review clinical trials on medicinal products for human use are undergoing major changes due to

[19]Marie Therese. Lysaught, "Docile bodies: Transnational research ethics as biopolitics" (2009) 34 Journal of Medicine and Philosophy.
[20]European Group on Ethics in Science and New Technologies, "Statement on Clinical Trials", 2013

legislative reforms. The current definition is striking: "'Ethics committee' means an independent body established in a Member State in accordance with the law of that Member State and empowered to give opinions for the purposes of this Regulation, taking into account the views of laypersons, in particular patients or patients' organizations" (art. 2.11). [21]

The repealed Directive from 2001 defined an ethics committee as: "an independent body in a Member State, consisting of healthcare professionals and non-medical members, whose responsibility it is to protect the rights, safety and wellbeing of human subjects involved in a trial and to provide public assurance of that protection, by, among other things, expressing an opinion on the trial protocol, the suitability of the investigators and the adequacy of facilities, and on the methods and documents to be used to inform trial subjects and obtain their informed consent" (art. 2k). [22]

Definitions are important because of the impact they have on discourse and practice in research. The experience I have acquired as a member of two research ethics committees makes it possible to offer a practical perspective, although not exempt from criticism, with the intention of highlighting the following: research ethics committees in clinical research are weakly defined in the new European legislation, and the impact of this in practice should be of concern; the main characteristics of these bodies are being diluted, with the negative consequences this may have for research regarding the goals being pursued: Public interests and public goods or private and personal initiatives? It is of concern if research ethics committees lose, via European legislation, what makes them distinctive - their independence and multidisciplinarity-, and instead they come to respond to institutional, commercial, personal and illegitimate pressures rather than the objectives for which they were initially created.

There is a trend to incorporate as members of biomedical research ethics committees, individuals that represent the interests of the community, the public and/or members of associations of patients affected by the specific diseases that are going to be studied. By incorporating such individuals, the aim is to promote multidisciplinarity and plurality, as well as transparency in decision making and public trust in the research being conducted, especially publicly funded research that will have health benefits for the public. However, patients' associations can be created and supported by the pharmaceutical, food and biotechnology industries. Is this the desire of patients or of the industry behind it? Patient's associations represented in research ethics committees may act as lobbies in favour of specific interests and to promote research and marketing of certain drugs or products of interest to the industry.

[21]Regulation (EU) No 536/2014 of the European Parliament and of the Council of 16 April 2014 on clinical trials on medicinal products for human use, and repealing Directive 2001/20/EC.

[22]Directive 2001/20/EC of the European Parliament and of the Council of 4 April 2001 on the approximation of the laws, regulations and administrative provisions of the Member States relating to the implementation of good clinical practice in the conduct of clinical trials on medicinal products for human use.

Authors such as Evans argue that the institutionalization of bioethics in the US through the establishment of governmental advisory committees avoids democratic control by the public. In his opinion, although bioethics should be a space open to deliberation and public debate, scientists do not support public involvement in their research, arguing that the public is unable to understand it. Bioethics did not arise to increase or promote individual freedom, but rather, to regulate and control the population in order for research to freely follow its course and achieve agreed upon objectives – those determined in decisions that preceded its approval and development – through research ethics committees, whose deliberative and decision-making process is inaccessible to the average citizen.[23]

In the opinion of Annas, also regarding the US context, the change in name from "committees on human research" to Institutional Review Boards (IRBs) would indicate that the primary role of these committees is to defend the interests of the institutions in which they are embedded. This author notes that the success of these committees lies in the specificity of their mandate, in their decision making process – established by federal law – and in the support they receive from doctors and foundations that finance biomedical research. Identifying with the needs and interests of the institution on which they depend is a disadvantage for IRBs, which in many cases do not have the experience necessary to analyze complex research proposals. Thus, it is not surprising that – protected by regulations – IRBs have approved research that otherwise could never have taken place because of its potential devastating effect on human beings.[24] This critical current reveals that behind the rhetoric of the principles of autonomy, beneficence and justice, essential to bioethics are the efforts of the biomedical research industry to maintain the support of ethics committees, especially in developing countries, where much transnational research is being conducted and where the research takes precedence over improving sanitary and educational conditions. It appears that what is needed would be to create ethics committees in biomedical research and -train their members in the countries where research involving human beings is taking place.

Although the need for training for members of ethics committees in biomedical research is not disputed, in my opinion, local specificities and cultures in capacity building must be taken into consideration, rather than the imposition of a particular model. It is not about exporting ideologies to local governments and researchers. Research ethics committees must avoid a bioethics protocol that serves institutional interests distant from and even contrary to their function as guarantor of the rights of human research subjects.

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[23] J.H Evans, *Playing God?. Human Genetic Engineering and the Rationalization of Public Bioethical Debate* (The University Chicago Press 2002)

[24] George J. Annas, "At law: Ethics committees: from ethical comfort to ethical cover" (1991) 21 *The Hastings Center Report*.

4. Conclusions and proposals

The protection of the rights and interests of participating individuals and those involved in biomedical research, their safety and their well-being, are the reason for the existence of ethics committees in biomedical research. Thus, research ethics committees are mechanisms to protect human subjects in biomedical research, as they allow a way of doing bioethics based on respect for internationally recognized human rights and universally accepted bioethical principles.

Research ethics committees represent a practical bioethics useful in democratic societies: if training and strengthening of skills in bioethics are fostered; and if procedures for debate and decision making are developed, to allow committees to adequately perform the duties assigned to them. It is thus a matter of taking into consideration the contribution they can make based on the expertise and aptitudes of their professional and lay members. The need to establish research ethics committees is justified in particular because of their independent and interdisciplinary character, and the transparency and integrity of their work procedures. The deliberative process carried out by ethics committees is an additional value in dealing with bioethical research issues. Because of the profile of their members, research ethics committees contribute to social cohesion on controversial issues that can divide the public and for which there are no unshakable and risk free answers.

It is necessary to strengthen a line of research in bioethics that analyzes the situation of ethics committees, that is critical and that will contribute to revising and improving the conditions for the creation of committees, their composition, functions, working procedures, and the training and capacity building of their members. These committees have become necessary to address ethical, legal and social research issues in research based on scientific evidence. In addition, they have an important role in training and raising awareness about bioethics.

Research ethics committees in the biomedical setting are still today closely linked with clinical on medicinal products for human use, as are often their members. There has been no in-depth analysis about who should have the competence to make decisions, and what changes are needed to properly review other types of biomedical research, such as big data research or research that involves social interventions. In particular, there has not been enough discussion about the evaluation of research that involves applying genome editing techniques, which is becoming widespread today and lacks adequate regulation. From a theoretical perspective, there is a high level of consensus that research ethics committees should assess the adequacy of research projects, in relation to the benefits for participants in the research or for the persons or communities participants represent. Both the economic cost and access to the benefits of the research are parameters that research ethics committees should include in their review.

The implementation of new regulations in the field of research with human beings should be analyzed in the face of possible distortions and instrumentalization of

research ethics committees. Research ethics committees should not generate a false sense of security; nor should they carry out a bioethics protocol removed from the ends for which they were established, or to provide support to private, institutional and illegitimate interests.