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Human Research Bioethical challenges: From international to Costa Rica´s institutional regulations

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ABSTRACT : This paper presents a comparative research on regulation, which moves from international research ethics framework, by analysing CIOMS International Ethical Guidesfor Health-Related Research with Human Beings and goes to national and institutional regulation of human research in Costa Rica, searching for bioethical foundations, such as human respect, justice, and beneficence. Characterizing each one, and analysing each regulation, to see whether national and institutional articles, still have bioethical contents, and if so, how is it presented. Ultimately, the paper argues for the promotion of justice on regulations, to give protection of the rights and well being of vulnerable people, give an appropriate response, secure a reasonable availability and compensation for damages.

KEY WORDS : *Bioethics, Costa Rica, ethics, human research, regulation, CIOMS.*

Resumen
Este artículo presenta una investigación comparativa sobre la normativa, que parte del marco de la ética de la investigación con seres humanos internacional, analizando las Guías Éticas Internacionales para la Investigación con Seres Humanos de CIOMS, y se dirige a la regulación nacional e institucional de la investigación con seres humanos en Costa Rica, buscando fundamentos bioéticos, como el respeto humano, la justicia y la beneficencia. Por medio de la especificidad de cada fundamento, se analiza cada normativa, para ver si los artículos nacionales e institucionales aún tienen contenidos bioéticos y, de ser así, cómo se presentan. Finalmente, el trabajo aboga por la promoción de la justicia en la normativa, para dar protección a los derechos y el bienestar de las personas vulnerables, dar una respuesta adecuada y, asegurar una disponibilidad razonable y una indemnización por daños.

Palabras claves
Bioética, Costa Rica, ética, investigación con seres humanos, normativa, CIOMS.

I. INTRODUCTION

Numerous international instruments have been formulated based on events that have left marks in the history of humanity: declarations, reports, guidelines, were written after living experiences related to experimentation with human beings that stained moments in the lives of many with pain. people, memories that remember what happened and should not be repeated. They represent, therefore, great ideals with a reflection of universality, but also underlying memories of voices whose whisper must remain in time.

Bioethics has developed hand in hand with these instruments, declaring principles and conquering ever greater spaces of action, which frames its most important challenge: its application. The difference between a dead letter and a living letter is that the latter is part of everyday life, each person who conducts research with human beings and puts into practice the bioethical foundations, gives it life.

This article analyses the path that the bioethical foundations have travelled from one of these instruments, the CIOMS (Council for International Organizations of Medical Sciences) International Ethical Guidelines for Health-Related Research with Human Beings, specially formulated to provide support in the formulation of policies typical of countries with socioeconomic characteristics that may represent a greater challenge in terms of vulnerability, in the face of multicentre research or simply sponsored by another State.

How has the application of bioethical foundations been in research with human beings? This document offers a look at this question, which is presented from Costa Rica, analysing the regulations and the case of CECUNA, considering bioethical foundations of Respect for people, Beneficence and Justice.

II. REGULATING RESEARCH

The divisions between disciplines are not absolute limits, between law and bioethics there is a semi-permeable barrier, which allows the enrichment of both areas of knowledge. Through regulations, ethical guidelines are expressed that, moving from moral duty to civil obligation, seek a permanent place in the sphere of everyday life. However, this does not represent either the guarantee of its application, nor the approach of the essential in the writing of its content. In addition, there are variables in the context that promote a constant review of bioethical proposals.

One of the first instruments of great importance in the application of bioethics in the field of research with human beings, was the Nuremberg Code (1947), after the Second World War, in which numerous experiments were carried out with people. those who were not consulted about their interest in taking part in the studies. In response to this situation, it presents one of the main contributions: voluntary consent for participation in research.

A few years later, the Belmont Report (1978) framed the need to continue generating regulations in the face of researchers who repeatedly ignored the relevance of previous instruments. This report contains three fundamental principles: Respect for people, Beneficence and Justice. This triad is taken up in the CIOMS Ethical Guidelines (2002), where the implications of each foundation in different areas related to research with human beings are explored in greater depth, in 21 guidelines. In general, the following fragments express their content:

-Respect for people:

> Respect for autonomy, which implies that people capable of deliberating on their decisions are treated with respect for their capacity for self-determination; and Protection of people with diminished or impaired autonomy, which implies that security against harm or abuse must be provided to all dependent or vulnerable people. (CIOMS, 2002, p.11-12)

-Beneficence:

> It refers to the ethical obligation to maximize benefit and minimize harm. This principle gives rise to guidelines that establish that the risks of the research are reasonable considering the expected benefits, that the research design is valid, and that the researchers are competent to conduct the research and to protect the well-being of the subjects. research. Furthermore, beneficence prohibits deliberate harm to people; This aspect of beneficence is sometimes expressed as a separate principle, not maleficence (do no harm). (CIOMS, 2002, p. 12)

-Justice:

> Give each one what is due (...) especially, to distributive justice, which establishes the equitable distribution of burdens and benefits when participating in research. Differences in the distribution of burdens and benefits are justified only if they are based on morally relevant distinctions between people; one of these distinctions is vulnerability (...) responding to their health needs and priorities, so that any product that is developed is reasonably within their reach and, as much as possible, leaving the population in a better position to obtain effective health care and protect your health. (CIOMS, 2002, p.12-13)

These principles include other concepts such as informed consent[1], confidentiality[2], adequate response[3] and reasonable availability[4], which must also be taken into account when developing research with human beings, which includes process studies, controlled trials of interventions (diagnostic, preventive or therapeutic), to determine the consequences of interventions and studies on human behaviour; using physical, chemical or psychological observation or intervention, generating records, among others. In addition, it must always be carried out by qualified and experienced professionals who propose a protocol that must be scientifically and ethically evaluated by one or more independent evaluation committees of the researchers (CIOMS, 2002, p.14-15).

[1]"It consists of a decision to participate in an investigation, made by a competent individual who has received the necessary information, has understood it properly and, after considering the information, has reached a decision without having been subjected to coercion, intimidation or intimidation. undue influences or incentives. " (CIOMS, 2002, p. 26)

[2]On the handling of the information of the people participating in an investigation and the precautions to safeguard their privacy. (CIOMS, 2002, p.89)

[3]"The ethical requirement that research respond to the health needs of the population or community in which it is conducted requires decisions about what is necessary to meet this requirement." (CIOMS, 2002, p. 47)

[4]It refers to the fact that a product or knowledge generated in an investigation is available for the benefit of the proposed population after the end of the study. (CIOMS, 2002, p.48)

In Costa Rica, before the Decree of the Constitutional Chamber[5] of 2010, the national investigation was regulated by the Regulation for Investigations in which Human Beings Participate, which consisted of 20 articles. However, ruling 001668-10 resolved the action of unconstitutionality as it is a regulatory norm in matters that must be regulated by law (Constitutional Chamber, 2010); Therefore, there was a legal vacuum in the country in research with human beings, until 2014, when the Biomedical Research Regulatory Law[6] was enacted, which defines its range of application to the public and private sectors of the State.

Law No. 9234 (2014) also contemplates in its second article, as principles of biomedical research, Respect for the dignity of people, Beneficence and Justice; however, it adds Nonmaleficence and Autonomy, as if they were not contemplated in the previous ones, following the principialist formulation of Beauchamp and Childress (1979).

Based on the reading and analysis of the CIOMS Ethical Guidelines and Law No. 9234, the following table was prepared that synthesizes the content of each foundation:

Table 1: Bioethical foundations in research

Respect for persons (Respect for the dignity of persons)	1. Respect for persons (general consideration).
	2. Respect for autonomy.
	3. Protection of people with diminished autonomy (including cases in which consent is required).
	4. Protection of information to guarantee confidentiality.
Beneficence	1. Beneficence (general consideration).
	2. Maximize the benefit and minimize the harm and mistakes (reasonable risks according to the benefit).
	3. Prohibition of deliberate harm to people.
	4. Valid research design.
	5. Competence and suitability of researchers, evaluators, consultants and institutions.
Justice	1. Justice (general consideration).
	2. Distributive justice: equitable distribution of burdens and benefits.
	3. protection of the rights and well-being of vulnerable people (includes refraining from practices that increase injustice)
	4. Appropriate response: It should respond to their health needs and priorities, including those of vulnerable populations.
	5. Reasonable availability: Any product that is developed is reasonably within their reach and, as much as possible, leaves the population in a better position to obtain effective health care and protect their health.
	6. Compensation for damages, fines and measures for non-compliance.

[5]Decree No. 1668 of January 27, 2010.

[6]"A type of activity designed to develop or contribute to generalizable knowledge on health in human beings. It can be observational, epidemiological, or non-interventional or experimental, clinical or interventional. For the purposes of this law, any reference to research will be understood as biomedical research with human beings in the field of health. " (Law No. 9234, 2014, art. 2)

Table 1 is decisive, because it served as the basis for analysing each legal instrument and monitoring the bioethical foundations, illustrating its percentage of representation in each regulation, elucidating in turn strengths and shortcomings in each category.

Analysed regulations include:

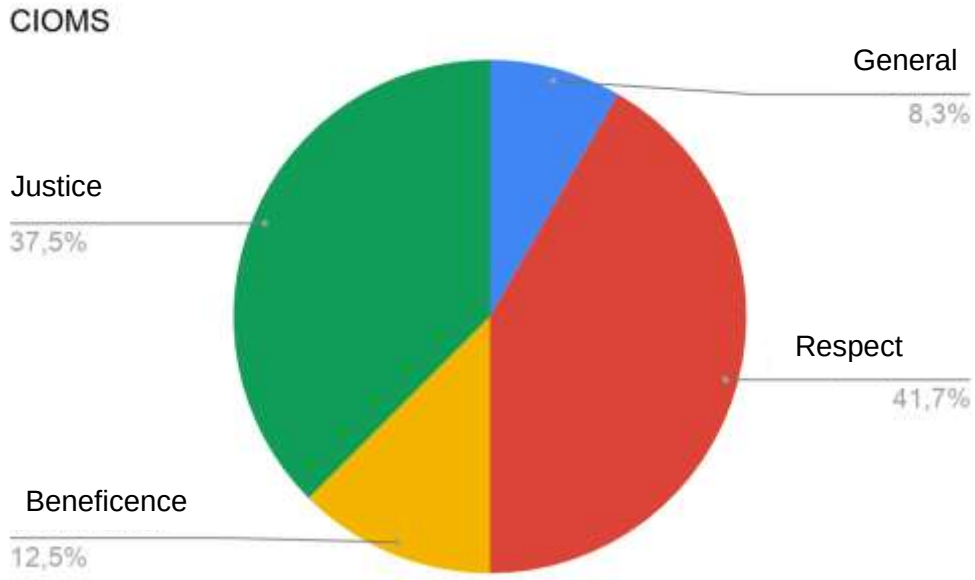
Table 2: Regulations

Nomenclature	Extension	Type	Year
CIOMS	Ethical Guidelines of CIOMS	International	2002
31078-S	Regulation for research involving human beings	National (CR)	2003
9234	National Biomedical Research Regulatory Law	National (CR)	2014
39061-S	Regulation to the Biomedical Research Regulatory Law and 39533-S: Regulation Reform to the National Biomedical Research Regulatory Law	National (CR)	2015
NE	Ethical Standards for Scientific Research in Institutional Health	Institutional (UNA)	2004
NE-M1	Amendment to the Ethical Standards for Scientific Research in Institutional Health	Institutional (UNA)	2004
NE-M2	Modification to the Ethical Standards for Scientific Research in Institutional Health	Institutional (UNA)	2004
NE-M3	Regulations, Rules and Procedures of the Scientific Ethics Committee of the National Institutional University	Institutional (UNA)	2009
NE-M4	Modification to the Regulation of the Scientific Ethics Committee of the National Institutional University	Institutional (UNA)	2010
NE-M5	Regulations, Rules and Procedures of the Scientific Ethics Committee of the National Institutional University	Institutional (UNA)	2013
R1-CEC	Regulation of the Scientific Ethics Committee of the National Institutional University	Institutional (UNA)	2015
R-M1-CEC	Regulation of the Scientific Ethics Committee of the National Institutional University	Institutional (UNA)	2017

II. Bioethical foundations in regulations

The first instrument analysed was the CIOMS Ethical Guidelines, whose 21 statements were classified in a table made from the categories in Table 1, first in relation to Respect for people, Beneficence and Justice, and then considering the subcategories that compose them. The result is indicated in graph 1:

Figure 1: CIOMS Ethical Guidelines, General Distribution



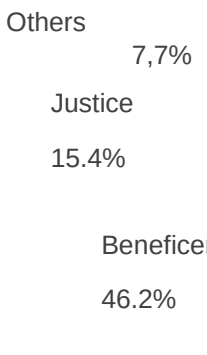
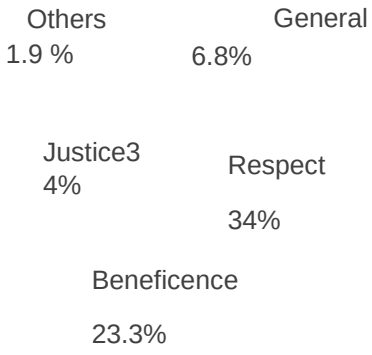
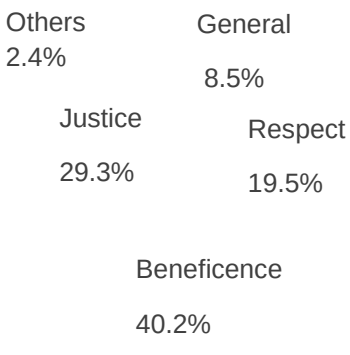
Graph 1 illustrates a prevalence of two areas: Justice and Respect for people. Most guidelines are intended to promote these bioethical foundations, allocating fewer guidelines to Beneficence.

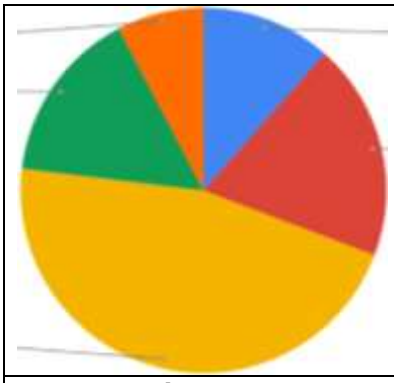
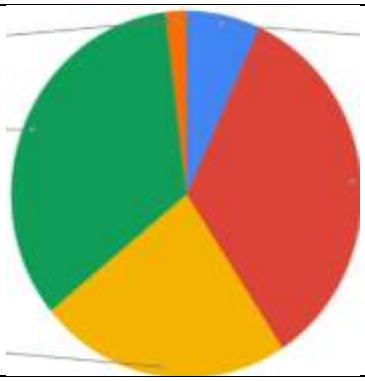
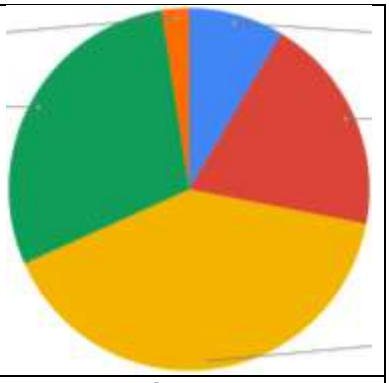
In a more specific review, within Respect for people, autonomy, and the protection of people with diminished autonomy are considered mostly, leaving only a guideline for the protection of confidentiality, which shows a greater concern for people of general form. Regarding Beneficence, most of the guidelines correspond to the maximization of the benefit and the reduction of the damage, so that competition and suitability do not have their own guideline, rather they are included in the comments. And finally,about Justice, a similar relationship is exposed between all the subcategories, being the need to protect vulnerable people and give an adequate response to the communities, which predominate. There are also general guidelines, where the three categories are integrated, the following stands out for its bioethical content:

> The ethical justification for biomedical research in human beings lies in the expectation of discovering new ways to benefit people's health. Research can be ethically justified only if it is conducted in a way that respects and protects the subjects of that research, is fair to them, and is morally acceptable in the communities in which it is conducted. In addition, since research without scientific validity is unethical, since it exposes research subjects to risks without possible benefits, researchers and sponsors must ensure that proposed studies in humans are in accordance with generally accepted scientific principles and are based on an adequate knowledge of the relevant scientific literature. (CIOMS, 2002, guideline 1)

Subsequently, the national regulations were analysed:

Table 3: Comparison of national regulations

Regulation for research involving human beings (31078-S)	Biomedical Research Regulatory Law (9234)	Regulation to the Biomedical Research Regulatory Law and 39533-S: and its Reform (39061-S)
		

		
2003, 19 articles	2014, 87 articles	2015, 31 articles

Regardless of individual differences, an evident increase in Beneficence is shown, due to the high content of articles referring to the competencies and suitability required for the different actors involved, from researchers to CEC members, so there are few destined for the prohibition of Cause damage; for example, in the Regulations to Law No. 9234 there are none.

If they are compared with the previous graph, a reduction in the principle of Justice can be noticed, because the number of articles referring to the application of this foundation is less. Why are fewer articles destined to regulate Justice? However, it should be noted that Law No. 9234 is the one that most contemplates it among the three, although the largest number of articles refer to compensation for damages, fines, sanctions, and penalties; only one is related to the need to respond adequately to the participating population. In the same way, the Regulation to the Law has the least number of articles destined to reasonable availability for the population in which the study was carried out, after the development of an investigation.

In an approach to the assignment of articles to Respect for people, in Law No. 9234 a majority can be found aimed at autonomy and confidentiality, while the protection of people with autonomy is less represented. And in its Regulations, it is verified that for the protection of people with diminished autonomy there are 11 articles and 9 for confidentiality, which is very interesting due to the preponderance given to the person who participates in the investigation and the management of their information.

The third article of Law No. 9234 is selected as a reference for the integration of bioethical foundations due to its content:

> The life, health, interest, well-being, and dignity of the participants in health research, in which human beings participate, will prevail over the interest of science, economic or commercial interests. All health research in which human beings participate must respond to a Human Rights approach. (Law 9234, Art. 3)

Finally, the articles that make up the CECUNA standards from 2004 to 2017 were analysed. Basically, they are 2 sets of ethical standards, the first was modified 5 times and the second only 1 time.In both cases it can be observed how the Beneficence has more than half of the designated articles, with Justice as the one with the least allocation, a big difference if the graph of the CIOMS Ethical Guidelines is reviewed. It must be considered that the prevalence of the principle of Beneficence is related not only to the weighting of the harm and the benefit, but also with the competence and suitability. It should be noted that there is a clear intention in these standards that the risks in research involving human beings are reasonable.

There is a similarity with the Law and its Regulations about Justice: less weight in importance (due to the scarcity of articles) to the need to ensure an adequate response and reasonable availability. This circumstance could mean a lower opportunity to address problems inherent to the community where the research is carried out and the difficulty of having access to the benefits generated from it. Among the few articles destined for Justice, the Protection of vulnerable people is the predominant consideration.

The following table summarizes the findings regarding the expression of the bioethical foundations mentioned in the regulations studied:

Table 4: Comparison of the regulations analysed according to the Bioethical Foundations studied
Period 2002-2017

	Regulations					
	CIOMS	**31078-S**	**9234**	**39061-S**	**NE**	**R-CEC**

General	8,3%	11,5%	6,8%	8,5%	10,8%	10,1%
Respect	**41,7**%	19,2%	**34**%	19,5%	26,2%	21,5%
Beneficence	12,5%	**46,2**%	23,3%	**40,2**%	**50,8**%	**50,6**%
Justice	37,5%	15,4%	**34**%	29,3%	7,7%	12,7%
Others	0%	7,7%	1,9%	2,4%	4,6%	5,1%

This table expresses the differences in percentages assigned to each foundation according to the instrument analysed. In a horizontal reading, it is possible to observe the fluctuations in the allocation of a single principle, for example, the increase in the Charity that mostly owns more articles, and the percentage decrease in both the Respect for people, as in the principle of Justice, which only in Law No. 9234 is close to the CIOMS Ethical Guidelines.

Specifically, a comparison was made between the regulations regarding the aspects of each subcategory with the highest and lowest number of statements. This comparison with respect to the principle of Respect for people is indicated in table 5:

Table 5: Comparison between regulations, specific distribution: Respect

2002-2017

	Regulations					
Respect	**CIOMS**	**31078-S**	**9234**	**39061-S**	**NE**	**R-CEC**
Higher incidence	Autonomy			Decreased Autonomy	Autonomy	
Less incidence	Confidenciality		Decreased Autonomy	Autonomy	Decreased Autonomy	

In the first subcategory, Respect for people, most of the instruments assigned more articles to Respect for autonomy, while the Protection of people with diminished autonomy was the least addressed, (note that it is the same in Law 9234 and the Regulations of the CECUNA). It also highlights that CECUNA includes more articles on the Protection of confidentiality than CIOMS.

The comparison between the regulations studied regarding the principle of Beneficence is indicated in Table 6:

Table 6: Comparison between regulations, specific distribution: Beneficence

2002-2017

	Regulations					
Beneficence	**CIOMS**	**31078-S**	**9234**	**39061-S**	**NE**	**R-CEC**
Higher incidence	Maximize benefit and minimize harm	Competence and suitability				
Less incidence	Competence and suitability	Maximize benefit and minimize harm	Deliberate Damage Prohibition			Deliberate Damage Prohibition and Valid Design

Regarding Beneficence, more statements of Competence and suitability were included in all instruments except CIOMS; and the fewest articles assigned were to regulate the Prohibition of deliberate harm.
In the subcategory of "Justice", table 7 shows many statements designated to the Protection of vulnerable people than to Reasonable availability and adequate response.

Table 7: Comparison between regulations, specific distribution: Justice
2002-2017

	Regulations					
Justice	**CIOMS**	**31078-S**	**9234**	**39061-S**	**NE**	**R-CEC**
Higher incidence	Greater Protection of the vulnerable and adequate response	Distributive justice	Compensation and punishment	Protection of the rights and well-being of vulnerable people		
Less incidence	Reasonable availability					
	Distributive justice and compensation	Protection of the vulnerable, adequate response and compensation			Adequate response	

The CIOMS Ethical Guidelines were shown to have a higher bioethical content in the analysis, while the other regulations are directed more towards content related to administration, such as suitability and competencies that refer to the actors involved. This reflects what happens at the time of implementing the bioethical foundations, some categories lose weight, such as Justice, showing deficiencies in subcategories such as reasonable availability and adequate response.

Where is justice?
After this analysis, regulations show a decrease in articles related to Justice and its subcategories, in the revision of protocols there is also a tendency to have a weak commitment to the application of this principle, and consequently, the people who carry out Research omits to comment on its importance. Mentioning its subcategories, having less articles defined as a response to justice, means that to give protection of the rights and wellbeing of vulnerable people, give an appropriate response, secure a reasonable availability and compensation for damages, there are very few legal options. Thus, it is valid to assume the need to promote institutional, even national, policies that encourage the application of the principle of Justice.

III. CONCLUSION REMARKS

Despite the mistakes, research with human beings allows the generation of knowledge that benefits and opens new possibilities; It is not about stopping research, but rather that it be regulated and carried out considering bioethics as the main column.
Research with human beings is necessary, but it must always be carried out in a fair way, respecting all the people involved, maximizing the benefit and minimizing the harm; Considerations that may seem simple, but whose complexity appears at the moment in which they are transferred to specific cases, through protocols.
Therefore, it is necessary to review the norms, be aware of improvements, possible transformations in the structures, that give strength to the application of the principles in the investigation, identify deficiencies in the protocols. And if the omission of subcategories is discovered whether in protocols or regulations, it is possible to propose changes, because bioethics is not a composition of letters, but of actions.

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