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Documentary analysis of benefit-sharing in biomedical research

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Abstract

Benefit-sharing, an important aspect of research in developing countries, ensures that natural resources and local traditional knowledge are recognized and valued. This study had the objective of analyzing, in official documents of graduate medical programs, the type of justice adopted to comply with the benefit-sharing framework, the compatibility with requirements in international documents, and the feasibility of plans contained in dissertations and theses. Documentary analysis and a structured questionnaire were used to verify the compliance with criteria that define benefit-sharing. Two thirds of the studies analyzed presented no context units that could be characterized as benefit/benefit-sharing. The studies considered as providing benefits (33.3%) presented correspondence to contractual justice and lack of plans that ensured rights to participants. General and specific regulations for a continuing education program for members of ethics committees and researchers need to be updated.

Keywords: Bioethics. Cost-benefit analysis. Health vulnerability. Documentary analysis. Human Rights.

Resumo

Análise documental sobre benefícios em pesquisas biomédicas

A repartição de benefícios, aspecto importante da pesquisa em países em desenvolvimento, garante que recursos naturais e conhecimento tradicional local sejam reconhecidos e valorizados. Este estudo visou verificar, nos documentos oficiais dos programas de pós-graduação em saúde, o tipo de justiça adotado para cumprimento da norma de repartição de benefícios, a compatibilidade com as exigências de documentos internacionais e a exequibilidade dos planos presentes nas dissertações e teses. Utilizou-se análise documental e questionário estruturado para verificar a adequação aos critérios definidores de repartição de benefícios. Dois terços das pesquisas analisadas não apresentavam unidades de contexto passíveis de caracterização como benefício/repartição de benefício. As pesquisas consideradas para prever benefícios (33,3%) apresentavam correspondência com a justiça contratual e ausência de planos que garantissem direitos a seus participantes. Há necessidade de atualização dos regulamentos gerais e específicos e de programa de educação continuada para membros dos comitês de ética e pesquisadores.

Palavras-chave: Bioética. Análise custo-benefício. Vulnerabilidade em saúde. Análise documental. Direitos humanos.

Resumen

Análisis documental acerca de los beneficios en la investigación biomédica

La distribución de beneficios, un aspecto importante de la investigación en países en desarrollo, asegura que los recursos naturales y el conocimiento tradicional local sean reconocidos y valorizados. Este estudio tuvo como objetivo comprobar, en los documentos oficiales de los programas de posgrado en salud, el tipo de justicia adoptada para el cumplimiento de la norma de distribución de beneficios, la compatibilidad con las exigencias de documentos internacionales y la viabilidad de los planes presentes en las disertaciones y tesis. Se utilizó análisis documental y cuestionario estructurado para verificar la adecuación a los criterios definitorios de distribución de beneficios. Dos tercios de las investigaciones analizadas no presentaban unidades de contexto posibles de caracterización como beneficio/distribución de beneficios. Las investigaciones consideradas para prever beneficios (33,3%) presentaban correspondencia con la justicia contractual y ausencia de planes que aseguraran derechos a sus participantes. Hay necesidad de actualización de los reglamentos generales y específicos y de un programa de educación continua para miembros de los comités de ética e investigadores.

Palabras clave: Bioética. Análisis costo-beneficio. Vulnerabilidad en salud. Análisis de documentos. Derechos humanos.

Research

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In recent years, research in developing countries has constituted an issue that evokes ethical reflection, as there is often an imbalance of power between researchers and participants in studies. Conducting research in an ethical, egalitarian manner and with respect for local cultures is essential. Some issues concerning ethical aspects have been raised, such as the lack of resources to fund research in developing countries, the method for obtaining informed consent, and the interference of international organizations in the definition of what should be researched, which may lead to the exploitation of research participants by researchers [1].

The *Declaration of Helsinki* (DoH) [2], created in 1964 and updated several times since then, is an important document that establishes the ethical standards for research in human beings, which serves as a reference document for national researchers. The DoH states that, for a research to be ethical, there must be informed consent, benefits for participants, adherence to ethical standards regarding methods, and care as to data privacy and confidentiality. However, The DoH has received some criticism, according to which it is excessively Western and based on Eurocentric perspectives on ethics [3].

One of the important ethical issues in research in developing countries concerns the use of placebo in clinical trials. Often, there is resistance from the local public to participate in studies involving placebo, as they leave participants without access to treatments that already exist [4]. However, according to the DoH [2], in some cases the use of placebo in clinical studies may be justifiable, provided that there is no harm to the patient and other effective treatment measures are guaranteed.

There is a need to involve the local community in research so their opinion is considered and to prevent research from being considered a type of scientific colonialism. The 90/10 rule exposes the perverse face of research ethics due to the disagreement between the definition of what is researched and the local needs of a developing nation, subordinate to the impositions of companies and universities of rich countries [4,5].

The ethical aspects of research in developing countries should be treated rigorously so there are benefits for all participants, which requires a delicate balance between the needs of researchers and the well-being of persons participating in research [1,4,5]. The commitment to ethics and transparency in research is fundamental to ensure that the results are meaningful and that individuals involved are treated with respect and dignity, assuring them, at any stage, support and access to the resulting products, techniques and other benefits.

Benefit-sharing is a crucial aspect of research in developing countries as it ensures that local traditional knowledge and natural resources are properly recognized and valued. That is particularly important in areas that are rich in biodiversity, where local communities often need to be involved in the research process. Benefit-sharing can include various means of collaboration, such as royalty payments, technology transfer, capacity-building, and local economic development [6].

The benefit-sharing principle is distinctly present in international documents, such as the *Declaration of Helsinki* [2,6], the *Convention on Biological Diversity* (CBD) [7], the *Universal Declaration on Bioethics and Human Rights* (UDBHR) of the United Nations Educational, Scientific and Cultural Organization (UNESCO) [8], and national documents, such as the National Health Council (CNS) Resolution No. 466/2012 [9].

The CNS Resolution 466/2012 [9] establishes a series of guidelines with the objective of ensuring that local communities associated with genetic resources and traditional knowledge are consulted and benefited, including information on research results and guarantee of assistance whenever necessary when their information is used in scientific research.

The CNS describes in a public-access manual the most frequent pending issues in clinical research protocols, including those related to benefit-sharing [10]. Although ethics councils monitor the different phases of research with the requirement of compliance with standards and submission of reports, would these measures be sufficient to attest the respect for benefit-sharing?

Considering the flaws pointed out by the CNS [10] that indicate the ethical deficiency of national projects; the alignment between the guidelines of the National Research Ethics Committee (CONEP)/CNS [9] and the international documents guiding research ethics; and the need for ethical analysis based on bioethical principles concerning human rights without limitation to the rules of good conduct and manuals, we question the proper application of these international guidelines and declarations, related to the fundamental theory of the benefit-sharing framework in official documents and in dissertations and theses of graduate programs (PPG) in the medical field in the state of Alagoas.

The research had as objectives: 1) to examine in official documents of graduate programs in the medical field in Alagoas State the type of justice adopted to comply with the benefit-sharing framework found in international documents guiding research considering the national context of a developing country and 2) check the compatibility of the means of compliance with the benefit-sharing framework with the requirements of the *CBD*[2]/*Declaration of Helsinki*[7] or UDBHR[8] and the feasibility of plans contained in dissertations and theses of graduate medical programs in Alagoas.

Method

This is a study based on documentary analysis within the field of bioethics. The research aimed to identify and analyze content related to the benefit-sharing framework contained in the UDBHR, in *the Convention on Biological Diversity*[2]/*Declaration of Helsinki*[7], in official documents of health research programs in the state of Alagoas, and in research projects already defended in the form of master's and doctoral dissertations and theses and published in public domain repositories between 2020 and 2023. As this is an analysis of documents in the public domain, the research project did not require the authorization of a research ethics committee.

Documentary analysis is a research technique that uses documents as data sources to study a certain phenomenon. These documents can be varied, such as texts, images, reports, legislation, among others, and are systematically and critically analyzed to extract information relevant to the research[11,12].

In the health care field, documentary analysis can be used to study public policies, technical standards, patient records, scientific articles, medical records, among other sources of information. This technique enables researchers to have access to secondary data that can complement or confirm the information obtained in other stages of the research[11,12].

To use documentary analysis in health research, it is important to be familiar with the technique, be aware of the content of the selected documents and establish clear criteria for data coding and analysis. In addition, it is necessary to ensure data reliability and validity through appropriate data collection and analysis methods[11,12].

For the analysis of the documents—dissertations and theses and general graduate and specific regulations for graduate programs—we carried out full readings, including existing annexes. Three researchers participated in different stages of the research: the supervisor, a doctor with a postdoctoral degree in bioethics, who conceived the project and supervised all stages, and two undergraduate students in medicine, who collected and organized data and helped in the interpretation of the results.

We defined the following as inclusion criteria: bureaucratic documents of graduate programs in the medical field of universities of Alagoas, public and private, that conduct clinical and biological research; up to three dissertations or theses published in the repositories of the universities; and different supervisors for each thesis or dissertation analyzed.

We excluded from the research PPG documents that were not available on the web with their own domain and free access and programs related exclusively to the field of health education; theses and dissertations defended but not published in the repositories of universities or on the official PPG platforms.

To search online for theses and dissertations in the different PPG repositories, we used the following filters: "health sciences," "graduate programs," "date of publication 2020-2023," "theses and dissertations," and "type of open access." In the repository of the Federal University of Alagoas (UFAL), after applying the established filters, we selected analyzable documents corresponding to ten PPG of health programs on the Maceió *campus*: School of Nursing (EENF), School of Medicine (FAMED), School of Nutrition (FANUT), Institute of Biological and Health Sciences, Institute of Pharmaceutical Sciences (ICF), and Institute of Chemistry and Biotechnology (IQB).

Initially, we selected for analysis: 41 dissertations/theses from EENF (PPG in nursing), 31 dissertations/theses from FAMED (29 dissertations in the PPG in Medical Sciences and two dissertations in the PPG Professional Master's Degree in Family Health), 33 dissertations/theses from FANUT (PPG in Nutrition), 17 dissertations/theses from ICF (16 dissertations in the PPG in Pharmaceutical Sciences and one thesis in the Multicentric PPG in Biochemistry and Molecular Biology), two theses in IQB (PPG in Biotechnology of the Northeast Biotechnology Network (RENORBIO). In addition, the "health sciences" filter for the ICBS PPGs was removed in order to cover programs compatible with the analyzed theme, and 68 dissertations/theses were found (38 works of the PPG in Health Sciences, 29 works of the PPG in Biological Diversity and Conservation in the Tropics, and one work in the Multicenter PPG in Biochemistry and Molecular Biology).

In the repository of the Centro Universitário Superior de Maceió (CESMAC), 30 dissertations were found in the PPG Professional Master's Degree in Health Research. After applying the inclusion criteria, we selected for final analysis: three dissertations of the PPG in Nursing, three dissertations of the PPG in Medical Sciences, two dissertations of the PPG in Family Health, three dissertations of the PPG in Nutrition, two dissertations and one thesis of the PPG in Health Sciences, three dissertations of the PPG in Biological Diversity and Conservation in the Tropics, one dissertation of the Multicentric PPG in Biochemistry and Molecular Biology, two dissertations and one thesis of the PPG in Pharmaceutical Sciences, and one thesis of the Multicentric PPG in Biochemistry and Molecular Biology, two theses of the PPG in Biotechnology of the Northeast Biotechnology Network (RENORBIO), and three dissertations of the PPG Professional Master's Degree in Health Research.

To achieve objective 1, we analyzed what could be extracted from the information consistent with reference documents for bioethics. The following were used as parameters for content analysis and interdocumentary correspondence: the *Universal Declaration on Bioethics and Human Rights* [8], *Convention on Biological Diversity* [2]/*Declaration of Helsinki* [7], specifically on the principle of benefit-sharing. The following chronological steps were followed for documentary analysis: 1) definition of categories of analysis; 2) definition of registration units; 3) documentary exploration in search of context units that codify registration units; and 4) treatment and interpretation of results. Groupings of content of interest (in this work, principle of benefit-sharing) that are related are defined as "categories of analysis." "Registration units" refer to the contents of interest proper, previously identified in the reading of the texts corresponding to the principle of benefit-sharing contained in the bioethical documents UDBHR [8], *Convention on Biological Diversity* [2]/*Declaration of Helsinki* [7]. "Context units" are defined as excerpts from the documents under analysis that enable codifying "registration units," that is, that allow verifying whether the registration units (contents of interest) are contemplated by the analyzed text.

The prior definition of the categories of analysis and registration units allowed the texts of the selected documents to be properly explored, with subsequent treatment and interpretation of the results. In addition, textual citations specific to the benefit-sharing principle identified in the selected documents (context units) were used to exemplify and qualitatively deepen the interpretation of the quantitative results.

The relations between the registration and context units in the documents were considered partial or total. When we found no context units that could decodify the registration units, it was considered that the content was not provided in the analyzed document. Partial approach registration units were thus considered when no textual correspondence was found in the selected documents to at least one of the tracker terms specific to each registration unit and/or when they allowed misinterpretation of the concept of the principle.

To achieve objective 2, that is, checking the compatibility and feasibility of the requirements necessary for the principle of benefit-sharing in dissertations and theses, we adopted a questionnaire founded on reflection based on the UDBHR [8]. As general criteria for reflection and construction of the questionnaire and actions for a documentary analysis related to the principle of benefit-sharing, the following were considered:

- analysis of the research project, which consists of examining the research project in question to understand its characteristics and objectives (local or multicentric);
- full reading of the project, the proposed activities and the resources involved;
- identification of the correspondence between the lines of research and topics studied and the national health agenda;
- identification of the genetic resources used, which may include human or animal biological samples, as well as associated traditional knowledge;
- origin of genetic resources, that is, if they were collected in protected areas or traditional communities and if they were obtained through partnerships with other institutions or companies;
- identification of benefits for the communities or populations involved, which may include direct benefits, such as new treatments or diagnostics for diseases, and indirect benefits, such as improved quality of life or scientific knowledge;
- analysis of research participants, which may include patients, volunteers, researchers, and local communities, and how they may be affected by the results;
- identification, based on the information collected, of the possible beneficiaries of the research, which may be local communities or populations, other research institutions, society in general, etc.;
- planning of benefit-sharing between research participants and potential beneficiaries, including the dissemination of results, the release of new treatments or technologies, the capacity-building of local health care professionals, and the establishment of partnerships with other research institutions;
- regular monitoring and assessment of fair and equitable benefit-sharing, which includes collecting feedback from research participants and beneficiaries, analyzing the results and reviewing the benefit-sharing plan, if necessary, and only collecting feedback from participants will not be fulfilled at the moment, as it requires submission of the project to the ethics committee;
- verification of access and benefit-sharing agreement, as provided for in the Nagoya Protocol, which may include the participation of local communities in decision-making and sharing of benefits generated;
- verification of data sharing plans to ensure that the results can be used by other researchers and local communities;
- verification of intellectual property policies that respect the rights of local communities and ensure fair sharing of benefits; and
- verification of the researcher's commitment to the principle of benefit-sharing, with willingness to dialog and negotiate with the local communities involved.

For interpretation of the results, the concept and expanded considerations on the principle of benefit-sharing were considered according to the documents *CBD/Declaration of Helsinki* [2,7] and UDBHR [8].

Results

After applying the inclusion and exclusion criteria, we admitted for analysis: five theses and 22 dissertations of the graduate programs in the area of health sciences of the Federal University of Alagoas, Maceió *campus*, and of the Centro Universitário Superior de Maceió, in addition to the general regulations for graduate programs of two institutions and 11 regulations specific to PPGs. The other institutions did not meet the research inclusion criteria.

Analysis of theses and dissertations

Two thirds of the studies analyzed provided no benefits or context units that could be characterized as benefit-sharing. Among the studies that provided benefits (33.3%), six dissertations and one thesis, four were conducted at the public university and three at the private university. All provided benefits were considered correlated with the contractual justice model (Table 1) and had an indirect and long-term beneficiary nature, not guaranteeing the real benefit, as observed in the relation between the registration and context units described below: monetary and non-monetary benefits (RU): *The development of an independent municipal system for heterocontrol of fluoride concentration in supply waters* [13] (CU); patent (RU): *This application was registered and received the Computer Program Registration Certificate (Annex A) issued by the National Institute of Industrial Property – INPI* [14] (CU); contribution (RU): *The synthesis of a dental adhesive with silver nanoparticles biosynthesized with red propolis from Alagoas resulted in a material with antimicrobial activity and stable matrix with the active principle immobilized within the material* [14] (CU); and the right to information on the results of the research (RU): *Knowledge of the fluoride concentration of the water used in the establishment* [13] (CU). There was no identification of context units that characterized the provided benefits as distributive justice.

Table 1. Identified benefits related to contractual justice in PPG theses and dissertations in the health area of two university institutions in Maceió/AL

Registration units – contractual justice	N	(%)
Monetary and non-monetary benefits	2	9.52%
Other contractual forms	0	–
Patent	2	9.52%
Compensation	0	–
Reward	0	–
Contribution	3	14.28%
Access to post-study benefits	0	–
Right to information on research results	1	4.76%

All studies we related to the national health agenda and involved participants from local communities. However, some important criteria for verifying the compatibility and feasibility of the requirements of the benefit-sharing framework, benefit-sharing planning, access and benefit-sharing agreement, and data-sharing plan were not contemplated (Table 2).

Table 2. Frequency (%) of criteria associated with the principle of benefit-sharing in PPG theses and dissertations in the health area of two university institutions in Maceió/AL

	Criteria
1	Correspondence between the lines of research and issues studies and the national health agenda (100%)
2	Identification of genetic resources: human or animal biological samples; traditional knowledge
3	Origin of genetic resources: protected areas/ traditional communities Partnerships with other institutions or companies
4	Identification of benefits: Direct (0.0%) Indirect (7=33.3%)
5	Research participants: patients, volunteers, researchers, and local communities (100%)
6	Beneficiaries: local communities/populations/other research institutions/society in general (100%)
7	Benefit-sharing planning: dissemination of results/ availability of new treatments or technologies/ training of local health care professionals/ establishment of partnerships with other research institutions (0.0%)
8	Access and benefit-sharing agreement: participation of local communities in decision-making and sharing of benefits generated (0.0%)
9	Data sharing plan: Is there a guarantee that the results can be used by other researchers and local communities? (0.0%)
10	Intellectual property policies: respecting the rights of local communities and ensuring fair sharing of benefits? (0.0%)
11	Researcher commitment: willingness to dialog and negotiate with the local communities involved (0.0%)

Review of general regulations for graduate programs and specific regulations for the programs

As for the categories of analysis related to contractual justice, only two of the nine provided registration units were contemplated by the 11 PPG regulations analyzed: the contribution unit, present in five regulations

(45.4%); and the other contractual forms unit, present in a single regulation (9.1%). Only the contribution unit was contemplated in the two general institutional regulations analyzed.

As for distributive justice, of the ten registration units provided, three were contemplated by the 11 PPG regulations analyzed: the providing new or diagnostic and therapeutic modes or products resulting from research unit, present in three regulations (27.3%); the support to health care services unit, present in two regulations (18.2%); and the access to scientific and technological knowledge unit, contemplated by a single regulation (9.1%).

The two general regulations analyzed did not contemplate any of the registration units established for the categories of analysis specific to distributive justice. Only the contribution registration unit related to contractual justice was contemplated.

Discussion

It is observed that there is little guidance in the local regulations analyzed for the two models of justice, with a predominance of contractual justice and insufficient progress in adapting to the current standards of CONEP [15]. The standards of the general institutional regulations and specific regulations of the PPGs present an increasing dilution of the binding to the rules of CONEP [15], although the specific regulations of the PPGs have some context units related to distributive justice, although insufficient in quantity and quality to be related to the principle of benefit-sharing according to the UDBHR [8]. This inadequacy can impact research ethics and indicates the need to review all regulations to adapt them to the new Law 14,874/2024 [15], which provides for research with human beings and establishes the National System for Ethics in Research with Human Beings, as well as to plan the training of researchers from both institutions and members of local ethics committees with regard to understanding the bioethical foundations of benefit-sharing and influencing justice models for the guidance and supervision of good clinical practices.

In the UDBHR [8], the promotion of capacity development is important in all phases of research and includes the creation and strengthening of independent ethics committees with competence to review projects and processes. The promotion of these capacities finds applicability and resonance in research ethics and scientific integrity with the appropriate review of projects to the most current ethical standards.

For Roje and collaborators [16], efforts to foster and promote the integrity of scientific research must be implemented simultaneously at three levels—researcher, institution, and system—to provide greater adherence and implementation, which will also impact research ethics.

It is noted that the general regulations do not guide the inclusion of plans in graduate works about compliance with the benefit-sharing framework, and only describe generic requirements. The preparation of these normative documents seems to have been carried out without knowledge and association with any bioethical current. Despite the advance of bioethics and the growing recognition of the benefit-sharing framework, the context units identified in the analyzed documents repeat and perpetuate what has already been proposed for a long time without valuing conscious and critical thinking on this issue.

In addition, it is clear that the inadequacy of general regulations and local PPGs and research projects was due, until then, to the lack of well-defined rules and systematized objectives and supervision of local committees by the federal agencies Ministry of Health/CNS/CONEP. Thus, the inadequacy of research projects is of a structural nature and begins with the lack of clarity on the sharing of benefits in health research by the highest levels, regulating and influencing the general regulations of the graduate and research deans, with negative effects on the planning and execution of local research projects.

We also did not observe context units sufficient in quantity and quality or associated work plans in all documents of the research projects analyzed that characterized the guarantee of benefits. In most research projects analyzed, when benefits were provided, the wording acquired contours of indirect and long-term benefit, making it impossible to guarantee execution and reciprocity with responsibility.

The lack of knowledge of the principle of benefit-sharing was explicit whenever the description of the benefit was reported to authorities and the research participant was excluded from the decision—*Technical report for managers of the Professor Alberto Antunes University Hospital (HUPAA) on the need for dental care for patients with liver cirrhosis*[13]—or the text did not constitute a real benefit to the participant and exposed the defensive profile of the research, of assumed protection to the researcher against the possibility of lawsuit for error, damage, negligence, an aspect of contractual justice related to principlist bioethics, criticized for generating a defensive medical practice[17].

Paranhos, Garrafa, and Melo consider that, if, to minimize damage, it is necessary to provide treatment for adverse events directly or indirectly related to the research, it will still not characterize a benefit, only a damage reduction measure[18]. In other documents analyzed, the wording is very vague, not allowing the identification and guarantee of any immediate benefit, thus assigning responsibility to the future through promises—the *benefits for this study will be a guiding point for the promotion of new approaches*[19], it will *serve as a input for the promotion of new care techniques and guidance of nursing itself to the community and to the professionals of the class themselves*—*or showing lack of* knowledge of the concept of benefit related to scientific research—*it is also considered as a benefit the expectation of publishing articles in journals and also disseminating the work in the scientific meeting with colleagues of the ESF organized by the Health Department, thus contributing to the deconstruction of the invisibility of albino people*[20]. In the UDBHR[8], knowledge sharing is not limited to scientific dissemination but refers to the right of vulnerable populations to access the knowledge necessary for their own development, supporting the development of informed and active citizens capable of applying scientific knowledge according to the local socio-cultural context. The researchers also confuse the development of techniques resulting from research with shared benefit, even *if there is no immediate benefit to the participants or the institution and do not present detailed planning: As a direct benefit of the research (after the intervention), an intracanal medication may be obtained*[21] or *contribute to the development of techniques in acustofluidic devices in order to evaluate cells and parasites individually*[21]. Even more critical is the situation in which the researcher describes the research project itself as a benefit, which shows total ignorance of the ethical precepts related to research with human beings.

All these studies were approved by the local ethics committee. These failures show the automatic reproduction of a methodological writing model and the informed consent form (ICF) copied from other studies, without reading or knowledge of the principles, standards, and rules that govern ethics in research with human beings, and the alienated adoption of the principlist, contractualist, defensive ethical model. Given this adopted ethical model, which confers hegemony and prescriptive force to contractual justice, distributive justice is forgotten or idealized and in its name there is inadequate reproduction of the practice of defensive research based exclusively on the promises of the ICF.

According to Roberts, Sibum, and Mody[22], the pursuit of improved health, patient healing, and disease prevention has long been driven by an uncomfortable combination of humanitarian ideals and commercial and military pecuniary interests that determine and interfere with scientific integrity. This model of adopting automatic writing about benefits to research participants is due to the precarious knowledge about research ethics and insufficient standardization in the PPG regulations (9.1%), which results that the most basic right—to information on results—is considered in only 4.7% of the analyzed studies.

Advances in critical bioethical reflection, of Latin American and African origin, resulting from the moral discomfort in the face of the situation of imposition of the 90/10 rules and the double standard, of protection for the pharmaceutical research industry in the northern hemisphere countries, position health as a human right and impose the adoption of the national health agenda as a guiding standard for respecting the dignity and autonomy of research participants in developing countries or in the southern hemisphere [9,23-26].

It is noted as a positive factor that all studies we related to the national health agenda and involved participants from local communities, excluding the possibility of the external imposition of 10/90 rules and double standards. However, this positive aspect is weak when we consider the distance between the intention and the act, the responsibility with the protection of the research participants and a project writing that is automatic and insufficient to comply with CNS Resolution No. 466/2012 [9] and the associated ethical requirements of the ICF. For the CNS, the *ICF is the most frequent reason for pending issues issued by CONEP, mainly due to inadequate drafting of the document, insufficient information or failure to ensure the rights of research participants* [27]. The research must be planned and executed with the conscious responsibility of protection throughout its duration for the guarantee of rights and continued sharing of the benefits achieved with it with the participants and, when relevant, with the control group and vulnerable communities.

To ensure post-study access to the products resulting from the research, CNS Resolution 466/2012 [9], item III.3.d, determines that free and indefinite access to the best prophylactic, diagnostic, and therapeutic methods that have proven effective must be ensured by the sponsor to all participants at the end of the study. Subitem d.1 states that *access will also be guaranteed in the interval between the end of individual participation and the end of the study, in which case this guarantee can be given through an extension study, according to a duly justified analysis by the participant's attending physician* [28].

Two types of benefit-sharing define, in the interaction of political and economic forces, the directioning of responsibilities and guarantees to the right to immediate access and in all phases of health research: that determined by *CBD* [7] and the *Declaration of Helsinki* [2], partial and that rewards research participants based on fairness of exchanges; and that determined by the UDBHR [8], governed by human rights and that guides the expansion of access to research results to all research participants and society, when relevant.

The bioethical aspects present in texts of PPGs in the field of health in the state of Alagoas are compatible with the guidelines of the *Declaration of Helsinki* [2] and the *Convention on Biological Diversity* [7]. The results demonstrate a research ethics view limited to the contractual, technical, defensive justice model, and with a reduced possibility of guaranteeing participants the right of access to research results, including the right to information.

Although the concept of benefit-sharing (article 15) is not consensual, it is considered, in the UDBHR [8], the coordination with other principles, such as solidarity and cooperation (article 13), and equality, justice, and equity (article 10), imposing normative force to the expansion and improvement of the respect and living conditions of historically vulnerable individuals, populations or communities [8,24,26].

If principlist bioethics of Anglo-Saxon origin emphasizes the principle of autonomy, critical bioethics, Latin American and from African countries, in line with the UDBHR [8], highlights the principle of distributive justice, with emphasis on equity for resource allocation, social responsibility, protection of the vulnerable and education for active citizenship, solidarity and cooperation, and research results with access and sharing for participants and vulnerable communities.

Why claim distributive justice and human rights as normative models for reviewing regulations governing research at the university? Economic inequality and poverty levels are still very high, which are reflected in low educational levels; the economic and educational asymmetry between researchers and research participants is a dependency factor and can generate seduction and consent without adequate knowledge of the ICF clauses; in general, research participants have different levels and layers of vulnerabilities [23], although they have economic, social, and educational inequality in common.

Paranhos, Garrafa, and Melo conclude, after reviewing the literature, *that there are still several situations in which the most vulnerable are at risk. Not by chance, such situations occur precisely in the poorest countries, where, then, their vulnerability is sought to be relativized, thus intensifying the benefits due to them and the damage risks to which they are potentially exposed* [29].

Morrison, Humphries, and Lawson conducted a systematic review of research related to access to and sharing of benefits of genetic resources and found gaps in: the analysis of implementation effectiveness at the national level; the addressing of apparent conflicts between support to intellectual property with promotion of exclusivity for traditional knowledge and challenges to exclusivity of intellectual property for patents; the examination of traditional knowledge of local communities (in contrast to Indigenous peoples); and lack of practical examples quantifying the sharing of benefits from research results and commercial application[26].

As a consequence of these bioethical reflections, to understand the limitations still present in scientific research and to overcome them with cooperative and solidarity practices, it is expected that access to health is understood as a right to the highest possible standard in each context, with the development of policies and application of continuous resources that create conditions for the expanded and equitable achievement of this goal, including the training of human resources and the expansion and enhancement of research facilities directed by the national health agenda.

Final considerations

The general and specific regulations for graduate programs present normative, technical wording with little guidance for considering distributive justice and for raising awareness and adapting research projects to the benefit-sharing framework as proposed by the Ministry of Health. The documents analyzed show reduced responsibilities in benefit-sharing in relation to what is proposed in the document that establishes the National System for Ethics in Research with Human Beings.

The projects are aligned and respect the national health agenda; the majority (two thirds) do not consider the bioethical principle of benefit-sharing; when provided, the benefits we related to long-term contractual justice, thus compromising feasibility; there is a need for information and knowledge about the principle of benefit-sharing among researchers so this right is respected with planning that guarantees its fulfillment at all research stages.

More broadly, there is a need to update and adapt the general and specific regulations for graduate programs of the universities analyzed, as well as for continuing education program for members of the ethics committees and researchers. In the education field, in undergraduate programs, ethics education must consider the relation with research and human rights as provided for in UNESCO's *Universal Declaration on Bioethics and Human Rights*. The bioethical training of undergraduates of medical programs with regard to health research needs to be implemented and expanded to encompass human rights and national health care needs. Participation in research projects that study the practical application of principles related to the main theoretical currents of bioethics is a strategy for critical learning.

References

1. Collins JE, Sirakaya A, Vanagt T, Huys I. Developing a methodology to balance benefit-sharing: application in the context of biodiversity beyond national jurisdiction. Genetic Resources [Internet]. 2020 [acesso 27 jan 2025];1(1):24-39. DOI: 10.46265/genresj.2020.1.24-39
2. Ballantyne A, Eriksson S. Research ethics revised: the new CIOMS guidelines and the World Medical Association Declaration of Helsinky in context. Bioethics [Internet]. 2019 [acesso 27 jan 2025];33(3):310-11. DOI: 10.1111/bioe.12581
3. Kass NE. An ethics framework for global health research. Lancet [Internet]. 2009 [acesso 27 jan 2025];373(9657):481-7. DOI: 10.2105/ajph.91.11.1776
4. Greco D. Doble estândar. In: Tealdi JC, editor. Dicionário Latinoamericano de Bioética. Bogotá: Unesco; 2008. p. 360-71.

5. Solbakk JH, Vidal SM. Clinical research in resource-poor settings. In: ten Have HAMJ, Gordijn B, editores. Handbook of global bioethics. Dordrecht: Springer; 2014. p. 527-50.
6. Schroeder D. Sharing of benefits. In: ten Have HAMJ, Gordijn B, editores. Handbook of global bioethics. Dordrecht: Springer; 2014. p. 203-24.
7. Secretariat of the Convention on Biological Diversity. Convention on Biological Diversity: text and annexes [Internet]. Montreal: Secretariat of the Convention on Biological Diversity; 2011 [acesso 27 jan 2025]. Disponível: http://www.cbd.int/convention/text
8. Organização das Nações Unidas para a Educação, Ciência e Cultura. Declaração Universal sobre Bioética e Direitos Humanos [Internet]. Paris: Unesco; 2005 [acesso 27 jan 2025]. Disponível: http://bit.ly/2eJgY1p
9. Conselho Nacional de Saúde. Resolução nº 466, de 12 de dezembro de 2012. Aprova as diretrizes e normas regulamentadoras de pesquisas envolvendo seres humanos. Diário Oficial da União [Internet]. Brasília, p. 59, 13 jun 2013 [acesso 27 jan 2025]. Seção 1. Disponível: https://tinyurl.com/yc5ps5cz
10. Conselho Nacional de Saúde. Manual de orientação: pendências frequentes em protocolos de pesquisa clínica [Internet]. Brasília: CNS; 2015 [acesso 20 maio 2022]. Disponível: https://tinyurl.com/yzf9fyu2
11. Lima Junior EB, de Oliveira GS, dos Santos ACO, Schnekenberg GF. Análise documental como percurso metodológico na pesquisa qualitativa. Cadernos da Fucamp [Internet]. 2020 [acesso 27 jan 2025];20(44):36-51. Disponível: https://tinyurl.com/yc2z22wm
12. Ana WPS, Lemos GC. Metodologia científica: a pesquisa qualitativa nas visões de Lüdke e André. Revista Eletrônica Científica Ensino Interdisciplinar [Internet]. 2018 [acesso 27 jan 2025];4(12):531-41. DOI: 10.21920/recei72018412531541
13. Omena AMA. Condição oral e qualidade de vida relacionado à saúde bucal do paciente no pré transplante de fígado [dissertação] [Internet]. Maceió: Centro Universitário CESMAC; 2022 [acesso 27 jan 2025]. p. 32. Disponível: https://tinyurl.com/mrfusp5f
14. Lôbo TLGF. Síntese e caracterização de um adesivo dentinário com nanopartículas de prata biossintetizadas com própolis vermelha de Alagoas [dissertação] [Internet]. Maceió: Ufal; 2021. p. 128. Disponível: https://www.repositorio.ufal.br/handle/123456789/10921
15. Brasil. Lei nº 14.874, de 28 de maio de 2024. Dispõe sobre a pesquisa com seres humanos e institui o Sistema Nacional de Ética em Pesquisa com Seres Humanos. Diário Oficial da União [Internet]. Brasília, nº 103, p. 6, 28 maio 2024 [acesso 27 jan 2025]. Seção 1. Disponível: https://www.planalto.gov.br/ccivil_03/_ato2023-2026/2024/lei/l14874.htm
16. Roje R, Elizondo AR, Kaltenbrunner W, Buljan I, Marušić A. Factors influencing the promotion and implementation of research integrity in research performing and research funding organizations: a scoping review. Account Res [Internet]. 2023 [acesso 27 jan 2025];30(8):633-71. DOI: 10.1080/08989621.2022.2073819
17. Wispe J. Autonomy: how it has become problematic for medicine. Dialog [Internet]. 2022 [acesso 27 jan 2025];61(4):304-11. DOI: 10.1111/dial.12779
18. Paranhos FRL, Garrafa V, Melo RL. Estudo crítico do princípio de benefício e dano. Rev. bioét. (Impr.) [Internet]. 2015 [acesso 27 jan 2025];23(1):12-9. DOI: 10.1590/1983-80422015231041
19. Soares JO. O cotidiano da família de crianças com transtorno do espectro autista à luz da Teoria das Transições de Melleis [dissertação] [Internet]. Maceió: Ufal; 2023 [acesso 27 jan 2025]. p. 30. Disponível: https://www.repositorio.ufal.br/handle/123456789/12010
20. Rodrigues RLP. Direito à saúde da pessoa albina: perfil e itinerário terapêutico e busca por ações de ruptura das iniquidades em saúde em um município agreste alagoano [dissertação] [Internet]. Maceió: Ufal; 2021 [acesso 27 jan 2025]. p. 53. Disponível: https://www.repositorio.ufal.br/handle/123456789/9517
21. Silva AE. Acustofluídica como inovação tecnológica para a bioespectroscopia aplicada ao estudo das leishmanioses [tese] [Internet]. Maceió: Ufal; 2022 [acesso 27 jan 2025]. p. 41. Disponível: https://www.repositorio.ufal.br/handle/123456789/9165
22. Roberts LL, Sibum HO, Mody CCM. Integrating the history of science into broader discussions of research integrity and fraud. History of Science [Internet]. 2020 [acesso 27 jan 2025];58(4):354-68. DOI: 10.1177/0073275320952268

23. Florencia L, Vanderpoel S. Identifying and evaluating layers of vulnerability. Bioeth [Internet]. 2013 [acesso 27 jan 2025];27(6):325-32. DOI: 10.1111/bioe.12035

24. Kamau C, Prinsen L, Thaldar D. Benefit-sharing with human participants in health research in South Africa: a call for clarity. Dev World Bioeth [Internet]. 2024 [acesso 27 jan 2025];1-10. DOI: 10.1111/dewb.12456

25. International Bioethics Committee. Draft report of the IBC on the principle of the sharing of benefits [Internet]. Paris: Unesco; 2015 [acesso 27 jan 2025]. Disponível: https://unesdoc.unesco.org/ark:/48223/pf0000233230

26. Morrison C, Humphries F, Lawson C. A regional review of genetic resource access and benefit sharing: key issues and research gap. Environ Policy Law [Internet]. 2021 [acesso 27 jan 2025];51(5):273-96. DOI: 10.3233/EPL-201028

27. Conselho Nacional de Saúde. Op. cit. 2015. p. 5.

28. Conselho Nacional de Saúde. Op. cit. 2013. p. 5.

29. Paranhos FRL, Garrafa V, Melo RL. Op. cit. 2015. p. 18.

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Participation of the authors

Francisco José Passos Soares conceived the project, supervised the students in data collection, organization of results and final discussion. Heytor Cesídio Gomes Grangeiro collected data on the compatibility and feasibility of the benefit-sharing plans and helped organize the results and search and review the literature. Juan Lennon Aureliano Fernandes was responsible for collecting data on the identification of benefits related to the type of justice, analysis and organization of the results.

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