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Readability of assent forms used in research with children

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Abstract

This article analyzes the readability of assent forms aimed at children aged 6 to 12, present in theses and dissertations defended between 2012 and 2019, which were accessed through the theses portal of the Coordination for the Improvement of Higher Education Personnel. Among 45 productions, only 16 provided assent forms for children, which were subjected to the Flesch index and lexical analysis using IRAMUTEQ. Lexical achievement above 80% demonstrated five classes in the descending hierarchical classification: guarantee of anonymity, understanding for authorization, invitation to participate, participant rights, and research theme. In the word cloud, "research" and "principal investigator" were the most recurrent expressions. Only one document presented readability compatible with the elementary school level (1st to 5th year), and the majority included words that were difficult to understand. Image language can improve children's understanding, favoring their autonomy and empowerment.

Keywords: Consent forms. Child. Ethics, research. Child advocacy. Ethics committees, research. Personal autonomy.

Resumo

Leiturabilidade de termos de assentimento utilizados em pesquisas com crianças

Este trabalho analisa a leiturabilidade de termos de assentimentos direcionados a crianças de 6 a 12 anos, presentes em teses e dissertações defendidas entre 2012 e 2019, as quais foram acessadas pelo portal de teses da Coordenação de Aperfeiçoamento de Pessoal de Nível Superior. Dentre 45 produções, somente 16 disponibilizaram termo de assentimento para crianças, os quais foram submetidos ao índice de Flesch e a análise lexical pelo Iramuteq. O aproveitamento léxico, superior a 80%, demonstrou cinco classes na classificação hierárquica descendente: garantia do anonimato, compreensão para autorização, convite para participar, direitos do participante e temática da pesquisa. Na nuvem de palavras, "pesquisa" e "pesquisador responsável" foram as expressões mais recorrentes. Somente um documento apresentou leiturabilidade compatível com o nível do ensino fundamental (1° ao 5° ano), e a maioria incluía vocábulos de difícil compreensão. A linguagem imagética pode melhorar a compreensão da criança, favorecendo sua autonomia e empoderamento.

Palavras-chave: Termos de consentimento. Criança. Ética em pesquisa. Defesa da criança e do adolescente. Comitês de ética em pesquisa. Autonomia pessoal.

Resumen

Lecturabilidad de los formularios de autorización utilizados en estudios con niños

Este estudio analizó la lecturabilidad de los formularios de autorización para estudios con niños de entre 6 y 12 años de edad en tesis defendidas de 2012 a 2019, presentes en la página de la Coordinación para la Mejora del Personal de Educación Superior. Hubo 45 trabajos, solo 16 presentaron formulario de autorización para niños, los cuales se sometieron al índice de Flesch y al análisis léxico por Iramuteq. El uso del léxico (superior al 80%) mostró cinco clases en la clasificación jerárquica descendente: garantía de anonimato, comprensión para la autorización, invitación a participar, derechos de los participantes y tema de investigación. Los términos más recurrentes fueron "estudio" e "investigador responsable". Un documento presentó lecturabilidad compatible con la primaria (1.° a 5.° grado), y la mayoría incluía palabras difíciles de entender. El lenguaje con imágenes puede ayudar a mejorar la comprensión de los niños, favoreciendo su autonomía y empoderamiento.

Palabras clave: Formularios de consentimiento. Niño. Ética en investigación. Defensa del niño. Comités de ética en investigación. Autonomía personal.

The authors declare no conflict of interest.

Research

Scientific research with children as participants has contributed to filling relevant gaps in health care provision [1], and investigators are responsible for creating spaces for them to be heard. To this end, it is necessary to transmit information in a language appropriate to the participant's understanding and cognitive development, addressing research procedures and the risks and benefits of participation [2,3]. Using elaborate and complex language in assent forms (AF) does not always convey information appropriately to children [4].

According to Resolution 466/2012 of the National Health Council (CNS), the AF is a *document prepared in accessible language for minors or those legally incapable, through which, after research participants are duly informed, will express their agreement to participate in the research, without prejudice to the consent of their legal guardians* [5].

This document must contain the study objectives, methods, benefits, and risks and inform them of any inconvenience that may be caused to children, respecting their singularities so that they can understand the research. In 2023, the National Research Ethics Committee (CONEP) published Circular Letter 11/2023 [6], with general guidelines for preparing AF, establishing the obligation to present this document in studies carried out with children older than seven.

In Brazil, children legally do not have the power to express consent to participate in scientific research. However, they have the right to have their will and individuality recognized through formal assent [7]. Thus, they must be recognized as human beings with integrity, personality, and ability to actively participate in society, including the right to participate in scientific investigations [8].

Studies with children are fundamental because they enable the recognition of these individuals' voices in the search to improve the quality of care according to their perspectives and needs. Paradoxically, the low availability of studies with this group has driven the off-label use of medicines in pediatrics [7,8].

Furthermore, protecting children's best interests is harmed when they are prevented from participating in studies aimed at them [7,8]. In addition, children are understood as active and innovative social agents who engender their distinct cultures and play a significant role in forming adult sociocultural structures [9].

In this context, the inclusion of children in the investigative process must occur horizontally. This implies that the investigator's experiences and learning from their interactions with children should not merely serve as mechanisms for validating or refuting their pre-existing conceptual constructs. Experiences shared by children with the investigator can effectively be integrated into the structure of theoretical production, leading to the reconfiguration of theoretical paradigms related to understanding childhood [9,10].

Clear information necessary for conscious decision-making must precede the child's understanding of research procedures, risks, and potential benefits. However, investigators usually write the AF like the informed consent form (ICF) for adults [7]. These texts are inaccessible to children and are questionable regarding their legibility and readability.

Legibility refers to fonts' size, type, and color in word formatting and grammatical construction of sentences, paragraph spacing, and visual formatting elements [11,12]. "Readability" or "learnability" refers to the ease of reading, speed, and understanding of the meaning of a text and is related to the form of writing and the choice of language adopted in writing [11]. Documents that are more accessible to the reader are legible and easy to read.

Studies on the quality of information contained in clinical research AF showed that most participating children were unaware of elementary aspects of the research, such as objective, duration, risks, and benefits, which demonstrates the need to conduct additional studies [2,13]. In this sense, children's participation in scientific research must involve the right to refuse and obtain necessary and appropriate information for the participant's age group through AF.

Therefore, the children's right to be heard and to have preferences and choices must be respected when making decisions regarding their own participation, as well as in other aspects of

research [8]. At the same time, it is necessary to question how the readability of AF can favor the legibility of the document and the child's understanding of its content.

This study analyzed the readability of AF for school-age children, as published in theses and dissertations from 2012 to 2019.

Method

Study design

This is a documentary search on AF present in theses and dissertations available on the theses portal of the Coordination for the Improvement of Higher Education Personnel (CAPES) [14]. In this type of research, the data subject to in-depth analysis is extracted from documents [15]. The IRAMUTEQ software was used in the documents to calculate the readability index and lexicographic analysis.

The theses and dissertations that served as data sources were defended in Brazilian graduate programs training masters and doctors. The following inclusion criteria were applied: a study conducted with children aged 6 to 12 and the availability of AF. Productions with AF available whose participants had disabilities/deficiencies were excluded, even if they were within the defined age range.

The choice of this source was based on the premise that academic productions generate new thoughts in the fields of teaching, assistance, and research. Furthermore, CAPES has been decisive in the success achieved by the national system for training masters and doctors, which has greatly influenced the changes resulting from the advancement of knowledge and society's demands [15].

Operationalization of data collection

Data collection took place from July 12th to September 2nd, 2019, using the keyword "assent" in the search field of the CAPES theses and dissertations catalog. The time filter (2012 to 2019) was applied since the explicit requirement to use AF for research involving children as participants was established in 2012, with the publication of CNS Resolution 466/2012 [5].

The studies whose full texts were not available for download were searched in other databases, such as Virtual Health Library and Google Scholar, and, when found, were included in the study. After reading the abstracts and methods of the identified studies, assent forms whose research participants were children in the determined age range were selected for analysis.

Data analysis

The AF extracted from academic productions was analyzed according to the Flesch Reading Ease Index (FREI) and the Flesch-Kincaid Readability Index (FKRI), both validated for the Portuguese language by Brazilian researchers in 1996 [16,17], as the Flesch Index for Brazilian Portuguese (IF-BR). The extracted texts were subjected to lexicography using IRAMUTEQ [18-20].

The FREI and FKRI have already been used in some studies to evaluate the legibility and ease of reading of ICF [21], explanatory notes [22], during construction and validation of a booklet for self-care to prevent pressure injuries [23], among others. The IF-BR consists of compiling and adapting two formulas from the FREI and FKRI. The Brazilian version evaluates the length of sentences and the size of words, with different weights in its formula due to the languages having significant differences.

The IF-BR generates the result of readability and the education necessary for the individual to understand what is being read. This index can be calculated using the following formula: IF-BR = 164,835 – [1,015 × (total words ÷ total de sentences) – [84.6 × (total syllables ÷ total words)] [16,17]. It groups the text on a 100-point scale, in which the result is categorized according to readability and the level of education necessary to understand its content. The higher the score, the lower the ideal level of education to understand what is read and, thus, the easier it becomes to read the text.

Therefore, with a score from 0 to 25, the document is considered very difficult to understand, requiring a higher level of education. For a score between 25 and 50 points, the text is considered difficult to understand and requires a high school level of education. When a score of 50 to 75 is obtained, the document is considered

easy to understand and compatible with the level of education from the 6th to the 9th year of elementary school. Finally, when reaching a score of 75 to 100, understanding the document is very easy and compatible with the educational level of elementary school's 1st to 5th year.

The lexicographic analysis of the AF was carried out using the free version of IRAMUTEQ, a software that enables various processes and statistical analyses of texts with qualitative variables [18,24]. The percentage referred to in the content is the occurrence of the word within the text segments (TS), which is considered good when a level of achievement equal to or greater than 75% is reached [18,20,25].

The content of each AF was adapted to the informational language for processing the text and the set of texts, constituting the *corpus* of analysis. The program features used for this analysis were descending hierarchical classification (DHC) and word cloud.

The DHC is a type of qualitative analysis in which, from the processed texts, word classes with similar meanings and TS different from other classes are obtained. The DHC systematizes the analysis of different texts in a dendrogram, which graphically organizes the classes with their possible associations [19,20]. Thus, this mechanism sizes the TS or elementary context units, classified according to the highest frequency vocabularies and highest chi-square values in the class, to understand the most significant words for the qualitative analysis of the data [18,24,25].

The word cloud is a graphical representation generated by the software itself. It is used to quickly identify words visually according to their most relevant occurrence [19]. This strategy visually complements the DHC, providing a view of the most frequent words or expressions within the *corpus*.

The texts were previously organized and prepared in LibreOffice Writer to begin the analysis process in IRAMUTEQ. Each was separated by a command line, comprising only one variable chosen according to the number of each Form (**** *tale_01; **** *tale_02... **** *tale_16). After that, the file was saved as a text document using character encoding in the UTF-8 standard.

Afterward, the entire file was reviewed, typing and punctuation errors were corrected, acronyms were standardized, and words were combined with the underline sign, as, without this sign, they would be processed separately. This review followed the software manual to make the most of the words in the *corpus*.

After the TS demarcation, the classes were determined, and the association between them was presented using a DHC. In this same movement, the word cloud was generated.

Results

Of the 96 studies retrieved in the search, 45 had AF, among which 16 were included in this study. They had a form aimed at children aged 6 to 12. Of the 16 forms selected, 12 were available in master's theses and 4 in doctoral dissertations.

The years in which the studies were completed varied between 2014 and 2018 and most of the AFs were concentrated in 2016 and 2018, with four for each year. The years 2015 and 2017 had three forms each, and 2014, the year with the lowest number, had two studies with forms.

Regarding the graduate program, psychology had the largest number of studies, accounting for five (31.25%), followed by nursing, with four (25%). Graduate programs in human communication health, research and innovation processes in health, education, agroecology, nutrition, health sciences and medicine, and human health each accounted for one (6.25%) study.

The results of the IRAMUTEQ software show that DHC stands out. It lexicographically qualified 145 TS and categorized five classes. Vocabulary processing in DHC lasted 11 seconds, with an 82.76% utilization rate.

Using illustration as a language resource in communicating with the child was absent in 14 (87.5%) forms, and only two (12.5%) had any image. In one of the forms with an image, a drawing of SpongeBob, a popular character from the children's world, was used to be the interlocutor of the message about

the study to be conducted, and the word "play" replacing "research." Another used "comic strip" and words that suited children's reality in their environment.

According to the IF-BR, nine (56.25%) AF presented very difficult readability, with scores compatible with the level of secondary school and higher education, and six (37.5%) were compatible with the level of 6th to 9th year, that is, children aged between 11 and 14 years. Only one had a readability index appropriate to the age range of 6 years to 11 years of age (Table 1).

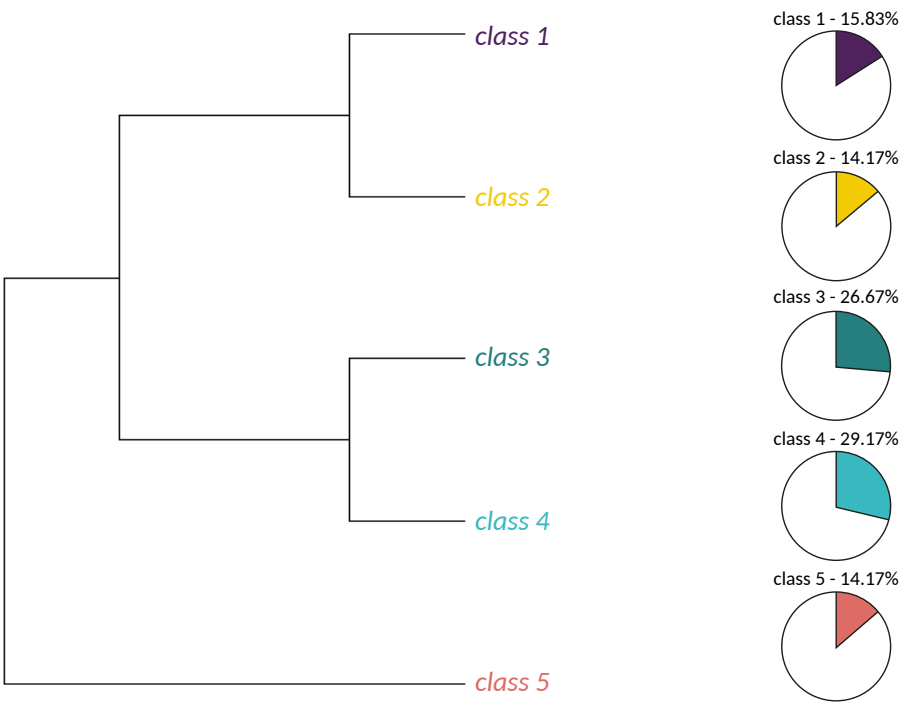
Regarding the distribution of AF with complex language, psychology stands out, with three, followed by nursing, nutrition, medicine, physical therapy, and speech therapy, with one each. The only study classified as very difficult and requiring higher education to read and understand was in nutrition. The very easy and appropriate one for school age was in nursing.

The analysis of words in IRAMUTEQ generated a DHC with five classes of words (Figure 1): guarantee of anonymity, understanding for authorization, invitation to participate, participant rights, and research theme.

Table 1. Readability of the assent forms for theses and dissertations, according to the Flesch index - Brazilian version in Portuguese. Brazil, 2014-2018

Score	Readability	Education level	Number of forms (n=16)	Percentage (%)
100-75	Very easy	1st to 5th year	1	6.25
75-50	Easy	6th to 9th year	6	37.5
50-25	Difficult	High school	8	50
25-0	Very difficult	Higher education	1	6.25

Figure 1. Descending hierarchical classification of the lexicon of 16 assent forms



Class 1 (guarantee of anonymity) presented TS corresponding to 15.83% of the words, with particular emphasis on the investigator's responsibility in guaranteeing the secrecy and confidentiality of the research participant. The forms stated that information identifying the child would be preserved and that the research results would be disclosed in events and scientific publications. However, words such as "secrecy," "confidential," "scientific publications," and "privacy" are uncommon in the children's universe.

The information from this research will be confidential and published only in scientific events or publications without the volunteer's identification.

Everything you say will be kept confidential, and we will present the results under other names so that no one can recognize you.

Your name will not be identified, and I will be guaranteed confidentiality regarding the confidential data involved in the research, ensuring absolute privacy.

The research results will be published in a confidential manner without identifying your or your mother's name or any information that could identify you.

In class 2 (understanding for authorization), TS corresponded to 14.17%, and the words refer to the need for the child to understand what is written in the form before agreeing to participate in the research. This set of TS records the study's objectives and the risks and benefits of participating as a research volunteer, but the language of the text is unusual for children. In general, to clarify terms that are difficult to understand, there is an alert so that doubts can be asked of the investigator.

Your guardian must authorize and sign a consent form to participate in this research. You and your guardian must authorize and sign this form, agreeing that if there are any words or terms that you do not understand, feel free to ask.

We want you to understand what the research will be like. Please read this information, and if you have questions, ask anything you do not understand. If you freely agree to participate, sign on the last page.

In class 3 (invitation to participate), the second with the highest number of TS (26.67%), the most significant element was the invitation to participate in the research. Among the most straightforward terms ("invited," "volunteer," and "community"), others were included, such as "data collection" and "schistosomiasis" (popularly known as water belly), which can be challenging to understand for children.

You are being invited to participate in a study.

You are being invited as a volunteer to participate in the research.

I invite you to participate in this research. During data collection, I will ask you some questions in three moments.

You are invited to participate so we can understand more about schistosomiasis in children and adolescents living in your community.

Class 4 (participant rights) corresponded to the largest number of TS (29.17%). It describes the voluntary nature of participating in the research and the right to withdraw from participation. However, terms such as "harm" and expressions such as "right to refuse," "freedom and right to refuse," and "ana research phase" could be better explained to the child.

Your participation is voluntary; that is, you participate if you want, and refusing to participate will not change how you will be served.

You decide whether to participate in this research (...). You will only participate if you want to, and if you decide to refuse to participate, it is your right, and no harm will occur.

You also have the freedom and right to refuse participation or withdraw your assent at any research phase without any harm.

In class 5 (research theme), in which additional information on specific elements of the research was included, TS was equivalent to 14.17%. This set of texts records the title of the research,

the theme, and the procedures, emphasizing an AF whose readability was classified as very easy (Table 1), being suitable for children from the 1st to the 5th year of elementary school.

Another form adopted infantilized words, such as "little animals," "little leg," and "little arm," as part of a narrated story, even using the colloquial expression "head in the clouds" to indicate carelessness on the part of the person who exposes themselves to contaminated water.

Small animals come out of the eggs and enter the that lives in this water. When they come out of the snail, they swim and look for a little leg or a little arm taking chances in the water [narrated story].

In another segment, the words used can induce the child's decision-making by saying that, by participating in the study, they will receive treatment against the parasite under investigation.

But first, it is important to know that schistosomiasis is a disease caused by a worm that lives in a person's belly and attacks various body organs [...]. *After taking the medicine and participating in this research, our team will treat you if you have schistosomiasis or other worms.*

Em In another segment, the child's voice is incorporated into the form's text through the word "our."

This material goes to the laboratory to see what happens to our body. This will happen several times because we are growing and our body changes.

In this sense, the language adopted in writing the AF to describe the research procedures is inadequate, difficult to understand, and induces decision-making. The word cloud generated in IRAMUTEQ facilitates the visualization of the most recurring words in the 16 AF, with "research" being central and most relevant (Figure 2).

Figure 2. Word cloud of 16 assent forms from theses and dissertations, Brazil, 2014-2018

The words "participation," "legal guardian," "child," and "principal investigator" also gained more visibility in the cloud, to the detriment of those related to research procedures: "right to refuse," "secrecy," "confidential," and "volunteer."

Discussion

The majority (nine out of 16) of AF have readability classified as difficult and very difficult, compatible with secondary and higher education levels, and therefore incompatible for children aged between 6 and 10. Furthermore, they used unsuitable words and expressions for children to understand.

Applying the defining elements of readability and readability of texts is a quality indicator [26]. These elements can be applied in the field of child health research, as this is an age group whose learning of scientific concepts is expanded by inclusion in the school context. Therefore, readability and legibility are fundamental elements in writing an AF since understanding the text is a determining factor in guaranteeing the individual's right to decide clearly about a given action [27].

In addition to being an instrument, the AF acts as a mechanism for ethical protection and respect for the child's dignity in their decision-making to participate as a research volunteer. Good drafting of this form ensures that voluntary participation is free from coercive or manipulative elements. Unclear wording prevents the child from being fully informed about the research procedures and having the right to choose to participate, not participate, or refuse to continue participating, which are fundamental issues regarding respecting the right to autonomy.

The concept of autonomy concerns people's ability to govern themselves and make their own choices that guide their actions. Therefore, for a person, whether a child or not, to have autonomy, they must be able to make their choices and act intentionally with freedom. To do this, they need to be appropriately informed about the objectives of the action and be aware of the consequences of the available choices [26].

In this sense, the consent freely granted by the child needs to occur through the most comprehensive explanation possible, representing a form of respect for the voluntary and autonomous nature of participation in research. Therefore, the developmental characteristics specific to each age group must be considered when adjusting language.

Furthermore, AF informs and facilitates an open dialogue where children can express their concerns, doubts, or discomforts. In this way, the child is understood as an active partner in the research process, not a passive subject.

Regarding the age group, it is essential to know that the child understands the information from the AF, so infantilized words, exclusively textual writing, excessively technical, and repeating the content of the ICF of legal guardians do not provide information. Therefore, the investigator must know the stages of the child's cognitive development in different age groups and the level of education at the time of assent.

Cognition is understood as a set of brain/mental skills necessary to acquire knowledge [28]. Thus, investigators can obtain more genuine and meaningful insights by ensuring children understand their participation.

Research that evaluated aspects that influence children's ability to give conscious consent to their participation in clinical research concluded that age and level of education are the factors that most impact the ability to understand and make autonomous decisions [29]. Therefore, there is a problem regarding the application of AF in the age profile since 93.75% of the forms do not suit the age group and the children's education level.

Despite being mandatory to submit research protocols with children to the CONEP Ethics Committee (CEP) system, the results of this study identified that the majority of AF present low readability, adopting language inappropriate for the understanding of children aged between 6 and 12. Words and expressions specific to the research and the investigators' language were written in terms without explanatory notes or expressions equivalent to the world of children.

CNS Resolution 466/2012 [5] recommended that an IEC/IRB be an interdisciplinary and independent collegiate part of the IEC/IRB CONEP System for analyzing research ethics in Brazil. Institutions that conduct studies involving human beings are responsible for evaluating the ethical aspects of research to ensure participant protection. The IEC/IRB defends the participant's dignity, rights, safety, and well-being.

This collegiate is a social control body formed by users of the Unified Health System, representing research participants. It has a multidisciplinary and multi-professional character, with professionals from the health, exact, social, and human sciences, including, for example, jurists, theologians, sociologists, philosophers, individuals dedicated to the study of bioethics, and at least one representative of users of the institution.

As all studies are analyzed and approved by an IEC/IRB, the results of low form readability highlight a cascade of failures in this instance, which regulates and evaluates ethical aspects, including principal investigators who develop and use the forms.

Another essential point to evaluate is the use of images. This study's findings demonstrated that only two forms used images: one presented a comic book with language adapted for children, and the other featured a character from a popular children's cartoon, SpongeBob, without any relation to the study presented.

In some studies, using images in AF is strategic to provide playful elements, intending to improve children's understanding of the research [2,30]. However, caution should be taken when using characters loved by children, especially those of school age. In their imaginary formations, they tend to accept what these characters say, believing they can transmit what best suits their lives [31].

However, if the information is morally questionable, it will have repercussions on children [32]. In this way, using famous characters loved by children can strongly influence their acceptance of participating in the research as volunteers. This type of persuasion source cannot be used in research.

In some forms, the words "game" and "play" were used as euphemisms for "research" to mitigate the weight of this expression with more pleasant ones [33]. This is not assertive; after all, it would be an erroneous form of convincing, considering that the child may consider that they are actually playing [34]. Furthermore, the term "secrecy" was widely used in AF, and considering the need to adapt words to the child's universe, it is suggested that "secrecy" be replaced with "secret," for example.

Confidentiality, secrecy, and respect for privacy comprise moral precepts of healthcare professions and simultaneously indicate the rights of the participant and the duties of the professional [35,36]. The AF must include this information to preserve the participant's identity and guarantee all their rights. Furthermore, it is necessary to respect the particularities of each age, cognitive development, and level of education. Therefore, it is recommended to use simple words, replacing technical terms with those understandable by children, which are more common in children's world, but avoiding infantilized expressions and the excessive use of diminutives.

Notably, the fear of breach of confidentiality was one of the reasons why volunteers refused to participate in research, equivalent to 17% of those interviewed [37]. Therefore, communicating that the investigator will guarantee the participant's anonymity, even if they are a child, can increase the feeling of security, become an assertive act, and reduce the risk of refusal.

Another item in one of the IRAMUTEQ classes was the right to refuse and/or withdraw from the research. The investigator must respect the participant's decision to refuse to continue as a research volunteer [37], always preserving the most significant benefit of the child's participation in the research and their best interests.

In this way, informing the right to refuse and/or withdraw even after the start of the research provides greater autonomy to the participant [26]. However, for children, it is essential to use playful elements at this time through images and/or words appropriate to their age [2,13]. Therefore, it is recommended to use figures in the AF that demonstrate a relationship with the research and/or with the act of assenting, but in a way that does not induce the child to accept or remain in the research.

In the class of words related to understanding for authorization, more than half of the AF presented inadequate readability, meeting only a normative requirement of the regulation without providing clear and understandable information for the children's age and education. Studies with poorly understandable information may still comply with the Resolutions without necessarily being well understood by participants [38].

The research theme (DHC class 5) included words from one of the 16 AF with the best readability quality, aligned with the children's cognitive abilities and age group. Additionally, the primary purpose of this alignment is to provide a meticulously adapted AF model with accessible and understandable language for children participating in clinical investigations.

The central words in the word cloud privilege research and its attributes ("principal investigator," "participate," "wanting"), while on the periphery are terms that relate to the child. It is essential to know that the participant must be the central point of all the research that involves them so that they understand what is happening and can accept it autonomously [3].

Agreement to participate in any research must ensure that participants obtain sufficient and transparent information about the details of their involvement and understand the research procedures, their rights, and the voluntary nature of participation [39]. Preparing an ethical AF requires that the research content is clearly presented and adapted to the participant's cognitive and educational level to provide a less tense moment for the child's decision-making capacity [3,13,38].

As a limitation of the study, the low availability of AF in academic productions and the lack of a descriptor in the Health Sciences Descriptors (DeCS) database for "assent" or "assent form" stand out, which limits the visibility of publications on the topic. In DeCS, there are only definitions of terms referring to research with adults or therapeutic and diagnostic procedures with children.

Another issue was that the methodology was restricted to documentary analysis without a field investigation with the investigators and the child volunteers in clinical studies. These aspects limit the potential transferability of results to similar situations, i.e., academic graduate productions, without involving professional master's degrees and doctorates.

Final considerations

The AF used in research conducted with children between 6 and 12 years old analyzed in this study had IF-BR compatible with secondary and higher education, and only one in 16 documents used images to communicate the research content to the child. The low readability of the form with difficult-to-understand words influences the child's autonomous decision-making to participate as a research volunteer.

Therefore, it is essential to develop new strategies to improve the understanding and communication of these participants and guarantee them autonomy, respect, dignity, and empowerment. To this end, it is necessary to use children's language and the particularities of the children's universe to translate what the norms regulating ethics in research with children recommend.

Thus, for a more autonomous assent, documents must be prepared in adapted language and with specific materials for these research participants, such as representative images of children. Furthermore, another recommendation is to use the FREI and FKRI indices to check AF's degree of legibility and readability.

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Participation of the authors

Thamires da Silva Papera and Ivone Evangelista Cabral participated in the study design, data collection, analysis, interpretation, and discussion of results. Fernanda Ferreira da Silva Lima and Jéssica Renata Bastos Depianti participated in the result analysis and interpretation. Tania Vignuda de Souza and Aldaiza Marcos Ribeiro contributed to data interpretation. All authors contributed equally to content writing, critical review, and final version approval, taking responsibility for its content integrity.

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