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Assent form: research with children and adolescents

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Abstract

This literature review seeks, through a qualitative approach, to address ethical aspects related to the design of assent forms for research involving children and adolescents. The gap in Brazilian resolutions regarding their composition is also discussed. Finally, some of the most relevant pieces of information for designing the document are suggested.

Keywords: Child. Personal autonomy. Informed consent. Human experimentation.

Resumo

Termo de assentimento: pesquisas com crianças e adolescentes

Esta revisão bibliográfica busca abordar os aspectos éticos relacionados à elaboração de termos de assentimento para pesquisas envolvendo crianças e adolescentes, por meio de abordagem qualitativa. Discute-se, ainda, a lacuna existente nas resoluções brasileiras em relação a sua composição. Por fim, são sugeridas algumas das informações mais relevantes para a elaboração do documento.

Palavras-chave: Criança. Autonomia pessoal. Consentimento livre e esclarecido. Experimentação humana.

Resumen

Formulario de asentimiento: investigación con niños y adolescentes

Esta revisión bibliográfica busca abordar los aspectos éticos relacionados con la elaboración de los formularios de asentimiento para la investigación con niños y adolescentes, mediante un enfoque cualitativo. También se discute la brecha en las resoluciones brasileñas con relación a su composición. Por último, se sugieren algunas informaciones más relevantes para la elaboración del documento.

Palabras clave: Niño. Autonomía personal. Consentimiento informado. Experimentación humana.

Research

The author declares no conflict of interest.

Children and adolescents represent approximately 30% of the Brazilian population. According to the census carried out by the Brazilian Institute of Geography and Statistics (IBGE) in 2022, of the 203,062,512 million people in Brazil, more than 50 million were in the age group between 0 and 19 years [1]. Young people have increasingly been the focus of public health care initiatives, as they are considered vulnerable and susceptible to health-related problems, such as sexually transmitted infections (STIs), unwanted pregnancy, abortion, drug use, among others [2].

This requires further research on factors related to the occurrence of these problems, aiming at clarification and thus contributing to prevention [3]. However, studies with children and adolescents face challenges in the scope of research ethics, especially as to the autonomy of these individuals [4].

According to the National Health Council (CNS) Resolution 466/2012 [5], which approves the directives and regulatory standards for research involving human beings, and resolution 510/2016 [6], which provides for the standards applicable to research in human and social sciences (HSS) and to any and all research that adopts methodologies specific to these sciences, underage research participants must receive the assent form (AF), which provides information about the study, in clear language, including objectives, methods, benefits, risks, for them to give assent [5,6].

This does not exclude the need to obtain consent from parents or guardians, and they must receive the informed consent form (ICF), which contains the necessary information about the study, so they express their agreement to participation in the research [5].

Although Brazil lacks more normative or legal provisions, since the aforementioned resolutions prevail, according to the International Guidelines for Biomedical Research in Human Beings, there are situations in which the assent of the minor is acceptable without authorization of their parents or guardians. This is valid in cases where the young person is emancipated, married or lives independently, and in research on subjects that may lead parents or guardians to inhibit their participation [7].

On the other hand, very young children, unable to understand the research context, or who are facing a serious disease that has no available treatment, can participate in research without the need to give their assent [7].

The Child and Adolescent Statute (ECA), Law No. 8,069/1990, Art. 2 , defines: *a child, for the purposes of this Law, is a person aged below 12 years, and an adolescent is a person aged between 12 and 18 years* [8].

There are questions as to the time after which minors can be considered as autonomous individuals and in which cases they could make decisions autonomously [3]. According to the Brazilian Civil Code, Law No. 10,406/2002:

Art. 3 – Minors under 16 (sixteen) years of age are absolutely unable to personally perform the acts of civil life.

Art. 4 – Those over sixteen and under eighteen years of age are incapable in relation to certain acts or the manner of performing them.

Art. 5 – Minority ceases at the age of eighteen, when the person is qualified to perform all acts of civil life [9].

As for the participation of minors in research, according to research ethics committee (REC) network system and the National Research Ethics Committee (CONEP), which regulates the practice of scientific research with human beings in Brazil, it is understood that underage individuals are naturally vulnerable and, therefore, should not be the subject of studies when information can be obtained from individuals with full autonomy [5].

It is noted that participants who, despite being of legal age, lack full autonomy to consent to their participation are also considered legally incapable, such as individuals with disorders, mental illnesses or in situations of substantially decreased decision-making capacity [5].

For the participants' proper understanding, the AF must employ language that is appropriate to the different age groups. A general AF should be avoided for participants under the age of 18 years. Ideally, appropriate AFs should be designed for each age group, according to the

participants' understanding [10]. The AF design may employ drawings, figures, characters, illustrative stories, etc. so minors, to the extent of their understanding, comprehend the importance of the research, in addition to procedures, risks and other information [11].

The AF does not grant minors the autonomy to decide for themselves on their participation in the research. As a requirement for the presentation of the AF, the ICF must be signed by a person responsible for the minor, who must be an adult, legally capable of making decisions [5]. The ICF is the document in which the consent of the legal guardian is requested and must contain, in easy-to-understand language, the relevant information regarding the research to which it is inviting, so the guardian expresses their decision, autonomously and consciously [5].

Brazilian resolutions on research ethics lack clear guidelines as to when the AF must be presented or in which situations it is really necessary. Research with underage participants has peculiar characteristics and, thus, requires clearer guidelines, which in fact guide the design of the AF and when it should be applied [4].

Based on the above, this article seeks to conduct a literature review, through a qualitative approach, addressing ethical aspects related to the design of an AF for research involving children and adolescents.

Method

For this study, we conducted bibliographic survey on the theme proposed in the Virtual Health Library (VHL), in the item "Health Sciences in General," which comprises the following databases: Medical Literature Analysis and Retrieval System Online (MEDLINE), Latin American and Caribbean Health Sciences Literature (LILACS) and Scientific Electronic Library Online (SciELO). To screen the results, in the search filter fields we used the combined terms "research with children" and "research with adolescents," "assent form" and "assent." Articles in English or Spanish were also accepted.

We adopted the following inclusion criteria: articles whose discussion revolved around the issue of ethics in research with minors; and publicly available articles. Initially, we decided to select only publications from the last ten years; however, because this theme is scarce in the literature, this criterion was disregarded.

Articles that did not discuss children and adolescents as research participants were discarded. We used 19 articles as references for the discussion of this study.

The theoretical framework referring to the Brazilian regulatory system was based on CNS resolutions on ethics in research involving humans and their complements. We also consulted the Brazilian Civil Code [9], and ECA [8].

Results and discussion

The CNS Resolution 466/2012 only mentions assent in relation to its definition, in the following items:

II.2 – Free and informed assent – assent of the research participant, child, adolescent or legally incapable, free of vices (simulation, fraud or error), *dependence, subordination or intimidation. Such participants must be informed about the nature of the research, its objectives, methods, expected benefits, potential risks and the inconvenience that it may cause them, to the extent of their understanding and respecting their singularities;*

(...)

II.24 – Assent Form – document prepared in language accessible to minors or those legally incapable, through which, after the research participants are duly provided with clear information, they will express their assent to participation in the research, without prejudice to the consent of their legal guardians [5].

CNS Resolution 510/2016 establishes the same recommendations for what it defines as registration of consent and/or assent and adds some guidelines on the process of assent and the free and informed consent:

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Art. 5 – The process of communication of assent and free and informed consent can be carried out through its oral expression, in writing, sign language or by other means that prove appropriate, duly considering the individual, social, economic and cultural characteristics of the person or group of persons participating in the research and the methodological approaches applied [6].

Recently, CONEP published Official Letter 11/2023 [12], which provides guidelines related to the process of obtaining the assent of research participants under the age of 18 years and persons with "lack of autonomy," permanent or temporary, to consent. This document recommends some items that must be present in the assent form or registration, such as the investigational product, the purpose of the research, the procedures that will be carried out, possible inconveniences, expected benefits, right to compensation, among others.

Brazilian resolutions on ethics in research involving human beings do not mention the initial age group to which this document should be applied. However, CONEP advises in its substantiated opinions that the AF be applied after the child becomes literate, around 6 years of age, according to the National Pact for Literacy at the Right Age (PNAIC) [13].

In addition, it is recommended that the AF be designed in language adapted to the age of the research participants, that is, to the extent of their understanding, according to the different age groups; hence it is not appropriate to present a single general AF for all participants under 18 years of age [10]. The AF design may employ graphic resources, such as drawings, characters, illustrative stories, leaflets, so children or adolescents understand the importance of the study and relevant information [11].

Some authors emphasize the most relevant aspects that must be clearly informed in the AF to request the assent of children or adolescents, including the research objectives, methodology, expected benefits and foreseen risks [14]. It is essential to explain the purpose of the study, what is under study and why it is under study, and why the child or adolescent was chosen. For example, if the research is on a new drug, the function of that drug and the disease to be treated must be justified and clarified [15].

In addition, it should be communicated that participant data will not be shared with people not involved in the study, so as not to generate inconveniences, and that, when the research results are published, it will not be possible to identify the participants, as the researcher and their team must be committed to confidentiality and secrecy [15]. In addition, the AF must include the contact information of the researcher in charge, in case of doubts and for the provision of immediate, full and free assistance in situations where the participant suffers any damage resulting from the study [15]. In addition, the contact information of the REC (and CONEP, if applicable) must be included, as well as a brief explanation of its function, so the participants can resort to it in case of doubts about the ethics of the research and about their own rights [12].

Other fundamental issue concerns participant autonomy, and the guarantee of the possibility of refusing participation or opting out of the research, that is, the minor must be aware that, even if their parents or guardians have agreed with the research, they are free to make their decision and can opt out of the study at any stage, without being subject to any penalty [14]. Their opinion must be listened to and considered according to the interest of the child or adolescent and respect for their rights. The process of obtaining assent must be structured on the basis of the right to be informed and the right to assent [16]. By considering the will of this population, researchers establish a good professional relationship and comply with bioethical principles [17].

The person invited to participate in the research who does not wish to give their assent must be respected, especially if the expected benefits are uncertain. Maintaining the balance between the consent of parents or guardians and the assent of the minor is essential to achieve the necessary empathy between the health care team and the patient and their family, in addition to complying with the ethical and legal principles of the medical practice [18].

It is noted that the AF should not be a reproduction of the ICF for adults. Text-heavy and extensive models can be difficult for minors to

understand; thus, they should be replaced with an invitation format, with short sentences [11]. An AF for research with children can be designed in comic book format, with language adapted to the age group, with some illustrations [19] and appealingly-sized and interactive fonts [20]. The strategy of using playful language arouses the children's curiosity and encourages them to ask important questions about the research, especially about the methodology adopted [21].

On the other hand, as the age range increases, the AF is expected to be accordingly more complex. Therefore, an AF geared toward adolescents, who are more developed and have greater capacity to understand, does not require texts adapted for younger children, and can be designed in textbook format, with interspersed questions [22].

It is noted that the process of obtaining assent involves the establishment of a relationship of trust between researcher and participant, which must always be based on dialog and questioning. More important than the formal signature of the document, such process must be clear, objective, spontaneous and in a mutual climate of trust, valuing interactive communication [6].

It is crucial to analyze how the community deals with the theme that will be addressed by the research and ensure that the participants do not feel inconvenienced during the transmission of information. For example, discussing STIs or some diseases related to poor hygiene may be taboo in some locations. Considering these sensitivities will enable researchers to choose the best approach to ensure that study information is effectively transmitted to the group involved in the research [23].

In addition, the researcher, or the person delegated to obtain consent, should perceive the participants' capacity to understand and, if necessary, adapt the form to their conditions. The fact that a form is approved by a REC is no guarantee that the participant will truly understand it. Typically, pharmaceutical companies have a standard model for their researches. However, cultural and educational differences should be considered and, therefore, the method for presenting information, if relevant, should be adapted, respecting the conditions of each individual, so as to achieve the best means of communication and enable the participants to fully understand the information [24].

The inclusion of an additional step to confirm the understanding of important concepts of the research could be interesting to ensure adequate assent of the youth population. Complementation with educational components, such as a questionnaire with feedback, supplementary materials and other means, can be a useful resource to ensure full understanding of the study [25].

It is noted that communicating information about health-related research poses the risk of conveying an overly optimistic view and has the potential to lead to therapeutic misunderstanding, in which participants confuse the research objectives with those of the treatment and do not understand that the main purpose of clinical research is to produce knowledge, regardless of whether they benefit directly, which can lead them to make decisions that are not based on proper understanding [26,27].

In addition to excessive expectations, illiteracy, low education level, and unfamiliarity with clinical research and technical terms limit understanding. Such issues can lead a person to participate in a study due to the hope of receiving treatment without a correct understanding of the process and their own rights [23]. Therefore, researchers must assume ethical and legal responsibility for ensuring properly informed assent/consent and not allowing blind and erroneous optimism about research [26].

Final considerations

The AF is one of the most important documents for ethical assessment of research involving children and adolescents, because, through it, underage participants exercise their right to autonomy, to choose to participate or not in a study, after being duly informed.

Proper assent, to be considered as such, must be obtained through a voluntary decision of the participants, based on clear information, with language accessible to the age group of the target public, as the objective of the AF is to provide information to support the participants' decision-making process. The design of an extensive document, with technical terms, long sentences, difficult to understand, can compromise the decision-making

of individuals, thus violating the principle of consent, which is expressed in the Universal Declaration on Bioethics and Human Rights.

However, Brazilian resolutions have a gap as to the composition of AFs, as the main national resolutions on ethics in research involving human beings contain few recommendations about the basic information that should be part of AFs. The REC/CONEP system, which is responsible for protecting research participants, should provide researchers with guidelines on the design of the AF and recommend what information should be included and how it should be described.

It is expected that the discussions conducted here can foster reflection on the subject and contribute to CONEP on the development of ethical guidelines for research with underage participants, who should be especially protected, as they are naturally more vulnerable. Furthermore, it is expected that this article, which sought information on ethical aspects related to the design of AFs for research involving children and adolescents, can contribute to improve the design of AFs, in order to reduce compliance issues in the REC/CONEP system and streamline the ethical assessment process.

References

1. Brasil. Pirâmide Etária. Instituto Brasileiro de Geografia e Estatística [Internet]. 2022 [acesso 23 ago 2024]. Disponível: https://bit.ly/3XDm73d
2. Almeida RAAS, Corrêa RGCF, Rolim ILTP, Hora JMD, Linard AG, Coutinho NPS, Oliveira PDS. Knowledge of adolescents regarding sexually transmitted infections and pregnancy. Rev bras enferm [Internet]. 2017 [acesso 23 ago 2024];70(5):1033-9. DOI: 10.1590/0034-7167-2016-0531
3. Guariglia F, Bento SF, Hardy E. Adolescentes como voluntários de pesquisa e consentimento livre e esclarecido: conhecimento e opinião de pesquisadores e jovens. Cad saúde pública [Internet]. 2006 [acesso 23 ago 2024];22(1):53-62. DOI: 10.1590/S0102-311X2006000100006
4. Jager ME, Gonçalves J, Dias ACG, Beck CLC. Ética em pesquisa com adolescente: uma revisão da literatura nacional. Rev Psicologia em Foco [Internet]. 2013 [acesso 23 ago 2024];5(5):134-49. Disponível: https://bit.ly/3z219Ss
5. Conselho Nacional de Saúde. Resolução n° 466, de 12 de dezembro de 2012. Dispõe sobre ética em pesquisas envolvendo seres humanos. Diário Oficial da União [Internet]. Brasília, p. 59, 13 jun 2013 [acesso 23 ago 2024]. Seção 1. Disponível: http://conselho.saude.gov.br/resolucoes/2012/Reso466.pdf
6. Conselho Nacional de Saúde. Resolução n° 510, de 7 de abril de 2016. Trata sobre as diretrizes e normas regulamentadoras de pesquisa em ciências humanas e sociais. Diário Oficial da União [Internet]. Brasília, n° 98, p. 44-6, 24 maio 2016 [acesso 23 ago 2024]. Disponível: https://conselho.saude.gov.br/resolucoes/2016/Reso510.pdf
7. Council for International Organizations of Medical Sciences. International Ethical Guidelines for Biomedical Research Involving Human Subjects [Internet]. Genebra: CIOMS; 2002 [acesso 23 ago 2024]. Disponível: https://bit.ly/3XiWK5z
8. Brasil. Lei n° 8.069, de 13 de julho de 1990. Dispõe sobre o Estatuto da Criança e do Adolescente e dá outras providências. Diário Oficial da União [Internet]. Brasília, n° 135, p. 13563, 16 jul 1990 [acesso 23 ago 2024]. Disponível: https://bit.ly/3pmAhoZ
9. Brasil. Lei n° 10.406, de 10 de janeiro de 2002. Institui o Código Civil. Diário Oficial da União [Internet]. Brasília, p. 1, 11 jan 2002 [acesso 23 ago 2024]. Disponível: https://bit.ly/2Xqtoaq
10. Orientações sobre o Termo de Assentimento Livre e esclarecido (TALE). Empresa Brasileira de Serviços Hospitalares [Internet]. 2024 [acesso 23 ago 2024]. Disponível: https://bit.ly/3MMNCB7
11. Miranda JOF, Santos DV, Camargo CL, Nascimento SCL, Rosa DOS, Souza GMS. Construção e aplicação de um Termo de Assentimento: relato de experiência. Texto & contexto enferm [Internet]. 2017 [acesso 23 ago 2024];26(3):e2460016. DOI: 10.1590/0104-07072017002460016
12. Conselho Nacional de Saúde. Ofício Circular n° 11, de 26 de julho de 2023. Orienta sobre o processo de obtenção do assentimento de participantes de pesquisa menores de 18 anos e de pessoas com "ausência

de autonomia", permanente ou temporária, para consentir [Internet]. Brasília: CNS; 2023 [acesso 23 ago 2024]. Disponível: https://conselho.saude.gov.br/images/comissoes/conep/documentos/CARTAS/SEI_MS_0034999751_Oficio_Circular.pdf

13. Brasil. Ministério da Educação. Pacto Nacional de Alfabetização na Idade Certa. Documento Orientador de 2017 [Internet]. Brasília: MEC; 2017 [acesso 23 ago 2024]. Disponível: https://bit.ly/3B09YN2
14. Gaiva MAP. Pesquisa envolvendo crianças: aspectos éticos. Rev. bioét. (Impr.) [Internet]. 2009 [acesso 23 ago 2024];17(1):135-46. Disponível: https://bit.ly/3AX7nDA
15. World Health Organization. Informed Consent form templates – informed assent form template for children/minors. [Internet]. Geneva: WHO; 2023 [acesso 23 ago 2024]. Disponível: https://bit.ly/3XA1HYZ
16. Salgado RSE. Niños, niñas y adolescentes frente a la investigación clínica. Med leg Costa Rica [Internet]. 2002 [acesso 23 ago 2024];19(2):125-33. Disponível: https://bit.ly/47qOZzg
17. Oliveira TGP, Muylaert CJ, Reis AOA. Crianças como sujeitos na pesquisa: uma revisão integrativa. Psicol hosp (São Paulo) [Internet]. 2012 [acesso 23 ago 2024];10(2):2-16. Disponível: https://bit.ly/4ehUQsS
18. Hirschheimer MR, Constantino CF, Oselka GW. Consentimento informado no atendimento pediátrico. Rev paul pediatr [Internet]. 2010 [acesso 23 ago 2024];28(2):128-33. DOI: 10.1590/S0103-05822010000200001
19. Albres NA, Sousa DVC. Termo de assentimento livre e esclarecido: uso de história em quadrinhos em pesquisas com crianças. Revista Sinalizar [Internet]. 2019 [acesso 23 ago 2024];4. DOI: 10.5216/rs.v4.57756
20. Varejão CS, Espírito Santo FH, Ribeiro MNS. The importance of applying the statement of assent to children and adolescents: a qualitative study. Invest Educ Enferm [Internet]. 2023 [acesso 10 set 2024];40(2). DOI: 10.17533/udea.iee.v40n2e07
21. Francisco DJ, Azevêdo EMS, Ferreira AR. O termo de assentimento livre e esclarecido em uma pesquisa com robótica educacional: reflexões de um percurso. Rev Humanid Inov [Internet]. 2021 [acesso 10 set 2024];8:334-43. Disponível: https://revista.unitins.br/index.php/humanidadeseinovacao/article/view/2791
22. Soll D, Guraiib MM, Rollins NC, Reis AA. Improving assent in health research: a rapid systematic review. BMC Medical Research Methodology [Internet]. 2020 [acesso 10 set 2024];20(1):114. DOI: 10.1186/s12874-020-01000-3.
23. Lobato L, Gazzinelli A, Pedroso LS, Barbosa R, Santos FMM, Gazzinelli MF. Conhecimento de crianças sobre o termo de assentimento livre e esclarecido. Rev. bioét. (Impr.) [Internet]. 2016 [acesso 11 set 2024];24(3):542-56. DOI: 10.1590/1983-80422016243154
24. Biondo-Simões MLP, Martynetz J, Ueda FMK, Olandoski M. Compreensão do termo de consentimento informado. Rev Col Bras Cir [Internet]. 2007 [acesso 10 set 2024];34(3):183-8. DOI: 10.1590/S0100-69912007000300009
25. Lee S, Kapogiannis BG, Flynn PM, Rudy BJ, Bethel J, Ahmad S *et al*. Adolescent medicine trials network for HIV/AIDS interventions. Comprehension of a simplified assent form in a vaccine trial for adolescents. Journal of Medical Ethics [Internet]. 2013 [acesso 10 set 2024];39(6):410-2. DOI: 10.1136/medethics-2012-101286
26. Woods S, Hagger LE, McCormack P. Therapeutic misconception: hope, trust and misconception in paediatric research. Health Care Analysis [Internet]. 2014 [acesso 23 ago 2024];22(1):3-21. DOI: 10.1007/s10728-012-0201-8
27. Lidz CW. The therapeutic misconception and our models of competency and informed consent. Behavioral Sciences & the Law [Internet]. 2006 [acesso 23 ago 2024];24(4):535-46. DOI: 10.1002/bsl.700

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