Revista Bioética
ISSN: 1983-8042
bioetica@portalmedico.org.br
Conselho Federal de Medicina
Brasil

Lobato, Lucas; Gazzinelli, Andréa; Scarpelli Pedroso, Lorena; Barbosa, Roberta; Meira Santos, Fabricia Madalena; Gazzinelli, Maria Flávia
Conhecimento de crianças sobre o termo de assentimento livre e esclarecido
Revista Bioética, vol. 24, núm. 3, 2016, pp. 542-556
Conselho Federal de Medicina
Brasília, Brasil

Children's knowledge of the terms of informed assent

Lucas Lobato[1], *Andréa Gazzinelli*[2], *Lorena Scarpelli Pedroso*[3], *Roberta Barbosa*[4], *Fabricia Madalena Meira Santos*[5], *Maria Flávia Gazzinelli*[6]

Abstract

The objective of this study is to describe the knowledge of children and adolescents regarding the information disclosed by the terms of assent used in pediatric clinical research, and report the attitudes of the participants. It is an experimental study with a quantitative approach, conducted in cities in the Northeast of Minas Gerais, Brazil, with 142 participants from 7 to 15 years old, chosen for a clinical study of schistosomiasis. These children and adolescents participated in the assent process using the corresponding term. We evaluated the participants through a semi-structured questionnaire. The average knowledge of participants regarding the survey information was 41.22%, with only 1.4% having a high level of knowledge. This study concluded that most children are unaware of the information regarding the research and were unaware of their rights as research participants.

Keywords: Informed consent. Research, ethics. Child-Adolescent-Comprehension. Bioethics.

Resumo

Conhecimento de crianças sobre o termo de assentimento livre e esclarecido

Este estudo tem como objetivo descrever o conhecimento de crianças e adolescentes sobre as informações divulgadas pelo termo de assentimento em pesquisa clínica pediátrica, além de relatar as atitudes dos participantes. Trata-se de estudo experimental com abordagem quantitativa, realizado em municípios do Nordeste de Minas Gerais com 142 participantes de 7 a 15 anos, escolhidos para estudo clínico sobre esquistossomose. Essas crianças e adolescentes participaram do processo de assentimento, com a utilização do termo correspondente. Avaliaram-se os participantes com questionário semiestruturado. O conhecimento médio dos participantes sobre as informações da pesquisa foi 41,22%, com apenas 1,4% apresentando alto grau de conhecimento. Concluiu-se que a maioria das crianças desconhece as informações sobre a investigação e seus direitos enquanto participantes de pesquisa.

Palavras-chave: Consentimento livre e esclarecido. Ética em pesquisa. Criança-Adolescente-Compreensão. Bioética.

Resumen

Conocimientos de los niños sobre el documento de consentimiento libre e informado

Este estudio tiene como objetivo describir los conocimientos de los niños y adolescentes sobre la información divulgada por el documento de consentimiento en la investigación clínica pediátrica, además de describir las actitudes de los participantes. Se trata de un estudio experimental con un enfoque cuantitativo, llevado a cabo en ciudades del noreste de Minas Gerais, Brasil, con 142 participantes, de 7 a 15 años de edad, seleccionados para un estudio clínico sobre esquistosomiasis. Estos niños y adolescentes participaron en el proceso de consentimiento mediante el documento de consentimiento correspondiente. Se evaluó a los participantes con un cuestionario semiestructurado. El conocimiento promedio de los participantes sobre la información de la encuesta fue del 41,22%, siendo que solo un 1,4% presentó un alto grado de conocimiento. Se concluye que la mayoría de los niños desconoce las informaciones sobre la investigación y sobre sus derechos en tanto participantes de la misma.

Palabras clave: Consentimiento informado. Ética en investigación. Niño-Adolescente-Comprensión. Bioética.

Aprovação CEP-UFMG CAAE 49078315.0.0000.5149

1. **Mestre** lucaslobato87@gmail.com – Universidade Federal de Minas Gerais (UFMG) **2.** **Doutora** andreag@enf.ufmg.br – UFMG **3.** **Graduanda** lorenanip@yahoo.com.br – UFMG **4.** **Graduanda** robertabarbosa30@yahoo.com.br – UFMG **5.** **Especialista** fabi.meira@yahoo.com.br – UFMG **6.** **Doutora** flaviagazzinelli@yahoo.com.br – UFMG, Belo Horizonte/MG, Brasil.

Correspondência
Lucas Lobato – Escola de Enfermagem da Universidade Federal de Minas Gerais, Departamento de Enfermagem Aplicada – Av. Alfredo Balena, 190, sala 508 CEP 30130-100. Belo Horizonte/MG, Brasil.

Declaram não haver conflitos de interesse.

The development of pediatric biomedical research is an ongoing need for the development of knowledge and technologies aimed at improving the quality of life of children and adolescents. In addition to considering the scientific and methodological criteria in conducting pediatric research, such research should be conducted strictly according to internationally recognized standards of research ethics [1-3].

One of the fundamental ethical prerequisites for conducting biomedical pediatric research is the involvement of children and adolescents in the decision-making process regarding their participation in the investigations. Although in most countries (such as Brazil) minors under 18 have no legal capacity to consent, it is currently strongly recognized the right of children and adolescents to be informed about the research and actively involved in the decision-making process [4-5].

The free, prior and informed consent process (FPIC) is an ethical principle essential to guarantee the right of children and adolescents as participants in biomedical research. Nationally and internationally recognized for its importance, the FPIC is founded on respect for people and human dignity, and affirms the vital importance of allowing them to exercise their moral right to self-determination [6-9]. The guarantee of these rights seeks to promote and respect free expression, and consider the views of participants in decisions that affect their lives [10].

In order for FPIC to achieve its ethical goal, there are three compelling elements: information, knowledge and willingness [4,11]. The information should be communicated to children and adolescents so that they can understand the nature of the research, its objectives, methods, expected benefits, potential risks and the discomfort that it can cause to them, considering their understanding, and respecting their singularities [6]. Knowledge regarding the nature of the research, and regarding their rights as participants, is very important for children and adolescents to become actively involved in decision-making, ensuring their willingness and subsequent evaluation of their participation.

For the researchers responsible for scientific research, obtaining the FPIC for volunteers to participate in biomedical research is considered a challenge. Studies show that this process has been insufficient to achieve its ethical goal, since children and adolescents do not understand a great deal of the information about the research in which they are involved [4,12-15]. In this sense, obtaining the FPIC from these participants may represent failure of the principle of respect for people [16], because it only formally fulfills the ethical determination to provide participants with information and clarification about the study.

Obtaining ethically valid FPIC becomes a problem of greater magnitude in research conducted in developing countries, where a set of extrinsic sources of vulnerability that can harm the participant's knowledge about the research information is observed: high rates of illiteracy, poor education, lack of familiarity with medical research, and limited access to health services [17-20]. These factors can predispose people to participate in a study, in order to get treatment without real understanding of the process characteristics and/or their rights.

The difficulty of obtaining an ethically valid FPIC can also be a problem in pediatric research in Brazil, because of the country's low socioeconomic levels [21-25]. In Brazil, where the research participant's rights are explicitly protected by national resolution [6], it is essential to evaluate the ethical quality of the FPIC for participants in biomedical pediatric research. Despite this need, national studies focus on assessing the quality of free, prior and informed consent for adults in research and clinical practice [19,26-28], devoting little attention to the quality of FPIC for children and adolescents [29].

Proposal and objective

This study aimed to analyze the quality of FPIC for volunteers in the pediatric clinical research entitled *Resistance induction model for the treatment of schistosomiasis in endemic areas* (*Modelo de indução de resistência pelo tratamento da esquistossomose mansoni em áreas endêmicas* - TMRC), which aimed to identify children and adolescents who, after chemotherapy for *Schistosoma mansoni*, developed immune resistance induced by the treatment.

The research was initiated in 2014, in municipalities within the Northeast of the State of Minas Gerais (Jequitinhonha Valley). 562 participants were recruited for clinical research, considering the following inclusion criteria: residing in these municipalities, aged between seven and fifteen years (inclusive) and diagnosed with schistosomiasis.

Children and adolescents, with their parents, were invited by the researchers to participate in a meeting with the TMRC research team, for an explanation of the clinical research. Meetings were held in one municipal school in each municipality where

the research was developed. There was no incentive for the participation of children and adolescents, although snacks were offered to them during the meetings. If participants lived far away from school, a driver would go to their homes, making the invitation and offering transportation to the meeting place. In the event of a positive response from both parties, a second meeting was scheduled in order to carry out the process of assent/consent.

In this second meeting, parents and children were invited to participate in the study that led to this article, whose objective was to evaluate the ethical quality of the FPIC for participants in a pediatric clinical research. After the assent of children and the consent of their legal guardians, another consent process was conducted for the TMRC clinical research. Then, we evaluated the knowledge of the information disclosed in this process and the attitudes about the possibility of their participation. According to the above, the objectives of this study are:

- Describe the knowledge of children and adolescents regarding the information of the pediatric clinical research consent terms;
- Describe the attitudes of children and adolescents regarding participation in pediatric clinical research.

Methodology

Study design

This is an experimental study with a longitudinal configuration and a quantitative approach. Children and adolescents who volunteered in this study participated in the FPIC process, through the terms of consent used for participating in the TMRC research. In this process, the document was read by a member of the research team, along with the potential research participant.

Study locations

The research was developed in four municipalities of the middle region of the Jequitinhonha Valley: Ponto dos Volantes (PDV), Itaobim (IT), Joaíma (JO) and Monte Formoso (MF). These cities have an average distance of about 590 km in relation to Belo Horizonte, and are recognized for their low socioeconomic indicators and the precariousness in the provision of essential public services. Moreover, their municipal human development index (índice de desenvolvimento humano municipal - IDHM) ranges from low to medium [21].

Population and sample

The study population corresponds to children and adolescents aged 7-15 years (inclusive), of both genders, who were invited to join the TMRC study and residents in the municipalities of Monte Formoso, Ponto dos Volantes, Itaobim e Joaíma. A non-probabilistic intentional sample[30] was adopted and a sample of 142 participants was obtained. Considering that the TMRC research currently has 486 participants, the sample corresponds to 30.8% of the population. Of this population, 284 (58.4%) are male. Regarding place of residence, 24 reside in Joaíma (5.2%), 370 in Ponto dos Volantes (82.1%) and rural area nearby, and 67 in Joaíma (14.2%). The average age was 10.67 years (standard deviation of 2.68 years).

Measuring instrument

To measure the participants' understanding of the information from the consent terms and assess their attitudes, a structured questionnaire composed of open and closed questions was created. Socio-demographic data were collected by another instrument: the Personal Digital Assistant (PDA, model Dell Axim X50).

Questions addressed the knowledge of the participants regarding the TMRC research (methods, objectives, risks and benefits, in addition to the participant's rights) and information about schistosomiasis (modes of transmission, methods of diagnosis and epidemiology of the disease). Sociodemographic data measured age, gender and formal schooling.

The preparation of the questions was based on questionnaires used for the same purpose in research with adults[26,28,29,31-34], on the international guidelines for research ethics[1,35], and on Resolution 466 of the Brazilian National Health Council (Conselho Nacional de Saúde)[6].

Data collection

Data collection was conducted through structured interviews, and sociodemographic data was obtained from interviews with the legal representatives of the participants, in their own homes on the same day of the assent process applications. This collection was conducted in participants' homes in order to ascertain the veracity of the information reported by the participant. The gathering of data on the knowledge of the information and attitudes reported by participants in the FPIC process was conducted individually with children and adolescents,

 http://dx.doi.org/10.1590/1983-80422016243154

ten minutes after their participation in the consent process, through a questionnaire applied by a researcher trained for this purpose.

The inclusion criteria in this study was eligibility for the TMRC research. The criteria chosen for exclusion was illiteracy. In this case, the process of FPIC utilized oral disclosure of information, guided by the reading of the terms of consent by a member of the research team, in the presence of witnesses designated by the participant, who had access to the same information as the children.

Consent terms

The assent terms used in the FPIC process described the necessary information to understand the research: research objectives, methodology, possible risks and benefits, participants' rights to continue or decline their participation, procedures to be carried out during the investigation, and voluntary participation without sanction to the right for treatment of the disease [6].

This document focused on the description of the study only via written text, without adding graphic elements. The preparation of the document did not include the use of reading skill levels, to adapt them to the education of children. Therefore, the terms of assent created were only guided by the requirement to transmit this information as determined by the ethics review committees (ERC).

The terms of assent used had three pages: Flesch readability index, amounting to 49 (hard); the other in the amount of 10.82, and 327 words considered complex (three or more syllables in their composition).

Obtaining free, prior and informed consent

The process of obtaining the FPIC occurred by the reading of the text, conducted by a researcher (trained for this activity) in groups with a maximum of three children. They placed participants in a circle, so that all stayed at a similar distance to the person responsible for the assent. First, the researchers requested the attention of the participants and then began the reading with the children, who could stop the reading at any time in case they had any questions. If the reader noticed that some of the children were distracted, the child's attention would be redirected to the reading of the document. The understanding of the child throughout the reading was never evaluated.

The reading was conducted in an airy room with fans and electric lighting, with compromising the assent process. No reward was promised to the children in the event of subscription, although snacks (cake, cookies and juice) were provided after the assent process. The room in which this process occurred was allocated for that specific purpose, without any noise or external intervention that could interfere with the assent process.

Data analysis

In order to ensure the reliability of data and identify nonconformities, the study used a dual independent typing of all questionnaires [36]. In case of disagreement, a third researcher checked the original document (which was kept secret) to ascertain the correct completion of the response.

Initially, the data was treated by descriptive statistics. We conducted analysis of children's and adolescents' sociodemographic characteristics, using the relative and absolute frequencies (for qualitative variables) and average, mean, and interquartile ranges (for quantitative variables). Participants' understanding of the information disclosed in the FPIC process was also verified considering the absolute and relative frequencies of responses from participants in the open and closed questions.

To determine the average understanding of participants regarding the information set forth in the assent terms, a research knowledge index (RKI) was created. This index sought to represent the knowledge of participants regarding eleven questions related to the TMRC research, and was calculated by setting the sum of the correct answers divided by the total number of questions. Therefore, this result was expressed as a percentage, with a value between 0 and 100. As this was a continuous variable, the descriptive analysis used average, mean and interquartile ranges.

The results of the RKI were classified according to categories of accuracy, based on interquartile ranges (P25, P50, P75). If the percentage of correct answers on the question was equal to or less than 25%, it was categorized as "low". In turn, percentages between 25% and 50% and between 50% and 75% were considered, as "lower-moderate" and "upper-moderate", respectively. Finally, a percentage of accuracy higher than 75% was categorized as "satisfactory/ adequate" [23].

Results

A sample of 142 children and adolescents was determined for this study, 80 male (56.3%) and 74 living in urban areas of the municipalities in which they lived (52.1%); the remaining 68 (47.9%), in turn, lived in rural areas. Of the total participants, 121 lived in Ponto dos Volantes and adjacent rural areas (85.2%), 14 in Joaíma (9.9%) and 7 in Itaobim (4.9%). The average age of participants was 10.90 (standard deviation 2.6), comprising 19 participants aged 7 years (13.4%), 11 aged 8 years (7.7%) 23 aged 9 years (16.2%), 13 aged 10 years (9.1%), 12 aged 11years (8.4%), 18 aged 12 years (12.7%), 18 aged 13 years (12.7%), 12 aged 14 years (8.5%) and finally 16 aged 15 years (11.3%).

Regarding participants' education, it was verified that 1 (0.7%)had completed the 1st year of primary education, 13 (9.1%) had completed the 2nd year, 20 (14.1%) had completed the 3rd year and 11 (7.7%) had completed the 4th year. Of the remainder, 11 (7.7%), 9 (6.3%), 17 (11.9%), 25 (17.6%), 21 (14.7%) and 15 (10.5%) had, respectively, completed the 5th, 6th, 7th, 8th and 9th years of primary education; 9 participants were enrolled in the 1st year of high school, while 1 was in the 2nd year.

When asked about the purpose of the research, only 12 (8.4%) showed that they knew the purpose of the clinical research was "to learn more about the schistosomiasis", while 50 (35.2%) reported one of two options: 24 (16.9%) mentioned that the objective of the research was to "carry out the treatment of schistosomiasis" and 26 (18.3%) cited "tests for the diagnosis of the disease". A smaller ratio of children (4) reported that the aim of the research was to "help people" (2.8%), and 19 referred to "improve health" (13.4%). On the other hand, 22 (15.5%) of them "did not know" the goal of the researchers, while 35 mentioned "other reasons" (24.6%).

Table 1 details the absolute and relative frequencies of the responses of children and adolescents regarding the benefits provided for participating in the clinical research. It is evident among the participants that the largest percentage (32.1%) believed that the treatment for schistosomiasis was a benefit provided for participating, while 9.5% reported learning about the disease as a benefit.

When asked about the possibility of risk due to the participation in the TMRC clinical research, most (73.3%) declared there were no risks. Among those who reported the possibility of risk, 10 cited the side effects of the drug for schistosomiasis (26.3%); 7, that pain would be a side effect (18.4%); 8 considered the conducting of blood tests (5.6%); 6 cited other risks (15.8%) and 7 reported not knowing (18.4%).

Table 1. Absolute and relative frequencies of children's and adolescents' responses regarding the benefits of the TMRC clinical research, Minas Gerais, 2015

Question	Options	Responses	
		n	%
What arethe benefits of participating in the research?	Cure/treat schistosomiasis	44	32,1
	Learn more about the disease	13	9,5
	Prevent schistosomiasis	21	15,3
	Diagnose schistosomiasis	6	4,4
	Improve one's own health	28	20,4
	Others	3	2,2
	Do not know	22	16,1
Total		**137**	**100**

Note: The answer considered correct with regard to this question is highlighted in bold.

Table 2 details the absolute and relative frequencies of the responses of children and adolescents regarding the information concerning the TMRC clinical research. Most children and adolescents were aware of the right to receive treatment for schistosomiasis when participating in the clinical research (83.1%). They were also aware of the need for blood and stool tests (56.3% and 63.1%, respectively), decline participation (66.9%), and the right to say to their parents that they did not want to participate (62.7%)

Regarding the attitude of the participants towards the TMRC clinical research, it was verified that the majority of participants (59.9%) were aware that they could talk to their parents or legal representatives about the decision to participate. Virtually all participants (99.3%) believed that the research would improve their health, and less than half (31.7%) reported being fearful of participating in the research. It was found that 68 participants (47.9% of the children) confirmed that someone could influence their decision to participate in the investigation. These 68 children and adolescents were asked who could influence their decision to participate in the investigation: most cited their mothers (69.1%), followed by their fathers (13.2%), five indicated other family members (7, 4%), five

http://dx.doi.org/10.1590/1983-80422016243154

others indicated the researcher or other staff member (7.4%), and two referred to "others" (6.1%).

Table 2. Absolute and relative frequencies of the responses of children and adolescents regarding the information concerning the TMRC clinical research, Minas Gerais, 2015

Question	Responses	
	n	%
Low		
Objective of the TMRC clinical research	12	8.5
Need to participate in the TMRC clinical research meetings	13	9.2
Risks of participating in the TMRC clinical research	17	12.0
Right to receive treatment even if not participating in the research	25	17.6
Lower-moderate		
Duration time of the TMRC clinical research	49	34.5
Benefits of participating in the TMRC clinical research	57	40.1
Upper-moderate		
Need to do blood tests during the TMRC clinical research	80	56.3
Children's right to express to their parents that they do not wish to participate in the research	89	62.7
Need to do stool tests during the TMRC clinical research	89	63.1
Right to withdraw participation, if that is the child's wish	95	66.9
High		
Right to receive treatment for schistosomiasis during the clinical research	118	83.1

Tabela 3. Absolute and relative frequencies of the of correct responses ratio in the research knowledge index. Minas Gerais, 2015

Score achieve in the RKI (%)	AF	RF	acRF
Low			
0.0	1	0.70	0,7
9.09	12	8.45	9.1
18.18	11	7.75	16.9
Lower-moderate			
27.27	18	12.68	29.5
36.36	26	18.31	47.8
45.45	22	15.49	63.3
Upper-moderate			
54.55	31	21.83	82.2
63.64	15	10.56	95.7
72.73	4	2.82	95.6
High			
81.82	1	0.70	99.3
90.91	1	0.70	100
Total	**142**	**100**	

Nota: AF: absolute frequency; RF: relative frequency; acRF: accumulated relative frequency.

In the descriptive analysis of the research knowledge index, the average knowledge of the participants was 41.2% (standard deviation of 17.97) with minimum and maximum values of 0 and 90.9%, respectively. It was observed that 16.9% had low average ratio of correct answers, while about 1% showed a high ratio. The largest percentage of children and adolescents had lower-moderate ratio of correct responses (46.5%), while 40% had upper-moderate. It is noteworthy that 50% of participants had up to 36.6% average accuracy in RKI.

Discussion

This research has achieved its objectives of describing the knowledge of children and adolescents regarding the TMRC clinical study divulged in the FPIC process and participants' attitudes about their participation and decision. The objective of linking this knowledge to years of schooling was also achieved. It is possible to conclude that the FPIC process was insufficient to ensure that the majority of participants were made aware of the information about the research.

The results of this study showed that most participants were unaware of essential information about the research that had been presented in the assent process, such as the study objective, duration, risks and benefits. In this sense, these participants may have suffered losses in their decision-making process and, therefore, may not have provided an ethically valid FPIC. It is fair to say that, in this case, the FPIC process failed to protect the dignity of these participants [38]. This diagnosis is important, especially on the national ambit, where research participants' rights are explicitly protected by normative regulation [6].

The lack of knowledge regarding the information provided in the FPIC for the pediatric research process is not exclusive to research conducted in Brazil. Similar results were seen in pediatric studies, clinical and non-clinical, in developed countries [10,13,39,40]. These studies show that children and adolescents were unaware of their rights and of possible risks, benefits and objectives of the research, moreover, they did not make voluntary decisions.

This occurrence leads to the question that is thoroughly addressed in the approach to the topic of adult consent in clinical research: are there differences in the quality of consent between developed and developing countries?[41] Although there is no consensus regarding this question, it is appropriate to reflect on specific protection strategies in research, considering the level of development of the places where they are conducted. The same goes for pediatric research, in which the misunderstanding of research key aspects can bring ethical implications to the assent, especially when these participants need protection because of their intrinsic vulnerability [22]. In this case, it would be valid to question the existence of differences in the quality of children's and adolescents' assent between developed and developing countries. This issue should be included on the agenda of future studies.

The relationship between the human development index and the consent of the participants, however, should not be considered without regarding other variables. Studies indicate that sociodemographic factors in the research development context (such as age, income, access to electronic media, previous participation in research) are associated with knowledge about research information [27,28,41]. In this sense, one should consider the context in which the research is conducted as a criterion for identifying the vulnerability of participants.

The results of this study show that younger participants showed a similar ratio of correct answers to those with higher ages. For example, participants of all ages had an average knowledge of approximately 50%. Although age is associated with knowledge about the research, which was also evident in other pediatric studies [10,40,42], children from 6 to 15 years demonstrated ability to understand the TMRC research information disclosed in the FPIC process. It should be stressed that this study considered that the children had contact with the research information when responses given coincided with the information disclosed in the assent process. In the case of this concurrence, the answer was considered correct. In this sense, the researchers defined the which answers were considered correct, however, without ignoring that, from an intuitive or logical point of view, other possibilities could also be correct.

Therefore, to set an age limit for participation in the FPIC process, considering only the child's knowledge capacity, would exclude these participants from exercising their right to information and their participation in decisions that would affect their lives. To protect them, we should think of mechanisms and strategies that include them in the decision-making process, since even very young children have the ability to make reasonable decisions if they understand relevant information about the research [43].

One such strategy is the use of tools that promote understanding of the research information, extensively studied in research with adults [31,44]. For pediatric research, one of the main options would be to adapt the language of the terms of assent to the age and education of participants, with the use of images, drawings and simpler language to explain the information about the research and the rights of participants [13,40,45,46]. In addition to these recreational and educational resources, it is important that researchers are aware of the most significant aspects of colloquial communication of the group with which they work, to suit the scientific discourse to the specific language of the participants, thereby promoting understanding.

This, however, does not isolate the need to consider the child's age and their cognitive and moral development in the process of disseminating information. Similarly, consideration should be given to participants' education level, as well as to the skills they acquired through formal education. According to Piaget, for example, children aged 7 to 12 years are at the concrete operational stage, in which their perception becomes more objective and less imaginative. At this stage, the child acquires the ability to think of an action and reverse this same thought. From 11 or 12, the child reaches the "formal operational stage", in which the child is able to perform logical operations based on hypotheses; in other words, the child can reason about verbal statements, that is, about propositions [47]. Therefore, there is the need to investigate strategies for communicating information for each specific age group.

To facilitate understanding, it is also essential to ensure that participants do not feel inhibited during the process of transmitting information. This can occur in certain groups, specifically with children and young people amongst whom there may be some competition to draw the attention of the researcher, or derision among themselves, which would inhibit the most shy and vulnerable from expressing themselves. It is also necessary to verify how the group, or community, deals with the topic to be presented by the researcher.

In some places, talking about diseases can be embarrassing, especially when referring to diseases whose transmission is related to dirt or excrement, or even to sexual organs and the sexual act, as with sexually transmitted diseases. This precaution will allow the researcher to adopt the most appropriate strategy for the effective dissemination of information regarding the study for the group that will participate in the research.

An important result of this study is the finding that most participants are unaware of the possible risks associated with participation in the TMRC research, a situation not observed in other pediatric research [13]. The participants of this research have been shown to be unaware that their participation could have risk the possibility of adverse effects when ingesting the anthelmintic medication, as indicated in the assent form. Regarding parents, the knowledge of the research information was not assessed. Therefore, it is not possible to make this comparison, although it is believed that this issue is very relevant. Besides the ethical problems, the ignorance of risks could lead to problems in the conduct of research and its sampling criteria, given that this problem is associated with the dissent of children and adolescents in pediatric research [48].

This lack of knowledge may even be associated with the fact that most children and adolescents reported having no fear of participating in the research, even with the application of venipunctures for blood tests. It is known that participants in this age group often fear this procedure, because of the possibility of experiencing the pain that venipuncture can cause the participant, who may already have been subjected to such an examination [49]. It is therefore possible that children may associate this expressed and felt pain with the risk of participating in the research.

The ignorance of risks can be explained by the superimposition of the images of the physician and the researcher [26,50]. In research conducted in the region of this study, it was found that the social representation of this type of researcher, for children and adolescents, is strongly associated with the doctor's figure, in such a way that places researchers as a sort of "keeper of knowledge" [51]. Those subjects delegate, without reservation, the decisions concerning their lives and health to this figure that represents knowledge and salvation and is considered the provider of health care.

The situations set forth in this discussion, together with other results described in this study, indicate the need to add educational strategies to the process of obtaining the FPIC. The development of interventions that favor the ethically valid FPIC is essential for the protection of participants from possible manipulation, and to ensure that they are aware of the real risks they will be exposed to and of the likely direct and indirect benefits from their participation in the research [52,53].

Final considerations

This study represents the first empirical research in Brazil about the knowledge of children and adolescents regarding the information disclosed in the free, prior and informed consent process. From this perspective, this study adds to the knowledge of the assent in a previously examined field and among populations that were under-represented in similar studies.

From the results of this study, we conclude that a large portion of potential participants in the clinical study was unaware of essential information disclosed in the FPIC process, such as the purpose of the clinical research, its benefits and possible risks. It also concludes that the participants' voluntary decision may be violated, by not knowing their rights to receive the treatment offered by the research, even in the case of dissent, and the possibility of conferring with parents about their decision.

The constant evaluation of the quality of the free, prior and informed consent is strongly recommended, in particular the process of obtaining it and of providing decisions. If encouraging the participation of children in decision-making process is an essential ethical requirement, then it is important to improve knowledge regarding the information, which is legally required in the FPIC process. In this sense, every effort should be made to ensure that children and adolescents have access to sufficient information and knowledge to make their choice regarding participation. It, therefore, justified the initiative to develop interventions capable of creating conditions for the potential research participant to provide ethically valid free, prior and informed consent, which is an essential requirement for respecting human dignity and, therefore, for ethics in research.

We suggest that these activities are appropriate to the age of the participants, their cognitive development, and the context in which the research takes place. Regarding the latter issue, the concern refers to conducting research with

vulnerable populations, whose decision process should be protected [29]. We stress the importance of the FPIC process being individualized, considering the characteristics of the participants, their expectations and doubts. We believe that, in this manner, children and adolescents will decide in an informed way about their participation in clinical research.

Referências

1. World Medical Association. Declaration of Helsinki. 59th WMA General Assembly. Seoul: WMA; 2008.
2. Kottow M. História da ética em pesquisa com seres humanos. R Eletr Com Inf Inov Saúde. 2008;2(Suppl 1):7-18.
3. Council for International Organizations of Medical Sciences. International ethical guidelines for biomedical research involving human subjects. Genebra: Cioms/OMS; 1993.
4. Bray L. Developing an activity to aid informed assent when interviewing children and young people. J Res Nurs. 2007;12(5):447-57.
5. Kuther TL. Medical decision-making and minors: Issues of consent and assent. Adolescence. 2003;38(150):343-58.
6. Brasil. Conselho Nacional de Saúde. Resolução nº 466, de 12 de dezembro de 2012. Aprova diretrizes e normas regulamentadoras de pesquisa envolvendo seres humanos. [Internet]. 2012 [acesso 10 jul 2015]. Disponível: http://bit.ly/1mTM1S3
7. Coyne I. Children's participation in consultations and decision-making at health service level: a review of the literature. Int J Nurs Stud. 2008;45(11):1682-9.
8. Ungar D, Joffe S, Kodish E. Children are not small adults: documentation of assent for research involving children. J Pediatr. 2006;149(suppl 1):S31-3.
9. Roth-Cline M, Nelson RM. Parental permission and child assent in research on children. Yale J Biol Med. 2013;86(3):291-301.
10. Chappuy H, Doz F, Blanche S, Gentet JC, Tréluyer JM. Children's views on their involvement in clinical research. Pediatr Blood Cancer. 2008;50(5):1043-6.
11. Hurley JC, Underwood MK. Children's understanding of their research rights before and after debriefing: informed assent, confidentiality, and stopping participation. Child Dev. 2002;73(1):132--43.
12. Koelch M, Singer H, Prestel A, Burkert J, Schulze UFeger JM. "...because I am something special" or "I think I will be something like a guinea pig": information and assent of legal minors in clinical trials – assessment of understanding, appreciation and reasoning. Child Adolesc Psychiatry Ment Health. 2009;3(1):2.
13. Hunfeld JA, Passchier J. Participation in medical research: a systematic review of the understanding and experience of children and adolescents. Patient Educ Couns. 2012;87(3):268-76.
14. Lee S, Kapogiannis BG, Flynn PM, Rudy BJ, Bethel J, Ahmad S *et al*. Comprehension of a simplified assent form in a vaccine trial for adolescents. J Med Ethics. 2013;39(6):410-2.
15. Tam NT, Huy NT, Thoa LTB, Long NP, Trang NT, Hirayama K *et al*. Participants' understanding of informed consent in clinical trials over three decades: systematic review and meta-analysis. Bull World Health Organ. 2015;93(3):186-98.
16. Wendler DS. Assent in paediatric research: theoretical and practical considerations. J Med Ethics. 2006;32(4):229-34.
17. Annas GJ, Grodim MA. Human rights and maternal-fetal HIV transmission prevention trials in Africa. Am J Public Health. 1998;88(4):560-3.
18. Filho JM. Termo de consentimento livre e esclarecido na prática reumatológica. Rev Bras Reumatol. 2011;51(2):179-83.
19. Meneguin S, Zoboli ELCP, Domingues RZL, Nobre MR, César LAM. Entendimento do termo de consentimento por pacientes partícipes em pesquisas com fármaco na cardiologia. Arq Bras Cardiol. 2010;94(1):4-9.
20. Schmitz EF, Cunha DJD, Goldim JR. Índices de legibilidade em termos de consentimento livre e esclarecido de projetos de pesquisa do Hospital de Clínicas de Porto Alegre. In: Anais do III Congresso Brasileiro de Bioética e I Congresso de Bioética do Cone Sul; 2000; Porto Alegre, Rio Grande do Sul, Brasil. Porto Alegre: Universidade Federal do Rio Grande do Sul; 2000.
21. Programa das Nações Unidas para o Desenvolvimento. Atlas do desenvolvimento humano do Brasil. [Internet]. Pnud; 2003 [acesso 5 dez 2015]. Disponível: http://bit.ly/191tPbN
22. Rogers W, Ballantyne A. Populações especiais: vulnerabilidade e proteção. In: Diniz D, Sugai A, Guilhem D, Squinca F, organizadores. Ética em pesquisa: temas globais. Brasília: Letras Livre; 2008. p. 123-51.
23. Lobato L, Gazzinelli MF, Gazzinelli A, Soares AN. Conhecimento e voluntariedade para participação em pesquisas: um estudo descritivo com participantes de um ensaio clínico. Cad Saúde Pública. 2014;30(6):1305-14.

24. Lobato L, Caçador BS, Gazzinelli MF. Legibilidade dos termos de consentimento livre e esclarecido em ensaios clínicos. Rev. bioét. (Impr.). 2013;21(3):557-65.
25. Goldim JR. Consentimento e informação: a importância da qualidade do texto utilizado. Rev HCPA. 2006;26(3):117-22.
26. Gazzinelli MF, Souza V, Araujo LH, Costa RM, Soares AN, Maia CPC. Teatro na educação de crianças e adolescentes participantes de ensaio clínico. Rev Saúde Pública. 2012;46(6):999-1006.
27. Biondo-Simões MLP, Martynetz J, Ueda FMK, Olandoski M. Compreensão do termo de consentimento informado. Rev Col Bras Cir. 2007;34(3):183-88.
28. Lobato L, Gazzinelli MF. O consentimento informado nos países em desenvolvimento é realmente autônomo?: Um estudo descritivo com participantes de um ensaio clínico sobre Helmintoses. Acta Bioeth. 2015;21(1):127-36.
29. Gazzinelli MF, Lobato L, Matoso L, Ávila R, Marques RC, Brown AS *et al*. Health education through analogies: preparation of a community for clinical trials of a vaccine against hookworm in an endemic area of Brazil. Plos Negl Trop Dis. 2010;4(7):e749.
30. Gil AC. Como elaborar projetos de pesquisa. 5ª ed. São Paulo: Atlas; 2010.
31. Joffe S, Cook EF, Cleary PD, Clark JW, Weeks JC. Quality of informed consent: a new measure of understanding among research subjects. J Natl Cancer Inst. 2001;93(2):139-47.
32. Lindegger G, Milford C, Slack C, Quayle M, Xaba X, Vardas E. Beyond the checklist: assessing understanding for HIV vaccine trial participation in South Africa. J Acquir Immune Defic Syndr. 2006;43(5):560-6.
33. Lansimies-Antikainen H. [Internet]. Realization of informed consent in health research. [tese]. [acesso 23 mar 2016] Kuopio: Faculty of Social Sciences of the University of Kuopio; 2009. Disponível: http://bit.ly/2ebjUE3
34. Matoso LF, Oliveira-Prado R, Abreu MN, Fujiwara RT, Loverde PT, Kloos H *et al*. Longitudinal analysis of antigen specific response in individuals with Schistosoma mansoni infection in an endemic area of Minas Gerais, Brazil. Trans R Soc Trop Med Hyg. 2013;107(12):797-805.
35. Council for International Organizations of Medical Sciences. International ethical guidelines for biomedical research involving human subjects. [Internet]. Geneva: Cioms; 2002 [acesso 16 set 2015]. Disponível: http://bit.ly/1m3gbXb
36. Day S, Fayers P, Harvey D. Double data entry: what value, what price? Control Clin Trials. 1998;19(1):15-24.
37. Lima RAG. Direitos da criança e do adolescente: desafios atuais. Rev Latino-Am Enfermagem. 2012;20(3):425-6.
38. John T, Hope T, Savulescu J, Stein A, Pollard AJ. Children's consent and paediatric research: is it appropriate for healthy children to be the decision-makers in clinical research? Arch Dis Child. 2008;93(5):379-83.
39. Burke TM, Abramovitch R, Zlotkin S. Children's understanding of the risks and benefits associated with research. J Med Ethics. 2005;31(12):715-20.
40. Mandava A, Pace C, Campbell B, Emanuel E, Grady C. The quality of informed consent: mapping the landscape: a review of empirical data from developing and developed countries. J Med Ethics. 2012;38(6):356-65.
41. Tait AR, Voepel-Lewis T, Malviya S. Do they understand? (part II): assent of children participating in clinical anesthesia and surgery research. Anesthesiology. 2003;98(3):609-14.
42. Coyne CA, Xu R, Raich P, Plomer K, Dignan M, Wenzel LB. Randomized controlled trial of an easy-to-read informed consent statement for clinical trial participation: a study of the Eastern Cooperative Oncology Group. J Clin Oncol. 2013;21(5):836-42.
43. Gazzinelli MF, Souza V, Campos ELW, Fernandes MM, Lobato L. Decisão autônoma e o comportamento requerido em um ensaio clínico: estudo com uma população socioeconomicamente vulnerável. Texto Contexto Enferm. 2014;23(4):944-53.
44. Tait AR, Voepel-Lewis T, Malviya S. Presenting research information to children: a tale of two methods. Anesth Analg. 2007;105(2):358-64.
45. Campbell FA, Goldman BD, Boccia ML, Skinner M. The effect of format modifications and reading comprehension on recall of informed consent information by low-income parents: a comparison of print, video, and computer-based presentations. Patient Educ Couns. 2004;53(2):205-16.
46. Pádua GLD. A epistemologia genética de Jean Piaget. Revista FACEVV. 2009(2);22-35.
47. Wolthers OD. A questionnaire on factors influencing children's assent and dissent to non--therapeutic research. J Med Ethics. 2006;32(5):292-7.
48. Soares VV, Vieira LJES. Percepção de crianças hospitalizadas sobre realização de exames. Rev Esc Enferm USP. 2004;38(3):298-306.
49. Almeida CH, Marques RC, Reis DC, Melo JMC, Diemert D, Gazzinelli MF. A pesquisa científica na saúde: uma análise sobre a participação de populações vulneráveis. Texto Contexto Enferm. 2010;19(1):104-11.
50. Gazzinelli MFC, Souza V, Pereira FB, Araujo LHL, Fernandes MM, Melo PF *et al*. Representações sociais de crianças participantes de um ensaio clínico sobre o pesquisador: de detentor do saber à criança curiosa. Saúde soc. 2014;23(2):582-91.
51. Goldim JR, Pithan CF, Oliveira JG, Raymundo MM. O processo de consentimento livre e esclarecido em pesquisa: uma nova abordagem. Rev Assoc Méd Bras. 2003;49(4):372-4.

52. Hussain-Gambles M. South Asian patient's views and experiences of clinical trial participation. Fam Pract. 2004;21(6):636-42.

Recebido: 6.4.2016
Revisado: 18.8.2016
Aprovado: 22.8.2016

Participation of the authors

All authors participated in data analysis and preparation of the manuscript. The collection of field data was performed by Lucas Lobato, Andrea Gazzinelli, Lorena Scarpelli Pedriso, Roberta Barbosa and Maria Flávia Gazzinelli. The final revision of the manuscript was done by Lucas Lobato, Andrea Gazzinelli, Fabricia Meira Madalena Santos and Maria Flávia Gazzinelli. The research planning was conducted by Lucas Lobato, Andrea Gazzinelli and Flávia Gazzinelli.

Appendix

Free, Prior and Informed Consent Terms for children and adolescents

Resistance induction model for the treatment of schistosomiasis in endemic areas

This is a document about a research to study schistosomiasis. After you read the terms and clarify all your doubts, you can freely decide whether to participate or not. If you accept, you must sign the last page of these terms. This signature means that you are assenting, or in other words, agreeing to participate in this research. If you do not want to or cannot participate, there is no problem. Just let us know and do not sign this document.

You are being invited to participate in this research so we can learn more about the schistosomiasis infection in children and adolescents, like you, who live in your community. In this research, we intend to find out the answer to the following question: "Why do some people, after treatment with medicine, get infected with the schistosomiasis and others do not, even if they do the same things?".

Your parents have agreed that you participate in this research, but you will participate only if you want to do so. There is no problem if you do not want to participate, or even if you change your mind, you may later want to leave the project at any time. Your decision is the most important.

Schistosomiasis is a disease caused by the worm *Schistosoma mansoni*, which infects people when in contact with water contaminated with feces that have schistose eggs. Larvae leave these eggs and enter a snail, which also lives in this water. When the larvae come out of this snail, they swim looking for someone who is washing clothes, pots or even bathing. Then they enter the body, become adult worms that lay eggs, and this makes the person sick. This disease, if not treated properly, can lead to serious health problems, such as the growth of some body organs. There is effective treatment for this disease, but people can easily become infected again if they enter contaminated water.

If you agree to participate, we will ask some questions about your health, what do you know about schistosomiasis and how is your contact with streams, lakes and reservoirs water. We will also request two (2) samples of your feces. A member of our team will give you a container, and explain how to put your stool in the jar and where to take it to be tested. We will examine your stools to see if you are infected with some kind of worm. We will also have to collect your blood.

The research will take approximately three (3) years. We will visit you several times during this period (including this visit). We will deliver the results of your stool test, even if you do not have worms. During this study, we will do an interview with you and/or your parents to obtain socioeconomic and demographic information, as well as details regarding activities involving contact with water. There is no risk related to the interview, as it does not include questions that might cause embarrassment.

In the case of female children and adolescents, you will be asked if you already have menstruated and, if so, a urine sample for a pregnancy test will be requested. The objective of this test is just to make sure you are not pregnant. Those who are pregnant may not participate in this research.

We will also collect about a tablespoon (14 ml) of blood from your arm. This material will be sent for laboratory tests to assess your body's defenses against the worm.

There are small risks and discomforts that may occur during the collection of your blood, such as mild pain in the vein puncture or bruising where the needle was inserted. Although the amount of blood collected is small and does not cause any health problems, you may feel dizzy after or during collection.

If you have schistosomiasis, you will be treated with praziquantel in specific dosages of 50 or 60 mg/kg, according to their age. Four weeks after treatment (28 days), another stool test will be made to ascertain whether the treatment was effective, when another 14 ml of blood will be collected. If you remain positive for schistosomiasis, new treatment will be carried out until the absence of worm eggs in your feces is confirmed.

After treatment with the medicine, the researchers will make several visits to examine you and see if there was any change in your living conditions and to the activities involving contact with water. These visits will be carried out within 12, 24 and 36 months. During these visits, we will also collect feces to check if you became infected by worms again, and will collect blood to observe how your body reacts to the schistosomiasis infection. In the

12, 24 and 36 months visits, teens who have already menstruated will be requested to provide a urine sample to conduct a new pregnancy test.

You will be treated at all stages of the research, if you test positive for schistosomiasis and/or other worms that you might be infected by. This treatment is free and performed according to the Ministry of Health's recommendations. All professionals involved in the treatment are trained and qualified to deal with any problems that may occur as a result of the medicine, such as dizziness, nausea, vomiting or other symptoms that might arise. It is known that the medicines used for the treatment of schistosomiasis do not have serious unwanted effects; however, if there is any problem, the research team will take all necessary measures. You will be forwarded, in more serious cases, to the Vale do Jequitinhonha or São Miguel hospitals to receive all necessary medical treatment for free.

You and your parents will not spend money on participation in this research. Any and every expense arising from the research, such as tests, health team work and medicine involved in your comprehensive treatment are the sponsor's responsibility. In case there are costs associated with your participation in the study, such as transportation and food on the days of your consultations or examinations, you will be refunded.

It is important you know that worms can harm your health. Weakness, difficulty concentrating at school or pain in the stomach can be caused by worms. Treatment can help you improve your health. If you agree to participate in this research, you will have the benefit of knowing if you are infected with schistosomiasis and by other worms, and you will be treated by the research team at no cost to you, your parents or guardians. Moreover, you can learn about worm infections and how to prevent these diseases. You can also help other people who are infected with schistosomiasis. You can stop participating at any time without losing the benefits of the treatment you are entitled to.

If you have any questions or need any assistance related to the research, you can ask or call one of those responsible for the research.

Dr. Rodrigo Correa de Oliveira – Leading researcher

Avenida Augusto de Lima, 1715, Barro Preto

CEP: 30190-002 Belo Horizonte – MG

Tel: (31) 3349-7775

Research Ethics Committee (Comitê de Ética em Pesquisa)

Avenida Augusto de Lima, 1715, Barro Preto

CEP: 30190-002 Belo Horizonte – MG

Tel: (31) 3349-7825

Signatures

You will sign two copies of this assent terms: one you will keep and the other will remain with the leading researcher.

The person responsible for the children or adolescents must sign the consent form for their child because the child is underage.

In the case of adolescents aged 13 to 17, the signatures will be obtained in separate documents (one copy for the adolescent and one for the parent or guardian).

I read, discussed and understood this assent form. My questions were answered. I freely agree to participate in this research.

Participant's name: _____ *(please print)*

Participant's signature: _____

Witness:

Witness' name: _____ _____ *(please print)*

Witness' signature: _____

Date *(d/m/y)*

 http://dx.doi.org/10.1590/1983-80422016243154

Assent Terms

Let's start...

My name is Flavia Gazzinelli (or Lucas Lobato) and I am a lecturer and researcher. Do you know what a researcher does? I bet you already know what a lecturer does, but what is the job of a researcher?

But first, let me ask you. Do you know what research is? Research is important to discover new things, and we all do research all the time. We are very curious and want to know how things work, isn't that so? Why is the sky blue? Why is the sun hot? Do you know? So, to answer these questions of ours, we need to know how our world works, we need to do research. That's what the researcher does, RESEARCH. The researcher wants to find answers and invent new things.

Do you know why we're here?

Why do we want to invite you to participate in a research? This research is called: How assent terms that are adapted to participants' age effect the knowledge of children participating in clinical research.

We are curious to know if transforming a text, which is usually difficult to read, in an easier text would enable the children here from this region to learn more about what is written in this text. How do we make this text easier? We will exchange difficult words for easy ones, and explain what is written with pictures, songs and stories.

Why is the answer to this question important?

Here in this region, children decide to participate in research without knowing all about it. This is very bad. Imagine you participating in something without knowing about it? This happens because the texts that explain research are difficult to read. Now, if we find that a text that is simpler and has figures can make the children know more before deciding to participate, we can write texts in this way. Then, everyone can decide if they really want to participate in a research.

Do you need to participate?

You will only participate if you want to. Your parents have agreed that you can participate, but the most important is your decision. If you don't want to, nothing will happen to you. No one will be upset or angry, not even your parents. I will repeat: you will only participate if you wish to and if you want to help find the answer to the question we did before. Do you remember? We want your assent.

But what's assent?

Assent means that you agree and want to be part of a group of children and adolescents to participate in a survey. Your rights will be respected and you will receive all the information about this research, however basic it may seem.

What is the purpose of this document that we are reading?

This document is called assent terms. In this document, we want to pass on to you the information about the research for which you are being invited. It may be that this document has words you do not understand. Please if you have any questions, ask anyone among the study staff to explain anything you do not understand.

Can you can talk with your parents before you decide?

Yes. It is important that you talk to your parents about your decision. Ask about what they think, tell them what you want to do, whether or not you want to participate. You have as much time as you need for this. You can also discuss with us, the researchers, whenever you want. We will answer all your questions at any time. We are here to do the research together.

How will the research be done?

We will invite you to talk to a researcher. He will sit with you and will ask you to read a text with a lot of information about the research. We have two types of text, one easy and one difficult, remember? We do not know which one of these texts you will read, but with any of them you can clarify your doubts with the researcher with whom you will be talking. After you read and feel safe about what you read, we will ask you some questions. You may also be asked to attend a meeting with other children, in which you will tell us what you've learned. That's right. You will be asked to read a text and then we ask you what you understand. Easy, isn't it?

Who else will participate in the research?

Children and adolescents from this region, aged between 7 and 15 years, that study in municipal and state schools in the city will participate in the study. You might know several people who may participate because they are right here in town. They will also only participate if they want to, ok? Just like you. All are participating because they want to be part of the research with us.

What's good about participating in the research? What good can happen?

Besides helping us to answer the research questions, by agreeing to participate, you can learn more about the schistosomiasis worm, how you can catch the disease, how to prevent it, and learn to take care of your health. By learning all this, you can teach your parents, colleagues and whoever else you want. Knowledge is always important, isn't it?

And what's bad about participating in the study? Can something happen to you?

You may feel uncomfortable during the questions that we will ask or during the conversation with the researcher. If this happens, you do not have to answer the question. No problem with that. No one will be upset or angry. No one needs to do anything they do not want to. You can also ask to stop participating in the research, whenever you want. Just tell your parents or the researchers. This document has our phone number. You can call us.

You will not lose anything by it. Even without participating, we can teach you about schistosomiasis and the diseases in this region.

Will you will spend any money with the research?

No. If you live far away, we will give your parents enough money for transport, to also follow the research. We can also pick you up at home or go to your home to ask the questions. Do not worry about it.

Will anyone know what were your answers to the questions?

No one will know that you are participating in the research. We will not tell other people, nor give strangers the information you give us. What we find out with the research will be published, but without identifying the children who participated.

If you want to ask more about the research, who can you talk to?

You can talk to your parents, with us - the researchers, with your colleagues who will also participate. If you want, you or your parents can call collect to Belo Horizonte. The phone number is (31) 3409-9181 or (31) 98886-9892. Your parents can also call some people who are not linked to the research, but can help you answer questions about your participation. The address and telephone number are as follows: the Ethics Committee at the Federal University of Minas Gerais (Comitê de Ética da Universidade Federal de Minas Gerais - COEP). Address: Av. Antônio Carlos, 6627. Administrative Unit II - 2nd floor - Room 2005 - Campus Pampulha. Belo Horizonte, MG - Brazil. Phone: (31) 3409-4592

Post-informed assent

I, _____, accept participate in the research How assent terms that are adapted to participants' age effect the knowledge of children participating in clinical research. I understood the bad and the good things that can happen. I understood that I can say "yes" and participate, but that, at any time, I can say "no" and give up, and that no one will be angry. The researchers clarified my doubts and talked to those responsible for me. I received a copy of these assent terms and have read and agree to participate in the research.

 http://dx.doi.org/10.1590/1983-80422016243154