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Ethical issues and strategies for the voluntary participation of children in research

ASPECTOS ÉTICOS E ESTRATÉGIAS PARA A PARTICIPAÇÃO VOLUNTÁRIA DA CRIANÇA EM PESQUISA

ASPECTOS ÉTICOS Y ESTRATEGIAS PARA LA PARTICIPACIÓN VOLUNTARIA DE NIÑOS EN LA INVESTIGACIÓN

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ABSTRACT

Ethical issues about research with human beings have been addressed in health literature since decades. In spite of this, it is necessary to enhance actions to face many challenges, like the ones related to investigation of childhood. This paper presents and discusses ethical issues in research with children. It describes some strategies to perform with children, considering their developmental process and individual characteristics, in order to guarantee their voluntary participation in research.

KEY WORDS

Ethics, research.
Child.
Child health.
Child advocacy.
Personal autonomy.

RESUMO

A literatura de saúde tem abordado os aspectos éticos da investigação com seres humanos há décadas, mas ainda há desafios a serem reconhecidos e superados, tais como os referentes à pesquisa com crianças. Este artigo apresenta e discute aspectos éticos da pesquisa com crianças. Descreve estratégias de abordagem conformes às necessidades infantis, segundo seu processo de desenvolvimento e características individuais, para garantir a participação voluntária da criança na pesquisa.

DESCRIPTORES

Ética em pesquisa.
Criança.
Saúde da criança.
Defesa da criança.
Autonomia pessoal.

RESUMEN

La literatura de salud ha tratado de los aspectos éticos de la investigación con seres humanos hace décadas, pero aun hay retos que deben ser reconocidos y superados, tales como los referentes a la investigación con la población infantil. Este artículo presenta y discute aspectos éticos de la investigación con niños y niñas. Describe estrategias de abordaje adecuadas a las necesidades infantiles, según su proceso de desarrollo y características individuales, para garantizar la participación voluntaria de niños y niñas en investigaciones.

DESCRIPTORES

Ética en investigación.
Niño.
Salud del niño.
Defensa del niño.
Autonomía personal.

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INTRODUCTION

Children have been used in research for quite some time but their consent was not always asked. The history of scientific investigation is marked by the use of researchers' power or authority, especially with vulnerable groups such as orphans and poor children⁽¹⁾.

Research with children is necessary and justified by the production of specific knowledge or benefits that might arise from it to this group, and which cannot be achieved without children's involvement⁽²⁾.

This study presents and discusses ethical aspects of research with children younger than 12 years⁽³⁾ and describes approaching strategies that ensure their voluntary participation, particularly in research studies that do not present any direct or potential benefit to them. In this context, using pressure tactics in order to obtain their participation is inappropriate. When a study generates direct benefits to children, i.e. testing a new therapy that is the only alternative or a better alternative for a required treatment, it is acceptable, as a last resort, to submit a child to it based only on her/his legal guardians' consent⁽¹⁾. Even in such circumstances, though, all efforts should be made for children to freely participate so their dignity is preserved. However, when there is no real benefit, the only ethical way to involve children in research is obtaining their fully informed consent.

Up to the beginning of the 20th Century, children would be involved in research without any ethical consideration, orphaned or not. The justification of this practice even included the high costs of using animals⁽¹⁾. As such situations came to be acknowledged by the public, they caused indignation and some countries prohibited research with children⁽¹⁾.

Ethical standards currently enjoy the power of law, and aim to ensure the rights and integrity of people involved in research. From this perspective, the evaluation of ethical committees tends to be very rigorous when research addresses children. Especially in the health fields, the idea that children are not capable of discernment given their limitations is prevalent⁽⁴⁾. Such a view was important to classify children as a vulnerable group, which results in restrictions on research as described in the previous paragraph, though, it is insufficient to guide decision-making and actions related to the subject.

The critical point here is related to the understanding of the extent children are able to make decisions regarding their participation. Resolution 196/96⁽²⁾ of the National Council of Health, which is the agency that regulates research with human subjects in Brazil, establishes that children and adolescents have the right to obtain infor-

mation about research that potentially involves them. The guidelines of the Council for International Organizations of Medical Sciences⁽⁵⁾ and the Brazilian Statute for the Child and Adolescent⁽³⁾ in their turn state that children's consent must be obtained in order to participate in research, which is more than just providing information to them.

The Brazilian Commission of Ethics in Research (CONEP) states that children's consent must be obtained according to their level of discernment⁽⁶⁾ and the Resolution 251/97 of the Brazilian Council of Health establishes that the requirement to obtain the consent of the subjects themselves in order to carry out research on substances is extended to children (item IV q)⁽⁷⁾. Therefore, the process to obtain an informed consent requires a more active involvement of these subjects, with a view to express their authentic consent, which is not solely restricted to the children's guardians.

Even though the parents' informed consent is indispensable, it is not sufficient. The practice of concentrating the decision in the adults' sphere is based on a paternalist and romantic principle that children are incapable and therefore undefended beings⁽⁸⁾. However, based on the premise that children have rights and therefore the right to a voice, it is necessary that researchers ensure children participate in the decision to collaborate or not in the research.

The informed consent process includes the subjects' being fully informed and having full understanding of the procedures to which they will be subject to: the risks and potential distress, benefits and rights as well as their freedom to choose, voluntariness and clear manifestation of will⁽⁴⁾. The consent form, developed in this way, does not apply to children, since the child's universe does not include such concepts related to investigation. These concepts do not have such meaning to them since children have difficulty in grasping the abstracts and impersonal concepts of a consent form as opposed to their personal and visceral emotions and thoughts⁽⁹⁾.

Intrinsic to the concept of consent is the understanding that it concerns the person who consents. Therefore, the consent of legal guardians is called consent by procurator⁽⁴⁾ because it reflects their convictions, values and will and not that of the study's participant, in this case, the child. Since ethics in research refers to the commitment of ensuring the integrity of people involved, reserving to a child only the right to information, or even allowing them to participate only in specific situations, is not sufficient because it violates their interests.

However, such situations have been based on the legal impossibility to obtain a free and informed consent from children, given that this consent is based on an individual's

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ability to receive information and attribute meaning to it, acknowledge its relevance and recall facts. Since these abilities are established based on and judged by the adult universe and capacity, they reinforce the idea that children are not capable of consenting. It is worth highlighting that the way this consent is obtained in Brazil and in other Western countries follows a standard determined by a hegemonic social group, composed of literate adults, able to exercise abstract logic, mediated and generated by the domain of a refined or standard language. Consequently, it is possible that there are even adults who consent to participate in research without having full control over their decision.

All this justifies the importance of discussing the subject to which this study contributes, specifically in regard to the improvement of ways used to approach children, so that their participation is truly voluntary. This contribution is based on the experience of researchers from the research group Child Health Care^(a), whose view of childhood is based on sociology⁽¹⁰⁾ studies and focuses on valuing children's potential abilities. That is, characteristics inherent to childhood are understood and treated as a different kind of complexity instead of being limited or inferior to adults⁽¹¹⁾.

From this perspective, we understand that children's consent to participate in scientific research is an expression of their will and individuality, setting a condition that should be ensured in addition to parents' or legal guardians' informed consent. Additionally, the participation of children in a research project that takes into account their needs might be a positive experience, offering them a rare opportunity to be listened to by adults, to gain confidence in expressing opinions and to learn to think by themselves, especially in the case of school age children. Given the characteristics of these children's emotional development, they can feel rewarded with the attention they receive from the researcher and satisfaction for helping an adult. Therefore, their participation in research by itself is a gratification for them. In addition, the involvement of school age children in the study also makes them feel themselves to be in a unique position in relation to their peers and give them a certain status in their group⁽⁹⁾.

STRATEGIES TO APPROACH CHILDREN IN A STUDY

Strategies to approach children in situations of research should consider their developmental peculiarities and needs and individual characteristics. It implies the researcher knows the children's patterns of thinking, feeling and acting in different stages to select and create ef-

fective strategies. For that, each stage of contact with the child should be planned, even if during interactions with the child changes and adaptations are needed.

Initially, even though the research directly or indirectly benefits children, the researcher has to assume his/her personal interest in the development of the research and clearly explicate it, asking for the child's help or collaboration in achieving the established objectives. The research has to be honest and transparent, not deceiving children, be empathic, authentic and coherent⁽¹²⁾. These attitudes consist of showing understanding, acceptance and interest in children, even in face of their refusal to participate in data collection. In summary, the researcher has to transmit to the child her/his real intention and explicitly manifest gratitude at the end of the procedure.

When the researcher is a stranger to the child, his/her introduction is essential and should include the researcher's name and the meeting's purpose. Considering that the immediate activity in which the child will be involved matters more for her/him than the researcher's objective, researchers should ensure the child understands the procedures that will be implemented and what she/he might experience. In the case of children slightly older than seven years, the researcher can confirm their understanding asking them to tell what they understood. Younger children will unlikely be able to put into words what they understand, especially if the researcher is unfamiliar to them.

Children perceive adults as more powerful, which makes them vulnerable to an adult's maneuvers. For this reason, the researcher should avoid behavior that can reflect domination and instead adopt means that favor the free expression of a child's will, creating attractive conditions that encourage their participation and minimize distress such as approaching children in their own environment, in the presence of people they trust and clearly offering the possibility of refusal.

The decision to participate or not in a study has to be clearly and expressly manifested by words and gestures observed during the whole process that involves the child. The presence of a trusted adult at the moment of the invitation to participate in a given study gives children a greater sense of safety and consequently, if they wish, more freedom to refuse. It is also desirable for children to participate together with friends, peers or family members. These may or may not participate in the study. The important thing is that the presence of known people diminishes the threatening character of unknown experiences.

Aiming to reduce potential situations of embarrassment and emotional insecurity, data should be collected in the child's familiar environment such as day care, school or home, if possible⁽¹³⁻¹⁶⁾. Offering appropriate toys can also reduce the procedure's potentially frightening character⁽¹³⁾. It is important not to link the offering of toys

^(a) Registered in the directory of research groups of the National Council for Technology and Scientific Development (CNPq) since 1995. <http://dgp.cnpq.br/buscaoperacional/detalhegrupo.jsp?grupo=0067404JCDMVY2>

to any obligation to participate in the study: the child might want to play but not participate in the study and this refusal should not be an impediment to play. Respecting the child's desires as well as the gradual and successive approximations that are encouraged by the availability of toys promotes familiarity and the establishment of trust.

Participation can be interrupted at any moment in case the child verbalizes or shows signs of tiredness or discomfort, or attempts to leave the place or withdraws from the proposed activity. The researcher should confirm his/her impressions regarding the children's real desire to continue the activity by observing their expressions and asking whether or not they want to proceed. Agreement or refusal of a child to participate in an interview or procedure depends on the circumstances. Oftentimes, the refusal is temporary and can be reversed as the child perceives she/he is respected and acquires a broader understanding of the situation, feeling more confident to participate⁽¹³⁻¹⁵⁾. However, the persistent refusal of a child should be considered an ethical impediment in the context of research.

A way to confirm a child's desire to participate in a study in the case of school age children is to ask her/him to sign a consent form⁽¹⁶⁻¹⁷⁾. Even though there is no real need to ask a child's signature⁽⁶⁾, we have observed that children feel valued when they are asked to sign the form, which contributes to their autonomy⁽⁹⁾.

The conscious agreement of a child requires the researcher to provide information in accessible and understandable language in addition to other resources appropriate to communicate with them such as the use of models, images, photos and books for illustration, if the procedure involves unusual or uncomfortable situations for her/him. Assessments of skills development, anthropometric data, and vital signs are examples of such situations. Even though these are not painful or invasive procedures, they include alterations of familiar activities, use of equipment or instruments or limitation of body movements, which generate anxiety in the face of the unknown and loss of control. A therapeutic toy is a valuable resource during the instructional and emotional preparation of children⁽¹⁸⁾, because it facilitates their understanding and control over procedures and also alleviates tension that is due to fear.

The main element determining children's spontaneity is the existence of ties of trust with the researcher and for that one has to devote time to interaction. The time spent, which seems excessive in the beginning of a study with children, becomes a benefit for the researcher since the adoption of appropriate procedures is the only way to create trust and the possibility of participation and also

because it enhances the child's commitment in later stages of the research⁽¹³⁻¹⁵⁾.

Another point to stress is the need of the researcher to be flexible to alter his/her planning. For instance, in assessing development or visual acuity, it is necessary to frequently interrupt procedures due to a child's tiredness, lack of attention or interest⁽¹⁴⁻¹⁵⁾. These interruptions occur because children perceive the time necessary to perform activities as too long and the researcher needs to start again several times until the completion of data collection.

Sometimes, the procedure itself has to be reviewed due to unexpected demands, such as when a child asks to record her/his testimony alone in a room, only to be heard later by the researcher⁽¹⁶⁾. Thus, one has to be open to welcome creative initiatives related to the setting, sequence, form or any other aspect of the procedure with a view to facilitate the child's participation.

Because children younger than two years do not have the means to understand and decide whether to participate in a study, they can be included in a research project without their acknowledgment after their guardians' consent is obtained. They can be observed at a distance or during their daily activities such as playtime, mealtime and sleep as long as they are not distressed, that is, recommended precautions are taken in order not to disturb their routine⁽¹³⁾.

FINAL CONSIDERATIONS

The discussion presented here supports the development of research with children, ensuring that proposals are viable with the highest level of agreement and collaboration as possible, resulting in the production of knowledge capable of effectively benefiting children. Any kind of coercive measure, cannot only pose unnecessary and unjustifiable physical and psychological risk, but can also result in unreliable data, thus compromising the study.

It is worth highlighting that acknowledging the importance of involving the child in the consent process allow researchers to give children the opportunity to mature their decision-making abilities and strengthens them as people, which is a non-immediate benefit to their development.

Finally, in order to preserve children's rights and truly respect their autonomy, regardless of their stage of development, it is essential to promote a participatory process including gaining the children's consent to be included in the research, with the involvement of children themselves, their guardians and trusted people as well as that of the researcher.

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