CONSTRUCTION AND APPLICATION OF A CONSENT FORM: AN EXPERIENCE REPORT

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ABSTRACT
Objective: reporting the construction and application of a consent form for hospitalized children.
Method: a qualitative experience report study. Consent form construction was based on the guidelines of the World Health Organization and Resolution 466/2012. It was applied to 42 children between seven and ten years old, hospitalized in clinical-surgical units of a pediatric hospital.
Results: a consent form in the form of an illustrated booklet was constructed to meet the national ethical regulation of research with children. Its application revealed that the format used contributed to children’s understanding of the objectives of the study, allowing their consent and their collaboration in data collection. We also reaffirm the relevance of play (ludic) as a strategy for understanding among a children’s audience.
Conclusion: developing and applying the consent form as an illustrated booklet was a successful experiment for research with children, proving to be effective in clarifying their doubts regarding obtaining consent.


CONSTRUÇÃO E APLICAÇÃO DE UM TERMO DE ASSENTIMENTO: RELATO DE EXPERIÊNCIA

RESUMO
Objetivo: relatar a construção e aplicação de um termo de assentimento em crianças hospitalizadas.
Método: pesquisa qualitativa, tipo relato de experiência. A construção do termo de assentimento baseou-se nas orientações da Organização Mundial da Saúde e da Resolução 466/2012. A aplicação foi realizada com 42 crianças entre sete e dez anos, internadas em unidades clínico-cirúrgicas de um hospital pediátrico.
Resultados: um termo de assentimento em formato de cartilha ilustrada foi construído para atender a regulamentação ética nacional da pesquisa com crianças. Sua aplicação revelou que o formato utilizado contribuiu para o entendimento por parte das crianças sobre os objetivos do estudo, possibilitando seu assentimento e sua colaboração na coleta de dados. Ratificou-se ainda a relevância do lúdico como estratégia de compreensão do público infantil.
Conclusão: construir e aplicar o termo de assentimento no formato de cartilha ilustrada foi uma experiência exitosa para a pesquisa com as crianças, mostrando-se eficaz por esclarecer suas dúvidas face à obtenção do assentimento.
CONSTRUCCIÓN Y APLICACIÓN DE UN TÉRMINO DE CONSENTIMIENTO: RELATO DE EXPERIENCIA

RESUMEN

Objetivo: relatar la construcción y aplicación de un término de consentimiento en niños hospitalizados.

Método: investigación cualitativa, tipo relato de experiencia. La construcción del término de consentimiento se basa en las directrices de la Organización Mundial de la Salud y de la Resolución 466/2012. La aplicación se llevó a cabo con 42 niños de entre siete y diez años de edad, hospitalizados en unidades clínicas y quirúrgicas en un hospital pediátrico.

Resultados: un término de consentimiento en formato de folleto ilustrado fue construido para cumplir con la regulación ética de la investigación nacional con los niños. Su aplicación reveló que el formato utilizado contribuyó a la comprensión de los niños con relación a los objetivos del estudio, lo que permite su consentimiento y su cooperación en la recopilación de datos. Asimismo, reiteró la importancia de comprender la importancia de la estrategia lúdica en los niños.

Conclusión: construir y aplicar el término de consentimiento en el formato de folleto ilustrado fue una experiencia exitosa para la investigación con niños, siendo efectiva al responder a sus preguntas de cara a conseguir su aprobación.


INTRODUCTION

Conducting research with children demands an increased ethical concern, since they are participants in a singular condition of growth and development, thus more vulnerable to damage resulting from investigations.

When choosing hospital units as a collection site, even more difficulties are involved, considering that the practice of invasive and painful procedures in children for diagnosis and treatment is a common practice in the daily life of the hospital, making it even more difficult for researchers to approach this population.

Some researchers have discussed the proper way to respect the autonomy of children participating in health studies by proposing the use of non-textual methods to explain the study, careful definition of the age group and establishment of a trusting relationship/bond between those involved.

A consent form (CF) is an instrument that can be used to validate children’s autonomy by choosing whether or not to participate in a study. In Brazil, it was included in Resolution no. 466 of December 12, 2012, being considered as “a document elaborated in language accessible to minors or those legally incapable, through which after participants of the research are duly clarified, will explain their agreement or not to participate in the research, without prejudice to the consent of their legal guardians”.

Consent is a necessary and important piece for the current paradigm of free and voluntary participation in biomedical research, in addition to playing a relevant role in the process of developing the autonomy of children. However, there is often a lack of clarity regarding its content, the procedure to acquire it, a recommended age for its application, and a way to assess the child’s ability to consent.

Resolution 466/2012 also provides no further clarification regarding the consent form. This gap generates doubts/questions for the Brazilian researcher whose object of investigation involves children, such as: What is the best age range for CF application? In what way should it be applied? In the form of text or through images? What should be included as information?

In the classic work “Alice in Wonderland” (1865) there is a passage in which the protagonist thinks: “what is the use of a book without pictures or conversation?”, pointing to the fact that children learn early to interact with images, since they are everywhere, either by visualization or by production. Based on these premises and the experience acquired in the practice of nursing care of children, we have concluded that the child is more interested in reading material with images instead of text, which has led us to the construction of a CF in the form of an illustrated booklet, using language accessible to the pediatric age group.

Thus, the objective of this study was to report the construction and application of a consent form for hospitalized children.

METHOD

This is a qualitative experience report research on the construction and application of a Consent
Form (CF) to conduct doctoral research with hospitalized children.

**Construction of the consent form**

The main question considered for producing the CF was constructing a model with suitable language for children that would be able to guide research in a playful way, respecting the ethical precepts and considering their condition of vulnerability to hospitalization.

Human vulnerability and fragility imposed in situations of illness and hospitalization should be permanently evaluated and considered by health professionals who, in this process, become close to them and (co)responsible for their care and maintenance of life.  

With regard to scientific production, significant mistreatment and/or ethical neglect have been identified in current clinical practice with children, considering that they are not heard in most health services, thus reinforcing the vulnerable characteristics of this population.

In this perspective, constructing a CF that contemplates the ethical issues, clearly explaining the content and purpose of the research, and at the same time providing the children participating in the study with a moment of play and distraction seemed to be the most appropriate for the purpose of this research.

Considering this context, the CF construction started by searching websites of Ethics in Research Committees of Brazilian universities for previously used models in studies carried out with children. The terms found were all in text format, which from the researchers’ perspective would make it difficult for the children to understand the study objectives, and consequently their acceptance, which could not only compromise the consent, but also children’s permission for clinical evaluation by the health professionals involved in the research.

The text of the booklet was designed based on the guidelines of the World Health Organization for the construction of informed consent for children and minors, and on the guidelines from Resolution no.466/2012 for the construction of a Clear and Informed Consent Form.

The information contained in the booklet was: researcher identification, formal invitation (to participate), the age range of the children included in the study, prior consent of the accompanying person/guardian, freedom of choice in participating, freedom to withdraw from participation, purpose and objectives of the study, procedures performed with the child during data collection, the child’s participation duration in the study, record and confidentiality of the collected information, purpose and disclosure of results and consent, signature and/or marking of the option for participating or non-participating.

After defining the text, a professional in the design area was sought to develop the layout. The company responsible for the service had a minor adolescent intern with experience in this area who developed the illustrations for the text of the booklet, also suggesting female and male versions (Figure 1) in order to contemplate both genders.

![Figure 1 - Images of the female and male versions of the booklet covers](image-url)
After designing the text and images, we still felt the need to include something that would give the children a moment of fun and play. So the idea of including illustrations at the end of the booklet and a set of crayons for coloring was introduced.

After completing the first version of the booklet, it was applied to six children (four girls and two boys) aged between seven and ten years to evaluate their comprehension of the text. In the pilot, the children were able to understand the research proposal and agreed to participate. Thus, no adjustments to the initial version were required, and so the same version was applied for data collection.

The research project which this article is a part of followed the principles of Resolution no.466 of 2012, and was approved by the Research Ethics Committee of the Nursing School of the Universidade Federal da Bahia, according to opinion no. 964,177 of 2/25/2015, CAAE 40030314.7.0000.5531.

Application of the consent form

The study sites were the clinical and surgical units of a medium and large pediatric hospital, considered as a reference, located in the interior of Bahia, Brazil. The study description was based on application of the CF to 42 children among a population of 330 children (zero to ten years old), who were the sample.

Inclusion and exclusion criteria for applying the CF were defined. The included children were those aged between seven and ten years, clinically stable, and whose parents previously consented to their participation through the signing of the Clear and Informed Consent Form. Children of this age group with clinical instability or neurological alterations that compromised their understanding of the text did not participate in the study.

The age range established for the application of the CF was an issue discussed by the researchers, considering the existing gap in item II-24 of Resolution 466/2012 regarding this definition.

The age of consent can and should be determined by the Research Ethics Committees based on the legal regulations of each location, resulting in great variation all over the world considering the different regulations, cultures and religions.²

A study on the personalization or need to define the age for children’s consent in investigations states that an age limit, with the possibility of customizing consent, is more suited to children’s interests than a complete flexible criteria for personalization. The more vague the legal orientation on this question, the more likely it is that they will not be followed by ethics regulators and researchers.¹

The National Pact for Literacy at the Right Age (Pacto Nacional pela Alfabetização na Idade Certa) is a formal commitment assumed by the Federal government, the Federal District, the States and the Municipal governments to ensure full literacy of all children before the age of eight, at the end of their 3rd year of elementary school.¹⁰ Therefore, we consider that children aged seven or older would already be attending Elementary School and would have the ability to read and understand the study proposal better.

Data collection to describe the experiment occurred between May and August 2015 through observations by the researcher. Four topics were observed during application of the booklet: Did the child understand the research proposal contained in the CF? What were the child’s main questions about the research? Was the child reluctant to participate in the research after having access to the CF in the form of an illustrated booklet? Did the child color the illustrations in the booklet?

The parents/guardians of the children were consulted about the possibility of their children participating in the research, and those who agreed signed the CF. With this consent, the CF was used to explain the research proposal to the child and to consult their desire to participate. For children who did not yet have comprehensive reading, researchers or parents/guardians read them the term. Regarding the signature, a sheet containing a separate consent (Figure 2) could be signed and/or marked regarding the option to participate or not in the study, and the booklet remained with the child.

A box of crayons was given along with the booklets for coloring the illustrations.
RESULTS OF THE EXPERIENCE

Characterization of children who agreed to participate in the study

According to table 1, a five-year-old child and five six-year-old children were outside the age range determined for CF application. This is due to the fact that these children were included in the study sample because they experienced the booklet application as their roommate also requested that they were applied. Thus, they were also given the same opportunity to consent to their participation.

Table 1 - Age distribution, gender, child’s companion/guardian, child’s education level, parent’s education level and hospitalization time of children who agreed to participate in the study. Feira de Santana, Bahia, Brazil, May to October, 2015. (n = 42)

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<thead>
<tr>
<th>Variables</th>
<th>n (42)</th>
<th>%</th>
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<tbody>
<tr>
<td><strong>Age(years)</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>5</td>
<td>01</td>
<td>2.4</td>
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<tr>
<td>6</td>
<td>05</td>
<td>11.9</td>
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<td>7</td>
<td>07</td>
<td>16.7</td>
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<td>14</td>
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<td>9</td>
<td>06</td>
<td>14.3</td>
</tr>
<tr>
<td>10</td>
<td>09</td>
<td>21.4</td>
</tr>
<tr>
<td><strong>Gender</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Male</td>
<td>17</td>
<td>40.6</td>
</tr>
<tr>
<td>Female</td>
<td>25</td>
<td>59.4</td>
</tr>
</tbody>
</table>

The mother was the most present responsible/guardian at the time of collection (78.6%). Regarding hospitalization time, 77.2% of the children were hospitalized for a period of up to 14 days. These factors may have contributed to study participation, since the presence of the mother and shorter hospitalization time may have influenced the child’s sense of security.
As for education level, most children had incomplete elementary education due to their age group. However, 46.9% of the companions had not finished high school. This result highlights the problem of low schooling in Brazil, which is still a reality.

**Describing observation during consent form application**

All children demonstrated understanding the research proposal contained in the terms from the description of the study procedure (Figure 3). However, before agreeing many of them asked their parents/guardians what they thought about their participation, if they agreed, thus attaching responsibility to them for the decision and final consent. This posture can represent a reflection of the vulnerability conditions in being a child and being sick.

![Figure 3 - Picture of the booklets describing the study procedure](image)

Illness is a traumatic event for children and their family, especially when it requires hospitalization. In this context, it is essential that the health team consider the family as an important agent in child care, offering conditions so that family members can follow and participate in the process.\(^\text{11}\)

In this sense, a study proposes a model of “family decision making” where parents and children consent together could be appropriate for many research studies on child health in the process of deciding whether or not to participate in the research.\(^\text{12}\)

The main questions regarding the research were in the sense of understanding the purpose of clinical evaluation, whether they would undergo any painful procedure, and mainly if their veins would be punctured by nursing professionals.

All the doubts raised by the children were duly answered, which left them calm for accepting participation. Only one child was reluctant to participate in the research after having access to the CF. However, with the researcher’s explanation and support from their mother, who talked to her son, this child decided to participate, thus highlighting the importance of family presence and their collaboration in the research process with children.

The time spent on CF application to parents/guardians and the CF to the children was around ten minutes, and carried out by two researchers. Clinical evaluations of the children for the research were carried out around two hours after their consent. No children refused to participate at the time of the examination, which reinforces the safety transmitted to the children during the CF application.

We also observed that older children who were able to agree to participate were more collaborative during the clinical evaluation than younger children who did not have the opportunity to consent.

Most children colored the booklet illustrations and shared their art with the researchers and their roommates. In some situations, children who were not included in the research sample and who attended the CF application showed an interest in the booklet, mainly for the possibility of coloring it, and a copy was provided to such children as well. This confirms the idea that play and ludic should be used with children regardless of the environment/context.
In the hospitalization process, the hospital represents a prominent place and it should promote capturing the pleasure of playing and child development. Health professionals, especially nurses, need to develop skills that facilitate and promote play in the hospital setting in order to provide individual and complete care to children, since such activity is necessary for healthy child development.\(^{13}\)

In this sense, informed consent to vulnerable patients requires that new strategies be used to improve participant’s communication and understanding, such as videos or animated illustrations, allied to the time spent by the participant during formalization of the invitation to participate in the research.\(^{2}\) Moreover, consent must be based on a balanced and fair understanding of everything that is involved during and after the investigation process, and indications of disagreement or withdrawal by the child must be respected.\(^{14}\)

The novelty, currency and relevance of this manuscript are based on the scarcity of CF models in this format, according to Resolution no. 466 of 2012 in force, as well as in the gaps still existing in this theme. The described experience can contribute to the process of building and applying consent terms for research with children in the health area.

In addition, its use in care spaces translates into an ethical requirement that should be a discussion topic for the practice and training of pediatric nursing, considering that a younger age is one of the situations of vulnerability that can limit or reduce the conditions of free and conscious manifestation of one’s will or protection of their interests.\(^{15}\)

This study is limited to an experience report with few subjects and in a single context. The scarcity of publications focused on discussing strategies for obtaining children’s consent in scientific research also limits its analysis. In this sense, we suggest that further studies compare such strategies with a greater number of children in different contexts, in order to evaluate what would be the best way to promote their participation without violating the ethical norms prevailing in the country.

**CONCLUSION**

Building and applying a CF in the form of booklets proved to be a positive experience with the children who participated in this research. This instrument proved to be effective in reducing/clarifying children’s doubts about obtaining consent after reading and understanding the consent form. A predominance of images, its playfulness, the colors used in creating the booklets and the possibility of coloring by the children were important variables for the instrument’s success, since they are considered sensitive strategies for hospitalized children. Thus, the illustrated booklet was adequate for the cognitive level and vulnerability of the population in question.

We hope that the report of this experience contributes to Brazilian researchers who develop research with children in constructing the consent form, normalized by Resolution no. 466/2012 of the National Research Ethics Council.

Our experience was also able to signal the need to broaden discussions on this theme in the national context in relation to the pertinent content of the consent form, and to defining the age group that should consent its participation in investigations. For this, it is necessary to consider the singularity of the schooling level/quality of our children, considering a predominance of studies in the Unified Health System services where the majority of users are students of the underprivileged public school network.

**REFERENCES**


