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REVIEW ARTICLE

Informed assent in research with minors: proposal for minimum requirements

Asentimiento informado en la investigación con menores: propuesta de requerimientos mínimos

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Abstract

The purpose of this paper is to identify the minimum requirements for informed assent in research. A review of the literature and assent forms available on the websites of Ethics Committees from some Latin American universities was conducted, and a proposal for minimum elements for informed assent in research is provided. This work aims to contribute to designing standardized procedures that respect the rights of children and adolescents, promoting their active and voluntary participation in research projects, and highlighting the importance of forms adapted to their cognitive and cultural capacities.

Keywords: Ethics; Children; Teenagers; Research.

Resumen

El objetivo de este artículo es identificar los requerimientos mínimos para el asentimiento informado en investigaciones. Para ello, se realiza una revisión de la literatura y de los formatos de asentimiento disponibles en los sitios web de los comités de ética de investigación de algunas universidades latinoamericanas, y se presenta una propuesta de elementos mínimos para el asentimiento informado en investigación. Con este trabajo, se espera contribuir al diseño de procedimientos estandarizados que respeten los derechos de los niños, niñas y adolescentes, promuevan su participación activa y voluntaria en proyectos de investigación y destaquen la importancia de formularios adaptados a sus capacidades cognitivas y culturales .

Palabras clave: Ética; Niños; Adolescentes; Investigación.

Introduction

Informed assent is understood as a process of inclusion and the promotion of children's autonomy in decision-making processes (Pinto & Gulfo, 2013). The moral value of informed assent is grounded in respect for the autonomy of children and adolescents. This respect is grounded in the recognition that human beings are persons rather than mere objects. When a child expresses a preference regarding their own body, that preference should be respected. Disregarding the preferences of children and adolescents and overriding an objection expressed by the minor generates moral harm (Wasserman et al., 2019).

Consent and assent are not equivalent terms. Consent refers to a formal authorization granted by a person who has been adequately informed and possesses the legal capacity to decide on their participation in a research study. Assent, by contrast, likewise constitutes a form of permission, but it is granted by someone who lacks the legal capacity to consent on their own behalf. For this reason, participation must be accompanied by the consent of a legally responsible person, such as a parent or legal guardian in the case of minors. In line with the *Declaración de Helsinki* [Declaration of Helsinki], when a legally incompetent person, such as a minor, is able to express their willingness to participate in a research study, the researcher has the obligation to obtain such assent (Boceta et al., 2021).

On November 20, 1989, the General Assembly of the United Nations adopted the *Convention sobre los Derechos del Niño* (CDN) [Convention on the Rights of the Child], which establishes the promotion of the participation of children and adolescents, as well as their right to be heard and to have their opinions duly taken into account, as a fundamental principle. Krappmann (2010) acknowledges that the child is a human being with the right to be respected as a unique individual, with their own perspective and personal intentions, by other human beings and also by the State, its institutions, and other organizations. Krappmann further notes that the Convention departs from conservative perspectives that regarded children as incompetent, lacking a sense of responsibility, and in a situation of vulnerability.

> Article 12 of the *Convention on the Rights of the Child* stipulates that:
>
> 1. States Parties shall assure to the child who is capable of forming his or her own views the right to express those views freely in all matters affecting the child, the views of the child being given due weight in accordance with the age and maturity of the child.
>
> 2. For this purpose, the child shall, in particular, be provided the opportunity to be heard in any judicial and administrative proceedings affecting the child, either directly or through a representative or an appropriate body, in a manner consistent with the procedural rules of national law (Fondo de las Naciones Unidas para la Infancia [UNICEF], 2006, pp. 13–14).

The right to be heard implies that the child must be duly informed about the matter on which their opinion is sought. The child must be informed of the impact that their opinion may have on the outcome and of the possible consequences. Likewise, children have the right to provide assent when receiving therapy intended to cure, alleviate, or prevent illness under specific conditions (Krappmann, 2010).

Accordingly, the present study aims to identify the minimum requirements, from an ethical perspective, for the informed assent of children and adolescents in research. For the purposes of this study, minimum requirements are understood as those essential elements that ensure a balance between respect for the minor's autonomy and the ethical and legal requirements of research. From a legal perspective, the minimum requirements are aligned with international treaties, such as the *Convention on the Rights of the Child*.

From an ethical perspective, they are grounded in principles such as beneficence and justice. In practical terms, the aim is to ensure that assent forms are comprehensible, adapted to the age of minors, and designed to promote informed participation in the research process. The minimum requirements were identified through an analysis of the literature and of the informed assent forms available on the websites of the comités de ética de investigación (CEI) [research ethics committees] of various Latin American universities.

To this end, a review of the literature on informed assent in research involving minors was conducted. The selection criteria included peer-reviewed academic articles and ethical regulations published by international organizations. Priority was given to studies and documents published within the last five years in the PubMed, Scopus, and SciELO databases. The search terms used were Informed Consent by Minors OR Consent Forms OR Informed Consent AND Minors OR Child* AND Research.

Informed assent for research

The *Pautas Éticas Internacionales para la Investigación Relacionada con la Salud con Seres Humanos* [International Ethical Guidelines for Health-related Research Involving Humans] recommend that, before beginning research involving children and adolescents, the researcher and the CEI ensure that "the agreement (assent) of the minor has been obtained in keeping with the minor's capacity, after having received due information about the research adapted to their level of maturity" (Organización Panamericana de la Salud & Consejo de Organizaciones Internacionales de las Ciencias Médicas, 2017, p. 73). Assent must be obtained when the minor has the capacity to understand the research, and it must be complemented by the informed consent of the parents or legal guardians, who formally authorize the minor's participation in the study.

An integrative review that analyzed the factors related to the informed assent process, searching for scientific articles reporting primary qualitative and quantitative research focused on assent in persons under 18 years of age, published in the Web of Science, PubMed, CUIDEN, and CINAHL databases between 2014 and 2023, found that there is no consensus regarding the definition of informed assent or the minimum age for obtaining it. Nevertheless, there are factors that must be considered and adapted through innovative techniques consistent with the particular characteristics of children and adolescents. These factors include the following: children and adolescents must clearly understand that the guardian's permission is indispensable in order to participate in research; the informed assent form should contain brief texts; its length should not exceed five pages; simple and age-appropriate language should be used; the wording should be colloquial and accessible to children and adolescents; and the typeface should be large. With respect to format, adolescents prefer an attractive and interactive written document, such as comic strips; children, on the other hand, prefer comics or videos adapted to their age (Vega et al., 2024).

A fundamental aspect during the process of obtaining informed assent from minors is the recognition of non-verbal language. It is therefore recommended that the researcher create an atmosphere of trust and request assent on an individual basis, taking into account the characteristics, doubts, and expectations of each participant. Likewise, researchers should be understanding, respectful, and interested in the participants, conveying a genuine willingness to clarify their doubts so that they can freely decide whether or not to participate in the research (Vega et al., 2024).

A study that included interviews and surveys of minors participating in interventional and observational studies conducted at Boston Children's Hospital found that they prefer to assume a more active role in decision-making regarding their participation in research or, at the very least, that such decisions be shared with their parents. This finding is supported by the fact that minors prefer their decisions to be taken into account, since

the research is conducted on their own bodies (Paquette et al., 2020).

Another study, in which children and adolescents aged 6 to 18 undergoing chemotherapy at a hospital in Rio de Janeiro (Brazil) were interviewed, showed that participants aged 6 to 12 prefer to be accompanied by a responsible person and feel motivated to sign the assent document, which reflects satisfaction at taking part in the decision to enroll in the study. By contrast, participants aged 13 to 18 expressed a preference for taking the form home and returning it signed at a later time. They also tend to express their assent through gestures. Regarding the asking of questions about the research, the younger group posed them on the same day as the explanation, whereas adolescents raised them at a subsequent meeting. Information related to randomization required several explanations, as some children did not understand the existence of two groups (da Silva Varejão et al., 2022).

Lambert y Glacken (2011) described their theoretical and practical experiences in the process of obtaining informed assent from children for a non-therapeutic qualitative research study. On this basis, they proposed the following elements of children's informed assent: assessing the child's capacity and willingness to assent; establishing a relationship with the child; providing adequate and comprehensible verbal and written information; identifying signs of refusal, whether subtle or obvious, ensuring that the child is not pressured; assessing the child's understanding through questions and feedback; establishing ongoing negotiation throughout the assent process; and allowing sufficient time for the child to reflect on whether or not to participate in the research. These aspects are essential for validating the assent process, and it is therefore recommended that such a process be supervised or audited by an CEI in order to verify that the assent genuinely reflects the child's will.

A scoping review that explored the ethical issues involved in digital data collection in research with minors recommends treating consent as a provisional and ongoing process, in which the minor's voluntariness is assessed at each interaction and the minor is reminded of their right to withdraw their participation at any time. It is likewise essential to maintain an open dialogue with minors throughout the research process in order to assess their perceptions and their level of understanding regarding the study and the use of their data. The use of multimodal methods to communicate research information is also recommended—such as digital videos, touch interfaces, and interactive presentations—in order to make the process more inclusive and comprehensible for minors (Facca et al., 2020). Moreover, if assent is obtained verbally, it is suggested that it be recorded by the researcher (Vega et al., 2024).

In addition, another study developed an adaptable informed assent form for research on rare diseases. The development of the material involved the participation of minors, who suggested including a glossary to explain certain terms, interactive elements, child-friendly diagrams, diagrams or images explaining the flow of personal data, and the publication of summaries of the results obtained from pediatric patients' data (Landi et al., 2024).

Common and divergent elements of informed assent forms

The regulations governing informed assent in Latin America display significant variation across countries, revealing challenges in their harmonization and application. In Argentina, Resolución N° 1480/2011 [Resolution No. 1480/2011] (2011), which approves the Guía para Investigaciones con Seres Humanos [Guidelines for Research Involving Human Beings], establishes that "the CEI shall determine the age from which the minor's assent will be required, according to the characteristics of each study" (para. 94). Although the minimum information to be provided to the minor is not specified, the need to respect the child's "deliberate objection" to research procedures is acknowledged. In contrast, Ley N.° 3301 [Law No. 3301] (2010), on the Protection of the Rights of Subjects in Health

Research, establishes that assent is requested from the age of 14 and that, in the event of a discrepancy between the minor and their legal guardian, the decision rests with the CEI or a judge.

In Brazil, both Resolución N.° 466 [Resolution No. 466] (2012), which approves the guidelines for research involving human beings, and Resolución N.° 510 [Resolution No. 510] (2016), which regulates research in the Human and Social Sciences whose methodological procedures entail the use of data obtained directly from participants or of identifiable information, or that may generate risks greater than those encountered in everyday life, stipulate that the information provided to the minor must be adapted to their level of understanding and must address the objectives, methods, rights, risks, and benefits.

In Chile, Ley N.° 20.120 [Law No. 20.120] (2006), on scientific research on human beings and their genome, which also prohibits human cloning, does not mention informed assent. However, Norma Técnica N.° 57 [Technical Standard No. 57] (2001), which regulates the conduct of clinical trials using pharmaceutical products in human beings, establishes that, in research involving children, consent must be obtained to the extent of their capacity.

In Colombia, Resolución N.° 8430 [Resolution No. 8430] (1993), which establishes the scientific, technical, and administrative standards for health research, states that the minor must accept their participation, but it lacks a clear reference to the concept of informed assent. Likewise, in Costa Rica, Ley N.° 9234 [Law No. 9234] (2014), the Biomedical Research Regulatory Law, establishes that minors aged 12 and above must give their informed assent in accessible language. In Ecuador, Acuerdo N.° 00005-2022 [Ministerial Agreement No. 00005-2022] (2022), the Reglamento sustitutivo del reglamento para la aprobación y seguimiento de comités de ética de investigación en seres humanos (CEISH) [Replacement regulation for the approval and monitoring of research ethics committees involving human beings] y comités de ética asistenciales para la salud (CEAS) [health-care ethics committees], requires that the minor's assent be obtained, but without specifying the content of the information to be provided.

In Mexico, neither the Norma Oficial Mexicana NOM-012-SSA3-2012 [Mexican Official Standard NOM-012-SSA3-2012] (2013), which sets out the criteria for conducting health research projects in human beings, nor the Reglamento de la Ley General de Salud en materia de investigación para la salud [Regulations of the General Health Law on health research] (1987), specifies the information that must be provided to the minor. Finally, in Peru, Decreto Supremo N.° 021-2017-SA [Supreme Decree No. 021-2017-SA] (2017), which approves the Clinical Trials Regulation, establishes that documented authorization must be obtained from children aged 8 and above, without specifying what information should be provided to them.

The following section reviews informed assent forms available on the websites of the Research Ethics Committees of seven Latin American universities and one hospital. The selection of the forms was based on their accessibility on the committees' websites, which allowed for a detailed analysis of representative official documents. The CEIs were selected on the basis of the public availability of their documents online. The criteria identified may be applied to other contexts, provided that the necessary adaptations are made in accordance with the legislation and cultural particularities of each country.

The first aspect that stands out is the variability in the age at which informed assent for research is requested. At the Universidad de São Paulo (Brasil), the assent forms are referred to as *Termo de Assentimento Livre e Esclarecido or Termo de Anuência Livre e Esclarecida* (TALE) [Free and Informed Assent Form] and are applied to participants aged 6 to 18 (Universidade de São Paulo Instituto de Ciências Biomédicas, n.d.). This age range is similar to that established by the Universidad Central del Ecuador (2022). By contrast, the Universidad Nacional Autónoma de México (n.d.) does not specify a minimum age for requesting the form referred to as *Carta de consentimiento informado para menores de*

edad o incapaces [Informed consent letter for minors or incapacitated persons], which is not required for participants older than 16 years.

At the Universidad El Bosque (2018), in Colombia, the informed assent form is applied to minors between 7 and 14 years of age. Likewise, the Research Ethics Committee for Human Beings (CEISH) of the Faculty of Medicine of the Universidad de Chile (2020) recommends requesting assent from the age of 8. On the other hand, the CEISH of the Faculty of Social Sciences of the Universidad de Chile (n.d.) provides an assent form directed at young children. In the case of the Universidad Peruana Cayetano Heredia (n.d.), in Peru, the minimum age for obtaining assent is 8 years, whereas the Universidad de Costa Rica (n.d.) sets the minimum age at 12 years.

In terms of content, the informed assent forms share common elements, such as the introduction of the researcher, the research objectives, the procedures, the risks or discomforts, risk minimization, the benefits, voluntariness, confidentiality, the right to refuse to participate and to withdraw from the research, and contact information. However, some divergences are observed in the description of the communication of results, reimbursement, compensation, incentives, and the future use of samples, reflecting the particular features of each form. For example, only one of the forms required a description—adapted to the minor's comprehension abilities—stating that the research results would be shared but that the information provided would remain confidential (Universidad El Bosque, 2018). Likewise, only one form contained information on the future use of the information obtained, both for data and for the storage of biological samples. It indicated that the samples would be identified by codes and stored for 10 years for the purpose of evaluating certain diagnostic tests. It further emphasized that, even if the participant did not consent to their sample being stored, they could still take part in the study (Universidad Peruana Cayetano Heredia, 2022).

In general, the storage of data related to health information or biological materials is authorized by the minor's parents or guardians, without taking into account the views of the child or adolescent. However, some countries apply the term "mature minor" to refer to the child or adolescent who, owing to their cognitive and emotional development, possesses sufficient capacity to understand and make informed decisions about their participation in research. For example, in Canada, in pediatric cohort research, new and explicit informed consent must be sought from mature minors both for their continued participation and for the use of identifiable samples and data, except in cases where an CEI grants a waiver. This practice recognizes the progressive autonomy of minors and ensures that their decision to continue in the research is voluntary and well-informed (Murdoch et al., 2023).

Similarly, in Ecuador and Chile, two informed assent forms were identified for minors between 3 and 6 years of age, which included the introduction of the researcher, the objective of the research, and the procedures. One of these documents provided information on confidentiality, voluntariness, and the option to participate or not. In this regard, Bakker et al. (2021) recommend that, in the case of children aged 2 to 6 years, assent be requested in an informal but specific manner.

Proposal for informed assent forms

A model informed assent form is proposed that ensures effective understanding and respect for the progressive autonomy of minors. Such forms should contain the following essential elements:

1. The introduction of the principal investigator and their institutional affiliation.
2. The objective of the research, its rationale, and the reasons why the minor has been selected.

3. An explanation of the voluntary nature of participation, guaranteeing the minor's right to refuse to participate.
4. A clear description of the procedures in which the minor will take part, including the number of questions or activities planned and the estimated duration of their participation.
5. A detailed description of the possible risks and the mitigation strategies.
6. The benefits to the participant or an indication that there are none, as well as any indirect benefits.
7. Information on the measures to protect confidentiality and the mechanisms for safeguarding personal data.
8. Information on the minor's right to ask questions of trusted adults, to refuse to participate, and to withdraw from the study at any time, regardless of parental authorization.
9. Where applicable, information on possible compensation, incentives, or reimbursements.
10. A description of the mechanisms for communicating or sharing the results of the research.
11. Where applicable, a request for authorization to use the data or samples obtained in future research.
12. The contact information of the principal investigator and of the CEI that approved the study.

The design of informed assent forms must be adapted to the age group of the participants. For children aged 7 to 11, it is recommended to use accessible language and visual resources that include images and simple explanations. For adolescents aged 12 to 14, it is appropriate to incorporate additional information on the handling of the data collected, confidentiality, and information protection measures. For adolescents aged 15 to 17, in turn, assent should resemble the informed consent signed by their legal guardians. In research requiring a high level of privacy, such as that related to sexual health or substance use, adolescents older than 14 could give their consent autonomously, provided that their maturity is established and that the CEI approves it (Agencia Nacional de Investigación y Desarrollo, s. f.).

Furthermore, although the minor's participation requires both their assent and the consent of the parents or legal guardians, the CEI must maintain an active role in protecting the minor's interests, especially in those exceptional situations in which the parents or guardians attempt to impose their will, expectations, or personal interests on the participant's decision. In such cases, the committee must ensure that the final decision genuinely reflects the minor's will and safeguards their well-being and best interests.

It is also recommended that the forms be validated with minors prior to their implementation, using attractive formats that incorporate images, cartoons, and striking colors, as well as simple and accessible language that avoids technical jargon. Finally, obtaining the assent of children belonging to Indigenous communities must be grounded in decolonized processes, led by the community itself and oriented toward prioritizing its cultural values. Recommended practices include fostering joint consent between parents and children, ensuring the active participation of the community, and strengthening the relationships between researchers and community members. In this context, the assent of Indigenous children cannot be separated from their family and community environment, given that both play a fundamental role in decision-making (Peltier et al., 2024).

Synthesis of findings: common patterns, differences, and challenges in informed assent forms

The analysis of informed assent forms and of the regulations in force in various Latin

American countries makes it possible to identify a series of common patterns and significant differences. It also reveals various challenges and regulatory gaps that persist in the regulation of this process.

Among the common patterns identified, the need to adapt information to the minor's cognitive level stands out, in order to ensure that the language and concepts used are comprehensible for their age and stage of development. In addition, most of the regulations and forms reviewed establish that the minor's assent must be obtained together with the prior consent of their legal guardians. Likewise, these forms tend to include basic information on the research objectives, the planned procedures, the possible risks and discomforts, the measures intended to minimize such risks, the expected benefits, the confidentiality of the data, and the minor's right to withdraw from the study at any time.

With regard to the differences identified, variations are observed in the minimum age established for requesting assent, which ranges from 6 to 14 years, depending on the country or institution concerned. Furthermore, the level of detail of the information provided varies significantly. While some forms specify the estimated time of participation and the number of activities or questions to be answered, others omit these aspects. Similarly, differences are identified in the procedures intended to ensure the minor's understanding, among them the validation of assent through comprehension-check questions and the use of visual resources that facilitate the understanding of the information provided.

The challenges in the regulation of informed assent, in turn, include the lack of consensus regarding the minimum age for obtaining it, since, in some countries, this decision is left to the discretion of the CEIs, which gives rise to discrepancies in its application. Another relevant challenge is the absence of specific guidelines for assessing the minor's capacity to understand the research and to make an informed decision. Moreover, it is observed that, in most cases, the final decision on the minor's participation in the research continues to depend exclusively on their legal guardians, without a mechanism being guaranteed to allow their express opposition or deliberate refusal to participate to be taken into account.

Finally, various gaps and limitations are identified in current practices related to informed assent. A critical aspect is the absence of specific regulations on the use of incentives or compensation to promote the participation of minors, which could pose an ethical risk if these strategies are not managed appropriately. Likewise, only one of the forms reviewed included information on the future use of data and biological samples, which points to a possible lack of transparency in this area. Similarly, it was observed that, although some forms refer to the confidentiality of the data, they do not clearly describe the concrete procedures intended to ensure its protection.

These findings highlight the need to strengthen and harmonize the standards applicable to informed assent, in order to ensure that minors participate effectively in decision-making regarding their involvement in research. In this regard, the implementation of innovative strategies, such as the use of visual materials and the validation of assent through interactive questions, could help improve the understanding of the information and promote greater autonomy for minors in this context.

Conclusions

Informed assent forms must be adapted to the capacities of children and adolescents, taking into account factors such as age, degree of maturity, and sociocultural context. Although there are common elements among the countries analyzed, the diversity observed in their implementation reveals the need to establish and harmonize good practices. Nonetheless, the minimum requirements proposed in this study should be understood as a flexible guide that allows for adaptation to the particularities of each

type of research, as well as to the regulations and sociocultural characteristics of each context.

It is likewise essential that the design of the forms and the process of obtaining informed assent promote the active and voluntary participation of minors, ensuring their understanding of the purpose of the research and of the implications arising from their participation. In this regard, the incorporation of innovative tools and inclusive approaches can contribute significantly to improving the accessibility, comprehensibility, and effectiveness of these processes.

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