

Ethical Pathways to Informed Consent When Collecting Information from Children in Research

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Abstract

Background: Informed consent is an ethical practice that should be guaranteed before a child is involved in a research. The position of the child in research has also become a subject of debate with regards to ethics. Though many countries may have unique provisions for conducting research with children, it is the goal of every regulatory mechanism to guarantee the autonomy, rights and protection of children in research.

Discussion: The form in which the information about a research is presented to a child can either weaken or strengthen the capacity of child to provide informed consent. The Medical Research Council suggests that many children would be competent to give consent if the information about the study is provided in an appropriate form and they are helped through the process of decision-making.

It is ethically unacceptable to exclude children with cognitive challenges or learning disabilities from research based on their condition. Any research with children should be designed to integrate children with these forms of condition, except it is vital to exclude them.

Even when the capacity of a child to provide informed consent is apparent, it is good ethical practice to involve the parents of the child in the decision making process especially for a research that carries any form of risk or discomfort. Notwithstanding this position, researchers always face challenges with obtaining active parental consent. Parental consent waiver is one of the options for dealing with the challenges associated with obtaining active parental consent. Most times parental waiver is a decision reached at recruitment points where a child with capacity to give informed consent insists that his or her parents should not be informed if he or she would participate in the research.

Summary: It is now clear that researchers must seek to position a child as one who can make informed choices. These emerging perspectives should support the selection of design, methodology and intervention for children with a goal to strengthen their capacity and autonomy to give informed consent.

Keywords: Children; Child; Informed consent; Research ethics; Parental consent

Background

Conducting research with children is important because, establishing their perspectives is vital to promoting and ensuring their well-being [1,2]. Today, many countries, funders and ethics committees are institutionalizing appropriate and well-established research code of conduct that conforms to best practices with special attention to children. However, a reoccurring debate question has been: Should children be accorded a 'special consideration' when involved in research? If so, to what extent should this be and how? This ongoing debate is mainly focused on addressing risk management related issues such as undermining the capacity of a child to understand the goal of the research and maybe coercion of children to participate in research against their will [3]. Some commentators have suggested that the discussion on providing special consideration when researching with children is over-emphasized [4-7]. But, special attention for children is essential because of their capacity to express autonomy and independence vis-à-vis cognitive abilities, experience and level of knowledge [8]. These factors are the ore reasons why special consideration is advocated for children in research.

These emerging opinions about children who are between the ages of 1-17; their level of self-awareness and knowledge has become a core deliberation in social science research, especially when they are considered as participants. The background to these considerations concerning children can largely be attributed to the fields of childhood sociology [9,10] and children's rights [11]. From these two fields, a child is perceived as one who possesses knowledge with complete human dignity and this has repositioned a child differently within many

settings [7,12-16]. The purpose of this paper is to discuss the capacity of a child to give informed consent, practical ways to support a child to consent or assent and how a child unable to give informed consent is considered in research. This paper will also examine parental consent and issues around it. In summary, the paper will conclude with key considerations that will support future studies involving children.

Discussion

Current ethical research principles for involving children date back to 1947 during the Nuremberg trials which happened after World War Two. The Nuremberg code of 1947 was derived from the Nuremberg trials [17]. This code provides the ethical direction for moral, legal and ethical principles concerning the involvement of human subjects in research. The primary principle is that every human being involved in a research must be accorded the respect to volunteer him or herself. This practice is what is now generally referred to as informed consent. The underlying condition of this principle is that a research study can only be endorsed to be carried out if it accentuates self-dignity of the

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participant. This initial expression of ethics was done about the time human rights formulation principles emerged [18].

The Declaration of the Helsinki 1964 and 2013 [19] was another notable code that emerged after the Nuremberg code. This code is regarded as one of the most dominant codes of ethical conduct because it has gone through constant amendment and change. The Declaration of Helsinki focus principally on medically related research, but its provisions have given an expansive importance and have equally been applied across non-medical research [20]. Both the Nuremberg and Declaration of Helsinki codes provide some essential and similar ethical principles. One of such similarities is that research participants' well-being must always take precedence over the interest of the researcher and the study. The ethical responsibility of researchers towards specific population like children is also similar in both codes. To end with, many countries adopt as a guideline and derive their national ethical principles from the provisions of these two codes [20].

If these codes have informed the ethical guidelines for many countries, it is important to check research regulation documents and other relevant sources of authority that shows what the position of the child is in research. Sweden, Scotland, Northern Ireland, United States of America and Australia have been selected because these countries have guidelines about researching with children that addresses risk related issues from different standpoints.

In Sweden, there are two key components of research ethics regulation: (1) The Act on Ethical Review of Research Involving Human [20], (2) The Professional ethics of the individual researcher. The provision of the Act supersedes the provisions of the professional ethics, but the ethical professional responsibilities of the researcher are stated in ethics committees' documents as being very vital. The provision of the Act that is specific to children's involvement in research addresses the kind of information that should be provided to data collectors and pre-conditions for informed consent. The Act specifies that information and consent during a research should not be sought from persons less than 18 years, but suggests that if the participant is aged 15 or over, but less than 18 years, and can realize what the research entails, he or she is to be informed about the research and requested to consent for participation. This is sometimes construed to mean that children who are 15 and above possess legal rights and capacity to grant their consent for participation and that parental consent may not be mandatory. Additionally, the Act is interpreted to mean that children less than 15 years old will need parental consent not considering if the child comprehends the goal of the research. In Sweden, the issues of perceived competence of a child often arise.

In Scotland, the 1995 Children Act of Scotland makes provision for a child who is 12 years and above to give consent provided the child is sufficiently knowledgeable and mature to form an opinion. It also provides that a person in parental responsibility cannot override the decision of a competent child if the child declines to participate in a research. If the child does, then such decision must suffice or be upheld. The Act further provides that a child less than 16 years old can give a consent that is binding on him or her to be involved in medical research, so long as the healthcare provider or researcher deems the child to be competent. The Age of Legal Capacity (Scotland) Act 1991[21], provides that "a person under the age of 16 years shall have legal capacity to consent on his own behalf to any surgical, medical or dental procedure or treatment where in the opinion of a qualified medical practitioner attending him, he is capable of understanding the nature and possible consequences of the procedure or treatment?" In Northern Ireland, the Children Act of 1989 and Northern Ireland

Order of 1995 provides for parental responsibility in relation to the child's participation in research, including the right to give consent for medical treatment [22]. The Northern Ireland Order also provides that a person with parental responsibility can override a competent child's decision to decline a beneficial service, if it is judged to be in the best interest of the child. The United States of America's National Commission for the Protection of Human Subjects [23] suggests that a child that is seven years and above should be requested to assent to participate in research and that the choice of the child of any age should be upheld except the child's involvement will not offer health benefits. The Federal regulations code, title 45 public welfare, Part 46 protection of human subjects; Regulations for children are in Subpart D of the United State Department of Health and Human Services [23] provides that in circumstances where a child presents a condition that is life threatening and a parent or legal representative is not available to give consent, healthcare providers can grant consent. This is known as 'emergency exception rule' also known as the doctrine of 'implied consent' [23]. The conditions to be met before this rule is applied are: the child is in a life threatening condition, a parent or guardian is not available to provide consent, and treatment cannot be deferred until consent is given. The rationale for this rule is the ethical basis for seeking the best interest of the child [23].

The Australian government Code for the Responsible Conduct of Research [24,25] provides for ethical conduct of research with a moderate focus on children. The first and most important consideration is the capacity of a child to understand what the research study entails and then to ascertain if the consent the child provides is sufficient for his or her involvement. In deciding the capacity of the child to give consent, the code emphasizes that the researcher must recognize the ongoing development of the child's ability to participate. The provisions in the code about children reflect the United Nations Convention on the Rights of the Child [26] and this indicates an influence of the child's rights thinking. The concept of a competent child to give consent is implied in the code.

What is evident from the provisions concerning children from the different instruments of regulations profiled is the formal ethical regulation concerning the involvement of children and gaining their consent to participate in a research study. It is also clear that involving children in research entails both ethical and practical concerns. Significantly, the apparent risk about children is undecided from the various Acts. At some points the child is seen to possess capacity to make a decision and at other points, that capacity is lacking. However, the child is seen to be protected from harm in all instances, but the capacity of the child to comprehend the goal of research is in contrast. It is unclear whether a child's involvement in research is considered a risk or not. These are the underlying reasons why commentators continue to have changing opinion about a child's involvement in a research.

Capacity of a child to give informed consent in research

A child's capacity to give informed consent is not based on age only, but also on the child's ability to comprehend and weigh the options and what involvement in a research would entail [27]. Sometimes, factors such as the goal of the research study, methods and the kind of information to be collected are the basis for deciding the capacity of a child rather than age [28].

The form in which information about a research is presented to the child can influence his or her decisions about participation. The child can exercise capacity to consent if information about research is in a form that can aid understanding [4]. The Medical Research Council [27] suggests that many children would be competent to give consent

if the information about the study is provided in an appropriate form and they are helped through the process of decision-making. The child's capacity to consent increases as the child is engaged through the complex processes of decision making and these can be age related or experience-based [2,11]. So for a child to be assessed as having capacity to consent and participate in a research, he or she must be able to understand, retain and communicate the information in the material that supports decision-making. The child must be able to consider the information and then reach a decision either to decline or continue. In situations where a competent child insists that neither parents nor family members should be involved in the decision making process, such a choice should be respected [7,27].

Some take the position that the capacity of a child to give informed consent is closely related to research method [17] For instance, participatory techniques have been utilized for studies involving children in recent times. This has shown to improve the way children engage with people and culture [29]. These methods do not only accomplish the research goals, but also empowers children to participate in decision-making activities at a future time. There are research methodologies that present risks when studying children, but may not be considered risky when studying adults such as a teacher-led study [30]. Inappropriate research methodologies and coercion on a child are the major risks faced by researchers when involving children in research [13]. For example when teachers are used to recruit students in a school-based study, this method of recruitment may not be devoid of undue influence owing to the respect that students have for their teachers [31]. Again, since school activities are perceived by students to be mandatory, students may have that perception about a study when they are asked to participate. The pointer here is the power imbalance that occurs between an adult researcher and child subject. A solution to this power imbalance is to allow the interface between researchers and the students more directly. Research methods should be made suitable to meet the capacity of the child as one who can give an informed consent [6,30-32]. The approach should be such that recognizes the child's capacity to provide informed consent and this position reflects contemporary thinking of research ethics as provided in the Scottish and Australian regulations. Children live in a world dominated by adults. They experience unbalanced power relationship with adults because their activities are controlled and limited by adults. The challenge is not a child's capacity to give informed consent, but the position ascribed to him or her.

Children unable to give informed consent

It is unethical to exclude children with cognitive challenges, learning disabilities or physically challenged from a research based on their condition [33,34] A basic characteristic of an ethically acceptable research is the respect for an individual and recognizing peculiar differences like gender, class, age, disability and culture among research participants. So, any research with children should integrate systematically from the design stage and throughout the research process how children with such vulnerable conditions will be supported to understand the goal of a study and subsequently provide informed consent if they are subjects in the study.

Involving children with disability in research should be guided by the provisions of National Disability Authority [35] guidelines. Principally, if a child with disability must partake in research then the researcher must of a necessity obtain parental consent or consent of person with parental responsibility. It is sufficient for a researcher to obtain consent from one parent or person with parental responsibility before involving a child with disability in research, but in the best

interest of the child and for good practice, involving a second parent or people close to the child is recommended [27,34]. In a situation where the parents of a child with disability are less than the legal age for adult, they can only be allowed to give consent on behalf of the child if they are competent to do so or if the aim of the research is not against the child's interest. If the child's involvement would offer potential benefits to the child, then the consent of a parent who is less than the legal age can suffice. Where opinions of people who are closely related to the child are divided about the child's participation, such a child should be excluded from the study except the child has a health condition and treatment is the only option available.

To strengthen the parental consent given in favour of a child with disability by person with such responsibility, the child must be supported to endorse such consent. Obtaining informed consent from a child with disability is always challenging, but researchers have the professional ethical responsibility to support them in arriving at a decision. In supporting a child with disability to give informed consent, that child must be seen as a capable moral agent that can understand the goal of the research if an appropriate method of communication is utilized. It is unethical to ride on the consent of parents alone, simply because a child is seen to have a disability [36]. To genuinely obtain informed consent from a child with disability, researchers should not generally request parents to participate on behalf of the child. If this happens, it will definitely weaken the capacity of the child and demonstrate issues of power over the child. Even though parents or proxies are to be adequately informed and requested to give consent about the child's participation, the rights and anonymity of a child with disability must be at the core of all deliberations concerning them. Research information materials should in appropriate formats and language (recognizing the child's age and abilities) for the purpose of the research. When augmentative modes of communication such as Braille, large prints, recorded information about the study and pictures are used, it enhances the child's capacity to comprehend and afterwards make an informed decision. Conclusively, a child with disability must be sufficiently involved in the decision-making process concerning him or her, an appropriate right-based methodology that reflects their anonymity should be employed and studies involving them should be empowering and inclusive.

Children who are not protected by an effective provision of law due to natural hazards, war, displacement and social discrimination are also a sub-population of vulnerable children [4]. Unfortunately, children who live in extreme poverty, drought and war zones always face increased risk of unethical practice when they are involved in [37]. For instance, children at refugee camps can be induced with food supplies to participate in research against their will [37]. These children in vulnerable circumstances do not always have adults, care-givers or persons with parental responsibilities to support their decision and so they are sometimes coerced into research against their choice [37]. Institutional review boards should ensure that further safeguards are in place to protect the welfare and rights of such children. For instance the United States regulations provides that children who are orphaned or separated from parents or relatives can only be involved in a research: if such research is specific to separated children or if the study is conducted at health facilities, children camps or schools. Since research regulations may not address children in these conditions specifically, institutional review boards should ensure that further safeguards and appropriate mechanisms should be integrated in research protocols to protect the rights and welfare of vulnerable children to minimize undue influence [38]

Informed parental consent

It is the responsibility of the researcher to make efforts to ensure that informed consent is valid [2]. The researcher must show that every important and necessary measure has been taken to obtain valid consent from research participant. One such measure is to ensure that requisite information has been given to support sufficient understanding of the research. Parental informed consent is an example of such requirements when children are involved in research. In Northern Ireland, parental consent is mandatory for persons less than 18 years before there are involved in research. Where a child is an orphan or cared for by the state, a legal institution like school authority or orphanage must provide informed consent [6,39]. This practice is consistent with standard ethics as a child without biological parents, or has parents with diminished autonomy is safeguarded from possible risks and harm.

Even when a child is assessed to have capacity to give informed consent, it is standard ethical practice to involve the parents of the child in the decision making process especially for a research that carries any form of risk or discomfort [6,39,40]. Notwithstanding this position, researchers always face challenges with obtaining active parental consent [41]. Sometimes, the failure of parents to respond to the request for consent rather than refusal to consent is usually the case [30]. Non-response from parents may also be a reflection of their unwillingness to allow their children participate in a given study. Factors such as literacy level of parents to read and comprehend research information, non-receipt of consent and information materials due to loss or misplacement of forms and many other reasons have been identified as reasons for non-parental response [30]. As part of an effective planning for research, investigators should ensure research information materials are easy-to-read and put in appropriate languages for parents. The consideration to adapt local languages is a possible way to address language barriers. Telephone calls to parents whose children are in research can be used as a stop-gap measure where non-receipts of forms due to loss are the case. However, review boards must ratify that it is ethically correct to do this [6,39].

There may also be some socio-economic difference between parents who give consent and those who do not [42]. Parents who do not return consent forms are also likely to be from a deprived socio-economically background or live as single parents [42]. These differences may pose a challenge in a study involving children given that children from disadvantaged homes may reduce the chances of achieving a fair representation of the entire population of their peers [42]. This inadequate representation can be challenging for researchers undertaking socio-metric studies where a large involvement of children is crucial to the integrity of the study. This is one reason why researchers subscribe to applying passive parental consent in a study involving children [43-45]. Passive parental consent is appropriate where research with children is with zero or minimal risks, for instance collecting samples of human tissue and blood have high risk implications. Passive parental consent basically seeks to inform parents about the possibility of involving their children in research. Passive parental consent has been identified to yield high rate of participation in studies involving children than those that hinge solely on active parental consent [30].

In practice, passive parental consent is usually applied in a school-based study. Parents are just informed of a proposed study that may involve their children. However, consent is sought from the children at the period of data collection. Information sheets and signed consent forms are requested to be returned if parents are not willing to allow their children participate in the [30]. Some institutional review boards are unwilling to permit the use of passive parental consent except under specific circumstances. In an instance where a methodology is perceived to constitute 'less than minimal risks' for children, then passive consent

can be passed, but it unlikely that most ethics committee will subscribe to passive parental consent [43]. In a study investigated whether the type of parental consent affects prevalence estimates of risk behaviours in a National Youth Risk Behaviour Survey. Findings showed that from the sample of 143 students, passive and active consent were 65% and 35% respectively while students' rate of participation were 86.7% and 77.3% for passive and active parental consent respectively. Therefore, it was concluded that type of parental consent does not influence prevalence estimates for risky behaviours that are self-reported.

Parental consent waiver is another provision similar to passive parental consent. Basically when parental consent waiver is contemplated, the parents of the child in research are not informed about the child's participation at all. Most times parental waiver is considered at recruitment points where a child with capacity to give informed consent insists that his or her parents should not be informed if he or she would participate [41,46]. So, while some children will accept that their parents be informed, others totally decline from involving parents. However, in a research that may adversely affect the welfare of the child, obtaining active parental consent should not be waived neither should the right of a child to consent be extinguished simply because parental consent is mandatory. It is worthy of note that, speaking for the rights of a child in research does not lessen the importance of parental informed consent in anyway, but it should be applied in a way that is attendant with the child's developing capacity. The rights of a child do not stop at development, survival and protection but extends to basic civil rights like the right to freedom of expression and self-concerning decisions.

Summary

In this paper, I have hoped to show that researchers have an obligation to render whatever support is obliged to guarantee the interest of children in research. A child should not be excluded from a research simply because he or she has a disability [2,8]. Children's effective participation in research is connected with their understanding of the methodology, research information and expected roles. So while researchers plan to involve children in research, they must be clear on how informed consent will be established. It is advised that extra efforts be made to achieve informed consent in research involving children with learning difficulties and cognitive challenges.

Arguments have been made in this paper for suitable research methods for child-based studies. Researchers should be mindful about factors that could influence children to agree to participate in activities that they would have declined. Power disparities and status between children and adults are the main ethical issues for research involving children. A teacher-led study, where a teacher has a stake in ensuring student participation is a good example. The social shame of declining may have an effect on the child, as the non-participation of the child will be known to his school mates and this can bring about humiliation.

This paper has argued for the rights of children in making informed decisions regardless of their abilities. Informed parental consent is decisive for the child in research, but the concurrence of the child is equally important and should be solicited by researchers. As much as parents and adults control the activities of children, the rights to expression and decision-making of a child should be promoted in research. The child should be repositioned as a moral agent that is capable of making informed choices if he or she is helped through the decision-making process [47,48]. In conclusion, efforts must be made to achieve active participation of children in research and the approach for children should guarantee their anonymity and that of other specific sub-population of children. I hope this paper will stimulate further debate about the position of a child in research.

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