

Self-Determination is Not an Appropriate Model for Understanding Parental Permission and Child Assent

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The ethical justification for the enrollment of human subjects in research requires at least two procedural safeguards: scientific and ethical review by an independent committee with diverse membership and the informed and voluntary consent of the prospective subject. For research involving children, both of these safeguards are modified given the vulnerability of children to either undue influence or coercion (1) (45 CFR 46.111b). There are limits set to the risks that a child may be exposed to in research that does not offer direct benefit (1) (45 CFR 46.404 and 45 CFR 46.406; 21 CFR 50.51 and 21 CFR 50.53) and limits set to the justification of risks that a child may be exposed to in research that offers the prospect of direct benefit (1) (45 CFR 46.405; 21 CFR 50.52). As Erb et al. (2) rightly point out, voluntary and informed consent in research involving children involves a combination of parental permission and child assent. Although it provides a valuable summary of permission and assent for clinical research in pediatric anesthesia, their discussion misses the mark to the extent that they apply a model of self-determination to this process. In fact, the additional requirements for research involving children arise from the difficulty in applying a model of self-determination to parental permission and child assent.

The underlying premise of informed consent as "self-determination" was established in 1914 by Judge Cardozo when he argued that "every human being of adult years and sound mind has a right to determine what shall be done with his own body" (3). As a result, social and legal policy requires full disclosure of material facts, risks, benefits, and alternatives regarding certain medical/surgical interventions. There is considerable variability among states concerning standards of disclosure in the clinical setting. Pennsylvania, for example, requires disclosure of any information that a reasonably

prudent patient would consider relevant and substantial in the decision-making process (4). Oregon requires only general information, alternatives, and risks; further disclosure is required only when the patient makes a specific request (5). Louisiana requires that the consent form specifically disclose the known risks of death, brain damage, quadriplegia, loss of limb/function, and disfiguring scars (6).

The National Commission suggested a standard of "the reasonable volunteer" as an approximation of the information that should be disclosed as part of voluntary and informed consent for research. This research standard was proposed as more stringent than "the information commonly provided by practitioners in the field or in the locale" or that "reasonable persons would wish to know" in the clinical setting (7). The federal regulations contain specific requirements on the information that is required for informed consent in research (1) (45 CFR 46.116 and 21 CFR 50.25). Although few states specifically incorporate research into statutes governing informed consent, the legal right of self-determination for a competent adult in both the clinical and research setting is safeguarded by established case law and state legislation. The failure to fulfill this duty of obtaining informed consent may result in either a cause of action for battery or negligence, depending on the specific jurisdiction.

How are we to understand parental permission and child assent? Is it appropriate to apply the model of self-determination (and thus the same informational requirements) to either parental permission or child assent? The regulatory requirement for parental permission and child assent emerges from the discussion of respect for persons found in The Belmont Report (7). Individuals who are not capable of self-determination should be protected. Parental permission thus functions to protect a child while the capacity for self-determination matures. Although child assent should reflect "the evolving nature of a child's capacity to participate," the meaning and function of child assent can only be

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understood in the context of parental permission (7).

The principal of respect for persons includes the ability for both the child and parent to exercise voluntary choice concerning research participation. However, the nature of the choice and the information necessary to exercise that choice differ. Parental permission serves to protect the child and thus requires detailed information concerning the nature and purpose of the research, the risks and benefits, and alternatives to research participation. In effect, the disclosed information required for a voluntary and informed parental permission is the same as that required for informed consent (1) (45 CFR 46.116 and 21 CFR 50.25). Nevertheless, the purpose of parental permission is not self-determination but protection.

Child assent is limited to a simple preference for research participation (1) (45 CFR 46.402b). As Erb et al. (2) point out, there is "limited guidance concerning the operational meaning of assent." However, they fail to fully appreciate the consequences of this limited definition. For example, they imply that a child's abilities to "identify benefits and risks of the proposed research" or to "reason about consequences regarding participation" are important in establishing a child's capacity to assent. Although the presence of these abilities, particularly for an adolescent, may establish the capacity to assent, the absence of these abilities does not establish the inability of a younger child to assent. A 7-yr-old child of normal developmental capacity is certainly able to state whether he or she agrees to a nontherapeutic blood test. If capacity to assent is limited to older children who are capable of hypothetical reasoning about research consequences, we may inappropriately waive the assent of younger children. Once a parent has determined that exposure to the risks (and benefits) of research is permissible, a child may or may not assent to participate in the research for any reason whatsoever. If we choose to ignore the opinion of a younger child, it should only be under the conditions that would justify waiver of a child's assent based on potential benefit that is otherwise not available (45 CFR 46.408).

Erb et al. (2) note the lack of research on "what information is needed by children for them to give meaningful assent." One of the difficulties in assessing the information that exists is the failure to explore the different meanings of assent for children at different levels of developmental maturity. Assent, and thus the information and understanding necessary for assent, may mean one thing to a 7-yr-old child and quite another to a 14-yr-old adolescent. Thus, their discussion of providing understandable information (including the informational elements, oral presentation, and written documentation) is hampered by a lack of clarity concerning the different roles of parent and child.

The standard of "the reasonable child volunteer" suggests that the information needed for assent to research participation will vary depending on the developmental capacity of the child. In addition, this informational and decision-making standard will differ from "the reasonable adult volunteer" and will likely fail to protect a child in the absence of parental permission. Although assent may enhance the "moral status of children" by allowing for limited self-determination in some circumstances (i.e., saying "no"), the extent to which assent, taken alone, safeguards a child from potential risks (or secures a child's "best interest") is at times questionable.

The Food and Drug Administration (FDA) recently incorporated the special protections found in 45 CFR 46, subpart D, into 21 CFR 50 with the exception of the waiver of parental or guardian permission found in 45 CFR 46.408c (1). This section allows for a waiver of parental permission by the IRB if the research is designed for conditions or for a subject population in which parental permission is not a reasonable requirement to protect the subjects. The FDA argued that such a waiver is inconsistent with existing FDA regulations that limit a waiver of parental permission to those same conditions that would justify a waiver of informed consent (21 CFR 50) (1). This decision by the FDA can be interpreted as a refusal to apply the model of self-determination to adolescent assent (if capable) or as an implicit endorsement of the importance of parental protection in FDA-regulated research. Either way, the controversy over this waiver illustrates the difficulty in applying a model of self-determination to the complex interaction of parental permission and child assent. A simpler approach would be to recognize the ability of some children such as adolescent subjects to provide informed consent under certain research conditions. Although this approach has been used in limited clinical conditions, such as the provision of family planning services, the extension of this model to research is controversial and may require enabling state legislation.

Taken alone, neither parental permission nor child assent can be understood from the perspective of self-determination. Similarly, the informational needs for parental permission and child assent vary based on the different functions each serves (i.e., protection and preference) and on the developmental maturity of the child. In the absence of empirical evidence about what "the reasonable child volunteer" would want to know, the researcher should explore with the potential child participant what information that particular child would want to know. A young child may simply want to know what is going to happen and why. An older child may want to know how the risks and benefits of the research compare with the alternatives. Unless the requirement for assent is waived, given a therapeutic benefit that would otherwise be unavailable (based on

the parent's assessment of risk and benefit), assent should be obtained from any child who is old enough to realize that the research is not for his or her benefit but for the benefit of others. The burden of obtaining child assent should not be self-determination, but simply an affirmative agreement to be used as a means to another person's end. The burden of parental permission is to protect a child from assuming unreasonable and unjustified risks given his or her immaturity. The burden of independent committee review is to be sure those research risks occur within the limits established by the special protections for research involving children.

References

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