

Children and Research Participation: Who Makes What Decisions

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Introduction

The three federal research funding agencies in Canada—the Canadian Institutes for Health Research, the Natural Sciences and Engineering Research Council, and the Social Sciences and Humanities Research Council—recently created the Panel on Research Ethics (announced November 9, 2001). The mandate of this inter-agency panel is, in part, to ensure that the Tri-Council Policy Statement (TCPS) on research involving humans remains a “living” document; that is, this panel is charged with updating and revising the TCPS. In this paper, I call attention to the TCPS sections that apply to research involving children (i.e., individuals below the legal age of majority). In particular, I argue that the use of assent and dissent for children’s role in decision-making about research participation is inadequate. This inadequacy stems from a failure to fully recognize and appreciate the developing decision-making skills of children. Accordingly, I offer an alternative approach to involving children in decision-making about research participation. This approach is based on the decisional capacities of children and links these developing capacities to different levels of involvement in decision-making about participation in research.

While the relevant TCPS sections for children and research participation include Articles 2.5-2.7 and 5.3, I am most interested in the claims made about assent and dissent in Article 2.7:

Where free and informed consent has been obtained from an authorized third party, and in those circumstances where the legally incompetent individual understands the nature and consequences of the research, the researcher shall seek to ascertain the wishes of the individual concerning participation. The potential subject’s dissent will preclude his or her participation.

[Explanation] Many individuals who are not legally competent are still able to express their

wishes in a meaningful way, even if such expression may not fulfil the requirements for free and informed consent. Prospective subjects may thus be capable of verbally or physically assenting to, or dissenting from, participation in research. Those who may be capable of assent or dissent include: (a) those whose competence is in the process of development, such as children whose capacity for judgement and self-direction is maturing...¹

The TCPS limits the role of children in decision-making about research participation to being able to assent, verbally or physically, and dissent. Neither assent nor dissent is defined; no other, or expanded, role for children in decision-making is considered. The concern for the vulnerability of children and the need to protect them is commendable. And yet, if children are to be treated with respect and dignity, as the TCPS also states, it seems plausible to argue that an improved recognition of the developing decisional capacities of children requires a more nuanced approach to their role(s) in decision-making about research participation. This is the focus of the discussion below.

Setting the Stage

Research involving children poses a number of difficulties, the most perplexing of which concerns the role that children should play in decision-making about their research participation. In the neonatal period, and during early infancy, this is a non-issue since these children clearly cannot be involved in any decision-making, let alone decision-making regarding research participation. Beyond this early developmental stage, however, the issue is considerably more complex.

Decision-making is a skill set that is mastered over time. It includes (but is not limited to) the ability to sift through emotions, to decipher ambiguous information, to interpret facial expressions, to decode tones of voice, to weigh options, and to make value judgments. From a very early



age, even before children have any significant verbal skills, they are invited by their parents and others to practice the most basic of these requisite skills, as when they are encouraged to choose between two breakfast cereals. With time and practice, a range of decision-making skills is mastered, and there is a move from simple and safe decisions to complex and value-laden decisions. Typically, different (and more or less) skills are required for different types of decisions and these skills are often practiced on an as-needed basis, proceeding by trial and error. The mastery of these skills will depend on the child's physical, emotional, and developmental status, unique personality, life experience, social and moral maturity, and cognitive capacities. The point, as regards the issue of children's decision-making concerning research participation, is that different skills are required for different kinds of research, and some children will have mastered some of these skills prior to reaching the legal age of majority.

This fact behooves those of us who support research involving children (including parents, researchers, and Research Ethics Board (REB) members) to carefully consider how best to protect children's interests, while at the same time respecting and nurturing their developing decision-making capacities. As explained above, current practice is to request assent from, and respect the dissent of, children. This common practice is unsatisfactory, however, since it fails to meaningfully acknowledge and respect the changing nature of children's abilities to participate in discussions about research, and to make independent decisions about their participation in research. Indeed, the use of assent and dissent as meaningful moral categories frequently promotes the goal of protecting children's interests (e.g., protecting them from research harm), at the expense of recognizing and nurturing their decision-making abilities.

In this paper, I suggest that there are four, possibly five, categories of child research participants, and that in each category there are unique consultation and decision-making roles for children, their parents, researchers and REB members.² Of particular interest is the expanding role for children in decision-making about research participation, and how this shifts what is ethically required of others. But first, it is appropriate to review the preconditions for respectful research involving children.

Children and Research Participation

Children should not be excluded from research of potential medical benefit for themselves, or of potential medical benefit for children as a group, simply because they are children. To exclude them from research participation solely on this basis would be to unfairly deny them the potential benefits of medical research including the potential to ameliorate, alleviate, or prevent physical or psychological problems. The obligation to protect children from unnecessary research harm must be balanced with the recognition that children, individually and

as a group, can benefit from research participation. Indeed, along with others, I believe that research involving children is ethically acceptable,³ provided a number of ethical preconditions are met. Most important among these are the requirements that the research must have scientific merit, must be done with legally competent adults first (where appropriate and feasible), there must be a proportionate harm-benefit ratio (as contrasted with a minimal risk threshold),⁴ and finally there must be appropriate involvement of children in the decision-making process and a morally valid authorization or consent to research participation.

Scientific Merit

Scientific merit includes both scientific validity and scientific value. A study is scientifically valid provided it is designed to yield reliable information, according to accepted principles of research practice, concerning the hypothesis being tested. For example, the results of a study whose sample size is too small, or skewed, or poorly controlled, cannot be generalized toward confirmation or disconfirmation of the hypothesis, and the study is therefore invalid. A second and distinct understanding of the requirement of scientific merit focuses upon "value" rather than (mere) "validity." A study may be well-designed relative to its hypothesis, and therefore scientifically valid, but may nonetheless be of no value because the hypothesis itself is trivial or otherwise uninteresting.⁵ In my view, a necessary condition of ethically acceptable research involving children is that the research be scientifically valid and of scientific value.

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The Descending Order of Permissibility

Years ago, Hans Jonas argued persuasively that the most vulnerable among us should be the last to participate in research and be exposed to research risks.⁶ Consistent with this view, whenever appropriate and feasible, research involving legally competent adults should precede equivalent research involving either legally competent or incompetent children. This will not be possible, however, for the study of childhood diseases, especially those diseases that result in significant morbidity and mortality during childhood. This will be possible, and indeed is required, for a range of other studies where the health concern is not unique to children. In my view, a necessary condition of ethically acceptable research involving children is that the research could not be done, or already has been done, in competent adults.

A Proportionate Benefit-Harm Ratio

With all research involving humans, all measures should be taken to minimize the risk of harm and to maximize the potential for benefit. Further, with all research involving humans there should be a proportionate (if not a favourable) benefit-harm ratio. On this last point, there is considerable disagreement in the literature. For example, many argue that children should not be involved in research that exposes them to more than minimal risk.⁷ This view is inconsistent, however, with the view that children should not be denied the potential benefits of research participation. Consider, for example, the plight of children afflicted with lethal conditions where the research risks may be high (certainly more than minimal), but so too are the potential research benefits. What matters, I contend, is that the potential for benefit be at least equivalent to, if not better than, the potential for research harm. The requirement of a proportionate (and if possible a favourable) benefit-harm ratio does not set a threshold limit on the allowable level of risk for research involving children; rather, it attends to the relationship between the potential benefits and the potential harms. As the importance and/or likelihood of potential benefit from the research increases, a proportionate increase in the significance and/or likelihood of potential harms is tolerated.⁸ Accordingly, I do not align myself with those who restrict the participation of children in both research and the related decision-making based on the level of risk associated with the research. In my view, a necessary

To exclude them from research participation solely on this basis would be to unfairly deny them the potential benefits of medical research including the potential to ameliorate, alleviate, or prevent physical or psychological problems.

condition of ethically acceptable research involving children is a proportionate (or favourable) benefit-harm ratio.

I do recognize the inherently subjective nature of the assessment of the benefit-harm ratio and do not assume that children, parents, researchers, or REB members will necessarily concur in this assessment. For all research that

has REB approval, the REB will have determined, using a broad societal understanding of benefit and harm, that there is a proportionate (or favourable) benefit-harm ratio. It does not follow that the ratio will be perceived in this way by the parents and children invited to consider research participation. They

will need to make their own assessment of the benefit-harm ratio and the interpretation of a legitimate decision-maker (parent or child) will be authoritative as regards research participation.

Respectful Involvement of Children and Morally Valid Consent

Respectful involvement of children in decision-making regarding research participation requires a process that is both interactive and iterative. Meaningful interaction with children requires of those providing them with information that they listen and respond to the concerns identified by children. In this way, researchers and parents can develop a fuller understanding of the issues relevant to the children as potential research participants, and this will allow them to better assess and effectively promote a particular child's developing capacity for independent decision-making.

As a child's decision-making abilities increase and improve, the child's role in determining whether, when, and how to participate in research increases. In direct proportion to this change, the role of the parents and researchers shifts. As such, I submit that a necessary condition of ethically acceptable research involving children is that there be appropriate involvement of children in discussions and decisions regarding research participation.

Who Makes What Decision?

While it may be generally accepted that children's wishes about participating in research should be respected, the involvement of children in such decisions "is neither routine nor standardized."⁹ My aim here is to help conceptualise different decision-making roles for children with different decisional capacities. In so doing, I hope to minimize the



harm done to children by excluding them from decision-making processes that they are capable of participating in, and also to provide a framework in which to nurture and develop children's decision-making capacities.

Five broad categories of children can be described based on their developing abilities. These are: children with no language comprehension and no decisional capacity (e.g., neonates and early infants); children with some language comprehension but limited decisional capacity; children with good language comprehension and developing decisional capacity; children with good language comprehension and sufficient/substantial decisional capacity who are mature but not emancipated minors; and, children with good language comprehension and sufficient/substantial decisional capacity who are both mature and emancipated minors. "Emancipated" refers to those minors who: (i) have a court-ordered emancipation (e.g., teenagers living apart from their parents who petition the court to be treated as though they have reached legal majority); (ii) are statutorily emancipated (e.g., married minors or minors who are parents); or (iii) have medical emancipation (e.g., minors seeking treatment for a specific medical condition such as a sexually transmitted disease). No age limits are given for any of these categories. I assume that the decision-making abilities of particular children develop at different rates, and so parents and researchers, in good faith, will have to assess the child's abilities and proceed according to the requirements for the appropriate category. I also presume that parents and researchers are well-intentioned, willing and able to fairly assess the child's abilities and to support the child in developing decision-making capacities.

In the following, I will discuss each category of children with respect to decision-making about research participation, noting what roles will be played by the children, parents, researchers, and REBs. Figure 1 captures these points for the purposes of comparison and summary.

Category One: No language comprehension, no decisional capacity

There is no role in discussion about research participation for a child with no language comprehension and no decisional capacity (e.g., a neonate, early infant, or severely compromised older child). To state the obvious, no useful purpose is served in explaining any proposed research to a child who cannot understand even the simplest of explanations.¹⁰ Full decision-making authority rests with the parents who may authorize or refuse research participation for their child.

In making the decision about their child's participation in research, parents typically will consider a number of factors including the nature and objectives of the proposed research, as well as the potential medical benefits and harms that may result from research participation. As well, a number of context specific factors will be considered including the child's general state of health and well-being, the risk of overexposure to research (as sometimes happens with chronically ill children or children with rare disorders), and the nature of any ongoing relationship with the investigator (as sometimes happens with cancer care, for example, where the researcher is also the specialist clinician responsible for the child's ongoing care). Taken together, an evaluation of such factors will lead the parents to conclude that there is, or is not, an appropriate balancing of the potential benefits and harms of research participation. If they determine that there is a proportionate benefit-harm ratio (i.e., the potential harms are believed to be in proportion to the potential benefits), they may authorize research participation.

When parents authorize research involving their children who lack language comprehension and decisional authority, they should be present or available when the research is conducted. One reason for this is that during the course of the research, new information may become available that may require a reassessment of the benefit-harm ratio. For example, known possible side-effects or harms may be experienced, new unanticipated side-effects or harms may occur, or the child may protest.¹¹ This protest, whether vocal or behavioural, would constitute a harm and require some kind of response. Depending upon the situation, the parents may want to withdraw the child from research or may want to authorize the use of restraints. The use of restraints could reduce or increase the harms of research. For example, the use of physical restraints may frighten the child, while the use of chemical restraints may have a calming effect.

With this category of research participant, the researcher's responsibilities are: to ensure full disclosure to the parents about the nature, objectives, benefits and harms of research; to check for substantial understanding of the information provided; and to be satisfied that the parents are well-intentioned in their decision-making. As well, if certain side effects or harms are experienced during the course of the research, or if the child protests, the researcher should ensure that the parents have this information and are able to factor this into their continuing analysis of the benefit-harm ratio. If there is any doubt about the parents' intentions and the researcher believes the benefit-harm ratio is unfavourable, she may have an obligation to withdraw the child from the research. At times, this obligation may override the parents' decision regarding their child's continued participation in research.

Category Two: Some language comprehension, and limited decisional capacity

A child with some language comprehension and limited decisional capacity should have some role in the decision-making process regarding her research participation. This role might properly be described as “receptive”, in contrast with “decisional”. The child should be told what will be done to her and why, and she should be invited to ask and answer questions related to the proposed research. The information should be provided not for the purpose of having her make a decision about research participation, but rather to prevent any harm she may experience from having something done to her without knowing why, and to promote her developing autonomy as she learns decision-making skills.

With this second category of child research participants, decision-making authority continues to rest with the parents who may authorize or refuse research participation on behalf of their child. This authority, as noted previously, comes with responsibilities. In this particular instance, the parents have two additional obligations: to make sure that relevant information about the proposed research is shared with their child; and to heed any verbal (or other) protest from their child. The latter obligation requires parents to stop and reassess the situation when their child protests with particular attention paid to: (i) any harm anticipated or experienced by the child; and (ii) any harm that may arise from a parental decision to override their child’s protest. An important point here is that a child’s protest is not sufficient to preclude or discontinue research participation. Parents are primarily responsible for making decisions about research involving children in this category; their child’s protest is relevant to their assessment of the harm-benefit ratio of research participation, but is not authoritative.

The researcher dealing with children in this category has similar additional responsibilities. She, like the parents, must help ensure that the child understands the relevant information about the proposed research and, in the event that the child protests and the protests appear to go unheard by the parents, she must be prepared to advocate for the child. If the child objects to being enrolled in research, and these objections are ignored by the parents, this may mean not acting on the parents’ authorization. If the child protests during the course of the research, this may mean overriding the parents’ decision and withdrawing the child from the research. The researcher’s decision to override the parents’ decision would have to be well-grounded in her own subjective assessment of the harm-benefit ratio in which she has thoroughly weighed in the possible harm to the child as a result of having her protests ignored.

Category Three: Good language comprehension, developing decisional capacity

As a child’s language comprehension and decisional capacity improve, her role in the decision-making process moves along a continuum. The major differences between categories two and three is that, in category three, full decisional authority no longer rests with the parents. The child’s agreement and protest both carry more weight. This is due to the child’s developing decision-making skills and the responsibility others have to acknowledge this burgeoning autonomy. In effect, a shift from protecting the child’s interests to promoting the child’s developing autonomy begins in category three.

Significantly, children in this category are to be provided with information about the proposed research not only for informational purposes, but also for decision-making purposes. This is not to suggest that these children have all the relevant skills and abilities to make important decisions about research participation. There are important differences between the ability to understand information in the abstract, the ability to anticipate and appreciate the possible/probable consequences of certain actions or choices, and the ability to weigh this information in terms of one’s life goals and plans, particularly when these are in the process of being shaped. To be sure, these abilities are limited in children with developing decisional capacity, and for this reason their decision-making authority is limited in important ways. Their agreement to participate in research is necessary, but not sufficient, for research to proceed. On the other hand, their protest usually will be independently authoritative; that is, sufficient to preclude their participation in research. The only exception would be for cases in which the parents could persuade all but their children that they were mistaken in their assessment of the relevant facts and values, and that the potential benefits of research participation outweighed both the potential harms of research participation and the additional harm of overriding their children’s preference(s). A unique role for researchers in dealing with children in this transitional category is in supporting the parents in their efforts to help their child practice her decision-making abilities. Researchers will need to listen carefully and closely to children in order to discern what they want to know and the level of their abilities to understand more or less complex information. Research suggests that what children want to know may be quite different from the sort of information typically sought by parents and provided by researchers.¹² Researchers will also need to attend to the familial and social context in which the child is situated to better understand the ways in which the child may be accustomed to participating (or not) in decision-making. This will be necessary to ascertain what may be appropriate



involvement for the child.¹³ In addition to facilitating meaningful involvement for the child in the decision-making process, the researcher may have a pivotal role to play in those few instances where the parents contest the authority of their child's decision not to participate in, or to withdraw from, research.

Category Four: Good language comprehension, sufficient decisional capacity – mature but not emancipated minors

The mature, but not emancipated, child (minor) has significant decision-making authority: (i) the child's refusal is always authoritative; and, (ii) the child's consent will be necessary in order for the research to proceed and is sometimes sufficient. Limiting conditions on (ii) do exist since for some research interventions, the child's consent will not be sufficient for the research to proceed – parental agreement will also be necessary. The child's consent is not sufficient when: (i) parental authorization is legally required; (ii) research participation places positive obligations on the parents (e.g., parents need to give the child a ride to the research site); and (iii) the research involves more than minimal risk. There may be harmful consequences to research participation that could affect the parents as well as the child (e.g., increased disability for the child and increased caregiving responsibility for the parents). If these conditions hold (see Comment below), this means that parents have limited decision-making authority. Parental agreement will sometimes be necessary for research to proceed, but it is never sufficient; the child must also consent.

The researcher must ensure full disclosure to the child about the research. Further, the researcher must determine whether the child's consent is sufficient, or if parental agreement is also required (as in the above-identified situations). When the parents are involved, they will also be fully informed about the research. The child's research participation should only be disclosed to parents when parental agreement is required, and/or when parents are responsible for making other decisions for which information about the research protocol is needed. The researcher should discuss withdrawal with the child if she believes that the benefit/harm ratio has become unfavourable. Withdrawal is not automatic; the child's decision to take a risk must be respected (except in those cases where parental involvement is required and parental agreement is withheld). The REBs' role is to ensure the research meets the specified preconditions; full disclosure to the child (and to the parents, when appropriate) will be required. Documentation of the

child's consent and, when necessary, parental agreement will be expected.

Comment: While there may be a moral difference between this category and category five, it is unclear what potential significance this difference may indicate. Suggestions have been made above to provide guidance in determining which situations would require parental agreement and which ones would not. However, the question remains that if the child is deemed to be mature and capable of making her own decisions: is it right to deny her this choice in some cases?

To emancipate means to free from restraint, control, or the power of another. The child who is mature, but not emancipated, is still in a parent-child relationship or guardianship context. This context raises serious questions about parental responsibility and accountability, and seems to provide justification for arguing that parental agreement to their child's participation in research is appropriate (in some cases). But is it clear what these situations are? There may, for example, be disagreement about condition (iii). On the one hand, although the child may be as intellectually competent as many adults, she is not responsible for her decisions in the same way as an adult because of limits on her ability to estimate long-term consequences for herself relative to personal life goals and objectives. Thus, parental agreement is needed. On the other hand, mature minors may well have the same decisional capacities as adults and, therefore, exceptions for risky research cannot be justified; whether these minors are emancipated or not is irrelevant.

In effect, category four raises the question of whether to err on the side of autonomy, recognizing the mature child's decision-making abilities, or to err on the side of protecting the child from harm. It may be that erring on the side of autonomy is more important than protecting these children from the harms that may result from their research participation. Put another way, the harm of overriding or ignoring the mature child's decision-making abilities may be greater than the possible harms of the research. If this is the case, then the above-described situations where parental agreement would be required will need to be re-evaluated and/or discarded. This could imply, for example, that categories four and five should collapse together with the description of the decision-making roles for category five holding for all mature minors (whether they are emancipated or not).

However, some will want to argue that, while the mature child still lives at home and is not yet emancipated, parental involvement in the decision-making process can be beneficial for the child. By asking the parents to agree, this could initiate dialogue between the parents and the child in

which the child's reasoning, awareness of the possible harms, and, understanding of the potential effects of research participation on the other family members could be explored. The child could gain further practice in decision-making without having to bear the full responsibility of her choice. As Lainie Freedman Ross contends, "Granting autonomy to competent children too early may be autonomy-restricting over a lifetime because it abandons the child to his own decision making without providing a protected period in which he can develop the capacities needed to flourish."¹⁴

Category Five: Good language comprehension, sufficient decisional capacity – mature emancipated minors

Full decision-making authority rests with the child who may consent to, or refuse, research participation. There is no obligation to share information about research participation with the parents, and there is no obligation to heed the parent's objections. The child is believed to be as competent as an autonomous adult and is treated as such, i.e., her consent/refusal is binding. The underlying assumption is that the child is fully responsible and accountable for her decision. The parents have no decision-making authority. The researcher and the REB have the same obligations as for any legally competent adult research participant or any research involving legally competent adults.

Conclusion

I have argued that children must be included in the decision-making process about research participation. Further, as the decision-making abilities of children improve and increase, the role that children should play in this process must reflect their growing autonomy. Five different categories of children have been identified and details regarding the respective decision-making roles and responsibilities for children, parents, researchers, and REBs have been outlined. These categories do much to further our understanding of how children can be involved respectfully in the decision-making process; and yet there is more work to do. Some difficult issues such as the moral and practical import of distinguishing between mature children who are and are not emancipated still require further attention. Meanwhile, changes in current practice are needed so that we can both protect children's interests and demonstrate respect for their developing decision-making abilities.

At a minimum, the above-described categories call for a reassessment of the current role of children in decision-making about research participation. Specific recommendations for the Panel on Research Ethics include:

(1) expanding the role of children in decision-making about research participation based on their decisional capacities to accord with the four, potentially five, categories outlined; (2) developing a position statement on the fourth and fifth categories that would help further the debate about the significance of emancipation with respect to the ability of minors to consent to research participation; (3) defining and clarifying the language used to describe what decision-making role children have; and (4) outlining the roles of the parents, researchers, and REBs in the TCPS to better indicate what (shared) responsibilities each has as to including children more appropriately in decision-making about research participation.

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Figure 1: Decision-making Roles with respect to Children and Research Participation

Category of Children	Child's Role	Parent's Role	Researcher's Role	REB's Role
No language comprehension, no decisional capacity	No decision-making authority -may protest, but protest does not preclude research	Full decision-making authority (authorization/refusal) -based on assessment of proportionate benefit/harm ratio -should be present or available during research or delegate responsibilities to another -should withdraw child if benefit/harm ratio becomes unfavourable	Ensure full disclosure to parents about research participation -should withdraw child if benefit/harm ratio becomes unfavourable -can override parental decision re: issue of withdrawal	Protect children's interests by only approving research that meets the specified preconditions -require full disclosure to parents and their authorization -require documentation of authorization
Some language comprehension, limited decisional capacity	No decision-making authority -limited role in decision-making process (receptive) -may ask and answer questions -may protest, but protest does not necessarily preclude research participation	Full decision-making authority (authorization/refusal) -based on assessment of proportionate benefit/harm ratio -obligation to share information with child about research participation and address questions -should be present or available during research or delegate responsibilities to another -must heed child's protest -should withdraw child if benefit/harm ratio becomes unfavourable	Ensure full disclosure to parents about research participation -ensure relevant disclosure to child about research participation and address child's questions -must heed child's protest -should withdraw child if benefit/harm ratio becomes unfavourable -can override parental decision re: issue of withdrawal	Protect children's interests by only approving research that meets the specified preconditions -require full disclosure to parents and their authorization -recognize developing decision-making skills by requiring relevant information be shared with child -require documentation of authorization and discussion with child
Good language comprehension, and developing decisional capacity	Increasing role in decision-making process that includes limited decision-making authority -agreement to participate is necessary, but never sufficient -protest is authoritative and	Limited decision-making authority -parental agreement is always required; in some instances, a child's protest is authoritative -obligation to share information with child about research participation and address questions -must give child an	Ensure full disclosure to parents about research participation -ensure relevant disclosure to child about research participation and address child's questions -ensure child is given opportunity to express her wishes -should ensure parents	Protect children's interests by only approving research that meets the specified preconditions -require full disclosure to parents and their agreement -recognize developing decision-making

	precludes research participation except when parents judge that potential benefit of research participation outweighs potential harm of research participation <u>and</u> additional harm of overriding child's preference(s)	opportunity to express her wishes and take these wishes into account in assessing benefit/harm ratio -should be present or available during research or delegate responsibilities to another -should withdraw child if benefit/harm ratio becomes unfavourable	are taking child's wishes into account- should withdraw the child if benefit/harm ratio becomes unfavourable -can override parental decision re: issue of withdrawal	skills by requiring relevant information be shared with child and child's agreement -require documentation of agreement by parents and child -respect and defend that child's protest can be authoritative in some cases
Good language comprehension and sufficient/substantial decisional capacity: Mature but not emancipated minors	Significant decision-making authority -child's consent to participate is necessary and sometimes sufficient (parental agreement is sometimes necessary) -child's refusal is always authoritative (no exceptions)	Limited decision-making authority -parental agreement is sometimes necessary for child's research participation (e.g., when legally required, participation has consequences for parents, and, possibly, for more than minimal risk research), but it is never sufficient	Ensure full disclosure to child about research participation -must determine if child's consent is sufficient or if parental agreement is also required -ensure relevant disclosure to parents about research participation when they are legitimately involved in decision-making -should discuss withdrawal with child if benefit/harm ratio becomes unfavourable	Recognize children's decision-making ability -approve research that meets the specified preconditions -ensure full disclosure to the child and, when necessary, to the parents -require documentation of consent of child and, when necessary, parental agreement
Good language comprehension, and sufficient/substantial decisional capacity: Mature emancipated minors	Full decision-making authority (consent/refusal) -no obligation to share information with parents re: research participation	No decision-making authority	Same obligations as for any legally competent adult research participant	Same obligations as for research involving legally competent adults



1. Medical Research Council of Canada, Natural Sciences and Engineering Research Council of Canada, and Social Sciences and Humanities Research Council, *Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans* (Ottawa: Public Works and Government Services Canada, May 18, 1999 Update), online: Natural Sciences and Engineering Research Council of Canada <<http://www.nserc.ca/programs/ethics/english/sec02.htm>> (date: accessed 5 May 2002) Art. 2.7.
2. For further discussion of these categories, as well as their development in the Workshops, see: Françoise Baylis, Jocelyn Downie, & Nuala Kenny, "Children and Decision-Making in Health Research" (1999) 21(4) IRB: A Review of Human Subjects Research 5.
3. See e.g. Robert J. Levine, *Ethics and Regulation of Clinical Research*, 2nd ed. (Baltimore: Urban Schwarzenburg, 1986) at 240; Françoise Baylis, "Mandating Research with Children" (1999) 21(1) IRB: A Review of Human Subjects Research 10; Committee on Drugs, "Guidelines for the Ethical Conduct of Studies to Evaluate Drugs in Pediatric Populations" (1995) 95(2) Pediatrics 286.
4. Françoise Baylis & Jocelyn Downie, "An Ethical and Criminal Law Framework for Research Involving Children in Canada" (1993) 1 Health L.J. 42.
5. Benjamin Freedman, "Scientific Value and Validity as Ethical Requirements for Research: A Proposed Explication" (1987) 9(6) IRB: A Review of Human Subjects Research 7.
6. Hans Jonas suggests involving persons in research according to a descending order of permissibility. "...those [persons] who...are most cognizant of the cause of research-members of the medical profession...-come first; the highly motivated

and educated, also least dependent...come next; and so on down the line." Hans Jonas, "Philosophical Reflections on Experimenting with Human Subjects," in Paul A. Freund ed., *Experimentation with Human Subjects* (New York: George Braziller Inc., 1969) at 23.

7. See e.g. Benjamin Freedman, "In Loco Parentis: Minimal Risk as an Ethical Threshold for Research Upon Children" (1993) 23(2) Hastings Center Report 13.
8. *Supra* note 4 at 60.
9. *Supra* note 2 at 6.
10. *Ibid.* at 8.
11. Dissent is not a helpful concept since it is typically confused with or considered to be the same as a competent person's refusal. A more useful concept is that of protest. It is understood that a child's protest must be heeded, but that it is not necessarily authoritative.
12. See, for example, Barbara M. Sourkes, *Armfuls of Time: The Psychological Experience of the Child with a Life-Threatening Illness* (Pittsburgh: Pittsburgh University Press, 1995) at 31-44, 53-60; Rona Abramovitch *et al.*, "Children's capacity to agree to psychological research: Knowledge of risks and benefits and voluntariness" (1995) 5(1) Ethics & Behaviour 25.
13. See N. Kenny & P. Miller, "Comment: Research Involving Children: Clarifying Roles and Authority" (2000) 11(2) The Journal of Clinical Ethics 151 at 154.
14. Lainie Freedman Ross, *Children, Families, and Health Care Decision Making*, (Oxford: Clarendon Press, 1998) at 12. See also e.g. Abbyann Lynch, "Research Involving Adolescents: Are They Ethically Competent to Consent/Refuse on Their Own?" in Gideon Koren, ed., *Textbook of Ethics in Paediatric Research* (Malabar, Florida: Krieger Publishing Company, 1993) at 125.

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