Understanding Consent in Research Involving Children: The ethical Issues

A Handbook for Human Research Ethics Committees and Researchers:

Merle Spriggs
Children's Bioethics Centre

Campus Partners

THE UNIVERSITY OF MELBOURNE

Murdoch Childrens Research Institute
Healthier Kids. Healthier Future.

The Royal Children's Hospital Melbourne

Research Team

Lead Investigator: Dr Merle Spriggs
Children's Bioethics Centre
Murdoch Childrens Research Institute
PO BOX 911
Parkville, Vic. 3052, Australia.
Phone: +61 3 9090 5237
Email: merle.spriggs@mcri.edu.au
Website: http://www.mcri.edu.au/projects/ConsentInResearch/

Co-investigators: Associate Professor Lynn Gillam; Professor Colin Thomson; Associate Professor Justin Oakley

Steering Committee: Dr Helen Liley; Professor Wendy Rogers; Assoc. Prof. Jane Halliday; Assoc. Prof. Sylvia Metcalfe; Dr Craig Olsson; Dr Catherine Lees; Dr Arnold Smith; Dr Lyndal Bond; Ms Malar Thiagarajan.

Acknowledgments

Thanks for the valuable input from:

- Associate Professor Lynn Gillam
- Professor Colin Thomson
- Professor Wendy Rogers
- Dr Judith Munro
- Ms Alexandra Robertson
- Dr Catherine Lees
- Dr Craig Olsson
- Associate Professor Jane Halliday
- Ms Georgina Hall

This project is funded by a grant from the Alfred Felton Bequest which is managed by the ANZ Trustees

Table of Contents

Purpose of this Document

This handbook on consent in research involving children and young people provides guidance on:

- What is in the *National Statement*?[1] Direct quotes from the *National Statement* within shaded text boxes are in quotation marks.
- What is regarded more generally as ethically appropriate (see "basics" in the relevant sections).
- What is known to be contentious (this will be discussed under the heading of "complex issues").

This handbook together with a project website is an educational resource developed for Human Research Ethics Committees (HRECs) and researchers. The questions in this handbook are based on actual issues of concern expressed in key informant interviews with members of HRECs who review research involving children and young people and researchers who conduct that research.[2] The questions reflect ethical issues that are being encountered by researchers and HREC members and the concerns on which they seek further guidance.

This project was funded by a grant from the Alfred Felton Bequest which is managed by ANZ Trustees.

The responsibility to decide what is ethically appropriate is shared by the researcher and the HREC to which the project is submitted. It is the researcher's responsibility to decide what he or she considers is ethically sound in order to achieve the goals of the research and to provide reasons to the HREC. It is the HRECs responsibility to determine whether the research proposal meets the relevant standards, taking into account the researcher's arguments. Decisions about what is ethically appropriate research need to be justifiable by reference to the *National Statement* and can be based on other consistent guidelines. Resolution of ethically complex or ambiguous proposals can usually be worked out collaboratively. This handbook is not in itself authoritative about what will be approved. It provides guidance about what the issues are and how to understand and deal with them. As the *National Statement* points out, making ethical decisions "requires, from each individual", deliberation on values and principles of ethical conduct, "exercise of judgement, and an appreciation of context."[3]

[1] National Health and Medical Research Council, Australian Research Council, Australian Vice-Chancellors' Committee [Internet]. *National Statement on Ethical conduct in Human Research*. Canberra: Australian Government; 2007. Available from http://www.nhmrc.gov.au/publications/synopses/_files/e72.pdf
[2] Merle Spriggs. 2010. Ethical difficulties with consent in research involving children: Findings from key informant interviews. *AJOB Primary Research.* 1 (1) (In press).
[3] *National Statement* (2007), p.13.

Designing Research with Children: Frequently Asked Questions (FAQS)

1. Can a child or young person consent for him or herself without the additional consent of a parent or guardian?

Basics:

Yes, sometimes. Mature minors (adolescents who have decision making capacity) do not always require parental consent either in law or ethics.

What does the *National Statement* say?

Young people can consent without additional consent of a parent or guardian in 2 types of situations:

1. Where the young person is "mature enough to understand". See [4.2.8] for precise wording.

Or

2. Where the young person is of developing maturity, the risk of research participation is no more than discomfort, the aim is to benefit young people, and there are additional good reasons not to involve parents. See [4.2.9] for precise wording.

In the research design, researchers need to spell out how they will judge vulnerability and capacity to consent, describe proposed discussions with children, and demonstrate that the requirements of chapter 4.2 will be satisfied. See [4.2.2] for precise wording.

2. Is parental consent always needed?

No. Parental consent generally provides additional protection when a young person is not able to understand or appreciate what research entails or the young person is not willing to properly consider information, but there are also situations where seeking parental consent is (i) inappropriate or (ii) offers no protection.
For instance, (i) where parents are neglectful or abusive – however, consent from another adult might be appropriate where that adult is a person who has responsibility for the child or young person's safety, security and wellbeing, (ii) in some situations asking for parental consent may be risky rather than protective e.g. in some internet-based research that does not involve the collection of identifiable information, the act of obtaining parental consent may end up providing the researcher with additional information such as a name and address or at least a location – and the collection of this identifiable information increases the risk of breach of confidentiality to individuals. (See case 2 in case studies).

What does the *National Statement* say?

The *National Statement* does not have a definition of "guardian" or "appropriate person". There are different laws in the states and territories. [*National Statement*, page 9]

3. Is it acceptable for parents to give information about their children without their children's permission? At what age does that begin and end?

- Yes when:
  - The child is too young or does not have cognitive capacity to speak for him or herself sufficient for the purposes of the research.

  - The child's cognitive capacity will depend to some degree on the nature of the research and the questions being asked.

  - Parents may need to speak for children in some research, not because the child does not have cognitive capacity, but because information needed is about something the child would not have knowledge of e.g. information about the child's health in infancy. Nevertheless, children whose consent is not sufficient to authorize research but who are able to understand some relevant information should be included in discussions about the research and have the opportunity to say if they do not want their personal information shared

- No when:
  - Information is obtained from the parent because the parent thinks the child would be unwilling to participate, and that child has the cognitive capacity to understand some relevant information but not to consent for him or herself. In order to prevent harm and as a demonstration of respect, the child or young person's reasons for not wanting to participate should be heard.

- Although there may be less ethical difficulty in recruiting adults as proxy informants, adults are often not reliable informants about children. For some research e.g. qualitative research where the experiences of children and young people are the focus, there is good reason to work directly with children and young people.

- At what age does that begin and end?
  - No fixed age. Can only give an indication based on levels of maturity.

4. What constitutes assent and dissent?

Assent

- The **term** "assent" is not used in the *National Statement*, but is widely referred to in the research community.[4] In the US and UK guidelines it is defined as 'affirmative agreement to participate' and mere failure to object is not deemed assent. The term is established in the literature and there are some good reasons for adopting the term "assent".[5]

What does the *National Statement* say?

The *National Statement* does not use the term "assent" but refers to "consent" from young people of developing maturity whose consent is "necessary" but "not sufficient" to authorise participation. See Chapter 4.2

The guidelines also talk about engaging young children with limited cognitive capacity in discussions at their level of understanding, even though their "consent" is not required [4.2].

- The term "assent" gives recognition to the role for children that lies between no involvement in discussions and full decisional authority. There is no requirement for a signature. Some people take the view that obtaining a signature from children can detract from "the important goal of engaging the child in discussion".[6]

- Assent is not authoritative i.e. it is not sufficient to authorise participation in research.

- Assent should not be confused with informed consent, nor with autonomous decision making. Agreement can come without understanding. For example, a child can agree to a blood test but not understand the implications of the procedure. A 16-year-old who is mature enough to meet legal and ethical tests of competence gives consent, not assent.

[4] The term assent is referred to in US, UK, Canadian and New Zealand guidelines but not defined in Canadian or New Zealand guidelines. US Department of Health and Human Services. Subpart D—Additional protections for children involved as subjects in research (45CFR 46), *Federal Register*, March 8, 1983;48:9818 [Internet]. Available from http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.htm#46.402 ; Medical Research Council. Medical research involving children. Revised 24 August 2007.[Internet]. Available from http://www.mrc.ac.uk/Utilities/Documentrecord/index.htm?d=MRC002430 ; Canadian Institutes of Health Research, Natural Sciences and Engineering Research Council of Canada, Social Sciences and Humanities Research Council of Canada, Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans. 1998 (with 2000, 2002 and 2005 amendments). Available at http://www.pre.ethics.gc.ca/english/policystatement/policystatement.cfm ; New Zealand: Health Research Council of New Zealand. Ethics Reports and Guidelines. Available at http://www.hrc.govt.nz/root/Publications/Ethics_Reports_and_Guidelines.html

[5] M. Spriggs & L. Gillam. (2008). Consent in paediatric research: An evaluation of the guidance provided in the 2007 NHMRC *National Statement on Ethical Conduct in Human Research. Medical Journal of Australia.* 188(6): 360-362.

[6] Ungar, David, Joffe, Steven and Kodish, Eric. (2006). Children are not small adults: documentation of assent for research involving children. *Journal of Pediatrics*. 149(1) (supplement):S31-S33

- The underlying value of assent is respect for persons or the welfare and interests of the child.

- Child assent should only be used in conjunction with parental consent (Miller and Nelson 2006).

Dissent

- Dissent is an aspect of assent. An important function of assent is to give a child the opportunity to say no to research participation.

- Dissent occurs when the child is asked but says "no".

- If, in a particular study, a child does not have a choice and their refusal or dissent does not count, they should be told in advance.

- "Dissent" gives recognition to a child's objections and to the desire to refuse to engage in or withdraw from research.

- A child might not make an explicit request to withdraw from research but there are verbal and behavioural signs identified by child development experts (see below) that indicate when a child does not want to continue [7].

    - Behavioural indicators include:
        - passivity
        - lack of cooperation
        - fussiness
        - silence
        - crying or puckering
        - constant looks towards the door
        - lack of eye-contact with the researcher
        - signs of boredom such as multiple yawns

    - Verbal indicators include:
        - "I want to go to the toilet"
        - "I'm tired"
        - 'When will I be done"
        - Responding repeatedly to direct and age-appropriate questions with "I don't know"

References:
Miller, Victoria A., and Nelson, Robert M. (2006). A developmental approach to child assent for nontherapeutic research. *Journal of Pediatrics*. 149(1) (supplement):S25-S30

[7] Keith-Spiegel P. (1983). Children and consent to participate in research. In Melton, Gary B., Koocher, Gerald P. and Saks, Michael J. *Children's competence to consent*, New York; Plenum Press. Pp.179-211

5. What is the function of a child's assent and dissent?

Assent

- A requirement for assent protects children from psychological or other harm. Children benefit from knowing what will happen, having a say and being listened to even though they do not have decisional authority.

- A requirement for assent respects the child as a person. Part of that is to provide opportunities for children to develop autonomy. However, assent is not authoritative - it is not sufficient to authorise participation in research.

- A requirement for assent cannot be relied on as self-protection for the child (Miller and Nelson 2006).

- Assent allows children to choose to the extent that they are able (Miller and Nelson 2006).

- If children do not have a choice and their refusal or dissent does not count, we should not pretend that a requirement for assent is to provide a choice. Children need to know if they do or do not have a choice.

Dissent

- Including the concept of dissent means that children's objections and distress get taken into account even when the child is incapable of taking part in discussions or deciding.

- When the concept of dissent is recognised, it is more likely that the harm of overriding a child's preference will be included in the calculation of benefit and harm.

- Dissent does not function only at the point of enrolment. Dissent can be about a child wanting to withdraw from research.

Given that the *National Statement* does not use the terms assent and dissent, Australian researchers should interpret this advice as a way to clarify the issues. It might help distinguish different senses of consent which are used in the chapter on children and young people in the *National Statement*.[8] It also directs researchers attention to the importance of considering specifically the **child's willingness to participate in addition to parental consent.

[8] M. Spriggs & L. Gillam. (2008). Consent in paediatric research: An evaluation of the guidance provided in the 2007 NHMRC *National Statement on Ethical Conduct in Human Research. Medical Journal of Australia.* 188(6): 360-362.

References:
Botkin, Jeffrey, R. (2003). Preventing exploitation in pediatric research. *American Journal of Bioethics*. 3(4):31-32

Joffe Steven (2003). Rethink "affirmative agreement," but abandon "assent", *American Journal of Bioethics*. 3 (4): 9-11

Miller, Victoria A., and Nelson, Robert M. (2006). A developmental approach to child assent for nontherapeutic research. *Journal of Pediatrics.* 149(1) (supplement):S25-S30

6. For how long is a parent's consent sufficient to authorise a child's continued involvement in long-running research?

What does the *National Statement* say?

Where "projects are complex or long-running, or participants are vulnerable" consent may need to be "renegotiated or confirmed" so that research participants are "given the opportunity to continue their participation or withdraw" [2.2.8]. This practice takes account of children and young people's increased level of understanding which may or may not alter their willingness to continue in the research.

For a parent's consent to be sufficient to authorise research, it must be informed and voluntary, and the parent must have an understanding of the implications of the proposed research and of participation in it [See Chapter 2.2. General requirements for consent].

In terms of the length of time that a parent's consent is sufficient to authorise research without input or with some input from the child or young person, it would be a good idea for researchers to specify and HRECs to approve the length of time after which consent will be renegotiated or confirmed. This may depend on the duration of the project and the age of the participants e.g. it could be proposed that children enrolled by their parents at a very young age in a longitudinal study could be asked for their assent at particular developmental levels e.g. around 13 years old, 16 years old and for their consent at 18 years. Re-consenting at 18 years would be legally necessary if it has been done earlier because the young person is now legally an adult – parental consent is no longer legally operative. In this situation, proceeding without seeking new consent amounts to proceeding with no consent. Of course, children and young people can also withdraw at any time they choose. [Although the *National Statement* relies of levels of maturity, for practical reasons it would make sense to nominate ages or length of time for the purpose of re-consenting children e.g. re-consent child every 2 or 3 years to take account of changes in the level of maturity].

7. Is it acceptable to offer or pay money or incentives of any kind to children and young people?

What does the *National Statement* say?

The *National Statement* does not refer to payment or incentives at all in the chapter on children and young people. More generally it says:

- Information on payments to participants should be communicated to participants [2.2.6 (j)]. The suggestion in 2.2.6 seems to be that this information should be included with essential information necessary for a person's voluntary decision to participate. Where children and young people are concerned, it is important for information about payment to be distinct from information on potential benefits. Children and young people should not look upon payment or incentives as a benefit of the research.

The *National Statement* distinguishes between reimbursement and payment.

- "It is generally appropriate to reimburse the costs to participants of taking part in research, including costs such as travel, accommodation and parking. Sometimes participants may also be paid for time involved. However, payment that is disproportionate to the time involved or any other inducement that is likely to encourage participants to take risks, is ethically unacceptable" [2.2.10]. The guidance on reimbursement is not that helpful where children and young people are involved. It is likely to be parents who are reimbursed e.g. for parking and time involved. The guidance on payment is of specific importance to children for whom payment of any kind may be persuasive for them to take risks that they do not understand.

- Issues about incentives only arise when cash/valuables over and above reimbursement of expenses are offered.

- Incentives are acceptable except when they lead participants or those deciding for them to ignore or significantly undervalue serious risks.

  This means that participants must be able to appreciate the risks involved. If children and young people do not or are unable to appreciate the risks, there are two other levels of protection that can come into play:

  i. The requirement for parental consent is meant to ensure that risks are not ignored or undervalued; and
  ii. HRECs should not approve research involving incentives and serious risks where some parents may be enticed to ignore or undervalue the serious risks.

- Small incentives to improve recruitment levels are ethically acceptable where research involves low risk or negligible risk (i.e. no more than discomfort). In research that involves more than low risk, small incentives paid to children and young people to encourage sufficient enrolment may also be ethically acceptable

if (a) parent's give their permission and (b) an HREC thinks the research is valuable and that the level of incentive, while boosting recruitment, is not such that it would cause subjects to ignore or undervalue the risks.

- It is imperative that risks are identified and potential participants/families are scrupulously informed of the risks.

- Offering incentives to secure the involvement of children and young people in risky research is likely to be viewed as exploitative, undermining public trust in and support for research involving children and young people.

- Nondisclosure about offers of cash, movie tickets or iTunes vouchers until a child's participation in research is completed is a common practice. The reasoning behind this is to avoid the potential to distort decision making about participation. However, if this becomes widely known, participants may assume they will be offered some incentive – so this practice does not totally deal with the problems of incentives for children.

Complex issues:

- **Payment to homeless adolescents.**

This could be problematic. Homeless adolescents are likely to be in need of money which may encourage them to ignore or undervalue risks. Researchers, therefore, need to make an argument why payment to homeless adolescents is acceptable – why payment will not lead to harm to the participant.

- **Payment to youth with substance abuse problems**

Payment sometimes happens but it is controversial because: (i) they will use the incentive (whether cash or something they can sell) to buy drugs and engage in self harm; also, (ii) addiction or substance abuse will interfere with decision-making. Researchers need to make an argument why incentives or payment will not lead to harm to the participant.

- **Parents "bribing" children.**

Researchers may be aware that parents are bribing children with incentives and rather than confronting parents, researchers should not go ahead if the child is clearly unwilling.

References:
Appelbaum Paul S., Lidz Charles W. And Klitzman Robert. 2009. Voluntariness of consent to research: A conceptual model. *Hastings Center Report* 39(1):30-39.
Friedman Ross, Lanie. 2006. *Children in medical research*. Oxford: Clarendon Press. Ch 7.

8. Is it acceptable to involve children in research if they won't directly benefit?

What does the *National Statement* say?

The *National Statement* indicates in a number of places that it can be acceptable to involve participants where there is no direct benefit. See [1.6] and [1.8].

The chapter on children does not indicate anything different for children. It simply says there must be "no reason to believe" that participation is "contrary" to the child or young person's "best interests". See [4.2.13]

Yes, it can be acceptable, but it depends on the relative risks and benefits. It must be intended to benefit children as a population. And the risk must be acceptably low, or non-existent. An example where it is acceptable is taking extra blood during diagnostic or treatment procedures for legitimate research purposes. While there is no direct benefit for a child, there is also no additional risk or discomfort over and above the treatment procedure they are undergoing.

Reference:
Nicholson R. *Medical research with children: Ethics, Law, and Practice*. 1986. Oxford University Press, Oxford.

Further reading:
Advisory Committee on Human Radiation Experiments. 1995. Final Report. Chapter 7 Non-therapeutic research on children. Available at http://www.hss.energy.gov/HealthSafety/ohre/roadmap/achre/index.html

9. How much should children be told about the research when they are not the ones giving consent?

As much as they can understand.

The following are some of the reasons for giving information to non-competent children in the research context:

- It is psychologically good and less frightening for children to know what to expect.
- To preserve the child's trust in parents, health care professionals and the research enterprise.
- The disclosure of information allows the child to co-operate.
- Informing children in an appropriate way about the nature of the research demonstrates respect and allows children to express an opinion about whether or not they want to participate
- It demonstrates respect for the child. Respect is not dependent on decision-making competence.

Reference:
Spriggs, Merle & Gillam, Lynn. Deception of children in research. [Forthcoming].

10. Is opt-out consent ever okay?

- First of all, it is important to be clear about what is meant by "opt-out" consent. To implement "opt-out" consent, means that a person will be included by default unless they chose to "opt-out." The default option should not preclude other choices.

- Examples of opt-out consent:

    - A group of senior high school student visiting a museum are told that their written comments on the visit will be used for research purposes, unless they tick the box indicating that they do not want this to happen.

    - Parents of a child with cancer are told that leftover tissue from their child's diagnostic tests may be used for research purposes unless they tick the box indicating that they do not want this to happen.

What does the *National Statement* say?

- The term "opt-out" consent is not used in the *National Statement*. Nevertheless, it is a term that is in current use and one that came up in a number of the key informant interviews with researchers and with HREC members.
- Although it does not use the term, the *National Statement* implies that an "opt-out" form of consent could occur in a school based setting. See section [4.2.10 to 4.2.12]. Parents can give "standing consent" (for example at the beginning of each school year) to their child's involvement in certain types of research. They are notified of each project and can withdraw consent for a project or for their standing consent at any time. The aim seems to be to facilitate low risk, beneficial research. The ethical risk is that some children may be included whose parents don't want them involved in a particular study e.g. where information does not reach the parent. There is a lack of clarity in the idea of "standing parental consent". It is not clear what sort of consent (opt-in or opt-out) is required at the start of the year.

Things to consider about opt-out consent:

- Is choice preserved? Is there really an option to "opt-out"? If not, it would seem to be something other than "opt-out" consent. Is a request for an "opt-out" option really a request for a waiver of consent in disguise? Opt-out consent and a waiver of consent are very different because a waiver of consent actually means that no consent is given, whereas opt-out is a different method of giving consent.

- Researchers want to use opt-out consent as a default option because it works to increase the consent rate. It is less costly and time consuming. Opt-out consent can assist in making outcomes of a project more reliable because of greater numbers and less selection bias.

- However, opt-out consent is ethically risky because it relies on inertia or inattention rather than fostering autonomy. [9] The risk is that people will participate without understanding or really wanting to. It is therefore incumbent upon researchers and HRECs to ensure that the use of opt-out consent is ethically defensible.

Reference:
Halpern S. D., Ubel P. A and Asch D. A. 2007. Harnessing the power of default options to improve health care. *New England Journal of Medicine.* 257 (13): 1340-1344.

[9] Halpern S. 2007. Halpern S. 2008. [Conference presentation] Default options and the ethics of opt-out HIV testing. American Society for Bioethics and Humanities (ASBH) 10th Annual Meeting, Cleveland, Ohio, USA.

11. How can we make sure that existing power relationships don't impact on the consent process of children and young people?

What does the *National Statement* say?

There is some guidance in relation to parental consent in the chapter on 'people highly dependent on medical care who may be unable to give consent' [4.4] especially in relation to neonates in intensive care. There is also some guidance in the chapter on "people in dependent or unequal relationships" which deals with relationships such as teachers and students [4.3].

The guidelines suggest that steps should be taken to minimise the risk that the parent's decision to participate is compromised by their dependency on medical personnel. See [4.4.11.b].

Where the researcher has a pre-existing relationship with the potential participants or is also the treating doctor, the guidelines suggest an independent person make the initial approach and/or seek consent. See [4.3.9 and 4.4.12].

Suggestions for minimising the effect of power relationships:

- Spell out in an explicit way to children that they can say no, how they can withdraw from research and that the person conducting the research will not be upset e.g. "If you want to stop answering questions, all you have to do is say 'I'd like to stop,' or 'I don't want to answer that question.' I will not be mad or sad if you decide to stop"[10]

- Research in the education setting. Researcher/teachers should be clear about:

    - What happens if a child or young person does not want to take part in or withdraws from research? Do they leave the classroom? Where do they go? What do they do?

[10] Hurley, J.C. and Underwood M.K. (2002). Children's understanding of their research rights before and after debriefing: Informed assent, confidentiality, and stopping participation. *Child Development*. 73 (1):132-143. P.142

Difficult Issues Encountered in Carrying out Research

Issues that researchers might not think about, or question, until they occur during research:

12. Can a parent ask to know what their child said on a survey?

- There are strong ethical reasons why parents should not have access to what their child says on a survey.
    - Children may be harmed (they may be embarrassed, they may even be punished) if their confidentiality is breached.
    - Children's trust in research and researchers may be harmed if their responses are not kept confidential.
    - The validity of the data could be compromised if children and young people think that it will not be kept confidential e.g. their responses may be guarded or they will respond with what they think adults want to hear. (There is some empirical research that suggests this is what children may believe anyway [Hurley & Underwood]).
    - Children and young people may not agree to participate if confidentiality cannot be guaranteed with the result that valuable research will be harder to do or will not get done at all.
    - In order for valuable research to get done, it is essential that there is confidentiality and that researchers know that the confidentiality they have set up cannot be impinged upon.[11]
- Generally, the children of parents who are not willing to give consent on the basis that they will not see their child's response, should not participate.
- If HRECs and researchers think there is good reason for parents to be able to see answers if they want to, they should make sure that the child knows and understands what the ground rules are.

[11] Parkinson Patrick (2002). Research and promises of confidentiality to children, *Australian Journal of Family Law* 16 AJFL 1: 2-3

- There are other ways to address a parent's desire to see what their child says in a survey:

    - Parents can view questionnaires prior to giving consent but not have access to their child's response.

    - Parents who ask to see responses to surveys (e.g. experiences with bullying) should be encouraged to initiate discussions with their children outside of the research setting. Researchers can assist in protecting children's privacy by providing parents with guidelines on how to approach such sensitive topics with their children (Yuile et al.pp.74-75)

- If a parent asks to see responses to a survey, the researcher should refer the matter to the HREC. Researchers should not give out information to parents in the first instance.

References:

Hurley, J.C. and Underwood M.K. (2002). Children's understanding of their research rights before and after debriefing: Informed assent, confidentiality, and stopping participation. *Child Development*. 73 (1):132-143

Yuile, A., Pepler, D., Craig, W. and Connolly J. (2006). The ethics of peeking behind the fence: Issues related to studying children's aggression and victimization , In Leadbeater, B., Banister, E., Benoit, C., Jansson, M., Marshall, A. and Riecken T. (2006). *Ethical issues in community-based research with children and youth.* Tonronto: University of Toronto Press. Pp. 70-89

Parkinson Patrick (2002). Research and promises of confidentiality to children, *Australian Journal of Family Law* 16 AJFL 1: 2-3

Cashmore Judy. (2006). Ethical issues concerning consent in obtaining children's reports on their experience of violence, *Child Abuse & Neglect* 30(9): 969-977

13. Do parents have the right to limit information to their child?

This is relevant where the parents consent, but information is provided to the child for the purpose of the child's assent. For example, researchers may give a child a simplified version of the plain language statement.

What does the *National Statement* say?

The *National Statement* says nothing about limiting information to children and young people but there is general guidance on "limited disclosure" in the chapter on "qualifying or waiving conditions for consent." See [2.3.1 – 2.3.4].

The *National Statement* has nothing to say about the special situation that exists with parental permission and child assent and to whom information should be provided in the context of research involving children.

- Some reasons for limiting information are acceptable and some are not?

  Acceptable reasons:

  To promote understanding. Not disclosing all of the aims and methods of a research project to very young children is understandably a somewhat common practice. Young children may have limited understanding, so limiting information can promote understanding.

  Unacceptable reasons:

  When it is intended to hide something from the child which the researchers intended to disclose under the HREC approved protocol.

- As participants, parents do not have the authority to override the requirements of ethically approved research. When the child's limited understanding is not the issue and parents say that they do not want their child to be given certain information about a study, the best solution is not to include that child in the study. If the reason that we give children information is so that they have a meaningful choice and as a demonstration of respect, withholding information or misrepresenting the nature of research is not acceptable unless there are good reasons which stand up to scrutiny.

Reference:
Spriggs M. & Gillam L. Deception of children in research [Forthcoming].

14. Is it acceptable for researchers to limit information?

Researchers may wish to limit the information about the project that is given to:

(a) parents consenting on behalf of young children;

(b) young people consenting for themselves;

(c) older children whose assent is being asked for.

What does the *National Statement* say?

The *National Statement* says nothing about limiting information to children and young people but there is general guidance on "limited disclosure" in chapter 2.3.

"Limited disclosure" is said to cover a "spectrum" from "not fully disclosing or describing the aims or methods of observational research in public contexts, all the way to actively concealing information and planning deception of participants.

Limited disclosure may be **acceptable** where the research "involves no more than low risk to participants"; potential benefits justify both the limited disclosure and "any risk to the community's trust in research and researchers"; and, "the precise extent of limited disclosure is defined".

Limited disclosure is **not acceptable** where there is reason "for thinking that participants would not have consented if they had been fully aware of what the research involved"; there is a suitable alternative involving fuller disclosure; or, participants are exposed to an increased risk of harm as a result of the concealment or deception. For precise wording and the full list of conditions see [2.3.1 and 2.32].

- Limiting information is not acceptable without good reason. Examples of what constitute good reasons are given in the *National Statement* and listed above.
- Reasons for limiting information must be clearly articulated to the HREC because of the interest that researchers have in recruiting subjects and the reasons must stand up to scrutiny.
- Increased recruitment in itself is not an acceptable reason to limit information.

Reference:

Spriggs M. & Gillam L. Deception of children in research [Forthcoming].

15. What should a researcher do in a situation where a child or young person seems to be agreeing to participate without paying attention to the information that is being provided to them?

Where the young person is of developing maturity and is giving assent

- This kind of situation shows how parental consent acts as a kind of safety net when a young person has not thought much about the implications of taking part. It may be helpful if the researcher raises their concern with the parents before proceeding.

Where the young person's consent on its own is sufficient to authorise participation

- Where approval has been given by an HREC for research for which only the young person consents, the researcher is obliged to provide as much information as is required to enable the young person to provide informed consent. If the young person cannot give consent that is sufficiently informed, they cannot take part. This is the same consideration as for adults being asked to consent. If the project is low risk (no more than discomfort), it may be reasonable to continue and recruit the young person even if the researcher does not think that they have thought their decision through. If it is higher risk, it may be better to err on the side of safety and not include this young person.

- If the young person is included, the researcher should be on the lookout for signs that the young person does not really want to be involved (behavioural indicators such as constant looks towards the door, lack of eye-contact with the researcher and multiple yawns and verbal indicators such as "I'm tired", "When will I be done")[12] and be prepared to stop.

[12] Keith-Spiegel P. Children and consent to participate in research. In Melton G., Koocher G. P. and Saks M. J. *Children's competence to consent*. New York: Plenum Press. 1983. Pp. 179-211: p.197

Specific types of research

Genetic research

What does the *National Statement* say?

There is a chapter devoted to human genetics which includes guidelines on family involvement, community involvement, other information to be given and confidentiality. See chapter 3.5. See sections 3.5.6 and 3.5.8 for main implications and risks posed by genetic research.

This chapter contains no reference to children and young people and there is no reference to genetic research in the chapter on children and young people.

Further guidance of a general nature can be found in Chapter 3.2 Databanks – which applies to genetic research using stored data; and Chapter 3.4 Human Tissue Samples – which applies to genetic research using human tissue samples. These chapters also, contain no specific reference to children and young people.

There is some guidance in the chapter on "general requirements for consent" e.g.:

- Where projects are complex or long running, consent may need to be "renegotiated or confirmed". See [2.2.8]
- "Consent to future use of data and tissue in research" may be classified as "specific", "extended" and "unspecified". See [2.2.14] for precise definitions, procedures and implications of these types of consent.

Points to consider:

- How long will the child or young person be involved in the research? If the time period encompasses changing level/s of maturity, re-consent is ethically required. It is possible that increased understanding that comes with increased cognitive capacity may alter the young person's willingness to remain in the research.

- Genetic research might involve **just "spitting in a cup"** and this might be all that a very young child can understand and agree to. In that case, it is ethically appropriate to proceed as long as parents understand the implications and parental consent has been given. Older children who are capable of understanding need to know **more than what is involved** in giving a genetic sample or genetic information. They need to know the **implications and risks** of participating in the research e.g. the possibility of stigmatisation, discrimination etc. Increasing cognitive capacity highlights the need for re-consent when participation is for an extended period of time.

- Is the child or young person likely to face pressure from family members to participate? If yes, the researcher should consider how this could be managed. For example, the setting in which the young person's consent is sought might be changed.

More complex issues in genetic research: Some implications and risks which need to be understood for fully informed consent.

- **When individual test results are disclosed:**

  - Do young people and parents understand that, compared to clinical genetic information, individual research results "are likely to be much more uncertain, ambiguous, and may involve tests which have not been clinically validated"? (Patenaude, Senecal & Avard, 2006).

  - When testing for disease-susceptibility or for complex traits or behaviours, what is the prevalence and penetrance of a gene and to what extent is the gene associated with other effects? Does the child or young person (and parents) understand that a single gene can be associated with more than one effect (pleiotropy) and the possible implications (eg. anxiety, increased risk of stigma and discrimination) when genetic test results in research are disclosed?

  - Do young people and parents understand the difference between association and causality? That is, do they understand that the gene mutation might not actually cause the phenotype.

- **Gene-based prevention trials:**

  - Have the benefits, risks and implications of the disclosure of test results in gene-based prevention trials been (i) identified by researchers; (ii) disclosed in the consent process; and (iii) understood by children and parents?

  - If the implications are not understood, the intention of promoting healthy behaviour could actually lead to harm. [4.2.14].Gene-based smoking prevention trials illustrate this point. Adolescents who are told they have a genetic risk of nicotine addiction might feel there is no point in trying to quit while those who are told they do not have a genetic risk might mistakenly think they can smoke without risk (Geller, 2005).

References:

Burke W. and Diekema D. S. 2006. Ethical issues arising from the participation of children in genetic research. *The Journal of Pediatrics* 149:S34-S38

Cooper, Zachary, N., Nelson, Robert M. and Ross, Lanie F. (2006) Informed consent for genetic research involving pleiotropic genes: An empirical study of ApoeE research. *IRB: Ethics & Human Research.* September-October 28(5):1-11

Geller G. 2005. The ethics of predictive genetic testing in prevention trials involving adolescents. In Kodish, E. (2005). *Ethics and research with children*. Oxford: Oxford University Press, pp. 194-220

Patenaude, Andrea Farkas, Senecal, Karine and Avard, Denise. (2006). Whither pediatric research and predisposition genetic testing. GenEdit 4(2): 1-9.

Clinical research

If a young person is deemed competent to consent to treatment for a particular condition, does that mean that they are automatically competent to consent to research in that context?

No, not necessarily:

- **Research and treatment are different**. They have different objectives, procedures and justifications. There is also a different risk/benefit ratio. The goal of treatment is always the benefit of the patient, so that any risks involved in treatment can be expected to be monitored carefully and personally and there will be no ethical interest that will compete with changing treatment whenever that is seen to be for the patient's best interests. The goal of research is the discovery of knowledge and, although researchers do have ethical responsibilities for the welfare of participants, that welfare is not the researcher's primary responsibility and there will always be a competing ethical interest (namely the completion of the research) that can compete with the care of participants. Therefore, it cannot be assumed that consent in the research setting is ethically equivalent to consent in the clinical setting.

- **A decision to participate in research can be more complex and require a greater level of competence and understanding**. Risks can be greater in research or more uncertain because of the experimental context. The fact that the effectiveness and safety of a drug or intervention is not known means that the risks are, to an important extent, unknown and so may be greater than in treatment with an established drug or intervention.

- **Giving young people independent access to treatment does not in itself indicate a particular level of competence.** It is often assumed that independent access necessarily means that the young person is competent. This might be the reason for giving access, but it could also be to protect from harm. Independent access could be a public health response "designed to encourage adolescents to seek health care for problems which they might deny, ignore, or delay if they had to inform their parents and/or get parental permission".[13]

  It is a common mistake to assume that parental consent is not needed because young people can consent to other activities. For instance, Kelly and Halford (2007) argue that 16-year-olds in Australia have the "maturity and capacity" to make an "informed decision" because they can legally consent to sexual intercourse (and deal with risks such as unwanted pregnancy and/or sexually transmitted disease). Based on this, they conclude that the same 16-year-old's consent should be adequate "to fill in a form reporting anonymously on their sexual behavior." [14] Their view that parental consent is not needed may be appropriate but the reasons are wrong. Consenting to sexual intercourse is not the same

[13] Friedman Ross, Lanie. (2006). *Children in medical research*. Oxford: Clarendon Press. Pp.92-3
[14] Kelly A. B. and Halford W. K. (2007). Responses to ethical challenges in conducting research with Australian adolescents. *Australian Journal of Psychology*. 59(1):24-33. p. 26

as consenting to involvement in research. Reasons matter. Mistaken reasons can lead to an ethically inappropriate conclusion.

References:
Friedman Ross, Lanie. (2006). *Children in medical research*. Oxford: Clarendon Press. Chapter 5 – see section on parental waivers.

Hunter, D & Pierscionek, B.K. (2007). Children, Gillick competency and consent for involvement in research. *Journal of Medical Ethics*. 33(11):659-662.

Internet-based research

What does the *National Statement* say?
Internet-based research is referred to as "on-line research" in the *National Statement*. Some methods of on-line data collection are outlined in the section on qualitative research. See [3.1]

According to the *National Statement*, some internet-based research seems to be exempt from review on the basis that it is simply collecting material that is in the public domain. Working out if research is exempt seems to entail some form of review. In deciding to exempt research from ethical review, institutions "must recognize" that they are "determining that the research meets the requirements of the *National Statement* and is ethically acceptable [5.1.23]. Researchers are also required to "keep an auditable record of any research he or she is undertaking that is exempted from ethical review in accordance with paragraphs 5.1.22 and 5.1.23" and institutions are required to make "publicly accessible (for example in annual reports) summary descriptions of all its research projects for which consent has been waived" [2.3.8]. Given this, and the potentially contentious or sensitive nature of some internet research, institutions may decide it is preferable to require HREC review.

Guidance
Apart from general guidance on consent in research involving children and young people [4.2], the *National Statement* has nothing specific to say about internet-based research on or with children. There is some general guidance to be found scattered throughout various parts of the Statement e.g. in the sections on risk [2.1] , on qualitative methods [3.1], institutional responsibilities [5.1], and in the chapters on qualifying or waiving conditions for consent [2.3], and responsibilities of HRECs, other ethical review bodies, and researchers [5.2].

- The following classification of potential harms and assessment of risk seems to be particularly relevant to internet based research:
    - Physical harm is not the only kind of harm research subjects are exposed to. Other potential harms include:
        - psychological harms: including feelings of worthlessness, distress, guilt, anger or fear related, for example, to disclosure of sensitive or embarrassing information ...
        - devaluation of personal worth: including being humiliated, manipulated or in other ways treated disrespectfully or unjustly;
        - social harms: including damage to social networks or relationships with others; discrimination in access to benefits, services, employment or insurance; social stigmatisation ...
        - economic harms: including the imposition of direct or indirect costs on participants;
        - legal harms: including discovery and prosecution of criminal conduct [2.1]

Assessing the ethical acceptability of risk includes:

- Identifying the risks, if any
- Assessing the likelihood and severity of the risks
- Identifying whom (participants and / or others) the risks may affect
- Establishing the means for minimising risks
- Identifying the potential benefits
- Identifying to whom benefits are likely to accrue [2.1.3].

Before deciding to waive the requirement for consent, an HREC or other review body must be satisfied that : Involvement carries no more than low risk [2.3.6 (a)]; It is impracticable to obtain consent [2.3.6 (c)]; There is no known or likely reason for thinking that participants would not have consented if they had been asked [2.3.6 (d)]

- **Is consent needed?**

  - Researchers generally do not need consent to use information that is in the public domain - but what is public and what is private on the internet is not so clear and the immature judgment of some young people may mean that a distinction between public and private is not meaningful. Some young people may not seem to be concerned about their privacy but this may be due to a lack of maturity, understanding and imagination. Recent research findings show that young people can be "somewhat naive" about the appropriateness and the "potential negative consequences" of the information they post on social networking sites.[15] Added to this, are the difficult issues around consent in research involving children and young people.

  - If information is potentially identifiable, consent is probably needed. Identifiable information increases the risk of harm to individuals through identification. If there is no identifiable information, consent may not be needed. But, arguably, it is better to err on the side of safety and obtain consent.

  - A decision to forgo consent should be clearly articulated and justified in terms of the nature of the study (method of data collection etc.) and the level of risk. A case can be made in terms of the requirements for a waiver of consent [2.3.5 – 2.3.8] An example is content analysis – simply counting instances of something. Privacy is sufficiently protected because names, identities and original messages have no bearing. There is unlikely to be any risk of harm to individuals through identification.

[15] J. Peluchette & K. Karl. Social networking profiles: An examination of student attitudes regarding use and appropriateness of content. *CyberPsychology & Behavior* 2008; 11(1):95-97: 96

- **Is parental consent needed in addition to a young person's consent or agreement to take part?**

    - Parental consent is not ethically required in all internet-based research involving young people. As discussed earlier, some young people may have capacity to consent for themselves.

    - Parental consent may be needed when information is potentially identifiable. Identifiable information makes risks to individuals higher and may mean that the safety net of parental consent is preferable.

    - There is also a need to consider whether seeking parental consent would make things worse e.g. by putting a young person from a dysfunctional home at risk or result in disclosure to the researcher of additional identifying information about the identity and location of the young person. Parental consent may be "contrary to the best interests" of the child or young person when it offers no protection or makes matters worse.

    - Researchers need a clear plan and HRECs have to be satisfied that the procedures set up to obtain and validate young person's informed and voluntary agreement to participate are sufficient and appropriate in the circumstances.

    - Note: Before planning a project using a social networking site, researchers might want to consider the site's terms and conditions which in the case of MySpace, apply to Members and to Visitors (who simply browse the MySpace website).[16] Terms and conditions may have relevance to researchers.

      For instance:

        - MySpace can reject, refuse to post or remove postings, suspend or terminate access to MySpace Services if the agreement is violated or if a User is perceived as a threat to MySpace or its Users.

        - If you recruit by having your own MySpace profile and MySpace believes that you are incorrectly representing yourself as being under 18, MySpace can delete your profile and terminate your membership without warning.

        - MySpace "reserves the right" to "investigate", terminate membership and "take appropriate legal action" against anyone who: "solicits personal information from anyone under 18"; posts content that "contains restricted or password only access pages"

[16] MySpace Terms & Conditions. February 28th, 2008. Available at: http://www.myspace.com/index.cfm?fuseaction=misc.terms (Accessed 7th May 2009)

- **If the internet is a public space, can research be done without consent?**

  - On the internet, the distinction between what is public and what is private is much less clear than in other places (e.g. newspapers) and is not a useful indicator of the need for consent.

  - Research suggests that young people think of their communication on the internet as 'private' when it is not seen or read by people such as parents and teachers – regardless of who else sees it.[17]

  - It is safer not to rely on the idea that the internet is a public space to justify not seeking consent.

References:

Spriggs Merle. 2009. Consent in cyberspace: Internet-based research involving young people. *Monash Bioethics Review,* 28; (4): 32.1 – 32.15.

Eysenbach Gunther, Till James E. (2001). Ethical issues in qualitative research on internet communities, *BMJ.* 323: 1103-1105 Charles Ess and the Association of Internet Researchers

(AoIR) ethics working committee. (2002). Ethical decision-making and internet research: Recommendations for the AoIR ethics working committee. Approved by AoIR, November 27, Available online: [link: www.aoir.org/reports/ethics.pdf]

Frankel, M. S. & Siang, S. (1999). Ethical and legal aspects of human subjects research in cyberspace, Available at: http://www.aaas.org/spp/sfrl/projects/intres/main.htm]

Moreno, Megan A., Fost, Norman C., and Christakis Dimitri A. (2008). Research ethics in the MySpace Era, *Pediatrics*. 121 (1): 157-161

Bruckman Amy (2002). Ethical Guidelines for Research Online, Available at http://www.cc.gatech.edu/~asb/ethics/

Kitchin Heather A. (2003). The Tri-Ccouncil policy statement and rresearch in cyberspace: Research ethics, the internet, and revising a 'living document'. *Journal of Academic Ethics*. 1:397-418

[17] Stern Susannah R. (2004). Studying adolescents online: A consideration of ethical issues, pp.274-287., In Elizabeth A. Buchanan. Readings in virtual research ethics: Issues and controversies. Hershey PA: Information Science Publishing. P.277