Case studies:
Questions & Comments

Understanding Consent in Research Involving Children: The ethical Issues

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Table of Contents

Purpose of this Resource

This resource provides guidance on thinking through ethical issues in research involving children and young people and presents some models for best practice. Some cases will be easy and some will be hard. It is intended that there will be some contrasts.

The cases could be used for training Human Research Ethics Committees (HRECs) and in research ethics education for researchers who are going to conduct research with children.

Some cases are real, some are based on real life cases and some are fictitious. They are labelled accordingly.

Cases are designed to raise issues for deliberation by Human Research Ethics Committees and researchers in situations in which they have not found sufficiently clear guidance in the *National Statement*. Any guidance provided in this resource is meant to build on the *National Statement.*

We welcome new case studies to add to this resource. To add a case, email merle.spriggs@mcri.edu.au

Note –The term "assent" is not used in the National Statement, but it is widely referred to in the research community and it is established in the literature. We use the term here to signify the role for children that lies between no involvement in discussions and full decisional authority.[1]

[1] 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.

CASE 1

[Fictitious case]

Adolescent invited to take part in research without parental consent: Consent to research versus consent for other activities.

A 14-year-old youth suffering depression does not want to discuss his problems with his parents. He seeks help from a community health centre. On his first visit he is provided with counselling and asked to return for a second visit where the possibility of medication will be discussed. He is reassured that his parents do not have to be involved if he does not want them to be. Researchers from the centre are looking for people to take part in a study that will find out if a new investigational drug can help in the treatment of depression. They invite the fourteen year old to participate in the randomised controlled trial. The researchers say that parental consent is not needed for the 14-year-old to access treatment so they do not need to obtain parental consent for him to participate in the research.

Questions:

1. Is the researchers' view correct?

Comments:

The researchers view is not correct here. Allowing independent access to treatment by the 14-year-old is not in itself an indication of his competence. It does not mean that his consent is sufficient to authorise participation in a randomised controlled trial of an experimental drug. There are three reasons why the researchers' reasoning is not right:

i. **Research and treatment are ethically different**. They have different objectives, procedures and justifications. The goal of treatment is always the benefit of the patient. Any risks involved in treatment can be expected to be monitored carefully and individually 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. Although researchers do have ethical responsibilities for the welfare of participants, that welfare is not the researcher's primary responsibility. 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.

ii. **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 the drug 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.

iii. **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".[2]

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." [3] Their view that parental consent is not needed is appropriate but the reasons are wrong. Consenting to sexual intercourse is not the same as consenting to involvement in research. Reasons matter. Mistaken reasons can lead to an ethically inappropriate conclusion.

2. Does it depend on the nature of the research?

Comments:

Yes, it depends on the nature and complexity of the research [4.2 Intro]

The 14-year-old's consent alone may be adequate to allow participation in a different study in which the decision to take part requires understanding of less complex information, and/or consideration of less significant consequences – for example, an anonymous questionnaire about the user friendliness of the clinic where there is no medical or privacy risk.

[2] Friedman Ross, Lanie. (2006). Children in medical research. , Oxford: Clarendon Press. Pp.92-3
[3] 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

CASE 2

[Fictitious case]

Consent issues in research involving MySpace

Sixteen-year-old Sophie has chosen the option to set her MySpace profile to public viewing. She has filled in the 'about me', and 'I'd like to meet' areas of her profile and has included requests to 'E-mail me'. Her profile is intentionally constructed in the hope of receiving feedback from those who view it.

A researcher is conducting a study on bullying at school and young people's experience of it. He is recruiting and collecting data via the internet from children and young people aged 12 to 16. In the first stage of the study he proposes to collect data from what is posted on Sophie's MySpace site without Sophie's consent and without parental consent. In the second stage of the study, the researcher plans to post/email questions for Sophie to answer i.e. to generate new data. The researcher will sign up as Sophie's friend and then, if accepted, will post questions for her to answer, without making clear that this is research.

Questions:

<u>First stage of project:</u>

1. Is Human Research Ethics Committee (HREC) approval needed?

Comments:

*This is a new research area. There are no detailed or universally accepted ethics guidelines.

In the *National Statement*, internet-based research fits the description of human research. Research is an "investigation undertaken to gain knowledge and understanding" and human research is "research conducted with or about people, or their data." [4] Institutions are required to see that any human research they conduct or for which they are responsible is "ethically reviewed and monitored in accordance with the *National Statement*" [5.1.1.(b)]. However, research that "is negligible risk research" and "involves the use of existing collections of data or records that contain only non-identifiable data about human beings" can be exempted from review [5.1.22]. According to the *National Statement*, in deciding to exempt research from ethical review, institutions "must recognise" that they are "determining that the research meets the requirements of the *National Statement* and is ethically acceptable [5.1.23]. Researchers are required to

[4] 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 p.101 and p.3.

"keep an auditable record of any research" they are "undertaking that is exempted from ethical review in accordance with paragraphs 5.1.22 and 5.1.23" [5.1.8]. And, institutions are to "make publicly accessible summary descriptions of all research projects for which consent was waived e.g. in its annual report" [2.3.8] While not conclusive, this implies a need for HREC review.

The definition of what constitutes human subject research may be different in other countries e.g. Canadian regulations[5] and U.S. regulations.[6] Some have argued that under U.S. and Canadian regulations, internet-based research is exempt from Institutional Review Board (IRB) or ethics committee review. For example, under Canadian regulations, research "based exclusively on publicly available information, documents, records, works, performances, archival materials or third-party interviews, is not required to undergo ethics review."[7] Another view is that internet-based research moves into a human subject paradigm "when engaging active analyses, where researchers participate in communications; or when researchers identify themselves and gather information through online communications."[8]

A lack of applicability and clarity in the various guidelines suggests a need to update the various guidelines or develop universal guidelines for internet-based research, especially the combination of internet-based research and young people.

2. Can the researcher use content from Sophie's MySpace profile without Sophie's consent?

Comments:

This is contentious. There are different views:

- Consent is needed
- Consent is not 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

[5] 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). Research requiring ethics review http://www.pre.ethics.gc.ca/english/policystatement/section1.cfm#1A Article 1.1.c (Accessed 23 April 2009)

[6] Code of Federal Regulations. TITLE 45 — PUBLIC WELFARE. Department of Health and Human Services PART 46. PROTECTION OF HUMAN SUBJECTS, Revised June 23, 2005. Effective June 23, 2005 Available at http://www.hhs.gov/ohrp/documents/OHRPRegulations.pdf (Accessed 23 April 2009)

[7] *Tri-Council Policy Statement* Article 1.1.c

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

can be "somewhat naive" about the appropriateness and the "potential negative consequences" of information they post on social networking sites.[9] 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. 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.

If the researcher does not want to get consent, he or she could make a case according to the *National Statement* criteria for waiver of consent [see sections 2.3.5 to 2.3.8] The main criteria relevant in this case are as follows:

- A waiver of consent must be granted by an HREC (for using personal information in medical research) or other review body (other research) [2.3.5].
- Before waiving the requirement for consent, an HREC or review body must be satisfied that:
    - the research is "no more than low risk" [2.3.6 (a)] i.e. "the only foreseeable risk is one of discomfort" [2.1.6].
    - "the benefits from the research justify any risks of harm associated with not seeking consent" [2.3.6. (b)]
    - "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)]
    - "There is an adequate plan to protect the confidentiality of data" [2.3.6 (f)]
- "Given the importance of maintaining public confidence in the research process" institutions are to make publicly accessible summary descriptions of all research projects for which consent was waived e.g. in its annual report [2.3.8]

3. Can the researcher use the potentially identifiable content on the basis of Sophie's consent alone without parental consent?

Comments:

Parental consent is not needed if the research does not involve the collection of identifiable information e.g. content analysis – simply counting instances of something.

Parental consent might be needed when information is potentially identifiable. Identifiable information makes risks to individuals higher.

If risk involves more than discomfort, a decision to forgo parental consent should be clearly articulated and justified in terms of the nature of the study which includes level of risk etc. or in terms of other additional protections such as procedures set up to obtain and validate young people's informed and voluntary agreement to participate. It may be possible to establish young people's competence to consent

[9] 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

via the internet e.g. with mandatory questions which show that the young person does or does not understand what participation entails. There is also a need to consider whether seeking parental consent would make things worse e.g. (i) by putting a young person from a dysfunctional home at risk; (ii) result in disclosure to the researcher of additional identifying information about the identity and location of the young person. Parental consent may be "impracticable" for reasons other than that suggested in the *National Statement*. It can be "impracticable" 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 people's informed and voluntary agreement to participate are sufficient and appropriate in the circumstances.

4. **If parental consent is deemed necessary but logistically difficult to obtain, can the researcher wait for 15 months until Sophie turns 18 and then use the data without parental consent but with Sophie's consent?**

Comments:

Yes. But as a researcher you have to make clear to Sophie that it is **old content** (data from the 1st stage) that you want to use. It may actually be good practice to wait until Sophie turns 18 because she is then better able to make an informed choice.

Second stage of project:

5. **For the second stage of the study, is Sophie's electronic acceptance of the researcher as a 'friend' equivalent to consent? Is it enough consent? What should the researcher disclose?**

Comments:

Acceptance as a "friend" is not equivalent to consent if the researcher/friend has not disclosed that they are conducting research. Sophie needs to know further details such as what the research is about, the data collection methods and how and where the research will be reported and she needs to know that involvement is voluntary, that she does not have to be involved.

Normally, a researcher [who is not a cyber researcher] could not use the justification that he or she is a friend to collect and use personal communications without the consent of the friend - but again depending on the nature of the research, the information and how it is reported etc.

The issue is about appropriate conduct for **researchers** on MySpace, not ordinary users who are **not** conducting research.

The use of information from social network sites and acceptance of a researcher as a "friend" were recent topics of discussion on an online discussion forum for

individuals concerned about and involved in human subject's protection. See http://www.irbforum.org/ to join IRB Forum and access discussion threads.

6. Is parental consent needed for the second stage of the study?

Comments:

While parental consent might not be needed in the first stage of the project (see question 3), that does not mean that it is not needed in the second stage. The question of consent in stage 2 is independent from stage 1. In stage 2 different data is collected via a different method. The researcher interacts with participants e.g. he causes Sophie to say things she otherwise would not have said. The need for parental consent will depend on the questions asked, the likelihood of harm through identification and whether the HREC is satisfied that the young person understands relevant information. At 16, parental consent is probably not needed for Sophie but researchers should clearly set out the procedures they will use to secure and validate Sophie's informed and voluntary agreement to participate in the research. (Parental consent may be required for younger children involved in this study. As in question 3, a decision to forgo parental consent should be clearly articulated).

Note: Before planning a project using a social networking site such as MySpace, 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).[10]

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. The following terms and conditions may have relevance to researchers:

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

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

CASE 3

[Based on real life case]

Unobtrusive observation: Research involving an on-line support group

A psychologist researching young people who engage in self-harming behaviours has chosen an online support group to obtain data. He has chosen a 'pro-anorexia' online support group. Members of the group advise on how to become and remain anorexic. An important feature of the group is that it allows unguarded self-disclosure while offering anonymous support and acceptance amongst its members. The proposed study will provide health professionals with an 'insight that may otherwise be unattainable' and this insight 'can contribute to the development of effective therapies and treatments' for anorexia.[11] Unobtrusive, passive observation is the method chosen by the researcher in order to protect the group from disruption and to avoid interviewer bias. This method can be likened to eavesdropping on the on-line exchanges and the members of the group do not know that they are being observed and researched.

Questions:

1. **When is unobtrusive observation on the internet without consent acceptable?**

Comments:

In public places unobtrusive observation without consent is generally regarded as ethically acceptable, at least in some circumstances. So, it may be acceptable on-line e.g. where there is no expectation of privacy and no threat of harm to individuals through identification and participants are not part of a group that is vulnerable or susceptible to forms of harm which the research may exacerbate. However, observational research on the internet can involve risk where off-line observational research may not e.g. search engines such as Google can link quotes from public on-line sites to individuals. This could compromise confidentiality and could harm individuals if the communication is of a sensitive nature. This should be taken into account. If researchers want to do this they must make a case to the HREC as to why they are justified in conducting the research without consent – see *National Statement* chapter 2.3.

[11] Gavin, Rodham and Poyer, "The presentation of 'Pro-Anorexia' in online group interactions" 326. This case is based on a study about issues of identity in 'pro-anorexia' online group interactions.

2. Does it depend on what sort of group it is?

Comments:

The acceptability of unobtrusive observation, the need for HREC review and consent can depend on what sort of group it is and the vulnerability of the members in the group. Members of a pro-anorexia group could be considered a vulnerable group because of their psychiatric status e.g. care should be taken to determine whether participant's mental illness "increases their susceptibility to some forms of discomfort or distress" [NS 4.5.2].

The nature of some groups is such that even unobtrusive observation can end up with researchers unintentionally destroying the thing they are researching e.g. internet communities such as support groups in which members do not expect to be observed by outsiders:

> *When I joined this, I thought it would be a support group, not a fishbowl for a bunch of guinea pigs. I certainly don't feel at this point that it is a safe environment, as a support group is supposed to be, and I will not open myself up to be dissected by students or scientists.*[12]

3. If the researcher changes pseudonyms and paraphrases quotes, is this sufficient to avoid identification of individuals?

Comments:

It may not be if the group is from a relatively small population and easily recognised because they are a minority group e.g. a pro-anorexia site. Search engines such as Google add to the possibility of identification of individuals even if pseudonyms are used.

Further questions:

4. If a researcher felt that the identity of individuals in a 'pro-anorexia' website support group need not be protected given that they promote harm to self and others, would this be relevant?

Comments:

On the face of it there may seem to be no justification for protecting the identity of individuals who promote harm to self and others but it should be remembered that

[12] Eysenbach Gunther, Till James E. (2001). Ethical issues in qualitative research on internet communities, BMJ. 323: 1103-1105. P.1104

adolescents with anorexia are a vulnerable group with a mental illness. In any case, the research context is not the appropriate forum in which to expose or "out" people. Confidentiality should be protected for **all** participants.

5. If the researcher felt that the members would be better served if the group was disrupted, is this relevant to the ethics of the research?

Comments:

No. If there is a need to disrupt the group it should be done in a more sensitive way, without causing additional harm, and it should be done in another context entirely such as public health.

This situation could be compared to research about illegal activities. It is generally accepted that it is not ethically appropriate for researchers to attempt to stop illegal behaviour or expose criminals in the process of research. These activities are to be left to appropriate authorities such as the police.

CASE 4

[Real life case]

Opt-out consent and the role of parental consent in a study in a child care centre.

An experiment designed to study the spread of germs in a U.S. child care centre was closed down after a parent complained that the experiment was done without consent. Researchers sprayed a solution containing DNA fragments of a plant virus on toys, doorknobs and other surfaces in a number of day-care centres to track the spread of germs. The purpose was to find more effective ways of controlling germs in a child-care setting. No health risk to the children was anticipated.

The DNA-based "marker" solution was placed in one toddler classroom in each of 14 day-care centres. "There were 249 children, 1 to 2 years old, in those classrooms. Hundreds more children were present in other areas of the day-care centres and potentially were exposed to the marker as it was spread."

A letter outlining the study was left with each child's belongings but written consent was not sought until after the children had been exposed to the solution. Researchers then approached parents asking for permission to swab the children's hands to see if the solution was present. According to one proponent of the study: "parents were given the opportunity to opt out of the experiment, but none did". [13]

Questions:

1. **Is leaving a letter with the children's belongings a good enough way of contacting parents?**

Comments

No. Unless parents receive the letter, "opt-out consent" amounts to no consent. Information could be mailed out but that can be unreliable also. Personally handing the information to parents would ensure that they receive it and that they do have the opportunity to "opt-out".

[13] Bill Sizemore. A study in ethics: A parent's complaint shut down a germ-tracking medical experiment in local day-care centres and raised questions about researchers' responsibility to get informed consent. The Virginian-Pilot, 3 August, 2003.

2. Is opt-out consent from the first phase of the study ethically acceptable, or should it be opt-in?

Comments

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 choose to "opt-out."

Seeking opt-out consent is different to not seeking consent – it changes the process by which people indicate that they have given consent. Usually, people have to take action to give consent; in opt-out consent, taking no action is the way to indicate consent.

In general, opt-out consent is regarded as rather problematic but possibly justified in some circumstances. Because of the age of the children and the child-care setting, there are good reasons for consent to be opt-in [see comments on question 4].

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.

3. Is the first phase of the study really ethically different from the second phase?

Comments

The key question is whether the differences make an ethical difference – although this does not settle the question of whether opt-in or opt-out consent is needed.

The main difference is interaction between the researcher and some children (hand swabbing) in the second phase of the study. It is not physically more risky, but it is noticeable to the child, it maybe upsetting etc.

One way of trying to think through the issues is to imagine yourself as a parent whose child is involved in the study.

4. Was parental consent needed at all?

Comments

Ethical issues include: potential for harm; respect for parents; and public trust.

The main justification for thinking that parental consent **is not needed**:

- There was no risk to the children and the research was potentially beneficial plus, it is hard to see why parents would object

Justification for thinking that parental consent **is needed**:

- Parents should be informed when something is done to their child that is not part of the regular day-care routine even if no harm is anticipated. Parents might not know about all activities that their children are involved in during the day but there is an expectation that activities are part of an established child care program rather than being determined by goals of a research project.
- There is some value in getting parental consent other than the protection it confers before including infants in research. Parent's interest in making decisions concerning their children is the basis of that value.[14]
- The support of the public is needed for research to proceed and even the perception of a failure of consent can have an adverse effect on public trust in research. It is recognised that scandals such as the retention of children's organs by hospitals in the UK have adversely affected the donation of tissue for legitimate research - even research that is not directly linked to the scandal. [15] There is evidence that in Australia, unauthorised retention of children's organs led to reduced trust in health professionals.[16]

[14] Buchanan A.E. and Brock D. W. (1990) Deciding for others: The ethics of surrogate decision making. Cambridge: Cambridge University Press. Chapter 5.
[15] Seale, C, Kirk D, Tobin M, et al. Effect of media portrayals of removal of children's tissue on UK tumor bank. *BMJ* 15 August 2005; 331:401-403
[16] Monagle P., Rob B., Driscoll S. and Bowes G. 2002. Organ retention following paediatric and perinatal autopsy: Where to from here? *Journal of Paediatric Child Health* 38: 405-408

CASE 5

[Real life case]

Research involving infants: Risky research and the framing of risk.

Effect of exposure to 15% oxygen on breathing patterns and oxygen saturation in infants: interventional study.

Researchers carried out a study investigating the response of healthy infants to airway hypoxia (low oxygen) after reports that two infants had died from sudden infant death syndrome (SIDS) after intercontinental flights. The study involved 34 healthy infants. Most were recruited from an obstetric unit while 13 were recruited from families receiving support in caring for an infant after a previous infant had died from SIDS. During the course of the study four infants had severe falls in oxygen saturation. A finding from the study was that 'exposure to airway hypoxia similar to that experienced during air travel or on holiday at high altitude may be harmful to some infants'.

In response to the question of whether it was ethically justified to expose healthy infants to 15% oxygen, the researchers claim that "Many infants travelling on aeroplanes or to holidays at high altitude are exposed to similar or even more markedly reduced partial pressures of inspired oxygen. Yet this exposure is considered safe".

See the study and commentaries by an ethicist and the chair of the ethics committee that approved the research in BMJ 1998 vol. 316: 887-894 [link to free access article - http://www.bmj.com/cgi/content/full/316/7135/887]

Parkins K. J., Poets C. F., O'Brien L. M., Stebbens V. A. and Southall D. P. (1998). Effect of exposure to 15% oxygen on breathing patterns and oxygen saturation in infants: interventional study. BMJ 1998; 316: 887-891

Julian Savulescu. (1998). Commentary: Safety of participants in non-therapeutic research must be ensured. . BMJ 1998; 316: 891-892

Vivian Hughes (1998). Commentary: Ethical approval of study was warranted. BMJ 1998; 316: 892-893

Parkins K. J., Poets C. F., O'Brien L. M., Stebbens V. A. and Southall D. P. (1998). Authors' reply. BMJ 1998; 316: 893-894

Questions:

1. **Rather than talking about the small risk of sudden death, is it acceptable to describe the risks of participation as involving no more risk than what infants are exposed to if they were travelling on an aeroplane or taken on a holiday to an area of high altitude?**

Comments:

Possible justifications for framing risk in terms of aeroplane travel and holidays in areas of high altitudes are: (a) to save parents from too much worry, and (b) to frame risk in a way that is easily understood.

(a) is not an acceptable justification. Full disclosure of risks is necessary for parents to be able to make an informed decision about their child's participation. In general (b) is a good thing, but in this case it may mislead in the sense that it may deflect consideration away from whether the risk is worth taking for this purpose (i.e. research). As Savulescu argues: "People judge that some risks are worth taking, but it is up to them to make that evaluation. Though driving a car or flying in an aeroplane does entail risk, it is wrong to assume that a person would take on this risk to participate in research."

One way of trying to think through this is to imagine yourself as a parent invited to consent for your child to take part in the research. Would you want researchers to frame risks in a way that does not cause you too much worry or would you rather be "scrupulously informed" of risks no matter how small?

2. **Is the study too risky for children i.e. parents shouldn't be allowed to even be asked?**

Comments

A study is clearly high risk if it has a **high** probability of causing **severe** harm. This study has as **very low** probability of causing severe harm (or death), but not zero probability. This makes its level of risk disputable. There would be two views on this:

(a) It is too much risk and the project should not be allowed to proceed – parents should not even be offered the choice;

(b) There is a degree of risk, but it is not excessive. Parents should be given **full explicit** information about the risk, and allowed to make their own decision.

Different ethics committees are likely to have different views.