

# Case Studies

Understanding Consent in  
Research Involving Children: The  
ethical Issues

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# Purpose of this Resource

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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](mailto: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.<sup>1</sup>

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<sup>1</sup> 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

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

# CASE 2

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[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:

#### First stage of project:

1. Is Human Research Ethics Committee (HREC) approval needed?
2. Can the researcher use content from Sophie's MySpace profile without Sophie's consent?
3. Can the researcher use the potentially identifiable content on the basis of Sophie's consent alone without parental consent?
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?

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

# CASE 3

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[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.<sup>2</sup> 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?
2. Does it depend on what sort of group it is?
3. If the researcher changes pseudonyms and paraphrases quotes, is this sufficient to avoid identification of individuals?

### **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?
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?

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<sup>2</sup> 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.

# CASE 4

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[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”.<sup>3</sup>

### **Questions:**

1. Is leaving a letter with the children’s belongings a good enough way of contacting parents?
2. Is opt-out consent from the first phase of the study ethically acceptable, or should it be opt-in?
3. Is the first phase of the study really ethically different from the second phase?
4. Was parental consent needed at all?

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<sup>3</sup> 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.

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