

Frequently Asked Questions: Involving Children in Research¹

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This paper provides answers to the frequently answered questions about involving children in research. More detailed information can be found in:

Gibson, F. and Twycross, A. (2007) Children's participation in research: A position statement on behalf of the Royal College of Nursing's Research in Child Health (RiCH) Group and Children's and Young People's Rights and Ethics Group, *Paediatric Nursing*, 19(4): 14-17.

What is Consent?

Q: What is consent?

Consent is the invisible act of evaluating information and making a decision, and the visible act of signifying the decision (Alderson and Morrow 2004).

Q: What is the difference between consent and assent?

- *Assent* is defined as the child or young person's permission or affirmative agreement to participate in research (Broome and Richards 1998).
- Unlike consent, assent is not a legally mandated process.
- Assent requires that children have an understanding of the research process and are informed about what they are expected to do (Lindeke et al. 2000).
- Further, Piercy and Hargate (2004) state that assent is an opportunity given to children to express their opinions and concerns surrounding participation in research, providing them with a formal means to be included or excluded.
- There appears very little to distinguish *assent* from *consent*. However, the legal position remains unclear in relation to *assent*.

Q: What are the key principles relating to obtaining consent from children?

The key principles relating to obtaining consent in children are that:

- In competent children informed consent should be obtained before commencing data collection

¹ In this paper the word *children* is used to mean children and young people from birth to 16 years

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- Parents/guardians should be involved in the decision to participate wherever possible, and in all cases where the child is not yet competent
- A child's refusal to participate/continue in research should be respected
- If a child becomes upset by a procedure, researchers must accept this as a valid refusal
- Consent should be considered an on-going process

Who Should Give Consent: Parent or Child?

Q: When should the child be asked to give consent?

The Medical Research Council (2004) suggest that where children have sufficient understanding and intelligence to understand what is proposed, it is their consent and not that of their parents that is required by law. This is supported by the National Children's Bureau (NCB) (2003).

Children can give consent if they are capable of choosing between alternative courses of action (RCN, 2006).

An exception to this is *clinical trials*. In 2001 the European Union adopted the EU Clinical Trials Directive (2001/20/EC) as a framework for good management in trials of medicines for human use. The subsequent UK Medicines for Human Use (Clinical Trials) Regulations became law in 2004. The EU Clinical Trials Directive states that the informed consent of the parents or legal representative must be obtained before a minor⁴ can take part in a clinical trial. This appears to contradict moves towards ensuring children's rights to be involved in decisions are upheld. However, the directive does state that minors should be given information about the study and that their refusal to take part should be respected.

Q: When is obtaining consent from the parents necessary?

See above

In relation to consenting to take part in a research study children under the age of 16 years can give their consent to take part in a research study if they satisfy the criteria of Gillick competence Alderson and Morrow (2004):

- They have been counselled and do not wish to involve their parents
- They have sufficient maturity to understand the nature, purpose and likely outcome of the proposed research

Information about the **legal position** in relation to **consent to medical treatment** across the four UK countries can be found at:

http://www.brook.org.uk/content/M5_3_consenttreatment.asp [Accessed 1st September 2006].

⁴ A *minor* is a child under the age of 16 years

Obtaining Informed Consent

Q: How do I know whether a child is capable of giving informed consent?

The Department of Health (DH) (2001a) states that when deciding whether a person is capable of giving valid (informed) *consent* three main elements need to be considered. The person:

- Needs to be capable of making that particular decision (competent);
- Must be acting voluntarily – that is not being coerced;
- Must be provided with sufficient information to enable them to make an informed decision.

An individual assessment should be made as the age children are able to give consent will vary: it is wrong to assume that even young children are incompetent to consent.

Q: What information do children need when deciding whether to participate in a research study?

Children need sufficient information before they can decide whether to participate in a research study or not. This includes information about:

1. The purpose of the research
2. Any possible risks
3. How great or small the risks might be
4. Any possible benefits
5. What they will have to do if they participate in the study
6. Who the researchers are

If the research involves having a *new or different treatment* than they would normally have, children also need information about what the standard treatment would be, and any possible alternatives.

(See DH 2001b for further information)

Q: What issues should be considered when deciding whether children are *competent* to make an informed decision?

Deciding whether children are competent to consent on their own behalf is sometimes difficult and it is necessary to use your professional judgement. In this situation the researcher or practitioner should consider whether the child or young person understands the following issues:

- What the research is about?
- Who is carrying out the research?
- Who is funding the research?
- Exactly what is expected of participants – e.g. completion of questionnaire, taking part in a focus group, having additional bloods taken

- How will the information participants provide be recorded? – e.g. written record, audio tape
- What will happen to the information provided by participants?
- What is the degree of anonymity and confidentiality provided?
- How will the information be used?
- Who will see the results of the study?
- What benefits might the study have for participants and the wider community?
- Are there any potentially harmful side effects of taking part in the study?
- That they have the right to refuse to take part in the study without any adverse consequences
- That they can withdraw from the study at any point without any adverse consequences

(adapted from NCB 2003; NRES 2007)

The information needs outlined above must be provided in a developmentally appropriate way (Ungar et al. 2006; Gibson and Twycross 2007).

Q: Who is responsible for ensuring informed consent is obtained from children?

- It is the role of the principal investigator or designated trained person to ensure that the information is given in a form that the child can understand, that the child (and if appropriate parents) has given informed consent and that the child's understanding has been assessed.
- However as a researcher you also have a responsibility to ensure that children have given informed consent to participate in a study

Q: How can we be sure a child understands the information being shared?

A child's understanding can be assessed by:

- Listening to the sorts of questions the child asks about the practical implications of the study
- Listening to their expressions of hopes and fears
- Picking up cues where they are seeking reassurance about what will happen during procedures

(Alderson and Montgomery 2001)

Q: What should I do if the child does not seem to understand what taking part in the study involves?

- If a child does not seem to understand, more time may be needed for discussion, leaving the child and returning for a second visit to give them some space to talk to their parents or other professionals might be helpful.
- Information sheets written specifically for children will compliment this process of dialogue and leave the child with something tangible to refer to when talking to their parents or other professionals.

Information leaflets

Q: What needs considering when designing information sheets?

- Both content and presentation are important
- Researchers should resist the temptation to simply cut and paste from their proposal and then make the font larger or add pictures
- Sufficient information needs to be included in the information leaflet to enable children to make an informed decision.
- That the required information is included (see *What information do children need when deciding whether to participate in a research study?*)
- Clear information leaflets are crucial so that children can read them, or understand when someone reads it to them.
- Alderson and Morrow (2004) suggest using:
 - Short lines, words, sentences and paragraphs
 - One main idea per sentence
 - Requests rather than commands
 - The active rather than passive voice
 - A personal approach rather than an impersonal one
 - Specific details rather than vague ones
 - Appropriate pictures may be a useful addition.
 - Be creative with mode of presentation, for example, taped information can be played to children with reduced vision.

Q: Are different information sheets needed for children of different ages?

The National Research Ethics Service (NRES) (2007) recommends that information sheets be produced for the following age ranges:

- 5 years and under
- 6-10 years
- 11-15 years

See <http://www.nres.npsa.nhs.uk/> for additional information.

- See previous section on what information children need to decide whether to take part in research or not.
- The same information should be provided to children of all ages, it's the level of detail that is expanded upon.
- Generally by 6-7 years of age most children have begun to learn to read
- Reflect the development of children's reading and language skills in the different age bands.

Q: How many languages should information leaflets be translated into?

- Leaflets should be translated into other languages as appropriate for your population
- The back translation process should be used to check for clarity and accuracy

Documentation

Q: What should I document about the consent process?

- Good practice indicates that the researcher talking to the child about a study should document the process in their research records, making clear the child's role in the decision-making process
- A statement that the child understood, that the child provided affirmative agreement and was under no coercion or undue influence should also be recorded (Ungar et al. 2006).
- Such documentation is preferred to reliance on a signature on a form which serves no legal or contractual function in young children.
- Although when working with young people a signature symbolises respect for their maturity and is therefore is an important addition to the documentation.

Ethical Guidelines

Q: Where can I find ethical guidelines about research with and/on children

Several ethical guidelines have been produced:

- Royal College of Paediatrics and Child Health (2000) Guidelines for the Ethical Conduct of Medical Research Involving Children Available from:
http://www.rcpch.ac.uk/publications/bpsu/ethics_advice_summary_may_2001.pdf
- National Children's Bureau (2003) Guidelines for Research Available from:
http://www.ncb.org.uk/dotpdf/open%20access%20-%20phase%201%20only/research_guidelines_200604.pdf
- Medical Research Council (2004) Medical research involving children Available from:
<http://www.mrc.ac.uk/Utilities/Documentrecord/index.htm?d=MRC002430>
- Royal College of Nursing (2006) Informed consent in health and social care research Available from:
http://www.rcn.org.uk/publications/pdf/informed_consent_in_health_and_social_care_research.pdf

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- Directive 2001/20/ED of the European Parliament and the Council of 4 April 2001 on the approximation of the laws, regulations and administrative provisions of the Member States relating to the implementation of good clinical practice in the conduct of clinical trials on medicinal products for human use.
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- National Children's Bureau (2003) *Guidelines for Research*, London, NCB.
- National Research Ethics Service (formerly COREC) (2007) *Information sheets and consent forms: Guidance for researchers and reviewers*, Version 3.1. Available from: www.nres.npsa.nhs.uk/recs/guidance.htm#consent [Accessed on April 10th 2007]
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- Royal College of Paediatrics and Child Health Ethics Advisory Committee (2000) Guidelines for the ethical conduct of medical research involving children. *Archives of Disease in Childhood*, 82, 177-182.
- Royal College of Nursing (2005) *Informed Consent in Health and Social Care Research: RCN Guidance for Nurses*, RCN Publishing, London.
- United Nations (1989) *Convention on the Rights of the Child*. New York, United Nations.
- Ungar D et al (2006) Children are not small adults: documentation of assent for research involving children. *Journal of Pediatrics*, 149, S31-S33.

Other resources

CERES (Consumers for Ethics in Research) www.ceres.org.uk

Department of Health (2001) *Consent – What You Have A Right To Expect: A Guide For Parents*. London, Department of Health.

Institute of Medicine of *The National Academies* (2004) *Ethical conduct of clinical research involving children*. Washington, The National Academies.

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