Guidelines for Health Research with Children

These ethical guidelines on health research with children were developed by Nicola Peart and David Holdaway (for full references refer to the original article)[1] and updated in 2007 by Nicola Peart. For further information on issues relating to research with children refer to:

i. Peart N, Holdaway D. 1998. Legal and ethical issues of health research with children. *Childrenz Issues* 2: 42–6.

ii. Peart N. 2000. Health research with children: the New Zealand experience. *Current Legal Issues* 3: 421–39.

iii. Ministry of Health. 1999. *Consent in Child and Youth Health: Information for practitioners*. Wellington: Ministry of Health.

The special vulnerability of children makes consideration of involving them as research participants particularly important. To safeguard their interests and to protect them from harm, special ethical considerations should be in place for reviewing research with children.

Principles

1. These Guidelines are based on six principles, which are mostly taken from the Guidelines of the Royal College of Paediatrics and Child Health 1999 and the European Convention for the Protection of Human Rights and Dignity of the Human Being with Regard to the Application of Biology and Medicine 1996.

   i. Research involving children is important for the benefit of all children and should be supported, encouraged and conducted in an ethical manner.

   ii. Children are not small adults; they have their own unique set of interests.

   iii. Research should only be done with children if comparable research with adults could not answer the same question and the purpose of the research is to obtain knowledge relevant to the health needs of children.

   iv. A research procedure which is not intended directly to benefit the child participant is not necessarily unethical.

   v. All proposals involving health research with children should be submitted to an accredited ethics committee.

[1] Peart N, Holdaway D. 2000. Ethical Guidelines for Health Research with Children. *New Zealand Bioethics Journal* 1(2): 3–9.

vi. Legally valid consent should be obtained from the child or from a proxy who is legally entitled to give consent on behalf of the child, such as a parent or guardian. When proxy consent is obtained the assent of the children should, wherever possible, also be obtained by the researcher.

Nature and design of research

2. Before undertaking research with children the investigator must ensure that:

   i. Children will not be involved in research that might equally well be carried out with adults.
   ii. The purpose of the research is to obtain knowledge relevant to the health needs of children.
   iii. If a choice of age groups is possible, older children should be involved in preference to younger ones.
   iv. The research is designed or supervised and carried out by people experienced in working with children.
   v. The number of children involved is limited to the number which is scientifically and clinically essential.

Risk

3. Research procedures or interventions which are intended to provide direct therapeutic benefit to the child participants may be undertaken if:

   i. The risk is justified by the anticipated benefit to the child participants.

   ii. Any relation of the anticipated benefit to the risk is likely to be at least as favourable to the child participant as any available alternative.

4. Research procedures or interventions which are not intended to be of direct benefit to the child participants, but which are likely to yield generalisable knowledge about the child's disorder or condition which is of vital importance for the understanding or amelioration of the child's disorder or condition, may be undertaken if:

   a. Any risk represents a minor increase over minimal risk.

   b. The interventions or procedures present experiences to the child participants which are reasonably commensurate with those inherent in their actual or expected medical, psychological, social or educational situations.

5. Research procedures which are not intended to be of direct benefit to the child participants, and do not come within the scope of research set out in paragraph 4

above, may be undertaken only if the risk presented by the interventions to the child participant is:

i. minimal, and

ii. commensurate with the importance of the knowledge to be gained.

Informed consent

Information

6. When inviting children to participate in any research the investigator must ensure that the children, and where appropriate the children's parents, guardians or caregivers, have been fully informed about the research in a manner best suited to their needs.

   i. Each child must be given full information about the research in a form that he or she can readily understand.

   ii. Children must be advised of their right to decline participation and their right to withdraw from the research at any time without giving a reason.

   iii. Investigators must give the children an opportunity to ask questions and to have those questions answered to the children's satisfaction.

   iv. If proxy consent is required, the person giving proxy consent must also be given full information about the research and be advised of the child's right to decline participation or withdraw from the research at any time.

   v. The person giving proxy consent must be given an opportunity to ask questions and have them answered to their satisfaction.

Consent

7. Before undertaking research with children the investigator must ensure that legally valid consent is sought on the basis of the information provided:

   i. The consent of a child of or over the age of 16 must be obtained and has the same effect as if the child were of full age, provided the child does not lack competence for reasons other than age.

   ii. If the child is below the age of 16, but has the competence to understand the nature, risks and consequences of the research:

(a) the consent of the child must be obtained, and
(b) that consent will have the same effect as if the child were of full age.

iii. If the child is below the age of 16, and lacks the necessary competence to give legally effective consent:

(a) proxy consent to the child's participation must be obtained
(b) the child's assent must be obtained unless the child is unable to communicate
(c) the refusal of a child to participate in research must be respected unless:

1. according to the research protocol the child would receive therapy for which there is no medically acceptable alternative, or
2. the research comes within the scope of paragraph 3 above.

iv. Consent and assent are dynamic, continuous processes and should be checked throughout the study to ensure they are maintained. If during the study the child attains competence to give legally effective consent, the child's consent must be obtained and will replace the proxy consent.

v. Only one parent or legal guardian is required to give proxy consent. However if there is more than one parent or guardian, and the research is not routine, then there is an expectation that the person giving proxy consent will consult all of the other parents or legal guardians. The researcher should make the person giving proxy consent aware of their duty to consult and, if practicable, the time to consult.

vi. If the researcher becomes aware that the person who gave proxy consent to the child's participation has been replaced, proxy consent should be obtained from the child's new legal guardian as soon as practicable.

vii. Care must be taken to ensure that no pressure is placed upon a child to consent to participate in research, especially if the procedures are not intended to be of direct benefit to the child participants (as in paragraphs 4 and 5 above).

viii. The requirement for written consent should take into consideration the age and competence of the child.

Withdrawing consent

8. Consent and assent can be withdrawn at anytime and there must be no penalty to the participant if they choose to withdraw. The following points should be taken into consideration when consent or assent is withdrawn:

i. Withdrawal from the study should be managed in a clinically responsible manner to avoid harm to the child.

ii. If the child gave legally effective consent to participate in the research, the child may withdraw consent at any time during the research without giving reasons.

iii. If the child gave assent to participate in the research, the child may withdraw his or her assent at any time during the research without giving reasons. The child's wish to withdraw from the research should be respected unless:

(a) according to the research protocol the child would receive therapy for which there is no medically acceptable alternative, or
(b) the research comes within the scope of paragraph 3;

and proxy consent is obtained to the child's ongoing participation in the research.

iv. If proxy consent is obtained to the child's participation in the research, the person giving proxy consent may withdraw consent at any time without giving reasons. The child must then be withdrawn from the study, unless:

(a) the child has become competent to give legally effective consent and consents to continue to participate in the research, or
(b) proxy consent is obtained from another person who is able to give proxy consent to the child's ongoing participation, or
(c) withdrawal is against the child's interests and the Court consents to the child's ongoing participation.

v. If the person who gave proxy consent to the child's participation has been replaced and the person who is now entitled to give proxy consent refuses to give proxy consent to the child's ongoing participation in the research, the child must be withdrawn from the study, unless:

(a) the child has become competent to give legally effective consent and consents to continue to participate in the research, or
(b) proxy consent is obtained from another person who is able to give proxy consent to the child's ongoing participation, or
(c) withdrawal is against the child's interests and the Court consents to the child's ongoing participation in the research.

Inducements

9. Families and children must not receive any financial payments or other reward for participating in the research. Only expenses resulting from participation may be reimbursed.

Health research data

10. Retention and use of personally identifiable health research data:

    i. Research data pertaining to the child participants should be retained by the researcher for ten years after the child has attained the age of 16.

    ii. Children have the right to withdraw consent to the continued use or retention of personally identifiable health research data once they attain the age of 16.

Points to consider

11. Ethics committees should consider the following points:

    i. Does the research have an identifiable prospect of direct benefit to the individual child participant? Can that benefit be achieved through alternative means?

    ii. Does the research have an identifiable prospect of risk to the individual child participant? What safeguards are proposed to minimise these risks? When procedures involving greater than minimal risk to children are anticipated, are convincing scientific and ethical justifications given?

    iii. Is the inclusion of healthy participants justified?

    iv. Do studies involving placebo controls place the child at greater risk by withholding from selected participants potentially therapeutic research drugs or interventions?

    v. When possible, have appropriate studies been conducted on animals and adults first? Will older children be enrolled before younger ones?

    vi. Are mechanisms in place to ensure that children are involved as research participants in ways that do not undermine their dignity as young persons?

    vii. Are there special problems that call for the presence of a monitor or advocate during consent procedures?

viii. Are special needs of adolescents such as counselling and confidentiality accounted for in the research design?

ix. Are there any special problems such as confidentiality and reporting that might arise in sensitive research such as research about child abuse or sexual practices of teenagers?

x. If conditions present in children have implications for other family members' health statuses, are appropriate mechanisms proposed for dealing with the larger family unit (for example, genetic risks or HIV infection)?

xi. Should parents be required to be present during the conduct of the research?

xii. Are proposed participants to be very young?

xiii. Are the procedures involved painful?

xiv. Must participants stay overnight in the hospital when they otherwise would not have to?

Applicable laws and regulations

12. Section 36 of the Care of Children Act 2004 governs consent to any medical surgical or dental procedure in relation to a child. Right 7 of the Code of Health and Disability Services Consumers Rights 1996 is also applicable in relation to consent to treatment and/or research.