Chapter 12 dealt with the general legal requirements concerning consent to participate in research. The difficulty of obtaining informed consent from people with impaired capacity was discussed. Capacity to consent may also be an issue in research with children, but here there are additional concerns as well. Children have unique physical, psychological, mental and emotional characteristics which make them specially vulnerable. Their special vulnerability was recognised in the aftermath of World War II when the Nuremberg Code was adopted in 1947. Article 1 of that Code effectively excluded children from participating in medical and scientific research, by imposing the requirement that all participants have the legal capacity to consent. Though this Code did not completely halt research with children, some countries, such as the United Kingdom, imposed very severe restrictions, which for many decades prevented children from participating in a wide range of research. This policy had a detrimental effect on children, because it excluded them from the benefits of research. It is now widely accepted that children should be involved in research, if their health and well-being is to be promoted, provided their rights and interests are properly secured.\footnote{M. Hill, 'Participatory Research with Children', \textit{Child and Family Social Work} (1997) 2:171–183; The American National Institute of Health, \textit{Policy and Guidelines on the Inclusion of Children as Participants in Research Involving Human Subjects} (1998).} This approach was endorsed by the General Assembly of the United Nations when it adopted Article 24 of the Convention on the Rights of the Child in 1989.

Research Guidelines

Several national and international instruments were drawn up in the 1990s which – to a greater or lesser extent – regulate health research with children. They are listed at the end of this chapter. The Paediatric Society of New Zealand followed suit in 2000,
when it adopted the *Ethical Guidelines for Health Research with Children.* These guidelines are similar to leading foreign and international guidelines and should be read in conjunction with the guidelines and rules applicable to health research in general. These guidelines are also included as an appendix to the *Operational Standard for Ethics Committees* published by the Ministry of Health in 2002.

Unlike in most other countries, these guidelines appear to have legal standing in New Zealand by virtue of the Code of Health and Disability Services Consumers’ Rights 1996 (Code of Rights). This Code is a lawfully promulgated set of regulations under the Health and Disability Commissioner Act 1994 and an enforceable part of New Zealand law. It applies to health service delivery and to research and teaching in the health sector.

Right 4(2) of the Code of Rights provides: ‘Every consumer has the right to have services provided that comply with legal, professional, ethical and other relevant standards.’ There can be little doubt that New Zealand’s *Guidelines for Health Research with Children* will be regarded as a relevant ethical standard of this kind.

There are no guidelines of similar legal standing for non-health related research with children. But this does not mean there are no guidelines. Some organisations, such as universities and professional organisations, have developed their own codes of conduct for research with humans and have included special provisions for child participants. Researchers involved in such organisations are expected to comply with those instruments or risk disciplinary proceedings. Even in the case of non health-related research there may be advantages in looking at the *Ethical Guidelines for Health Research with Children,* as they are based on general legal and ethical principles.

**Ethical Guidelines for Health Research with Children**

These guidelines are based on the following six principles:

1. Research involving children is important for the benefit of all children and should be supported, encouraged and conducted in an ethical manner.
2. Children are not small adults; they have a unique set of interests.
3. 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.
4. A research procedure which is not intended directly to benefit the child participant is not necessarily unethical.
5. All proposals involving health research with children should be submitted to an accredited ethics committee.
6. Legally valid consent should be obtained from the child, parent or guardian as

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appropriate. When parental consent is obtained, the assent or consent of the children should wherever possible also be obtained.

In our view these principles are equally applicable to non-health-related research if the reference to 'health' in principles 3 and 5 are omitted.

There are two particularly contentious issues when conducting research with children:

- consent of the child or a proxy to the child's participation;
- risk of harm to the child.

Other issues of special relevance to research with children are dealt with at the conclusion of this chapter.

Consent

As was explained in the general chapter on consent, a fundamental requirement for the involvement of humans in research is their informed and voluntary agreement to participate. Failure to obtain the necessary consent could expose health researchers, in particular, to both civil and criminal liability, to disciplinary proceedings and to investigation by the Health and Disability Commissioner if a complaint is made concerning a breach of the Code of Rights.\(^3\)

Other forms of research for which consent has not been obtained may give rise to similar forms of liability, especially if the research intrudes upon the physical person of the child.

Competence to Consent

The legal validity of consent depends on the competence of research participants to understand fully the nature of their involvement and on the absence of any improper influence or pressure in the consent process. Special considerations apply when the research involves child participants because of the power imbalance between children and adults.

There are three particularly important questions in relation to the consent of a child:

1. Does the child have the necessary competence to give legally effective consent?

2. If the child lacks that competence, or if their competence is in doubt, can they nonetheless participate with proxy consent from a parent or guardian?

3. If proxy consent is legally permissible, should the child’s consent or assent be obtained as well?

Each of these questions will be dealt with separately, but some of the answers are not straightforward or legally certain.

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\(^{3}\) See Chapter 17 'Liability for Misconduct in Research'.
Children aged sixteen and over

Children are presumed to be fully competent when they attain the age of majority, which in New Zealand is twenty years. From that age onwards, any competence they may have lacked solely by virtue of their age ceases. But Parliament has recognised that even children below that age have the capacity to give legally effective consent to a wide range of activities. Section 25 of the Guardianship Act 1968 provides, for instance, that:

the consent of a child of or over the age of 16 years to any donation of blood by him, or to any medical, surgical or dental procedure to be carried out on him for his benefit by a person professionally qualified to carry it out, shall have the same effect as if he were of full age.

The effect of this section is that sixteen-year-olds are deemed to have the capacity to consent to participate in any medical research that is for their benefit and their consent is effective without the need to obtain parental permission.4

Children aged under sixteen

The common law determines capacity to consent not by age but by the ability to understand the information provided and to make an informed choice. Children under the age of sixteen may therefore have the capacity to consent to participate in research. The House of Lords said in the famous case of Gillick v West Norfolk and Wisbech Area Health Authority that capacity evolves gradually as children mature; and that children below the age of sixteen may be legally competent to consent to medical treatment.5 This decision has been applied in New Zealand in a variety of contexts and accords with the United Nations Convention on the Rights of the Child.6 Right 7(2) of the Code of Rights arguably goes a step further by stating the presumption that everyone is competent until proven otherwise.

Gillick reflects a common-sense approach to a child's increasing capacity to make their own decisions and its principle is of general application. This means that if a child is 'Gillick competent', researchers should be able to rely on the child's consent to participate without the need to obtain proxy consent from a parent or guardian, even if the child is below the age of sixteen.

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4 The Care of Children Bill, currently before Parliament, proposes to repeal the Guardianship Act, but a section similar to s 25 has been inserted in the Bill and clarifies that a child over the age of sixteen has the right not only to consent but also to refuse medical treatment: cl 35.

5 [1986] AC 112.

Assessing competency

The problem with the Gillick competency test is that it is not easy to use. An age criterion below which a child's consent would have no legal effect would be much simpler, but that is not the current legal position. The researcher will have to assess each child individually to determine whether they have the necessary maturity and understanding to give legally effective consent. This assessment must relate not merely to the child's general level of competence, but to the child's competence in relation to the particular research project. The child must understand all of the following:

- the nature and purpose of the research;
- the procedures;
- the risks and benefits of the research;
- the consequences of agreeing or refusing to take part.

The child must then be able to make a voluntary, rational choice whether or not to participate.

Some children may have the ability to understand and make an informed choice about participating in a harmless survey, but may lack that ability in relation to a drug trial. Much will therefore depend on the nature of the research and the risks to participants. Children over the age of sixteen are expected to be mature enough to make an informed decision about participation in most, if not all, research, whereas children under the age of seven or eight will normally lack that ability. So, the former will generally have the required legal capacity to consent without the need to obtain parental consent as well, whereas the seven- or eight-year-old child will normally lack this capacity.

The capacity of children between those ages varies from child to child. It increases as they mature. The closer they are to adulthood, the more likely it is that they will have the required legal competence. This is reflected in Articles 5 and 14 of the UN Convention on the Rights of the Child, which require states to recognise the evolving capacities of children. Article 12 is of particular relevance:

State Parties shall assure to the child who is capable of forming his or her own views the right to express those views freely in all matters affecting the child, the views of the child being given due weight in accordance with the age and maturity of the child.7

When is Proxy Consent Necessary?

Competent children

If the child is Gillick competent, their consent should be sufficient and their refusal should be binding. There should be no need to involve proxies in the decision-making process. To insist on proxy consent when the child is clearly competent undermines that child's rights. A proxy's unintentional omission to consent or unreasonable refusal may deny the child the opportunity to be involved in worthwhile research.

7 The Care of Children Bill adopts this principle in cl 5.
This principle is not always fully appreciated. As one commentator points out, adults act as gatekeepers controlling researchers’ access to children. School principals, for instance, commonly require parental consent if external researchers wish to conduct research at the school with some of its students. This requirement is sometimes imposed irrespective of the nature of the research or the maturity of the students. The school clearly has the right to decide whether to permit the research to take place on its premises and whether to inform parents that students may be invited to take part. But, if the potential student participants have the necessary maturity and understanding to decide for themselves whether they wish to take part, parental consent is not necessary and should not be a condition of their participation.

For the same reason, a competent child’s refusal to participate in research should be respected even if the research is of direct benefit to that child. Whether this principle will be adhered to in New Zealand if the child would be receiving experimental treatment for a disease for which no medically acceptable alternative is available is not clear. The English courts have held that a competent child does not have the right to refuse life-saving medical treatment, but this stand has been criticised and New Zealand courts may not follow that approach. Besides, the English approach was adopted in the context of conventional treatment, not experimental treatment or research. It is therefore quite likely that a competent child’s refusal to participate would be effective.

Consent once given is not final. It is an ongoing process and needs to be affirmed throughout the research. As the research progresses, the participants’ understanding of what is involved increases and they may wish to withdraw. Researchers should be alert to behaviour indicating an unwillingness to continue and give child participants the option of declining further participation.

Children with questionable competence
If a researcher has doubts about a child’s competence to consent, or feels uncomfortable about relying solely on the child’s decision, because of the invasive nature of the research, for instance, it may be desirable to involve the child’s parent or guardian in the decision-making process. However, this should only be done with the child’s permission. Right 7(3) of the Code of Rights provides that consumers with diminished competence retain

9 See for example the comments expressed by Ron Paterson in his paper ‘Legal and ethical dilemmas’ at the Ministry of Health’s Workshop on Consent in Child and Youth Health in 1998 at p 49 before he became the Health and Disability Commissioner. In R v Laufer, supra note 5, the jury decided that the 13 year old Tovia Laufer lacked the necessary competence to refuse medical treatment for a cancerous tumour on his knee. The Care of Children Bill extends s 25 of the Guardianship Act to permit a child over sixteen to refuse medical treatment: cl 35.
10 Code of Rights, Right 7(7). See also Valentine, supra note 6.
the right to make informed choices and give informed consent to the extent appropriate to their level of competence. Although this Code applies only in the health context, we believe this principle is of general application. Children who are of questionable competence should at the very least be accorded the respect and dignity of deciding whether their parent or guardian should be approached for assistance in the consent process.

If the child refuses to have a parent involved, this should be respected even if this means that the child has to be excluded from the research. If the child consents to parental involvement in the decision-making process and the child is not clearly incompetent, their views should be accorded primary importance. Respect for the child is paramount.¹¹

Children lacking competence
Children who lack the necessary competence to give legally effective consent cannot participate in research unless an adult has the power to consent on their behalf and does so. Whether proxy consent can lawfully authorise a child’s participation in research is discussed below.

Child’s assent
Even if proxy consent has been granted, incompetent children should still be involved in the consent process to the extent of their ability. Although they cannot give legally effective consent, their willingness to participate must be ascertained and their ‘assent’ obtained in whatever manner they can express it. Article 12 of the UN Convention on the Rights of the Child stipulates that all children have the right to express their views on matters which affect them, and that those views should be given due weight in accordance with their age and maturity. The tendency to ignore this requirement, because of time constraints or a presumed inability of the children to understand, is a serious breach of these principles.

Obtaining a child’s assent may not be easy. The children may not know they have been enrolled in a research project and, even if they do, they may not be accustomed to adults seeking their point of view. Research has shown that the manner of the researcher’s approach to the child participants and their parents directly affects their willingness to engage in the research and the quality of data obtained. Gollap makes some useful suggestions in her article ‘Interviewing children: a research perspective’.¹²

Child-centred information
As always, information must be made available to the children in a form and language they can understand. If the children are able to read, it may be appropriate to provide a

¹¹ The Care of Children Bill, currently before Parliament, supports this view.
simply worded information sheet and give them the opportunity to consent in writing. This is likely to give children the sense that they are being respected and that their views are valued. The older they are, the closer the procedures should be to those normally applicable to competent children and adults.

A child’s refusal
All the research guidelines insist that an incompetent child’s refusal to participate in research must be respected. Nevertheless, the New Zealand Ethical Guidelines for Health Research with Children still permit a child’s refusal to be overridden by their guardian if the child would receive therapy in the research for which there is no medically acceptable alternative. The research is then really treatment, albeit of an experimental kind. It is difficult to envisage any other circumstances in which a child’s refusal might legitimately be overridden.

Incompetent children can make their unwillingness to participate known in a variety of ways. Very young children might cry or show their unhappiness in some other way. Older children may be more verbal. Care should be taken to guard against parental pressure, no matter how well-meaning the parent may be.

Is Proxy Consent Lawful?
If a child lacks the necessary competence to give legally effective consent to a proposed activity, it is assumed that parents or guardians have the power to consent on behalf of the child. This assumption is generally correct, provided the activity is lawful in all other respects. Parental consent cannot legitimise otherwise unlawful acts. However, in the context of research there is some uncertainty about the legal effect of proxy consent by virtue of the New Zealand Bill of Rights Act 1990. Section 10 of that Act provides:

> Every person has the right not to be subjected to medical and scientific experimentation without that person’s consent. [emphasis added]

This section appears to apply to all persons and does not seem to leave room for proxy consent. Such an interpretation would have been in keeping with the Nuremberg Code, but that Code was adopted as a response to inhumane experiments conducted in Nazi Germany. Its cautionary approach is now widely seen as detrimental to the well-being of children, as it has precluded children from sharing in the benefits of research.

Section 5 of the New Zealand Bill of Rights Act permits such reasonable limits on the rights it affirms as can be ‘demonstrably justified in a free and democratic society’, provided those limits are prescribed by law. The Ethical Guidelines for Health Research with Children probably meet these requirements and are arguably part of our law by virtue of Right 4(2) of the Code of Rights. We believe that the conditions specified there, under which children may participate in some health research on the basis of a proxy consent, would qualify as a reasonable limitation on the right expressed in s 10. The conditions imposed by those guidelines are similar to those adopted in other democratic societies and they comply with the UN Convention on the Rights of the
Children. They permit incompetent children to participate in health research with proxy consent in carefully defined circumstances.

This interpretation makes more sense than one that would prevent all children from enjoying the benefits of research because they lack competence to consent. Nevertheless, this interpretation of the New Zealand Bill of Rights Act has not been tested in court. So there is still some uncertainty as to the legitimacy of conducting medical or scientific experiments on children who are not competent to give legally effective consent.

Section 10 of the New Zealand Bill of Rights Act applies only to medical or scientific experimentation and may therefore not apply to other forms of research. The general assumption that proxy consent may authorise a child's participation in such research would then apply. As explained above, in the section dealing with incompetent children, even if proxy consent is lawful the child's assent or willing co-operation is also required.

Who can Give Proxy Consent?

Proxy consent will be necessary where the child is under sixteen and does not have sufficient understanding to give their own consent. It will also be necessary where the child is over sixteen and lacks the capacity to consent on their own behalf.

In law, a guardian has a right to control the upbringing of a child until the age of twenty. This is explicitly stated in s 25(3) of the Guardianship Act in relation to medical treatment, but it is also a principle of general application.

The researcher will have to identify the child's guardian. Generally speaking, when the parents of the child are married or are living together as husband and wife at the time the child is born, both parents will be guardians. If the parents are not married or the father is not living with the mother at the time of birth, the mother will be the guardian. The father can become a guardian if he applies to the court and it makes an order for him to be a guardian. Guardianship continues even after parents separate. It is also possible for others such as grandparents, foster parents or step-parents to be appointed guardians by the court. They do not have this status as of right but can obtain it through a court order. Adoptive parents take on the guardianship rights of the natural parents through the process of adoption.13

It is not legally necessary to have the consent of all guardians to carry out research on a child. The Act requires the consent of 'a' guardian. If the other guardian(s) object then they can challenge the decision of the consenting guardian in the Family Court. The Court may decline to intervene or decide that the consent should be withdrawn if it is not in the best interests of the child. Any research carried out before the court order withdrawing consent would be lawful because at that time the consent of the guardian was still effective. In order to pre-empt the possibility of a guardian who has not been consulted trying to have consent withdrawn, it is good practice to consult both guardian

13 The Care of Children Bill, currently before Parliament, proposes some changes to the guardianship provision.
parents. This will not always be possible where the parents are separated. There will be situations where one guardian parent is agreeable and the other is not. The research can then go ahead on the consent of one guardian provided the research is in the best interests of the child.

If there is no guardian in New Zealand, or if the guardian is incapable of giving consent, it can be given by any person in New Zealand who is acting in the place of a parent. If there is no such person, consent can be given by a district court judge.

Inducements to Consent
Whether it is lawful to pay or otherwise remunerate research participants is uncertain. Some people argue that it is perfectly appropriate to pay participants for services rendered. Others are concerned it may invalidate consent. If the payment induces the participating children or their parents to consent when no reasonable person would have done so, their consent may not be legally effective. The payment would then constitute an improper inducement. Health research guidelines generally prohibit such payments, out of concern that they might induce participants to withhold important medical information that would exclude their participation.

Inducements may take a number of forms, such as financial payments, vouchers, special treatment or some other advantage which would not otherwise be available to the participant. Even the promise of a burger, mentioned at the right time, may be sufficient to persuade some children to take part when they would not otherwise have done so. But this is not necessarily improper. It is perfectly proper to remunerate participants for their out-of-pocket expenses, time, discomfort or inconvenience, provided it is in the form of compensation and does not invalidate the consent given. This is not an easy call to make, and it will depend on a variety of factors, such as the risk of harm from non-disclosure, the nature of the remuneration and the likely impact on the child participant and their parents or guardians. If it is intended to remunerate the participants in some way, research guidelines generally stipulate that this should be disclosed to the ethics committee responsible for reviewing the project.

Risk of Harm
The term ‘risk of harm’ means both the probability and the magnitude or severity of harm occurring as a result of participating in research. ‘Harm’ should be interpreted broadly. It includes the physical, psychological and emotional hazards, and not only harm to the child, seen through their eyes, but also harm to the child’s family. We are concerned here only with harm caused by the research project itself, not harm arising from some other cause, such as accidents en route to the research venue.14

As was explained earlier in chapter 12, many forms of research carry some risk of harm to participants, and research guidelines therefore attempt to limit the risk to

14 Liability for harm caused by research is discussed in chapter 17.
which participants may properly be exposed. When the participants are children, the limits are usually stricter, especially if the research is not intended to be of direct benefit to participants. The degree of risk to which children may be exposed has been addressed principally in the context of health research. But the issues raised in that context have general relevance.

Health Research

The Ethical Guidelines for Health Research with Children distinguish between research procedures or interventions that are intended to provide direct therapeutic benefit to child participants and those which do not have that purpose.

Therapeutic interventions

Research interventions that have a therapeutic purpose may be undertaken if the risk to the child is clearly outweighed by the anticipated benefit to the child and the risk/benefit ratio is likely to be at least as favourable as it would be if the child was undergoing conventional procedures. The researchers have to carry out a risk/benefit analysis, to the extent that the relevant information is known from earlier investigations, plus an analysis of the procedures the child would otherwise receive, and then compare the two. If the risk from participating in the research is greater than the risk associated with conventional treatment, the research will be deemed unethical.

For example, in a clinical trial comparing a current drug with a new one for treatment of a disease from which the child is suffering, the researchers have to consider the potential risks and benefits of both drugs and be satisfied that the child will be no worse off on the new drug. The greater the potential benefit from participating in research, the greater the risk to which the child may be exposed. Conversely, if the risk of harm to the child participant is greater than the anticipated benefit, the research is unethical.

Non-therapeutic interventions

Research that is not intended to be of direct therapeutic benefit to child participants is not necessarily unethical. The research may yield information of relevance to the health needs of children generally or to the needs of children who are suffering from the same disorder or condition as that child. Although not of direct benefit to participants, both types of research may be ethical, because they are expected to produce information of benefit to the future well-being of children. Much research on Sudden Infant Death Syndrome (SIDS or cot death) falls into this category. The infant participants are not intended to benefit from the research, but the knowledge gained may save other children’s lives.

When there is no direct benefit to the children in the research, the Ethical Guidelines for Health Research with Children impose an absolute limit on the degree of permissible risk to which they may be exposed. If the aim of the research is to yield knowledge relevant to the health needs of children generally, the risk to participants must be minimal
and commensurate with the importance of the knowledge likely to be gained. On the other hand, if the participants are suffering from a particular condition or disorder and the purpose of the research is to gain knowledge of vital importance for the understanding or the amelioration of that condition or disorder, a minor increase over minimal risk is acceptable.

What is meant by ‘minimal risk’ is not always clear. A variety of definitions are used in different guidelines. In an attempt to clarify more precisely what is permissible, the British Paediatric Association listed the types of interventions that may be conducted on children in various forms of research. In the context of non-therapeutic research, the list explicitly excluded all forms of invasive interventions and procedures, such as blood sampling by venepuncture, because of children's fear of needles. This restrictive approach was strongly criticised, because it prevented valuable research and ignored the fact that there are ways of reducing or eliminating such fears. The Association’s successor, the Royal College of Paediatrics and Child Health, amended the guidelines in 1999 to permit invasive interventions if there are good reasons for using them.15

New Zealand's Ethical Guidelines for Health Research with Children do not provide a similar list of permissible interventions. In keeping with the approach adopted elsewhere in the world, ‘minimal risk’ is defined in broad terms as:

- the probability and magnitude of harm or discomfort anticipated in the research must be no more likely and not greater than the risks ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests.

Although ‘a minor increase over minimal risk’ is vague, some valuable research may not be possible without a little more leniency of this kind. Ethics committees will have to determine whether the research satisfies this criterion.

Non-health Research

Similar criteria might apply to non-health research because the same issues are likely to arise. Research in non-health areas may be to the child's benefit, but often that is not its primary purpose. Non-health research may also inflict harm on its participants, particularly emotional or psychological harm. Such research might therefore be considered under the same criteria. For instance, interviews with children about their experience of their parents’ separation or divorce might be of direct benefit to the child participants, but it may also be stressful. The risk of such stress might still be outweighed by the benefits children may derive from disclosing their experiences and from having their needs identified. Even if there is no direct benefit to them, the risk of harm might be only a slight increase over the minimum and therefore justifiable in the light of the knowledge gained, which may be of considerable importance for other children in those circumstances.

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15 The RCPCH Guidelines are published in Archives of Disease in Childhood (2000) 82:177.
OTHER ISSUES OF PARTICULAR RELEVANCE TO CHILDREN

RESEARCH DESIGN

Given the special vulnerability of children and their particular needs, research projects involving them should be designed or supervised by people experienced in dealing with children. The interventions, techniques and methodologies should be geared towards this class of participants. Techniques that are effective with adult participants may not work with children. Special measures may be necessary, such as using EMLA cream to anaesthetise the area from which blood will be drawn, or adopting some of the suggestions made by Gollop for conducting interviews with children. 16 Professor Anne Smith, Director of the Children’s Issues Centre at the University of Otago, recommends involving children in the development and planning of the research or seeking their views on proposed research instruments. This gives children respect and recognises them as full participants in the project.

The number of children involved should be limited to the minimum number required to ensure the results are scientifically reliable, particularly if there is some risk of harm. Where possible, researchers should give preference to older children rather than younger ones. Older children are less vulnerable and more likely to be able to give informed consent.

PRIVACY AND CONFIDENTIALITY

Children, like adults, are entitled to have their privacy respected and their confidences maintained. However, parents often feel entitled to have access to information about their child. This may not always be appropriate or sensible. Researchers should therefore consider in advance what their response would be to a parental request for access to information researchers have collected regarding that child. If the child is competent to consent to participate in the research, then information should not be disclosed to the child’s parents without the child’s consent. Even if the child lacks the necessary maturity to give legally effective consent, and the parent has provided proxy consent, it may be appropriate to obtain the child’s consent to that disclosure. Respect for the child is paramount.

As is explained in chapter 5, some research may elicit sensitive information which may be of interest to people not directly involved in the research, such as the child’s parents or the police. A child might disclose information to the researchers about their own or a parent’s criminal behaviour, such as sexual abuse within the family. Researchers should consider this possibility and decide how they intend to deal with it. They should document their proposed response in their application for ethical approval of the project.

Rule 11(4) of the Health Information Privacy Code is of some assistance in this regard. It was inserted in response to concerns about improper use of parents’ right of

16 Gollop ‘Interviewing children’.
access to health information about their child under s 22F of the Health Act. Broadly, speaking, Rule 11(4) permits health researchers to refuse parents access to information about their child if the child does not wish the information to be disclosed to one or both of its parents, or if the disclosure would be contrary to the interests of the child.

Retention of Research Data
There are a variety of rules about retention of data, including research data, which are discussed in chapter 5. However, when the data pertain to children, a longer period of retention is recommended in the Ethical Guidelines for Health Research with Children in case they contain information of value to child participants in adulthood. This principle may be particularly important in the health context, but it is also one of general application.

Duties on Completion of Research
Some guidelines, such as the Interim Good Clinical Research Practice Guideline, require the researchers to notify participants that the research has been concluded and to ensure they are followed up appropriately by a health practitioner. These requirements clearly apply to child participants.

In addition, as a sign of respect to participants, ethics committees commonly require researchers to provide participants with a summary of their findings on completion of the project. Children are entitled to the same respect and should be treated in much the same way. If the children can read, it might be appropriate to send them a summary of the findings written in language suitable to their age and ability. If they are too young to read, the summary should be made available to their parents. Although this may seem more a matter of courtesy than a legal requirement, health researchers in particular are reminded of their obligations under Rights 4(2) and 6 of the Code of Rights; the latter includes a duty to provide participants with the results of research.

Research guidelines, codes and conventions

New Zealand

Other countries
- Code of Federal Regulations, Title 45 (1991)—USA.
- Medical Research Council of Canada, the Natural Sciences and Engineering

17 See chapter 9 ‘Clinical trials’.


Royal College of Paediatrics and Child Health, Guidelines for the Ethical Conduct of Medical Research Involving Children (1999) – United Kingdom.


National Health and Medical Research Council, National Statement on Ethical Conduct in Research Involving Humans (1999) – Australia.

INTERNATIONAL

• Nuremberg Code (1947).

• World Medical Association, Declaration of Helsinki (1964, 2002).


• World Health Organization, Operational Guidelines for Ethics Committees that Review Biomedical Research (2000).

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