Ethics of Research in Children

Paediatrics & Child Health Division

The Royal Australasian College of Physicians
Acknowledgements

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Preamble

The Royal Australasian College of Physicians takes the position that high quality research in children and young persons should be encouraged. The potential beneficiaries of such research include participants, their peers, future generations of children, children when they reach adulthood and thus society as a whole.

Research involving human participants is premised on two fundamental moral commitments:

(1) to improve human welfare by advancing scientific knowledge; and
(2) to protect the dignity and wellbeing of the research participant (respect for persons and beneficence).

Justice requires that the benefits and burdens of research be distributed fairly among all groups in society, taking into account age, gender, social and economic status, culture, and ethnicity. The World Health Organization (WHO) estimates that 90 per cent of the resources devoted to health research are applied to diseases which cause less than 10 per cent of the present global disease burden. From a global perspective, health care service inequities between rich and poor countries are perpetuated by health research priorities. Children and young people have also tended to be disadvantaged by lack of appropriate research, sometimes because of concerns for their safety. The RACP recognises that the interests and needs of children differ from those of adults in research, as in other areas of life. However the participation of children in research should be encouraged, particularly in the emerging area of drug treatment in children, provided adequate safeguards are put in place.
Definitions

The policy is limited to the ethics of research in infants, children and young persons. Research is difficult to define comprehensively. For the purposes of this policy, research is defined as systematic, original investigation, designed to develop or contribute to knowledge. There is an understanding of intent to make the knowledge widely available, and therefore there is usually (but not invariably) an expectation that the knowledge can be generalised (i.e. has external validity).

An important and related activity is quality assurance audit, which is a vital activity of all good clinical services and includes activities whose primary purpose is to monitor, evaluate, or improve the quality of health care delivered by individuals or organisations. Research and quality assurance audit are not clearly demarcated activities, but form a continuum. Both should be conducted using good scientific methods and ethical principles, by or in consultation with well-qualified individuals. Some quality assurance requires review by a Human Research Ethics Committee.

Because of the role of paediatricians in diagnosing and treating disease, the approach of this policy is inevitably skewed towards research within a medical model. However, the principles apply equally to other models.

For the purposes of this document, the term child is used as a collective term for infants, children and young persons from birth until the 18th birthday.

Special consideration needs to be given to the emergence of reasoning ability and autonomy during those 18 years, and in places in the document, distinctions are made between infants, children and young people. The ability to understand sophisticated information and the ability to make autonomous decisions are key expectations for informed consent in adults. These capacities are absent in infants, but emerge during childhood and are often well developed by mid to late adolescence.
This policy uses the term *Human Research Ethics Committee (HREC)* to encompass the following:

- **HRECs** constituted according to the Australian National Statement on Ethical Conduct in Research Involving Humans NHMRC 2007 and registered with the NHMRC;

- Health Research Council Ethics Committees constituted under the New Zealand Health Research Council Act 1990; and

- Health and Disability Ethics Committees constituted under the New Zealand Health and Disabilities Act 2000.
Application

RACP Fellows and trainees who are designing, conducting or supervising research that involves children are expected to comply with this policy. The policy also represents the College’s recommendations for all researchers undertaking research that involves children. It is envisaged that the policy will assist clinicians whose patients may be involved in research conducted by others, those charged with the responsibility of approving (e.g. Human Research Ethics Committees) or supervising research, and the public in general to understand how the interests of children and young people should be considered in the setting of research.

Context

Wherever uncertainty exists about the application of this policy, consultation should be sought from a research ethics committee with experience in research involving children. This policy promotes and is intended to be consistent with the publications listed below. However the policy has an intentional focus on ethical issues where the protection of infants, children and young people involves different considerations from similar research in adults. The documents below address numerous additional issues that are important or even crucial to the ethical design, but where the principles and application are the same or very similar in all age groups. For matters not covered in this policy, the reader is referred to them. These issues include, but are not limited to: confidentiality, the provision of feedback to research participants, the notification of relevant health care providers, indemnity and compliance with internationally accepted guidelines and declarations:

Australia

- *National Statement on the Ethical Conduct of Research Involving Humans* NHMRC 2007;

- *Revision of the Joint NHMRC/AVCC Statement and Guidelines on Research Practice: Australian code for the responsible conduct of research Second consultation draft* NHMRC February 2006;
When does Quality Assurance in Health Care Require Independent Ethical Review NHMRC 2003;

Guidelines Under Section 95A of the Privacy Act 1988 NHMRC 2001; and

Other NHMRC guidelines that contain material relevant to research involving children.

New Zealand


Consent in Child and Youth Health: Information for Practitioners. Ministry of Health 1998;

Operational standard for ethics committees. Ministry of Health; and

Other HRC & MOH guidelines that contain material relevant to research involving children.
Rationale for research in children

The RACP acknowledges the value of conducting research in children, and indeed the entitlement of children and young people now and in the future to receive the benefits of good research conducted on and for them. There are several reasons why good research in children is essential for improving child health. For example, there are substantial physiological and psychological differences between children at different developmental stages and between children and adults. Indeed, many childhood disorders and issues affecting the well-being of children (e.g. injuries) can only be understood in the context of development. Disease susceptibility, pathophysiology, and broader health determinants can differ markedly. Some childhood diseases and conditions are unknown or not relevant in adulthood. Children can be more or sometimes less vulnerable to toxicity than adults. In addition, interventions early in life can have unanticipated and sometimes irreversible long term effects. In addition, researchers themselves gain experience by conducting research studies in children, and this is likely to foster the future of research in children.

Research in children should be conducted where it will:

- ensure optimal diagnosis, assessment, treatment and prevention of disease during childhood;
- advance the health and welfare of children;
- identify the determinants of child health
- contribute to understanding the pathophysiology of childhood disease;
- contribute to understanding of the childhood origins of adult health or disease; and/or
- improve the methodology of research in children.

While much research in children is vital, there is a special duty of care to weigh the risks and burdens of research participation against the potential benefits. It is necessary that research conducted in children has high scientific merit and integrity and is undertaken with proper respect, justice and
beneficence for child participants. This is especially true since children may have only a limited or no understanding of what the research entails and their participation is therefore completely involuntary.

In general, research should not be conducted in children in the following circumstances:

- where the information can be gained equally well in adult volunteers;
- where it will expose children to significant risk that exceeds the magnitude and likelihood of potential benefit; and
- where suitable preliminary studies have not been conducted in adults first. For example, children should not usually be the subject of ‘first in man’ and other early phase studies of new drugs. There are clear exceptions to this principle such as testing drugs or devices in diseases found most commonly, or exclusively in children.

Although respect for persons mandates that the individual rights and needs of children are considered, in nearly all circumstances their best interests are served when researchers also consider impact on the family. In this regard, researchers should have an awareness and respect for cultural diversity in family structure and function.

The guidelines that follow are intended to assist in applying these principles to research in children. In exceptional circumstances where a researcher may need to depart from these principles and guidelines, sufficient justification would need to be provided as to why this is necessary and the relevant human research ethics committee would need to carefully assess these reasons.
The balance of risk and benefit

In considering research proposals involving children, the risks to the child must be balanced against the likely benefits to the child, family and community. On one hand, concern to protect children from the potential harms of research may deny them potential benefits. On the other hand, to ensure that this vulnerable group is not exploited, it is important to assess carefully the potential benefits and harm to children from the research. The foreseeable risks should be kept as low as possible, and the potential benefits from the development of treatments and furthering of knowledge must outweigh any foreseeable risks. A substantial risk of serious harm would render the research unethical except in special circumstances, usually life-threatening situations. Even with low risk, if there is only slight, uncertain, or no benefit to the child, research requires serious ethical scrutiny.

Risks include those relating to physical and emotional harm, pain and anxiety to the child or the family and/or cultural or community group. While elements of risk assessment should be conducted by all who are involved in the research including the children where feasible, their parents/guardians and their clinicians, researchers and research ethics committees have a clear duty to assess risk comprehensively.

Assessing the risk of benefit or harm

The assessment of risks takes into account the nature, likelihood and potential severity of harm, discomfort or inconvenience.

- Negligible risk research applies when there is no foreseeable risk of harm or discomfort, although inconvenience may be incurred. Examples could include procedures such as questioning, observing, measuring and obtaining bodily fluids without invasive intervention, (e.g. saliva or urine samples), provided that procedures are carried out in a sensitive way and privacy is adequately protected.
- Low risk research may incur physical or other discomfort, but does not result in distress. Low risk therefore includes procedures that might cause no more than brief pain or tenderness, small bruises or
scars (e.g. a blood test, especially if performed in the context of other clinically indicated tests).

- Certain high risk procedures such as lung or liver biopsy, arterial or lumbar puncture, and cardiac catheterisation are not justified for research purposes alone in children, so can be carried out only when research is combined with diagnosis or treatment intended to benefit the child.

These examples focus on tests and procedures and on direct physical risk and are intended only as a guide.

In considering the balance of potential benefits and harms, the following factors will need to be considered:

- Magnitude – For disease-related research, how severe is the condition that the research aims to alleviate and how is the knowledge that will be gained likely to be used?
- Probability – How likely is the research to achieve its aims?
- Beneficiaries – Is the research intended to benefit the child participants, and/or other children?
- Resources – Will potential benefits be limited because the treatment is very expensive, or difficult to deliver?
- Types of intervention – Is there a new treatment, procedure or health intervention which could replace one involving greater risk?
- Timing – Are the potential benefits likely to be brief or long-lasting, immediate or not evident until years later?
- Equity – Should a wider range of children be offered the potential benefits of participating in the research?

Investigators and reviewers of research should also take steps to minimise risk. The following are questions that will help determine whether this can be accomplished:

- Are the investigators qualified to perform the research, to recognise potential risks?
• Do they have appropriate skills and expertise in caring for children of the ages included in the study?
• Will research be performed in a setting appropriate for the physical and emotional needs of those age groups?
• For research that involves more than low risk, does the research protocol have an adequate plan for monitoring the safety of the child participants?
• Are the endpoints for early discontinuation of the research on the basis of clear harms or benefits appropriate?
• What are the procedures for ensuring confidentiality of the data? Can any additional reasonable steps be taken to remove identifiers from data?
• Does the research consider all the important adverse outcomes, including long term consequences?
• Is the safety of participants assured during any withholding of standard or active treatment?
• Are there mechanisms to deal with any harms that occur?

Approval and monitoring of research involving children

Research involving children or young people should be reviewed by people who have specific experience and knowledge of the interests and vulnerabilities of children. Where an HREC does not include such individuals, consultation (such as with a member of the Paediatrics & Child Health Division of the RACP or other appropriate person or ethics committee) is essential, especially if the study involves more than low risk.
Conduct of research involving children

1. The design of research involving children should:
   a. be undertaken by or include consultation with professionals who are trained and experienced in relevant aspects of child health (e.g. clinical care or population health);
   b. consider the possibility that children may be more vulnerable to short term adverse effects;
   c. consider that their immaturity may increase their potential for long term adverse effects (including carcinogenesis and teratogenesis) - commonly but not invariably, the risk of very long term adverse effects increases with decreasing age;
   d. be held to high standards of quality and scientific merit;
   e. wherever reasonable, include consultation with parents and children or young people themselves in its design; and
   f. respect (whenever relevant) that children need uninterrupted access to education and routines for nourishment and sleep.

2. Research involving children should:
   a. be conducted or supervised by researchers with training and experience in relevant aspects of child health (e.g. clinical care or population health);
   b. take place in circumstances and in an environment that provides for the wellbeing of the child and family; and
   c. usually take place after informed consent has been provided.
Consent and assent to research in children

Respect for persons requires that participation in research usually occurs after the participant has made a voluntary decision, based on sufficient information and understanding, and free of coercion or inappropriate incentives. The term *informed consent* is applied to this process, and it traditionally includes the following elements:

- The provision of information and explanation;
- Assessment of the recipient’s understanding and capacity to decide; and
- Reasonable assurance that an agreement to participate is voluntary;
- Reasonable time and opportunity to ask and ascertain answers to all questions.

The application and documentation of each of these elements is expected to be in proportion to the burdens and risks of participation. For example, higher demands are traditionally placed on studies involving invasive or intrusive procedures or collection of highly sensitive data than on studies involving only low risk observation. Having said this, some of the research studies condemned most harshly for lack of informed consent in previous decades have consisted of observation of ‘natural history’ of disease. It follows that although (even when competent adults are involved) there are circumstances in which the requirement for informed consent cannot be met, it is mandatory that any omission of consent, concealment or deception be justified to a research ethics committee and other provisions must be put in place to protect participants and demonstrate respect for them.

In the case of children and young people, parent(s) or legal guardian(s) generally have ethical and legal responsibility for weighing information and making decisions in the best interests of their child. However, children have emerging potential for understanding information, for making decisions and envisaging their consequences, and desire for autonomy. The capacity for understanding and for rational, autonomous decision making emerges gradually, rather than as a quantum step. Thus, there is no age above which all
children can participate fully. However, it is unlikely that children below school age will be able to, and disorders of cognitive or social development may limit an older child’s capacity. In research, principles of ethics and good paediatric practice are met when older children and adolescents are provided with information and opportunity for choices appropriate to their cognitive age, and are invited to participate.

There are some circumstances in which the capacity of parent(s) to make decisions in the best interests of their child is diminished. Those circumstances include parental mental illness, suspected parental abuse or neglect of the child, or where a child has chosen to live apart from parents or appointed guardian. Notwithstanding the fact that these young people may be forced by circumstances or have chosen to function more autonomously than their peers in all areas of their lives, they are among the most vulnerable members of society. While they should not be lightly denied the benefits of research participation and their capacity for decision making should be respected, special care is needed to ensure that they are not harmed or distressed.

The practical steps in adhering to the above principles include:

1. Agreement to participate should usually be sought from both the parent/guardian (informed consent) and from those children who are capable of understanding decisions and their consequences. Although often regarded as a synonym for consent, there is a useful tradition in ethics of using the term *assent* for concurrence or agreement, without the formal and legal expectations of informed consent. For the purposes of this document, this tradition is applied to agreement on the part of a child where an appropriate adult is taking formal responsibility for the decision to participate;

2. In some cases, the consent of other people or agencies may be advisable, or required by law;

3. Where parents/guardians are providing consent, information must be provided to the parent or guardian about the purpose, methods,
demands, risks, and burdens of the research project, as well as any declarations of interest. The description of risks should include consideration of threats to the child’s and family’s privacy and autonomy where appropriate.

4. The person seeking consent should assess, as far as possible, that the person giving consent understands the information, and is capable of making a decision in the best interests of the child. If the capacity of a parent or guardian to provide informed consent is clearly impaired, and where there is little or no expectation of benefit to the child inherent in the research, participation of the child is inadvisable. Where the child clearly stands to benefit, the decision of a legal surrogate (individual, such as the other parent if he or she has parental rights, or responsible government entity) will need to be sought.

5. The decision to participate must be free of coercion or any inappropriate incentives. The alternatives to participation and the treatment offered if consent is withdrawn should nearly always meet prevailing standards of high quality, evidence-based care. Any deviation from this requires specific justification.

6. Where children are asked for assent, information should be provided to them using spoken or written words, illustrations or other means appropriate for their cognitive age, and where necessary, adapted to their culture. It is likely to be appropriate to also describe the alternatives to participation and consequences of withdrawal. Testing written information sheets and assent forms by having children of similar age read and comment on them, is encouraged.

7. Children younger than those expected to provide assent still deserve age-appropriate explanation of the experiences they will encounter in the context of research.

8. In nearly all circumstances, refusal on the part of a child or young person who is capable of providing assent should be respected. This is most compelling in the context of research that has little or no potential for direct benefit to the child.
9. In the case of infants and those children not capable of providing assent, refusal to participate in research is more difficult to interpret. In general, it is the parent/guardian who should decide whether the burden of any distress caused by research procedures outweighs any advantages of participation.

10. Some countries have legal definitions of circumstances in which minors are deemed competent to give consent for treatment or research participation. The New Zealand *Code of Health and Disability Services Consumers Rights* (1966) allows minors to consent to treatment or research and requires a practitioner to make an independent judgement of the competence of a child to give informed consent with respect to treatment. This is explained in the Ministry of Health document *Consent in child and youth health: Information for practitioners*. An expectation is established that researchers will outline on what basis they will judge the capacity of the young person to provide consent.

In Australia, the age at which children are deemed to have the capacity to consent to treatment varies state by state, as follows (current as at 12/2005):

- **NSW**: 14  *Minors (Property and Contracts) Act 1970 NSW s. 49(2)*
- **SA**: 16*  *Consent to Medial Treatment and Palliative Care Act 1995 (SA) s. 6*
- **ACT**: 18  *Age of Majority Act 1974 (Act) s. 5*
- **NT**: 18  *Age of Majority Act 1974 (NT) s. 4*
- **QLD**: 18  *Law Reform Act 1995 (QLD) s. 17*
- **TAS**: 18  *Age of Majority Act 1973 (TAS) s. 3*
- **VIC**: 18  *Age of Majority Act 1977 (Vic) s. 3*
- **WA**: 18  *Age of Majority Act 1972 (WA) s. 5*

*SA: Treatment is allowable where the child consents and:
(i) the medical practitioner who is to administer the treatment is of the opinion that the child is capable of understanding the nature, consequences and risks of the treatment and that the
treatment is in the best interest of the child’s health and well-being; and

(ii) that opinion is supported by the written opinion of at least one other medical practitioner who personally examines the child before the treatment is commenced.

The practitioner may administer medical treatment to the child (Consent to Medial Treatment and Palliative Care Act 1995 (SA) s. 12).

In regard to Australian Common Law, the High Court in: Department of Health and Community Services v JWB and Another (Marion’s Case) (1992) 106 ALR 385 accepted the test in Gillick v West Norfolk AHA [1986] AC 112 (HL) that a child can consent to a procedure as a “mature minor”. This will be established where the child has “achieved a sufficient understanding and intelligence to enable him or her to understand fully what is being proposed”.

The case established the capacity of the child to consent to be a question of fact to be determined in each case, depending on the age and level of maturity of the child and the nature of the procedure. A child who is “Gillick-competent” is legally competent to give an effective consent to a medical procedure by him or herself.

Thus in some circumstances it is appropriate for a young person alone to consent to treatment, and it is reasonable that this should apply to some research, particularly where the potential benefits significantly outweigh risks, for example in some school based survey. The Australian NHMRC National Statement on Ethical Conduct in Research Involving Humans (2007, paragraph 4.2.9) specifies conditions in which this can be approved by an Australian HREC.

The RACP also recommends that in these circumstances:

a. particular sensitivity is needed when there are other inequalities of power or status between researcher and participant, (eg doctor/patient, teacher/student) in addition to the inequality that is inherent in difference in age; and
b. the young person is encouraged to choose someone he or she sees as supportive and independent of the research team to witness the provision of information and signing of consent.

11. When children are recruited to long term research studies, consent for participation is likely to have been obtained originally from a parent or guardian with or without the child’s assent. In many such studies, particularly intervention and intrusive observational studies but also many databases and DNA or tissue banks utilising identifiable data, the young person’s affirmation of consent must be sought at an age when he or she has the capacity and/or statutory right to provide autonomous consent. Mechanisms for this need to be designed at the inception of the study.

12. Where research involves more than one child in a family (e.g. collection of data to define a pedigree), each child should be considered individually for purposes of consent.

13. Only in rare instances should rewards be offered to children for participation in research, particularly during the consent process. Rewards are virtually never appropriate to prevent children withdrawing from a study.

14. Inducement should be subjected to careful ethical scrutiny. The dividing line between inducement and benefit is a fine one. At what point does the provision of medical services or reimbursement for a participant’s time amount to an undue influence on a participant’s decision to take part in the research? Inducements which have been considered acceptable during research include money in the form of payments for travel, inconvenience or work lost, and meals or other sustenance needed while directly participating in the research, health care for individuals or their families during the trial, and non-therapeutic community health interventions. Decisions about which particular inducements are ethically acceptable will depend on local circumstances and local consultation is vital in making appropriate distinctions.
Research focused on presymptomatic screening or diagnosis

Such research in children carries risks and benefits qualitatively similar to similar research in adults. However, the balance between risks and benefits may shift with age, particularly when age of onset of symptoms is late or uncertain. Certain principles deserve consideration in research involving presymptomatic screening or diagnosis in children.

- In diseases that are unlikely to manifest or be preventable during childhood, screening should be deferred until the child can make an appropriate decision about participation. Where there are compelling reasons to deviate from this, it may be appropriate to use fully anonymous samples and data, or to defer any disclosure of individual results until the child can make a mature choice.

- For tests whose validity is uncertain, the risks posed by that uncertainty need to be evaluated in considering the impact of the research. Steps may need to be taken to mitigate the effects of false positive or false negative results.
Research involving genotyping in children

Genotyping (used here broadly to mean obtaining individual genetic information) may be used in research for a variety of reasons, including:

- testing the association of genetic factors with individual characteristics, such as disease risk, in order to decipher pathophysiology;
- assessing individual risk of disease in participants or in their family members;
- assessing neoplastic conditions or predisposition to them; and
- developing or testing prevention, surveillance or treatment options.

Just as with other types of research, generalisation is potentially hazardous because intensity and likelihood of adverse and beneficial effects to individual participants varies widely from one study to another. So too, do the potential risks and benefits to genetic subgroups within society. While identification of genetic risk factors may enable early identification and treatment of individuals and allow allocation of resources for groups, there is also the risk of racial and or genetic vilification. These issues have been and are being discussed extensively in other documents. However, the RACP endorses several key principles in respect to children:

- The use of children (as opposed to adults) in studies involving genetic information should be clearly explained and justified to a research ethics committee;
- The possibility of coercion in situations where the identification of genetic information benefits other family members more than (or to the potential detriment of) the child should be carefully weighed;
- The risk that genetic information could negatively influence future choices for the child such as access to life and health insurance and employment should be considered and the risks, if any, made clear;
- Unless the link between genotype and disease risk is well established, and identification of participants is necessary for the study or is clearly justified for the benefit of participants, robust methods for deleting identifiers should be used and consideration should be given to concealing individual results from participants and their families, while
still fulfilling obligations to make aggregate results of research available to participants wherever possible. It is likely to be more appropriate to build in mechanisms for contact with participants to arrange later retesting than to reveal research results that have not been obtained in an accredited clinical laboratory;

- The potential of genetic pedigree studies to identify non-paternity and other unexpected family relationships should be weighed, parents/participants informed of the risk and plans made to assist with the consequences; and
- Consultation with professionals skilled in genetic counselling pertaining to children is often advisable in the design, review and conduct of genetic research in children.

The importance of re-affirming consent when children’s genetic data are held for many years, is explained in step 7 in the section on Consent and Assent to Research in Children.
**Research in developing countries**

The ethical issues involved in conducting research on children in developing countries are complex. In some instances, the scale and severity of disease, poverty, and other adverse conditions are such that ensuring justice in respect of both individual rights and public good is much harder than in developed conditions. At the same time, people in developing countries can be more vulnerable to both personal and collective adverse effects of research, and avenues for reporting or redressing harm are limited.

Researchers must consider the application of ethical principles in view of issues such as access to treatment and impact of fear, stigma and denial, autonomy for vulnerable populations, capacity building and sustainable care to communities. Research should be conducted within an ethical framework that is appropriate to the social and medical context of the developing country. However, any deviation from accepted ethical practice in Australia and New Zealand requires detailed explanation and justification to a research ethics committee that has experience in reviewing such research.
Privacy and confidentiality

Where research involves the collection, storage, disclosure or other use of a child's personal information, respect for privacy must be maintained at all times. Researchers must ensure that the research conforms to the relevant national, (and in Australia, State or Territory) privacy legislation. The consent of the child and/or Parent/Guardian should be obtained where identifiable personal information is obtained for use in research registers, for use in future research projects or if the information will be disclosed to other persons for use in future research projects. In some circumstances, it may be considered appropriate for research to be conducted without obtaining the consent of participants. In these situations a HREC must be satisfied that there are sufficient procedures for data security and the research has a public benefit. For child participants enrolled in research registers and long term research, it is necessary for the researcher to reaffirm consent of the child participant at an age when he or she has the capacity and/or statutory right to provide autonomous consent.
References

The following documents have also been used in the development of this policy.


• *Guidelines for Genetic Registers and Associated Genetic Material*. NHMRC 1999.


• *MRC Ethics Guide; Medical Research Involving Children*: 2004 Medical Research Council.


• *Values & Ethics: Guidelines for Ethical Conduct* Aboriginal and Torres Strait Islander Health Research NHMRC 2003.