Youth health research ethics: time for a mature-minor clause?

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Health priorities in young people have changed in recent decades, with a recognition that psychosocial disorders such as depression, substance misuse and self-harm account for a greater burden of disease than physical illness. The youth research agenda has broadened, with a stronger focus on prevention and early intervention and an expansion of settings to include primary care and community environments.

Societal views of young people’s rights have also changed. The civil, political, economic, social and cultural rights of children and youth are embodied in the United Nations Convention on the Rights of the Child (UNCRC). A purely protective framework in international law has given way to one that acknowledges the right of young people, in accordance with their age and maturity, to make their own decisions on matters affecting their lives.

Changes in both the attitudes to youth and youth health priorities have markedly altered approaches to consent for clinical treatment. The implications for research are now emerging. In the United States, the National Commission for the Protection of Human Subjects of Research recognises situations in which the requirement for parental consent for adolescents under 18 years to participate in minimal-risk research can be waived. In the United Kingdom, young people aged 16 and older are considered capable of giving informed consent, and those under 16 may consent to take part in minimal-risk research if participation is in their best interests and they are “mature minors” (see below) and refuse parental involvement.

The rationale for these changes goes beyond a changing societal view of young people. There is evidence that adolescents’ involvement in research has been hampered by absolute requirements for parental consent. For example, the requirement for active parental consent for school-based surveys has been shown to lower response rates by 40%–67% and cause under-representation of at-risk groups.

Abstract

- Research into adolescent health issues is hampered by absolute requirements for parental consent.
- Society’s recognition of adolescents’ autonomy and decision-making capacity has been embodied in the legal recognition of the mature minor’s right to make decisions on matters affecting his or her life. Psychological research indicates that young people from 14 years have decision-making capacity.
- US and UK research ethics guidelines acknowledge the mature-minor principle, but Australian guidelines are out of step with international practice.
- An absolute requirement for parental consent in Australian research ethics guidelines is potentially unethical if it denies mature adolescents’ autonomy and is a barrier to participation, study validity and improved health outcomes through research findings.
- There are grounds for considering a mature-minor clause in the National Health and Medical Research Council research ethics guidelines, particularly in the context of youth participation in minimal-risk research.

Australian research ethics guidelines are out of step with practice in other Western countries: the National Health and Medical Research Council (NHMRC) National statement on ethical conduct in research involving humans requires consent from both young people and their parents to involve adolescents under 18 years of age in any type of research. We believe there is an urgent need to reconsider the NHMRC guidelines for young people’s participation in research, particularly minimal-risk research involving mature minors, if we are to effectively use research to improve young people’s health status.

Clinical application of the mature-minor principle

The historical notion of children as property items, owned by their parents and lacking the right to consent to medical treatment, has changed. Children are now recognised as autonomous beings with discrete rights and interests. In the United Kingdom, the 1986 case *Re Gillick* established that children who satisfy the test of competency (ie, are deemed by their doctors to be “mature minors”) can validly consent to their own medical treatment without parental consent. The mature-minor principle was confirmed in Australian common law in 1992, with the High Court of Australia stating that “parental power to consent to medical treatment on behalf of a child diminishes gradually as the child’s capacities and maturity...”
such as sexual health, is the fear that parents will be
young people from accessing healthcare for sensitive issues,
From the age of 14 years, and clearly from 15 years,
mature-minor doctrine. Indeed, a major barrier deterring
young people from accessing healthcare for sensitive issues,
such as sexual health, is the fear that parents will be
informed. It is usually in consulting about these sensitive
issues that adolescents refuse to inform parents, leaving
clinicians needing to assess mature-minor status before pre-
scribing treatment that is in the adolescent’s best interests.

However, the gravity and nature of the treatment are also
taken into account when assessing a minor’s capacity to fully
understand all aspects of the situation and to objectively
weigh up treatment options. For example, mature minors
are commonly prescribed oral contraceptives confidentially.
However, a mature minor would not be deemed sufficiently
mature to consent to a life-altering procedure, such as
reassignment or sterilisation, for which even parental
consent is insufficient. A parent’s or guardian’s consent
is necessary if the minor is unable to make voluntary and
informed decisions, judged by various indicators of matur-
ity. For example, clinicians would need to involve a
parent or guardian in the care of a 12–14-year-old girl with
chlamydial infection if she were habitually meeting older
boys and not able to fully comprehend the risks of this
behaviour or the need to protect herself.

Implications for research

While few would deny that young people have a right to
treatment, the right to participation in research, covered by
the UNCRC, is not often appreciated. Furthermore, the
right of adolescents, as a group, to benefit from research
findings can only be upheld if they are given access to
participation. On the other hand, there is a need to balance
the right of young people to participate in research with their
right to privacy and protection from risks and exploitation.

Consistent with earlier attitudes to children, human ethics
committees and bodies producing research guidelines have
taken a prominent role in protecting young people. How-
ever, research on child development and cognitive decision-
making suggests that such caution is unwarranted. Usually
from the age of 14 years, and clearly from 15 years,
adolescents have the cognitive capacity for making informed
decisions. Cognitive maturation also needs to be bal-
anced with the insights that life experiences contribute to
personal-risk assessment.

In our efforts to protect adolescents, could an absolute
requirement for parental consent for a child’s participation
in research be unethical? A particular danger of being overly
protective is that young people may become “research
orphans”, with little progress made in attending to their
health issues. Denying young people the right to partici-
pate in minimal-risk research because they refuse (or are
unable) to obtain parental consent denies them their auton-
omy and the potential benefits of research, and compro-
mises the research’s validity. This is particularly
applicable for high-risk young people such as homeless
youth, intravenous drug users, or school truants.

What are the risks of research?

The risks of involving young people in research vary, ranging
from potentially major side effects from novel therapeutic
interventions to minimal risk for participation in descriptive
studies or health surveys. Minimal-risk research may be
described as research in which the risk of harm is “not
greater than ordinarily encountered in daily life during
performance of routine physical or psychological examina-
tions or tests”. While some people may be concerned that
surveys of health-risk behaviours that include questions
about sexual intercourse or self-harm might encourage these
behaviours, there is no evidence to support this view.

Important ethical issues that arise in relation to minimal-
risk research with young people (eg, financial compensation,
privacy, the implications of uncovering people at risk of harm
or illegal activity) are similar for adults, but with the added
complexity of the potential need to involve parents or guardi-
ans. Ethics committees need to ensure that these issues are
identified in the research plan and mitigated against.

On the other hand, there are potential benefits to young
people from participating in research. Health surveys may
provide them with a greater understanding of their own
behaviours, which may assist them in seeking help. The
process of obtaining informed consent may lead to increased
self-respect and decision-making capacity in young peo-
ples who also value the opportunity to be altruistic.

Moving forward

To bring Australia into line with US and UK policy, NHMRC research guidelines should, at the very least, adopt
the mature-minor principle to allow adolescents to partici-
pate in minimal-risk research.

Based on studies of adolescents’ decision-making capac-
ity, there are grounds for ethics committees to consider
allowing young people aged over 14 years to participate in
minimal-risk research without parental consent and with-
out a formal mature-minor assessment.

In research involving more than minimal risk, it is essen-
tial to protect young participants. Ethics committees have a
central role in deciding the level of protection required and
the necessary level of involvement of adolescents and their
parents in providing consent to participate. The mature-
minor assessment offers one level of protection. Independent
clinicians or other suitably trained professionals could
perform the assessment as part of the consent protocol.

There are challenges in implementing this approach.
Researchers would need a thorough understanding of require-
ments for adolescents’ informed consent. Ethics committees
would need to be fully informed about adolescents’ develop-
mental capacities with respect to the mature-minor concept, as
well as having a sound understanding of the changing nature of
health risks faced by young people in contemporary Australia.
FOR DEBATE

We believe it is time for research ethics to become consistent with clinical practice and the law in tackling modern challenges to young people’s health. The pending 5-year review of our NHMRC research ethics guidelines presents an opportunity for the Australian research community to debate the issues and to consider a mature-minor clause. It is essential that consumers and community members, including young people and parents, are engaged in this debate in order to align research practice with community values and attitudes.\(^{1,5,11,15,20,23}\)

Competing interests

None identified.

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Chapter nine is the third of four chapters providing details about the Assessment phase of the Intervention Research Framework. This chapter focuses on the recruitment of a study sample....

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