



Inclusion with Protection: Obtaining informed consent when conducting research with adolescents

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Produced by the UNICEF Office of Research, this series of briefs on research methods is intended to share contemporary research practice, methods, designs, and recommendations from renowned researchers and evaluators. The primary audience are professionals, including UNICEF staff, who conduct, commission or interpret research and evaluation findings in development contexts to make decisions about programming, policy and advocacy.

This brief is one of seven on research methodologies designed to expand and improve the conduct and interpretation of research on adolescent health and well-being in low- and middle-income countries (LMICs). Building on the recent [Lancet Commission on Adolescent Health and Wellbeing](#), these briefs provide an overview of the methodological quality of research on adolescents. They cover topics including: indicators and data sources; research ethics; research with disadvantaged, vulnerable and/or marginalized populations; participatory research; measuring enabling and protective systems for adolescent health; and economic strengthening interventions for improving adolescent well-being.

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INTRODUCTION

Adolescents – no longer children, not yet adults – are unique beings with human rights, developmental needs and tremendous potential. Enormous progress has been made in the 20th century in our scientific understanding of adolescent health and development, including the increasing recognition of adolescence as a critical period in a life course of well-being.¹ Research on health, development and well-being has contributed immensely to current understanding of adolescence, its challenges and its opportunities.

Adolescents are often excluded from research studies – and therefore from the potential benefits of research – because of confusion about whether they should be regarded as children or as adults, and who has the right and ability to give consent for adolescents to participate in research. Moreover, uncertainty about the proper ethical balance between protection from research and inclusion in research has often resulted in adolescent exclusion.

This brief focuses on the rapidly evolving capacities of adolescents to make informed choices about their involvement in research. The brief provides a broad introduction to research ethics as they apply to adolescents and reflects on ethical considerations to simultaneously promote the inclusion of adolescents

¹ Patton et al., 'Our Future'. <[http://www.thelancet.com/journals/lancet/article/PIIS0140-6736\(16\)00579-1/fulltext](http://www.thelancet.com/journals/lancet/article/PIIS0140-6736(16)00579-1/fulltext)>, accessed 16 January 2017.

in research and protection from research-related risks. This paper builds on the concepts of *evolving capacities* and *best interests* as enunciated in the Convention on the Rights of the Child (CRC).² The concept of *evolving capacities* is particularly useful in guiding ethical thinking about research with adolescents.

This brief addresses:

- The value of research with adolescents and the importance of balancing inclusion and protection
- The evolution in social thinking about adolescents' human rights and legal protections
- Ethical principles and research ethical guidelines
- Current scientific understanding about adolescents' decisional capacity and their capability to provide informed consent
- What to do when parents or guardians are not able to act in the best interests of the adolescent
- Some observations about diversity among adolescents
- Ethical recommendations when conducting research with adolescents and the practical application of these recommendations to adolescent research.

This paper is intended to provide UNICEF staff, sponsors of research, policy-makers, ethics committee members and researchers with principles and approaches to the common challenges in conducting research with adolescents.

Box 1. Summary of key points

- Inclusion of adolescents in research is essential if adolescents are to reap the full benefits of research. The concepts of *evolving capacity* and *best interests* as enunciated in the CRC are useful in guiding ethical thinking about research with adolescents.
- Respect for persons and the evolving capacity of adolescents to make informed decisions should be central to considerations about adolescent research involvement and who should provide informed consent for adolescent participation.
- Inclusion of adolescents in research and protection from research risk are compatible goals. Achieving these twin goals requires a nuanced understanding of adolescent development and the social context of adolescents' lives.

Box 2. Ethical definitions

- *Inclusion* in research is the right to participate in research and to receive individual benefit, or for a group of individuals, to receive benefit.
- *Protections* are safeguards built into research projects to prevent harm to individuals or groups.
- *Respect for persons (also called respect for autonomy)* encompasses both the right of autonomous individuals to make free decisions about research participation consistent with their own values and preferences, and the right of vulnerable persons to be protected from research risk.
- *Justice or equity* entails a fair distribution of the benefits and burdens of research. Justice is commonly considered at both the individual and the population level. The principle of justice is an important rationale for policies promoting inclusion in research.
- *Beneficence* is the obligation to do good and to avoid harm. In research, one commonly weighs risks and benefits. This is closely related to the concept of *best interests* in the CRC (see Box 3).
- *Informed consent* follows from the principle of respect for persons and is an essential practice in conducting research. In practice, informed consent entails providing *information*, assessing *comprehension* of the information provided, and ensuring the consent is *voluntary* and not coerced by circumstances or persons involved in the research.
- *Assent* is a child's affirmative agreement to participate in research. The concept of assent recognizes the emerging developmental capacity of children, even where they may not be fully capable of providing informed consent. Assent is commonly obtained from children beginning at age 7.
- *Parental permission* is the agreement of parent(s) to their child's participation in research. The terms permission and assent are used to distinguish these processes from the usual informed consent process. In providing permission, parents are not research subjects and do not experience risks or benefits from the research.
- *Minimal risk* is defined as, 'the probability and magnitude of harm or discomfort anticipated... are not greater... than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests'.*

* US Department of Health and Human Services, 'Protection of Human Subjects', 45 Code of Federal Regulations part 46, 2007.

² United Nations, Convention on the Rights of the Child (CRC), 1989, <www.unicef.org/crc/>, accessed 16 January 2017.

BACKGROUND

Research with adolescents: balancing protection and inclusion

Research with adolescents is essential to improve adolescent well-being. Participation by and protection for adolescents in research are critical if adolescents are to benefit from research.³ Research can guide the creation of improved policies and programmes and appropriately tailored services and infrastructure – to strengthen adolescent resilience, promote wholesome development, reduce adolescent morbidity and mortality, improve nutritional status, promote educational success and mental health, prevent risk behaviours, and prevent or treat infectious disease.⁴ Prior research provides multiple examples of benefits, including the influence of multiple social spheres (e.g. family, peers, culture) on adolescent well-being, the creation of HIV prevention programmes, and new understandings of the social, economic and health benefits of education. Importantly, research evidence from programme evaluations and epidemiological associations often drives new investments in programmes for children and adolescents.

Research ethics – particularly as applied to children and adolescents – is often seen as a balancing act between *protection* from research harm and *inclusion* in research which may bring benefit. Children up to 18 years of age are often seen as a *vulnerable population* that needs protection from the risks of research involvement. This vulnerability stems from the reduced ability of younger children to make reasoned choices about research inclusion, the lower social status of children, and the power imbalance that renders children susceptible to adult coercion. The ability of adolescents to make reasoned choices is addressed specifically below. Inclusion is essential for children – individually and/or collectively – to benefit from research. The twin impulses towards protection and inclusion are reflected in national and international policies promoting research protections⁵ and those promoting research inclusion.⁶

Barriers to conducting research with adolescents include: misunderstandings of adolescents' cognitive abilities and capacity to provide informed consent; an overzealous valuing of protection over inclusion; institutional self-protection including from ethics committees; and antiquated attitudes about adolescents as not holding equal rights to adults.

The balance between protection and inclusion often becomes fraught with confusion. Achieving a sensible balance is also influenced by debates about who can provide informed consent for adolescent research involvement. Given the complexity of issues, ethics committees that lack expertise in adolescent health and development are likely to feel uncomfortable and uncertain when dealing with adolescent research. Legal barriers (and perceived legal barriers) may also impede research. These include a lack of clarity around informed consent and how the age of consent to research relates to the age of consent to medical treatment or to specific health services (e.g. consent to HIV testing and treatment). The result of such uncertainty is that adolescents are excluded from research that may benefit them individually and collectively.

This brief addresses these ethical issues and barriers to adolescent inclusion in research. However, to understand research ethics as applied to adolescents, one first needs to understand the basics of adolescents' legal and human rights, the basic principles of research ethics, and how adolescents are different from children.

3 Santelli, J. S. et al., 'Guidelines for Adolescent Health Research: A position paper of the Society for Adolescent Medicine', *Journal of Adolescent Health*, vol. 33, no. 5, pp. 396–409, 2003, <<https://www.ncbi.nlm.nih.gov/pubmed/14596961>>, accessed 16 January 2017.

4 Catalano, R. F. et al., 'Worldwide Application of Prevention Science in Adolescent Health', *Lancet*, vol. 379, no. 9826, pp. 1653–1664, 2012; Patton et al, 'Our Future'.

5 Council for International Organizations of Medical Sciences, *International Ethical Guidelines for Biomedical Research Involving Human Subjects*, CIOMS in collaboration with the World Health Organization, Geneva, 2002; US Department of Health and Human Services, 'Protection of human subjects', 45 Code of Federal Regulations part 46, 2007.

6 National Institutes of Health, 'NIH Policy and Guidelines on the Inclusion

of Children as Participants in Research Involving Human Subjects', 1998, <<http://grants.nih.gov/grants/guide/notice-files/not98-024.html>>, accessed 16 January 2017; Graham, A., et al., *Ethical Research Involving Children*, UNICEF Office of Research – Innocenti, Florence, 2013.

Box 3. Legal and human rights definitions

- The CRC (1989) defines a *child* as a person below the age of 18 years, unless under national laws applicable to the child, majority is attained earlier (e.g. if they have been emancipated; see definition of emancipation below).
- The *age of majority* is the age at which adolescents become adults and attain the legal rights and privileges of adulthood. Most nations (and the CRC) define the legal age of majority as 18.
- *Emancipation* is the achievement of adult legal status before the usual age of majority due to marriage, motherhood, military service, or other specific circumstances. Likewise, adolescents may be considered emancipated if they are functionally independent of parents, because of orphanhood or other circumstances.
- *Evolving capacities* is the concept that a child's capacities for autonomous decision-making develop with age and maturity. It recognizes the need for varying requirements for protection, participation and opportunity for autonomous decision-making among children and adolescents of varying age and maturity.* This concept first emerged in the international sphere through the CRC. These 'evolving capacities' are related to the ability of an adolescent to provide truly informed consent.
- While the CRC does not offer a precise definition of *best interests*, this term clearly recognizes the personhood of the child, as well as the need to provide protection and promote the human rights of the child as enumerated by the CRC. The notion of best interests is related to the ethical principle of beneficence.
- *Minor consent laws* allow adolescents to access health care independently before the age of majority for specific conditions such as emergency care, pregnancy and mental health conditions, and treatment for sexually transmitted infections.
- The concept of *mature minor* derives from common law. Mature minors are minor adolescents who demonstrate the capacity to make independent judgements when faced with specific life decisions. Allowing independent access to abortion and contraception is often based on the concept of mature minor. The concept of mature minor is not recognized by all nations.

* Lansdown, G., *The Evolving Capacities of the Child*, UNICEF Innocenti Research Centre, Florence, 2005, <<https://www.unicef-irc.org/publications/pdf/evolving-eng.pdf>>, accessed 16 January 2017.

Adolescents' legal and human rights

National laws and international human rights documents provide an important context and an essential conceptual basis for thinking about ethical research with adolescents. In the 20th century, systems of legal rights and protections for children and adolescents developed at subnational, national and international level, including rights and protections regarding research.⁷ National laws set to protect children include those to prevent child labour, child abuse, child marriage and service of children in the military. Laws also guarantee the rights of children to education, safety, health and other supportive conditions. Protective laws commonly recognize the essential roles of parents as guardians of children's welfare, but also recognize where parents – because of poverty or other circumstances – cannot fulfill this role.

The most comprehensive international statement of child rights and protections is the CRC adopted by the United Nations General Assembly in 1989. The CRC covers children – including adolescents below the age of 18, unless the relevant laws recognize an earlier age of majority – and is a comprehensive document covering many rights and responsibilities, including rights of children to health, education, protection from harm, participation and self-expression, and the rights and responsibilities of parents. The Committee on the Rights of the Child provides ongoing interpretation of the CRC in light of new needs and new scientific understandings.

Essential concepts outlined by the CRC are the recognition of children as rights holders and obligations to consider the *best interests* of the child, and their *evolving capacities* to make sound decisions and participate in promoting their own welfare.⁸ These concepts are paralleled in the emphasis on protection and inclusion in the field of research ethics.

7 Grodin, M. A., and Alpert, J. J., 'Children as Participants in Medical Research', *Pediatric Clinics of North America*, vol. 35, no. 6, p. 1389, 1988; Lederer, S. E., and Grodin, M. A., 'Historical Overview: Pediatric experimentation', in *Children as Research Subjects: Science, ethics & law*, edited by M. A. Grodin and L. H. Glantz, Oxford, Oxford University Press, New York, 1994, pp. 3–25.

8 Lansdown, *The Evolving Capacities of the Child*.

Box 4. Excerpts from the Convention on the Rights of the Child

Article 5 of the CRC states:

*States Parties shall respect the responsibilities, rights and duties of parents... in a manner consistent with the evolving capacities of the child.**

And Article 12 states:

States 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.

The Committee on the Rights of the Child, in its General Comment No. 15 (2013), addresses the implications of the evolving capacities principle on the rights of children to make decisions about their health care:

*The Committee recognizes that children's evolving capacities have a bearing on their independent decision-making on their health issues. It also notes that there are often serious discrepancies regarding such autonomous decision-making, with children who are particularly vulnerable to discrimination and often less able to exercise this autonomy. It is therefore essential that supportive policies are in place and that children, parents and health workers have adequate rights-based guidance on consent, assent and confidentiality.***

The Committee also highlights the need to take into account evolving capacities regarding access to counselling without parental consent:

*In accordance with their evolving capacities, children should have access to confidential counseling and advice without parental or legal guardian consent, where this is assessed by the professionals working with the child to be in the child's best interests. States should clarify the legislative procedures for the designation of appropriate caregivers for children without parents or legal guardians, who can consent on the child's behalf or assist the child in consenting, depending on the child's age and maturity. States should review and consider allowing children to consent to certain medical treatments and interventions without the permission of a parent, caregiver, or guardian, such as HIV testing and sexual and reproductive health services, including education and guidance on sexual health, contraception and safe abortion.****

* United Nations, Convention on the Rights of the Child, (CRC) 1989.

** United Nations, Committee on the Rights of the Child, General Comment No. 15 (2013) on the right of the child to the enjoyment of the highest attainable standard of health (art. 24), CRC/C/GC/15, 2013.

*** Ibid.

National laws regarding adolescents' rights and protections include laws that define emancipation status, the age of majority, and the conditions under which minor adolescents are able to consent independently to health care services (so-called minor consent laws). These laws also define the conditions and minimum ages under which adolescents can engage in sexual activity, marry, consume alcohol, obtain a driver's licence, access contraception and accept criminal responsibility. Consistent with the CRC, many nations recognize the age of majority as 18 years. However, considerable diversity exists among nations in the ages at which minors can consent to various activities (e.g. counselling,

abortion, HIV testing and treatment, medical treatment, research).⁹ Importantly for this research brief, no international consensus exists on the age of consent to participate in research. Many legal systems, however, recognize the concept of a *mature minor*, a minor adolescent who demonstrates the capacity to understand and make reasonable independent decisions about their own well-being. For example, the idea of a mature minor is found in UK case law (*Gillick vs Wisbech Area Health Authority*).¹⁰

9 Patton et al., 'Our Future'.

10 *Gillick vs West Norfolk and Wisbech Area Health Authority* [1985] UKHL 7.

Box 5. Guidelines for conducting research on HIV sexual and reproductive health among adolescents in Kenya

Few nations have guidelines that specifically address adolescents' participation in research, instead relying on guidelines focused on all children despite considerable developmental differences among children. In 2015 – faced with the enormous challenge of HIV among adolescents – Kenya adopted national guidelines which address the range of ethical and legal dilemmas faced by researchers and institutions dealing with adolescents, HIV, and sexual and reproductive health. These guidelines provide a framework for interpreting the ethical and legal regulations for protecting adolescent participants in research and promote the ethical inclusion of adolescents in research. They provide guidance to researchers and serve as a resource of research ethics committees and other institutions involved in reviewing research with adolescents. The guidelines provide guidance on ethical norms for adolescents' health and harmonize these norms for Kenya.

The guidelines provide a comprehensive approach to the key legal and ethical dilemmas facing researchers and research ethics committees. In particular they develop a nuanced approach to informed consent by adolescents that directly addresses issues related to evolving capacities and the ability to provide a fully informed consent, emancipated or mature minors, dissent and assent, and circumstances when it may be appropriate to waive parental permission. The guidelines also provide advice on ensuring confidentiality of adolescent participants in research, promoting adolescent participation in research, addressing key stakeholders and communities, and research with key populations of especially vulnerable adolescents such as orphans, street adolescents, sexual minorities and adolescents who are exploited.*

* Ministry of Health, Government of Kenya, *Guidelines for Conducting Adolescent HIV Sexual and Reproductive Health Research in Kenya*, 2015, <www.maishamaarifa.or.ke/admin/Content/Uploads/downloads/national-guidelines-for-conducting-adolescent-hiv-sexual-and-reproductive-health-research-in-kenya.pdf>, accessed 16 January 2017.

These legal concepts are designed to protect children and adolescents from harms and to guarantee adolescents' rights to make certain decisions with increasing maturity. The *capacity* to make independent decisions is linked to brain development and worldly experience, as well as abilities to understand and weigh information and make decisions.

In many countries multiple legal systems coexist.¹¹ Legal traditions include *formal or civil law* (as discussed above), *common law* (developed by court precedent) such as the mature minor concept, and finally *customary or religious law*, which may operate alongside formal laws – particularly in LMICs. Customary and religious laws may not recognize adolescents' rights as defined by the CRC or may contradict formal national legal systems, for example a religious law that condones child marriage. Thus, consent on behalf of adolescents by adults other than parents (such as husbands of child brides, extended family members, village elders or religious leaders) may play a role in decisions on the well-being of adolescents and their participation in research. Such practices may be at odds with research ethics concepts such as respect for individual autonomy.

Research ethical principles

During the second half of the 20th century ethical principles, codes and regulations for research were developed and codified. This development was propelled by the atrocities committed by countries during World War II¹² but also by research abuse committed by researchers in the fields of pediatrics, psychology, public health and other professions.¹³

Research ethics are generally guided by three ethical principles: *respect for persons*, *beneficence* and *justice*.¹⁴ Likewise, research on ethical thinking about adolescents is built on ethical thinking regarding children – recognizing the *evolving capacities* of each and the differences in influence of social context for each.¹⁵

12 US Government Nuremberg Military Tribunal, 'The Nuremberg Code', Law 10, in *Trials of War Criminals before the Nuremberg Military Tribunals under Control Council, 1947*, <<https://history.nih.gov/research/downloads/nuremberg.pdf>>, accessed 16 January 2017.

13 Beecher, H. K., 'Ethics and Clinical Research', *New England Journal of Medicine*, vol. 274, 1966, pp. 1354–1360; Lederer and Grodin, 'Historical Overview'; Jones, J. H., *Bad Blood: The Tuskegee Syphilis Experiment*, Free Press, 1981.

14 Council for International Organizations of Medical Sciences, *International Ethical Guidelines for Biomedical Research Involving Human Subjects*, CIOMS in collaboration with the World Health Organization, Geneva, 2002; Graham, A., et al., *Ethical Research Involving Children*, UNICEF Office of Research – Innocenti, Florence, 2013; National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research, *The Belmont Report: Ethical Principles and Guidelines for the Protection of Human Subjects of Research*, 1978, <www.hhs.gov/ohrp/regulations-and-policy/belmont-report/index.html#>, accessed 16 January 2017.

15 Lansdown, *The Evolving Capacities of the Child*.

11 Patton et al., 'Our Future'.

This brief focuses on key ethical concepts related to research on adolescents, but first outlines a brief overview of linkages to the broader research ethics literature.

The concept of *respect for persons*, means treating people as autonomous beings and not as a means to an end. The principle of respect for persons follows notions of informed and voluntary consent and of honouring the capacity of individuals to make decisions that are in their own best interests. Respect for persons also demands that special protections be extended to groups with diminished autonomy, such as children. This principle speaks directly to the notion of *evolving capacities* from the CRC. These special protections for children commonly include involvement of parents in the informed consent process and obtaining *parental permission* for research involvement. The involvement of children in research is often allowed only when research risks are low or where potential benefits justify risks. With younger children, informed consent processes are tailored to their specific circumstances and abilities. With adolescents, respect for persons should involve recognizing and supporting evolving capacities, developmental sensitivities and rights to participation. The active participation of adolescents in research (and other realms that effect their well-being) is increasingly seen as essential. (For more information, see Brief 5 in this series, 'Adolescent Participation in Research: Innovation, rationale and next steps'.) With children who are too young to make informed choices on their own, and thus to give informed consent, researchers should nonetheless seek to obtain the child's affirmative agreement or assent, in addition to parental permission.

Beneficence is the ethical obligation to do good and to avoid harm. In research this means maximizing benefits and minimizing risks. Inclusion policies – to extend the benefits of research to women, minorities, children and adolescents – are motivated by the principle of beneficence. Beneficence is similar to the notion of *best interests* found in the CRC. Beneficence focuses on the obligation to do good, while best interests focuses on understanding what is good for children and adolescents.

Justice entails a fair distribution of the benefits and the burdens from research. *Equity* is the same idea and commonly used in human rights discussions. This is important in the selection of research participants. Certain population groups should not be put at risk for the benefits of others. Likewise, groups (e.g. women, younger children and adolescents) should not be excluded from research that may have direct or indirect benefits to them. If groups are excluded we may lack knowledge on how to treat them or how best to promote their well-being. Thus, with exclusion children become 'therapeutic orphans' and adolescents are denied the best approaches to prevention.

In addition to these ethical principles, there are a variety of national and global guidelines on research ethics for those undertaking specific studies. The best known are:

- The Declaration of Helsinki from the World Medical Association <www.wma.net/en/30publications/10policies/b3/>
- The International Ethical Guidelines for Biomedical Research Involving Human Subjects from the Council for International Organizations of Medical Sciences (CIOMS) in collaboration with UNESCO and the World Health Organization <www.cioms.ch/>
- The United States Federal Policy for the Protection of Human Subjects ('Common Rule') <www.hhs.gov/ohrp/regulations-and-policy/regulations/common-rule/>.

These ethical guidelines and regulations provide guidance on the creation of research ethics committees, protections for research subjects, informed consent and protections for vulnerable populations such as children. Guidance from CIOMS on research with adolescents (Guideline 17) parallels guidance from the US government on research with children (Subpart D), while neither has a specific section on research with adolescents. Both CIOMS and Subpart D recognize the importance of obtaining parental permission and child or adolescent assent and the potential for waiving parental permission, where appropriate.

The most detailed guidance for conducting ethical research with children, including adolescents, is provided by the international project Ethical Research Involving Children by UNICEF and partners, available at

<<http://childethics.com/>> in six languages. Internally, UNICEF has also institutionalized procedures for ethical conduct in its evidence generating activities, and has developed training materials to support its implementation.

INFORMED CONSENT AND ADOLESCENTS' EVOLVING CAPACITIES

A key mechanism to protect people identified in all international guidelines is the use of informed consent, which has its basis in respect for persons and relies on three interdependent factors. Research participants must be:

- provided with information about the research
- able to comprehend that information
- allowed to participate voluntarily.¹⁶

Information provided about a particular study covers:

- the rationale for the study
- the proposed procedures involved
- the risks and benefits to individuals and groups
- voluntary participation
- privacy and confidentiality
- how and where to seek additional information.

Comprehension is influenced by the clarity of information provided and the cognitive capacity of the research participant. A person's abilities are a function of intelligence, maturity and experience.

Consent is generally obtained from each research participant, although proxy consent or permission may be sought from a guardian or surrogate for individuals or groups. For example, parental permission is commonly used with young children, who are unable to consent for themselves. Voluntary participation means participants are free from coercion (an overt threat of harm) or undue influence (such as excessive compensation or incentives to participate). Researchers who obtain parental permission should also seek the adolescent's assent.

Ethical research with adolescents builds on the ethical principles and the legal history discussed above. It must also consider the developmental status of adolescent research subjects – particularly adolescents'

ability to make independent decisions about research involvement, to protect themselves from research risk, and to express their agency effectively. Critical to these considerations is an understanding of adolescents' *evolving capacities* as expressed in the CRC.¹⁷ Evolving capacities (the ability to provide truly informed consent) is directly informed by research on neurodevelopment and cognition during adolescence.¹⁸ Capacity is also linked to the previous life experiences of the adolescent, including experience with illness and self-care, adverse social events and environments, risk behaviours, and use of health care systems. Decision-making is also situation specific, influenced by the emotional state of the adolescent and the complexity and risk posed by a specific study.

Adolescence is a period of multiple transformations including rapid changes in the physical body and the brain; we now recognize that neurodevelopmental maturation continues into the early adult years.¹⁹ Adolescents demonstrate expanding understanding of the world, heightened self-awareness, interest in autonomy, greater desire for privacy, sensitivity regarding body image, increasing sense of altruism, and a tolerance for risk.

Box 6. Adolescents' decisional capacity: key points

- New and old research from neuroscience and psychology supports the notion that early adolescents are capable of making informed choices about involvement in health care and research.
- Preteens should be allowed to voice their interests but may often want the advice or support of parents or adults in making a decision.
- Early adolescents generally are able to make sensible decisions about research and health care independently – in the absence of coercion and unhealthy influences such as peer pressure.
- Given knowledge and with appropriate safeguards, middle adolescents are competent to make to make effective decisions about almost all important matters in their lives, including their health.
- Legal and policy safeguards and support are needed for decisions made in contexts of heightened emotions or where there is potential for coercion or undue influence.

16 National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research, *The Belmont Report*.

17 Lansdown, *The Evolving Capacities of the Child*.

18 Patton et al., 'Our Future'.

19 Ibid.

Adolescents display cognitive abilities for agency, judgement and self-protection; these are fundamental to the capacity to provide informed consent and to make decisions themselves about research participation. Research on informed consent suggests that from age 12 adolescents have decision-making competence.²⁰ 14-year-olds are as capable as adults in understanding multiple viewpoints and considering conflicting information and their ability to make decisions about research participation is similar to that of adults.²¹ Children at age 9 are able to express their preferences, understand risk and benefits, and make decisions similar to young adults (age 21); they are less able to consider multiple conflicting points.²²

Adolescence is often characterized by asynchronous development of the affective, reward-focused processing system and the deliberative, reasoning processing system.²³ Decision-making in adolescence may be particularly influenced by the social and emotional context.²⁴ Adolescents demonstrate cognitive capacity similar or greater than adults in calm and emotionally neutral situations. However, in emotionally charged situations, emotions are more likely to drive decision-making.²⁵ Steinberg has described *hot* and *cold cognition* in adolescents' decision-making and executive functioning. During *hot cognition* states, which involve affectively charged social interactions with peers such as drinking or engaging in risk taking behaviours, adolescents may make particularly poor decisions. Adolescents also have a much higher tolerance for risk taking than adults, which may increase in the presence of peers. The perception of peer endorsement alone may be sufficient to trigger risk taking. Conversely in *cold cognition* (controlled and non-emotional) settings, adolescents' decision-making is similar to that of

adults. Cold cognition is more common in classrooms, medical offices and research enrollment settings; thus it is important to assess the social context when obtaining informed consent.

Capacity is linked to previous life experiences of the adolescent including illness and self-care, adverse social events and environments, risk behaviours and use of health care systems. Therefore experience with decision-making in real-world situations increases adolescents' capacity to make decisions in those same situations. For example, an adolescent who has experienced chronic illness will be more likely to understand the balance of risks and benefits than an adolescent who has not experienced this illness. Similarly, a potential benefit from involvement in carefully managed research will be an increase in adolescents' capacity, which comes from expanding their experience base.

Whether or not an individual adolescent (or adult) has the capacity to provide informed consent is an empirical question. We assume adults have the capacity to provide informed consent unless we have evidence to the contrary, but assume the opposite for children. While the weight of evidence from research on decision-making finds that adolescents have the capacity to provide informed consent, additional research is needed to understand and support their capacity to make decisions about research.

This research on cognition and capacity broadly supports current ethical practices in conducting research with younger children and adolescents. For research involving children from about age 7, researchers commonly solicit both child *assent* and *parental permission*. *Assent* is a child's agreement to participate in research, which recognizes both emerging decisional capacity in children and that many children may not be fully capable of providing informed consent. *Parental permission* is the agreement of a parent or parents to their child's participation in research. Parental permission is a form of proxy consent and recognizes that parents are the people most likely to understand their child's needs, to protect the child from harm, and to balance risks and benefits.

It is important to note that obtaining informed consent is an essential but imperfect mechanism to protect people from research harm. Other important

20 Hein, I. M., et al., 'Informed Consent Instead of Assent is Appropriate in Children from the Age of Twelve: Policy implications of new findings on children's competence to consent to clinical research', *BMC Medical Ethics*, vol. 16, pp. 1–7, 2015.

21 Weithorn, L. A., 'Children's Capacities to Decide about Participation in Research', *IRB: Ethics & Human Research*, vol. 5, no. 2, pp. 1–5, 1983.

22 Ibid.

23 Smith, A. R., Chein, J., and Steinberg, L., 'Impact of Socio-Emotional Context, Brain Development, and Pubertal Maturation on Adolescent Risk-Taking', *Hormones and Behavior*, vol. 64, no. 2, pp. 323–332, 2013.

24 Steinberg, L., 'A Social Neuroscience Perspective on Adolescent Risk-Taking', *Developmental Review*, vol. 28, no. 1, pp. 78–106, 2008; Crone, E. A., and Dahl, R. E., 'Understanding Adolescence as a Period of Social-Affective Engagement and Goal Flexibility', *Nature Reviews Neuroscience*, vol. 13, no. 9, pp. 636–650, 2012; Blakemore, S. J., 'Imaging Brain Development: The adolescent brain', *Neuroimage*, vol. 61, no. 2, pp. 397–406, 2012.

25 Patton et al., 'Our Future'.

mechanisms include the development of study protocols, independent review by research ethics committees, and community consultation. An essential protection is that all studies have investigators who are well trained in ethics and research and who are sensitive to the potential for research harm and vigilant in trying to prevent that harm.

Research protection for adolescents may rely on their informed consent and/or proxy consent by a parent. Such decisions depend on the age and cognitive maturity of the adolescent, and the level of risk involved (see Box 8, 'Informed consent and research risk when researching with adolescents').

Box 7. Adolescence, brain science and research participation

Scientific research on the adolescent brain has provided new insights into adolescent behaviours, attitudes and thinking processes.* Adolescents' decision-making is influenced by age, social context, experience, emotional states, and the risk and complexity of a particular study.

Unfortunately brain science has often captured the popular imagination in simplistic ways, particularly the finding that the frontal cortex does not mature until the mid-20s. This scientific 'fact' has been used to reinforce adult beliefs about adolescents' immaturity; however, it does not do away with years of scientific research on adolescents' cognition and decisional capacity, which shows significant gains during this period.

Simplistic interpretations of brain research have been used to justify misguided public policies, for example advocates for abstinence promotion have suggested adolescents are too immature to engage in sexual behaviour, and therefore sexuality education should be limited to the benefits of abstinence and the dangers of sexually transmitted infections.

Brain science research is rapidly evolving. Research ethics committees reviewing studies on adolescents must have appropriate expertise and should include a professional (e.g. psychologist, physician) who works with adolescents and understands adolescent development.

* Crone and Dahl, 'Understanding Adolescence as a Period of Social-Affective Engagement and Goal Flexibility'; Steinberg, 'A Social Neuroscience Perspective on Adolescent Risk-Taking'; Blakemore, S. J., 'Development of the Social Brain in Adolescence', *Journal of the Royal Society of Medicine*, vol. 105, no. 3, 2012, pp. 111–116; Smith, Chein and Steinberg, 'Impact of Socio-Emotional Context, Brain Development, and Pubertal Maturation on Adolescent Risk-Taking'.

WHEN GUARDIANS AND PARENTS MAY NOT BE ABLE TO ACT IN THE BEST INTERESTS OF THE CHILD

Parents are essential in protecting younger children from harm in research and in other important realms. Parental permission can also protect adolescents from risk research. However, parents may be unable to fulfill their duty to protect. Laws around child abuse, child labour and child marriage are designed to address this failure to protect. Likewise, laws allowing adolescents to seek health care independently from parents recognize the potential for conflicts of interest between parents and adolescents; under these circumstances, parental permission is not appropriate. Parents may coerce adolescents to make decisions contrary to their best interests: to marry; to continue or abort a pregnancy; to work instead of attending school; to use contraception or to forbid contraceptive use; to participate in research or to be forbidden to do so. Moreover, adolescents may be more knowledgeable about their own situation than their parents are.²⁶ They may have priorities and preferences at odds with their family and community of origin.

Likewise, it is important to acknowledge that adults (including members of research ethics committees) are often uncomfortable with adolescents' attitudes and behaviours. Research ethics committee members may show greater sympathy for parents than for adolescents – as committee members are often parents themselves.

Where a conflict exists between the interests of a parent and those of a minor adolescent, a variety of mechanisms can be invoked. Where adolescents are capable of making a rational decision, they can and where appropriate should be empowered to make their own decisions. For minimal risk research, even young adolescents can make such decisions, in the absence of undue influence and charged emotional states. Where the risk of research is considerable, an individual assessment of decisional capacity may be needed. Practically, such an assessment generally involves a conversation between the adolescent and a knowledgeable, independent adult (e.g. a health professional not involved in the research) with a

26 Nuffield Council on Bioethics, *Children and Clinical Research: Ethical issues*, 2015, <nuffieldbioethics.org/wp-content/uploads/Children-and-clinical-research-full-report.pdf>, accessed 16 January 2017.

recommendation from the adult to the researchers or ethics committee. Where an adolescent's capacity is lacking and/or the risks are high, an alternative kind of proxy consent should be used. This may include appointing a temporary guardian or advocate, obtaining advice from a trusted health professional or teacher, or consulting community leaders.²⁷ In these situations, researchers should also obtain the adolescent's assent.

DIVERSITY AMONG ADOLESCENTS

While research committees commonly rely on age as a marker for legal capacity and cognitive capacity, enormous diversity exists in levels of empowerment, agency and capacity for independent decision-making among adolescents (just as among adults). Empowerment and capacity for independent decision-making are influenced by age, but also by gender dynamics, poverty and social disadvantage, and marginalization.

Adolescents may be disadvantaged and marginalized because of poverty, immigration or refugee status, family disintegration, disability, adverse childhood experiences, lack of parental commitment or capacity, orphanhood, homelessness, trafficking, sexual minority status and incarceration.²⁸ They also may be marginalized because of stigmatization or because they lack legal status within a country. They may suffer inequalities in education, health and protection because of their marginalized status; exclusion from research may exacerbate these inequalities.

Disadvantaged and marginalized adolescents are often excluded from research because obtaining parental permission is problematic. Parents may be physically unavailable, functionally estranged or simply uncooperative. However, disadvantaged and marginalized adolescents may be functionally emancipated and capable of providing informed consent. (For details, see Brief 4 in this series, '[Research with Disadvantaged, Vulnerable and/or Marginalized Adolescents](#)'.)

Box 8. Informed consent and research risk when conducting research with adolescents

- It is important to consider the intersection of adolescents' capacity to provide informed consent and the level of risk entailed by a specific research project.
- For minimal risk research, in cold-cognitive and non-emotionally charged states, and in the absence of coercion or undue influence, even young adolescents (aged 10+) can be assumed to have capacity to provide informed consent.
- For research involving greater risk or where decision-making is impaired by emotions or coercive conditions, an individual assessment of capacity to provide informed consent and/or the use of proxy consent (e.g. parental permission) may be needed.

INTEGRATING PERSPECTIVES ON LEGAL, HUMAN RIGHTS AND DEVELOPMENTAL CHANGES

Drawing on this review of perspectives from the CRC, developmental changes and the law, we would suggest the following rubric in assessing adolescents' capacity to provide informed consent:

- Within the conventional age range of adolescence (age 10–19), the oldest adolescents (age 18–19) are considered to be legal adults with adult cognitive function (notwithstanding comments discussed above). Variations to this law may exist in some countries.
- Evidence suggests that for questions related to participation in research, adolescents (age 14–17) are cognitively similar to young adults.²⁹
- Younger adolescents may be less able to recognize the complexity of an informed consent decision but still generally make informed decisions – in the absence of coercion and undue influence and in non-stressful and non-emotional states.
- Almost all adolescents are able to make decisions about minimal risk research (e.g. research involving questionnaires or blood drawing) if the informed consent process is carefully and sensitively constructed.

27 Santelli et al., 'Guidelines for Adolescent Health Research'.

28 Auerswald, C. L., Piatt, A. A., and Mirzazadeh, Ali, 'Research with Disadvantaged, Vulnerable, and/or Marginalized Adolescents', UNICEF Research Brief no. 4, 2017 (forthcoming).

29 Hein et al., 'Informed Consent Instead of Assent is Appropriate in Children from the Age of Twelve'; Weithorn, 'Children's Capacities to Decide about Participation in Research'.

Box 9. Waiver of parental permission in research with adolescents

Parental permission is a commonly used mechanism for protection of children and minor adolescents in research, both to prevent harm and to maximize benefit to the individual child or adolescent. Parents are normally the people who best understand and are best able to represent the interests of the child. Research ethics committees commonly think they are providing the best protection to children and adolescents when they require parental permission for research involvement. However, parental permission is problematic where:

- a conflict exists between the best interests of the child or adolescent, and the interests of the parent, for example, for research on sexual abuse, where a parent may be abusing an adolescent
- an adolescent is capable of making independent decisions about medical or mental health care or other social services and/or is legally empowered to make these kind of decisions
- the adolescent is legally emancipated because of age or status (married or serving in the military), or is functionally emancipated (living independently)
- parents are functionally incapacitated (e.g. because of mental illness), unavailable, or otherwise unable to provide informed permission
- the adolescent is estranged from the parents
- the adolescent is capable of providing informed consent for the research, based on the principle of evolving capacity.

Any of these circumstances may be a rationale for waiving parental permission. Waiver of parental permission should follow the principles from the CRC of *best interests* and *evolving capacity*.

Even where adolescents are capable of providing informed consent or legally empowered to do so, they may value consultation with parents or other family members. Researchers and research ethics committee should actively encourage such voluntary consultation and design informed consent processes to accommodate such consultation.

Box 10. Case study on inclusion vs. protection: randomized clinical trials for HIV prevention

Interventions to prevent HIV infection among adolescents have included sexuality education; behaviour change trials in schools, community and clinics; vaccine and vaginal microbicide trials; male medical circumcision; cash transfer programmes; and pre-exposure prophylaxis (PrEP) with antiviral agents active against HIV. Adolescents, and particularly adolescent girls, are at considerable risk for HIV especially in generalized epidemics, as has occurred in sub-Saharan Africa.* HIV prevalence rises as children enter adolescence in sub-Saharan Africa, particularly among adolescent girls; for example, in Swaziland HIV prevalence among adolescent girls and young women aged 15–24 years is 22.7 per cent.** Risks and benefits also vary among these interventions, with greater risk in biomedical trials than in educational and behavioural trials. While adolescents under age 18 are frequently allowed into trials of educational interventions, they have frequently been excluded from trials of HIV vaccines and PrEP, although these interventions would clearly be helpful to adolescents. Such trial efficacy must therefore be extrapolated from adults to adolescents, although adherence and HIV risk factors may be quite different between the two groups. If adolescents are not included in HIV prevention trials, it will be difficult to optimize prevention.

* PrEP is the taking of HIV antiviral medicine by an HIV negative person to prevent becoming HIV infected. Clinical trials have demonstrated high protection from HIV infection when daily adherence to daily PrEP is high.

** Mavedzenge, S. N. et al., 'The Epidemiology of HIV among Young People in Sub-Saharan Africa: Know your local epidemic and its implications for prevention', *Journal of Adolescent Health*, vol. 49, pp. 559–567, 2011.

The next two sections describe ethical ground rules with recommendations, and practical applications, integrating principles and specific applications.

ETHICAL GROUND RULES AND RECOMMENDATIONS WHEN CONDUCTING RESEARCH WITH ADOLESCENTS

In light of the emerging literature on neurocognition, recognizing that parents may not always act in the best interests of their children and in acknowledging the diversity of experiences of young people and their evolving capacities, the following section discusses five ethical ground rules or recommendations when conducting ethical research with adolescents.

Shifting thinking about adolescents: from subjects of research to agents in research

From subjects to agents, research ethics committees and researchers need to shift their thinking: adolescents should not be mere subjects of research but agents in research. Consistent with their evolving capacities, adolescents should be welcomed as active partners in research and as the primary decision-makers about their own research involvement – not as passive recipients of research. This shift in perspective is based on the principle of showing *respect for persons* and the notion that adolescents are persons with human rights and *evolving capacities*, as expressed in the CRC. Understanding of evolving capacities should be guided by research on neurodevelopment including decisional capacity to make informed choices. Research with adolescents should be guided by an empathic respect for their diversity, social context and life experiences; their evolving decisional capacity and increasing desire for privacy; and their emerging sense of autonomy and altruism. Showing respect for adolescents also includes recognizing that they are embedded in key social institutions and the importance of respecting parents, community and culture.

In sum, adolescents are the best sources of information about their own lives, may have priorities at odds with their family and community of origin, and should have the right to make important decisions affecting their own lives.

Moving from inclusion vs protection to inclusion with protection

Adolescents should be included in studies that are important to their well-being. For adolescents to benefit from research, either as individuals or in groups, they must be included in studies which are pertinent to their current or future well-being. Too often adolescents are excluded from low-risk research in the name of protection and the complexities of informed consent. The requirement for parental permission should not be used as a barrier to research or an excuse for excluding adolescents. Research ethics committees and investigators should promote inclusion of adolescents in research with appropriate safeguards to prevent harm (inclusion with protection).

Where appropriate governments should remove unnecessary age restrictions and parental consent requirements that impede adolescents from participating in research. Consistent with the CRC, national laws should recognize the evolving capacities of adolescents to make independent decisions on their well-being and the variation in risks represented by different research programmes. Young people should be able to consent to taking part in research independently if they are capable of understanding the nature and consequences of the research (the risks and benefits of the study), able to assess their own best interests, and able to make a voluntary choice (particularly where the research risk is low). If governments prefer to define a minimum age below which consent of a parent or guardian is required in all cases, this should be set at early adolescence. Children above such a minimum age should be able to consent independently; if the research is potentially relatively risky, adolescents can be assessed by the social or health professional not connected to the research as sufficiently mature to make an informed decision. Furthermore, marriage should not be a precondition for participating in research. Adolescent girls who are married should be assumed to be able to give consent and to determine what is safest and in their best interests, without consent by their husbands.

Harmonizing laws and regulations influencing research participation by adolescents

Laws and regulations concerning adolescents giving informed consent to take part in research should be harmonized with laws on the legal capacity of adolescents, particularly laws allowing adolescents to consent to health care independently, defining emancipation status, and recognizing the concept of mature minors. National and international research guidelines should promote harmonization, building on the principles of the CRC – including the notions of *best interests* and *evolving capacities*.

Respecting adolescents as persons and rights holders

Respect for adolescents should be based on *evolving capacities* as defined in the CRC. Research ethics committees and investigators conducting research with adolescents should be knowledgeable about adolescent development and well-being. Additionally, the committees reviewing adolescent research should include at least one member with appropriate expertise in adolescent development.

Building on science

Ethical research should address the important needs of adolescents. It should answer important questions and consider the potential implications of research findings. Listening to the expressed needs of adolescents, families, communities and professionals should be part of research priority setting processes.

Research ethics and particularly the notion of evolving capacities should be based on current scientific understanding of adolescent neurodevelopment, with explicit recognition of the role of development, environment and experience in shaping cognition. More research is needed on how to conduct ethical research with adolescents, especially about adolescents' capacity to provide informed consent in a variety of contexts. Research is also needed on new ways to work with parents and communities and new models for participatory research with adolescents.

PRACTICAL APPLICATIONS WHEN CONDUCTING RESEARCH WITH ADOLESCENTS

Inclusion

Adolescents should be included in research which is important to their well-being. Investigators, research ethics committee, regulators and funders should promote the inclusion in research of adolescents, including hard-to-reach populations such as disadvantaged and marginalized adolescents, so they may enjoy the benefits of research.

Participation

Adolescents should be involved in decision-making about research planning, data collection and interpretation. This can be implemented through youth advisory groups or participatory action research. (For details see Brief 5 in this series, '[Adolescent Participation in Research: Innovation, rationale and next steps](#)'.)

Respecting families, communities and culture

Adolescents are embedded within social structures including families, communities and other cultural groups. Researchers and research ethics committees should understand and respect these social institutions:

- When waiving parental permission, researchers should create opportunities for adolescents to consult parents, other family members and/or other trusted adults when deciding to participate in research. Adolescents themselves should, where relevant, decide whom and/or when to consult others.
- Community consultation (including consultation with parents, community members and leaders, and youth advocates) may also be helpful in protecting adolescents involved in research – and is useful in refining research questions and methods.

Adolescent expertise on research ethics committees

These are some guidelines for research advisory committees when conducting research with adolescents:

- Research ethics committees, including institutional review boards and other panels which review research protocols related to adolescent well-being, should include a member or members with expertise in adolescent well-being, health and development.
- Research ethics committees should recognize adolescents as rights holders and the need to consider the *best interests* of the adolescent and their *evolving capacities* to make independent decisions and to participate in protecting their own welfare.
- Members of research ethics committees (and researchers conducting research with adolescents) should receive training and be knowledgeable on research ethics as applied to adolescents. This training should include information on human rights and the CRC, evolving capacities and neuroscience, social and developmental changes occurring during adolescence, and diversity among adolescents.
- Researchers and research ethics committees should have rights-based guidance on consent, assent and confidentiality with adolescents.

Informed consent

Informed consent can often be obtained directly from adolescents, particularly for minimal risk studies, for studies that present the possibility of direct benefit, and for studies that involve procedures commensurate with adolescents' experience. These are some guidelines for gaining informed consent when conducting research with adolescents:

- Consistent with the CRC, national laws should recognize the *evolving capacities* of adolescents to make independent decisions regarding their health, based on the science of adolescent neurodevelopment. Wherever possible, adolescents should be able to consent independently if they are capable of understanding the nature and consequences of the research or service and are able to assess their own best interests.
- Where informed consent is obtained directly from the adolescent, adolescents should be encouraged to seek the advice of parents, other family

members or trusted adults, where appropriate.

- Governments should consider removing rigid age restrictions and unnecessary parental consent requirements that impede adolescents' access to research.
- Research ethics committees should seriously consider not requiring parental permission for research involving procedures and circumstances (e.g. behavioural questions) where adolescents are able to consent in non-research settings.
- Informed consent is commonly waived for certain research involving adults and children, for example, when abstracting and reviewing previously collected information such as data from medical records. Under such circumstances, informed consent could also be waived for research with adolescents – contingent on reflection on access to and potential for re-identification of data.
- Likewise, informed consent with adults may be obtained with a waiver of documentation of informed consent, when such waiver contributes to prevention of harm, e.g. when conducting an anonymous survey on a sensitive subject where a signature on a consent form might allow identification of the person's responses. The use of such waivers could also be considered when obtaining adolescents' informed consent.
- For studies involving considerable risk and the potential for direct benefit, there should be serious consideration of the possibility of adolescents being able to consent independently if they are assessed by a social or health professional as having the maturity to provide informed consent.

The intersection of research risks and adolescents' decisional capacity

These are some considerations relating to adolescents' decisional capacity and different levels of research risk:

- Decisions to obtain informed consent from adolescents and to waive parental permission should depend on the capacity of the adolescent to make informed decisions. These decisions also depend on the level of risk and benefit involved. Thus, when research risk is higher, individual assessment of an adolescent's capacity is prudent.
- Highly risky research with little benefit should not be allowed with children and adolescents before the age of majority. Such research is ethically

- problematic even with competent adults.
- For minimal risk research, even younger adolescents (age 10+) are able to make decisions themselves, as long as the study has been reviewed by an ethical review committee, the consent process is sensitively constructed, and consent is obtained in the absence of coercion and undue influence. Input from community representatives can be important in these situations, when research involves potentially sensitive topics.
 - For studies involving greater than minimal risk, but offering the potential for individual benefit, an individual assessment of adolescents' capacity to provide informed consent may be needed when the adolescents consent themselves and parental permission is waived. Such an assessment should be made by a social or health professional not conducting the study.
 - For research involving a small increase over minimal risk, the study should be reviewed by a research ethics committee, the research should be commensurate with the adolescent's life experience, the informed consent process should be sensitively constructed, and consent should be obtained in the absence of coercion and undue influence.

Sensitivity to harms and benefits unique to adolescents

Adolescents may display developmentally appropriate sensitivities related to research harm or risk. These include heightened desire for autonomy, privacy and confidentiality; greater tolerance of risk; heightened self-awareness; sensitivities about body image and identity; and a strong sense of altruism. Researchers and research ethics committees need to recognize these sensitivities to prevent harm to and promote the inclusion of adolescents in research.

CONCLUSION

The ethical conduct of research with adolescents requires attention to ethical principles and the unique personhood of these rapidly developing individuals. Researchers and ethics committees need to consider the unique developmental stage of adolescents in making ethical decisions. With a careful consideration of adolescent development, the dual goals of inclusion in research and protection from research risks can be attained. We hope that the ethical values and practical applications described in this brief will prove useful to researchers and ethics committees working with adolescents.

GLOSSARY

<u>Adolescents</u>	Persons aged 10–19 years, as defined by the World Health Organization and UNICEF.
<u>Age of majority</u>	The age at which adolescents become adults and attain the legal rights and privileges of adulthood.
<u>Assent</u>	A child’s affirmative agreement to participate in research. The concept of assent recognizes the emerging developmental capacity of children, even where they may not be fully capable of providing informed consent. Assent is commonly obtained from children beginning at age 7.
<u>Beneficence</u>	Obligation to do good and to avoid harm. In research, one commonly weighs risks and benefits. This is closely related to the concept of <i>best interests</i> in the CRC.
<u>Best interests</u>	Recognition of the personhood of the child and the need to provide protection and promote the human rights of the child, as enumerated by the CRC.
<u>Child</u>	The CRC defines a child as a person below age 18, unless under national laws applicable to the child, majority is attained earlier.
<u>Child brides</u>	Girls in a formal marriage or informal union before age 18.
<u>Emancipation</u>	The achievement of adult legal status before the usual age of majority due to marriage, motherhood, military service, or other specific circumstances.
<u>Equity</u>	Defined by UNICEF as ‘a fair chance for every child’, equity refers to fairness or justice in the way children are treated. Equity requires securing all children’s rights to education, and their rights within and through education to realize their potential and aspirations, and implementing and institutionalizing arrangements that help ensure all children can achieve these aims.
<u>Evolving capacities</u>	The concept that children’s capacities evolve.
<u>Inclusion</u>	The right to participate in research and to receive individual benefit or for a group of individuals to receive benefit.
<u>Informed consent</u>	Based on the principle of respect for persons, obtaining informed consent is an essential practice in conducting research. It entails providing <i>information</i> , assessing <i>comprehension</i> of the information provided, and ensuring the consent is <i>voluntary</i> and not coerced by circumstances or persons involved in the research.
<u>Justice</u>	A fair distribution of the benefits and burdens of research. Justice is commonly considered at both the individual and the population level.
<u>Mature minor</u>	Minor adolescents who demonstrate the capacity to make independent judgements when faced with specific life decisions.
<u>Minimal risk</u>	‘The probability [that the] magnitude of harm or discomfort anticipated... are not greater... than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests.’*
<u>Minor consent laws</u>	Laws that allow adolescents to access health care independently before the age of majority for specific conditions such as emergency care, pregnancy and mental health conditions, and treatment for sexually transmitted infections.
<u>Parental permission</u>	The agreement of parent(s) to their child’s participation in research.
<u>Protections</u>	The safeguards built into research projects to prevent harm to individuals or groups.
<u>Respect for persons</u>	The right of autonomous individuals to make free decisions about research participation consistent with their own values and preferences, and the right of vulnerable persons to be protected from research risk.

* US Department of Health and Human Services, ‘Protection of Human Subjects’.

READINGS FOR FURTHER EXPLORATION

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