

# THE INTERNATIONAL NORMATIVE FRAMEWORK FOR ETHICALLY ACCEPTABLE CONSENT APPROACHES TO ADOLESCENT RESEARCH

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Guidance on ethical considerations in planning and reviewing research studies on sexual and reproductive health in adolescents



Convention on the Rights of the Child

# Convention on the Rights of the Child

Adopted and opened for signature, ratification and accession by General Assembly resolution 44/25 of 20 November 1989 entry into force 2 September 1990, in accordance with article 49

## Preamble

### International Ethical Guidelines for Health-related Research Involving Humans

Prepared by the Council for International Organizations of Medical Sciences (CIOMS) in collaboration with the World Health Organization (WHO)



The Lancet Commissions



Our future: a Lancet commission on adolescent health and wellbeing

George C Patton, Susan M Swager, John S Santelli, David A Ross, Roma Ayyub, Nicholas B Allen, Marika Azevedo, Peter Anzures, Wendy Balkin, Christopher Bond, Rebecca Edwards, Eliza Kennedy, Jennifer Mahon, Terry McGovern, Ali H Madadi, Vikram Patel, Suzanne Pitzer, Nicola Pless, Elizabeth Taylor, Jane Whittall, Chahine Waked, Corina Brown, Collette L Auerwald, Adnan Hameed

## ETHICAL RESEARCH INVOLVING CHILDREN



### Improving the Methodological Quality of Research in Adolescent Well-being

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The University of Melbourne

#### Innocenti Research Briefs - Methods

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 wellbeing 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.

The briefs are written by leading experts in adolescent health and well-being. To read other briefs in this series, visit <https://www.unicef.org/adolescent-research-methods/>

Series editors: John Santelli and Nikola Balvin

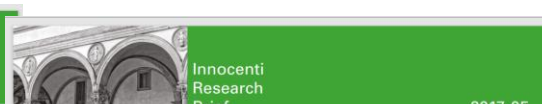
#### INTRODUCTION

The world is home to 1.2 billion adolescents – the largest cohort in history. Adolescence is a critical period of cognitive, emotional, physical and sexual development with consequences across the life course of the individual and a strong influence on whether the next generation has a healthy start to life.

The significance of this period of rapid development has gained prominence in the international arena with the Sustainable Development Goals (SDGs) and the new Global Strategy on Women's, Children's and Adolescents' Health, bringing a greater focus on adolescents as both recipients of interventions to improve their well-being and as decision-makers and implementation partners in their own lives. Despite the increasing focus on adolescents, when compared to children under 5 years old and adults, there is a lack of comprehensive data collection systems and a limited evidence base for effective interventions. This is particularly true for younger adolescents and those who are disadvantaged, vulnerable and/or marginalized. The relative absence of comprehensive data collection systems and research means that in most countries there is insufficient understanding of adolescent health and well-being, and inadequate local research to fully inform programme and policy responses, including those related to adolescent rights and responsibilities. This is even more the case in low- and middle-income countries, which are home to 90 per cent of the

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

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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.<sup>1</sup> 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 growing 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

<sup>1</sup> Patton et al., 'Our Future', [http://www.thelancet.com/series/ourfuture/](http://www.thelancet.com/series/ourfuture) article:PIIS0140-6736(16)00179-1 (Lancet), accessed 16 January 2017.



### Research with Disadvantaged, Vulnerable and/or Marginalized Adolescents

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#### INTRODUCTION

Disadvantaged, vulnerable and/or marginalized adolescents (DVMAs) are individuals aged 10–19, who are excluded from social, economic and/or educational opportunities enjoyed by other adolescents in their community due to numerous factors beyond their control. These include factors at the social level (such as economic inequality, violence, stigma, racism, migration), family level (including neglect and abuse) and individual level (e.g. disability, ethnicity). DVMAs include adolescents who are immigrants or refugees; sexual minorities; orphans; incarcerated; those who have run away or been turned out of their homes following neglect and/or abuse; those who are trafficked; and those who belong to a stigmatized indigenous, ethnic, tribal or religious group. Though gender plays an important role within each of these categories and for the group as a whole, in this brief we do not treat all girls and young women as DVMAs.

As a result of their social exclusion, DVMAs suffer from health inequities, or avoidable inequalities in their health and well-being compared to the well-being of other adolescents. Research is needed to inform ways to address these inequities.

When carrying out research with DVMAs it is necessary to address not only the obstacles to research with adolescents overall (see Brief 3 in this series, 'Inclusion with Protection: Obtaining informed



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## DECLARATION OF HELSINKI

Medical Research Involving Human Subjects

# COMMON THEMES: ADOLESCENT RESEARCH

- Persons in their own right and as worthy and capable of recognition, respect and voice in research.
  - Right to have a say and to be heard, as afforded to them under the UNCRC, including in the context of well-planned, ethical research.
- Involvement in any kind of research takes place in partnership with caring, skilled adults who need to provide appropriate support and guidance, in order to help them formulate their views and participate in a safe and meaningful way.
- Importance of research focused on understanding and improving adolescents' lives and circumstances underscored
- Engage critically with well-attested ethical principles of respect, benefit and justice during research
- Dialogue and a more reflexive approach in attending to complex ethical issues that can emerge with research involving adolescents promoted
- Ethical regulatory mechanisms and review processes may be experienced as supportive or restricting, but they do not ensure ethical practice, and cannot replace researchers' contingent ethics in the field.

# RESEARCH ETHICS & ADOLESCENTS

- Balancing act between protection from research harm and inclusion in research which may bring benefit - balance between protection and inclusion often fraught with confusion.
- Children up to 18 years of age often seen as a vulnerable population needing protection from risks of research involvement. This vulnerability stems from:
  - reduced ability of **younger children** to make reasoned choices
  - lower social status of children
  - power imbalance that renders children susceptible to adult coercion
- Barriers to conducting research with adolescents include:
  - misunderstandings of adolescents' cognitive abilities and capacity to provide informed consent
  - overzealous valuing of protection over inclusion
  - institutional self-protection including from RECs
  - antiquated attitudes about adolescents as not holding equal rights to adults
  - debates about who provides informed consent for adolescent involvement- legal barriers may impede research
- The result of such uncertainty is that adolescents get excluded from research that may benefit them individually and collectively.

# ADOLESCENTS: THE GLOBAL CONTEXT

- >1.2 billion adolescents globally
- Adolescence is a critical period of cognitive, emotional, physical and sexual development with consequences across the life course of the individual and a strong influence on whether the next generation has a healthy start to life.
- Significance of this period of rapid development
  - gained prominence in the international arena with SDGs & new Global Strategy on Women's, Children's and Adolescents' Health
  - hence greater focus on adolescents as both recipients of interventions to improve their well-being and as decision-makers and implementation partners in their own lives
- In most countries:
  - insufficient understanding of adolescent health and well-being, and inadequate local research to fully inform programme and policy responses, including those related to adolescent rights and responsibilities.
  - This is even more the case in LMICs, which are home to 90 per cent of the world's adolescents, and where research into issues of adolescent health and well-being – including sexual and reproductive health and HIV, nutrition, psychological well-being, injuries, social protection, child marriage, education and the transition to the labour force – is particularly vital.



# UNDERSTANDING ADOLESCENCE

- No longer children, not yet adults – are unique beings with human rights, developmental needs and tremendous potential.
- ***Respect for persons and the evolving capacity*** of adolescents to make informed decisions should be central to considerations about adolescent research involvement and informed consent considerations.

**Figure 1. Adolescence and health within the life course**



Source: Reproduced with permission from Patton et al., 'Our Future'

Health and well-being - central to developmental tasks of adolescents: acquisition of the emotional and cognitive capabilities for independence, completion of education and transition to employment, civic engagement and formation of lifelong relationships.

Adolescent years are those in which the foundations for adult health and well-being are laid.

Parent well-being important to child health, hence well-being in adolescence plays a role in determining the outcomes of the next generation.

Improving the health and well-being of young people before they become parents critically underpins the well-being of subsequent generations

# STARTING POINT: RESPECT RIGHTS, HUMAN DIGNITY AND WELL-BEING OF ADOLESCENTS

- UNCRC – central starting point
  - 1<sup>st</sup> & most complete international instrument to assert full range of rights
- Gives recognition of children as rights holders & draws attention to their protection and provision rights
  - obligations to consider the best interests of the child
  - obligations to consider their evolving capacities to make sound decisions and participate in promoting their own welfare
- While does not refer specifically to research, *“when read in conjunction with the UN Committee on the Rights of the Child General Comments, articles are elastic enough to address most aspects of children’s lives, including participation in research”* (ERIC)



**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.

abortion, HIV testing and treatment, medical treatment, research).<sup>9</sup> 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*).<sup>10</sup>



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

- Critical - adolescents' evolving capacities as expressed in CRC - ability to make independent decisions about research involvement: should be considered by REC as agents of research
- Evolving capacities resulting in ability to provide truly informed consent - directly informed by research on neurodevelopment and cognition during adolescence + linked to the previous life experiences of adolescent
  - from age 12 adolescents have decision-making competence
  - 14-year-olds
    - as capable as adults in understanding multiple viewpoints and considering conflicting information
    - ability to make decisions about research participation is similar to that of adults
- Parents not always best positioned to consent for adolescent
- Community consultation
- Obtaining informed consent is an essential but imperfect mechanism to protect people from research harm.

### 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.

- Adolescents are 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.
- Requirement for parental permission not to be used as barrier to research.
- RECs + investigators - promote inclusion of adolescents in research with appropriate safeguards.
- Governments should remove unnecessary age restrictions and parental consent requirements that impede adolescents from participating in research.
- Consistent with CRC, national laws should recognize the evolving capacities of adolescents to make independent decisions on their well-being
- Young people should be able to consent to taking part in research independently.
- 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.

## **Guidance on ethical considerations in planning and reviewing research studies on sexual and reproductive health in adolescents**

- Soliciting parental informed consent and a minor adolescent's assent can be particularly challenging in the context of research on sexuality and reproduction.
- Article 12 of CRC : child (adolescent) who is capable of forming own views must have right to express those views freely in all matters affecting him- or herself, with the views of the child being given due weight in accordance with his or her age and maturity
- CRC presses for the right of children to have their voices heard, but this does not mean they have full autonomy - does not give children right to control over all decisions irrespective of their implications either for themselves or others
- Decision-making capacity is still considered to be evolving. Hence, only a child's parent or legal guardian may legally provide consent for the child to participate in research
- Legally, children can only assent to research participation until they are old enough to provide legally valid consent. In these cases, both the authorization or consent of the parents and the child's assent or agreement must be obtained

# Guidance on ethical considerations in planning and reviewing research studies on sexual and reproductive health in adolescents

## 2.2.3 Informed consent

In the research context, informed consent is the formal process for getting permission before a person can participate in research. As the therapeutic and research contexts are distinct from each other and involve different risks, the informed consent requirements and processes for both should not be confused. While many settings permit children limited or exclusive decision-making power in relation to particular treatment and care options available to them, in most settings, children (by definition, people who have not reached the age of legal majority) lack capacity to decide to participate in research and therefore cannot provide legally valid, autonomous consent (exceptions to this are discussed in Section 2.2.2 Autonomy). Instead, parental or guardian consent is a prerequisite to the child's participation in research.

In summary, there are both legal and ethical requirements for consent:

- Legal requirements identify the people who can provide legally valid consent for a child's participation in research – usually the child's parents or legal guardians.
- Ethical requirements must also be considered. If a child has the capacity to make a decision concerning his or her involvement in research, then assent from the child as well as parental consent must be obtained. If a child does not have the capacity to decide upon participation in the research, then he or she should be appropriately involved in the decision so their voice is still heard (in order to uphold the rights outlined in Article 12 of the CRC). This process should be documented in line with any local requirements for “assent”.

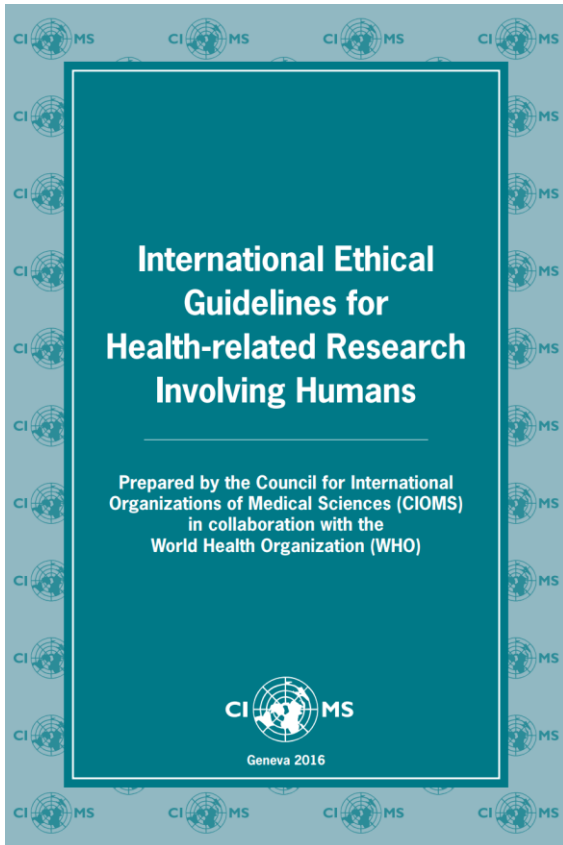
## Assent as central

Art 12: CRC designates that “children shall be assured the right to express their views freely in all matters affecting them, their views being given due weight in accordance with the child's age, level of maturity, and what is in their best interest”.

Ethically if child demonstrates decision-making capacity, the researcher should give due weight to the child's views on his or her participation in research activities, regardless of the child's legal capacity in the research setting.

# **Guidance on ethical considerations in planning and reviewing research studies on sexual and reproductive health in adolescents**

- **2.2.6 Waiver of parental informed consent**
- In some instances it may not be feasible to solicit permission from parent/ guardian, e.g. where unknown, untraceable or deceased / reasons of sensitivity - minors unwilling to participate if are required to tell their parents about the nature of the research
- Researcher may consider applying to REC for waiver of parental consent
  - If REC not empowered to award such waiver, researcher may apply to court - generally regarded as upper guardian of all children
  - In some countries, eg US, IRB may allow waiver
- WHO guidance for waivers:
  - research no more than minimal risk □
  - waiver will not adversely affect the rights and welfare of the subjects
  - research could not practically be carried out without the waiver
  - whenever appropriate, subjects are provided with additional pertinent information after participation
  - REC determines that research is to study conditions for which parental permission not a reasonable requirement to protect the subjects & an appropriate mechanism in place to protect the subjects & waiver not inconsistent with federal, state or local law
  - advisable for investigators to engage with the host community or community representatives to seek guidance on waiver processes - engagement to be documented and submitted to REC / IRB
  - REC to base decision on whether waiver in the best interests of the child.



## GUIDELINE 17:

# RESEARCH INVOLVING CHILDREN AND ADOLESCENTS

Children and adolescents must be included in health-related research unless a good scientific reason justifies their exclusion. As children and adolescents have distinctive physiologies and health needs, they merit special consideration by researchers and research ethics committees. However, their distinctive physiologies and emotional development may also place children and adolescents at increased risk of being harmed in the conduct of research. Moreover, without appropriate support, they may not be able to protect their own interests due to their evolving capacity to give informed consent. Specific protections to safeguard children's rights and welfare in the research are therefore necessary.

Before undertaking research involving children and adolescents, the researcher and the research ethics committee must ensure that:

- ▶ a parent or a legally authorized representative of the child or adolescent has given permission; and
- ▶ the agreement (assent) of the child or adolescent has been obtained in keeping with the child's or adolescent's capacity, after having been provided with adequate information about the research tailored to the child's or adolescent's level of maturity.



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# DECLARATION OF HELSINKI

## Medical Research Involving Human Subjects

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- 28. *'For a potential research subject who is incapable of giving informed consent, the physician **must seek informed consent from the legally authorised representative**. These individuals must not be included in a research study that has no likelihood of benefit for them unless it is intended to promote the health of the group represented by the potential subject, the research cannot instead be performed with persons capable of providing informed consent, and the research entails only minimal risk and minimal burden.'*



# PHILOSOPHY

Ethical Research Involving Children (ERIC) assumes that ethics is much more than procedural compliance with a prescribed set of rules or code of conduct that can deliver good or safe research in any given context. While such codes play an important role, the ERIC approach recognises the myriad ways in which researchers' own knowledge, beliefs, assumptions, values, attitudes and experience intersect with ethical decision-making. As such, ERIC requires critical reflection; cross-cultural, inter-sectoral and cross-disciplinary dialogue; context-specific problem-solving; and international collaboration, learning and engagement. In order to safeguard and promote the rights, dignity and well-being of children in and through research, ERIC calls on researchers and the research community to be open, reflexive and collaborative in their ethical decision-making, and to be specifically attuned to the relational dimensions of research ethics. The core ethical principles underpinning the ERIC approach are respect, benefit and justice.

# FURTHER CONSIDERATIONS

- Harm - may occur if the research is not done
- May be 'gate-kept' out of research
- Researchers have a responsibility to ensure that no harm is done to individual adolescents participating in the research (deontological), as well as attending to the long-term and/or greater good for adolescents as social groups (consequentialist)
- Researchers equipped with knowledge and skills have a responsibility to ensure that adolescents are not harmed because necessary research is not done
- Adolescent's opinions have not been sought sufficiently - needs urgent redress
- Justice principle – no adolescent to be discriminated against in terms of *interalia* age wrt participating in research.
- Critically important to acknowledge parents in gate-keeping roles are important in protecting adolescents from potential harm but may use power against the child & may not always have the best interests in mind
- Equally important to respect adolescent's reasons for not wanting parent involvement
- Change in laws based on evolving capacity?

# INTERNATIONAL CHARTER FOR ETHICAL RESEARCH INVOLVING CHILDREN

As a research community working with children, we are committed to undertaking and supporting high quality ethical research that is respectful of children's human dignity, rights and well-being. The following seven commitments guide our work:

## **ETHICS IN RESEARCH INVOLVING CHILDREN IS EVERYONE'S RESPONSIBILITY**

We, the research community, including all who participate in undertaking, commissioning, funding and reviewing research, are responsible for ensuring that the highest ethical standards are met in all research involving children, regardless of research approach, focus or context.

## **RESPECTING THE DIGNITY OF CHILDREN IS CORE TO ETHICAL RESEARCH**

Ethical research is conducted with integrity and is respectful of children, their views and their cultures. Involving children respectfully requires that researchers recognise children's status and evolving capacities and value their diverse contributions.

## **RESEARCH INVOLVING CHILDREN MUST BE JUST AND EQUITABLE**

Children involved in research are entitled to justice. This requires that all children are treated equally, the benefits and burdens of participating are distributed fairly, children are not unfairly excluded and that barriers to involvement based on discrimination are challenged.

## **ETHICAL RESEARCH BENEFITS CHILDREN**

Researchers must ensure that research maximizes benefits to children, individually and/or as a social group. The researcher bears primary responsibility for considering whether the research should be undertaken and for assessing whether research will benefit children, during, and as a consequence of, the research process.

## **CHILDREN SHOULD NEVER BE HARMED BY THEIR PARTICIPATION IN RESEARCH**

Researchers must work to prevent any potential risks of harm and assess whether the need to involve the individual child is justified.

## **RESEARCH MUST ALWAYS OBTAIN CHILDREN'S INFORMED AND ONGOING CONSENT**

Children's consent must always be sought, alongside parental consent and any other requirements that are necessary for the research to proceed ethically. Consent needs to be based on a balanced and fair understanding of what is involved throughout and after the research process. Indications of children's dissent or withdrawal must always be respected.

## **ETHICAL RESEARCH REQUIRES ONGOING REFLECTION**

Undertaking research involving children is important. Ethical research demands that researchers continually reflect on their practice, well beyond any formal ethical review requirements. This requires ongoing attention to the assumptions, values, beliefs and practices that influence the research process and impact on children.



*Thank you*