



**Biomedical Research  
and Training Institute**

# **Ethical issues in conducting research with adolescents and young people (AYP)**

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# Ethical principles underpinning research conduct

- **Respect for people**
  - Autonomy: free to make own decision
  - Protect those with diminished autonomy
- **Beneficence**
  - Do no harm
  - Minimise risks and maximise benefits
- **Justice**
  - Fairness: participant and location of study
    - Relevance to community
    - Relevance to participant population
    - Not just based on ease of conduct

*International ethical guidelines for health-related research involving humans. Geneva: Council for International Organizations of Medical Sciences; 2016*

<https://cioms.ch/wp-content/uploads/2017/01/WEB-CIOMS-EthicalGuidelines.pdf>

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# Challenges in AYP: Respect

- Capacity to understand and meet criteria for consent evolving

*Phase of physical, social, moral, emotional and cognitive development*

- Legal right to consent- prior to this can only assent
- Lack of legal guardianship

*Orphans, child-headed households, “left-behind”, street children, unaccompanied aliens etc*

- Socio-cultural expectation/requirement to defer to families



# Challenges in AYP: Beneficence

- Socio-cultural taboos on behaviours in adolescence
- Harm and risk of AGYW with participation
- Lack of protection
- Lack of skills (or perception of need) to provide information
- Power imbalances and vulnerable

*Interplays with ability to get consent /participation*



# Challenges in AYP: Justice

- Easier to recruit adults
- Lack of recognition of distinct needs and circumstances
- Ethical challenges
- Legal barriers: consent, criminalised behaviours



# Key principles

- Frameworks are meant to protect participants not inhibit research and ethical process shouldn't be a tick box exercise : reflection and discussion
- One size does not fit all- grey area + heterogeneity
- Cognisance with the terminology & local regulatory context  
(youth, young people, adolescents, minors, juveniles, emancipated minors, mature minors, teenagers.....)
- Use clearly-defined and consistent terminology
- Right to confidentiality and information



# Best interests

- **“Best interests”**: Broadly means well-being of an individual

*Determined by variety of factors*

-age, sex

-social background,

-physical and emotional security,

-physical, intellectual, emotional, social and cultural development

-disability, illness

-risk of physical or psychological harm that may be caused by:

subjecting AGYW to maltreatment, abuse, neglect, exploitation or such behavior towards others

any family violence

oppressive laws or state policies



# Addressing Justice

- **Justify the reason for including the study population**
  - information to be gained could not scientifically be obtained from adult subjects;
  - goal is to obtain knowledge relevant to the health needs of AYP
  - Risk is low and commensurate with importance of knowledge to be gained;
  - interventions at least as advantageous to the AYP as any available alternative
- **Conducting research in a setting where cultural or legal taboo towards a group e.g. homosexuality, injection drug use, sex work**
  - Solicit support from authorities: avoid if not possible
  - Form partnerships with local organizations / authorities: advocate for change





# Criteria for consent

- **Disclosure:** provide relevant information about the study

including its potential risks and benefits, rights to privacy and limitations to these rights (investigator's disclosure obligations)

- **Understanding:** Can appreciate and understand information provided

may be compromised by age, literacy, capacity to understand, severe physical or mental illness affecting comprehension

- **Capacity:** possess the decision-making ability

ability to understand material information, appreciate the situation and its consequences, consider the treatment options, and communicate a choice

**Voluntariness:** free of coercion and voluntary in nature



# Addressing Autonomy

- **Unless specific legal provisions, consent should be given by AYP alone**

Capacity to consent is related to the nature and complexity of the research

If meet criteria for consent: then can consent

- **Recognition that AYP have capacity & parental consent isn't absolute**
- **Even if no requirement to get consent/assent- ethically AYP should be meaningfully involved in the decision making process**
- **Waivers for “parental consent”**
  - Cannot be done without waiver (Affects validity of research)
  - Minimal risk
  - Demonstrate the ability to check that AYP understand the research
  - Safeguards in place to address any potential harms
  - Acting in best interest of AYP-does not affect rights/welfare



# Addressing beneficence

- **If conflict between confidentiality and disclosure:**
  - act in “best interests”

**If obligated to break confidentiality in best interests- inform AYP of possibility before their participation**

- **If a conflict between legal obligation and an ethical duty:**
  - obtain advice from governing ethics body
  - if no guidance or advice contrary to best interest principle, then researcher should always act ethically i.e. in the interest of the AYP
  - need to be cognisant that actions may have legal implications
  - not a light undertaking and therefore needs consultation and responsible, respectful and effective action including risk mitigation

# References

Guidance on ethical considerations in planning and reviewing research studies on sexual and reproductive health in adolescents. Geneva: World Health Organization; 2018

<https://apps.who.int/iris/bitstream/handle/10665/273792/9789241508414-eng.pdf?ua=1>

Guidelines for Conducting Adolescent HIV Sexual and Reproductive Health Research in Kenya. Government of Kenya Ministry of Health; 2015

<https://icop.or.ke/wp-content/uploads/2016/10/Adolescents-Guidance-on-HIV-SRH-Research.pdf>

