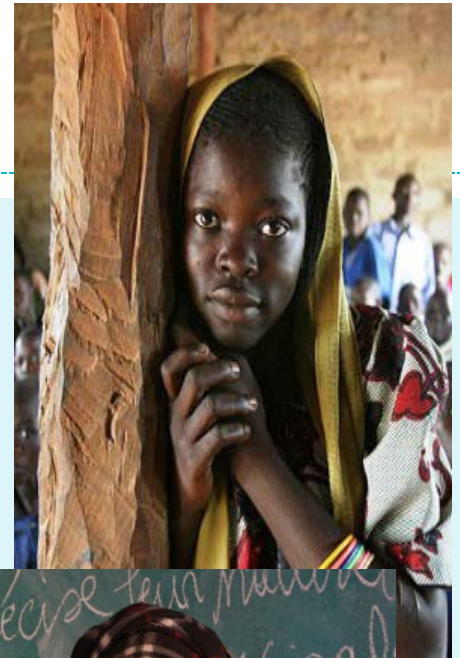


UNDERSTANDING THE ETHICAL AND LEGAL FRAMEWORK IN KENYA

Presented by Mr. Ambrose Rachier, Chairman, Kenya Medical Research Institute, Ethics Review Committee at the Stakeholders consultation on the MTN-034/IPM 045 open-label safety and adherence study of the dapivirine vaginal ring and oral PrEP (Meeting the HIV Prevention Needs of Adolescent Girls and Young Women)

*29-30 September, 2016,
Johannesburg, South Africa*



Overview of presentation

- **Matters of consent**
- **Confidentiality**
- **Mandatory reporting**

Matters of Consent

- In Kenya we classify them as mature or emancipated minors otherwise we would be unable to enroll them into a study.
- Parents are in denial that their children engage in sex
- Legally ...


Legally ...

- Adolescents can
 - Consent for VCT
 - Can be treated by a physician without the consent of the parent if the physician considers it is in the best interests of the child
- **Adolescents –ages 10-19**

A young person who is developing into an adult
(Cambridge Advanced Learner's Dictionary Third Edition)

- For Minors between 13-17
 - a. Consent from parent/guardian or any person in LOCO PARENTS; plus
 - b. Assent of the minor

Assent: An affirmative agreement of a child (aged 12-17 years) or an individual with impaired consent capacity to participate in research

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- Regarding parental consent, where the proposed research presents greater than minimal risk and there is no direct benefit to the minor then consent of both parents required (unless one parent is deceased, unknown or lacks legal capacity) then consent of one parent

- 
- Parental consent and assent to be in writing unless the ERC grants a waiver of documentation.

If Parent Says Yes/No To Participate	If Child Says Yes/No To Participate	Can Child Participate?
Yes	Yes	Yes
Yes	No	No
No	No	No
No	yes	No

- Mature or emancipated minor

- Interpreted to include any individual below 18 years of age who is

- a. Married
- b. Pregnant
- c. A mother
- d. Household head and

Who demonstrates a clear understanding of the requirements of consenting to participate in research . Such minor may give consent for himself or child but generally not for his siblings.

Confidentiality

- Any component that regards their reproductive health should be kept confidential.
- Unless their parents brought them to the study

Confidentiality: shall be upheld except where consent has been expressly given or disclosure is allowed by law.

Mandatory reporting

- Gender and sexual abuse must be reported to the police.
- The minor should be referred to a hospital that is in direct contact to a gender desk at a police station.
- The hospital is required by law to report assault to a minor

In conclusion ...

The overriding responsibility of the researcher is

- **Physical, mental and social well-being**
- **Risks reduced to a minimum**
- **Protection of the adolescent is more important than the rights of parents to know.**

Thank You!

