Informed Consent Process: Key Considerations

Objectives

- Apply GCP informed consent practices to recruitment of women for MTN-016.
- Understand the processes for obtaining informed consent for the woman versus the infants.
- Understand the infant data points collected under the woman's informed consent.

Basic GCP

- Who is responsible for making sure participant is fully informed prior to signing consent?
  - Investigator of Record
  - By delegation, all study staff involved in the informed consent process
- Must be conducted per site SOPs
- Consent must be obtained before performing any "on-study" procedures

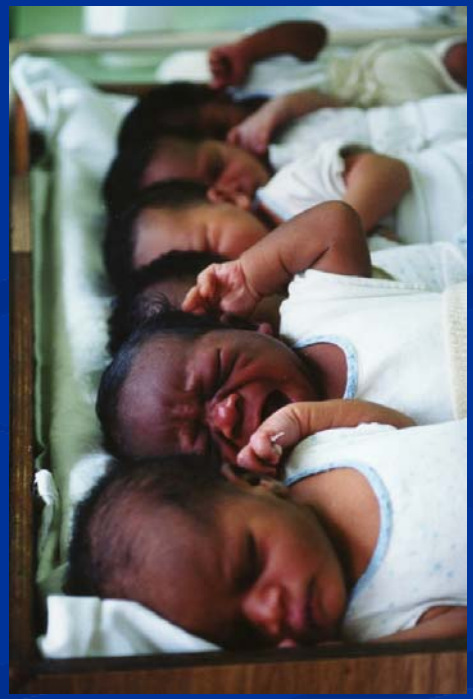
Types of Informed Consent in MTN-016

- Mother and Infant Screening & Enrollment
  - Obtained before/ after infant birth

- Informed consent for infant testing
  - Only babies of HIV-infected mothers

Infant Data Under Mom's IC

- Maternal consent allows for collection of infant data that are recorded on the L&D notes such as:
  - Infant Gender
  - APGAR scores
  - Length and Weight
  - Head and Abdominal circumference
  - Gestational Age



MTN-016

- Mothers may enroll in the study without consenting their infants.
- Infants may NOT enroll in the study without the mother being enrolled.

Informed Consent Process

Briefly **describe the steps** in the consent process and tell the potential participant and/or guardian the how long it takes to complete.

ASK — Does she have time to complete this today?

ASK — Is she ready to have the **informed consent form** read to her or read it herself?

Read consent form, section by section, asking if she has questions and discussing as you go along.

ASK — Does she feel comfortable that she understands all aspects of the study?

MTN microbicide trials network

1. **Women may enroll in MTN-016 if they became pregnant while enrolled on an HIV prevention trial.**

   True False

2. **The main purpose of this study is to see if using a medication to prevent HIV affects the health of pregnant women and their babies.**

   True False

3. **You will have blood drawn at every study visit.**

   True False

Participants must demonstrate understanding of all required points before signing/marking the consent form

8. **Once you enroll, you may not withdraw from this study at any time.**

   True False

9. **There is no direct benefit to you for participating in this study.**

   True False

10. **Your visits will be conducted to protect your privacy.**

    True False

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Comprehension Checklists

- Checklists & Literacy Assessments are study source documents.
  - Must be retained in participant's study chart.
  - Must enter PTID and date at the top.
  - All items must be completed to document eligibility for the study.

Informed Consent Comprehension Checklist

- This is a big responsibility!
- Assessment of understanding is subjective.
- The checklist is a tool to help assess understanding.
- Take as much time as needed.
- Consult other team members if needed before proceeding.

Documentation

- Each informed consent process must be documented in a signed and dated chart note.
- To avoid lengthy notes, use of an informed consent coversheet is suggested.
  - If used, coversheet should be listed as a study source document in site SOPs.
  - If used, a brief chart note is still required, but it is not necessary to transcribe all information from coversheet into chart note.

For Illiterate Participants

SIGNATURES

Participant Name	Participant Signature	Date
Mary Phiri		**25 NOV 2009**

Participant name and date written by Martha Moore. MM 25 NOV 09

Martha Moore		**25 NOV 2009**
Name of Staff Person Conducting Consent Discussion	Study Staff Signature	Date

Debra Ross		**25 NOV 2009**
Witness Name	Witness Signature	Date

Documentation

- Participants must be offered signed copies of their informed consent forms.
  - If they refuse a copy, document this in a chart note and offer the participant an alternate form of study contact information.

Wild Card Question

- If the mother decides not to enroll into MTN-016 but is willing to bring in her baby for all infant visits after birth, is the infant enrolled?

Wild Card Question

- What if the mother enrolls into 016, completes her 2nd quarterly visit, but then leaves the area for family reasons. She returns with an 65 week old child and would like to enroll him now.
- What if the mother in the scenario above returns with a 49 week old child?

Wild Card Answer

- An infant must be less than 1 year old to be eligible for enrollment into MTN-016.

Scenario

Rachel enrolls into MTN-016 through VOICE at her 2nd + hCG test. She gives birth on her EDD, and contacts you.

- When is her newborn enrolled?

Scenario Answer

Rachel's newborn IS enrolled. Rachel consented at Screening and Enrollment for herself through pregnancy outcome and her then unborn infant from birth through his/her first year of life.

Eligibility states all live births to mothers enrolled in MTN-003.

MTN-016

Infant HIV Testing Consent Process

Infant HIV Testing
Informed Consent Process

- Mothers diagnosed with HIV infection may elect to have their infants tested through MTN-016.
- No blood may be drawn on infants prior to obtaining an informed consent for testing from the infant's parent/guardian.
- Testing may occur at a scheduled or interim visit.