Strategies for Conducting High Quality Research in Pregnant Women and Infants

Kenneth Kintu, MB ChB, DPPM, MSc
Investigator / Study Coordinator
MU-JHU CARE Ltd., Kampala, Uganda
Outline

- Who are we?
- Review of strategies used at MUJHU to enhance:
  - Recruitment
  - Enrollment
  - Retention
  - Data collection & Regulatory
- How these strategies can be applied to MTN 016
Who Are We?

- Makerere University-Johns Hopkins University Research Collaboration (MUJHU).
- Located within Mulago National Referral Hospital Complex, Kampala, Uganda
- Conducting research on pregnant women and infants since 1988 (Phase I-III trials such as HIVNET 006, HIVNET 012, PETRA, HIVIGLOB, HPTN 027 & HPTN 046)
Recruitment Strategies

- Collaboration and linkage with hospitals
  - Potential Participate referral
  - Involve hospital staff as part time research staff
- Involvement of former Volunteers
- Intensive counselling
- Living within 15-20 km radius or stable home
- Study preparation
  - Involvement of CAB
  - Community sensitization
  - Health workers workshops
Enrollment Strategies

- Review of key study processes by more than one staff
- Use of Study ID card
  - Provides emergency study contact information
  - Helps identify study participants who present at ANC, L&D, and at the MUJHU clinic
- Key study contact at Lab
Retention Strategies

- Home/Health visitors
  - Develop personal relationship with participants
  - Prepare & update detailed participant locator form
  - Remind participants of upcoming visits and follow-up on late/missed study visits and resolution of SAE
Retention Strategies

• One stop centre (pharmacy, lab, clinic, vaccination, nutrition, ART)

• Hospitalization support (L&D for women and special care unit for infants)

• Ongoing counseling at study visits

• Transport and meals
Retention Strategies Contd.

• Male/ Partner involvement.
• Tracking missed study visits
  ▫ Database generates list of expected visits each day
  ▫ Health visitors f/u with women who miss visits
• Weekly study meetings
Data Collection & Regulatory

- Data Collection:
  - MUJHU research staff at offsite units (e.g. L&D) assist in collection of baseline study data.
  - Quality control of data are conducted at various locations within the hospital & clinic by QC coordinators.
  - QA coordinator identifies trends.

- Regulatory
  - Have well-trained educated staff with specific training on vulnerable populations.
  - Maintain good relationship with local IRB.
Lessons for MTN 016

• Designated study staff (ANC, L&D and Lab)

• Partner involvement

• Community preparedness

• One stop centre

• Experienced staff
Lessons for MTN 016

• Child friendly environment (play area, formula, pampers)

• Home/health visitors close personal relationship

• Qualified regulatory staff with sufficient time
Thank you!