

Strategies for Conducting High Quality Research in Pregnant Women and Infants

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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!