

# Follow-up of participants in the STEP Trial

HVTN Full Group Meeting  
November 7, 2007

# Why continue follow-up in STEP?

- Important questions about differences in HIV infection rates in vaccine vs. placebo
  - Are there biological or behavioral factors driving these differences? (Extended follow-up will provide more power to evaluate these questions)
  - Do these differences persist or disappear on extended follow-up? (Need longer-term follow-up to evaluate)
- These issues are of critical importance to our study volunteers and the field
  - Want broad array of investigators, staff, community members to weigh in on how study follow-up should happen

# What is being done to reduce volunteers risk?

- Participants receive regular extensive risk reduction counseling, condoms, linkage to local prevention services
- Participants have been counseled about potential for increased risk in those who received the vaccine
- All participants have and will continue to be “unblinded” about treatment assignment at their request

# Why not unblind all participants now?

- We are looking at the best options on how to define if the potential of increased risk in Adenovirus seropositive vaccine recipients continues to be present during extended follow up, mitigates over time or is affected by a behavioral or other factor that we can define with greater precision
- A concern in unblinding all volunteers is that we may successfully help vaccine group to reduce risk but be less successful with risk reduction for placebo group
- If vaccine and placebo arms have different levels of risk, it will be difficult to interpret differences in HIV infection rates between the groups
  - Due to vaccine?
  - Due to differences in risk?

## Follow up of all Study Participants is an important management and scientific Goal

- We want to help all volunteers reduce their risk
- Retention in the study is critically important; participants should unblind if they think that will help them stay in follow-up or minimize their potential risk

# Session overview

- Peter Gilbert will present information on the strengths and weaknesses of analyzing data from voluntary blinded follow-up
- Glenda Gray will talk about why and how unblinding was handled in the HVTN 503 (Phambili) study
- Roundtable discussion of study investigators, staff, community members, and invited guests and YOU!

# Many places to provide input into this decision

- Today's roundtable
- Question and Answer session 4-6pm
  - All invited
  - Eliza Anderson Amphitheater
- STEP Study Team meeting Thursday 12-1:30 pm
  - 4 staff and CAB members per study site
  - Additional study site members and CAB if space available
- Scientific Steering Committee meeting
  - HVTN and Merck PI's, Co-PIs
  - Invited CAB, CER, guests
- Find Mike, Susan, Dan, Ann at any time to give us your input!!