



## **MTN-016 (EMBRACE) Operational Guidance 2: Developmental Screening Assessment Page 1 of 1**

The purpose of this Operational Guidance is to clarify that sites enrolling into MTN-016 from the parent protocol MTN-008 should continue to conduct the developmental screening assessment for any infants that were enrolled under V1.0 of the MTN-016 protocol.

Version 2.0 of the MTN-016 protocol was finalized on 11 February 2014 and eliminated the developmental screening assessment from the list of required study procedures for infants at study months 6 and 12.

However, Section 2.2 of the amended protocol states:

*It is anticipated that new parent trials will open and operate under Version 2.0 of the MTN-016 protocol, e.g., excluding participants from MTN-003 (Vaginal and Oral Interventions to Control the Epidemic [VOICE]) and MTN-008.*

If MTN-008 sites submit protocol V2.0 to their regulatory bodies and receive approval, they should continue to conduct the developmental screening assessment for any infants enrolled in the study under protocol V1.0. This includes completing the Infant Developmental Screening form at the appropriate visits (months 6 and 12). All MTN-008 sites should inform their IRBs of this request from the NIAID Medical Officer and the MTN-016 Management Team. Any questions about this guidance from the site or regulatory bodies can be forwarded to the MTN-016 Management Team.

All Operational Guidance documents must be printed and filed with regulatory documentation.