

MTN 003B Operational Reminder: Re-consenting Participants under Protocol Version 2.0



- ❖ Sites may begin re-consenting current MTN 003B participants and participants who have already exited MTN 003B as soon as they have all required IRB and regulatory approvals. This includes participants on ALL oral arms from VOICE.
- ❖ Re-consenting participants on a new informed consent version should follow standard informed consenting procedures as described in the site specific SOP.
- ❖ The re-consenting process should include sufficient time for the participant to ask questions.
- ❖ No procedures listed in MTN 003B Protocol Version 2.0 should be completed until the participant has been re-consented.
- ❖ Do not update the current MTN 003B CRFs with any data collected under protocol version 2.0. SCHARP is drafting a separate CRF set to capture all data collected under protocol version 2.0, including participant re-consent.