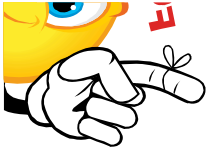


MTN-016 (EMBRACE) Operational Reminder Eligibility Source Documentation



- ❖ All eligibility criteria should have complete source documentation per DAIDS Source Documentation SOP

(found on-line at:

http://www.hptn.org/web%20documents/Regulatory_Resources/SourceDocSO Pv2.pdf.)

- ❖ If your site chooses not to use an eligibility checklist* (refer to the MTN website at <http://www.mtnstopshiv.org/node/1584> for a template) staff must document that every eligibility criterion has been satisfied, including the woman and infant exclusion criterion:

“Has any condition that in the opinion of the investigator or designee, would complicate interpretation of study outcome data, make participation in the study unsafe, or otherwise interfere with achieving the study objectives.

- ❖ Failure to do so constitutes a source document protocol violation.
- ❖ Action item: confirm that EMBRACE participants enrolled at your site have all eligibility criteria documented in full, whether on the eligibility checklist or a detailed chart note.

**Note that this checklist has been updated recently to include participants contributed by the MTN-020 parent protocol.*