MTN-020 (ASPIRE) Operational Guidance 7:
Additional Clarifications to Coenrollment Guidelines

This operational guidance to MTN-020 sites provides clarifications to the coenrollment guidelines in ASPIRE and coenrollment exceptions.

According to protocol section 5.4:

> *Should any participant report or should study staff discover concurrent participation in contraindicated studies after enrolling in MTN-020, the IoR/designee will consult the Protocol Safety Review Team (PSRT) regarding ongoing product use and other potential safety considerations associated with co-enrollment.*

Study staff should continue to follow this guidance. However, moving forward, the IoR/designee should notify the PSRT if they discover participants are concurrently enrolled in any studies other than ASPIRE, MTN-015, or MTN-016, regardless of whether coenrollment is contraindicated or falls under one of the following exceptions listed in section 5.4 of the ASPIRE protocol:

- *Participants may take part in ancillary studies approved by MTN-020 Protocol Chair*
- *Participants who become infected with HIV may take part in observational and/or interventional studies for HIV-positive persons*
- *Participants who become pregnant may take part in observational studies, including pregnancy registries approved by MTN-020 Protocol Chair*

PSRT notifications should include the PTIDs of any coenrolled participants, coenrollment date (if known), as well as any available details about study design and objectives.

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