MTN-020 (ASPIRE) Operational Guidance 1: Communication Filing

For ASPIRE, the study management team includes Network Lab, SCHARP, Regulatory, Pharmacy, FHI 360, Pitt-CORE, MTN Regional Physician and the Protocol Chairs. To ensure that all communications between the study sponsor and/or management team and study sites are filed consistently, please print and file the following communications:

- All site responses to priority emails (thereby indicating they were read and responded to)
- All study management team and/or sponsor communications that document agreements or significant decisions involving trial administration or conduct, protocol deviations, eligibility and informed consent, safety and/or study endpoints, or study product and randomization
- All notifications of critical events that are submitted to the Division of AIDS
- ASPIRE Protocol Team call minutes
- Final reports from assessment visits conducted by FHI 360, Network Lab, or others on the study management team- the completed list of action items stemming from the report should also be filed with the final report
- Emails from the study management team that specify to print and file with regulatory documentation
- All monthly Regulatory Activity Checklists containing MTN-020-specific information that are sent to the MTN Regulatory Department should be printed and filed with study regulatory documentation

Communications that are PTID-specific should be printed and filed in the participant binder. Communications that are overarching (i.e. are not PTID-specific) can be printed and filed in regulatory documentation.

All clinical site monitoring reports and correspondence can be accessed through the DAIDS-ES system and do not need to be printed and filed.

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