**Sample Informed Consent Coversheet for MTN-016**

**Type of Informed Consent: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

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| **PTID:** |
| **Name of study staff person completing informed consent process/discussion (and this coversheet):** |  |
| **Date of informed consent process/discussion:** |  |
| **Start time of informed consent process/discussion:** |  |
| **Language of informed consent process/discussion:** |  |
| **Is the participant/guardian comfortable/fluent in other language(s) that are used at this CRS for ASPIRE?**  | [ ]  Yes: (List) \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_[ ]  No  |
| **Is the participant/guardian of legal age to provide independent informed consent for research?** | [ ]  Yes[ ]  No ⇒ STOP. Participant/infant is not eligible for MTN-016. |
| **Can the participant/guardian read?** | [ ]  Yes[ ]  No ⇒ A literate impartial witness should be present during the entire informed consent process/discussion. Refer to site and DAIDS SOPs for specific instructions.  |
| **Version number/date of informed consent form used during informed consent process/discussion:** |  |
| **Did the participant comprehend all information required to make an informed decision?** | [ ]  Yes[ ]  No ⇒ Explain in comments section. |
| **Were all participant/guardian questions answered?** | [ ]  N/A (participant/guardian had no questions)[ ]  Yes [ ]  No ⇒ Explain in comments section. |
| **Was the participant/guardian given adequate time/opportunity to consider all options, in a setting free of coercion and undue influence, before making her informed decision?** | [ ]  Yes[ ]  No ⇒ Explain in comments section. |
| **Did the participant choose to provide written informed consent?** | [ ]  Yes[ ]  No |
| **Did the participant/guardian accept a copy of the informed consent form?** | [ ]  NA (participant/guardian chose not to provide informed consent)[ ]  Yes[ ]  No ⇒ Offer alternative form of study contact information to participant/guardian. |
| **IC process completed prior to initiation of study procedures** | [ ]  Yes[ ]  No |
| **End time of informed consent process/discussion:** |  |
| **Notes/Comments (continue on back if needed):** |
| **Signature of study staff person completing informed consent process/discussion (and this coversheet):** |  |