|  |  |
| --- | --- |
| **PTID** |  |
| **Version number/date of informed consent form used during informed consent process/discussion** |  |
| **Date of informed consent process/discussion** |  |
| **Start time of informed consent process/discussion** |  |
| **Is the participant of legal age to provide independent informed consent for research?** | Yes  No ⇒ STOP. Participant is not eligible for MTN-027. |
| **Is the participant literate?** | Yes  No ⇒ STOP. Participant is not eligible for MTN-027. |
| **Were all participant questions answered?** | Yes  No ⇒ Explain below in Notes/Comments section.  N/A ⇒ Participant had no questions. |
| **Was all information required for the participant to make an informed decision provided in a language that was understandable to the participant?** | Yes  No ⇒ Explain below in Notes/Comments section. |
| **Did the participant comprehend all information required to make an informed decision?** | Yes  No ⇒ Explain below in Notes/Comments section. |
| **Was the participant given adequate time and opportunity to consider all options, in a setting free of coercion and undue influence, before making her informed decision?** | Yes  No ⇒ Explain below in Notes/Comments section. |
| **Did the participant choose to provide written informed consent?** | **Screening/Enrollment**  Yes  No ⇒ STOP. Participant is not eligible for MTN-027. |
| **Long-Term Specimen Storage and Future Testing**  Yes  No⇒ CONTINUE. Participant may still enroll in MTN-027. |
| **Participation in the Extra Samples Group (Rectal Fluid)**  Yes  No⇒ CONTINUE. Participant may still enroll in MTN-027. |
| **Did the participant accept a copy of the informed consent form?** | Yes  No ⇒ Offer alternative form of contact information. |
| **End time of informed consent process/discussion** |  |
| **Was written informed consent provided prior to the conduct of any study procedures?** | Yes  No ⇒ Explain below in Notes/Comments section. |
| Notes/Comments (include any deviation from SOP; continue on back if needed) | |
| **Printed name of study staff person completing IC process/discussion (and this coversheet)** |  |
| **Signature of study staff person completing IC process/discussion (and this coversheet)** | **Date:** |