|  |  |
| --- | --- |
| **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-028. |
| **Is the participant literate?** | [ ]  Yes[ ]  No ⇒ A literate impartial witness should be present during the entire informed consent process/discussion. Refer to site and DAIDS SOPs for instructions. Record name of witness here:Record relationship of witness to participant here: |
| **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?** | [ ]  Yes[ ]  No ⇒ STOP. Participant is not eligible for MTN-028 |
| **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):** |  |