**[Sample] Informed Consent Coversheet for MTN-026**

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| --- | --- |
| **Name or 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:** |  |
| **Is the participant comfortable/fluent in other language(s) that are used at this CRS for MTN-026?**  | [ ]  Yes: (List) \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_[ ]  No  |
| **Participant choice of language for the IC process and written ICF:**  |  |
| **Is the participant of legal age to provide independent informed consent for research?** | [ ]  Yes[ ]  No ⇒ STOP. Participant is not eligible for MTN-026. |
| **Can the participant read?** | [ ]  Yes[ ]  No ⇒ STOP. Participant is not eligible for MTN-026. |
| **Version number/date of informed consent form used during informed consent process/discussion:** |  |
| **Were all participant questions answered?** | [ ]  Yes[ ]  No ⇒ Explain in Notes/Comments.[ ]  NA (participant had no questions) |
| **Did the participant comprehend all information required to make an informed decision?** | [ ]  Yes[ ]  No ⇒ Explain in Notes/Comments. |
| **Was the participant given adequate time and opportunity to consider all options, in a setting free of coercion and undue influence, before making an informed decision?** | [ ]  Yes[ ]  No ⇒ Explain in Notes/Comments. |
| **Did the participant choose to provide written informed consent?** | [ ]  Yes[ ]  No ⇒ STOP. Participant is not eligible for MTN-026.  |
| **Did the participant accept a copy of the informed consent form?** | [ ]  NA (participant chose not to provide informed consent)[ ]  Yes[ ]  No ⇒ Offer alternative form of study contact information |
| **End time of informed consent process/discussion:** |  |
| **Was informed consent signed prior to conducting study procedures listed in the ICF?** | [ ]  Yes[ ]  No ⇒ Explain in Notes/Comments. |
| **Notes/Comments (include any deviation from SOP; continue on back if needed):** |
| **Signature of study staff person completing informed consent process/discussion (and this coversheet):** |  |