Sample Informed Consent Coversheet for MTN-024/IPM 031

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

|  |  |
| --- | --- |
| 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 of legal age to provide independent informed consent for research? | [ ]  Yes[ ]  No ⇒STOP. Participant is not eligible for MTN-024/IPM 031. |
| Can the participant read? | [ ]  Yes[ ]  No ⇒ STOP. Participant is not eligible for MTN-024/IPM 031. |
| Version number/date of informed consent form used during informed consent process/discussion: |  |
| Were all participant questions answered? | [ ]  Yes[ ]  No ⇒ Explain below in Notes/Comments section. |
| 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 |
| Did the participant accept a copy of the informed consent form? | [ ]  Yes[ ]  No ⇒Offer alternative form of study contact information[ ]  NA (participant chose not to provide informed consent) |
| End time of informed consent process/discussion: |  |
| Was informed consent signed prior to conducting study procedures listed in the ICF? | [ ]  Yes[ ]  No ⇒Explain below in Notes/Comments section. |
| 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): |  |

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