|  |  |  |  |
| --- | --- | --- | --- |
| **ICF Version Number** |  | **Date of Approved ICF** |  |
| Is the person of legal age to provide independent informed consent for research? | | Yes  No ⇒STOP. Participant is not eligible for MTN-039. | |
| Can the person read and understand English? | | Yes  No ⇒STOP. Participant is not eligible for MTN-039. | |
| Start time (HH:MM) of IC process/discussion | |  | |

***COMPLETE BEFORE IC DISCUSSION***

***COMPLETE AFTER IC DISCUSSION***

|  |  |
| --- | --- |
| Was the IC process/discussion conducted per site SOP for MTN-039? | Yes  No 🡪 Explain departures from site SOP below |
| Was all information required to make an informed decision provided to participant in a language that was understandable? | Yes  No 🡪 Explain in Notes/Comments below |
| Were all participant questions answered? | N/A (Participant had no questions.)  Yes  No 🡪 Explain in Notes/Comments below |
| Was comprehension assessed and did the participant demonstrate understanding of all information required to make an informed decision? | Yes  No 🡪 Explain in Notes/Comments below |
| Was the participant given adequate time/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 below |
| Did the participant choose to provide written informed consent? | Yes  No |
| Was a copy of the consent form offered to and accepted by the participant? | Yes  No 🡪 Offer alternative form of study contact information to participant.  N/A (Participant chose not to provide informed consent.) |
| End time (HH:MM) of IC process/discussion |  |
| “No study visit procedures took place prior to obtaining informed consent” | Initials of staff person obtaining consent \_\_\_\_\_\_\_\_\_\_ |
| **Notes/Comments:** | |
|  | |
| Study staff person completing informed consent process/discussion (and this coversheet): | |
| [Printed Name] | [Signature and Date] |