COMPLETE BEFORE IC DISCUSSION

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| **Participant Name** |  | **IC Discussion Date (DD/MMM/YYYY)** |  |
| ICF Version # / Date |  |
| Is the person of legal age to provide independent informed consent for research? | [ ]  Yes[ ]  No 🡪 STOP. Person is not eligible for MTN-045. |
| Language of the informed consent process/discussion |  |
| Is the person comfortable/fluent in other language(s) that are used at this CRS for MTN-045?  | [ ]  Yes: (List) \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_[ ]  No  |
| Can the person read? | [ ]  Yes[ ]  No 🡪 STOP. A literate impartial witness should be present during the entire informed consent process/discussion. Refer to DAIDS policies and site SOPs for specific instructions. Record name of witness here:Record relationship of witness to participant here:  |
| Start time (HH:MM) of IC process/discussion |  |

COMPLETE AFTER IC DISCUSSION

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| Was the informed consent process/discussion conducted per site SOPs for MTN-045? | [ ]  Yes[ ]  No 🡪 Record and explain departures from site SOPs below |
| Was all information required to make an informed decision provided in a language that was understandable? | [ ]  Yes[ ]  No 🡪 Explain in Notes/Comments below |
| Did the person comprehend all information required to make an informed decision? | [ ]  Yes[ ]  No 🡪 Explain in Notes/Comments below |
| Were all questions answered? | [ ]  N/A (Person had no questions.)[ ]  Yes[ ]  No 🡪 Explain in Notes/Comments below |
| Was comprehension assessed and did the person demonstrate understanding of all information required to make an informed decision? | [ ]  Yes[ ]  No 🡪 Explain in Notes/Comments below |
| Was the person 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 person choose to provide written informed consent? | [ ]  Yes[ ]  No  |

 Staff Initials and Date: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

|  |  |
| --- | --- |
| **Participant Name** |  |

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| Was a copy of the consent form offered to and accepted by the person? | [ ]  N/A (person chose not to provide informed consent)[ ]  Yes[ ]  No 🡪 Offer alternative form of study contact information |
| Was informed consent signed prior to conducting study procedures listed in the ICF? | [ ]  Yes[ ]  No 🡪 Explain in Notes/Comments below |
| End time (HH:MM) of IC process/discussion |  |
| **Notes/Comments:** |
|  |
| Study staff member completing informed consent process/discussion (and this coversheet): |
| [Printed Name] | [Signature and Date] |