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’s comprehension assessed, questions answered and ICF signature obtained separately from their partner? | 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] |