COMPLETE BEFORE IC DISCUSSION

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| **Participant Name** |  | **IC Discussion Date (DD/MMM/YY)** |  |
| ICF Version # |  | ICF Version Date |  |
| Is the person of legal age to provide independent informed consent for research? | [ ]  Yes[ ]  No 🡪 STOP. Participant is not eligible for MTN-035. |
| Language of the informed consent process/discussion |  |
| Is the person comfortable/fluent in other language(s) that are used at this CRS for MTN-035? | [ ]  Yes: (List) \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_[ ]  No  |
| Can the person read? | [ ]  Yes[ ]  No 🡪 STOP. Participant is not eligible for MTN-035. |
| Start time of IC process/discussion (HH:MM) |  |

COMPLETE AFTER IC DISCUSSION

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| Was the IC process/discussion conducted per site SOPs for MTN-035? | [ ]  Yes[ ]  No 🡪 Explain departures from site SOP below |
| Was all information required to make an informed decision provided 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 |
| Did the participant demonstrate an 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  |
| Did the participant accept a copy of the ICF? | [ ]  N/A (participant 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 of IC process/discussion (HH:MM) |  |

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| **Notes/Comments:** |
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| Study staff member completing informed consent process/discussion (and this coversheet): |
| [Printed Name] | [Staff Signature and Date] |