COMPLETE BEFORE DISCUSSION

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| Consent Type |  | | |
| ICF Version Number |  | Date of Approved ICF |  |
| Start time (HH:MIN) of IC process/discussion | |  | |
| Is the person of legal age to provide independent informed consent for research? | | Yes  No ⇒STOP. Participant is not eligible for MTN-042 | |
| Choice of language for the IC process and written ICF? | | English  Other (local language): | |
| Is the person comfortable/fluent in other  language(s) that are used at this CRS? | | Yes (list):  No | |
| Can the participant read? | | Yes  No 🡪A literate impartial witness should be present during the entire IC process/discussion. Refer to DAIDS policies and site SOPs for specific instructions. | |
| If indicated NO above, provide witness’ name and relationship to participant | | N/A  - Name:  - Relationship: | |

COMPLETE AFTER IC DISCUSSION

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| 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 questions answered? | N/A (Participant had no questions.)  Yes  No 🡪 Explain in Notes/Comments below. |
| Was comprehension assessed and did the participant/parent 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? | N/A (Participant chose not to provide informed consent.)  Yes  No 🡪 Offer alternative form of study contact information to participant/parent. |

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| End time (HH:MIN) of informed consent 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] |