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 otherlanguage(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] |