COMPLETE BEFORE DISCUSSION

|  |  |  |  |
| --- | --- | --- | --- |
| Consent Type | Adult Consent  Assent  Parental/Guardian Permission | Consenting for  *\*If separate ICFs are required, complete an IC coversheet for each.* | Screening  Enrollment  Long-Term Storage  **Combined (all of the above)** |
| ICF Version Number |  | Date of Approved ICF |  |
| What type of consent is this person legally able to provide? | | **Adult consent** (participant age 18+ or emancipated minor)  **Assent** (participant age 16-17) 🡪 requires parental/guardian permission  **Parental/guardian permission** (providing consent on behalf of participant who is a minor) | |
| Start time (HH:MIN) of IC process/discussion | |  | |
| 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

|  |  |
| --- | --- |
| 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 was provided?  *NOTE: Use of the Comprehension Assessment Tool is only required during the enrollment related IC*. | Yes  No 🡪 Explain in Notes/Comments below. |
| Was the participant/parent 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/parent choose to provide written informed consent? | Yes  No |
| Was a copy of the consent form offered to and accepted by the participant/parent? | N/A (Participant/parent chose not to provide informed consent.)  Yes  No 🡪 Offer alternative form of study contact information to participant/parent. |
| 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] |