COMPLETE BEFORE DISCUSSION

|  |  |
| --- | --- |
| ICF Version Number |  |
| Participant age | [ ]  18 +[ ]  under 18 (verify emancipated/mature minor status) |
| Emancipated/mature minor status per the following criteriaLesotho: * Age ≥15 AND one of the following:
	+ Marital status of currently married or living as married or previously married (separated, divorced, or widowed)
	+ Has any children
 | [ ] Yes [ ]  No[ ]  N/A – over 18 yrs |
| Choice of language for the IC process and written ICF? | [ ]  English[ ]  Other (local language):  |
| Can the participant read? | [ ] Yes [ ]  No 🡪A literate impartial witness should be present during the entire IC process/discussion. Refer to SOP.  |

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 demonstrate understanding of all information required to make 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. |
| 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] |