COMPLETE BEFORE DISCUSSION

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| --- | --- |
| ICF Version Number |  |
| Participant age | 18 +  under 18 (verify emancipated/mature minor status) |
| Emancipated/mature minor status per the following criteria  Lesotho:   * 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

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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 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] |