|  |  |
| --- | --- |
| **Consent Type** | [ ]  Informed Consent (Sexual Partner Subset)[ ]  Other:  |
| **ICF Version Number** |  | **Date of Approved ICF** |  |
| Start time (HH:MM) of IC process/discussion |  |
| Is the person of legal age to provide independent informed consent for research? | [ ]  Yes[ ]  No → STOP. Participant is not eligible. |
| Choice of language for the IC process and written ICF (must be in one of the study languages)? | [ ]  English[ ]  Other (local language): |
| Is the person comfortable/fluent in other language(s) that are used at this CRS? (i.e. preferred language for IDI if the participant consents and is chosen) | [ ]  Yes (list):[ ]  No |
| Can the participant read?  | [ ]  Yes[ ]  No → A literate impartial witness should be present during the entire IC process/discussion. Refer to site SOPs for specific instructions.  |
| If indicated NO above, provide witness’ name and relationship to participant | [ ]  N/AName: Relationship:  |

***COMPLETE BEFORE IC DISCUSSION***

***COMPLETE AFTER IC DISCUSSION***

|  |  |
| --- | --- |
| Was the IC process/discussion conducted per site SOP for MATRIX-003? | [ ]  Yes[ ]  No à Explain departures from site SOP below |
| Was all information required to make an informed decision provided to participant in a language that was understandable per site SOP? | [ ]  Yes[ ]  No → Explain in Notes/Comments below |
| Were risks and benefits of participation reviewed with participant?  | [ ] [ ]  Yes[ ] [ ]  No → Explain in Notes/Comments below |
| Were all participant questions answered? | [ ]  N/A (Participant had no questions.)[ ]  Yes → Detail in Notes/Comments below[ ]  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 |
| 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 the participant? | [ ]  Yes, participant accepted copy[ ]  Yes, participant chose not to accept a copy; therefore an alternate form of study staff contact information provided to participant[ ]  No → Complete a deviation and ensure participant is offered a consent and understands how to contact study staff during study participation if needed. [ ]  N/A (Participant chose not to provide informed consent.) |
| End time (HH:MM) of IC process/discussion*Note: If time is required on informed consent document, this time should correspond with the time on the consent document.*  |  |
| “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 and Date] |

**VERIFICATION OF INFORMED CONSENT DOCUMENT**

|  |
| --- |
| Second staff person verifying accuracy and completeness of consent document while participant is still in clinic |
| [Printed Name] | [Signature and Date] |