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| --- | --- | --- | --- |
| **Consent Type** | Combined S/E consent with addendums (future use, participant IDI, consent to  contact sexual partner and off-site visits)  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/A  Name:  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 → Document in Notes/Comment 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 for screening/enrollment? | 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; 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] |