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| --- | --- |
| **Consent Type** |  |
| **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?  | [ ]  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-001? | [ ]  Yes[ ]  No → Explain departures from site SOP below |
| Was all information required to make an informed decision provided to participant in a language that was understandable? | [ ]  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[ ]  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 and accepted by the participant? | [ ]  Yes[ ]  No → Offer alternative form of study contact information to participant.[ ]  N/A (Participant chose not to provide informed consent.) |
| End time (HH:MM) of IC 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 and Date] |