Sample Informed Consent Coversheet

MTN-003D

|  |  |
| --- | --- |
| **Participant Name:** |  |
| **Name of study staff person completing informed consent process/discussion (and this coversheet):** |  |
| **Is the participant of legal age to provide independent informed consent for research?** | Yes  No ⇒ STOP. Participant is not eligible for MTN-003D. |
| **Date of informed consent process/discussion:** |  |
| **Start time of informed consent process/discussion:** |  |
| **Language of informed consent process/discussion:** |  |
| **Was the informed consent process/discussion conducted according to site SOPs for MTN-003D?** | Yes  No ⇒ Record and explain departures from site SOPs below. |
| **Can the participant read?** | Yes  No ⇒ A literate impartial witness should be present during the entire informed consent process/discussion. Refer to DAIDS policies and site SOPs for specific instructions. Record name of witness here:  Record relationship of witness to participant here: |
| **Version number/date of informed consent form used during informed consent process/discussion:** |  |
| **Was all information required to make an informed decision provided in a language that was understandable to the participant?** | Yes  No ⇒ Explain below. |
| **Were all participant questions answered?** | Yes  No ⇒ Explain below. |
| **Did the participant comprehend all information required to make an informed decision?** | Yes  No ⇒ Explain below. |
| **Was the participant given adequate time and opportunity to consider all options, in a setting free of coercion and undue influence, before making her informed decision?** | Yes  No ⇒ Explain below. |
| **Did the participant choose to provide written informed consent?** | Yes  No |
| **Did the participant accept a copy of the informed consent form?** | NA (participant chose not to provide informed consent)  Yes  No ⇒ Offer alternative form of study contact information |
| **End time of informed consent process/discussion:** |  |
| **Notes/Comments (continue on back if needed):** | |
| **Signature of study staff person completing informed consent process/discussion (and this coversheet):** |  |