Sample Informed Consent Coversheet for MTN-014

|  |  |
| --- | --- |
| **PTID:** |  |
| **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-014. |
| **Date of informed consent process/discussion:** |  |
| **Start time of informed consent process/discussion:** |  |
| **Was the informed consent process/discussion conducted according to site SOPs for MTN-014?** | 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. |
| **Version number/date of informed consent form used during informed consent process/discussion:** |  |
| **Was all information required for the participant 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/opportunity to consider all options before making her informed decision?** | Yes  No ⇒ Explain below. |
| **Did this 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 to participant. |
| **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):** |  |