MTN 023/IPM 030 Sample Informed Consent Coversheet

Parent/Guardian or Continued Research Participation for Participants Who Turn 18 During Study Participation if required by IRB

|  |  |
| --- | --- |
| Name (or PTID) |  |
| Date of informed consent process/discussion |  |
| Start time of informed consent process/discussion |  |
| For which consent is this coversheet being used? | [ ]  Parent/Guardian Consent [ ]  Continued Research Participation for 18 Year Old Participant |
| Is the person of legal age to provide independent informed consent for research? | [ ]  Yes[ ]  No ⇒STOP. Obtain parent consent. |
| Can the person read and understand English? | [ ]  Yes[ ]  No ⇒A literate impartial witness should be present during the entire informed consent process/discussion. Refer to site and DAIDS SOPs for specific instructions. Note: this is only applicable for parent/guardian; participants are required to be literate in English to enroll in study. Record name of witness here:Record relationship of witness to participant here:  |
| Was all information required to make an informed decision provided in a language that was understandable? | [ ]  Yes[ ]  No ⇒ Explain below. |
| Were all questions answered? | [ ]  Yes[ ]  No ⇒ Explain below. |
| Was comprehension assessed to ensure all information required to make an informed decision was provided? | [ ]  Yes[ ]  No ⇒ Explain below. |
| Was there adequate time/opportunity given to consider all options before making an informed decision? | [ ]  Yes[ ]  No ⇒ Explain below. |
| Was a copy of the consent form offered and accepted? | [ ]  N/A (chose not to provide informed consent)[ ]  Yes[ ]  No ⇒ Offer alternative form of study contact information to parent/participant. |
| End time of informed consent process/discussion |  |
| **[ ]  “No study visit procedures took place prior to obtaining informed consent”.** **Initials of staff person obtaining consent\_\_\_\_\_\_.** |
| Notes/Comments: |
| Version number/date of informed consent form used during informed consent process/discussion | Version Number:  | Date of Approved Informed Consent Form:  |
| Name of study staff person completing informed consent process/discussion (and this coversheet) |  |
| Signature of study staff person completing informed consent process/discussion (and this coversheet) |  |

MTN 023/IPM 030 Sample Informed Assent Coversheet
Adolescent Female Participant

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| --- | --- |
| Participant Name (or PTID) |  |
| Date of informed assent process/discussion |  |
| Start time of informed assent process/discussion |  |
| **Note: The participant is not of legal age to provide independent informed consent for research ⇒Must obtain parent consent to enroll in study.** |
| Can the participant read and understand English? | [ ]  Yes[ ]  No ⇒STOP. Participant is not eligible for participation in study. |
| 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 the participant accept a copy of the assent form? | [ ]  N/A ⇒ Participant chose not to provide informed assent)[ ]  Yes[ ]  No ⇒ Offer alternative form of study contact information to participant. |
| End time of informed assent process/discussion |  |
| **[ ]  “No study visit procedures took place prior to obtaining informed consent”.** **Initials of staff person obtaining consent\_\_\_\_\_\_.** |
| Notes/Comments: |
| Version number/date of informed assent form used during informed assent process/discussion | Version Number:  | Date of Approved Informed Assent Form:  |
| Name of study staff person completing informed assent process/discussion (and this coversheet) |  |
| Signature of study staff person completing informed assent process/discussion (and this coversheet) |  |