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

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| --- | --- | --- |
| 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) |  | |