MTN-030/ IPM 041 Sample Informed Consent Coversheet

|  |  |  |
| --- | --- | --- |
| Name (or PTID) |  | |
| Date of informed consent discussion |  | |
| Start time of informed consent discussion |  | |
| Is the person of legal age to provide independent informed consent for research? | Yes  No ⇒STOP. Participant is not eligible for MTN-030. | |
| Can the person read and understand English? | Yes  No ⇒STOP. Participant is not eligible for MTN-030. | |
| Was all information required to make an informed decision provided in a language that was understandable? | Yes  No ⇒ Explain below. | |
| Were all questions answered? | N/A (Participant had no questions.)  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 (Participant 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) |  | |