**VOICE Termination Visit Vaginal Product Behavioral Form**

**General Information/instructions:**

* All interviewer instructions within the form appear in ***bold italics***.
* All question response options should be read to the participant unless they appear in *italics* (ex: *don’t remember* or *not applicable, always inserted the gel*) or you are instructed otherwise (ex: Q 40).
* Some question response options include clarification definitions in italics within parentheses. These should not be read to the participant unless the participant asks for clarification regarding their response options. (ex: Q 24)

Participant ID

-- Site Number Participant Number Chk

**VOICE Termination Visit Oral Product Behavioral Form**

Visit Date

dd MM yy

Two of the VOICE products – the tenofovir tablets and the tenofovir gel- have been discontinued because the study did not show that they prevented HIV infection among VOICE women. One of the reasons for this finding may be that women did not use the study products on a daily basis. It is important for us to understand if women in VOICE did not use the products daily, and if so, why. We would like to learn from your experience while you were enrolled in the VOICE trial and we very much appreciate your honesty in answering these questions.

First, I am going to ask you a series of questions that can be answered with yes or no regarding reasons you may have missed inserting the gel:

***Read each question except for #23.******The participant can answer yes to more than one question.***

***Yes No***

|  |  |  |  |
| --- | --- | --- | --- |
|  | You didn’t think you were at risk of HIV? |  |  |
|  | You didn’t like inserting the gel every day? |  |  |
|  | You were not interested in inserting the gel? |  |  |
|  | You didn’t like inserting the gel when you had your menstrual period? |  |  |
|  | You forgot to insert the gel every day? |  |  |
|  | You lost or ran out of gel? |  |  |
|  | You missed a visit and did not get resupplied? |  |  |
|  | Someone else used your gel? |  |  |
|  | Your sex partner did not want you to use the gel? |  |  |
|  | You changed or had a new sex partner? |  |  |
|  | You were not having sex? |  |  |
|  | You didn’t want others to know you were inserting the gel? |  |  |
|  | You moved or relocated? |  |  |
|  | You changed or got a new job? |  |  |
|  | You travelled away from home? |  |  |
|  | You were taking medications and you did not want to mix them? |  |  |
|  | You had side effects from inserting the gel? |  |  |
|  | You were sick? |  |  |
|  | You had been drinking alcohol? |  |  |
|  | You did not believe the gel worked? |  |  |
|  | You were sad or depressed? |  |  |
|  | Other (*specify*) \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |  |  |
|  | *Not applicable, always inserted the* *gel* |  |  |

1. How often during the study did you **miss or skip days**?

|  |  |
| --- | --- |
|  | Very often *(more than 1 time per week)* |
|  | Often (*2-5 times per month; includes response of 1 time per week)* |
|  | Sometimes (*about once a month*) |
|  | Occasionally (*less than once per month to once every 5 months*) |
|  | Rarely (*about once every 6 months or less)* |

1. When during the study did you start skipping doses?

|  |  |
| --- | --- |
|  | In the first 3 months |
|  | After the first 3 months, but during the first year |
|  | During the second year |
|  | *Don’t remember* |
|  | *Not applicable, always inserted the gel* |

Now I’d like to ask you some questions about your experience with research studies.

1. In how many research studies have you participated prior to the VOICE study?

# of studies

**→*if 0, go to item 28***

1. What was the name of the study or studies in which you participated?

Name of study:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Name of study: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

|  |  |
| --- | --- |
|  | *Don’t remember* |

1. Why did you participate in the VOICE trial? Was it…

***Read each sub-question.******The participant can answer yes to more than one question.***

|  |  |  |  |
| --- | --- | --- | --- |
|  |  | ***Yes*** | ***No*** |
| 28a. | For the financial reimbursement? |  |  |
| 28b. | For the free or better quality health care you received during the trial? |  |  |
| 28c. | To be tested for HIV? |  |  |
| 28d. | To get information about HIV prevention? |  |  |
| 28e. | To help test a product that may prevent women from getting HIV? |  |  |
| 28f. | Other (*specify*) \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |  |  |

1. What was **the most important** reason you participated in the VOICE trial?

|  |  |
| --- | --- |
|  | For the financial reimbursement? |
|  | For the free or better quality health care you received during the trial? |
|  | To be tested for HIV? |
|  | To get information about HIV prevention? |
|  | To help test a product that may prevent women from getting HIV? |
|  | Other (*specify*) \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |

The next series of questions I am going to ask you are about HIV/AIDS.

1. Think about the time **before** you enrolled in the study. At that time, what did you think about your risk of getting HIV? Was it…

|  |  |
| --- | --- |
|  | High risk (*good chance you might get HIV*) |
|  | Moderate risk (*some chance you might get HIV*) |
|  | Low risk (*low chance you might get HIV*) |
|  | No risk (*no chance you might get HIV*) |

1. Think about the time **you were inserting the** **gel**. At that time, what did you think about your risk of getting HIV? Was it…

|  |  |
| --- | --- |
|  | High risk (*good chance you might get HIV*) |
|  | Moderate risk (*some chance you might get HIV*) |
|  | Low risk (*low chance you might get HIV*) |
|  | No risk (*no chance you might get HIV*) |

Now I’d like to ask you some questions about your use and non-use of the gel.

1. In a typical month, how would you describe your ability to insert the gel as instructed?

|  |  |
| --- | --- |
|  | Very poor |
|  | Poor |
|  | Fair |
|  | Good |
|  | Very good |
|  | Excellent |

1. When you say [*category above*] in a typical month, **on how many days did you not** insert the gel? If you don’t remember exactly please guess as best as you can.

# of days

1. Did you ever not insert the gel for **1 week or more** in a row? Please count situations when you missed a study visit and did not get resupplied.

|  |  |
| --- | --- |
|  | Yes |
|  | No |
|  | *Not applicable, inserted the gel every day* |

1. On the days you did not insert the gel did you have sex?

|  |  |
| --- | --- |
|  | Yes |
|  | No |
|  | *Not applicable, inserted the gel every day* |

1. If you didn’t insert the gel every day, when did you **usually** insert the gel?

|  |  |
| --- | --- |
|  | I inserted the gel when I remembered |
|  | I inserted the gel on days I had sex |
|  | I inserted the gel when it was most convenient |
|  | *Other* (*specify*)\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |
|  | *Not applicable, inserted* *the gel every day* |

1. On the days that you had sex, how often did you insert gel up to 3 hours before sex?

|  |  |
| --- | --- |
|  | Never *(0%)* |
|  | Not very often *(1-25% of the time)* |
|  | Sometimes *(26-50% of the time)* |
|  | Most of the time *(51-75%)* |
|  | Almost all or all of the time *(76-100%)* |
|  | *Don’t remember* |

We realize that while you are in a study it is sometimes difficult or embarrassing to explain exactly what happened to you.

1. Did you ever report to the study staff or the computer that you inserted the gel when in fact you did not?

|  |  |
| --- | --- |
|  | Yes |
|  | No |

1. Did you ever give or throw away gel that you were unable to take?

|  |  |
| --- | --- |
|  | Yes |
|  | No |

1. Is it easier to be honest answering questions using the computer or speaking with an interviewer? ***Do not read responses*.**

|  |  |
| --- | --- |
|  | *More honest with the computer* |
|  | *More honest speaking to an interviewer* |
|  | *Equally honest with both computer and interviewer* |

Thank you for answering our questions.