

[Introductory Statement]: Hello, my name is *[Interviewer's name]* and I'll be your interviewer today. I want to begin by thanking you for taking the time to talk with me. Your experience and thoughts about the study are very valuable to future research so we really appreciate you taking the time to complete this interview today.

Some of the questions are sensitive but everything we discuss will be kept confidential. Audio from our session will be recorded and transcribed, but key identifiable information—such as names or places—will be made anonymous to protect your privacy. Any question you would rather not answer let me know and we can skip it. You have the right to withdraw at any point in the study. In total the interview should last about an hour.

In case of an adverse event or social harm that is reported during the interview, I will encourage you to report that information to clinical staff if you haven't already done so. I will also report an adverse event or social harm to study staff if you haven't already done so. An example of an adverse event is an undesirable experience associated with the gel such as an allergic reaction. An example of a social harm is experiencing difficulties in personal relationships as a consequence of study participation.

Do you have any questions before we get started?

My first few questions ask how you feel about the study broadly, but before we get into that I just want to stress that we're looking for feedback, whether it be good or bad. We really want to know what you think, so please don't hold back with your responses and answer as honestly as possible.

| <u>Section</u> | <u>Topic</u> | <u>Prompt</u> | <u>Probe</u> | <u>Notes</u> |
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| 1. General Study Experiences | 1.1 General experience and motivation for participating in the study. | We spoke a few weeks ago about your reasons to join the study. How, if at all, have your feelings about participating in this study changed since then? | <ul style="list-style-type: none"> a) Overall, how would you describe your experience participating in the study? b) How was your experience with the clinic staff? c) How was your experience with the study procedures? d) How did you feel about the different medical and laboratory procedures? e) Did you have any difficulties during the trial? f) Tell me more about that. | Interviewer: For probes a-d refer to Single Dose Survey section A1 & A 2 statements: Section A1 Probe a) refer to 1, Probe b) refer to 2, 4-6 Section A2 Probe c) & d) refer to 14 |

[Transition]: Now I want to switch gears and talk about your experiences using the gel and any problems you may have experienced.

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| 2. Gel Problems and adherence. | 2.1 General issues with gel. | Did you have any problems with the gel during the study? | <p>If YES:</p> <ul style="list-style-type: none"> • What happened? • How, if at all, did you resolve the problem? <p>If NO:</p> <ul style="list-style-type: none"> • That's wonderful to hear! Do you feel like you did anything specific that may have helped to prevent having any problems? • Were there any unexpected advantages with using this gel? | Interviewer: Refer to Single Dose Survey Section B, question B3. |
| | 2.2 Side effects from gel. | What, if any, side effects did you experience during the study? | Tell me more about that. | Interviewer: Refer to Single Dose Survey Section B, question B4-B7. |
| | 2.3 Perceived factors hindering gel adherence. | Some people could have difficulties using the gel consistently. Having been one of the few who have used the product, can you think of any reasons why you think men or women may have difficulty using the gel? | <ul style="list-style-type: none"> • What if anything would you recommend that users do to prevent the issue(s)? • What if anything would you recommend that users do to overcome the issue(s)? | |
| [Transition]: We will now talk about your experiences with gel insertion and direct observation therapy. | | | | |
| 3. Experience with DOT | 3.1 General impression with direct observation therapy. | Tell me about your experiences with inserting the gel over the 7-day period. | <p>IF INSERTED BY STAFF</p> <ul style="list-style-type: none"> • How did you feel about the clinic staff member inserting the gel into your body? <p>[OR]</p> <p>IF THEY INSERTED IT THEMSELVES:</p> <ul style="list-style-type: none"> • How did you feel with a clinic staff member watching you insert the gel into your body? • How clear were the instructions? Did | <p>Interviewer: Refer to Single Dose Survey Section A3.</p> <p>If inserted by staff, refer to statements: 3,5,7-11</p> <p>if inserted by themselves, refer to</p> |

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| | | | <p>you have any questions? If so, do you remember what it was regarding?</p> <ul style="list-style-type: none"> • Tell me how it felt to insert the gel into your body. | <p>statements: 1,2,6 Section C, questions C1</p> |
| <p>[Transition]: Next we will talk about how well you liked the gel.</p> | | | | |
| <p>4. Gel Acceptability</p> | <p>4.1 General impression of daily gel use.</p> | <p>Over the 7-day administration of the gel, how did you feel about having to use the gel on a daily basis?</p> | <p>a) What sensations did you feel when you had the gel inside your body?</p> <ol style="list-style-type: none"> What did you like best about the gel? What did you like least about the gel? <p>b) If you could change the product in any way, what would make you like it better?</p> <p>c) What are some of the characteristics that made you like the product?</p> <p>d) What are some of the barriers that made you dislike the product? Why?</p> | <p>Interviewer: Refer to Single Dose Survey Section B, questions B1 and B2 and Section D, questions D1-D8.</p> |

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| | <p>4.2 Gel discussions and social influence.</p> | <p>Outside of the clinic staff, did you talk to anyone about the gel?</p> | <p>NO:</p> <ul style="list-style-type: none"> • Were there any reasons in particular that led you not to talk to anyone about the gel? • If you had talked to someone, what would you have told them about the gel? <p>YES:</p> <ul style="list-style-type: none"> • What did you talk about? • Who did you talk to? • What did they ask about the gel? • How did they feel about your participation in the trial? • What would you tell other men or women about the gel? | |
| | <p>4.3 Perceived ability to talk about the gel with partner.</p> | <p>How comfortable would you feel discussing using the study gel with your sex partner(s)?</p> | <ul style="list-style-type: none"> • How would you describe the product? <ul style="list-style-type: none"> ○ What would you say? ○ When would you bring it up? • What would make talking about the gel easier? <p><i>[If participant says he/she did discuss with partner]</i></p> <ul style="list-style-type: none"> • Tell me about that conversation. • What did you talk about? • How did your partner respond? | |

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| | 4.4 Estimated likelihood they would use the gel to prevent HIV. | At the beginning of the study, you mentioned that if there were a similar rectal gel available that provided some protection against HIV, it would be <i>[very unlikely, unlikely, likely, or very likely]</i> that you would use the gel for anal sex. How, if at all, has your opinion changed now you've used the gel for 7 days? | <ul style="list-style-type: none"> • Tell me about why you would be [very unlikely, unlikely, likely, or very likely] to use the gel in the future? • What would make you more likely to use the gel? • What would you make you less likely to use the gel? | Interviewer: Refer to Baseline Behavioral Survey Section G, question G1. |
| | 4.5 Perceived factors of gel adherence for anal sex. | Thinking about your own life experiences, what issues would prevent you from using the gel for anal sex? | <ul style="list-style-type: none"> • Types of partner? (casual partner, committed relationship, one-time partner, etc). • Receptive vs insertive sex role? • Do you think you would use it for other sexually related activities? (i.e. anilingus/rimming, etc) | Interviewer: Refer to Baseline Behavioral Survey Section G, questions G2-G4. |
| | 4.6 Gel recommendations | Would you recommend the gel to others? | Why? | |
| [Transition]: Moving on to our final section, we're going to talk about gel design. | | | | |
| 5. Gel Product Marketing. | 5.1 Gel design by participant. | Similar to our last interview, we'd like to ask you to imagine that you are the marketing director for the study gel. Having used the product now for a longer period of time, what, if anything, would you change from your original marketing suggestions? | <ul style="list-style-type: none"> • What would you call this product? • Who would be your key audience? • What traits would make someone want to buy the product you're selling? • Describe how you would describe the product to your audience in order to convince them to try it out. • What negative qualities of the gel could be improved? | |

[Transition]: So that's everything we have for you today, but before we part ways, I wanted to ask...

6. Conclusion

6.1 Is there any part of your experience with the gel that we didn't have a chance to talk about?

6.2 Is there anything we did ask about that we should have asked differently?

6.3 Do you have any further questions or comments?

[Concluding Statement]: That's all the questions I have. Thank you so much for taking the time to talk with me today.