

**MATRIX-001 SAMPLE Informed Consent Comprehension Assessment (TRUE/FALSE)**

<b>Name:</b>		<b>Date:</b> <b>(DD/MM/YY)</b>	
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<b>No.</b>	<b>Question</b>	<b>T</b>	<b>F</b>
<b>1</b>	The main reason for this research study is to find out if using the study product (TAF/EVG vaginal inserts) is safe.	<input type="checkbox"/>	<input type="checkbox"/>
<b>2</b>	There are no risks to using the TAF/EVG vaginal inserts.	<input type="checkbox"/>	<input type="checkbox"/>
<b>3</b>	I may contact the study staff at any time during study participation if I have any questions or problems.	<input type="checkbox"/>	<input type="checkbox"/>
<b>4</b>	There are restrictions on use of vaginal products and sexual activity during study participation.	<input type="checkbox"/>	<input type="checkbox"/>
<b>5</b>	My participation is completely voluntary (my choice).	<input type="checkbox"/>	<input type="checkbox"/>
<b>6</b>	If I take part in the research study, I will have blood tests to look at my general health, have genital (cervicovaginal) samples including biopsy samples taken, and I will be tested for HIV. I will also answer questions about my experience using the vaginal inserts.	<input type="checkbox"/>	<input type="checkbox"/>
<b>7</b>	I can join this study even if I am currently (or have recently taken part) in another study of drugs, medical devices, vaginal products or vaccines.	<input type="checkbox"/>	<input type="checkbox"/>

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**ANSWER KEY:**

No.	Question	T	F
<b>1</b>	The main reason for this research study is to find out if using the study product (TAF/EVG vaginal inserts) is safe.	<input checked="" type="checkbox"/>	<input type="checkbox"/>
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<b>7</b>	I can join this study even if I am currently (or have recently taken part) in another study of drugs, medical devices, vaginal products or vaccines.	<input type="checkbox"/>	<input checked="" type="checkbox"/>

**Reviewed by:** \_\_\_\_\_ **Date:** \_\_\_\_\_

**Result:** [insert site specific language regarding assessment of comprehension according to site SOP]

**Comments:** \_\_\_\_\_  
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