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Visit Code

Date Form Completed

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Inclusion and Exclusion Criteria Form (IE)		
<i>Instructions: This form is to be completed for all screened participants</i>		
Inclusion Criteria		Yes
1.	Between 18-45 years of age	<input type="checkbox"/> ₁
2.	Presented and screened out of the VOICE trial	<input type="checkbox"/> ₁
3.	Able and willing to perform the study procedures	<input type="checkbox"/> ₁
4.	Able and willing to provide informed consent for study participation	<input type="checkbox"/> ₁
5.	Has tested HIV-negative within 90 days of enrollment, per VOICE screening laboratory results	<input type="checkbox"/> ₁
6.	Is currently not pregnant, per VOICE laboratory results or self-report	<input type="checkbox"/> ₁
7.	Willing and able to provide locator information to the research team	<input type="checkbox"/> ₁
If any answer above is ‘no’, the participant is ineligible		
Exclusion Criteria		Yes
8.	Has any condition that, in the opinion of the IoR./designee, would preclude informed consent, make study participation unsafe, complicate interpretation of study outcome data, or otherwise interfere with achieving the study objectives	<input type="checkbox"/> ₁
9.	Screened out of VOICE for any clinical condition, that in the opinion of the IoR, may require monitoring or care beyond the scope of this pilot study.	<input type="checkbox"/> ₁
If #8 or #9 is marked “yes” the participant is ineligible		
Comments: <i>Initial and date all comments.</i>		

Inclusion and Exclusion Criteria Form (IE)

Purpose: This form is used to document participants' eligibility (inclusion and exclusion criteria) to enroll in the Wisebag Pilot Study.

General Information/Instructions: This form is completed for all screened participants.

Overall instructions:

Enter the PTID in the top left corner of this form. Initial and date at bottom right hand corner of the page. This form should be completed after a participant has provided written informed consent.

Item-specific Instructions:

Item	Instruction
1	Confirm that the participant is between 18 and 45 years old (inclusive).
2	Confirm that the participant presented at and screened out of the VOICE trial.
3	Confirm that the participant is able and willing to perform the study procedures. If unsure about a participant's ability to perform study procedures, confer with the investigator of record.
4	Confirm that the participant provided written informed consent for study participation, and that the consent checklist was completed (this should have occurred prior to implementation of this form)
5	Confirm that the participant has tested HIV-negative within 90 days of enrollment, per VOICE screening laboratory results (SEH item 1)
6	Confirm that the participant is not pregnant per VOICE laboratory results or self-report
7	Confirm that the participant is willing and able to provide locator information to the study team (locator form completed)
8	Confirm that participant does not have any condition or status that, in the opinion of the IoR./designee, would preclude informed consent, make study participation unsafe, complicate interpretation of study outcome data, or otherwise interfere with achieving the study objectives
9	Confirm that the participant did not screen out of VOICE for a clinical condition that in the opinion of the IoR may require monitoring and/or care beyond the scope of the Wisebag Pilot Study.