

PTID

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Visit Code

Date Form Completed

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dd MMM yy

Enrollment Status Form (ESF)

Instructions: This form is to be completed for all screened participants

		Yes	No
1.	Woman provided written informed consent	<input type="checkbox"/> ₁	<input type="checkbox"/> ₂
2.	Confirmation that all eligibility criteria are met	<input type="checkbox"/> ₁	<input type="checkbox"/> ₂
3.	Woman enrolled/ randomized in the Wisebag pilot?		
	<input type="checkbox"/> ₁ Yes Randomization number: <input type="text"/> <input type="text"/> <input type="text"/>	<input type="checkbox"/> ₂ No Reason(s) woman was not enrolled/ randomized: <hr/> <hr/> <p style="text-align: center;">END FORM</p>	

Enrollment Date

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dd MM yy

Comments: *Initial and date all comments.*

Enrollment Status Form (ESF)

Purpose: This form is used to document participants' final screening, enrollment and randomization determination.

General Information/Instructions: This form is to be completed for all screened participants at the Enrollment Visit.

Overall instructions:

Enter the PTID in the top left corner of this form. Initial and date at the end of the form.

Item-specific Instructions:

Item	Instruction
1	Record whether the participant provided written informed consent (check IC in participant folder)
2	Confirm that all eligibility criteria are met (Items 1-7 are "Yes" and Items 8 and 9 are "No" on IE form)
3	Record whether the participant was randomized and enrolled into the Wisebag Pilot Study. If she was, record the 3 digit randomization number and proceed with the Enrollment Date field. If she has not, tick "No", describe the reason and end the form.
Enrollment date	This field should be completed for all participants who are randomized and enrolled into the Wisebag pilot.