Visit: SV3

ID: ____________________

Date: ____ / ____ / _________

Baseline Symptoms Questionnaire

Below is a list of problems or complaints people sometimes experience. For each item, if you did not have the problem **during the past month**, please check the box under "symptom did not occur".

If you did experience the problem **during the past month**, please check the box that best describes how bothersome it was for you. Use the key below:

Mild = symptom did not interfere with usual activities
Moderate = symptom interfered somewhat with usual activities
Severe = symptom was so bothersome that usual activities could not be performed.

Symptoms *(during the last month)*	Symptom did not occur	Symptom occurred and was:		
		Mild	Moderate	Severe
1. Poor appetite	❑ 1	❑ 2	❑ 3	❑ 4
2. Diarrhea/loose stools	❑ 1	❑ 2	❑ 3	❑ 4
3. Constipation	❑ 1	❑ 2	❑ 3	❑ 4
4. Nausea or upset stomach	❑ 1	❑ 2	❑ 3	❑ 4
5. Bloating or excess gas	❑ 1	❑ 2	❑ 3	❑ 4
6. Wheezing or difficulty breathing	❑ 1	❑ 2	❑ 3	❑ 4
7. Heart palpitations	❑ 1	❑ 2	❑ 3	❑ 4
8. Leg/ankle swelling	❑ 1	❑ 2	❑ 3	❑ 4
9. Aches or pains in muscles or joints	❑ 1	❑ 2	❑ 3	❑ 4
10. Fatigue or low energy level	❑ 1	❑ 2	❑ 3	❑ 4
11. Excessive thirst	❑ 1	❑ 2	❑ 3	❑ 4
12. Lightheadedness when standing up	❑ 1	❑ 2	❑ 3	❑ 4
13. Headache	❑ 1	❑ 2	❑ 3	❑ 4
14. Difficulty sleeping	❑ 1	❑ 2	❑ 3	❑ 4

15. Have you had any other symptoms in the past month that have not been noted on this form? Yes ❑1 No ❑2

16. **If yes,** please explain: ____

____

____

Office Use:

________________________ Clinician signature

__________ Date

Reviewed by (staff ID): ____________

Entered by (staff ID): ____________

Overview

The purpose of this self-administered form is to identify individuals who have symptoms that could either interfere with their further participation in the study or are potentially exclusionary items.

This form is administered at SV3. A similar version of this form (Form #78) is administered during follow-up. **Any positive responses** should be brought to the attention of a study clinician, who initiates appropriate action in accordance with the protocol, and then signs the form.

After the form is completed, the interviewer should review the form for completeness with the participant.

Administration Instructions

Place ID labels on pages 1 and 2.

Using a blue or black pen, check the SV# visit box.

Fill out the visit date on page 1. Be sure to use a four digit year.

Page	Question	Special Administration Instructions
1	1-14	Check to make sure only one response is marked for each symptom. If a symptom is left blank or more than one response is marked, review the symptom with the participant and mark one response.
2	15	If Yes, complete Q16.
	16	If Q15 = Yes, this question may not be left blank. Make sure the response is legible and review the other symptoms with the study clinician.

Coding Instructions

Any positive responses should be brought to the attention of a study clinician, who initiates appropriate action in accordance with the protocol, and then signs the form.

Review Instructions

Confirm that pages 1 and 2 have an ID label.

Make sure all items were completed (questions 16 and 18 can be blank if questions 15 and 17 are answered "No."

If participant answered "Yes" to question 15, review the notes in question 16 for completeness.