

## Vital Signs

Please mark if evaluation was not done

Any significant findings after the start of the study drug should be recorded on the Adverse Events page.

Please circle the correct measurement, when applicable.

**Weight** \_\_\_\_\_ kg or lb

**Sitting Pulse** \_\_\_\_\_ bpm

**Sitting Blood Pressure** \_\_\_\_\_ / \_\_\_\_\_  
systolic/diastolic  
MmHg

**Respirations** \_\_\_\_\_/minute

**Temperature** \_\_\_\_\_ degrees Centigrade or Fahrenheit





### Weekly Phone Calls for Weeks 1-3 After Visit 5

Phone Call Date \_\_\_/\_\_\_/\_\_\_\_\_

1. How are you feeling? \_\_\_\_\_  
\_\_\_\_\_

2. In the past week, have you had adequate relief of your stomach symptoms? No = 0 Yes = 1

3. Have you missed any doses of the study medication? No = 0 Yes = 1  
If yes, how many doses and reason.  
Number of missed doses \_\_\_\_\_  
Reason for missed doses \_\_\_\_\_  
\_\_\_\_\_

4. Have you started any new medicines ( either prescribed or over the counter) since your last visit? No = 0 Yes = 1  
If yes, what medicines? \_\_\_\_\_  
\_\_\_\_\_

5. Since starting the study have you noticed a change in your mood? No = 0 Yes = 1  
If yes, obtain description from the participant  
\_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_

If the participant describes a depressed mood, obtain answers to the following questions:

- a. I still enjoy the things I used to enjoy:
  - 1. \_\_\_ Definitely as much
  - 2. \_\_\_ Not quite as much
  - 3. \_\_\_ Only a little
  - 4. \_\_\_ Hardly at all
  
- b. I can laugh and see the funny side of things:
  - 1. \_\_\_ As much as I always could
  - 2. \_\_\_ Not quite as much now
  - 3. \_\_\_ Definitely not as much now
  - 4. \_\_\_ Not at all
  
- c. I feel as if I am slowed down:
  - 1. \_\_\_ Nearly all the time
  - 2. \_\_\_ Very often
  - 3. \_\_\_ Sometimes
  - 4. \_\_\_ Not at all

(Phone Call Date \_\_\_/\_\_\_/\_\_\_\_)

- d. I have lost interest in my appearance:
1. \_\_\_ Definitely
  2. \_\_\_ I don't take as much care as I should
  3. \_\_\_ I may not take as much care
  4. \_\_\_ I take as much care as ever
- e. I feel cheerful:
1. \_\_\_ Not at all
  2. \_\_\_ Not often
  3. \_\_\_ Sometimes
  4. \_\_\_ Most of the time
- f. I look forward with enjoyment to things:
1. \_\_\_ As much as I ever did
  2. \_\_\_ Rather less than I used to
  3. \_\_\_ Definitely less than I used to
  4. \_\_\_ Hardly at all
- g. I can enjoy a good book or radio or TV program:
1. \_\_\_ Often
  2. \_\_\_ Sometimes
  3. \_\_\_ Not often
  4. \_\_\_ Very seldom

Question 5 Total: \_\_\_\_\_

If the participant's score for the questions is > or = to 11, the participant is to be seen for an unanticipated study visit. The Principal Investigator at each site will encourage the participant to seek follow up care.

6. Have you seen your health care provider since the last call?      No = 0      Yes = 1

Date of Doctor visit    **Date** \_\_\_/\_\_\_/\_\_\_\_

If yes, why?

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7. Thank you for answering my questions. Please contact \_\_\_\_\_(name of PI) *and/or* \_\_\_\_\_(name of coordinator) **prior to stopping the study medication**. If you feel you can not wait until business hours, please go to your nearest ER and contact us during business hours.

Participant is to complete the following survey forms:

- |         |                                   |   |
|---------|-----------------------------------|---|
| CGI     | <input type="checkbox"/> Complete | <input type="checkbox"/> Incomplete Reason: _____ |
| SF – 36 | <input type="checkbox"/> Complete | <input type="checkbox"/> Incomplete Reason: _____ |
| NEPEAN  | <input type="checkbox"/> Complete | <input type="checkbox"/> Incomplete Reason: _____ |
| GSRS    | <input type="checkbox"/> Complete | <input type="checkbox"/> Incomplete Reason: _____ |
- 

**Changes:**

**Were any changes made on any of the above questionnaires?**

- NO       YES (If yes, see below)

If yes, study coordinator initial and date **HERE** that the changes were made by the study participant at the time of completion of questionnaires.

\_\_\_\_\_      |\_\_| |\_\_| |\_\_| |\_\_| |\_\_|  
Study coordinator initial      Month   Day   Year