| Study ID: _ | | |
|-------------|----|--------------|
| Visit Date: | | |
| | Mo | - Day - Year |
| | | Visit 11 |

Visit 11 Monthly Phone Call

| 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 started any new medicines (either prescribed or last visit? | over the counter) since your No = 0 Yes = 1 | |
| If no, go on to next question. If yes, what medicines? (also list medications on page 3) | | |
| 4. Since starting the study have you noticed a change in you If no, go on to 4.a. If yes, obtain description from the participant | r mood? No = 0 Yes = 1 | |
| If the participant describes a depressed mood, obtain a. I still enjoy the things I used to enjoy: | n answers to the following questions: 1Definitely as much 2Not quite as much 3Only a little 4Hardly at all | |
| b. I can laugh and see the funny side of things: | As much as I always could Not quite as much now Definitely not as much now Not at all | |
| c. I feel as if I am slowed down: | Nearly all the time Very often Sometimes Not at all | |
| d. I have lost interest in my appearance: | Definitely I don't take as much care as I should I may not take as much care I take as much care as ever | |

12/01/2009 Page 1 of 3

| Study ID: _ | | |
|-------------|----|--------------|
| Visit Date: | | |
| | Mo | - Day - Year |
| | | Visit 11 |

| e. I feel cheerful: | 1Not at all |
|--|--|
| | 2Not often 3. Sometimes |
| | 4. Most of the time |
| | |
| f. I look forward with enjoyment to things: | 1As much as I ever did |
| | 2. Rather less than I used to |
| | 3Definitely less than I used to4Hardly at all |
| | <u></u> |
| g. I can enjoy a good book or radio or TV program | |
| | 1Often |
| | 2Sometimes |
| | 3Not often 4Very seldom |
| | 4very seldom |
| Total:_ | |
| NOTE: Use SOP for Scoring the HADS questionnaire to sco If the participant's score for the questions is $>$ or $=$ to 11, the study visit. The Principal Investigator at each site will encoun | participant is to be seen for an unanticipated |
| 5. Have you seen your health care provider since the last call | ? No = 0 Yes = 1 |
| IF Yes, date of Doctor visit Date// | · |
| If yes, why? | |
| | |
| | |
| | |

 $12/01/2009 \\ Please \ mail \ or \ fax \ to \ the \ FDTT \ Data \ Coordinating \ Center \ per \ the \ Data \ and \ Event \ Reporting \ Information \ SOP.$

| Study ID: _ | | |
|-------------|----|--------------|
| Visit Date: | | |
| | Mo | - Day - Year |
| | | Visit 11 |

| after start of study drug Please list all medication and significant non-drug therapies. If there are no changes from previous visit, enter NO CHANG | SES (on line 1 below). |
|--|--|
| Start Date (visit 10) Period covered by this form: Month Day Year | End Date (visit 11) Month Day Year |
| Medication/Non-Drug Therapy (use trade name if possible) | Reason (Including Prophylaxis) |
| 1, | |
| 2 | |
| 3 | |
| 4 | |
| 5 | |
| 6 | |
| 7 | |
| 8 | · |
| 9 | · |
| 10 | |
| 11, | |
| 12 | |
| 13, | |
| 14 | |
| 15 | |
| | |
| 16 | |

 $12/01/2009 \\ Please \ mail \ or \ fax \ to \ the \ FDTT \ Data \ Coordinating \ Center \ per \ the \ Data \ and \ Event \ Reporting \ Information \ SOP.$