Study ID: _		
Visit Date:		
	Mo	- Day - Year
		Visit 12

Vital Signs		Please mark if evaluation was not done	
Any significant findings after	er the start of the study drug should be record	ded on the Adverse Events page.	
Please circle the correct mea	Please circle the correct measurement, when applicable.		
Height:	cm. or inches		
Weight	kg or lb		
Sitting Pulse	bpm		
Sitting Blood Pressure	systolic/diastolic MmHg		
Respirations	/minute		
Temperature	degrees Centigrade	e or Fahrenheit	
Notes:			

 $\frac{12/01/2009}{\text{Please mail or fax to the FDTT Data Coordinating Center per the Data and Event Reporting Information SOP.}}{\text{Possible Page 1 of 47}}$

Study ID: _	
Visit Date:	
	Mo - Day - Year
	Visit 12

Concomitant Medication/Significant Non-Drug	Therapies prior to and
after start of study drug.	
Please list all medication and significant non-drug therapies.	
If there are no changes from previous visit, enter NO CHANGES Start Date (visit 11)	6 (on line 1 below). End Date (visit 12)
Period covered by this form:	
Month Day Year	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	
17	
Is an additional Concomitant Medications/Significant Non-Drug Therapies page	e used?
Please ensure that the data on this page are consistent with the data on the Relevant N page of Visit 1.	Medical History/Current Medical Conditions

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

Study ID: _	
Visit Date:	
	Mo - Day - Year
	Visit 12

Participant is to complete the following separate survey forms: Symptom Check List 90		
SCL-90	☐ Complete	☐ Incomplete Reason:
Profile of M POMS	ood States ☐ Complete	☐ Incomplete Reason:
State – Trait STAI	Anxiety Inventory ☐ Complete	☐ Incomplete Reason:
Pittsburgh S PSQI	leep Quality Index ☐ Complete	☐ Incomplete Reason:
GSRS	☐ Complete	☐ Incomplete Reason:
CGI	☐ Complete	☐ Incomplete Reason:
Somatic Syr SSC	mptom Checklist ☐ Complete	☐ Incomplete Reason:
HADS	☐ Complete	☐ Incomplete Reason:
FBDSI	☐ Complete	☐ Incomplete Reason:
Bowel Disea	ase Questionnaire Version	n 6
BDQ-6	☐ Complete	☐ Incomplete Reason:
Semi – Struc	ctured Interview Complete	☐ Incomplete Reason:
Eating Disorder Examination Questionnaire		
EDE-Q	☐ Complete	☐ Incomplete Reason:
Trauma Que	estionnaire □ Complete	☐ Incomplete Reason:
Early Trauma Inventory Self Report – Short Form		
ETISR – SF	☐ Complete	☐ 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		
comple	tion of questionnaires	Study coordinator initial Month Day Year

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