Participant ID:	Date of Registration:	
Local ID:	Letters:	
Status:		
Site:		

OT04 - Semi-Annual Follow-Up Visit

O 104 - Semi-Annual Follow-Up Visit									
* These fields are required in order to SAVE the form									
* These fields are required in order to COMPLETE the form									
Date of Visit: *				<u>Date</u>					
Interviewer User ID: *									
B. MEDICAL HISTORY									
1. Have there been any changes in health since the last scheduled visit?									
2. Have there been any changes in concomitant medications since last scheduled visit?									
C. LIMITED PHYSICAL EXAM									
1. Collect the following physical assessments:									
a. Seated arm blood pressure:			Systolic	c mmHg Diastolic mi			nmHg		
b. Weight:					kg				
C. Height:					cm		in		
d. Abdominal Circumference					cm		in		
D. PREGNANCY MONITORING									
I. If FEMALE, does the participant have reproductive potential?							○Yes ○No		
2. Is the female participant sexually active?						○Yes ○No			
If YES to question D1 above, continue (If not, proceed to Section E.)									
a. Does she currently use a form of birth control?						○Yes ○No			
b. Does she plan on becoming pregnant in the next 6 months?						○Yes ○No			
c. Was urine pregnancy test completed at this visit?						○Yes ○No			
If yes, 1) was the test result positive?						○Yes ○No			
E. COMPLIANCE (The Study Coordinator should assess the participant's study drug compliance and record on Source Document)									
1. How many doses has the participant missed since the last study visit?									
2. Is the participant currently taking study drug?						○Yes ○No			
F. PROCEDURES PERFORMED									
The following procedures should be performed during this visit:									
a. Performed on this visit b. If NOT performed at this visit, specify date? date performed:									
1. Dispensation/return of study drug (if YES, complete the Study Drug Dispensation and Return Form - OT14) 1. Dispensation/return of study drug (if YES, complete the Yes No									