

SAMPLE
Good Clinical Practices
Study Documentation / Facilities Checklist

Protocol No.: SBK-25673 Brief Title: Early On-set Bipolar Investigator: John Smith

Reviewer: Mary Jones Date(s) of Study Review: 2/13/09-2/14/09

Current Number of Subject(s): 8 Required: 24 On Study: 3 Completed: 5 Dropped Out: 2

Answer the following questions. Comment as appropriate.

Checklist: Study Documentation	Yes	No	N/A	Comments
Final signed protocol	√			
Final signed amendments				Helpful Hints: The checklist is in a table format. Use the table dropdown box in the toolbar to add or delete rows as needed.
Amendment # 1 Effective Date: 4 /10/ 08 Addition of new personnel	√			
Amendment # 2 Effective Date 7/5/08 Addition of ECG at visit 2	√			
Amendment # 3 Effective Date: 11/12/08 Extend enrollment	√			
Signed Form FDA 1572 or IDE exemption letter	√			
Approved consent forms(CF)				
Initial Effective Period: 2/10/08 to 4/15/08	√			
CF #1 Effective Period: 4/16/08 to 7/15/08	√			
CF#2 Effective Period: 7/16/08 to 11/18/08	√			
CF#3 Effective Period 11/19/08 to present	√			
Copies of Advertisements			√	
Copies of Evaluation/Data Collection Tools				Not in file at time of audit, Copy obtained and put in file
QOL questionnaire		√		
Behavioral Evaluation Scale (BES)	√			
Symptom Diary	√			
IRB approval of protocol & Initial consent form				
IRB approval of amendments				
Amendment # 1	√			
Amendment # 2	√			
Amendment # 3	√			
IRB Approval of Advertisements			√	
IRB approval of Copies of Evaluation Tools	√			
IRB correspondence(letters, copies of emails)	√			
IRB continuing review				
Approval Period 2/10/08 to 2/9/09	√			

