

## OFF STUDY / DROP OUT

IRRITABLE BOWEL SYNDROME STUDY

Page 1 of 2

Patient Number	patid				Date of Study Participant	visitm				
Protocol Number	study				Visit/Contact	mmm	dd	yyyy		
Form Week	week			*Seq No.	seqno	**Step No.	stepno	Key Operator Code	keyop	

***This area completed by Clinic Staff only.***

\* Enter a '1' if this is the first of this form for this date. Designate subsequent forms on the same date with a 2, 3, etc.  
\*\* Enter the subject's current study step number. Enter '1' if the study does not have multiple steps.

### INSTRUCTIONS:

This form is to record the participant's permanent discontinuation from all follow-up visits for this protocol (i.e., the patient is Off Study).

1. Date of last study clinic evaluation (mmm/dd/yyyy): .....       
(Telephone contact is NOT considered a study clinic evaluation for reporting purposes unless specified by the protocol.)

2. Describe the primary reason for discontinuing study treatment: [280]

3. Based on the description above, choose the codes from the list on page 2 for the reason(s) the participant discontinued study treatment.

NOTE: If discontinuing study treatment due to participant decision and multiple reasons are provided, list in order from most to least important to participant.

a. Reason 1: .....

b. Reason 2: .....

c. Reason 3: .....

d. If reason code is 44-Participant stated other influences to discontinue' or '99-Other reason not listed,' specify [140]:

CONTIN

04-10-10/06-15-10

Date Form Keyed (DO NOT KEY): \_\_\_\_ / \_\_\_\_ / \_\_\_\_



**OFF STUDY - DROP OUT**

**OFF STUDY CODES**

**Study Staff-Initiated Reasons**

11. Completion of protocol-defined period of study evaluation
12. Randomization/Registration error
13. Eligibility failure - found not to meet eligibility after starting study
14. Unable to contact participant
15. Investigator/clinician decision

**Participant-Initiated Reasons**

**Logistical/practical:**

20. Participant stated too much time required
21. Participant objects to assessment battery
22. Participant stated conflicts with work schedule
23. Participant stated inconvenient location/transportation problems
24. Participant stated childcare problems
25. Participant moved/plans to move out of area
26. Participant stated wait to get treatment is too long

**Treatment/program-related:**

27. Participant does not want random or "chance" assignment
28. Participant does not want "experimental" treatments
29. Participant stated study is too intrusive/represents an invasion of privacy
30. Participant doubts any of the treatment could help
31. Participant stated program too long/intense for needs
32. Participant indicated program too short/superficial for needs
33. Participant prefers another treatment not offered by IBSOS
34. Participant objects to having to return for follow-ups for a year
35. Participant dislikes IBSOS treatment
36. Participant prefers group format

**Influences of others:**

37. Participant stated spouse/significant other influenced decision to discontinue
38. Participant stated other family member influenced decision to discontinue
39. Participant stated friends/co-workers influenced decision to discontinue
40. Participant stated treating physician influenced decision to discontinue
41. Participant stated therapist/counselor influenced decision to discontinue
42. Participant stated health care provider influenced decision to discontinue
43. Participant stated clergy influenced decision to discontinue
44. Participant stated other influences to discontinue, specify

**Miscellaneous Reasons**

98. Death
99. Other reason not listed, specify

