

PREMATURE DISCONTINUATION OF STUDY TREATMENT

IRRITABLE BOWEL SYNDROME STUDY

07-15-11
IBS4000(IBSOS1)/06-15-10

Page 1 of 2

Patient Number	[patid]	[]	[]	[]	Date of Study Participant	[visitm]	[]	[]	[]	[]
					Visit/Contact	mmm	dd	yyyy		
Protocol Number	[study]	[]	[]	[]		Institution Code	[instn]	[]	[]	[]
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 premature discontinuation from study treatment for this protocol
if the participant will continued to be followed on study.

1. Date of last study treatment session (mmm/dd/yyyy):

mb601	[]	[]	[]	[]
-------	-----	-----	-----	-----

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

mb604

mb605

mb606

mb607

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:

mb608

b. Reason 2:

mb609

c. Reason 3:

mb610

d. If reason code is '24-Participant stated other influences to discontinue treatment' or '99-Other reason not listed,' specify [140]:

mb611

mb612

CONTINUE ON NEXT PAGE

04-10-10/06-15-10/07-15-11

Date Form Keyed (DO NOT KEY): ____ / ____ / ____

51410



PREMATURE DISCONTINUATION OF STUDY TREATMENT

PREMATURE TREATMENT DISCONTINUATION CODES

Study Staff-Initiated Reasons

1. Investigator/clinician decision
2. Participant non-compliance

Participant-Initiated Reasons

Logistical/practical:

3. Participant stated treatment requires too much time
4. Participant stated treatment conflicts with work schedule
5. Participant stated inconvenient location/transportation problems
6. Participant stated childcare problems
7. Participant stated wait to get treatment is too long
8. Participant unable to continue treatment due to reasons beyond personal control (hospitalization, incarceration)

Treatment/program-related:

9. Participant does not want "experimental" treatment
10. Participant stated treatment is too intrusive/represents an invasion of privacy
11. Participant doubts any of the treatment could help
12. Participant stated treatment too long/intense for needs
13. Participant indicated treatment too short/superficial for needs
14. Participant prefers another treatment not offered by IBOS
15. Participant dislikes IBOS treatment
16. Participant prefers group treatment format

Influences of others:

17. Participant stated spouse/significant other influenced decision to discontinue treatment
18. Participant stated other family member influenced decision to discontinue treatment
19. Participant stated friends/co-workers influenced decision to discontinue treatment
20. Participant stated treating physician influenced decision to discontinue treatment
21. Participant stated therapist/counselor influenced decision to discontinue treatment
22. Participant stated health care provider influenced decision to discontinue treatment
23. Participant stated clergy influenced decision to discontinue treatment
24. Participant stated other influences to discontinue treatment, specify

Miscellaneous Reasons

99. Other reason not listed, specify

