OFF STUDY / DROP OUT

IRRITABLE BOWEL SYNDROME STUDY   **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 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): ....   mb501 ☐☐ ☐☐☐☐
    *(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]

    mb504 _____

    mb505 _____

    mb506 _____

    mb507 _____

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: mb508

    b. Reason 2: mb509

    c. Reason 3: mb510

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

        mb511 _____

CONTIN mb512 _____

04-10-10/06-15-10   Date Form Keyed (DO NOT KEY): _____ / ____ / ____

51685

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

04-10-10/06-15-10

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