



Participant ID: \_\_\_\_\_

Pin # \_\_\_\_\_

Discovery Site: \_\_\_\_\_

Clinical Center \_\_\_\_\_

CRF Date: \_\_\_\_/\_\_\_\_/\_\_\_\_

Visit #: \_\_\_\_\_

## COMPLEX MEDICAL SYMPTOMS INVENTORY

### Current IBS Symptoms (Rome III Criteria)

RESEARCH COORDINATOR ADMINISTERS TO PATIENT AT BASELINE CONTACT, IF NEEDED.

1. In the last 3 months, how often did you have discomfort or pain anywhere in your abdomen?  
<sub>0</sub> Never (**STOP**)  
<sub>1</sub> Less than one day a month  
<sub>2</sub> One day a month  
<sub>3</sub> Two to three days a month  
<sub>4</sub> One day a week  
<sub>5</sub> More than one day a week  
<sub>6</sub> Everyday
2. For women: Did this discomfort or pain occur only during your menstrual bleeding and not at other times?  
<sub>1</sub> Yes  
<sub>0</sub> No  
<sub>99</sub> Does not apply (either due to menopause or male)
3. Have you had this discomfort or pain 6 months or longer?  
<sub>1</sub> Yes  
<sub>0</sub> No
4. How often did this discomfort or pain get better or stop after you had a bowel movement?  
<sub>0</sub> Never or rarely  
<sub>1</sub> Sometimes  
<sub>2</sub> Often  
<sub>3</sub> Most of the time  
<sub>4</sub> Always
5. When this discomfort or pain started, did you have more frequent bowel movements?  
<sub>0</sub> Never or rarely  
<sub>1</sub> Sometimes  
<sub>2</sub> Often  
<sub>3</sub> Most of the time  
<sub>4</sub> Always
6. When this discomfort or pain started, did you have less frequent bowel movements?  
<sub>0</sub> Never or rarely  
<sub>1</sub> Sometimes  
<sub>2</sub> Often  
<sub>3</sub> Most of the time  
<sub>4</sub> Always
7. When this discomfort or pain started, were your stools (bowel movements) looser?  
<sub>0</sub> Never or rarely  
<sub>1</sub> Sometimes  
<sub>2</sub> Often  
<sub>3</sub> Most of the time  
<sub>4</sub> Always
8. When this discomfort or pain started, how often did you have harder stools?  
<sub>0</sub> Never or rarely  
<sub>1</sub> Sometimes  
<sub>2</sub> Often  
<sub>3</sub> Most of the time  
<sub>4</sub> Always



Participant ID: \_\_\_\_\_

Pin # \_\_\_\_\_

Discovery Site: \_\_\_\_\_

Clinical Center \_\_\_\_\_

CRF Date: \_\_\_/\_\_\_/\_\_\_

Visit #: \_\_\_\_\_

## COMPLEX MEDICAL SYMPTOMS INVENTORY

### Current IBS Symptoms (Rome III Criteria)

RESEARCH COORDINATOR ADMINISTERS TO PATIENT AT BASELINE CONTACT, IF NEEDED.

9. In the last 3 months, how often did you have hard or lumpy stools?
- <sub>0</sub> Never or rarely  
<sub>1</sub> Sometimes  
<sub>2</sub> Often  
<sub>3</sub> Most of the time  
<sub>4</sub> Always
10. In the last 3 months, how often did you have loose mushy or watery stools?
- <sub>0</sub> Never or rarely  
<sub>1</sub> Sometimes  
<sub>2</sub> Often  
<sub>3</sub> Most of the time  
<sub>4</sub> Always



Participant ID: \_\_\_\_\_

Pin # \_\_\_\_\_

Discovery Site: \_\_\_\_\_

Clinical Center \_\_\_\_\_

CRF Date: \_\_\_\_/\_\_\_\_/\_\_\_\_

Visit #: \_\_\_\_\_

## COMPLEX MEDICAL SYMPTOMS INVENTORY

### Current IBS Symptoms (Rome III Criteria)

RESEARCH COORDINATOR ADMINISTERS TO PATIENT AT BASELINE CONTACT, IF NEEDED.

#### IBS Diagnostic Criteria

Recurrent abdominal pain or discomfort\*\* at least **3 days/month in last 3 months** with symptom onset at least 6 months prior to diagnosis. This requires a Yes for each of the following criteria:

**Pain or discomfort at least 2-3 days/month (question 1>2)**

<sub>1</sub> Yes <sub>0</sub> No

**For women, does pain occur only during menstrual bleeding? (question 2=0 or 99)**

<sub>1</sub> Yes <sub>0</sub> No

**Pain or discomfort 6 months or longer? (question 3=1)**

<sub>1</sub> Yes <sub>0</sub> No

**In addition to fulfilling the above criterion, the participant must also have an association of their pain or discomfort with their bowel habit. They must have at least one Yes response in two of the three boxes below (Items #1-#3):**

1. Improvement with defecation

**Pain or discomfort gets better after BM at least sometimes (question 4>0)**

<sub>1</sub> Yes <sub>0</sub> No

2. Onset associated with a change in frequency of stool

**Onset of pain or discomfort associated with more stools at least sometimes (question 5>0)**

<sub>1</sub> Yes <sub>0</sub> No

**OR**

**Onset of pain or discomfort associated with fewer stools at least sometimes (question 6>0)**

<sub>1</sub> Yes <sub>0</sub> No

3. Onset associated with a change in form (appearance) of stool

**Onset of pain or discomfort associated with looser stools at least sometimes (question 7>0)**

<sub>1</sub> Yes <sub>0</sub> No

**OR**

**Onset of pain or discomfort associated with harder stools at least sometimes (question 8>0)**

<sub>1</sub> Yes <sub>0</sub> No

\*\*\*"Discomfort" means an uncomfortable sensation not described as pain.

**The items listed in the box below are for secondary scoring purposes only. These items are NOT Inclusion Criteria.**

**In pathophysiology research and clinical trials, a pain/discomfort frequency of at least two days a week is recommended for subject eligibility.**

**Pain or discomfort more than one day per week (question 1>4)**

<sub>1</sub> Yes <sub>0</sub> No

**Criteria for IBS-C**

**(question 9>0) and (question 10=0)**

<sub>1</sub> Yes <sub>0</sub> No

**Criteria for IBS-D**

**(question 9=0) and (question 10>0)**

<sub>1</sub> Yes <sub>0</sub> No

**Criteria for IBS-M**

**(question 9>0) and (question 10>0)**

<sub>1</sub> Yes <sub>0</sub> No

**Criteria for IBS-U**

**(question 9=0) and (question 10=0)**

<sub>1</sub> Yes <sub>0</sub> No