I C C T G

ICCTG PROTOCOL #1

Standard Visit Inventory

Patient ID: ___ ___ ___ ___ ___
Patient Initials: ___ ___ ___
Clinical Center: ___
Contact Week: ___ ___
Date: ___ ___ / ___ ___ / ___ ___
month day year
RC ID: ___ ___ ___ ___

(Research Coordinator completed at weeks 3, 10, 17, 24 and post treatment follow-up, if applicable.)

1. ***Is this the week number 3 visit?*** ❐1 Yes ❐0 No

*If **YES**, skip to **Part Two**. If **NO,** continue.*

Part One: COMPLIANCE

2. Date of last clinic visit Date: ___ ___ / ___ ___ / ___ ___
month day year

Column: A Amount Dispensed at last visit	B Amount Returned	C Amount Lost/ Destroyed	D How many were used? A - (B + C)	E How many should have been taken?	F Percent Compliance (D / E) x 100
Green Capsules: __ __ __	( )	( )	( ).	( )	3. __ __ __ %
White Capsules: __ __ __	( )	( )	( )	( )	4. __ __ __ %

Part Two: DISPENSING (Record on Study Medication Tracking Log)

5. Total number of **green** capsules dispensed today: ___ ___ ___

Week # __ to __

Peel label off bottle dispensed and apply here:
(Record on Study Medication Tracking Log)

For Post Treatment Follow-up Phase only:
*Peel label off **second bottle** dispensed and apply here:*
(Record on Study Medication Tracking Log)

6. Total number of **white** capsules dispensed today: ___ ___ ___

Week # __ to __

Peel label off bottle dispensed and apply here:
(Record on Study Medication Tracking Log)

For Post Treatment Follow-up Phase only:
*Peel label off **second bottle** dispensed and apply here:*
(Record on Study Medication Tracking Log)

Part Three: ADVERSE EVENTS

7. Since your last scheduled clinic contact, have you had any adverse experiences, abnormal laboratory values, hospitalizations, discontinued medications due to side effects, other complications or pre-existing conditions that worsened? ❒ $_1$ Yes ❒ $_0$ No

If ***YES***, *an Adverse Event Report MUST be completed (except for known ADRs).*

8. Have you either initiated or increased your narcotic drug usage since your last scheduled clinic contact? ❒ $_1$ Yes ❒ $_0$ No

If ***YES***, *this must be recorded on the patient's Daily Medication Diary.*

Part Four: MEDICATION UPDATE

9. Since your last scheduled clinic contact, have you taken any of the following? (See "Exclusionary and Restricted Medications" table and MOP)

a. Tagamet® (cimetidine) ❒1 Yes ❒0 No
(If YES, the patient must be taken off the study.)

b. Intravesical heparin ❒1 Yes ❒0 No
(If YES, the patient must be taken off the study.)

c. Use of more than one gram of aspirin per day for more than three days out of seven? (Bayer®, Anacin®, Excedrin®) ❒1 Yes ❒0 No
*If **YES,** this must be reflected on the patient's Daily Medication Diary.*

d. Use of more than one maximum allowable dose per day of acetaminophin or aspirin replacement products (NSAIDs) for more than three days out of seven? (Motrin®, Advil®) ❒1 Yes ❒0 No
*If **YES,** this must be reflected on the patient's Daily Medication Diary.*

e. Use of products that contain brompheniramine, diphenhydramine, or chlorpheniramine for more than three days out of seven (except for isolated incidences such as for a "cold")? (Benadryl®, Dimetane®) ❒1 Yes ❒0 No
*If **YES,** this must be reflected on the patient's Daily Medication Diary.*

Part Five: IC TREATMENT UPDATE

10. Since your last scheduled clinic contact, have you started any of the following treatments for your IC? ❒1 Yes ❒0 No

If ***YES,*** indicate as many as apply below:

❒1 Yes ❒0 No hydrodistentions
❒1 Yes ❒0 No bladder instillations
❒1 Yes ❒0 No biofeedback/mind-body techniques
❒1 Yes ❒0 No chiropractic treatment
❒1 Yes ❒0 No accupuncture/accupressure
❒1 Yes ❒0 No bladder holding/retraining therapy
❒1 Yes ❒0 No pain clinic
❒1 Yes ❒0 No peripheral or central electrical stimulation
❒1 Yes ❒0 No psychotherapy
❒1 Yes ❒0 No pelvic floor therapies
❒1 Yes ❒0 No massage therapy
❒1 Yes ❒0 No homeopathy and/or herbs
❒1 Yes ❒0 No L-arginine
❒1 Yes ❒0 No other, specify: ____
____
____