

ICCTG
 PROTOCOL #1

Screening Contact
 Checklist
 (Administrative)

Patient ID: _____
 Patient Initials: _____
 Clinical Center: _____
 Contact Week: 0
 RC ID: _____

(Research Coordinator completed to finalize the Baseline 1 and Baseline 2 visits)

<u>Baseline 1 Visit:</u>	<u>Completed</u>	If No , Comment:
1. Acquire signed Informed Consent	<input type="checkbox"/> Yes <input type="checkbox"/> No _____	
2. Assign Patient I.D. number (PTLOG)	<input type="checkbox"/> Yes <input type="checkbox"/> No _____	
3. Administer Patient Contact Information form (CONT)	<input type="checkbox"/> Yes <input type="checkbox"/> No _____	
4. Administer Baseline Symptoms 1 form (BSYM)	<input type="checkbox"/> Yes <input type="checkbox"/> No _____	
5. Administer Inclusion Criteria form (INCL)	<input type="checkbox"/> Yes <input type="checkbox"/> No _____	
6. Administer Exclusion Criteria form (EXCL)	<input type="checkbox"/> Yes <input type="checkbox"/> No _____	
7. Administer Deferral Criteria form (DEF)	<input type="checkbox"/> Yes <input type="checkbox"/> No _____	
8. Administer Medical History form (MED)	<input type="checkbox"/> Yes <input type="checkbox"/> No _____	
9. Collect urine sample. Complete Urine Analysis form (URINE) when results are available	<input type="checkbox"/> Yes <input type="checkbox"/> No _____	
10. Collect blood sample. Complete Lab Results form (LAB) when results are available	<input type="checkbox"/> Yes <input type="checkbox"/> No _____	
11. P.I. to perform physical examination (EXAM)	<input type="checkbox"/> Yes <input type="checkbox"/> No _____	
12. Perform residual urine volume (for men only). Record results on URINE form.	<input type="checkbox"/> Yes <input type="checkbox"/> No _____	
13. Instruct participant in completing Voiding Diary (VOID) - to be sent home with participant	<input type="checkbox"/> Yes <input type="checkbox"/> No _____	
14. Instruct participant in completing Patient Medication Diary (PTDIARY) - to be sent home with participant	<input type="checkbox"/> Yes <input type="checkbox"/> No _____	

Screening Checklist (Administrative)

Clinical Center: ____
RC I.D.: ____

Completed

If **No**, Comment:

15. Discuss follow-up visit schedule and schedule Baseline 2 visit

Yes No

Baseline 2 Visit:

1. Administer Baseline Symptoms 2 form (BSYM2)

Yes No

2. Review Inclusion Criteria form (INCL)

Yes No

3. Collect and review completed Voiding Diary (VOID)

Yes No

4. Collect and review completed Patient Medication Diary (PTDIARY)

Yes No

If participant is still eligible, continue. If not eligible, stop the visit now.

5. Review Exclusion Criteria form (EXCL)

Yes No

6. Review Deferral Criteria form (DEF)

Yes No

7. Complete the Eligibility and Confirmation form (ELIG)

Yes No

8. Complete Crosscheck form (CRSCK)

Yes No

If participant is still eligible, continue. If not eligible, stop the visit now.

8. Randomize participant

Yes No

7. Participant to complete the following forms:

Demographics (DEMO)

Yes No

IC Symptom and Problem Index (SYMPROB)

Yes No

Health Status Questionnaire (SF-36)

Yes No

MOS Sexual Functioning Scale (MOS)

Yes No

Symptom Ranking Cards (CARDS)

Yes No

Univ. of Wisconsin Symptom Survey (UNIVWIS)

Yes No

Screening Checklist (Administrative)

Clinical Center: ____

RC I.D.: ____

- | | <u>Completed</u> | If No , Comment: |
|---|--|-------------------------|
| 8. Review forms (listed above in #7) for accuracy and completeness | <input type="checkbox"/> Yes <input type="checkbox"/> No | _____ |
| 9. Obtain urine sample for banking (UTRAC) | <input type="checkbox"/> Yes <input type="checkbox"/> No | _____ |
| 10. Dispense study medication and discuss excluded and restricted medications | <input type="checkbox"/> Yes <input type="checkbox"/> No | _____ |
| 11. Complete Run-in Med Dispensing Log (RUNIN) | <input type="checkbox"/> Yes <input type="checkbox"/> No | _____ |
| 12. Complete Study Medication Tracking Log (MEDTRAC) | <input type="checkbox"/> Yes <input type="checkbox"/> No | _____ |
| 13. Distribute and discuss:
Patient Medication Diary (PTDIARY)
- to be sent home with participant | <input type="checkbox"/> Yes <input type="checkbox"/> No | _____ |
| 14. Discuss Run-in phase and schedule telephone contacts for weeks 1, 2, and 3 | <input type="checkbox"/> Yes <input type="checkbox"/> No | _____ |
| 15. Discuss follow-up visit schedule and schedule Week 3 clinic visit | <input type="checkbox"/> Yes <input type="checkbox"/> No | _____ |