

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)

Baseline 1 Visit:

Completed

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.: ____

Completed

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 | _____ |