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

	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	_____

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