CPCRN 2	*Randomized Clinical Trial #2 (Protocol – CP02)*	**Data Entry Form Version Log (08/22/2006)**

Form Name	Form Code	Version
Adverse Events and Serious Adverse Events	AE	V1.0.20050607
Adverse Events and Serious Adverse Events – Legend	AE-Legend	V2.0.20060719
Concomitant Medications	CMED	V2.0.20051212
NIH – Chronic Prostatitis Symptom Index	CPSI	V1.0.20051010
Demographics	DEMO	V1.0.20050607
Dispensing Log	DISP	V2.0.20051212
Drug Compliance	DCOMP	V2.0.20060816
Eligibility Checklist	ELIG	V2.0.20060816
EPS and Urine Testing	EUT	V1.0.20050607
Physical Exam	EXAM	V1.0.20050607
Participant Expectations Questionnaire	EXP	V1.0.20050607
Hospital Anxiety and Depression Scale©	HADS	NOT AVAILABLE
Clinical Lab Results	LABS	V2.0.20050902
McGill Pain Questionnaire® (MPQ)	MCGILL	NOT AVAILABLE
Medical History	MEDHX	V1.0.20050607
Pain Medication Questionnaire	PAIN	V1.0.20050927
Phase I – Participant Close Out	PHASEI	V1.0.20060816
Pre-screening Summary	PRESCR	V2.0.20050915
Randomization	RAND	V1.0.20050607
SF12 – Health Status Questionnaire®	SF12	NOT AVAILABLE
The Sexual Health Inventory for Men®	SHIM	NOT AVAILABLE
Study Stop Point	SSTOP	V3.0.20060822
Standard Telephone and Clinic Contact Summary	STCONT	V2.0.20060808
Symptom Assessment	SYM	V1.0.20051010
Treatment Stop Point	TSTOP	V1.0.20051010
Unmasking Record	UNMASK	V1.0.20050607
Urine Screening	URINE	V1.0.20050607
Forms and Visit Schedule	SCHEDULE	V3.0.20060810

Forms and Visit Schedule

Form Name	Phase I						Phase II			
	-1 to -4 Weeks (Screening)	**0 Weeks (Random-ization)**	**2 Weeks (Follow-up)**	**4 Weeks (Follow-up)**	**6 Weeks (Follow-up)**	**7 Weeks (Follow-up)**	**7 Weeks (Follow-up)**	**8 Weeks (Follow-up)**	**12 Weeks (Follow-up)**	**13 Weeks (Follow-up)**
	Visit 1 (*B1 Clinic*)	**Visit 2 (*B2 Clinic*)**	**Visit 3 (*Phone*)**	**Visit 4 *(Phone)***	**Visit 5 (*Clinic*)**	**Visit 6 *(Phone)***	**Visit 7 *(Phone)***	**Visit 8 *(Phone)***	**Visit 9 *(Clinic)***	**Visit 10 *(Phone)***
Prescreening/Screening/Baseline										
Pre-Screening Summary **(PRESCR)**										
Informed Consent **(Administrative)**	X									
Medical History **(MEDHX)**	X									
Eligibility Checklist **(ELIG)**	X	X								
NIH-Chronic Prostatitis Symptom Index **(CPSI)**	X	X	X	X	X	X	X	X	X	X
Randomization (RAND)		**X**								
Procedures and Labs										
Adverse Events/Serious Adverse Events **(AE)**		X	X	X	X	X	X	X	X	X
Concomitant Medications **(CMED)**		X	X	X	X	X	X	X	X	X
Clinical Lab Results **(LABS)**	X									
Demographics **(DEMO)**	X									
Dispensing Log **(DISP)**		X			X				X	
Drug Compliance **(DCOMP)**			X	X	X		X	X	X	
EPS and Urine Testing **(EUT)**	X				X					
Physical Exam **(EXAM)**	X									
Standard Telephone and Clinic Contact Summary **(STCONT)**			X	X	X	X	X	X	X	X
Urine Screening **(URINE)**	X									

Forms and Visit Schedule

Form Name	Phase I						Phase II			
	-1 to -4 Weeks (Screening)	0 Weeks (Randomization)	2 Weeks (Follow-up)	4 Weeks (Follow-up)	6 Weeks (Follow-up)	7 Weeks (Follow-up)	7 Weeks (Follow-up)	8 Weeks (Follow-up)	12 Weeks (Follow-up)	13 Weeks (Follow-up)
	Visit 1 (*B1 Clinic*)	Visit 2 (*B2 Clinic*)	Visit 3 (*Phone*)	Visit 4 (*Phone*)	Visit 5 (*Clinic*)	Visit 6 (*Phone*)	Visit 7 (*Phone*)	Visit 8 (*Phone*)	Visit 9 (*Clinic*)	Visit 10 (*Phone*)
Symptom Questionnaires										
Symptom Assessment **(SYM)**	X	X	X (GRA)	X (GRA)	X (GRA)	X (GRA)	X (GRA)	X (GRA)	X (GRA)	X (GRA)
Health Status Questionnaire® **(SF-12)**		X			X				X	
The McGill Pain Questionnaire® **(MPQ)**		X			X				X	
Hospital Anxiety and Depression Scale© **(HADS)**		X			X				X	
The Sexual Health Inventory for Men® **(SHIM)**		X			X				X	
Participant Expectations Questionnaire **(EXP)**		X			X					
Pain Medication Questionnaire **(PAIN)**		X			X					
PRN Forms										
Phase I Close Out **(PHASEI)** ****Required only when not going onto Phase II**					X**					
Study Stop Point **(SSTOP)**	PRN	PRN	PRN	PRN	PRN	PRN	PRN	PRN	**X**	
Treatment Stop Point **(TSTOP)**	PRN	PRN	PRN	PRN	PRN	PRN	PRN	PRN	**X**	
Unmasking Record **(UNMASK)**	PRN	PRN	PRN	PRN	PRN	PRN				
Administrative Forms										
Clinical Center Staff "Signature and Delegation of Responsibilities" Log **(STAFFLOG)**	X	PRN	PRN	PRN	PRN	PRN	PRN	PRN	PRN	

Forms and Visit Schedule

Form Name	Phase I						Phase II			
	-1 to -4 Weeks (Screening)	**0 Weeks (Random-ization)**	**2 Weeks (Follow-up)**	**4 Weeks (Follow-up)**	**6 Weeks (Follow-up)**	**7 Weeks (Follow-up)**	**7 Weeks (Follow-up)**	**8 Weeks (Follow-up)**	**12 Weeks (Follow-up)**	**13 Weeks (Follow-up)**
	Visit 1 (*B1 Clinic*)	**Visit 2 (*B2 Clinic*)**	**Visit 3 (*Phone*)**	**Visit 4 *(Phone)***	**Visit 5 (*Clinic*)**	**Visit 6 *(Phone)***	**Visit 7 *(Phone)***	**Visit 8 *(Phone)***	**Visit 9 *(Clinic)***	**Visit 10 *(Phone)***
Participant Daily Medication Diary **(PTDIARY)**	X	X	X	X	X	X	X	X	X	
Participant ID Assignment Log **(PTLOG)**	X									
Participant Contact Information **(PTCONT)**	X									
Participant Transfer **(TRANS)**	PRN	PRN	PRN	PRN	PRN	PRN	PRN	PRN	PRN	
Study Drug Tracking Log **(TRACK)**		X	X	X	X	X	X	X	X	
Visit Checklist	X	X	X	X	X	X	X	X	X	

C P C R N 2	*Randomized Clinical Trial #2 (Protocol – CP02)*	Participant ID: __ __ __ __ __	Participant Initials __ __ __
		Clinical Center: __ __	Visit Number __ __
		CRF Date: __ __/__ __/__ __ __ __	RC ID: __ __ __ __

Adverse Events and Serious Adverse Events

To capture "pre-existing medical conditions" as defined in the MOP at Visit 2, please record any baseline signs and symptoms that the participant is experiencing. Beginning at Visit #3, list all adverse events **(AEs)** that have newly occurred, changed, been resolved, or are ongoing at **EACH** visit.

1. Were there any newly reported AEs; resolutions of AEs; follow-ups to ongoing AEs; or pre-existing medical conditions to be reported at this visit? ❑$_1$ Yes ❑$_0$ No
   a. If YES, please list the total number of records at this visit: ___ ___

Event Number	MedDRA Code	Date of Onset	Grade	Duration	Frequency	Relation ship to Study Drug	Action taken regarding Study Drug	Treatment for event	Outcome	Date of Resolution	Was the Event Serious?	Pre-existing condition
AE #	**From CTC List**	mm/dd/yyyy Use the Check Box if Event is continuous from previous visit.	record one	record one	record one	record one	record one	record one	record most appropriate	mm/dd/yyyy Use the Check Box if Event is continuous from this visit.		
__ __ __	__ __ __ __ __ __ __ __	__ __/__ __/__ __ __ __ ❒								__ __/__ __/__ __ __ __ ❒		
Specify Event (CTC Criteria):			Description of Event/Comments:									
__ __ __	__ __ __ __ __ __ __ __	__ __/__ __/__ __ __ __ ❒								__ __/__ __/__ __ __ __ ❒		
Specify Event (CTC Criteria):			Description of Event/Comments:									
__ __ __	__ __ __ __ __ __ __ __	__ __/__ __/__ __ __ __ ❒								__ __/__ __/__ __ __ __ ❒		
Specify Event (CTC Criteria):			Description of Event/Comments:									
__ __ __	__ __ __ __ __ __ __ __	__ __/__ __/__ __ __ __ ❒								__ __/__ __/__ __ __ __ ❒		
Specify Event (CTC Criteria):			Description of Event/Comments:									

Principal Investigator's Signature: ______________________________ Date: ___ ___/___ ___/___ ___ ___ ___ PI ID: ___ ___ ___ ___

(MM/DD/YYYY)

Adverse Events and Serious Adverse Events

List all pre-existing medical conditions and/or adverse events that have newly occurred, changed, or resolved.

Grade	Duration	Frequency	Relationship to Study Drug	Action Taken Regarding Study Drug
1. Mild 2. Moderate 3. Severe 4. Life threatening or disabling 5. Fatal 88. Unknown 99. NA	1. Minutes 2. Hours 3. Days 88. Unknown 99. NA	1. Once 2. 2 to 3 episodes 3. 4 or more episodes 4. Daily 99. NA	1. Not related 2. Possibly related 3. Definitely related 88. Unknown/undetermined 99. NA	0. No action taken 1. Drug interrupted 2. Drug discontinued 3. Drug dosage reduced 99. N/A

Treatment for Event	Outcome	Was the Event Serious?	Pre-existing Condition
0. No 1. Yes 99. NA	1. Resolved/no follow-up needed 2. On-going/treatment continued *3. ER visit/prolonged hospitalization *4. Resulted in persistent or significant disability/incapacity *5. Congenital anomaly *6. Life threatening *7. Fatal 99. NA *Indicates Serious Adverse Events and **must** be reported to the IRB and DCC. PI signature needed on AEs and SAEs	0. No 1. Yes 99. NA	0. No 1. Yes 99. NA

C P C R N 2	***Randomized Clinical Trial #2 (Protocol – CP02)***	Participant ID: __ __ __ __ __	Participant Initials __ __ __
		Clinical Center: __ __	Visit Number __ __
		CRF Date: __ __ / __ __ / __ __ __ __	RC ID: __ __ __ __

Concomitant Medications

RESEARCH COORDINATOR COMPLETES AT VISITS 2, 3, 4, 5, 6, 7, 8, 9, AND 10.

LIST ALL THE OVER-THE-COUNTER MEDICATIONS AND PRESCRIPTIONS TAKEN AT ENTRY AND DURING THE COURSE OF THE STUDY.

*FOR VISITS 2 AND 5 ONLY: IF A PARTICIPANT REPORTS TAKING ANY MEDICATION FOR PELVIC/BLADDER PAIN, PLEASE COMPLETE A PAIN MEDICATION QUESTIONNAIRE (PAIN) FORM.

1. Were there newly reported medications or updates to the participant's medications at this visit? ❑$_1$ Yes ❑$_0$ No
   a. If YES, please list the total number of records at this visit: ___ ___

Line # 3-digits	**Drug Code#** From Medication Reference Tool	**Drug Name**	**Total Daily Dose** Total Daily Dose or PRN	**Fre-quency Taken**	**Unit**	**Route**	**Start Date** mm/dd/yyyy Use Check Box if Start Date is continued from a previous visit	**Stop Date** mm/dd/yyyy Use Check Box if participant is still using the medication listed.	**Exclu-sionary Med** 1 = Yes 0 = No	**Res-tricted Med** 1 = Yes 0 = No	**For Pelvic/ Bladder Pain** 1 = Yes 0 = No	**For Urinary Frequency /Urgency** 1 = Yes 0 = No
__ __ __							__ __/__ __/__ __ __ __ ❐	__ __/__ __/__ __ __ __ ❐				
__ __ __							__ __/__ __/__ __ __ __ ❐	__ __/__ __/__ __ __ __ ❐				
__ __ __							__ __/__ __/__ __ __ __ ❐	__ __/__ __/__ __ __ __ ❐				
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__ __ __							__ __/__ __/__ __ __ __ ❐	__ __/__ __/__ __ __ __ ❐				
__ __ __							__ __/__ __/__ __ __ __ ❐	__ __/__ __/__ __ __ __ ❐				

Additional comments, if needed:

Line #	**Comments**
__ __ __	
__ __ __	

Concomitant Medications Legend

Use the codes below in completing the CMED form.

Frequency	Unit	Route
1. Every day 2. A few times per week 3. A few times per month 4. Infrequently 5. PRN	1. mg 2. ml/cc 3. tablets 4. SC 5. tsp 6. drops 7. cream 8. spray 9. tbsp 98. other	1. oral 2. IV 3. IM 4. SC 5. topical 6. rectal 7. nasal 8. transdermal 9. inhalant 10. sublingual 98. other

CPCRN2	*Randomized Clinical Trial #2 (Protocol – CP02)*	Participant ID: __ __ __ __ __	Participant Initials __ __ __
		Clinical Center: __ __	Visit Number __ __
		CRF Date: __ __/__ __/__ __ __ __	RC ID: __ __ __ __

NIH – CHRONIC PROSTATITIS SYMPTOM INDEX

PARTICIPANT COMPLETES AT VISITS 1, 2, 3, 4, 5, 6, 7, 8, 9 AND 10.

Pain or Discomfort

1. In the last week, have you experienced any pain or discomfort in the following areas?
   a. Area between rectum and testicles (perineum) ❑1 Yes ❑0 No
   b. Testicles ❑1 Yes ❑0 No
   c. Tip of the penis (not related to urination) ❑1 Yes ❑0 No
   d. Below your waist, in you pubic or bladder area ❑1 Yes ❑0 No

2. In the last week, have you experienced:
   a. Pain or burning during urination? ❑1 Yes ❑0 No
   b. Pain or discomfort during or after sexual climax (ejaculation)? ❑1 Yes ❑0 No

3. How often have you had pain or discomfort in any of these areas over the last week?
   ❑0 Never
   ❑1 Rarely
   ❑2 Sometimes
   ❑3 Often
   ❑4 Usually
   ❑5 Always

4. Which number best describes your AVERAGE pain or discomfort on the days that you had it, over the last week?

❑	❑	❑	❑	❑	❑	❑	❑	❑	❑	❑
0	1	2	3	4	5	6	7	8	9	10

No Pain — Pain as bad as you can imagine

Urination

5. How often have you had a sensation of not emptying your bladder completely after you finished urinating, over the last week?
   ❑0 Not at all
   ❑1 Less than 1 time in 5
   ❑2 Less than half the time
   ❑3 About half the time
   ❑4 More than half the time
   ❑5 Almost always

6. How often have you had to urinate again less than two hours after you finished urinating, over the last week?
   ❑0 Not at all
   ❑1 Less than 1 time in 5
   ❑2 Less than half the time
   ❑3 About half the time
   ❑4 More than half the time
   ❑5 Almost always

NIH – CHRONIC PROSTATITIS SYMPTOM INDEX

PARTICIPANT COMPLETES AT VISITS 1, 2, 3, 4, 5, 6, 7, 8, 9 AND 10.

Impact of Symptoms

7. How much have your symptoms kept you from doing the kinds of things you would usually do, over the last week?
   - ❑0 None
   - ❑1 Only a little
   - ❑2 Some
   - ❑3 A lot

8. How much did you think about your symptoms, over the last week?
   - ❑0 None
   - ❑1 Only a little
   - ❑2 Some
   - ❑3 A lot

Quality of Life

9. If you were to spend the rest of your life with your symptoms just the way they have been during the last week, how would you feel about that?
   - ❑0 Delighted
   - ❑1 Pleased
   - ❑2 Mostly satisfied
   - ❑3 Mixed (about equally satisfied and dissatisfied)
   - ❑4 Mostly dissatisfied
   - ❑5 Unhappy
   - ❑6 Terrible

To be completed by the RC:

Overall Score: _____
(Sum of # 1 – 9)

Study Drug Compliance

RESEARCH COORDINATOR TO COMPLETE AT VISITS 3, 4, 5, 7, 8 AND 9.

1. Treatment Point: ❑$_1$ 2 Weeks ❑$_2$ 4 Weeks ❑$_3$ 6 Weeks ❑$_4$ 7 Weeks ❑$_5$ 8 Weeks ❑$_6$ 12 Weeks ❑$_7$ Supplemental

Study Drug Returned:

2.

Amount of 50 mg Capsules Dispensed (A)	Amount of 50 mg Capsules Returned (B)	Amount of 50 mg Capsules Lost/Destroyed (C)	Amount of 50 mg Capsules Used A-(B+C) (D)	Amount of 50 mg Capsules that should have been used (E)	Percent Compliance (D/E)X100 (F)

3.

Amount of 100 mg Capsules Dispensed (A)	Amount of 100 mg Capsules Returned (B)	Amount of 100 mg Capsules Lost/Destroyed (C)	Amount of 100 mg Capsules Used A-(B+C) (D)	Amount of 100 mg Capsules that should have been used (E)	Percent Compliance (D/E)X100 (F)

4.

Amount of 200 mg Capsules Dispensed (A)	Amount of 200 mg Capsules Returned (B)	Amount of 200 mg Capsules Lost/Destroyed (C)	Amount of 200 mg Capsules Used A-(B+C) (D)	Amount of 200 mg Capsules that should have been used (E)	Percent Compliance (D/E)X100 (F)

5. If the participant is less than 80% compliant, please provide reason(s):

_____

_____

_____

CPCRN 2	*Randomized Clinical Trial #2 (Protocol – CP02)*	Participant ID: __ __ __ __ __	Participant Initials __ __ __
		Clinical Center: __ __	Visit Number __ __
		CRF Date: __ __/__ __/__ __ __ __	RC ID: __ __ __ __

Demographics

PARTICIPANT COMPLETES AT VISIT 1.

1. What is your date of birth? __ __ / __ __ / __ __ __ __ (MM/DD/YYYY)
2. What is your gender? ❒1 Male ❒2 Female
3. What do you consider to be your ethnicity?
   ❒1 Hispanic or Latino
   ❒2 Not Hispanic or Latino
4. Using the categories below, what do you consider to be your racial background?
   a. North American Indian/Northern Native ❒1 Yes ❒0 No
   b. Asian/Asian American ❒1 Yes ❒0 No
   c. Black/African American ❒1 Yes ❒0 No
   d. Native Hawaiian/Other Pacific Islander ❒1 Yes ❒0 No
   e. White/Caucasian ❒1 Yes ❒0 No
   f. Other (Please specify) _____ ❒1 Yes ❒0 No
5. What is the highest educational level you have attained?
   ❒1 Less than high school
   ❒2 High school or GED
   ❒3 Some college
   ❒4 Graduated from college/university
   ❒5 Graduate or professional school after college/university
6. What is your current employment status?
   ❒1 Employed
   ❒2 Unemployed
   ❒3 Retired
   ❒4 Full-time homemaker
   ❒5 Disabled
7. What is your annual family income? (In U.S. dollars, please see the MOP for conversion method)
   ❒1 $10,000 or less
   ❒2 $10,001 to $25,000
   ❒3 $25,001 to $50,000
   ❒4 $50,001 to $100,000
   ❒5 More than $100,000
   ❒99 Prefer not to Answer
8. What is your ZIP (US) or Postal (Canadian) Code?
   a. ZIP Code (for US Residents) ___ ___ ___ ___ ___ ❒ N/A
   b. Postal Code (for Canadian Residents) ___ ___ ___ ___ ___ ___ ❒ N/A
9. Have any family members ever been diagnosed with Painful Bladder Syndrome (PBS) / Interstitial Cystitis (IC)? ❒1 Yes ❒0 No ❒88 Unknown
10. Have any family members ever been diagnosed with Chronic Pelvic Pain Syndrome (CPPS) / Chronic Prostatitis (CP)? ❒1 Yes ❒0 No ❒88 Unknown
11. Are you living with a spouse or partner? ❒1 Yes ❒0 No

Dispensing Log

RESEARCH COORDINATOR COMPLETES AT VISITS 2, 5 AND 9

1. Date study drug capsules/tablets dispensed: ___ ___ / ___ ___ / ___ ___ ___ ___

2. Date first dose of these study drug capsules/tablets started: ___ ___ / ___ ___ / ___ ___ ___ ___

3. Total number of 50 mg study drug capsules/tablets dispensed: (Record on Study Medication Tracking Log) ___ ___ ___

4. Total number of 100 mg study drug capsules/tablets dispensed: (Record on Study Medication Tracking Log) ___ ___ ___

5. Total number of 200 mg study drug capsules/tablets dispensed: (Record on Study Medication Tracking Log) ___ ___ ___

Affix and sign the drug label for the study drug capsules/tablets here.
Record on Study Medication Tracking Log

NOTE: By signing the label here, you are confirming that you have:

1. Checked the label on the bottle with the randomization number on the Randomization form, and
2. Confirmed that the drug is being given to the participant with the ID number written on this form.

CPCRN 2	*Randomized Clinical Trial #2 (Protocol – CP02)*	Participant ID: __ __ __ __ __	Participant Initials __ __ __
		Clinical Center: __ __	Visit Number __ __
		CRF Date: __ __/__ __/__ __ __ __	RC ID: __ __ __ __

Eligibility Checklist

RESEARCH COORDINATOR COMPLETES AT VISITS 1 AND 2.

Inclusion Criteria

Complete questions #1, #2 and #3 at Visit #1 only:

1. Participant has signed and dated the appropriate Informed consent document. ❑1 Yes ❑0 No
   a. If **Yes**, record date the form was signed __ __/__ __/__ __ __ __
2. Participant is male. ❑1 Yes ❑0 No
3. Participant is ≥ 18 years of age. ❑1 Yes ❑0 No
4. Participant has an overall score on the NIH-CPSI (overall score of ≥ 15 out of a potential of 0-43 points). ❑1 Yes ❑0 No
   a. Record the overall NIH-CPSI score. ____ ____
   (Please refer to the overall score on the CPSI form)
5. Participant has had symptoms of discomfort or pain in the pelvic region for at least a three (3) month period within the last six (6) months. ❑1 Yes ❑0 No
6. Participant has a non-zero pain domain score on the NIH-CPSI at the time of enrollment. ❑1 Yes ❑0 No

ALL INCLUSION CRITERIA RESPONSES MUST BE "YES" FOR THE PARTICIPANT TO BE ELIGIBLE FOR ENROLLMENT

Exclusion Criteria

Complete questions #7, #8 and #9 at Visit #2 only:

Question #7 is for Clinical Centers who do not have IRB approval for CPCRN-2 RCT#2 Amendment 2

7. Participant has evidence of facultative Gram negative or enterococcus with a value of ≥ 1,000 CFU/ml in mid-stream urine (VB2). ❑1 Yes ❑0 No

Question #7.1 is for Clinical Centers who do have IRB approval for CPCRN-2 RCT#2 Amendment 2

7.1 Participant has **continued** evidence of facultative Gram negative or enterococcus with a value of ≥1000 **and ≤ 100,000 CFU/ml** in mid-stream urine (VB2), **as demonstrated by repeat culture obtained no less than seven (7) days post antibiotic treatment.** ❑1 Yes ❑0 No
   a. Record the actual urine count in CFU/ml: ___ ___ ___, ___ ___ ___
   (Once Amendment 2 is approved, record the most recent urine count)
8. Participant has a calculated creatinine clearance of <60 mL/min. ❑1 Yes ❑0 No
   a. Record participant's age in years ___ ___ (years)
   b. Record participant's weight in kg ___ ___ ___.___ (kg)
   c. Record participant's serum creatinine (mg/dL) ____.____ (mg/dL)
   d. Record the calculated creatinine clearance (mL/min) ___ ___ ___ (mL/min)

Eligibility Checklist

RESEARCH COORDINATOR COMPLETES AT VISITS 1 AND 2.

Exclusion Criteria (Continued):

9. Participant has a platelet count <100,000/mm^3.	❑$_1$ Yes	❑$_0$ No
a. Record the actual platelet count in (mm^3)	__ __ __,__ __ __ (mm^3)	
10. Participant is allergic to antiepileptic/antiseizure medications.	❑$_1$ Yes	❑$_0$ No
11. Participant has a known allergy or sensitivity to pregabalin (Lyrica®).	❑$_1$ Yes	❑$_0$ No
12. Participant is taking thiazolidinedione antidiabetic agents (i.e. rosiglitazone and pioglitazone).	❑$_1$ Yes	❑$_0$ No
13. Participant has New York Heart Association Class III or IV congestive heart failure.	❑$_1$ Yes	❑$_0$ No
14. Participant has a history of thrombocytopenia or a bleeding diathesis.	❑$_1$ Yes	❑$_0$ No
15. Participant has a history of prostate, bladder, or urethral cancer.	❑$_1$ Yes	❑$_0$ No
16. Participant has a history of alcohol abuse	❑$_1$ Yes	❑$_0$ No
17. Participant has inflammatory bowel disease (such as Crohn's disease or ulcerative colitis, but not irritable bowel syndrome).	❑$_1$ Yes	❑$_0$ No
18. Participant has undergone pelvic radiation or systemic chemotherapy.	❑$_1$ Yes	❑$_0$ No
19. Participant has undergone intravesical chemotherapy.	❑$_1$ Yes	❑$_0$ No
20. Participant has been treated with intravesical BCG.	❑$_1$ Yes	❑$_0$ No
21. Participant has unilateral orchalgia without other pelvic symptoms.	❑$_1$ Yes	❑$_0$ No
22. Participant has an active urethral stricture.	❑$_1$ Yes	❑$_0$ No
23. Participant has a neurological disease or disorder affecting the bladder.	❑$_1$ Yes	❑$_0$ No
24. Participant has a neurological impairment or psychiatric disorder preventing his understanding of consent and his ability to comply with the protocol.	❑$_1$ Yes	❑$_0$ No

ALL EXCLUSION CRITERIA RESPONSES MUST BE "NO" FOR THE PARTICIPANT TO BE ELIGIBLE FOR ENROLLMENT

Deferral Criteria

Question #25 is for Clinical Centers who do not have IRB approval for CPCRN-2 RCT#2 Amendment 2

25. Participant has had previous gabapentin (Neurontin®) treatment within the past two (2) weeks.	❑$_1$ Yes	❑$_0$ No

Question #25a is for Clinical Centers who do have IRB approval for CPCRN-2 RCT#2 Amendment 2

25a. Participant has had previous gabapentin (Neurontin®) or **pregabalin (Lyrica®)** treatment within the past two (2) weeks.	❑$_1$ Yes	❑$_0$ No
26. Participant has had a urinary tract infection, with a urine culture value of >100,000 CFU/ml, in the past three (3) months.	❑$_1$ Yes	❑$_0$ No

Eligibility Checklist

RESEARCH COORDINATOR COMPLETES AT VISITS 1 AND 2.

Deferral Criteria (Continued):

27. Participant has had clinical evidence of urethritis, i.e. including urethral discharge or positive culture, in the past three (3) months, diagnostic of the following sexually transmitted diseases (STDs): gonorrhea, chlamydia, mycoplasma, or trichomonas.	❑$_1$ Yes	❑$_0$ No
28. Participant has had a prostate biopsy in the past three (3) months.	❑$_1$ Yes	❑$_0$ No
29. Participant has experienced symptoms of acute or chronic epididymitis in the past three (3) months.	❑$_1$ Yes	❑$_0$ No
30. Participant has been diagnosed with or treated for symptomatic genital herpes in the past twelve (12) months.	❑$_1$ Yes	❑$_0$ No
31. Participant has started, stopped, or changed dose level of ANY prescripton drugs with 5-alpha reductase activity (i.e. dutasteride or finasteride) in the past six (6) months.	❑$_1$ Yes	❑$_0$ No
32. Participant has started, stopped, or changed dose level of ANY prostatitis-specific medications within the past four (4) weeks.	❑$_1$ Yes	❑$_0$ No
33. Participant has undergone TURP, TUIP, TUIBN, TUMT, TUNA, balloon dilation of the prostate, open prostatectomy or any other prostate surgery or treatment such as alcohol ablation or thermal therapy less than one (1) year ago.	❑$_1$ Yes	❑$_0$ No

ALL DEFERRAL CRITERIA RESPONSES MUST BE "NO" FOR THE PARTICIPANT TO BE ELIGIBLE FOR ENROLLMENT

34. Did the participant meet all eligibility criteria at this visit?	❑$_1$ Yes	❑$_0$ No

CPCRN 2	*Randomized Clinical Trial #2 (Protocol – CP02)*	Participant ID: __ __ __ __ __	Participant Initials __ __ __
		Clinical Center: __ __	Visit Number __ __
		CRF Date: __ __/__ __/__ __ __ __	RC ID: __ __ __ __

EPS and Urine Testing

RESEARCH COORDINATOR COMPLETES AT VISITS 1 AND 5.

1. Date of participant's EPS and Urine Test __ __/__ __/__ __ __ __ (MM/DD/YYYY)

2. Has the participant remained abstinent for the past 48 hours? ❑$_1$ Yes ❑$_0$ No

---

The table below lists the species to be identified in each sample, and each species's appropriate code. Use these codes when completing the tables for the culture count for each modified four glass test sample.

Species	Species Code
Enterococcus Fecalis	07
Escherichia Coli	09
Klebsiella	10
Pseudomonas	11
Proteus	12
Other Enterobacteracea	13

VB2 - 48 Hour Culture

3. Date of 48 hour culture __ __/__ __/__ __ __ __ (MM/DD/YYYY)

4. Was there any growth? ❑$_1$ Yes ❑$_0$ No

If **Yes**, please complete the chart below, indicating what species were present, and the culture count measured in CFU/ml: **Enter total number of species recorded:** ___ ___

Species Code	Please enter actual count
___ ___	___ ___ ___,___ ___ ___ CFU/ml
___ ___	___ ___ ___,___ ___ ___ CFU/ml
___ ___	___ ___ ___,___ ___ ___ CFU/ml
___ ___	___ ___ ___,___ ___ ___ CFU/ml
___ ___	___ ___ ___,___ ___ ___ CFU/ml
___ ___	___ ___ ___,___ ___ ___ CFU/ml

EPS and Urine Testing

RESEARCH COORDINATOR COMPLETES AT VISITS 1 AND 5.

EPS

5. Was the participant able to provide an EPS sample? ❑$_1$ Yes ❑$_0$ No

   If **No**, please go to question #8.
   If **Yes**, please complete questions #6 and #7.

6. Estimated volume of EPS sample
   ❑$_1$ None
   ❑$_2$ 1 or 2 drops
   ❑$_3$ 3 or more drops

7. White Blood Cell Count (/hpf)
   ❑$_1$ ≤ 25
   ❑$_2$ 26 - 50
   ❑$_3$ 51-75
   ❑$_4$ 76-100
   ❑$_5$ > 100

   a. If ≤ 25, give actual count ___ ___ /hpf

VB3

8. Was the participant able to provide a VB3 sample? ❑$_1$ Yes ❑$_0$ No

   If **Yes**, please complete questions #9.

9. White Blood Cell Count (/hpf)
   ❑$_1$ ≤ 25
   ❑$_2$ 26 - 50
   ❑$_3$ 51-75
   ❑$_4$ 76-100
   ❑$_5$ > 100

   a. If ≤ 25, give actual count ___ ___ /hpf

CPCRN 2	*Randomized Clinical Trial #2 (Protocol – CP02)*	Participant ID: __ __ __ __ __	Participant Initials __ __ __
		Clinical Center: __ __	Visit Number __ __
		CRF Date: __ __/__ __/__ __ __ __	RC ID: __ __ __ __

Physical Exam

Clinician completes at Visit 1.

1. Height:
   a. Feet ___ ___
   b. Inches ___ ___
2. Weight: __ __ __ lbs.
3. Blood Pressure:
   a. Systolic (mmHg) __ __ __
   b. Diastolic (mmHg) __ __ __
4. Abdominal exam: ❒1 Normal ❒0 Abnormal

Pelvic Exam:

5. External Genitalia: ❒1 Normal ❒0 Abnormal ❒99 Not Applicable
   a. If **Abnormal** please specify: _____
6. Rectal / Bimanual exam: ❒1 Normal ❒0 Abnormal ❒99 Not Applicable

Men only (Check N/A for women)

7. Suprapubic Tenderness ❒1 Yes ❒0 No ❒99 Not Applicable
8. Penis Circumcised ❒1 Yes ❒0 No ❒99 Not Applicable
9. Prostate
   a. Enlarged ❒1 Yes ❒0 No ❒99 Not Applicable
   b. Irregular ❒1 Yes ❒0 No ❒99 Not Applicable
   c. Tender ❒1 Yes ❒0 No ❒99 Not Applicable
   d. Pelvic Wall (muscle) Tenderness ❒1 Yes ❒0 No ❒99 Not Applicable

Women only (Check N/A for males & post-menopausal women)

10. Pelvic floor musculature tenderness ❒1 Yes ❒0 No ❒99 Not Applicable
11. Uterus
    a. Absent ❒1 Yes ❒0 No ❒99 Not Applicable
    b. Normal ❒1 Yes ❒0 No ❒99 Not Applicable
    c. Abnormal ❒1 Yes ❒0 No ❒99 Not Applicable
       If **Yes** please specify: _____
12. Pelvic organ support
    a. Normal ❒1 Yes ❒0 No ❒99 Not Applicable
    b. Prolapse present, no vaginal points beyond the hymen ❒1 Yes ❒0 No ❒99 Not Applicable
    c. Prolapse present, at least one vaginal point beyond the hymen ❒1 Yes ❒0 No ❒99 Not Applicable
13. Menstruating ❒1 Yes ❒0 No ❒99 Not Applicable
    a. If **Yes**, date of last menstrual period: Date: __ __/ __ __/__ __ __ __ (MM/DD/YYYY)
    b. If **No**:
       ❒1 Premenopausal
       ❒2 Prior Hysterectomy
       ❒3 Postmenopausal

CPCRN 2	*Randomized Clinical Trial #2 (Protocol – CP02)*	Participant ID: __ __ __ __ __	Participant Initials __ __ __
		Clinical Center: __ __	Visit Number __ __
		CRF Date: __ __/__ __/__ __ __ __ __	RC ID: __ __ __ __

Participant Expectations Questionnaire

PARTICIPANT COMPLETES AT VISIT 2 AND 5.

As a participant in this study, we are very interested in what you expect.

1. Do you expect that participating in this study will help your pelvic pain/prostatitis symptoms?

   ❑$_1$ Yes ❑$_0$ No ❑$_{88}$ Unknown

2. Based on what you have heard about the study, how much do you expect your symptoms to change by the end of this study?

   ❑$_1$ Markedly worse
   ❑$_2$ Moderately worse
   ❑$_3$ Slightly worse
   ❑$_4$ No change
   ❑$_5$ Slightly improved
   ❑$_6$ Moderately improved
   ❑$_7$ Markedly improved

CPCRN 2	*Randomized Clinical Trial #2 (Protocol – CP02)*	Participant ID: __ __ __ __ __	Participant Initials __ __ __
		Clinical Center: __ __	Visit Number __ __
		CRF Date: __ __/__ __/__ __ __ __	RC ID: __ __ __ __

Clinical Laboratory Results

RESEARCH COORDINATOR COMPLETES AT VISIT 1.

Test	(A) Date of Specimen	(B) Test Result	(C) Clinically Significant?
1. Serum Creatinine (mg/dL)	___ ___/___ ___/___ ___ ___ ___ (MM/DD/YYYY)	____.____	❑1 Yes ❑0 No
2. Creatinine Clearance (mL/min)	___ ___/___ ___/___ ___ ___ ___ (MM/DD/YYYY)	____ ____ ____	❑1 Yes ❑0 No
3. Platelet Count (mm^3)	___ ___/___ ___/___ ___ ___ ___ (MM/DD/YYYY)	__ __ __,__ __ __	❑1 Yes ❑0 No

NOTE: The Serum Creatinine (mg/dL), the Creatinine Clearance (mL/min), and the Platelet count (mm^3) values, along with the Participant's age and weight (kg), which is listed below, needs to be recorded on the Eligibility (ELIG) form at Visit 2.

Principal Investigator's Signature: _____

Date of Principal Investigator's Signature __ __/__ __/__ __ __ __ (MM/DD/YYYY)

Principal Investigator's ID: ___ ___ ___ ___

Worksheet Section: (*This section is not entered in the DMS)*

The following is the calculation of creatinine clearance in men using the Cockcroft-Gault equation.

Age: ___ ___ years

Weight: ___ ___ ___.___ kg (Note: 1 kg = 2.2 lbs)

Serum Creatinine: ___.___ (mg/dL)

Cockcroft-Gault Creatinine Clearance Estimate:

$$\frac{(140 - \text{age (yrs)} \times \text{weight (kg)})}{\text{Serum Creatinine (mg/dL)} \times 72} = \text{Creatine Clearance (mL/min)} \_\_\_\_ \_\_\_\_ \_\_\_\_$$

NOTE: Please record the Serum Creatinine (mg/dL) and Creatinine Clearance (mL/min) results in the "Test Results" column listed above.

Medical History

RESEARCH COORDINATOR COMPLETES AT VISIT 1.

I'm going to ask you some questions . . .

1. Have you ever been diagnosed with interstitial cystitis ("IC"), chronic prostatitis, or chronic pelvic pain symptoms? ❑1 Yes ❑0 No
   a. If **YES**, at what age were you diagnosed? ___ ___ age
2. Do you know when your IC, chronic prostatitis, or chronic pelvic pain symptoms first began? ❑1 Yes ❑0 No
   a. If **YES**, at what age did they first begin? ___ ___ age

I am going to ask you some questions about some medical disorders and conditions. Please tell me if you have ever been diagnosed with any of the following:

Genitourinary Disorders: (Both Men and Women)

3. Bladder cancer ❑1 Yes ❑0 No ❑88 U/K
4. Urinary Tract Infection ❑1 Yes ❑0 No ❑88 U/K

(Women only)

5. Pelvic Inflammatory Disease (PID) ❑1 Yes ❑0 No ❑88 U/K
6. Endometriosis ❑1 Yes ❑0 No ❑88 U/K
7. Vulvodynia ❑1 Yes ❑0 No ❑88 U/K
8. Gynecologic cancer ❑1 Yes ❑0 No ❑88 U/K
9. Vulvovestibulitis ❑1 Yes ❑0 No ❑88 U/K

(Men only)

10. Acute / Chronic Bacterial prostatitis ❑1 Yes ❑0 No ❑88 U/K
11. Epididymitis ❑1 Yes ❑0 No ❑88 U/K

Respiratory Tract Disorders/Allergies: (Both Men and Women)

12. Have you been diagnosed with having any respiratory tract disorders and/or allergies? ❑1 Yes ❑0 No ❑88 U/K

    If **Yes**, which of the following:

    a. Asthma ❑1 Yes ❑0 No ❑88 U/K
    b. Drug allergies ❑1 Yes ❑0 No ❑88 U/K
    c. Food allergies ❑1 Yes ❑0 No ❑88 U/K
    d. Skin allergies (contact dermatitis) ❑1 Yes ❑0 No ❑88 U/K

Medical History

RESEARCH COORDINATOR COMPLETES AT VISIT 1.

e. Sinusitis	❑1 Yes	❑0 No	❑88 U/K
f. Hayfever, allergic rhinitis	❑1 Yes	❑0 No	❑88 U/K
g. Latex allergies	❑1 Yes	❑0 No	❑88 U/K
h. Other allergies	❑1 Yes	❑0 No	❑88 U/K

Gastrointestinal Disease (Both Men and Women)

13. Have you been diagnosed with having any gastrointestinal diseases?	❑1 Yes	❑0 No	❑88 U/K
If **Yes**, which of the following:			
a. Irritable bowel syndrome	❑1 Yes	❑0 No	❑88 U/K
b. Diverticulitis	❑1 Yes	❑0 No	❑88 U/K
c. Ulcerative Colitis/Crohn's Disease	❑1 Yes	❑0 No	❑88 U/K
d. Other gastrointestinal disease	❑1 Yes	❑0 No	❑88 U/K

Endocrine or metabolic disease (Both Men and Women)

14. Have you been diagnosed with having any endocrine or metabolic diseases?	❑1 Yes	❑0 No	❑88 U/K
If **Yes**, which of the following:			
a. Diabetes	❑1 Yes	❑0 No	❑88 U/K
b. Hypothyroid disease	❑1 Yes	❑0 No	❑88 U/K
c. Hyperthyroid disease	❑1 Yes	❑0 No	❑88 U/K
d. Other endocrine or metabolic disease	❑1 Yes	❑0 No	❑88 U/K

Hematopoietic, lymphatic, or infectious disease (Both Men and Women)

15. Have you been diagnosed with having any blood, lymphatic, or infectious diseases?	❑1 Yes	❑0 No	❑88 U/K
If **Yes**, which of the following:			
a. Epstein-Barr virus/Chronic Fatigue Syndrome	❑1 Yes	❑0 No	❑88 U/K
b. Tuberculosis	❑1 Yes	❑0 No	❑88 U/K
c. HIV/AIDS	❑1 Yes	❑0 No	❑88 U/K
d. Viral Hepatitis (A,B,C,D,E)	❑1 Yes	❑0 No	❑88 U/K

Medical History

RESEARCH COORDINATOR COMPLETES AT VISIT 1.

Psychiatric Disease (Both Men and Women)

16. Have you been diagnosed with having any psychiatric diseases? ❑1 Yes ❑0 No ❑88 U/K

If **Yes**, which of the following:

a. Depression ❑1 Yes ❑0 No ❑88 U/K

b. Eating disorder ❑1 Yes ❑0 No ❑88 U/K

c. Anxiety/panic attacks ❑1 Yes ❑0 No ❑88 U/K

d. Suicide attempt ❑1 Yes ❑0 No ❑88 U/K

e. Other psychiatric disease ❑1 Yes ❑0 No ❑88 U/K

Sexually Transmitted Disease (Both Men and Women)

17. Have you been diagnosed with having any sexually transmitted diseases? ❑1 Yes ❑0 No ❑88 U/K

If **Yes**, which of the following:

a. Gonorrhea ❑1 Yes ❑0 No ❑88 U/K

b. Syphilis ❑1 Yes ❑0 No ❑88 U/K

c. Chlamydia ❑1 Yes ❑0 No ❑88 U/K

d. HIV/AIDS ❑1 Yes ❑0 No ❑88 U/K

e. Genital herpes ❑1 Yes ❑0 No ❑88 U/K

f. Genital warts ❑1 Yes ❑0 No ❑88 U/K

g. Trichomonas ❑1 Yes ❑0 No ❑88 U/K

h. Other sexually transmitted disease ❑1 Yes ❑0 No ❑88 U/K

(Men only)

If **Yes**, please respond to the following:

i. Nongonococcal Urethritis ❑1 Yes ❑0 No ❑88 U/K

Cardiovascular Disease (Both Men and Women)

18. Have you been diagnosed with having any cardiovascular diseases? ❑1 Yes ❑0 No ❑88 U/K

If **Yes**, which of the following:

a. Hypertension ❑1 Yes ❑0 No ❑88 U/K

Medical History

RESEARCH COORDINATOR COMPLETES AT VISIT 1.

b. High cholesterol	❑1 Yes	❑0 No	❑88 U/K
c. Coronary artery disease (heart attack, chest pain)	❑1 Yes	❑0 No	❑88 U/K
d. Stroke	❑1 Yes	❑0 No	❑88 U/K
e. Arrhythmia	❑1 Yes	❑0 No	❑88 U/K

Neurologic Disease (Both Men and Women)

19. Have you been diagnosed with having any neurological diseases?	❑1 Yes	❑0 No	❑88 U/K
If **Yes**, which of the following:			
a. Lumbosacral/Vertebral Disc Disease	❑1 Yes	❑0 No	❑88 U/K
b. Numbness or tingling in limbs	❑1 Yes	❑0 No	❑88 U/K
c. History of seizuers	❑1 Yes	❑0 No	❑88 U/K
d. Migraine headaches	❑1 Yes	❑0 No	❑88 U/K
e. Peripheral Neuropathy	❑1 Yes	❑0 No	❑88 U/K
f. Other neurological disease	❑1 Yes	❑0 No	❑88 U/K

Autoimmune/Other Disorders: (Both Men and Women)

20. Have you been diagnosed with having any autoimmune/ other disorders?	❑1 Yes	❑0 No	❑88 U/K
If **Yes**, which of the following:			
a. Fibromyalgia or Fibromyositis	❑1 Yes	❑0 No	❑88 U/K
b. Autommune Disorders (ex. Lupus, Rheumatoid Arthritis, Sjogren's Scleroderma)	❑1 Yes	❑0 No	❑88 U/K
c. Other musculoskeletal, rheumatologic, or connective tissue disease	❑1 Yes	❑0 No	❑88 U/K

Now I am going to ask some questions about some surgeries that you may have had.

(Women Only)

Urological/Gynecologic Surgeries:

21. Have you ever had urological/gynecologic surgeries?	❑1 Yes	❑0 No	❑88 U/K
If **Yes**, please respond to the following:			
a. Pelvic organ prolapse repair	❑1 Yes	❑0 No	❑88 U/K

Medical History

RESEARCH COORDINATOR COMPLETES AT VISIT 1.

b. Hysterectomy ❑1 Yes ❑0 No ❑88 U/K

c. Oophorectomy ❑1 Yes ❑0 No ❑88 U/K

d. Incontinence surgery ❑1 Yes ❑0 No ❑88 U/K

22. How many children have you given birth to by the following:

a. By vaginal delivery ___ ___ ❒ Not Applicable

b. By caesarean section ___ ___ ❒ Not Applicable

23. Are you postmenopausal? ❑1 Yes ❑0 No ❑88 U/K

CPCRN 2	*Randomized Clinical Trial #2 (Protocol – CP02)*	Participant ID: __ __ __ __ __	Participant Initials __ __ __
		Clinical Center: __ __	Visit Number __ __
		CRF Date: __ __/__ __/__ __ __ __	RC ID: __ __ __ __

Pain Medication Questionnaire

PARTICIPANT COMPLETES AT VISITS 2 AND 5.

*__PLEASE NOTE__: This form is completed only by Participants who are taking medication for pain. If a Participant is not taking any medication for pain, please do not complete this form.

1. How often has access to pain medication(s) been a problem for you?
   - ❑0 Not at all
   - ❑1 Occasionally
   - ❑2 Quite often
   - ❑3 Very often

2. How much do you expect your pain medication(s) to relieve your symptoms of pain or discomfort?
   - ❑1 Markedly worse
   - ❑2 Moderately worse
   - ❑3 Slightly worse
   - ❑4 No change
   - ❑5 Slightly improved
   - ❑6 Moderately improved
   - ❑7 Markedly improved

3. Over the past week, how often has your current pain medication(s) helped in relieving your symptoms of pain or discomfort?
   - ❑0 None of the time
   - ❑1 A little of the time
   - ❑2 Some of the time
   - ❑3 Most of the time
   - ❑4 All of the time

4. Over the past week, how would you rate your current pain as compared to the time before you started your current pain medication(s)?
   - ❑1 Markedly worse
   - ❑2 Moderately worse
   - ❑3 Slightly worse
   - ❑4 No change
   - ❑5 Slightly improved
   - ❑6 Moderately improved
   - ❑7 Markedly improved

5. Over the past week, how much has your pain medication(s) allowed you to do what you usually like to do?
   - ❑0 None
   - ❑1 Only a little
   - ❑2 Some
   - ❑3 A lot

6. Over the past week, how much has your pain medication(s) reduced the time you think about your pain?
   - ❑0 None
   - ❑1 Only a little
   - ❑2 Some
   - ❑3 A lot

7. Over the past week, please rate your satisfaction with your pain medication(s).
   - ❑0 Delighted
   - ❑1 Pleased
   - ❑2 Mostly satisfied
   - ❑3 Mixed (about equally satisfied and dissatisfied)
   - ❑4 Mostly dissatisfied
   - ❑5 Unhappy
   - ❑6 Terrible

CPCRN 2	*Randomized Clinical Trial #2 (Protocol – CP02)*	Participant ID: __ __ __ __ __	Participant Initials __ __ __
		Clinical Center: __ __	Visit Number __ __
		CRF Date: __ __/__ __/__ __ __ __	RC ID: __ __ __ __

Phase I – Participant Close Out

RESEARCH COORDINATOR COMPLETES AT VISIT 5 **ONLY** IF THE PARTICIPANT GOES ONTO PHASE II.

The following questions are for Phase I - Participant Close-Out. (Participant and Research Coordinator complete at Visit 5 when the participant agrees to participate in Phase II of this trial.)

1. Do you think the current status of your symptoms is related to the study medications?
   ❑$_1$ Yes ❑$_0$ No

2. Which medication do you think you received?
   ❑$_1$ Pregabalin
   ❑$_2$ Placebo
   ❑$_{88}$ Couldn't tell

3. Referring to your response in question #2, what made you think that?
   ❑$_1$ CP was better
   ❑$_2$ CP was worse
   ❑$_3$ CP remained unchanged
   ❑$_4$ Experienced side effects
   ❑$_5$ Did not experience side effects
   ❑$_{98}$ Other: _____

Research Coordinator completes question #4:

4. Which medication do you think the participant received?
   ❑$_1$ Pregabalin
   ❑$_2$ Placebo
   ❑$_{88}$ Couldn't tell

NOTE: It is important to collect this information at Week 6 (Visit 5) when the participant is going onto Phase II. This information is important to the primary outcome analysis.

CPCRN 2	*Randomized Clinical Trial #1 (Protocol – CP02)*	Clinical Center __ __ CRF Date: __ __/__ __/__ __ __ __ RC ID: __ __ __ __

Pre-screening Summary

1. Month of Report: __ __/__ __ __ __ (MM/YYYY)

2. Number of subjects whose data sources were reviewed ___ ___ ___
3. Number of subjects who are not contacted ___ ___ ___
4. Summary of why subjects are not contacted:
   a. Ineligible ___ ___ ___
   b. Investigator's discretion ___ ___ ___
   c. Other ___ ___ ___

5. Number of subjects with initial contact this month ___ ___ ___
   a. Number who were contacted by phone ___ ___ ___
   b. Number who were contacted in person ___ ___ ___
   c. Number who were contacted by written correspondence ___ ___ ___

5.1 Number of subjects no longer considered for participation ___ ___ ___

5.2 Number of subjects under consideration for participation ___ ___ ___

6. Number of subjects who agreed to participate ___ ___ ___

6a. Number of subjects who agreed to participate but not yet screened ___ ___ ___

7. Number of subjects who declined to consider participation ___ ___ ___

8. Summary of why subjects declined to participate:
   a. Number of subjects who are not interested in participating/following protocol? ___ ___ ___
   b. Number of subjects who did not consider this study beneficial? ___ ___ ___
   c. Number of subjects who have concerns about the research processes? ___ ___ ___
   d. Number of subjects who have medical condition(s) unrelated to chronic pain that may interfere with participation? ___ ___ ___
   e. Number of subjects who prefer (additional) compensation? ___ ___ ___
   f. Number of subjects who have concerns about data privacy/ protection of personal medical information? ___ ___ ___
   g. Number of subjects who are not bothered enough by the symptoms to justify drug treatment. ___ ___ ___
   h. Number of subjects who have symptoms so severe they want active drug and will not risk placebo. ___ ___ ___

Pre-screening Summary

9. Number of subjects who learned about this study through:
   a. Physician for this study ___ ___ ___
   b. Other physicians ___ ___ ___
   c. Central database ___ ___ ___
   d. Newspaper ___ ___ ___
   e. Internet ___ ___ ___
   f. Other ___ ___ ___

CPCRN 2	*Randomized Clinical Trial #2 (Protocol – CP02)*	Participant ID: __ __ __ __ __	Participant Initials __ __ __
		Clinical Center: __ __	Visit Number __ __
		CRF Date: __ __/__ __/__ __ __ __	RC ID: __ __ __ __

Randomization

RESEARCH COORDINATOR COMPLETES AT VISIT 2.

1. Did the participant meet all of the eligibility criteria at the first baseline visit? ❑$_1$ Yes ❑$_0$ No
2. Does the participant still meet all of the eligibility criteria at the second baseline visit? ❑$_1$ Yes ❑$_0$ No
3. Record randomization number ___ ___ ___ ___ ___

CPCRN 2	*Randomized Clinical Trial #2 (Protocol – CP02)*	Participant ID: __ __ __ __ __	Participant Initials __ __ __
		Clinical Center: __ __	Visit Number __ __
		CRF Date: __ __/__ __/__ __ __ __	RC ID: __ __ __ __

Study Stop Point

RESEARCH COORDINATOR COMPLETES AT VISIT 5 IF THE PARTICIPANT OPTS NOT TO CONTINUE UNTO PHASE II OR WITHDRAWS FROM STUDY PRIOR TO VISIT 5.

RESEARCH COORDINATOR COMPLETES AT VISIT 9 IF THE PARTICIPANT CONTINUED UNTO PHASE II OR WITHDRAWS FROM STUDY BETWEEN VISITS 7 AND VISIT 9.

1. Has the participant successfully completed this phase? ❑1 Yes ❑0 No

   If **"yes"** to question #1, please stop here.

   If **No**, indicate reason for withdrawal:

   a. No longer willing to follow the protocol/interested in participating ❑1 Yes ❑0 No
   b. Participant dissatisfied with treatment ❑1 Yes ❑0 No
   c. Lost to follow-up ❑1 Yes ❑0 No
   d. Participant has personal constraints ❑1 Yes ❑0 No
   e. Adverse Event/Serious Adverse Event ❑1 Yes ❑0 No
   f. Physician's Discretion ❑1 Yes ❑0 No
   g. Other (Specify: _____) ❑1 Yes ❑0 No

2. Visit Number that the participant was last seen: ___ ___

3. Date that the participant was last seen: __ __/__ __/__ __ __ __ (MM/DD/YYYY)

The following questions are for Participant Close-Out. *(Participant and Research Coordinator completes if participant opts not to participate in Phase II.)*

4. Do you think the current status of your symptoms is related to the study medications? ❑1 Yes ❑0 No

5. Which medication do you think you received?
   ❑1 Pregabalin
   ❑2 Placebo
   ❑88 Couldn't tell

6. Referring to your response in question #5, what made you think that?
   ❑1 CP was better
   ❑2 CP was worse
   ❑3 CP remained unchanged
   ❑4 Experienced side effects
   ❑5 Did not experience side effects
   ❑98 Other: _____

Research Coordinator completes question #7:

7. Which medication do you think the participant received?
   ❑1 Pregabalin
   ❑2 Placebo
   ❑88 Couldn't tell

Study Stop Point

RESEARCH COORDINATOR COMPLETES AT VISIT 5 IF THE PARTICIPANT OPTS NOT TO CONTINUE UNTO PHASE II OR WITHDRAWS FROM STUDY PRIOR TO VISIT 5.

RESEARCH COORDINATOR COMPLETES AT VISIT 9 IF THE PARTICIPANT CONTINUED UNTO PHASE II OR WITHDRAWS FROM STUDY BETWEEN VISITS 7 AND VISIT 9.

The following section is for Study Close-out.

(PRINCIPAL INVESTIGATOR AND RESEARCH COORDINATOR COMPLETE WHEN PARTICIPANT STOPS PARTICIPATION IN THE STUDY.)

8. Physician Comments (optional): _____

_____

_____

SIGNATURES: Please complete the following section regardless of the reason for termination of study participation.

I verify that all information collected on the CPCRN-2 data collection forms for this participant is correct to the best of my knowledge and was collected in accordance with the procedures outlined in the CPCRN-2 Protocol and Manual of Procedures.

_____ Date: ___ ___/___ ___/___ ___ ___ ___

Principal Investigator's Signature (MM/DD/YYYY)

9. Did the PI sign this form? ❑$_1$ Yes ❑$_0$ No

_____ Date: ___ ___/___ ___/___ ___ ___ ___

Research Coordinator's Signature (MM/DD/YYYY)

10. Did the RC sign this form? ❑$_1$ Yes ❑$_0$ No

CPCRN 2	*Randomized Clinical Trial #2 (Protocol – CP02)*	Participant ID: __ __ __ __ __	Participant Initials __ __ __
		Clinical Center: __ __	Visit Number __ __
		CRF Date: __ __/__ __/__ __ __ __	RC ID: __ __ __ __

Standard Telephone and Clinic Contact Summary

RESEARCH COORDINATOR COMPLETES AT VISITS 3, 4, 5, 6, 7, 8, 9 AND 10.

1. What dose of the study medication are you currently taking?
   - ❒1 150 mg
   - ❒2 300 mg
   - ❒3 600 mg
   - ❒97 Not taking study drug
2. Is this a different dose from the previous contact? ❒1 Yes ❒0 No

If the answer to Question #2 is ***Yes*****,** please answer Questions 2a, 2b, and 2c.
If the answer to Question #2 is ***No*****,** please answer Question 2d only.

   a. What was the previous dose?
      - ❒1 150 mg
      - ❒2 300 mg
      - ❒3 600 mg
      - ❒97 Not taking study drug

   b. Please indicate the reason for this change in dose:
      - ❒1 Titration up (to maximum tolerable dose)
      - ❒2 Unable to tolerate previous higher dose
      - ❒3 Taper down (at end of study)
      - ❒4 Titration down
      - ❒5 Refused to take study drug

   c. Date dose was changed: ___ ___/___ ___/___ ___ ___ ____ (MM/DD/YYYY)

   d. Please indicate the reason for no change in dose:
      - ❒1 AE/Side Effect(s)
      - ❒2 Refused to titrate up
      - ❒3 Tapered down to previous fixed dose
      - ❒4 Refused to taper down

3. Since the previous contact, have you taken your study medication every day? ❒1 Yes ❒0 No

   If the answer to Question #3 is ***No*****,** please answer Question 3a and 3b.

   a. Please indicate how many days you have missed taking your study medication since the last visit. ____ ____

   b. Please indicate the reason why you have not taken your study medication every day.
      - ❒1 AE/Side Effect(s)
      - ❒2 Refused to take study medication
      - ❒3 Forgot to take study medication
      - ❒98 Other (Please Specify): _____

Please note for Questions 2b, 2d, and 3b. – If the reason for either a reduction in dose or no change in dose is due to the participant being unable to tolerate a higher dose or due to an AE, the symptom(s) related to the need for the dose reduction or no change in dose *MUST* be recorded on the **AE** form.

If a Phase II visit, please stop at Question #3.

Standard Telephone and Clinic Contact Summary

RESEARCH COORDINATOR COMPLETES AT VISITS 3, 4, 5, 6, 7, 8, 9 AND 10.

4. What is your best guess today as to which treatment you have been assigned?
   - ❑1 Definitely drug
   - ❑2 Probably drug
   - ❑3 Possibly drug
   - ❑4 Possibly placebo
   - ❑5 Probably placebo
   - ❑6 Definitely placebo

5. Referring to your response in question #4, what made you think that?
   - ❑1 CP was better
   - ❑2 CP was worse
   - ❑3 CP remained unchanged
   - ❑4 Experienced side effects
   - ❑5 Did not experience side effects
   - ❑98 Other: _____

Please complete Q#6 at Visit 5 ***only***:

6. Is this participant going onto Phase II? ❒1 Yes ❒0 No

CPCRN 2	*Randomized Clinical Trial #2 (Protocol – CP02)*	Participant ID: __ __ __ __ __	Participant Initials __ __ __
		Clinical Center: __ __	Visit Number __ __
		CRF Date: __ __/__ __/__ __ __ __	RC ID: __ __ __ __

Symptom Assessment

PARTICIPANT COMPLETES AT VISITS 1, 2, 3, 4, 5, 6, 7, 8, 9, AND 10.

1. Think about the pain/discomfort associated with your bladder, prostate, and/or pelvic region.
   a. **On average,** how would you rate this **pain/discomfort** during the past 4 weeks? (Please **circle** the number that best describes this **pain/discomfort**.)

No pain/discomfort **Most severe pain I can imagine**

0 1 2 3 4 5 6 7 8 9 10

   b. How long has this pain/discomfort described in Question #1a been present?

(Please **check** the option that best describes your answer.)

❑$_1$ less than 4 weeks ❑$_2$ 4 weeks or more

2. Urgency is defined as the urge or pressure to urinate.
   a. **On average,** how would you rate the **urgency** that you have felt during the past 4 weeks? (Please **circle** the number that best describes this **urgency**.)

No urgency **Most severe urgency I can imagine**

0 1 2 3 4 5 6 7 8 9 10

   b. How long has this urgency described in Question #2a been present?

(Please **check** the option that best describes your answer.)

❑$_1$ less than 4 weeks ❑$_2$ 4 weeks or more

3. Think about your frequency of urination compared to what you consider to be normal.
   a. **On average,** how would you rate your frequency of urination during the past 4 weeks? (Please **circle** the number that best describes this **frequency**.)

Totally normal **Most severe frequency I can imagine**

0 1 2 3 4 5 6 7 8 9 10

   b. How long has this frequency described in Question #3a been present?

(Please **check** the option that best describes your answer.)

❑$_1$ less than 4 weeks ❑$_2$ 4 weeks or more

   c. **On average**, during the past 4 weeks, how many times did you urinate in a 24-hour period? (Please **check** the option that best describes your answer.)

❑$_1$ 6 times or less ❑$_2$ 7-10 times ❑$_3$ 11 – 14 times ❑$_4$ 15 times or more

(Question #4 is for treatment/follow-up visits only)

4. As compared to when you started the study, how would you rate your overall symptoms now?

❑$_1$ Markedly worse
❑$_2$ Moderately worse
❑$_3$ Slightly worse
❑$_4$ No change
❑$_5$ Slightly improved
❑$_6$ Moderately improved
❑$_7$ Markedly improved

CPCRN 2	*Randomized Clinical Trial #2 (Protocol – CP02)*	Participant ID: __ __ __ __ __	Participant Initials __ __ __
		Clinical Center: __ __	Visit Number __ __
		CRF Date: __ __/__ __/__ __ __ __	RC ID: __ __ __ __

Treatment Stop Point

RESEARCH COORDINATOR COMPLETES AT VISIT 9, OR IF THE PARTICIPANT WITHDRAWS FROM TREATMENT PRIOR TO VISIT 9.

1. Date participant took final dose of study agent. __ __/__ __/__ __ __ __ (MM/DD/YYYY)
2. Has the participant stopped treatment early? ❑1 Yes ❑0 No
3. Use of unacceptable medication ❑1 Yes ❑0 No
4. Adverse Event, *as determined by the PI* ❑1 Yes ❑0 No
   a. Listed on Adverse Event form as AE #: ___ ___ ___
   b. Date of onset: __ __/__ __/__ __ __ __ (MM/DD/YYYY)
   c. Please specify: _____
5. Adverse Event, *as determined by the Participant* ❑1 Yes ❑0 No
   a. Listed on Adverse Event form as AE #: ___ ___ ___
   b. Date of onset: __ __/__ __/__ __ __ __ (MM/DD/YYYY)
   c. Please specify: _____
6. Participant dissatisfied with treatment ❑1 Yes ❑0 No
   a. Please specify reason: _____
7. Participant no longer interested in participating ❑1 Yes ❑0 No
   a. Please specify reason: _____
8. Participant was lost to follow up. ❑1 Yes ❑0 No
   a. Please specify reason: _____
9. Participant has personal constraints ❑1 Yes ❑0 No
   a. Please specify reason: _____
10. Physician's Discretion ❑1 Yes ❑0 No
    a. Please specify reason: _____
11. Other ❑1 Yes ❑0 No
    a. Please specify reason: _____

CPCRN 2	*Randomized Clinical Trial #2 (Protocol – CP02)*	Participant ID: __ __ __ __ __	Participant Initials __ __ __
		Clinical Center: __ __	Visit Number __ __
		CRF Date: __ __/__ __/__ __ __ __	RC ID: __ __ __ __

Unmasking Record

Research Coordinator completes if the study drug needs to be unmasked.

Photocopies of this form with signatures must be sent to the DCC.

1. Date of unmasking: __ __/__ __/__ __ __ __ (MM/DD/YYYY)
2. Time of unmasking: ___ ___:___ ___ ❑1 AM ❑2 PM
3. Randomization Number: ___ ___ ___ ___ ___
4. Was the DCC contacted within 24 hours of unmasking? ❑1 Yes ❑0 No
   a. If ***Yes***, name of person contacted: _____
   b. If ***No***, state the reason: _____
5. Was the study drug unmasked because of an SAE? ❑1 Yes ❑0 No
   a. Listed on Adverse Event form as AE # ___ ___ ___

P.I. Signature: _____ Date: __ __/__ __/__ __ __ __ (MM/DD/YYYY) PI ID: __ __ __ __

Directions: Fax this form to the DCC at (215) 573-4790.

Urine Screening

RESEARCH COORDINATOR COMPLETES AT VISIT 1.

1. Date urine sample obtained: __ __ / __ __ / __ __ __ __ (MM/DD/YYYY)
2. Dipstick Urinalysis: ❒$_1$ Normal ❒$_0$ Abnormal

   If **ABNORMAL**, please check if present:

   a. Nitrite ❒$_1$ Yes ❒$_0$ No
   b. Occult Blood ❒$_1$ Yes ❒$_0$ No
   c. Leukocytes ❒$_1$ Yes ❒$_0$ No
   d. Protein / Ketones ❒$_1$ Yes ❒$_0$ No

3. Did this participant have a positive urine culture (colony count of more **10^3** of uropathogens)? ❒$_1$ Yes ❒$_0$ No

(Question #s 4 and 5 for males only, check N/A for females)

4. Date residual urine volume measured: __ __ / __ __ / __ __ __ __ (MM/DD/YYYY)

   OR ❒ N/A

5. Was the residual urine volume greater than 100 cc as measured by ultrasound or catheter? ❒$_1$ Yes ❒$_0$ No ❒$_{99}$ N/A