C P C R N ***Randomized Clinical Trial #1***

FORMS ADMINISTRATION SCHEDULE

	Screening		+3 weeks	+6 weeks	+9 weeks	+12 weeks	Early Stop Treatment	Rescue Event
Form	Visit 1 *(clinic)*	Visit 2 *(clinic)*	Visit 3 *(phone)*	Visit 4 *(clinic)*	Visit 5 *(phone)*	Visit 6 *(phone)*	Visit 98 *(PRN)*	Visit 99 *(PRN)*
Eligibility Checklist (**ELIG**)	X							
NIH-CPSI (**CPSI**)	X	X	X	X	X	X	X	X
Randomization (RAND)		**X**						
SF-12 (**SF12**), Follow-Up Symptoms (**SYM**)		X	X	X	X	X	X	X
Demographics (**DEMO**)		X						
Dispensing Log (**DISP**)		X						
Concomitant Medication (**CMED**)		X		X				
Follow-Up Contacts (**FUP**)			X	X	X	X		
Adverse Events/Serious Adverse Events (**AE**)			X	X	X	X		
Medical History (**MED**)	X							
Physical Exam (**EXAM**)	X			X				
Four Glass Test Microscopy (**FGTM**)	X			X				
Four Glass Test Cultures (**FGTC**)	X			X				
Semen Sample (**SEMEN**)		X		X				
Uroflow and PVR (**URO**)		X		X*				
Voiding Log (**VOID**)		X		X				
Treatment Stop (**TSTOP**)				X			X	
Study Stop (**SSTOP**)						X		
Rescue Treatment Event (**RMED**)								X
Unmasking** (**UNMASK**)								
Patient Contact Information	X							
Visit Checklist	X	X	X	X	X	X	X	X
Study Medication Tracking Log		X		X			X	
Participant Status Log	X	X				X		
Participant ID Assignment Log	X							

* PVR Only.
** This form is completed only when clinically needed.

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Randomized Clinical Trial #1

Participant ID: ___ ___ ___ ___ ___
Participant Initials: ___ ___ ___
Clinical Center: ___ ___
Visit Number: ___ ___
Visit Date: ___ ___ / ___ ___ / ___ ___ ___ ___
RC ID: ___ ___ ___ ___

ADVERSE EVENTS AND SERIOUS ADVERSE EVENTS

List all adverse events that have newly occurred, changed, or resolved.

1. Were there any new adverse events, or follow-ups to adverse events from the previous visit, reported by the patient at this visit? ❑1 Yes ❑0 No
If YES, list the number of (S)AEs to be recorded at this visit. ___ ___

Adverse Event Number	Event Code	Date of Onset Mark box if AE is continuing from a previous visit	Grade	Duration	Frequency	Relationship to Study Drug?	Action taken regarding study drug?	Treatment for event?	Outcome	Date of Resolution Enter date OR check box if AE is continuing	Was the event serious?
AE #	**From CTC List**	mm/dd/yyyy	record one	record one	record one	record one	record one	record one	record most appropriate	mm/dd/yyyy	record one
__ __ __	__ __ __ __ __ __	__ __/__ __/__ __ __ __ ❑								__ __/__ __/__ __ __ __ ❑	
Specify Event (CTC Criteria):					Description of Event/Comment:						
__ __ __	__ __ __ __ __ __	__ __/__ __/__ __ __ __ ❑								__ __/__ __/__ __ __ __ ❑	
Specify Event (CTC Criteria):					Description of Event/Comment:						
__ __ __	__ __ __ __ __ __	__ __/__ __/__ __ __ __ ❑								__ __/__ __/__ __ __ __ ❑	
Specify Event (CTC Criteria):					Description of Event/Comment:						
__ __ __	__ __ __ __ __ __	__ __/__ __/__ __ __ __ ❑								__ __/__ __/__ __ __ __ ❑	
Specify Event (CTC Criteria):					Description of Event/Comment:						
__ __ __	__ __ __ __ __ __	__ __/__ __/__ __ __ __ ❑								__ __/__ __/__ __ __ __ ❑	
Specify Event (CTC Criteria):					Description of Event/Comment:						

Investigator's Signature: ____

Date of Signature: ___ ___ / ___ ___ / ___ ___ ___ ___ PI ID: ___ ___ ___ ___

Participant ID: ___ ___ ___ ___ ___
Participant Initials: ___ ___ ___
Clinical Center: ___ ___
Visit Number: ___ ___
Visit Date: ___ ___ / ___ ___ / ___ ___ ___ ___
RC ID: ___ ___ ___ ___

Key:

Grade:
0=None
1=Mild
2=Moderate
3=Severe
4=Life-threatening or Disabling
5=Fatal
88=UNK

Duration:
1=Minutes
2=Hours
3=Days
88=UNK

Frequency:
1=Once
2=2 or 3 Episodes
3=4 or more Episodes
4=Daily

Relationship to study drug?
1=Not Related
2=Possibly Related
3=Definitely Related
88=Unknown/ Undetermined

Action taken regarding study drug?
0=None
1=Drug Interrupted
2=Drug Discontinued
99=N/A

Treatment for event?
1=Yes
0=No

Outcome:
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

***Indicates Serious Adverse Events**
Outcome of Serious is based on PI's judgement

Was the event serious?
1=Yes
0=No

SAE Contact Information: (*Notify the following within 24 hours of knowledge of event*)
1. On-Site Investigator
2. Clinical Center IRB
3. DCC -- Phone: (215) 573-6318
   Fax: (215) 573-6262

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Randomized Clinical Trial #1

Participant ID: ___ ___ ___ ___ ___
Participant Initials: ___ ___ ___
Clinical Center: ___ ___
Visit Number: ___ ___
Visit Date: ___ ___ / ___ ___ / ___ ___ ___ ___
RC ID: ___ ___ ___ ___

CONCOMITANT MEDICATION

List all over-the-counter and prescription medications taken at entry and during the course of the trial.

1. Did the participant start or stop any medications at this visit? ❑1 Yes ❑0 No
   If YES, list the number of medications to be recorded at this visit. __ __

Line # 3-digits	Drug Code # from Medication Reference Tool	Drug Name	Total Daily Dose Total Daily Dose or PRN	Unit	Route	Start Date Check box if continuing from an earlier visit mm/dd/yyyy	Stop Date Check box if continuing from an earlier visit mm/dd/yyyy	Exclusionary/ Restricted Medication? 1 = Yes 0 = No	Was this for chronic prostatitis? 1=Yes 0=No
__ __ __						__ __/__ __/__ __ __ __ ❑	__ __/__ __/__ __ __ __ ❑		
__ __ __						__ __/__ __/__ __ __ __ ❑	__ __/__ __/__ __ __ __ ❑		
__ __ __						__ __/__ __/__ __ __ __ ❑	__ __/__ __/__ __ __ __ ❑		
__ __ __						__ __/__ __/__ __ __ __ ❑	__ __/__ __/__ __ __ __ ❑		
__ __ __						__ __/__ __/__ __ __ __ ❑	__ __/__ __/__ __ __ __ ❑		
__ __ __						__ __/__ __/__ __ __ __ ❑	__ __/__ __/__ __ __ __ ❑		
__ __ __						__ __/__ __/__ __ __ __ ❑	__ __/__ __/__ __ __ __ ❑		
__ __ __						__ __/__ __/__ __ __ __ ❑	__ __/__ __/__ __ __ __ ❑		
__ __ __						__ __/__ __/__ __ __ __ ❑	__ __/__ __/__ __ __ __ ❑		

Line #	If needed, briefly comment on Concomitant Medication (e.g. unit, route, etc.) below by line number

Participant ID: ___ ___ ___ ___ ___
Participant Initials: ___ ___ ___
Clinical Center: ___ ___
Visit Number: ___ ___
Visit Date: ___ ___ / ___ ___ / ___ ___ ___ ___
RC ID: ___ ___ ___ ___

CONCOMITANT MEDICATIONS

Use the codes below in completing the CMED form.

Unit	Route
1=mg 2=mL 3=tablets 4=capsules 5=teaspoons 6=drops 7=cream 8=spray 9=tablespoons 98=other	1=oral 2=IV 3=IM 4=SC 5=topical 6=rectal 7=nasal 8=transdermal 9=inhalant 10=sublingual 98=other

Participant ID: ___ ___ ___ ___ ___
Participant Initials: ___ ___ ___
Clinical Center: ___ ___
Visit Number: ___ ___
Visit Date: ___ ___ / ___ ___ / ___ ___ ___ ___
RC ID: ___ ___ ___ ___

NIH - CHRONIC PROSTATITIS SYMPTOM INDEX

Today's Date: ___ ___ / ___ ___ / ___ ___ ___ ___

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 your 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

Participant ID: ___ ___ ___ ___ ___
Participant Initials: ___ ___ ___
Clinical Center: ___ ___
Visit Number: ___ ___
Visit Date: ___ ___ / ___ ___ / ___ ___ ___ ___
RC ID: ___ ___ ___ ___

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

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)

CASE REPORT FORM VERSION LOG -- **DATA COLLECTION**

Form Code	Form Name	Latest Version Number
AE	Adverse Events and Serious Adverse Events	v2.0 041601
CMED	Concomitant Medication	v1.3 110601
CPSI	NIH - Chronic Prostatitis Symptom Index	v1.1 041601
CRFLOG	Case Report Form Version Log -- Data Collection	v1.1 102201
DEMO	Demographics	v1.1 041601
DISP	Dispensing Log	v1.0 041601
ELIG	Eligibility Checklist	v2.0 111201
EXAM	Physical Exam	v1.2 041601
FGTC	Four Glass Test - Cultures	v1.5 052401
FGTM	Four Glass Test - Microscopy	v1.3 060401
FUP	Follow-up Contacts	v1.4 050901
MED	Medical History	v1.1 041601
RAND	Randomization	v1.5 052401
RMED	Rescue Treatment Event	v1.4 042601
SCHEDULE	Forms Administration Schedule	v2.2 050301
SEMEN	Semen Sample	v1.5 102201
SF12	SF-12	v1.0 041601
SSTOP	Study Stop Point	v1.0 041601
SYM	Follow-up Symptoms	v1.0 041601
TSTOP	Treatment Stop Point	v1.1 041601
UNMASK	Unmasking Record	v1.2 042601
URO	Uroflow	v1.4 041601
VOID	Voiding Log	v1.1 041601

Participant ID: ___ ___ ___ ___ ___
Participant Initials: ___ ___ ___
Clinical Center: ___ ___
Visit Number: ___ ___
Visit Date: ___ ___ / ___ ___ / ___ ___ ___ ___
RC ID: ___ ___ ___ ___

DEMOGRAPHICS

To be completed by the study participant…

1. What is your date of birth? ___ ___ / ___ ___ / ___ ___ ___ ___

2. How do you describe yourself?
   - ❑1 Asian or Pacific Islander
   - ❑2 Black/African-American (not Latino/ Hispanic)
   - ❑3 Latino/Hispanic/Mexican-American
   - ❑4 Native American
   - ❑5 White/Caucasian (not Latino/ Hispanic)
   - ❑6 Multiracial
   - ❑7 Other

3. What is the highest educational level you have attained?
   - ❑1 Less than high school
   - ❑2 High school or GED
   - ❑3 Some college/university
   - ❑4 Graduated from college/university
   - ❑5 Graduate or professional school after college/university

4. Are you currently living with a spouse or partner?
   - ❑1 Yes
   - ❑0 No

5. What is your current employment status?
   - ❑1 Employed
   - ❑2 Unemployed
   - ❑3 Retired
   - ❑4 Disabled
   - ❑5 Homemaker

6. What is your ZIP (US) or Postal (Canadian) code?
   - a. ZIP Code (for US Residents) ___ ___ ___ ___ ___
   - b. Postal Code (for Canadian Residents) ___ ___ ___ ___ ___ ___

7. How were you referred to the CPCRN clinical trial?

- ❑1 Urologist for this study
- ❑2 Other urologist
- ❑3 Other non-urology physician
- ❑4 Newspaper
- ❑5 Internet
- ❑6 Other

To be completed by the RC…

8. Is the participant enrolled in the Chronic Prostatitis Cohort (CPC) Study?
   - ❑1 Yes
   - ❑0 No

   If ***Yes***,

   a. Participant's CPC Patient ID ___ ___ ___ ___ ___

   b. Participant's initials ___ ___ ___

Participant ID: ___ ___ ___ ___ ___
Participant Initials: ___ ___ ___
Clinical Center: ___ ___
Visit Number: ___ ___
Visit Date: ___ ___ / ___ ___ / ___ ___ ___ ___
RC ID: ___ ___ ___ ___

DISPENSING LOG

1. Date *CIPRO*® capsules dispensed: ___ ___ / ___ ___ / ___ ___ ___ ___

2. Total number of *CIPRO*® capsules dispensed: ___ ___ ___
(Record on Study Medication Tracking Log)

Affix and sign the drug label for the *CIPRO*® capsules here
Record on Study Medication Tracking Log

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3. Date *Flomax*® capsules dispensed: ___ ___ / ___ ___ / ___ ___ ___ ___

4. Total number of *Flomax*® capsules dispensed: ___ ___ ___
(Record on Study Medication Tracking Log)

Affix and sign the drug label for the *Flomax*® capsules here
Record on Study Medication Tracking Log

NOTE: By signing the labels 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.

Participant ID: ___ ___ ___ ___ ___
Participant Initials: ___ ___ ___
Clinical Center: ___ ___
Visit Number: ___ ___
Visit Date: ___ ___ / ___ ___ / ___ ___ ___ ___
RC ID: ___ ___ ___ ___

ELIGIBILITY CHECKLIST

Inclusion Criteria

1. ***Participant has signed and dated the appropriate Informed Consent document.*** ❑$_1$ Yes ❑$_0$ No

   a. If ***Yes***, record the date the form was signed. __ __ / __ __ / __ __ __ __

2. Participant is a male. ❑$_1$ Yes ❑$_0$ No

3. Participant must have 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

4. Participant has at least a moderate overall score on the NIH-CPSI (overall score ≥ 15 out of a potential of 0 - 43 points). ❑$_1$ Yes ❑$_0$ No

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

Exclusion Criteria

5. Participant has a history of prostate, bladder, or urethral cancer. ❑$_1$ Yes ❑$_0$ No

6. Participant has inflammatory bowel disease (such as Crohn's disease or ulcerative colitis, but not irritable bowel syndrome). ❑$_1$ Yes ❑$_0$ No

7. Participant has undergone pelvic radiation or systemic chemotherapy. ❑$_1$ Yes ❑$_0$ No

8. Participant has undergone intravesical chemotherapy. ❑$_1$ Yes ❑$_0$ No

9. Participant has been treated with intravesical BCG. ❑$_1$ Yes ❑$_0$ No

10.	Participant has been treated for unilateral orchialgia without pelvic symptoms.	❑$_1$ Yes	❑$_0$ No
11.	Participant has an active urethral stricture.	❑$_1$ Yes	❑$_0$ No
12.	Participant has a neurological disease or disorder affecting the bladder.	❑$_1$ Yes	❑$_0$ No
13.	Participant has undergone TURP, TUIP, TUIBN, TUMT, TUNA, balloon dilatation of the prostate, open prostatectomy, or any other prostate surgery or treatment such as cryotherapy or thermal therapy.	❑$_1$ Yes	❑$_0$ No
14.	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
15.	Participant has liver disease.	❑$_1$ Yes	❑$_0$ No
16.	Participant has a known allergy or sensitivity to ciprofloxacin hydrochloride (CIPRO®), tamulosin hydrochloride (Flomax®), or any of their known components.	❑$_1$ Yes	❑$_0$ No
17.	Participant has a history of seizure disorder.	❑$_1$ Yes	❑$_0$ No
18.	Participant is taking theophylline, phenytoin, probenecid, or warfarin.	❑$_1$ Yes	❑$_0$ No
19.	Participant requires ongoing use of magnesium, aluminum, or calcium-containing antacids.	❑$_1$ Yes	❑$_0$ No

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

Deferral Criteria

20.	Participant has been treated with tamulosin hydrochloride (Flomax®), doxazosin mesylate(Cardura®), terazosin HCL (Hytrin®), or alpha-blockers in the past four (4) weeks.	❑$_1$ Yes	❑$_0$ No
21.	Participant has been treated with ciprofloxacin hydrochloride (CIPRO®) in the past four (4) weeks.	❑$_1$ Yes	❑$_0$ No
22.	Participant has been treated with antimicrobial agents (oral or parenteral) in the past four (4) weeks.	❑$_1$ Yes	❑$_0$ No
23.	Participant has started, stopped, or changed dose level for **ANY** prostatitis-specific medications within the past four (4) weeks.	❑$_1$ Yes	❑$_0$ No
24.	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
25.	Participant has had clinical evidence of urethritis, e.g. including urethral discharge or positive culture, within the past three (3) months, diagnostic of the following sexually transmitted diseases (STDs): gonorrhea, chlamydia, mycoplasma or trichomonas, but not including HIV/AIDS.	❑$_1$ Yes	❑$_0$ No
26.	Participant has had a prostate biopsy in the past three (3) months.	❑$_1$ Yes	❑$_0$ No
27.	Participant has experienced symptoms of acute or chronic epididymitis within the past three (3) months.	❑$_1$ Yes	❑$_0$ No
28.	Participant has begun finasteride (Proscar®) or other androgen hormone inhibitors in the past six (6) months, or stopped finasteride (Proscar®) or other androgen hormone inhibitors within the past six (6) months.	❑$_1$ Yes	❑$_0$ No
29.	Participant has used bioflavonoid agents in the past two (2) weeks. [Example: Quercetin]	❑$_1$ 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 been taking zinc or iron supplements within the past two (2) weeks. ❑$_1$ Yes ❑$_0$ No

32. Participant has been treated with cimetidine in the past two (2) weeks. ❑$_1$ Yes ❑$_0$ No

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

⇨ **IF ANY RESPONSES TO THE DEFERRAL CRITERIA ARE "YES" INDICATE DATE PARTICIPANT WILL BECOME ELIGIBLE FOR RE-SCREENING.**

DATE: __ __/__ __/__ __ __ __ (mm/dd/yyyy)

Participant ID: ___ ___ ___ ___ ___
Participant Initials: ___ ___ ___
Clinical Center: ___ ___
Visit Number: ___ ___
Visit Date: ___ ___ / ___ ___ / ___ ___ ___ ___
RC ID: ___ ___ ___ ___

PHYSICAL EXAM

1. Height *(to be completed at screening only)*
   Enter either inches or cm.
   ___ ___ ___ . ___ inches
   ___ ___ ___ . ___ cm

2. Weight
   Enter either lbs. or kgs.
   ___ ___ ___ ___ . ___ lbs
   ___ ___ ___ ___ . ___ kgs

3. Blood Pressure
   ___ ___ ___ systolic (mmHg)
   ___ ___ ___ diastolic (mmHg)

4. Abdomen
   ❑1 Normal
   ❑2 Mass
   ❑3 Organomegaly

   a. Abdominal tenderness ❑1 Yes ❑0 No

5. Flanks
   ❑1 Normal
   ❑2 Mass

   a. Flank tenderness ❑1 Yes ❑0 No

6. Varicocele
   ❑0 Absent
   ❑1 Present

   a. Varicocele tenderness ❑1 Yes ❑0 No

7. Hydrocele
   ❑0 Absent
   ❑1 Present

   a. Hydrocele tenderness ❑1 Yes ❑0 No

8. Inguinal Hernia
   ❑0 Absent
   ❑1 Present

   a. Inguinal hernial tenderness ❑1 Yes ❑0 No

9. Is there any <u>tenderness</u> in the following areas?

a.	Coccyx	❑$_1$ Yes	❑$_0$ No
b.	Pubis	❑$_1$ Yes	❑$_0$ No
c.	Suprapubic area	❑$_1$ Yes	❑$_0$ No
d.	External pelvic floor (perineum)	❑$_1$ Yes	❑$_0$ No
e.	Internal pelvic floor (side walls)	❑$_1$ Yes	❑$_0$ No
f.	Cord/inguinal area	❑$_1$ Yes	❑$_0$ No

Prostate Exam

10. Size
- ❑$_1$ Normal
- ❑$_2$ Enlarged
- ❑$_{99}$ Not done

11. Consistency
- ❑$_1$ Normal
- ❑$_2$ Firm
- ❑$_3$ Soft
- ❑$_{99}$ Not done

12. Nodularity, irregularity, or asymmetry
- ❑$_1$ Yes ❑$_0$ No
- ❑$_{99}$ Not done

13. Prostatic tenderness
- ❑$_1$ Yes ❑$_0$ No
- ❑$_{99}$ Not done

Participant ID: ___ ___ ___ ___ ___
Participant Initials: ___ ___ ___
Clinical Center: ___ ___
Visit Number: ___ ___
Visit Date: ___ ___ / ___ ___ / ___ ___ ___ ___
RC ID: ___ ___ ___ ___

Genitalia

14. Foreskin
- ❑0 Absent
- ❑1 Normal
- ❑2 Abnormal

15. Glans
- ❑1 Normal
- ❑2 Abnormal

16. Epididymes
- ❑1 Normal
- ❑2 Abnormal

a. Epididymal tenderness ❑1 Yes ❑0 No

17. Testes
- ❑1 Normal
- ❑2 Abnormal

a. Testicular tenderness ❑1 Yes ❑0 No

Examiner's Signature: _____

Date of Signature: ___ ___ / ___ ___ / ___ ___ ___ ___ PI ID: ___ ___ ___ ___

Participant ID: ___ ___ ___ ___ ___
Participant Initials: ___ ___ ___
Clinical Center: ___ ___
Visit Number: ___ ___
Visit Date: ___ ___ / ___ ___ / ___ ___ ___ ___
RC ID: ___ ___ ___ ___

FOUR GLASS TEST - CULTURES

1. Date of participant's Four Glass Test ___ ___ / ___ ___ / ___ ___ ___ ___

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 four glass test sample.

Species	**Species Code**
Staphylococcus Epidermidis	01
Staphylococcus Aureus	02
Staphylococcus Other	03
Streptococcus Viridans	04
Staphylococcus Hemolyticus	05
Streptococcus Other	06
Enterococcus Fecalis	07
Corynebacterium	08
Escherichia Coli	09
Klebsiella	10
Pseudomonas	11
Proteus	12
Other	13

Participant ID: ___ ___ ___ ___ ___
Participant Initials: ___ ___ ___
Clinical Center: ___ ___
Visit Number: ___ ___
Visit Date: ___ ___ / ___ ___ / ___ ___ ___ ___
RC ID: ___ ___ ___ ___

48 Hour Culture Count

2. Date of 48 hour count ___ ___ / ___ ___ / ___ ___ ___ ___

VB2 - 48 hours

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

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

Species Code	< 100,000 OR ≥ 100,000	If < 100,000, please enter actual count
___ ___	❑$_0$ <100,000 ❑$_1$ ≥100,000	___ ___ , ___ ___ ___ CFU/ml
___ ___	❑$_0$ <100,000 ❑$_1$ ≥100,000	___ ___ , ___ ___ ___ CFU/ml
___ ___	❑$_0$ <100,000 ❑$_1$ ≥100,000	___ ___ , ___ ___ ___ CFU/ml
___ ___	❑$_0$ <100,000 ❑$_1$ ≥100,000	___ ___ , ___ ___ ___ CFU/ml

NOTE: If there is a culture count ≥100,000 for VB2, the participant is ineligible for this CPCRN trial.

5 Days Culture Count

4. Date of 5 day count ___ ___ / ___ ___ / ___ ___ ___ ___

VB1 - 5 Days

5. 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	< 100,000 OR ≥ 100,000	If < 100,000, please enter actual count
___ ___	❑$_0$ <100,000 ❑$_1$ ≥100,000	___ ___ , ___ ___ ___ CFU/ml
___ ___	❑$_0$ <100,000 ❑$_1$ ≥100,000	___ ___ , ___ ___ ___ CFU/ml
___ ___	❑$_0$ <100,000 ❑$_1$ ≥100,000	___ ___ , ___ ___ ___ CFU/ml
___ ___	❑$_0$ <100,000 ❑$_1$ ≥100,000	___ ___ , ___ ___ ___ CFU/ml

Participant ID: ___ ___ ___ ___ ___
Participant Initials: ___ ___ ___
Clinical Center: ___ ___
Visit Number: ___ ___
Visit Date: ___ ___ / ___ ___ / ___ ___ ___ ___
RC ID: ___ ___ ___ ___

VB2 - 5 Days

6. 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	< 100,000 OR ≥ 100,000	If < 100,000, please enter actual count
___ ___	❑$_0$ <100,000 ❑$_1$ ≥100,000	___ ___ , ___ ___ ___ CFU/ml
___ ___	❑$_0$ <100,000 ❑$_1$ ≥100,000	___ ___ , ___ ___ ___ CFU/ml
___ ___	❑$_0$ <100,000 ❑$_1$ ≥100,000	___ ___ , ___ ___ ___ CFU/ml
___ ___	❑$_0$ <100,000 ❑$_1$ ≥100,000	___ ___ , ___ ___ ___ CFU/ml

EPS - 5 Days

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

If ***Yes***, continue on to question #8.
If ***No***, go to question #9.

8. Was there any growth? ❑$_1$ Yes ❑$_0$ No ❑$_{99}$ Not done

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	< 100,000 OR ≥ 100,000	If < 100,000, please enter actual count
___ ___	❑$_0$ <100,000 ❑$_1$ ≥100,000	___ ___ , ___ ___ ___ CFU/ml
___ ___	❑$_0$ <100,000 ❑$_1$ ≥100,000	___ ___ , ___ ___ ___ CFU/ml
___ ___	❑$_0$ <100,000 ❑$_1$ ≥100,000	___ ___ , ___ ___ ___ CFU/ml
___ ___	❑$_0$ <100,000 ❑$_1$ ≥100,000	___ ___ , ___ ___ ___ CFU/ml

Participant ID: ___ ___ ___ ___ ___
Participant Initials: ___ ___ ___
Clinical Center: ___ ___
Visit Number: ___ ___
Visit Date: ___ ___ / ___ ___ / ___ ___ ___ ___
RC ID: ___ ___ ___ ___

VB3 - 5 Days

9. Was a VB3 sample collected? ❑$_1$ Yes ❑$_0$ No

If ***Yes***, continue on to question #10.

10. 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	**< 100,000 OR ≥ 100,000**	**If < 100,000, please enter actual count**
___ ___	❑$_0$ <100,000 ❑$_1$ ≥100,000	___ ___ , ___ ___ ___ CFU/ml
___ ___	❑$_0$ <100,000 ❑$_1$ ≥100,000	___ ___ , ___ ___ ___ CFU/ml
___ ___	❑$_0$ <100,000 ❑$_1$ ≥100,000	___ ___ , ___ ___ ___ CFU/ml
___ ___	❑$_0$ <100,000 ❑$_1$ ≥100,000	___ ___ , ___ ___ ___ CFU/ml

Participant ID: ___ ___ ___ ___ ___
Participant Initials: ___ ___ ___
Clinical Center: ___ ___
Visit Number: ___ ___
Visit Date: ___ ___ / ___ ___ / ___ ___ ___ ___
RC ID: ___ ___ ___ ___

FOUR GLASS TEST - MICROSCOPY

1. Date of participant's Four Glass Test ___ ___ / ___ ___ / ___ ___ ___ ___

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

---

VB1

3. White Blood Cell Count (/hpf)
   ❑$_0$ ≤ 25
   ❑$_1$ > 25

   If ≤ **25**, give actual count ___ ___ /hpf

4. Red Blood Cell Count (/hpf)
   ❑$_0$ ≤ 25
   ❑$_1$ > 25

   If ≤ **25**, give actual count ___ ___ /hpf

5. Yeast
   ❑$_0$ Absent
   ❑$_1$ Present

Participant ID: ___ ___ ___ ___ ___
Participant Initials: ___ ___ ___
Clinical Center: ___ ___
Visit Number: ___ ___
Visit Date: ___ ___ / ___ ___ / ___ ___ ___ ___
RC ID: ___ ___ ___ ___

VB2

6. White Blood Cell Count (/hpf)
   - ❑0 ≤ 25
   - ❑1 > 25

   If ≤ **25**, give actual count ___ ___ /hpf

7. Red Blood Cell Count (/hpf)
   - ❑0 ≤ 25
   - ❑1 > 25

   If ≤ **25**, give actual count ___ ___ /hpf

8. Yeast
   - ❑0 Absent
   - ❑1 Present

9. pH
   - ❑1 5.0
   - ❑2 5.5
   - ❑3 6.0
   - ❑4 6.5
   - ❑5 7.0
   - ❑6 7.5
   - ❑7 8.0

10. Glucose (mg/dl)
    - ❑1 0
    - ❑2 100
    - ❑3 250
    - ❑4 500
    - ❑5 1000
    - ❑6 2000

11. Protein (mg/dl)
    - ❑1 Negative
    - ❑2 Trace
    - ❑3 30 (+)
    - ❑4 100 (++)
    - ❑5 300 (+++)
    - ❑6 ≥ 2000 (++++)

Participant ID: ___ ___ ___ ___ ___
Participant Initials: ___ ___ ___
Clinical Center: ___ ___
Visit Number: ___ ___
Visit Date: ___ ___ / ___ ___ / ___ ___ ___ ___
RC ID: ___ ___ ___ ___

EPS

12. Estimated volume of EPS sample
- ❑1 None
- ❑2 1 to 2 drops
- ❑3 3 or more drops

If ***None***, go directly to question #19.

13. White Blood Cell Count (/hpf)
- ❑1 ≤ 25
- ❑2 26 - 50
- ❑3 51-75
- ❑4 76-100
- ❑5 >100

If ≤ **25**, give actual count ___ ___ /hpf

14. Macrophage
- ❑0 Absent
- ❑1 Present

If ***Present***, give actual count ___ ___ /hpf

15. Red Blood Cells
- ❑0 Absent
- ❑1 Present

16. Yeast
- ❑0 Absent
- ❑1 Present

17. Sperm
- ❑0 Absent
- ❑1 Present

18. Was there any remaining EPS sample sent to lab for storage? ❑1 Yes ❑0 No

If ***Yes***, date EPS sample sent to lab for storage ___ ___ / ___ ___ / ___ ___ ___ ___

Participant ID: ___ ___ ___ ___ ___
Participant Initials: ___ ___ ___
Clinical Center: ___ ___
Visit Number: ___ ___
Visit Date: ___ ___ / ___ ___ / ___ ___ ___ ___
RC ID: ___ ___ ___ ___

VB3

19.	Was a VB3 sample collected? If ***Yes***, continue,	❑$_1$ Yes ❑$_0$ No
20.	White Blood Cell Count (/hpf)	❑$_0$ ≤ 25 ❑$_1$ > 25
	If ≤ **25**, give actual count	___ ___ /hpf
21.	Red Blood Cell Count (/hpf)	❑$_0$ ≤ 25 ❑$_1$ > 25
	If ≤ **25**, give actual count	___ ___ /hpf
22.	Yeast	❑$_0$ Absent ❑$_1$ Present
23.	Prostate fluid form elements (e.g. fat bodies)	❑$_0$ Absent ❑$_1$ Present

Participant ID: ___ ___ ___ ___ ___
Participant Initials: ___ ___ ___
Clinical Center: ___ ___
Visit Number: ___ ___
Visit Date: ___ ___ / ___ ___ / ___ ___ ___ ___
RC ID: ___ ___ ___ ___

FOLLOW-UP CONTACTS

To be completed at all visits (all phone contacts and clinic visits):

1. Since your last contact, have you had any medical problems? ❑$_1$ Yes ❑$_0$ No
(Includes adverse experiences, abnormal laboratory values, hospitalizations, discontinued medications due to adverse events, other complications, or pre-existing conditions that have worsened)

⇨ If ***Yes***, an Adverse Event must be reported/recorded on the AE form

To be completed at Visit 4 (6 week clinic visit):

2. Are you still taking the study medications? ❑$_1$ Yes ❑$_0$ No

3. Since your last contact, have you taken any concomitant medications? ❑$_1$ Yes ❑$_0$ No

⇨ If ***Yes***, the medication must be reported/recorded on the Concomitant Medications form. (Refer to the Exclusionary Medication list in the MOP. Patients who have taken exclusionary meds must be taken off of the study medication.)

4. Compliance:

Capsules dispensed at the last visit **(A)**	Amount Returned **(B)**	Amount lost/destroyed **(C)**	Capsules Used **A-(B+C) (D)**	Amount that should have been used **(E)**	Percent Compliance **(D/E) x 100 (F)**
CIPRO® Capulses: ___ ___ ___	___ ___ ___	___ ___ ___	___ ___ ___	___ ___ ___	___ ___ ___
Flomax® Capulses: ___ ___ ___	___ ___ ___	___ ___ ___	___ ___ ___	___ ___ ___	___ ___ ___

Participant ID: ___ ___ ___ ___ ___
Participant Initials: ___ ___ ___
Clinical Center: ___ ___
Visit Number: ___ ___
Visit Date: ___ ___ / ___ ___ / ___ ___ ___ ___
RC ID: ___ ___ ___ ___

MEDICAL HISTORY

Prostatitis History

1. Do you know when your first episode of prostatitis was diagnosed? ❑$_1$ Yes ❑$_0$ No
   If ***Yes***, when was it diagnosed? __ __ / ___ ___ ___ ___ (month / year)

2. Do you know when your current episode of prostatitis was diagnosed? ❑$_1$ Yes ❑$_0$ No
   If ***Yes***, when was it diagnosed? __ __ / ___ ___ ___ ___ (month / year)

3. Have you ever had a prostate biopsy? ❑$_1$ Yes ❑$_0$ No ❑$_{88}$ Unknown

4. Have you ever had a bladder biopsy? ❑$_1$ Yes ❑$_0$ No ❑$_{88}$ Unknown

---

General Medical History

Have you ever had, or do you currently have a history of any of the following?

5. Cardiovascular disease ❑$_1$ Yes ❑$_0$ No ❑$_{88}$ Unknown

6. Gastrointestinal disease
   a. Irritable bowel syndrome ❑$_1$ Yes ❑$_0$ No ❑$_{88}$ Unknown
   b. Spastic colon ❑$_1$ Yes ❑$_0$ No ❑$_{88}$ Unknown
   c. Diverticulitis ❑$_1$ Yes ❑$_0$ No ❑$_{88}$ Unknown
   d. Other gastrointestinal disease ❑$_1$ Yes ❑$_0$ No ❑$_{88}$ Unknown

7. Genitourinary disease

a.	Childhood bladder problems	❑$_1$ Yes	❑$_0$ No	❑$_{88}$ Unknown
b.	Urinary stones	❑$_1$ Yes	❑$_0$ No	❑$_{88}$ Unknown
c.	Incontinence	❑$_1$ Yes	❑$_0$ No	❑$_{88}$ Unknown
d.	Interstitial cystitis	❑$_1$ Yes	❑$_0$ No	❑$_{88}$ Unknown
e.	Urinary tract infection	❑$_1$ Yes	❑$_0$ No	❑$_{88}$ Unknown
f.	Balanitis	❑$_1$ Yes	❑$_0$ No	❑$_{88}$ Unknown
g.	Peyronie's disease	❑$_1$ Yes	❑$_0$ No	❑$_{88}$ Unknown
h.	Erectile dysfunction	❑$_1$ Yes	❑$_0$ No	❑$_{88}$ Unknown
i.	Other genitourinary disease	❑$_1$ Yes	❑$_0$ No	❑$_{88}$ Unknown

8. Musculoskeletal, rheumatologic, or connective tissue disease

a.	Arthritis	❑$_1$ Yes	❑$_0$ No	❑$_{88}$ Unknown
b.	Fibromyalgia	❑$_1$ Yes	❑$_0$ No	❑$_{88}$ Unknown
c.	Reiter's syndrome	❑$_1$ Yes	❑$_0$ No	❑$_{88}$ Unknown
d.	Other musculoskeletal, rheumatologic, or connective tissue disease	❑$_1$ Yes	❑$_0$ No	❑$_{88}$ Unknown

9. Neurologic disease

a.	Migraine headaches	❑$_1$ Yes	❑$_0$ No	❑$_{88}$ Unknown
b.	Vertebral disc disease or surgery	❑$_1$ Yes	❑$_0$ No	❑$_{88}$ Unknown
c.	Numbness or tingling in limbs	❑$_1$ Yes	❑$_0$ No	❑$_{88}$ Unknown
d.	Other neurologic disease	❑$_1$ Yes	❑$_0$ No	❑$_{88}$ Unknown

10. Endocrine or metabolic disease

a.	Hypothyroid disease	❑$_1$ Yes	❑$_0$ No	❑$_{88}$ Unknown
b.	Hyperthyroid disease	❑$_1$ Yes	❑$_0$ No	❑$_{88}$ Unknown
c.	Diabetes	❑$_1$ Yes	❑$_0$ No	❑$_{88}$ Unknown
d.	Other endocrine or metabolic disease	❑$_1$ Yes	❑$_0$ No	❑$_{88}$ Unknown

11. Hematopoietic, lymphatic, or infectious disease

a.	Sinusitis	❑$_1$ Yes	❑$_0$ No	❑$_{88}$ Unknown
b.	Frequent upper respiratory infection	❑$_1$ Yes	❑$_0$ No	❑$_{88}$ Unknown
c.	Epstein-Barr virus	❑$_1$ Yes	❑$_0$ No	❑$_{88}$ Unknown
d.	Chronic fatigue syndrome	❑$_1$ Yes	❑$_0$ No	❑$_{88}$ Unknown
e.	Tuberculosis	❑$_1$ Yes	❑$_0$ No	❑$_{88}$ Unknown
f.	HIV/AIDS	❑$_1$ Yes	❑$_0$ No	❑$_{88}$ Unknown
g.	Genital herpes	❑$_1$ Yes	❑$_0$ No	❑$_{88}$ Unknown
h.	Other hematopoietic, lymphatic, or infectious disease	❑$_1$ Yes	❑$_0$ No	❑$_{88}$ Unknown

12. Dermatologic disease

a.	Psoriasis	❑$_1$ Yes	❑$_0$ No	❑$_{88}$ Unknown
b.	Other dermatologic disease	❑$_1$ Yes	❑$_0$ No	❑$_{88}$ Unknown

13. Psychiatric disease

a.	Depression	❑$_1$ Yes	❑$_0$ No	❑$_{88}$ Unknown
b.	Eating disorder	❑$_1$ Yes	❑$_0$ No	❑$_{88}$ Unknown
c.	Anxiety/panic attacks	❑$_1$ Yes	❑$_0$ No	❑$_{88}$ Unknown
d.	Suicide attempt	❑$_1$ Yes	❑$_0$ No	❑$_{88}$ Unknown
e.	Other psychiatric disease	❑$_1$ Yes	❑$_0$ No	❑$_{88}$ Unknown

14. Urological surgery

a.	Inguinal hernia repair	❑$_1$ Yes	❑$_0$ No	❑$_{88}$ Unknown
b.	Scrotal surgery	❑$_1$ Yes	❑$_0$ No	❑$_{88}$ Unknown
c.	Vasectomy	❑$_1$ Yes	❑$_0$ No	❑$_{88}$ Unknown
d.	Other urological surgery	❑$_1$ Yes	❑$_0$ No	❑$_{88}$ Unknown

15. Allergies

a.	Food allergies	❑$_1$ Yes	❑$_0$ No	❑$_{88}$ Unknown
b.	Hay fever/seasonal allergies	❑$_1$ Yes	❑$_0$ No	❑$_{88}$ Unknown
c.	Asthma	❑$_1$ Yes	❑$_0$ No	❑$_{88}$ Unknown
d.	Latex allergy	❑$_1$ Yes	❑$_0$ No	❑$_{88}$ Unknown
e.	Medical Allergies	❑$_1$ Yes	❑$_0$ No	❑$_{88}$ Unknown
f.	Other allergies	❑$_1$ Yes	❑$_0$ No	❑$_{88}$ Unknown

Participant ID: ___ ___ ___ ___ ___
Participant Initials: ___ ___ ___
Clinical Center: ___ ___
Visit Number: ___ ___
Visit Date: ___ ___ / ___ ___ / ___ ___ ___ ___
RC ID: ___ ___ ___ ___

RANDOMIZATION

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. Baseline 2 (Visit 2) NIH-CPSI

   a. Overall Score: _____
   ⇨ Must be initialed by the RC

4. Highest "48 hour" VB2 Culture count (from FGTC form)
   ❑$_0$ <100,000
   ❑$_1$ ≥100,000

5. PCR Test Results
   ❑$_0$ Negative
   ❑$_1$ Positive

⇨ **By initialing above and signing below, you are confirming that all the information contained on this form is correct to the best of your knowledge, and that this participant is eligible to participate in this study.**

6. Investigator's Signature: _____

   Date of Signature: ___ ___ / ___ ___ / ___ ___ ___ ___ PI ID: ___ ___ ___ ___

7. Signature of RC performing randomization: _____

   Date of Signature: ___ ___ / ___ ___ / ___ ___ ___ ___ RC ID: ___ ___ ___ ___

8. Perform computer randomization and record randomization number ___ ___ ___ ___ ___

Participant ID: ___ ___ ___ ___ ___
Participant Initials: ___ ___ ___
Clinical Center: ___ ___
Visit Number: ___ ___
Visit Date: ___ ___ / ___ ___ / ___ ___ ___ ___
RC ID: ___ ___ ___ ___

RESCUE TREATMENT EVENT

1. Date you started rescue medication or treatment: ___ ___/___ ___/___ ___ ___ ___

We are interested in learning how long the effect of treatment lasts after you stop taking the study drugs. Please indicate any of the following medications or treatments you are presently taking for your prostatitis or pelvic pain that you were not already taking prior to beginning the study. That is, record only those prostatitis medications/treatments that you have started since stopping the study medications. If you are unsure what category the medication/treatment falls into, please contact your RC for assistance.

		Yes	No
2.	Antibiotics or antimicrobials (oral or intravenous)	❑1	❑0
3.	Anticholinergics or antispasmodics	❑1	❑0
4.	Anticonvulsants	❑1	❑0
5.	Antidepressants	❑1	❑0
6.	Anti-inflammatory medications	❑1	❑0
7.	Anti-anxiety medications	❑1	❑0
8.	Alpha blockers	❑1	❑0
9.	5-alpha reductase inhibitors	❑1	❑0
10.	Narcotics	❑1	❑0
11.	Steroids	❑1	❑0
12.	Urinary tract analgesics	❑1	❑0
13.	Allopurinol	❑1	❑0
14.	Plant extracts or herbs	❑1	❑0
15.	Zinc	❑1	❑0
16.	Acupuncture or acupressure	❑1	❑0

Participant ID: ___ ___ ___ ___ ___
Participant Initials: ___ ___ ___
Clinical Center: ___ ___
Visit Number: ___ ___
Visit Date: ___ ___ / ___ ___ / ___ ___ ___ ___
RC ID: ___ ___ ___ ___

		Yes	No
17.	Biofeedback	❑1	❑0
18.	Electrical stimulation	❑1	❑0
19.	Prostate massage	❑1	❑0
20.	Special diet or nutritional supplements	❑1	❑0
21.	Stress reduction techniques	❑1	❑0
22.	Other	❑1	❑0

Please specify, _____

Drug Code: ___ ___ ___ ___ ___ ___ (to be completed by RC)

23.	Other	❑1	❑0

Please specify, _____

Drug Code: ___ ___ ___ ___ ___ ___ (to be completed by RC)

24.	Other	❑1	❑0

Please specify, _____

Drug Code: ___ ___ ___ ___ ___ ___ (to be completed by RC)

Participant ID: ___ ___ ___ ___ ___
Participant Initials: ___ ___ ___
Clinical Center: ___ ___
Visit Number: ___ ___
Visit Date: ___ ___ / ___ ___ / ___ ___ ___ ___
RC ID: ___ ___ ___ ___

SEMEN SAMPLE

1. Did the participant have uropathogens localized to semen at the screening visit? ❑$_1$ Yes ❑$_0$ No

NOTE: If the answer to #1 is "NO" at Visit 4, do not continue.

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

3. Was the patient able to provide a semen sample? ❑$_1$ Yes
❑$_2$ No, refused
If ***Yes***, please continue ❑$_3$ No, unable

Semen Microscopy

4. Volume of semen sample ___ ___ . ___ ml

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

If < 25, give actual count ___ ___.___ /hpf

6. Number of seminal plasma aliquots sent to lab for storage ___ ___

Participant ID: ___ ___ ___ ___ ___
Participant Initials: ___ ___ ___
Clinical Center: ___ ___
Visit Number: ___ ___
Visit Date: ___ ___ / ___ ___ / ___ ___ ___ ___
RC ID: ___ ___ ___ ___

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

Species	Species Code
Staphylococcus Epidermidis	01
Staphylococcus Aureus	02
Staphylococcus Other	03
Streptococcus Viridans	04
Staphylococcus Hemolyticus	05
Streptococcus Other	06
Enterococcus Fecalis	07
Corynebacterium	08
Escherichia Coli	09
Klebsiella	10
Pseudomonas	11
Proteus	12
Other	13

5 Day Culture Count

7. Date of 5 day count ___ ___/___ ___/___ ___ ___ ___

8. 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	< 100,000 OR ≥ 100,000	If < 100,000, please enter actual count
___ ___	❑$_1$ <100,000 ❑$_0$ ≥100,000	___ ___, ___ ___ ___ CFU/ml
___ ___	❑$_1$ <100,000 ❑$_0$ ≥100,000	___ ___, ___ ___ ___ CFU/ml
___ ___	❑$_1$ <100,000 ❑$_0$ ≥100,000	___ ___, ___ ___ ___ CFU/ml
___ ___	❑$_1$ <100,000 ❑$_0$ ≥100,000	___ ___, ___ ___ ___ CFU/ml
___ ___	❑$_1$ <100,000 ❑$_0$ ≥100,000	___ ___, ___ ___ ___ CFU/ml

Participant ID: ___ ___ ___ ___ ___
Participant Initials: ___ ___ ___
Clinical Center: ___ ___
Visit Number: ___ ___
Visit Date: ___ ___ / ___ ___ / ___ ___ ___ ___
RC ID: ___ ___ ___ ___

FOLLOW-UP SYMPTOMS

Today's Date: ___ ___ / ___ ___ / ___ ___ ___ ___

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

❑0	❑1	❑2	❑3	❑4	❑5	❑6
Markedly worsened	Moderately worsened	Slightly worsened	No change	Slightly improved	Moderately improved	Markedly improved

Participant ID: ___ ___ ___ ___ ___
Participant Initials: ___ ___ ___
Clinical Center: ___ ___
Visit Number: ___ ___
Visit Date: ___ ___ / ___ ___ / ___ ___ ___ ___
RC ID: ___ ___ ___ ___

TREATMENT STOP POINT

1. Date participant took final dose of *CIPRO*® medication: __ __ / __ __ / __ __ __ __

2. Date participant took final dose of *Flomax*® medication: __ __ / __ __ / __ __ __ __

3. Has the participant stopped treatment early? ❑1 Yes ❑0 No

   If ***Yes***, please state the reason for early withdrawal

   a. Use of unacceptable medication ❑1 Yes ❑0 No

      Listed on Concomitant Medications as Line #: ___ ___ ___

   b. Adverse Event, *as determined by the PI* ❑1 Yes ❑0 No

      Listed on Adverse Event form as AE #: ___ ___ ___

      Date of onset: __ __ / __ __ / __ __ __ __

      Please specify: _____

   c. Adverse Event, *as determined by the participant* ❑1 Yes ❑0 No

      Listed on Adverse Event form as AE #: ___ ___ ___

      Date of onset: __ __ / __ __ / __ __ __ __

      Please specify: _____

   d. Participant dissatisfied with treatment ❑1 Yes ❑0 No

      Please specify: _____

   e. Participant no longer interested in participating ❑1 Yes ❑0 No

      Please specify reason: _____

   f. Other ❑1 Yes ❑0 No

      Please specify reason: _____

C P C R N

Randomized Clinical Trial #1

Participant ID: ___ ___ ___ ___ ___
Participant Initials: ___ ___ ___
Clinical Center: ___ ___
Visit Number: ___ ___
Visit Date: ___ ___ / ___ ___ / ___ ___ ___ ___
RC ID: ___ ___ ___ ___

UNMASKING RECORD

1. Date of unmasking: ___ ___/___ ___/___ ___ ___ ___

2. Time of unmasking: ___ ___:___ ___ (24-hour)

3. Randomization Number: ___ ___ ___ ___ ___

4. Unmasking authorization attached? ❑$_1$ Yes ❑$_0$ No

5. Was the DCC contacted within 72 hours of unmasking? ❑$_1$ Yes ❑$_0$ No

   a. If **Yes**, name of person contacted: _____

   b. If **No**, state the reason: _____

6. Why was the drug unmasked?

   a. Serious Adverse Event ❑$_1$ Yes ❑$_0$ No

      Listed on Adverse Event form as AE # ___ ___ ___

   b. Other hospitalization ❑$_1$ Yes ❑$_0$ No

   c. Other ❑$_1$ Yes ❑$_0$ No

      Please specify: _____

DIRECTIONS: Fax this form to the DCC at (215) 573-6262. Please include original **AUTH**; DO NOT send **AUTH** copy revealing treatment assignment.

Participant ID: ___ ___ ___ ___ ___
Participant Initials: ___ ___ ___
Clinical Center: ___ ___
Visit Number: ___ ___
Visit Date: ___ ___ / ___ ___ / ___ ___ ___ ___
RC ID: ___ ___ ___ ___

UROFLOW

1.	Total voided volume	___ ___ ___ . ___ ml
2.	Peak flow	___ ___ . ___ ___ ml/sec
3.	Average flow	___ ___ . ___ ___ ml/sec
4.	Post-void residual	___ ___ ___ . ___ ml

Note: *At Visit 4 (week 6), complete Post-Void Residual* ***ONLY.***

Participant ID: ___ ___ ___ ___ ___
Participant Initials: ___ ___ ___
Clinical Center: ___ ___
Visit Number: ___ ___
Visit Date: ___ ___ / ___ ___ / ___ ___ ___ ___
RC ID: ___ ___ ___ ___

VOIDING LOG

1. Beginning date and time of log ___ ___ / ___ ___ / ___ ___ ___ ___

   ___ ___ : ___ ___ (military time)

2. Ending date and time of log ___ ___ / ___ ___ / ___ ___ ___ ___

   ___ ___ : ___ ___ (military time)

3. What time did you go to bed? ___ ___ : ___ ___ (military time)

4. What time did you get up for the day? ___ ___ : ___ ___ (military time)

5. Which number best describes your AVERAGE pain or discomfort on this day?

❑	❑	❑	❑	❑	❑	❑	❑	❑	❑	❑
0	1	2	3	4	5	6	7	8	9	10
No Pain										Pain as bad as you can imagine

Participant ID: ___ ___ ___ ___ ___
Participant Initials: ___ ___ ___
Clinical Center: ___ ___
Visit Number: ___ ___
Visit Date: ___ ___ / ___ ___ / ___ ___ ___ ___
RC ID: ___ ___ ___ ___

Enter the number of void records: __ __

Void Number (completed by the RC)	Time of void (military time)	Amount voided (CC's)	Did you wake to void?
___ ___	___ ___ : ___ ___		❑$_1$ Yes ❑$_0$ No
___ ___	___ ___ : ___ ___		❑$_1$ Yes ❑$_0$ No
___ ___	___ ___ : ___ ___		❑$_1$ Yes ❑$_0$ No
___ ___	___ ___ : ___ ___		❑$_1$ Yes ❑$_0$ No
___ ___	___ ___ : ___ ___		❑$_1$ Yes ❑$_0$ No
___ ___	___ ___ : ___ ___		❑$_1$ Yes ❑$_0$ No
___ ___	___ ___ : ___ ___		❑$_1$ Yes ❑$_0$ No
___ ___	___ ___ : ___ ___		❑$_1$ Yes ❑$_0$ No
___ ___	___ ___ : ___ ___		❑$_1$ Yes ❑$_0$ No
___ ___	___ ___ : ___ ___		❑$_1$ Yes ❑$_0$ No
___ ___	___ ___ : ___ ___		❑$_1$ Yes ❑$_0$ No
___ ___	___ ___ : ___ ___		❑$_1$ Yes ❑$_0$ No
___ ___	___ ___ : ___ ___		❑$_1$ Yes ❑$_0$ No
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___ ___	___ ___ : ___ ___		❑$_1$ Yes ❑$_0$ No
___ ___	___ ___ : ___ ___		❑$_1$ Yes ❑$_0$ No
___ ___	___ ___ : ___ ___		❑$_1$ Yes ❑$_0$ No
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___ ___	___ ___ : ___ ___		❑$_1$ Yes ❑$_0$ No
___ ___	___ ___ : ___ ___		❑$_1$ Yes ❑$_0$ No
___ ___	___ ___ : ___ ___		❑$_1$ Yes ❑$_0$ No

Participant ID: ___ ___ ___ ___ ___
Participant Initials: ___ ___ ___
Clinical Center: ___ ___
Visit Number: ___ ___
Visit Date: ___ ___ / ___ ___ / ___ ___ ___ ___
RC ID: ___ ___ ___ ___

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