MAPP research network	**Participant ID:** __ __ __ __ __ __	**Pin #** __ __ __ __
	Discovery Site: __ __	**Clinical Center** __ __
	CRF Date: __ __/__ __/__ __ __ __	**Visit #:** __ __

Eligibility Confirmation – EP Study Participants

Research Coordinator completes at Baseline contact.

1. Participant has signed and dated the appropriate Informed Consent document. ❑1 Yes ❑0 No
   a. If **Yes**, record date the form was signed __ __/__ __/__ __ __ __ (MM DD YYYY)
   b. Did the Participant give permission to prepare DNA from blood or cheek swab samples and to test DNA for genes related to the main goals of this study: to better understand how Interstitial Cystitis/Painful Bladder Syndrome in men and women, and Chronic Prostatitis/Chronic Pelvic Pain Syndrome work? (Answer to 1b ***MUST*** be ***Yes*** for Participant to be eligible.) ❑1 Yes ❑0 No
   c. Did the Participant give permission to prepare DNA from blood or cheek swab samples and to test DNA for genes unrelated to this study for other health conditions? (If answer to 1c is ***No***, Participant is still eligible if answer to 1b is ***Yes***.) ❑1 Yes ❑0 No
2. Is the participant male or female? ❑1 Male ❑2 Female
3. Participant is ≥ 18 years of age. ❑1 Yes ❑0 No

Inclusion Criteria

4. Participant reports a response of at least 1 on the pain, pressure or discomfort scale (SYM-Q, Question #1). ❑1 Yes ❑0 No
   a. Record the response from Q.#1 the SYM-Q form (must equal **1** or **greater**): ____ ____

For males or females (IC/PBS criteria)

5. Participant reports an unpleasant sensation of ***pain***, ***pressure*** or ***discomfort***, perceived to be related to the bladder and/or pelvic region, associated with lower urinary tract symptoms. ❑1 Yes ❑0 No
   a. If answer to Q5 is YES, have these IC/PBS symptoms been present for the majority of the time during any 3 months in the previous 6 months. ❑1 Yes ❑0 No ❑99 N/A
   b. If answer to Q5a is YES, have **these IC/PBS symptoms been present for the majority of the time during the most recent 3 months.** ❑1 Yes ❑0 No ❑99 N/A

FOR MALE OR FEMALE PARTICIPANTS WITH IC/PBS, INCLUSION CRITERIA RESPONSE FOR QUESTIONS 5a AND 5b MUST BOTH BE "YES".

For males only (CP/CPPS criteria)

6. Male Participant reports pain or discomfort in any of the 8 domains of the Male Genitourinary Pain Index (MGUPI) (items 1a, 1b, 1c, 1d, 2a, 2b, 2c, 2d). ❑1 Yes ❑0 No ❑99 N/A
   a. If answer to Q6 is YES, have these **CP/CPPS symptoms been present for the majority of the time during any 3 months in the previous 6 months.** ❑1 Yes ❑0 No ❑99 N/A
   b. If answer to Q6a is YES, have these CP/CPPS symptoms been present for the majority of the time during the most recent 3 months.* (*If answer to 6b is ***No*****,** participant is still eligible if answer to 6a is ***Yes***. ***Please note***, this is the ***ONLY*** Inclusion Criterion for which a ***No*** response is acceptable for eligibility.) ❑1 Yes ❑0 No ❑99 N/A

FOR MALE PARTICIPANTS WITH CP/CPPS, INCLUSION CRITERIA RESPONSE FOR QUESTION 6a MUST BE "YES". PLEASE RECORD "99-NA" FOR QUESTIONS 6, 6a, and 6b FOR FEMALE PARTICIPANTS.

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Eligibility Confirmation – EP Study Participants

Research Coordinator completes at Baseline contact.

Exclusion Criteria

7. Participant has an on-going symptomatic urethral stricture. ❑1 Yes ❑0 No
8. Participant has an on-going neurological disease or disorder affecting the bladder or bowel fistula. ❑1 Yes ❑0 No
9. Participant has a history of cystitis caused by tuberculosis, radiation therapy or Cytoxan/cyclophosphamide therapy. ❑1 Yes ❑0 No
10. Participant has augmentation cystoplasty or cystectomy. ❑1 Yes ❑0 No
11. Participant has an active autoimmune or infectious disorder (such as Crohn's Disease or Ulcerative Colitis, Lupus, Rheumatoid Arthritis, Multiple Sclerosis, or HIV). ❑1 Yes ❑0 No
12. Participant has a history of cancer (with the exception of skin cancer). ❑1 Yes ❑0 No
13. Participant has current major psychiatric disorder or other psychiatric or medical issues that would interfere with study participation (e.g. dementia, psychosis, upcoming major surgery, etc). ❑1 Yes ❑0 No

13a. Participant has severe cardiac, pulmonary, renal, or hepatic disease that in the judgment of the study physician would preclude participation in this study. ❑1 Yes ❑0 No

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

Exclusion Criteria for Males *ONLY*, (Please record 99 - N/A for Females)

14. Male Participant diagnosed with unilateral orchalgia, without pelvic symptoms. ❑1 Yes ❑0 No ❑99 N/A
15. Male Participant has a history of transurethral microwave thermotherapy (TUMT), transurethral needle ablation (TUNA), balloon dilation, prostate cryo-surgery, or laser procedure. ❑1 Yes ❑0 No ❑99 N/A

Exclusion Criteria for Females *ONLY*, (Please record 99 - N/A for Males) (*This question removed by Protocol Amendment #3)

16. Female Participant has a history of High Grade Squamous Intraepithelial Lesion (HGSIL) / high-grade cervical dysplasia. ❑1 Yes ❑0 No ❑99 N/A

Deferral Criteria – Treatment and history

17. Participant has had definitive treatment for acute epidymitis, urethritis, vaginitis. ❑1 Yes ❑0 No

If **YES**, date of last treatment: Date: __ __ / __ __ / __ __ __ __
MM DD YYYY
(Must be deferred for at least **3 months** after the last treatment.)

18. Participant has history of unevaluated hematuria. ❑1 Yes ❑0 No
(Must be deferred until hematuria evaluated.)

19. Participant has an active neurostimulator. **(*This question removed by Protocol Amendment #2)** ❑1 Yes ❑0 No
(Must be turned off by the investigative team and remain off for the duration of the study.)

Question #20 is a Deferral Criterion for Males *ONLY*, (Please record 99 – N/A for Females.)

20. Male Participant has had a prostate biopsy or Transurethral Resection of the Prostate (TURP) within the last three months. ❑1 Yes ❑0 No ❑99 N/A

If **YES**, date of prostate biopsy: Date: __ __ / __ __ / __ __ __ __
MM DD YYYY
(Must be deferred for **3 months** following prostate biopsy or TURP.)

MAPP research network	**Participant ID:** __ __ __ __ __ __	**Pin #** __ __ __ __
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Eligibility Confirmation – EP Study Participants

Research Coordinator completes at Baseline contact.

Deferral Criteria – Urine test results

***Please note, the following section requires that a urine specimen be collected from the Participant in order to assess eligibility via the following procedures (check each box to confirm specimen collected and procedure done):**

Male and Female Participants:

- ☐ Urine dipstick
- ☐ Urine culture (Must be documented on Urine Culture Result – UCR form)

Female Participants:

- ☐ Pregnancy Test

21. Participant has an abnormal dipstick urinalysis, indicating abnormal levels of nitrites and/or occult blood, that in the opinion of the Principal Investigator, warrants a deferral. ❑$_1$ Yes ❑$_0$ No

If **YES**, due to being positive for nitrites only, baseline screening will be stopped until 48 hr. urine culture can be evaluated. If the urine culture result is negative at 48 hrs., participant may be re-screened without further delays.

If **YES** due to positive dipstick for nitrites **AND** positive for 48 hr. urine culture, please confirm date of positive urine culture:

Date: __ __ / __ __ / __ __ __ __
MM DD YYYY

Must be deferred for **3 months** following positive dipstick for nitrites **AND** positive for 48 hr. urine culture.

Question #22 is a Deferral Criterion for females of childbearing potential *ONLY.*

(Please record 99 - N/A for males and females who are surgically sterile or postmenopausal.)

22. Female participant has a positive urine pregnancy test. (Must be deferred until after delivery.) ❑$_1$ Yes ❑$_0$ No ❑$_{99}$ N/A

- **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.**

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

24. Research Coordinator ID ___ ___ ___ ___ (4-digit ID)