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

Eligibility Confirmation – Control 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? ❑1 Yes ❑0 No
   (Answer to 1b ***MUST*** be ***Yes*** for Participant to be eligible.)
   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? ❑1 Yes ❑0 No
   (If answer to 1c is ***No***, Participant is still eligible if answer to 1b is ***Yes***.)
2. Is the participant male or female? ❑1 Male ❑2 Female
3. Participant is ≥ 18 years of age. ❑1 Yes ❑0 No

4. Please confirm the Type of Control for which this Participant is being screened. ❑1 Healthy Control ❑2 Positive Control

Inclusion Criteria

Questions 5, 6, and 7 are for *Healthy Controls ONLY*, please record "99 N/A" for Positive Controls.

5. Participant reports a response of ***"0" (zero)*** on the pain, pressure or discomfort scale (SYM-Q-Baseline, Question #1). ❑1 Yes ❑0 No ❑99 N/A
6. Participant reports no chronic pain in the pelvic or bladder region, and reports chronic pain in no more than one other body region. ❑1 Yes ❑0 No ❑99 N/A
7. Participant reports no urological symptoms that have been evaluated, but are still present. ❑1 Yes ❑0 No ❑99 N/A

FOR *HEALTHY CONTROLS* TO MEET ALL ELIGIBILITY CRITERIA, QUESTIONS 5, 6, AND 7 ABOVE MUST EACH BE "YES". FOR HEALTHY CONTROLS, PLEASE RECORD "99-N/A" FOR QUESTIONS 8, 9, AND 10 BELOW AND CONTINUE WITH THE EXCLUSION CRITERIA SECTION.

Questions 8, 9, and 10 are for *Positive Controls ONLY*, please record "99/NA" for Healthy Controls.

Participant meets the validated criteria for the following conditions*:

(* See corresponding CMSI diagnostic modules for Positive Control Participants)

8. Fibromyalgia (**CMSI-FM2**) ❑1 Yes ❑0 No ❑99 N/A
9. Irritable bowel syndrome (**CMSI-IBS2**) ❑1 Yes ❑0 No ❑99 N/A
10. Chronic fatigue syndrome (**CMSI-CFS2**) ❑1 Yes ❑0 No ❑99 N/A

FOR *POSITIVE CONTROLS* TO MEET ALL ELIGIBILITY CRITERIA, ONE OR MORE RESPONSES FOR QUESTIONS 8, 9, *AND/OR* 10 ABOVE (PER CMSI DIAGNOSTIC MODULE CRITERIA SPECIFIED) MUST BE "YES".

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

Eligibility Confirmation – Control Participants

Research Coordinator completes at Baseline contact.

Exclusion Criteria

11. Participant has an on-going symptomatic urethral stricture. ❑1 Yes ❑0 No
12. Participant has an on-going neurological disease or disorder affecting the bladder or bowel fistula. ❑1 Yes ❑0 No
13. Participant has a history of cystitis caused by tuberculosis, radiation therapy or Cytoxan/cyclophosphamide therapy. ❑1 Yes ❑0 No
14. Participant has augmentation cystoplasty or cystectomy. ❑1 Yes ❑0 No
15. 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
16. Participant has a history of cancer (with the exception of skin cancer). ❑1 Yes ❑0 No
17. 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

17a. 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)

18. Male Participant diagnosed with unilateral orchalgia, without pelvic symptoms. ❑1 Yes ❑0 No ❑99 N/A
19. 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)**

20. 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

21. 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.)

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

23. 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 #24 is a Deferral Criterion for Males *ONLY*, (Please record 99 - N/A for Females.)

24. 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 #** __ __ __ __
	Discovery Site: __ __	**Clinical Center** __ __
	CRF Date: __ __/__ __/__ __ __ __	**Visit #:** __ __

Eligibility Confirmation – Control 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

25. 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 #26 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.)

26. 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.**

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

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