



Participant ID: _____

Pin # _____

Discovery Site: _____

Clinical Center _____

CRF Date: ____/____/____

Visit #: _____

MAPP Phase II Eligibility Confirmation

Research Coordinator completes at **Screening Week 0** contact.

- 1i. Participant has signed and dated the appropriate Informed Consent document and has agreed to participate in **ALL** required Symptoms Patterns Study procedures (including **Biospecimen collections, MAPP Pelvic Exam, and Quantitative Sensory Testing**). ₁ Yes ₀ No
- a. If **Yes**, record date the form was signed _____ / _____ / _____
MM DD YYYY
- b. Did the Participant give permission for use of DNA for genetics studies? ₁ Yes ₀ No
(Answer to 1b **MUST** be **Yes** for Participant to be eligible.)
- c. Is the Participant eligible for the **Neuroimaging** MRI scan? ₁ Yes ₀ No
(Please see ELIG_SCAN2 CRF criteria)
2. Participant gender: ₁ Male ₂ Female
3. Participant is ≥ 18 years of age. ₁ Yes ₀ No
4. Participant is able to speak, read, and understand English. ₁ Yes ₀ No
5. Participant is under the ongoing care of a **MAPP Clinical Investigator**. ₁ Yes ₀ No

Inclusion Criteria

Inclusion Criterion per RICE Case Definition Questionnaire, Q.#1:

6. **In the past 3 months** Participant has had a feeling of pain, pressure, or discomfort in the lower abdomen or pelvic area -- that is, the part of the body that is above the Participant's legs and below the belly button: ₁ Yes ₀ No
7. **These symptoms have been present for the majority of the time during the most recent 3 months.** ₁ Yes ₀ No

Inclusion Criterion per SYM-Q, Q.#1:

8. Participant reports a response of at least **1** on the **pain, pressure or discomfort** scale for **UCPPS** symptoms during the **past 2 weeks** (SYM-Q, Question #1). ₁ Yes ₀ No
- a. Record the response from Q.#1 the SYM-Q form (must equal 1 or **greater**): _____

Diagnosis History (per AUA guidelines)

9. Participant has received a **clinical diagnosis** of: ₁ IC/BPS
₂ CP/CPPS
₃ Both IC/BPS and CP/CPPS
₄ *No **prior clinical diagnosis** of IC/BPS or CP/CPPS available

***Please note:** If the answer for Q.#9 above is "4 - No clinical diagnosis of IC/BPS or CP/CPPS available", MAPP Study Clinician must confirm Participant meets UCPPS criteria per protocol and the answer to **Q.#10 must be YES**.

10. Clinician familiar with UCPPS criteria confirms Participant meets UCPPS evaluation criteria per-protocol. ₁ Yes ₀ No

Clinician Initials: _____

ALL INCLUSION CRITERIA RESPONSES ABOVE MUST BE "YES" FOR THE PARTICIPANT TO BE ELIGIBLE FOR ENROLLMENT IN THE MAPPII SPS STUDY.*

***PLEASE NOTE: MAPPI EPS PARTICIPANTS WHOSE SYMPTOMS HAVE IMPROVED AND WHO DO NOT EXPERIENCE SYMPTOMS AS LISTED IN THE INCLUSION CRITERIA SECTION ARE ELIGIBLE FOR THE MAPPII SPS STUDY.**



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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 Cytosan/cyclophosphamide therapy. ₁ Yes ₀ No
- 14. Participant has augmentation cystoplasty or cystectomy. ₁ Yes ₀ No
- 15. Participant is currently undergoing dose titration or medication adjustments for a poorly controlled autoimmune or infectious disorder (such as Crohn's Disease, Ulcerative Colitis, Lupus, Rheumatoid Arthritis, Multiple Sclerosis, or HIV) which in the opinion of the Investigator could impact bladder symptoms. ₁ Yes ₀ No
- 16. Participant has a history of cancer (with the exception of skin cancer). ₁ Yes ₀ No
- 16a. Participant has a history of any pelvic malignancy (e.g. GI, GU, Gyn). ₁ Yes ₀ No
- 16b. Participant is having ongoing systemic treatment/therapy for any type of 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
- 18. 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 IN THE MAPP II SPS STUDY.

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

- 19. Male Participant diagnosed with unilateral orchalgia, without pelvic symptoms. ₁ Yes ₀ No ₉₉ N/A
- 20. 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

Deferral Criteria – Treatment and history

- 21. Participant has had definitive treatment for acute epididymitis, urethritis, vaginitis. ₁ Yes ₀ No

If **YES**, date of last treatment: Date: ____ / ____ / ____
MM DD YYYY
 (Must be deferred for at least **6 weeks** after the last treatment.)

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

- 28. Participant has had a cystoscopy with hydrodistention or kenalog injection. ₁ Yes ₀ No

If **YES**, date of hydrodistention or kenalog injection: Date: ____ / ____ / ____
MM DD YYYY
 (Must be deferred for **3 months** following hydrodistention or kenalog injection.)

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

- 23. 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.)



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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

24. Participant has an abnormal dipstick urinalysis, indicating abnormal levels of nitrites and/or occult blood, that in the opinion of the MAPP Clinical Investigator, warrants a deferral. ₁ Yes ₀ No

If **YES**, due to being positive for nitrites only, baseline screening will be stopped until minimum 24 hr. urine culture can be evaluated. If the urine culture result is negative for minimum 24 hr. urine culture, participant may be re-screened without further delays.

If **YES** due to positive dipstick for nitrites **AND** positive for minimum 24 hr. urine culture, please confirm date of positive urine culture:

Date: ____ / ____ / ____
MM DD YYYY

Must be deferred for **6 weeks** following positive dipstick for nitrites **AND** positive for minimum 24 hr. urine culture.

Question #25 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.)

25. Female participant has a positive urine pregnancy test. ₁ Yes ₀ No ₉₉ N/A
(Must be deferred until after delivery.)

- **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.**

26. Did the participant meet all eligibility criteria at this visit? ₁ Yes ₀ No

Please note:

MAPPI EPS participants whose symptoms have improved and who do not experience symptoms as listed in the Inclusion Criteria section are ELIGIBLE for the MAPPII SPS Study. Please record “1-Yes” for these participants above.

26a. Is the participant returning after having participated in the MAPP, Phase I EPS Study but symptoms have improved? ₁ Yes ₀ No

27. Research Coordinator ID _____ (4-digit ID)