Multidisciplinary Approach to Pelvic Pain (MAPP)

Trans-MAPP Epidemiology and Phenotyping Study (EPS)

DATA ENTRY CASE REPORT FORM VERSION LOG
CRFs for Control Participants*

***Please note that CRFs used for the Control Participants in the MAPP EPS study are identical to those used for Epidemiology and Phenotyping Participants unless otherwise noted.**

Form Name	Form Code	Latest Version Number
Prescreening Summary for Healthy Controls	**PRESCR-HEALTHY**	v1.0.20091001
Prescreening Summary for Positive Controls	**PRESCR-POSITIVE**	v1.0.20091001
Urologic CRFs (Females and Males):		
Demographics	**DEMO**	v1.0.20091125
SYM-Q- Baseline	**SYM-Q-Baseline**	v1.0.20091125
Fibromyalgia	**CMSI-FM2**	v1.0.20100422
Chronic Fatigue	**CMSI-CFS2**	v1.0.20100422
Irritable Bowel Syndrome	**CMSI-IBS2**	v1.0.20100422
Eligibility-Controls (Control Participants only)	**ELIG-Controls**	V5.0.20100621
Urine Culture Result	**UCR**	v1.0.20090805
Enrollment	**ENROLL**	v1.0.20090827
Interstitial Cystitis Symptom Index and Interstitial Cystitis Problem Index	**ICINDEX**	v1.0.20090801
AUA Symptom Index	**AUASI**	v1.0.20090801
RICE Case Definition Questionnaire	**RICE**	v1.0.20090801
Medical History	**MEDHX**	v4.0.20100709
Family Medical History	**FAMHX**	v1.0.20100512
Early In Life Infection History	**EIL-INF**	v1.0.20090801
Concomitant Medications	**CMED**	v1.0.20090801
Physical Exam	**EXAM**	v1.0.20090803
Study Stop	**SSTOP**	v3.0.20100421
Consent Withdrawal	**CONWITHDR**	v2.0.20110415
Reinstatement of Consent	**RECON**	v1.0.20110415
Specimens and Procedures		
Plasma Specimen Tracking	**PTRAC**	v1.1.20100218
Cheek Swab Specimen Tracking	**CTRAC**	v1.0.20091015
Urine Specimen Tracking	**UTRAC**	v1.1.20100218
Urine Specimen Tracking - Infectious Etiology Spec. (Male/Female)	**UMIETRAC** **UFIETRAC**	v2.0.20101012
Pain/Pressure Procedure	**PPT**	v3.0.20100318
Procedural or Unanticipated Problems	**PUP**	v3.0.20100616
Urologic CRFs - Females only		
Female Genitourinary Pain Index	**FGUPI-Baseline**	v1.0.20090819
Female Sexual Function Index	**FSFI**	v1.0.20090801
Female Self-Esteem and Relationship Questionnaire	**FSEAR**	v1.0.20090801
Urologic CRFs - Males only		
Male Genitourinary Pain Index	**MGUPI-Baseline**	v1.0.20090819
International Index of Erectile Function	**IIEF**	v1.0.20090801
University of Washington Ejaculatory Function Scale	**EFS**	v1.0.20091002
Male Self-Esteem and Relationship Questionnaire	**MSEAR**	v1.0.20090801

Multidisciplinary Approach to Pelvic Pain (MAPP)

Trans-MAPP Epidemiology and Phenotyping Study (EPS)

DATA ENTRY CASE REPORT FORM VERSION LOG
CRFs for Control Participants*

***Please note that CRFs used for the Control Participants in the MAPP EPS study are identical to those used for Epidemiology and Phenotyping Participants unless otherwise noted.**

Non-Urologic CRFs		
Brief Pain Inventory	**BPI**	v1.0.20090801
SF-12	**SF-12**	v1.0.20090801
PANAS	**PANAS**	v1.0.20090801
Hospital Anxiety and Depression Scale	**HADS**	v1.0.20090801
PROMIS - Anger - Short Form	**ANGER**	v1.0.20090801
PROMIS - Fatigue - Short Form	**FATIGUE**	v1.0.20090801
PROMIS - Sleep - Short Form	**SLEEP**	v1.0.20090801
Multiple Ability Self-Report Questionnaire	**MASQ**	v1.0.20090801
Perceived Stress Scale	**PSS**	v1.0.20090801
IPIP	**IPIP**	v1.0.20090801
Thoughts About Symptoms	**CSQ**	v1.0.20090801
Beliefs in Pain Control Questionnaire	**BPCQ**	v1.0.20090801
Childhood/Recent Traumatic Events Scale	**CTES**	v1.0.20090801
Complex Medical Symptoms Inventory - Baseline	**CMSI-Baseline**	v1.0.20090801
Vulvodynia	**CMSI-VDYN2**	v1.0.20100422
Migraine	**CMSI-MI2**	v1.0.20100422
Temporomandibular Joint Disorder (TMJD)	**CMSI-TMD2**	v1.0.20100422

MAPP Epidemiology and Phenotyping Studies Visit Schedule for Control Participants

Domain	INSTRUMENT	FORM CODE	Total Items	Visit #1, Screening/ Study Entry/ Phenotyping Visit
Pre-screening	Pre-screening: Healthy/Positive Controls	PRESCR-HEALTHY PRESCR-POSITIVE	PRN	
Screening Procedures				
Consent	Informed Consent Form	ICF	PRN	X
Demographics	Demographics	DEMO	12	X
Symptom Assessment	SYM-Q	SYM-Q	12	X
Syndrome Modules	Fibromyalgia	**CMSI-FM2**	5	X
	Irritable Bowel Syndrome	**CMSI-IBS2**	10	X
	Chronic Fatigue	**CMSI-CFS2**	19	X
Eligibility*	Eligibility - Control Participants	*ELIG_CONTROLS	**25**	X
	Urine Culture Result	*UCR	**3**	X
	Enrollment	*ENROLL	**3**	X
		Grand Total	89	**89**
Urologic CRFs (Females and Males):				
Symptoms	Interstitial Cystitis Symptom Index	ICINDEX	4	X
	Interstitial Cystitis Problem Index		4	X
	AUA Symptom Index	AUASI	7	X
	RICE Case Definition Questionnaire	RICE	5	X
Medical History	Medical History	MEDHX	21	X
	Early In Life Infection History	EIL-INF	10	X
	Family Medical History	FAMHX	1	X
Treatment	Concomitant Medications	CMED	PRN	X
Physical Exam	Physical Exam	EXAM	15	X
Study Stop/Withdrawal	Study Stop	SSTOP	7	X
	Consent Withdrawal	**CONWITHDR**	5	**PRN**
	Reinstatement of Consent	**RECON**	**2**	**PRN**
		Grand Total:	81	**79**
Urologic CRFs - Females only				
Symptoms	Female Genitourinary Pain Index	FGUPI	9	X
Sexual Function	Female Sexual Function Index	FSFI	19	X
	Female Self-Esteem and Relationship Questionnaire	FSEAR	12	X
		Grand Total:	40	**40**
Urologic CRFs - Males only				
Symptoms	Male Genitourinary Pain Index	MGUPI	9	X
Sexual Function	International Index of Erectile Function	IIEF	6	X
	University of Washington Erectile Function Scale	EFS	**3**	X
	Male Self-Esteem and Relationship Questionnaire	MSEAR	**14**	X
		Grand Total:	32	**32**

Domain	INSTRUMENT	FORM CODE	Total Items	Visit #1, Screening/ Study Entry/ Phenotyping Visit
Non-Urologic CRFs				
Symptoms				
Pain	BPI (Intensity)	**BPI**	7	**X**
	BPI (Body map)	**BPI**	2	**X**
Physical Function	BPI (Interference)	**BPI**	7	**X**
	SF-12	**SF-12**	12	**X**
Mood	PANAS	**PANAS**	20	**X**
	Hospital Anxiety and Depression Scale	**HADS**	14	**X**
	PROMIS - Anger - Short Form	**ANGER**	8	**X**
Cognition	Multiple Ability Self-Report Questionnaire	**MASQ**	38	**X**
Fatigue	PROMIS - Fatigue - Short Form	**FATIGUE**	7	**X**
Sleep	PROMIS - Sleep - Short Form	**SLEEP**	8	**X**
Stress	Perceived Stress Scale	**PSS**	10	**X**
		Grand Total:	133	**133**
Trait-like Personal Factors				
Personality	IPIP	**IPIP**	120	**X**
Cat	Thoughts About Symptoms	**CSQ**	6	**X**
LOC	Beliefs in Pain Control Questionnaire	**BPCQ**	13	**X**
Trauma History	Childhood/Recent Traumatic Events Scale	**CTES**	26	**X**
		Grand Total:	165	**165**
Co-morbid Diagnostics				
Symptom Test	Complex Medical Symptoms Inventory	**CMSI**	41	**X (Complete)**
Syndrome Modules	Vulvodynia	**CMSI-VDYN2**	8	**X**
	Migraine	**CMSI-MI2**	19	**X**
	Temporomandibular Joint Disorder	**CMSI-TMD2**	8	**X**
		Grand Total:	76	**76**
Specimens and Procedures				
Plasma	Plasma Specimen Tracking	**PTRAC**	14	**X**
Cheek swab	Cheek Swab Specimen Tracking	**CTRAC**	13	**X**
Urine	Urine Specimen Tracking	**UTRAC**	24	**X**
	Urine Specimen Tracking - Infectious Etiology (Male/Female)	**UMIETRAC UFIETRAC**	15	**X**
Pain/Pressure Procedure		**PPT**	1	**X**
Procedural or Unanticipated Problems		**PUP**	PRN	**PRN**
		Grand Total:	**67**	**67**

Urological Phenotyping Group,
Case Report Forms for Control Participants

Pre-screening

- Prescreening Summary for Healthy Controls – PRESCR-HEALTHY
- Prescreening Summary for Positive Controls – PRESCR-POSITIVE

CRFs for Screening Procedures and Eligibility Confirmation

- Demographics (DEMO)
- Symptom and Health Care Utilization Questionnaire Baseline (SYM-Q-Baseline)
- CMSI – Complex Medical Symptoms Inventory – (FM-Positive_Controls)
- CMSI – Complex Medical Symptoms Inventory – (IBS)
- CMSI – Complex Medical Symptoms Inventory – (CFS)
- Eligibility Confirmation – Control Participants (ELIG-Controls)
- Urine Culture Result – Deferral Criterion for Eligibility Confirmation (UCR)
- Enrollment (ENROLL)

CRFs for Data Collection and Participant Follow-up

- Interstitial Cystitis Symptom Index and Problem Index (ICINDEX)
- AUA Symptom Index (AUASI)
- RICE Case Definition Questionnaire (RICE)
- Medical History (MEDHX)
- Family Medical History (FAMHX)
- Early In Life Infection History (EIL-INF)
- Concomitant Medications (CMED)
- Physical Exam (EXAM)
- Study Stop (SSTOP)
- Consent Withdrawal (CONWTHDR)
- Reinstatement of Consent (RECON)
- Plasma Specimen Tracking (PTRAC)
- Cheek Swab Specimen Tracking (CTRAC)
- Urine Specimen Tracking (UTRAC)
- Urine Specimen Tracking - Infectious Etiology [Male/Female] – (UMIETRAC, UFIETRAC)
- Pain / Pressure Procedure – (PPT)
- Procedural or Unanticipated Problems (PUP)

CRFs for Female Participants ONLY

- Female Genitourinary Pain Index (FGUPI)
- Female Sexual Function Index (FSFI)
- Self-Esteem and Relationship Questionnaire, Female Pt.s (FSEAR)

CRFs for Male Participants ONLY

- Male Genitourinary Pain Index (MGUPI)
- International Index of Erectile Function, Short Form (IIEF)
- University of Washington Ejaculatory Function Scale (EFS)
- Self-Esteem and Relationship Questionnaire, Male Pt.s (MSEAR)

MAPP research network

Case Report Forms for Control Participants

Pre-screening

- Prescreening Summary for Healthy Controls – PRESCR-HEALTHY
- Prescreening Summary for Positive Controls – PRESCR-POSITIVE

MAPP research network	**Discovery Site:** __ __ **Clinical Center:** __ __ **CRF Date:** __ __/__ __/__ __ __ __

Pre-screening Summary for *- Healthy Controls -*

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

2. Number of subjects with initial contact ***this month*** ___ ___ ___
   a. Number who were contacted in person ___ ___ ___
   b. Number who were contacted by phone ___ ___ ___
   c. Number who were contacted in other ways ___ ___ ___

Status of subjects currently in the pre-screening process:

3. Number of subjects no longer considered for participation **("Pre-screening failures")** ___ ___ ___
4. Number of subjects with decision for participation **or** scheduled consent pending* ___ ___ ___
   (* For subjects whose decision to participate or scheduled consent is pending in the current month please update their status in subsequent months as still pending or in question 5 or 6. Pending values are reported for the current month only.)
5. Number of subjects consented **(Informed Consent form *must* be signed and dated)** ___ ___ ___
6. Number of subjects who declined to consider participation ___ ___ ___
   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 participation? ___ ___ ___
   h. Number of subjects who refused to provide biomarker specimens? (including blood, cheek swab specimen, and/or urine specimen) ___ ___ ___

Totals for Q.#s 3, 4, 5, and 6 *MUST* account for the total reported in Q.#2. If any subjects are reported as "Pending" in the previous month, their current status must also be documented in Q.#s 3, 4, 5, or 6 but NOT counted again in the total for Q.#2.

7. 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 ___ ___ ___

MAPP research network	**Discovery Site:** __ __ **Clinical Center:** __ __ **CRF Date:** __ __/__ __/__ __ __ __

Pre-screening Summary for *- Positive Controls -*

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

2. Number of subjects with initial contact ***this month*** ___ ___ ___
   a. Number who were contacted in person ___ ___ ___
   b. Number who were contacted by phone ___ ___ ___
   c. Number who were contacted in other ways ___ ___ ___

Status of subjects currently in the pre-screening process:

3. Number of subjects no longer considered for participation **("Pre-screening failures")** ___ ___ ___
4. Number of subjects with decision for participation **or** scheduled consent pending* ___ ___ ___
   (* For subjects whose decision to participate or scheduled consent is pending in the current month please update their status in subsequent months as still pending or in question 5 or 6. Pending values are reported for the current month only.)
5. Number of subjects consented **(Informed Consent form *must* be signed and dated)** ___ ___ ___
6. Number of subjects who declined to consider participation ___ ___ ___
   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 participation? ___ ___ ___
   h. Number of subjects who refused to provide biomarker specimens? (including blood, cheek swab specimen, and/or urine specimen) ___ ___ ___

Totals for Q.#s 3, 4, 5, and 6 *MUST* account for the total reported in Q.#2. If any subjects are reported as "Pending" in the previous month, their current status must also be documented in Q.#s 3, 4, 5, or 6 but NOT counted again in the total for Q.#2.

7. 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 ___ ___ ___

Urological Phenotyping Group,
Case Report Forms for Control Participants

CRFs for Screening Procedures and Eligibility Confirmation

- Demographics (DEMO)
- Symptom and Health Care Utilization Questionnaire Baseline (SYM-Q-Baseline)
- CMSI – Complex Medical Symptoms Inventory – FM-Positive_Controls
- CMSI – Complex Medical Symptoms Inventory - IBS
- CMSI – Complex Medical Symptoms Inventory - CFS
- Eligibility Confirmation – Control Participants (ELIG-Controls)
- Urine Culture Result – Deferral Criterion for Eligibility Confirmation (UCR)
- Enrollment (ENROLL)

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

Demographics

RESEARCH COORDINATOR COMPLETES AT BASELINE CONTACT.

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?
   ❒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 Code? ___ ___ ___ ___ ___
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
12. Research Coordinator ID ___ ___ ___ ___ (4-digit ID)

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

Symptom and Health Care Utilization Questionnaire - Baseline

PARTICIPANT COMPLETES THIS FORM AT THE BASELINE CONTACT.

Symptom Severity Scales

Pain, Urgency, Frequency Severity Scales

1. Think about the pain, pressure, and discomfort associated with your bladder/prostate and/or pelvic region. On average, how would you rate these symptoms during the past 2 weeks?

No pain or pressure or discomfort										**Most severe discomfort I can imagine**
❑	❑	❑	❑	❑	❑	❑	❑	❑	❑	❑
0	1	2	3	4	5	6	7	8	9	10

2. Urgency is defined as the urge or pressure to urinate. On average, how would you rate the urgency that you have felt during the past 2 weeks?

No urgency										**Most severe urgency I can imagine**
❑	❑	❑	❑	❑	❑	❑	❑	❑	❑	❑
0	1	2	3	4	5	6	7	8	9	10

3. Think about your frequency of urination. On average, how would you rate your frequency of urination during the past 2 weeks?

Totally normal										**Most severe frequency I can imagine**
❑	❑	❑	❑	❑	❑	❑	❑	❑	❑	❑
0	1	2	3	4	5	6	7	8	9	10

4. On average, during the past 2 weeks, how many times did you urinate in a 24-hour period?

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

Urologic or Pelvic Pain Symptom Severity Scales

5. Please rate the overall severity of your **UROLOGIC OR PELVIC PAIN SYMPTOMS** over the past 2 weeks:

No Symptoms										**Symptoms as bad as they can be**
❑	❑	❑	❑	❑	❑	❑	❑	❑	❑	❑
0	1	2	3	4	5	6	7	8	9	10

6. Please rate the overall severity of any persistent pain symptoms that were ***NOT*** **UROLOGIC OR PELVIC PAIN SYMPTOMS** (e.g. back pain, headache, etc) over the past 2 weeks:

No Symptoms										**Symptoms as bad as they can be**
❑	❑	❑	❑	❑	❑	❑	❑	❑	❑	❑
0	1	2	3	4	5	6	7	8	9	10

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

Symptom and Health Care Utilization Questionnaire - Baseline

PARTICIPANT COMPLETES THIS FORM AT THE BASELINE CONTACT.

7. Please rate your **MOOD** over the past 2 weeks:

Extremely Good Mood										**Extremely Bad Mood**
❑	❑	❑	❑	❑	❑	❑	❑	❑	❑	❑
0	1	2	3	4	5	6	7	8	9	10

8. What was your single most bothersome symptom over the past 2 weeks? (Please select only ***ONE*** answer.)

❑$_1$ Pain, pressure, discomfort in your pubic or bladder area

❑$_2$ Pain, pressure, discomfort in the area between: your rectum and testicles (perineum) **[*MALES only*], *-OR-*** the vaginal area ***[FEMALES only]***.

❑$_3$ Pain/ discomfort during or after sexual activity

❑$_4$ Strong need to urinate with little or no warning

❑$_5$ Frequent urination during the day

❑$_6$ Frequent urination at night

❑$_7$ Sense of not emptying your bladder completely

❑$_8$ Other: _____

We would like to know if your urologic or pelvic pain symptoms have caused you to seek medical care in the past 2 weeks:

9. Have your urologic or pelvic pain symptoms been severe enough that they caused you to do any of the following in the past 2 weeks:

a.	Contacted a healthcare provider (physician, nurse, physical therapist or other provider) by telephone or e-mail?	❑$_1$ Yes	❑$_0$ No
b.	Seen a healthcare provider in his/her office?	❑$_1$ Yes	❑$_0$ No
c.	Made a trip to an emergency room or urgent care center?	❑$_1$ Yes	❑$_0$ No
d.	Had a medication changed (new medication or different dose)?	❑$_1$ Yes	❑$_0$ No
e.	Undergone a medical procedure?	❑$_1$ Yes	❑$_0$ No

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

Symptom and Health Care Utilization Questionnaire - Baseline

PARTICIPANT COMPLETES THIS FORM AT THE BASELINE CONTACT.

10. Do you know when you had your most recent (or last) menstrual period?
(Question #10 is for Female Participants *ONLY*.
Please record *"99/Not Applicable"* for Male Participants.)

❑$_1$ Yes
❑$_0$ No
❑$_{99}$ Not Applicable

a. If **Yes**, please give the date of most recent (or last) menstrual period: Date: __ __ / __ __ / __ __ __ __
MM DD YYYY

b. If **No**, you have not had a menstrual period because of:

❑$_1$ Contraceptive ❑$_2$ Prior Hysterectomy ❑$_3$ Postmenopausal

Questions 11 and 12 below are for MAPP Epidemiology and Phenotyping Study Participants *ONLY*.
Please skip these questions for *ALL* Control Participants.

Flare Status Questions

11. Are you currently experiencing a flare of your urologic or pelvic pain symptoms? By this we mean, are you currently experiencing symptoms that are much worse than usual?

❑$_1$ Yes ❑$_0$ No

12. During the past year, how many flares of your IC/CP symptoms have you had? By this we mean, how many times have you experienced symptoms that were much worse than usual?

❑$_0$ None ❑$_1$ 1-4 flares ❑$_2$ 5-9 flares ❑$_3$ 10 or more flares

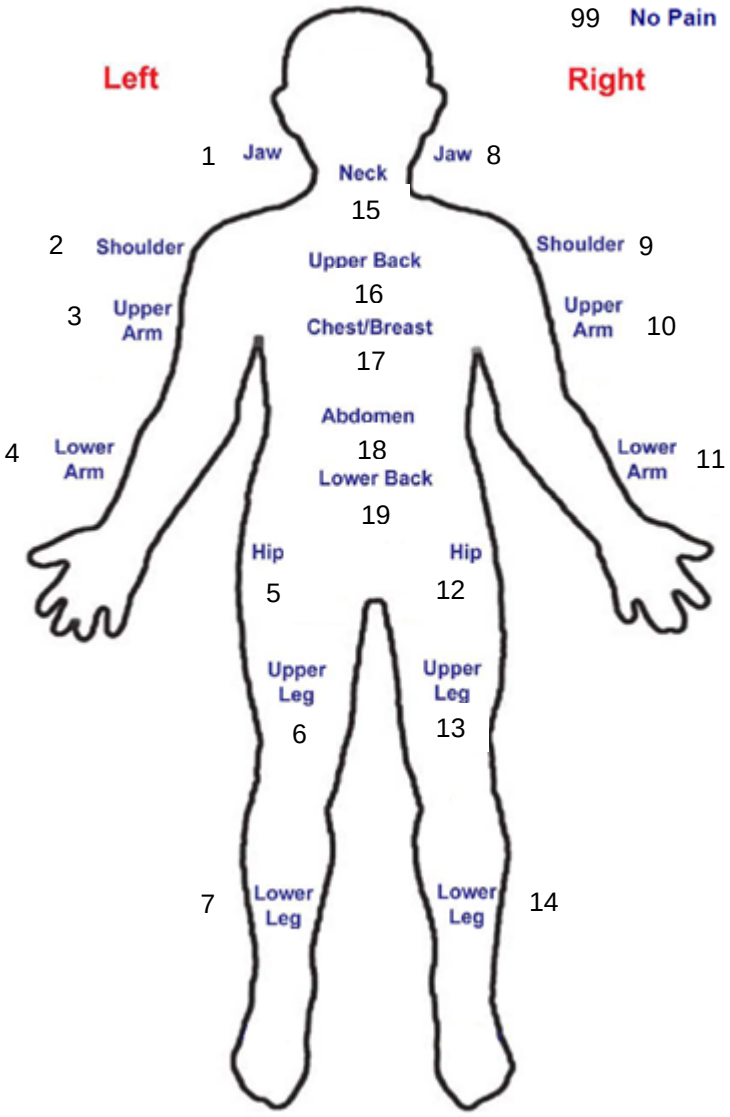
MAPP research network	**Participant ID:** __ __ __ __ __ __	**Pin #** __ __ __ __
	Discovery Site: __ __	**Clinical Center** __ __
	CRF Date: __ __/__ __/__ __ __ __	**Visit #:** __ __

COMPLEX MEDICAL SYMPTOMS INVENTORY

Fibromyalgia Symptoms Modified (ACR 2010 Fibromyalgia Diagnostic Criteria)

RESEARCH COORDINATOR ADMINISTERS TO PATIENT AT BASELINE CONTACT, *IF NEEDED.*

1. Please indicate below if you have had pain or tenderness over the past 7 days in each of the areas listed below. Check the boxes below for each area on the body diagram if you have had pain or tenderness. Be sure to ***mark both right side and left sides separately***.



- ❑99 No Pain
- ❑1 Left Jaw
- ❑2 Left Shoulder
- ❑3 Left Upper Arm
- ❑4 Left Lower Arm
- ❑5 Left Hip
- ❑6 Left Upper Leg
- ❑7 Left Lower Leg
- ❑8 Right Jaw
- ❑9 Right Shoulder
- ❑10 Right Upper Arm
- ❑11 Right Lower Arm
- ❑12 Right Hip
- ❑13 Right Upper Leg
- ❑14 Right Lower Leg
- ❑15 Neck
- ❑16 Upper Back
- ❑17 Chest/Breast
- ❑18 Abdomen
- ❑19 Lower Back

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

COMPLEX MEDICAL SYMPTOMS INVENTORY

Fibromyalgia Symptoms Modified (ACR 2010 Fibromyalgia Diagnostic Criteria)

RESEARCH COORDINATOR ADMINISTERS TO PATIENT AT BASELINE CONTACT, *IF NEEDED.*

2. Using the following scale, indicate for each item your severity over the past week by checking the appropriate box.

No problem
Slight or mild problems: generally mild or intermittent
Moderate: considerable problems; often present and/or at a moderate level
Severe: continuous, life-disturbing problems

	No Problem	Slight or Mild	Moderate	Severe
a. Fatigue	❑0	❑1	❑2	❑3
b. Trouble thinking or remembering	❑0	❑1	❑2	❑3
c. Waking up tired (unrefreshed)	❑0	❑1	❑2	❑3

3. During the past 6 months have you had any of the following symptoms?

a. Pain or cramps in lower abdomen	❑1 Yes	❑0 No
b. Depression	❑1 Yes	❑0 No
c. Headache	❑1 Yes	❑0 No

4. Have the symptoms in questions 2-3 and pain been present at a similar level for at least 3 months? ❑1 Yes ❑0 No

5. Do you have a disorder that would otherwise explain the pain? ❑1 Yes ❑0 No

MAPP research network	**Participant ID:** __ __ __ __ __ __	**Pin #** __ __ __ __
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COMPLEX MEDICAL SYMPTOMS INVENTORY

Current Chronic Fatigue Symptoms (Fukuda 1994 criteria)

RESEARCH COORDINATOR ADMINISTERS TO PATIENT AT BASELINE CONTACT, *IF NEEDED.*

Instructions: The following questions are related to periods of fatigue lasting at least 6 months. An episode of fatigue or exhaustion is defined as "beginning" when you no longer felt that you had your normal amount of energy. An episode of fatigue or exhaustion is defined as "ending" when you felt basically back to normal.

1.	Have you ever had a period of ongoing fatigue or exhaustion lasting at least 6 months?	❑1 Yes	❑0 No **(Stop)**
2.	Do you consider your fatigue lifelong [from birth]?	❑1 Yes	❑0 No
3.	Are you currently experiencing such a period of ongoing fatigue or exhaustion lasting at least 6 months?	❑1 Yes	❑0 No
4.	During the last 6 months, have you experienced ongoing fatigue or exhaustion?	❑1 Yes	❑0 No **(Stop)**
5.	When did this period of fatigue begin?	YEAR _____ MONTH _____	
6.	Are you currently still experiencing this period of fatigue?	❑1 Yes	❑0 No **(Stop)**
7.	Compared to before the fatigue began, in the last 6 months have you substantially reduced your work or educational activities because of your fatigue?	❑1 Yes	❑0 No
8.	Compared to before the fatigue began, in the last 6 months have you substantially reduced your personal or social activities because of your fatigue?	❑1 Yes	❑0 No
9.	Is your fatigue present only following exertion, strenuous work, or exercise? That is, do you have fatigue at no other time except following exertion, strenuous work, or exercise?	❑1 Yes	❑0 No
10.	Is your fatigue substantially relieved by rest?	❑1 Yes	❑0 No
11.	After you rest, do you feel back to normal, that is, back to how you felt before the period of fatigue began?	❑1 Yes	❑0 No
12.	In the last 6 months, have you experienced ***impairment of short-term memory or concentration***?	❑1 Yes	❑0 No
	a. If **Yes**, have these ***memory or concentration problems*** been severe enough to cause you to substantially reduce your occupational, educational, social or personal activities?	❑1 Yes	❑0 No
	b. If **Yes**, have you had ***memory or concentration problems*** either persistently or recurrently (either continuously or off and on) over the entire last 6 months?	❑1 Yes	❑0 No

MAPP research network	**Participant ID:** __ __ __ __ __ __	**Pin #** __ __ __ __
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COMPLEX MEDICAL SYMPTOMS INVENTORY

Current Chronic Fatigue Symptoms (Fukuda 1994 criteria)

RESEARCH COORDINATOR ADMINISTERS TO PATIENT AT BASELINE CONTACT, *IF NEEDED.*

13. In the last 6 months, have you experienced a ***sore throat***? ❑1 Yes ❑0 No

    a. If **Yes**, have you had a ***sore throat*** either persistently or recurrently (either continuously or off and on) over the entire last 6 months? ❑1 Yes ❑0 No

14. In the last 6 months, have you experienced ***muscle pain***? ❑1 Yes ❑0 No

    a. Have you had ***muscle pain*** either persistently or recurrently (either continuously or off and on) over the entire last 6 months? ❑1 Yes ❑0 No

15. In the last 6 months, have you experienced ***joint pain involving more than one joint WITHOUT swelling or redness***? ❑1 Yes ❑0 No

    a. Have you had this ***joint pain*** either persistently or recurrently (either continuously or off and on) over the entire last 6 months? ❑1 Yes ❑0 No

16. In the last 6 months, have you experienced ***headaches of a new type, pattern or severity***? ❑1 Yes ❑0 No

    a. Have you had this ***new type of headache*** either persistently or recurrently (either continuously or off and on) over the entire last 6 months? ❑1 Yes ❑0 No

17. In the last 6 months, have you experienced ***non-refreshing sleep or not feeling rested when you wake up***? ❑1 Yes ❑0 No

    a. Have you had ***non-refreshing sleep or not feeling rested when you wake up*** either persistently or recurrently (either continuously or off and on) over the entire last 6 months? ❑1 Yes ❑0 No

18 In the last 6 months, have you experienced ***fatigue or exhaustion***, after exertion, lasting more than 24 hours that you did not experience before the fatigue began? ❑1 Yes ❑0 No

    a. Have you had this ***new type of fatigue or exhaustion*** either persistently or recurrently (either continuously or off and on) over the entire last 6 months? ❑1 Yes ❑0 No

19. In the last 6 months, have you experienced ***tender lymph glands in your neck or armpits***? ❑1 Yes ❑0 No

    a. Have you had ***tender lymph glands*** in your neck or armpits either persistently or recurrently (either continuously or off and on) over the entire last 6 months? ❑1 Yes ❑0 No

MAPP research network	**Participant ID:** __ __ __ __ __ __	**Pin #** __ __ __ __
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COMPLEX MEDICAL SYMPTOMS INVENTORY

Current IBS Symptoms (Rome III Criteria)

RESEARCH COORDINATOR ADMINISTERS TO PATIENT AT BASELINE CONTACT, *IF NEEDED.*

1. In the last 3 months, how often did you have discomfort or pain anywhere in your abdomen?
   - ❑0 Never **(STOP)**
   - ❑1 Less than one day a month
   - ❑2 One day a month
   - ❑3 Two to three days a month
   - ❑4 One day a week
   - ❑5 More than one day a week
   - ❑6 Everyday

2. For women: Did this discomfort or pain occur only during your menstrual bleeding and not at other times?
   - ❑1 Yes
   - ❑0 No
   - ❑99 Does not apply (either due to menopause or male)

3. Have you had this discomfort or pain 6 months or longer?
   - ❑1 Yes
   - ❑0 No

4. How often did this discomfort or pain get better or stop after you had a bowel movement?
   - ❑0 Never or rarely
   - ❑1 Sometimes
   - ❑2 Often
   - ❑3 Most of the time
   - ❑4 Always

5. When this discomfort or pain started, did you have more frequent bowel movements?
   - ❑0 Never or rarely
   - ❑1 Sometimes
   - ❑2 Often
   - ❑3 Most of the time
   - ❑4 Always

6. When this discomfort or pain started, did you have less frequent bowel movements?
   - ❑0 Never or rarely
   - ❑1 Sometimes
   - ❑2 Often
   - ❑3 Most of the time
   - ❑4 Always

7. When this discomfort or pain started, were your stools (bowel movements) looser?
   - ❑0 Never or rarely
   - ❑1 Sometimes
   - ❑2 Often
   - ❑3 Most of the time
   - ❑4 Always

8. When this discomfort or pain started, how often did you have harder stools?
   - ❑0 Never or rarely
   - ❑1 Sometimes
   - ❑2 Often
   - ❑3 Most of the time
   - ❑4 Always

MAPP research network	**Participant ID:** __ __ __ __ __ __	**Pin #** __ __ __ __
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COMPLEX MEDICAL SYMPTOMS INVENTORY

Current IBS Symptoms (Rome III Criteria)

RESEARCH COORDINATOR ADMINISTERS TO PATIENT AT BASELINE CONTACT, *IF NEEDED.*

9. In the last 3 months, how often did you have hard or lumpy stools?

- ❑0 Never or rarely
- ❑1 Sometimes
- ❑2 Often
- ❑3 Most of the time
- ❑4 Always

10. In the last 3 months, how often did you have loose mushy or watery stools?

- ❑0 Never or rarely
- ❑1 Sometimes
- ❑2 Often
- ❑3 Most of the time
- ❑4 Always

MAPP research network	**Participant ID:** __ __ __ __ __ __	**Pin #** __ __ __ __
	Discovery Site: __ __	**Clinical Center** __ __
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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 #** __ __ __ __
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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 #** __ __ __ __
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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)

MAPP research network	**Participant ID:** __ __ __ __ __ __	**Pin #** __ __ __ __
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Urine Culture Result - Deferral Criterion for Eligibility Confirmation

Research Coordinator completes at Baseline Contact.

Deferral Criterion

1. Participant has had a positive urine culture in the past 6 weeks, or currently has a midstream urine culture (≥100,000 CFU/ml), with a single uropathogen. ❑$_1$ Yes ❑$_0$ No

If **YES**, date of positive urine culture: Date: __ __ / __ __ / __ __ __ __
MM DD YYYY

(Must be treated and deferred for at least **3 months** from the date of positive urine culture result.)

- **THIS DEFERRAL CRITERION RESPONSE MUST BE "NO" FOR THE PARTICIPANT TO BE ELIGIBLE FOR ENROLLMENT.**

2. Did the participant meet the above criterion and all other eligibility criteria at this visit? ❑$_1$ Yes ❑$_0$ No

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

MAPP research network	**Participant ID:** __ __ __ __ __ __	**Pin #** __ __ __ __
	Discovery Site: __ __	**Clinical Center** __ __
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Enrollment Confirmation

Research Coordinator completes at Baseline Contact.

1. Did the Participant successfully enroll in the Trans-MAPP Epidemiology and Phenotyping Study? ❑$_1$ Yes ❑$_0$ No

   If question 1 is **YES,** please complete question 1a.

   If question 1 is **NO**, please skip to question 2.

   a. Please record the date of the scheduled first bi-weekly contact: (***Please record NA for Control Participants.***) __ __/__ __/__ __ __ __ (MM DD YYYY) ❑$_{99}$ NA

2. Please select the ***primary reason*** the participant did not successfully enroll in the study:

   ❑$_1$ Participant not interested in participating/following protocol

   ❑$_2$ Participant does not consider this study beneficial

   ❑$_3$ Participant has concerns about the research processes

   ❑$_4$ Participant has medical condition(s) unrelated to chronic pain that may interfere with participation

   ❑$_5$ Participant prefers additional compensation

   ❑$_6$ Participant has concerns about data privacy / protection of personal medical information

   ❑$_7$ Participant not bothered enough by the symptoms to justify participation

   ❑$_8$ Participant refused to provide biomarker specimens

   (including blood, cheek swab specimen, and/or urine specimen)

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

Urological Phenotyping Group,
Case Report Forms for Control Participants

CRFs for Data Collection and Participant Follow-up

- Interstitial Cystitis Symptom Index and Problem Index (ICINDEX)
- AUA Symptom Index (AUASI)
- RICE Case Definition Questionnaire (RICE)
- Medical History (MEDHX)
- Family Medical History (FAMHX)
- Early In Life Infection History (EIL-INF)
- Concomitant Medications (CMED)
- Physical Exam (EXAM)
- Study Stop (SSTOP)
- Consent Withdrawal (CONWTHDR)
- Reinstatement of Consent (RECON)
- Plasma Specimen Tracking (PTRAC)
- Cheek Swab Specimen Tracking (CTRAC)
- Urine Specimen Tracking (UTRAC)
- Urine Specimen Tracking - Infectious Etiology [Male/Female] – (UMIETRAC, UFIETRAC)
- Pain / Pressure Procedure (PPT)
- Procedural or Unanticipated Problems (PUP)

MAPP research network	**Participant ID:** __ __ __ __ __ __	**Pin #** __ __ __ __
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Interstitial Cystitis Symptom Index and Problem Index
(O'Leary, Sant, Fowler, Whitmore, Spolarich-Kroll)

THE PARTICIPANT COMPLETES THIS FORM AT BASELINE, ALL FOLLOW-UP, AND PRIMARY ENDPOINT CONTACTS.

Interstitial Cystitis Symptom Index:

Q1. During the past month, how often have you felt the strong need to urinate with little or no warning?

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

Q2. During the past month, have you had to urinate less than 2 hours after you finished urinating?

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

Q3. During the past month, how often did you most typically get up at night to urinate?

0. ___ none
1. ___ once
2. ___ 2 times
3. ___ 3 times
4. ___ 4 times
5. ___ 5 or more times

Q4. During the past month, have you experienced pain or burning in your bladder?

0. ___ not at all
2. ___ a few times
3. ___ fairly often
4. ___ usually
5. ___ almost always

Add the numerical values of the checked entries;

Total Score: _____

Interstitial Cystitis Problem Index:

During the past month, how much has each of the following been a problem for you?

Q1. Frequent Urination during the day?

0. ___ no problem
1. ___ very small problem
2. ___ small problem
3. ___ medium problem
4. ___ big problem

Q2. Getting up at night to urinate?

0. ___ no problem
1. ___ very small problem
2. ___ small problem
3. ___ medium problem
4. ___ big problem

Q3. Need to urinate with little warning?

0. ___ no problem
1. ___ very small problem
2. ___ small problem
3. ___ medium problem
4. ___ big problem

Q4. Burning, pain, discomfort, or pressure in your bladder?

0. ___ no problem
1. ___ very small problem
2. ___ small problem
3. ___ medium problem
4. ___ big problem

Add the numerical values of the checked entries;

Total Score: _____

MAPP research network	**Participant ID:** __ __ __ __ __ __	**Pin #** __ __ __ __
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AUA Symptom Score Index

Participant completes at Baseline, Bi-monthly, Six-month, and Twelve-month Contacts.

To complete this self-test, simply click on one answer for each question. Once you have answered all seven questions, click the "calculate" button and you will be immediately given your score.

1. Over the past month, how often have you had a sensation of not emptying your bladder completely after you finished urinating?
   - ❑$_0$ 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
2. Over the past month, how often have you had to urinate again less than two hours after you finished urinating?
   - ❑$_0$ 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
3. Over the past month, how often have you stopped and started again several times when you urinated?
   - ❑$_0$ 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
4. Over the past month, how often have you found it difficult to postpone urination?
   - ❑$_0$ 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
5. Over the past month, how often have you had a weak urinary stream?
   - ❑$_0$ 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

MAPP research network	**Participant ID:** __ __ __ __ __ __	**Pin #** __ __ __ __
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AUA Symptom Score Index

Participant completes at Baseline, Bi-monthly, Six-month, and Twelve-month Contacts.

6. Over the past month, how often have you had to push or strain to begin urination?
   - ❑$_0$ 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

7. Over the past month, how many times did you most typically get up to urinate from the time you went to bed at night until the time you got up in the morning?
   - ❑$_0$ None
   - ❑$_1$ 1 time
   - ❑$_2$ 2 times
   - ❑$_3$ 3 times
   - ❑$_4$ 4 times
   - ❑$_5$ 5 times

Total symptom score: ____ ____

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

RICE Case Definition Questionnaire

Participant completes at Baseline Contact.

1. In the past 3 months, have you ever had a feeling of pain, pressure, or discomfort in your lower abdomen or pelvic area -- that is, the part of your body that is above your legs and below your belly button?

   ❑$_1$ Yes ❑$_0$ No

2. In the past 3 months, have you had a feeling of a strong urge or feeling that you had to urinate or "pee" that made it difficult for you to wait to go to the bathroom?

   ❑$_1$ Yes ❑$_0$ No **[go to Q4]**

3. Would you say this urge to urinate is mainly because of pain, pressure or discomfort or mainly because you are afraid you will not make it to the toilet in time to avoid wetting?

   ❑$_1$ Pain, pressure, discomfort
   ❑$_2$ Fear of wetting

4. In the past 3 months, before you urinate, as your bladder starts to fill, does your feeling of pain, pressure, or discomfort usually:

   ❑$_1$ Get worse
   ❑$_2$ Get better
   ❑$_3$ Stay the same

5. In the past 3 months (when you were having symptoms), how many times on average have you had to go to the bathroom to urinate during the day when you are awake? (Enter number of times)

   ___ ___

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

Medical History

Research Coordinator completes at Baseline Contact.

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

1. Do you know when your chronic pelvic pain symptoms first began? ❑1 Yes ❑0 No ❑99 N/A
   (Please record "99/NA" for Control Participants *ONLY* and proceed to question #2.)
   a. If **YES**, at what age did they first begin? ___ ___ age

1b. Have you had chronic pelvic pain symptoms for less than two years? ❑1 Yes ❑0 No

2. Have you ever been diagnosed with Painful Bladder Syndrome (PBS) / Interstitial Cystitis (IC)? ❑1 Yes ❑0 No
   a. If **YES**, at what age were you diagnosed? ___ ___ age

3. Have you ever been diagnosed with Chronic Pelvic Pain Syndrome (CPPS) / Chronic Prostatitis (CP)? ❑1 Yes ❑0 No
   a. If **YES**, at what age were you diagnosed? ___ ___ age

History of Antibiotic Treatment (Both Men and Women)

3b. Have you been prescribed and completed taking a course of antibiotics for **any condition** at any time in the previous two years? ❑1 Yes ❑0 No

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)

3c. Have you had any urinary tract infections (UTIs) in the past two years? ❑1 Yes ❑0 No ❑88 U/K

3c1. If Yes, please confirm how many UTIs you have had in the past two years:
❑1 One
❑2 Two
❑3 Three or more

(Women only)

4. Pelvic Inflammatory Disease (PID) ❑1 Yes ❑0 No ❑88 U/K ❑99 N/A
5. Endometriosis ❑1 Yes ❑0 No ❑88 U/K ❑99 N/A

(Men only)

6. Acute prostatitis ❑1 Yes ❑0 No ❑88 U/K ❑99 N/A
7. Epididymitis ❑1 Yes ❑0 No ❑88 U/K ❑99 N/A
8. Peyronie's Disease ❑1 Yes ❑0 No ❑88 U/K ❑99 N/A

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

9. 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

Medical History

Research Coordinator completes at Baseline Contact.

d. Skin allergies (contact dermatitis) ❑1 Yes ❑0 No ❑88 U/K

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)

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

a. If **Yes**, have you been diagnosed with diverticulitis? ❑1 Yes ❑0 No ❑88 U/K

Endocrine or metabolic disease (Both Men and Women)

11. 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

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

12. 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. Tuberculosis ❑1 Yes ❑0 No ❑88 U/K

b. HIV/AIDS ❑1 Yes ❑0 No ❑88 U/K

c. Viral Hepatitis (A,B,C,D,E) ❑1 Yes ❑0 No ❑88 U/K

Psychiatric Disease (Both Men and Women)

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

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

a. Anxiety disorder (e.g. generalized anxiety disorder, panic disorder, phobia, etc.) ❑1 Yes ❑0 No ❑88 U/K

b. Depression disorder (e.g. major depression, dysthymia, bipolar disorder) ❑1 Yes ❑0 No ❑88 U/K

c. Eating disorder (e.g. anorexia nervosa, bulimia) ❑1 Yes ❑0 No ❑88 U/K

d. Obsessive Compulsive Disorder (OCD) ❑1 Yes ❑0 No ❑88 U/K

e. Post Traumatic Stress Disorder (PTSD) ❑1 Yes ❑0 No ❑88 U/K

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

Medical History

Research Coordinator completes at Baseline Contact.

Sexually Transmitted Disease (Both Men and Women)

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

e. Genital warts ❑1 Yes ❑0 No ❑88 U/K

f. Trichomonas ❑1 Yes ❑0 No ❑88 U/K

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

(Men only)

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

h. Nongonococcal Urethritis ❑1 Yes ❑0 No ❑88 U/K ❑99 N/A

Cardiovascular Disease (Both Men and Women)

15. 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

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)

16. 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. History of seizures ❑1 Yes ❑0 No ❑88 U/K

c. Migraine headaches ❑1 Yes ❑0 No ❑88 U/K

d. Peripheral Neuropathy ❑1 Yes ❑0 No ❑88 U/K

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

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

Medical History

Research Coordinator completes at Baseline Contact.

Autoimmune/Other Disorders: (Both Men and Women)

17. Have you been diagnosed with having any autoimmune/ other disorders? ❑1 Yes ❑0 No ❑88 U/K

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

a. Autoimmune Disorders (ex. Sjogren's Syndrome, Scleroderma) ❑1 Yes ❑0 No ❑88 U/K

b. 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:

18. Have you ever had any urological/gynecologic surgeries? ❑1 Yes ❑0 No ❑88 U/K ❑99 N/A

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

a. Pelvic organ prolapse repair ❑1 Yes ❑0 No ❑88 U/K ❑99 N/A

b. Hysterectomy ❑1 Yes ❑0 No ❑88 U/K ❑99 N/A

c. Oophorectomy ❑1 Yes ❑0 No ❑88 U/K ❑99 N/A

d. Incontinence surgery ❑1 Yes ❑0 No ❑88 U/K ❑99 N/A

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

a. By vaginal delivery ___ ___ ❒99 Not Applicable

b. By Caesarean section ___ ___ ❒99 Not Applicable

(Men Only)

Urological Surgeries:

20. Have you ever had any urological surgeries? ❑1 Yes ❑0 No ❑88 U/K ❑99 N/A

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

a. Vasectomy ❑1 Yes ❑0 No ❑88 U/K ❑99 N/A

b. Scrotal surgery ❑1 Yes ❑0 No ❑88 U/K ❑99 N/A

c. Inguinal hernia repair ❑1 Yes ❑0 No ❑88 U/K ❑99 N/A

d. Transurethral Resection of the Prostate (TURP) ❑1 Yes ❑0 No ❑88 U/K ❑99 N/A

e. Internal urethrotomy for urethral stricture ❑1 Yes ❑0 No ❑88 U/K ❑99 N/A

f. Bladder neck incision ❑1 Yes ❑0 No ❑88 U/K ❑99 N/A

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

Medical History

Research Coordinator completes at Baseline Contact.

Now I am going to ask some questions about some treatments that you may have had *for pelvic symptoms*.

20g. Have you ever received any of the following treatments? ❑1 Yes ❑0 No ❑88 U/K

20g1. Neurostimulator ❑1 Yes ❑0 No ❑88 U/K

20g2. Physical Therapy ❑1 Yes ❑0 No ❑88 U/K

20g3. Other treatment (Please specify): _____ ❑1 Yes ❑0 No ❑88 U/K

_____

Research Coordinator/Technician, please review all fields of this form and confirm it is complete by recording your 4-digit ID in the space provided below:

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

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

Family Medical History Questionnaire

Participant completes at the Baseline Visit or at 6-Month or 12-Month Clinic Visit if not collected at Baseline.

We would like to get some information about your ***Family Members'*** Medical History. When answering the questions below, please refer to the following list of disorders:

*For the purposes of this questionnaire, Family Members include first degree blood relatives ***ONLY***.
These include: parents, grandparents, aunts, uncles, siblings, children.

Common Chronic Pain Disorders

- Irritable Bowel Syndrome (IBS)
- Inflammatory Bowel Disease (IBD; Crohns' disease, Ulcerative colitis)
- Fibromyalgia (FM)
- Interstitial cystitis/Painful Bladder Syndrome (IC/PBS)
- Chronic prostatitis/Chronic Pelvic Pain Syndrome (CP/CPPS)
- Endometriosis
- Temporo-Mandibular Joint Pain or Disorder (TMJ or TMD)
- Chronic fatigue Syndrome (CFS)
- Migraine Headaches
- Chronic Back, neck or shoulder pain
- Chronic chest pain unrelated to the heart
- Restless Leg Syndrome (RLS)
- Vulvodynia

Common Psychiatric Disorders

- Any Anxiety Disorder (including Panic Disorder, Phobia, Social Anxiety or General Anxiety)
- Depression
- Bipolar (Manic-Depressive) Disorder
- Post-Traumatic Stress Disorder (PTSD)
- Schizophrenia
- Anorexia Nervosa or Bulimia Nervosa (eating disorders)
- Substance abuse/dependence (Alcohol, Nicotine, Cocaine, etc.)

1. Were ANY of your first degree blood relatives (parents, grandparents, aunts and uncles, siblings, children) ever diagnosed with ANY of the above disorders? Please write an "X" next to the appropriate answer.

❑$_1$ Yes ❑$_0$ No ❑$_{99}$ Don't Know

If you answered "No", or "Don't Know", please stop. If "Yes", please go to the next page.

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

Family Medical History Questionnaire

Participant completes at the Baseline Visit or at 6-Month or 12-Month Clinic Visit if not collected at Baseline.

On this page, please indicate in the space provided which members of your immediate family were diagnosed with one of the medical problems listed above. (Follow the example listed). Include first degree blood relatives only - Do not include adopted, foster, step-relatives or those related by marriage.

Relative	Pain Disorder (yes/no)	If yes, please specify (Please see Common Chronic Pain Disorders listed below)	Psych. Disorder (yes/no)	If yes, please specify (Please see Common Psychiatric Disorders listed below)	Please specify how stressful their illness was for you in your childhood (0-10, 0=not at all, 10=extremely) *Please record 99 if Not Applicable.
Example: _2_ (Father)	*_1_ (Yes)*	*_3_ (Fibromyalgia)*	*_1_ (Yes)*	*_4_ PTSD*	*_7_*
___ ___	❑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	___ ___	❑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	___	___ ___

Legend:

Relative	Common Chronic Pain Disorders	Common Psychiatric Disorders
1. Mother 2. Father 3. Grandmother 4. Grandfather 5. Aunt 6. Uncle 7. Sister 8. Brother 9. Daughter 10. Son	1. Irritable Bowel Syndrome (IBS) 2. Inflammatory Bowel Disease (IBD; Crohns' disease, Ulcerative colitis) 3. Fibromyalgia (FM) 4. Interstitial cystitis (IC) or pelvic pain syndrome 5. Chronic prostatitis 6. Endometriosis 7. Temporo-Mandibular Joint Pain or Disorder (TMJ or TMD) 8. Chronic fatigue Syndrome (CFS) 9. Migraine Headaches 10. Chronic Back, neck or shoulder pain 11. Chronic chest pain unrelated to the heart 12. Restless Leg Syndrome (RLS) 13. Vulvodynia	1. Any Anxiety Disorder (including Panic Disorder, Phobia, Social Anxiety or General Anxiety) 2. Depression 3. Bipolar (Manic-Depressive) Disorder 4. Post-Traumatic Stress Disorder (PTSD) 5. Schizophrenia 6. Anorexia Nervosa or Bulimia Nervosa (eating disorders) 7. Substance abuse/ dependence (Alcohol, Nicotine, Cocaine, etc.)

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

Early in Life Risk Recommendations – Infection History

HOOTON

PARTICIPANT COMPLETES AT SIX-MONTH FOLLOW-UP CONTACT.

BLADDER INFECTION HISTORY

These first questions are about bladder infections or cystitis. Symptoms of bladder infections include painful urination, increased urge to urinate, and increased frequency of urination. We ask about kidney infections later.

1. Have you ever been told by a doctor or other healthcare provider that you had a bladder infection or cystitis? (We ask about kidney infections later.) ❑$_1$ Yes ❑$_0$ No

   If ***YES***, please answer questions 1a, 1b, and 1c below.

   IF ***NO***, please go to question #2.

   a. How old were you when you were diagnosed with your **first** bladder infection? ___ ___

   b. Approximately how many bladder infections have you been diagnosed with in your lifetime? ___ ___ ___

   c. Did you have any bladder infections as a child? ❑$_1$ Yes ❑$_0$ No

KIDNEY INFECTION HISTORY

The next questions are about kidney infections (also called pyelonephritis). They may have some of the same symptoms as a bladder infection, but can also include fever, chills, and severe back or side pain. Sometimes these infections require hospitalization.

2. Have you ever been told by a doctor or other health care provider that you had a kidney infection or pyelonephritis? ❑$_1$ Yes ❑$_0$ No

   If ***YES***, please answer questions 2a, 2b, and 2c below.

   IF ***NO***, please go to question #3.

   a. How old were you when you were diagnosed with your **first** kidney infection or pyelonephritis? ___ ___

   b. Approximately how many kidney infections or occurrences of pyelonephritis have you been diagnosed with in your lifetime? ___ ___ ___

   c. Did you have any kidney infections or pyelonephritis as a child? ❑$_1$ Yes ❑$_0$ No

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

Early in Life Risk Recommendations – Infection History
HOOTON
PARTICIPANT COMPLETES AT SIX-MONTH FOLLOW-UP CONTACT.

FAMILY HISTORY OF URINARY TRACT INFECTIONS (UTI)

We would like to know a little more about your family history of urinary tract infections (UTI's). It would be helpful if you could talk to your family members before answering these questions.

3.	To your knowledge does your natural ***mother*** have a history of UTIs, either bladder or kidney?	❑$_1$ Yes	❑$_0$ No	
4.	To your knowledge does your natural ***father*** have a history of UTIs, either bladder or kidney?	❑$_1$ Yes	❑$_0$ No	
5.	To your knowledge do either of your ***grandmothers*** have a history of UTIs, either bladder or kidney?	❑$_1$ Yes	❑$_0$ No	
6.	To your knowledge do either of your ***grandfathers*** have a history of UTIs, either bladder or kidney?	❑$_1$ Yes	❑$_0$ No	
7.	To your knowledge, do any of your natural ***sisters or half-sisters*** have a history of UTIs, either bladder or kidney?	❑$_1$ Yes	❑$_0$ No	❑$_{99}$ NA
8.	To your knowledge, do any of your natural ***brothers or half-brothers*** have a history of UTIs, either bladder or kidney?	❑$_1$ Yes	❑$_0$ No	❑$_{99}$ NA
9.	To your knowledge, do any of your natural ***daughters*** have a history of UTIs, either bladder or kidney?	❑$_1$ Yes	❑$_0$ No	❑$_{99}$ NA
10.	To your knowledge, do any of your natural ***sons*** have a history of UTIs, either bladder or kidney?	❑$_1$ Yes	❑$_0$ No	❑$_{99}$ NA

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

Concomitant Medications

Research Coordinator completes this form at the Baseline, Six-month, and Twelve-month Contacts.
LIST THE MOST RECENT DOSE OF ALL OVER-THE-COUNTER MEDICATIONS AND PRESCRIPTIONS.

1. Did the participant report taking any medications as of this visit? ❑$_1$ Yes ❑$_0$ No

Line # 3-digits	**Drug Code#** From Medication Reference Tool	**Drug Name**	**Date of Last Dose**	**Total Daily Dose** Total Daily Dose or PRN	**Frequency Taken** **(See Legend)**	**Unit** **(See Legend)**	**Route** **(See Legend)**	**For Urologic or Pelvic Pain Symptoms** 1 = Yes 0 = No
__ __ __			__ __/__ __/__ __ __ __					
__ __ __			__ __/__ __/__ __ __ __					
__ __ __			__ __/__ __/__ __ __ __					
__ __ __			__ __/__ __/__ __ __ __					
__ __ __			__ __/__ __/__ __ __ __					
__ __ __			__ __/__ __/__ __ __ __					
__ __ __			__ __/__ __/__ __ __ __					
__ __ __			__ __/__ __/__ __ __ __					

2. Research Coordinator ID: ___ ___ ___ ___ (4-digit ID)

Additional comments, if needed:

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

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

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

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

Physical Exam

Principal Investigator completes at Baseline Contact
and at Six-Month and Twelve-Month Contacts or as needed.

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
   a. If **Abnormal** please specify: _____
6. Rectal / Bimanual exam: ❒1 Normal ❒0 Abnormal
7. Pelvic floor musculature tenderness ❒1 Yes ❒0 No

Men only (Check N/A for women)

8. Suprapubic Tenderness ❒1 Yes ❒0 No ❒99 Not Applicable
9. Penis Circumcised ❒1 Yes ❒0 No ❒99 Not Applicable
10. 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

Post-prostate massage urine specimen collection (VB3):

11. VB3 specimen obtained ❒1 Yes ❒0 No ❒99 Not Applicable
12. Scrotal exam
    a. Varicocele ❒1 Present ❒0 Absent ❒99 Not Applicable
    b. Hydrocele ❒1 Present ❒0 Absent ❒99 Not Applicable
    c. Mass of testis/epididymis ❒1 Present ❒0 Absent ❒99 Not Applicable
    d. Hernia ❒1 Present ❒0 Absent ❒99 Not Applicable

Women only (Check N/A for males)

13. Uterus present? (If ***YES***, please answer 13a.) ❒1 Yes ❒0 No ❒99 Not Applicable
    a. If present ❒1 Normal ❒0 Abnormal
14. Pelvic organ support
    a. Prolapse present, no vaginal points beyond the hymen ❒1 Yes ❒0 No ❒99 Not Applicable
    b. Prolapse present, at least one vaginal point beyond the hymen ❒1 Yes ❒0 No ❒99 Not Applicable
15. Principal Investigator ID ___ ___ ___ ___ (4-digit ID)

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

Study Stop Point

*__For EPS Pt.s:__ Research Coordinator completes at Twelve-month in-clinic contact or at final contact if Participant withdraws from the study early.
*__For Healthy/Positive Control Pt.s:__ Research Coordinator completes at the conclusion of the Baseline visit.

1. Has the EPS participant successfully completed the 12-month phenotyping visit of the Trans-MAPP Epidemiology Phenotyping Study? ❑1 Yes ❑0 No
   -OR-
   Has the Healthy/Positive Control Participant successfully completed the Baseline visit?

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

   a. No longer willing to follow the protocol/interested in participating ❑1 Yes ❑0 No

   b. Lost to follow-up ❑1 Yes ❑0 No

   c. Participant has personal constraints ❑1 Yes ❑0 No

   d. Medical condition/event ❑1 Yes ❑0 No

   e. Physician's Discretion ❑1 Yes ❑0 No

   f. Other ❑1 Yes ❑0 No
      Specify: _____

   Female Participants only:

   g. Female Participant is pregnant ❑1 Yes ❑0 No ❑99 NA

      g1. If **Yes**, date of most recent menstrual period: __ __/__ __/__ __ __ __ (MM/DD/YYYY)

2. Number of Participant's last Contact: ___ ___

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

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

Study Stop Point

*__For EPS Pt.s:__ Research Coordinator completes at Twelve-month in-clinic contact or at final contact if Participant withdraws from the study early.
*__For Healthy/Positive Control Pt.s:__ Research Coordinator completes at the conclusion of the Baseline visit.

The following section is for Study Close-out.

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

4. 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 Trans-MAPP Epidemiology Phenotyping Study 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 Trans-MAPP Epidemiology Phenotyping Study Protocol and Manual of Procedures.

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

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

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

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

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

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

7. Research Coordinator ID: ___ ___ ___ ___ (4-digit ID)

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

Consent Withdrawal

Research Coordinator completes as needed at contact when Participant withdraws consent for the use of specimen(s) per the Participant's request or due to other reasons.

Research Coordinator: If the participant requests to withdraw consent for the use of stored specimen(s) in the MAPP Epidemiology and Phenotyping study, complete the Consent Withdrawal Case Report Form (***CONWTHDR***) below and confirm which specimen(s) have been requested to be disposed. Please see the Manual of Procedures for further details regarding withdrawal of consent for the use of stored specimen(s) and follow-up procedures.

Please always contact the TATC and the DCC in the event that a Participant withdraws consent.

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

2. Has the participant requested that any of his/her stored specimens be disposed? ❑1 Yes ❑0 No

If **YES**, which specimens should be disposed:

a. DNA related to the main goals of this study ❑1 Yes ❑0 No

a1. Date of request: __ __/__ __/__ __ __ __ (MM/DD/YYYY)

b. DNA for genes related to other health conditions only ❑1 Yes ❑0 No

b1. Date of request: __ __/__ __/__ __ __ __ (MM/DD/YYYY)

c. Non-DNA specimens ❑1 Yes ❑0 No
(Including plasma, biomarker urine, and infectious etiology urine specimens)

c1. Date of request: __ __/__ __/__ __ __ __ (MM/DD/YYYY)

3. Has the Participant requested that his/her data be removed from the DMS/archived? ❑1 Yes ❑0 No

a. Date of request: __ __/__ __/__ __ __ __ (MM/DD/YYYY)

4. Do stored specimens need to be disposed due to reasons other than Participant's request? ❑1 Yes ❑0 No

If **YES**, which specimens should be disposed:

a. DNA related to the main goals of this study ❑1 Yes ❑0 No

a1. Date of confirmation that specimens must be disposed: __ __/__ __/__ __ __ __ (MM/DD/YYYY)

b. DNA for genes related to other health conditions only ❑1 Yes ❑0 No

b1. Date of confirmation that specimens must be disposed: __ __/__ __/__ __ __ __ (MM/DD/YYYY)

c. Non-DNA specimens ❑1 Yes ❑0 No
(Including plasma, biomarker urine, and infectious etiology urine specimens)

c1. Date of confirmation that specimens must be disposed: __ __/__ __/__ __ __ __ (MM/DD/YYYY)

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

Consent Withdrawal

Research Coordinator completes as needed at contact when Participant withdraws consent for the use of specimen(s) per the Participant's request or due to other reasons.

5. For specimens that need to be disposed due to reasons other than Participant's request, confirm reason(s) why specimens must be disposed:
   a. Participant was improperly consented ❑1 Yes ❑0 No
   b. Participant was improperly screened/enrolled ❑1 Yes ❑0 No
   c. Per IRB concerns/directives ❑1 Yes ❑0 No
   d. Other reason(s), Please specify: _____ ❑1 Yes ❑0 No
6. Due to reasons other than Participant's request, does this Participant's data need to be removed from the DMS/archived? ❑1 Yes ❑0 No
7. Due to Participant's request or reasons other than Participant's request, is this Participant record now considered ***"Cancelled"*** and removed from the data set for reporting and analyses? ❑1 Yes ❑0 No
8. Comments:

_____

_____

_____

_____

_____

Please *always* update the Consent Withdrawal CRF with the date of specimen disposal below, as confirmed by the TATC:

9. Date of specimen disposal (confirmed by TATC): __ __/__ __/__ __ __ __ (MM/DD/YYYY)

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

Reinstatement of Consent

Research Coordinator completes as needed at contact when
Participant confirms reinstatement of consent for the use of specimen(s).

Research Coordinator: If the Participant confirms consent for the use of stored specimen(s) in the MAPP Epidemiology and Phenotyping study, complete the Reinstatement of Consent Report Form (***RECON***) below and confirm which specimen(s) the Participant has consented to have collected. Please see the Manual of Procedures for further details regarding reinstatement of consent for the use of stored specimen(s) and follow-up procedures.

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

2. Has the participant confirmed consent that specimens may be collected for which consent was previously withdrawn? ❑1 Yes ❑0 No

If **YES**, which specimens are confirmed to be collected:

a. DNA related to the main goals of this study ❑1 Yes ❑0 No

a1. Date of confirmation of consent: __ __/__ __/__ __ __ __ (MM/DD/YYYY)

b. DNA for genes related to other health conditions only ❑1 Yes ❑0 No

b1. Date of confirmation of consent: __ __/__ __/__ __ __ __ (MM/DD/YYYY)

c. Non-DNA specimens ❑1 Yes ❑0 No
(Including plasma, biomarker urine, and infectious etiology urine specimens)

c1. Date of confirmation of consent: __ __/__ __/__ __ __ __ (MM/DD/YYYY)

3. Comments:

_____

_____

_____

_____

_____

Plasma Specimen Acquisition Tracking Form

Affix **Plasma** Collection Kit Barcode here

To be Completed by Collection Site

Complete all fields. Register collection event through DCC web portal. Ship original form with specimen to the TATC. File a copy in the study binder at collection site. **Please sign in the provided box to confirm that informed consent from patient is on file; samples without proper consent cannot be shipped to the TATC.**

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

Research Coordinator ID: ___ ___ ___ ___ (4-digit ID)

Was a plasma specimen collected at this visit? ☐$_1$ Yes ☐$_0$ No

Collection date: ☐☐ / ☐☐ / 20☐☐ (M M / D D / Y Y)

Collection time: ☐☐ : ☐☐ (24 hrs) (H H : M M)

Time placed at 4°C: ☐☐ : ☐☐ (24 hrs) (H H : M M)

1) Confirm that a specimen was collected, record header information, RC ID, and collection date above. Check kit contents and place the kit barcode in the upper right hand corner of this sheet.
2) Perform venipuncture using the barcoded vacutainer provided, invert tube 8 times, and record time of collection.
3) Store the tube at 4°C until shipment and record the time the tube was stored at 4°C.
4) On collection day, ship specimens for next day delivery to the TATC using the provided shipping supplies and record shipment date.

Date shipped: ☐☐ / ☐☐ / 20☐☐ (M M / D D / Y Y)

Comments:

None ☐

I certify that informed consent was obtained from this patient for the collection and storage of these specimens.

Coordinator's signature

To be Completed by TATC

Complete all TATC Fields, enter data into the database and file form in the site study binder. Please contact Research Coordinator in case of discrepancies, record explanation, and initial and date any corrections made to this form.

Date received: ☐☐ / ☐☐ / 20☐☐ (M M / D D / Y Y)

Time received: ☐☐ : ☐☐ (24 hrs) (H H : M M)

Time in Centrifuge : ☐☐ : ☐☐ (24 hrs) (H H : M M)

Time stored: ☐☐ : ☐☐ (24 hrs) (H H : M M)

Condition of Samples/Specimens:
- ☐ No Issues (Intact)
- ☐ Spills/Leakage
- ☐ Tube Broken/Open
- ☐ Warm
- ☐ Other:

# of plasma aliquots made:

ID first tube	P	L	A	0	0	0				
ID last tube	P	L	A	0	0	0				

Specimen comments:

None ☐

Data entry comments:

None ☐ Data entry complete ☐

Initials of processing tech:

Initials of data entry tech:

Cheek Swab Specimen Acquisition Tracking Form

Affix **Cheek Swab** Collection Kit Barcode here

To be Completed by Collection Site

Complete all fields. Register collection event through DCC web portal. Ship original form with specimens to the TATC. File a copy in the study binder at collection site. **Please sign in the provided box to confirm that informed consent from patient is on file; samples without proper consent cannot be shipped to the TATC.**

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

Research Coordinator ID: ___ ___ ___ ___ (4-digit ID)

Was a cheek swab specimen collected at this visit? ☐1 Yes ☐0 No

Collection date: ☐☐ / ☐☐ / 20☐☐ (M M / D D / Y Y)

Collection time: ☐☐ : ☐☐ (24 hrs) (H H : M M)

1) Confirm that a specimen was collected, record header information, RC ID, and collection date above. Check kit contents and place the kit barcode in the upper right hand corner of this sheet.
2) Following the included instructions, collect two cheek swabs from patient, one from each cheek.
3) Transfer swab into tubes provided, add stabilization capsule and close tubes.
4) Label the tubes with the kit barcodes provided
5) Record collection time.
6) Store at room temperature until shipment.
7) Ship specimens to the TATC and record shipment date.

Date shipped: ☐☐ / ☐☐ / 20☐☐ (M M / D D / Y Y)

Comments:

None ☐

I certify that informed consent was obtained from this patient for the collection and storage of these specimens.

Coordinator's signature

To be Completed by TATC

Complete all TATC Fields, enter data into the database and file form in the site study binder. Please contact Research Coordinator in case of discrepancies, record explanation, and initial and date any corrections made to this form.

Date received: ☐☐ / ☐☐ / 20☐☐ (M M / D D / Y Y)

Time received: ☐☐ : ☐☐ (24 hrs) (H H : M M)

Condition of Samples/Specimens:
- ☐ No Issues (Intact)
- ☐ Tube Broken/Open
- ☐ Other:

# of cheek swab collection tubes received:

ID first tube	C	S	W	0	0	0				
ID last tube	C	S	W	0	0	0				

Specimen comments:

None ☐

Data entry comments:

None ☐ Data entry complete ☐

Initials of processing tech:

Initials of data entry tech:

Biomarker Urine Specimen Acquisition Tracking Form

Affix **Urine** Collection Kit Barcode here

To be Completed by Collection Site

Complete all fields. Register collection event through DCC web portal. Ship original form with specimen to the TATC. File a copy in the study binder at collection site. **Please sign in the provided box to confirm that informed consent from patient is on file; samples without proper consent cannot be shipped to the TATC.**

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

Research Coordinator ID: ___ ___ ___ ___ (4-digit ID)

Was a urine specimen collected at this visit? ☐1 Yes ☐0 No

Collection date: ☐☐/☐☐/20☐☐ (M M / D D / Y Y)

Collection time: ☐☐:☐☐ (24 hrs) (H H : M M)

Volume: ☐☐ (ml)

1) Confirm that a specimen was collected, record header information, RC ID, and collection date above. Check kit contents and place the kit barcode in the upper right hand corner of this sheet.
2) Perform Mid-Stream Clean-Catch urine collection using BZK antiseptic wipes and 90 ml urine cup provided and record volume and time of collection.
3) Invert the urine cup 3 times and fill the provided urinalysis tube using the transfer pipette.
4) Transfer the remaining urine to the two 50 ml barcode labeled conical blue top tubes provided. Immediately store the 50 ml tubes in a -80°C freezer until shipment. Record the time the tubes were placed in the freezer.
5) Perform urinalysis using a dipstick and record the results, then discard urinalysis tube.
6) Ship specimens to the TATC and record shipment date.

Glucose:
Bilirubin:
Ketone:
Specific Gravity:
Blood:
pH:
Protein:
Urobilinogen:
Nitrite:
Leukocytes:

Time placed in freezer: ☐☐:☐☐ (24 hrs) (H H : M M)

Date shipped: ☐☐/☐☐/20☐☐ (M M / D D / Y Y)

Comments:

None ☐

I certify that informed consent was obtained from this patient for the collection and storage of these specimens.

Coordinator's signature

To be Completed by TATC

Complete all TATC Fields, enter data into the database and file form in the site study binder. Please contact Research Coordinator in case of discrepancies, record explanation, and initial and date any corrections made to this form.

Date received: ☐☐/☐☐/20☐☐ (M M / D D / Y Y)

Time received: ☐☐:☐☐ (24 hrs) (H H : M M)

Date processed: ☐☐/☐☐/20☐☐ (M M / D D / Y Y)

Time Thawed: ☐☐:☐☐ (24 hrs) (H H : M M)

Time in centrifuge: ☐☐:☐☐ (24 hrs) (H H : M M)

Time refrozen: ☐☐:☐☐ (24 hrs) (H H : M M)

Condition of specimens:

- ☐ No Issues (Intact)
- ☐ Spills/Leakage
- ☐ Tube Broken/Open
- ☐ Thawed
- ☐ Other:

# of urine aliquots made:

ID first tube	U	R	I	0	0	0				
ID last tube	U	R	I	0	0	0				

Specimen comments:

None ☐

Data entry comments:

None ☐ Data entry complete ☐

Initials of processing tech:

Initials of data entry tech:

F IE Female Urine Specimen Acquisition Tracking Form

MAPP research network

Affix **IE Urine** Collection Kit Barcode here

To be Completed by Collection Site

Complete all fields. Register collection event through DCC web portal. Ship original form with specimen to the TATC. File a copy in the study binder at collection site. **Please sign in the provided box to confirm that informed consent from patient is on file; samples without proper consent cannot be shipped to the TATC.**

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

Research Coordinator ID: ___ ___ ___ ___ (4-digit ID)

Was a urine specimen collected at this visit? ☐1 Yes ☐0 No

Collection date: ☐☐ / ☐☐ / 20☐☐ (M M / D D / Y Y)

1) Confirm that a specimen was collected, record header information, RC ID, and collection date above. Check kit contents and place the kit barcode in the upper right hand corner of this sheet.
2) Perform Clean-Catch First-Void (VB1) and Mid-Stream (VB2) urine collection using saline wipes and 60 ml urine cups provided. Record collection time and collection volume for each catch type.
3) Invert the urine cups 3 times and transfer the collected urine specimen to the respective 50 ml barcode labeled conical orange top tube provided. Record tube IDs.
4) Immediately store the 50 ml tubes in a -80°C freezer until shipment. Record the time the tubes were placed in the freezer.
5) Ship specimens to the TATC and record shipment date.

VB1 & VB2

Collection time: ☐☐:☐☐ (24 hrs) (H H : M M)

Time placed in freezer: ☐☐:☐☐ (24 hrs) (H H : M M)

VB1 Volume collected: ☐☐ **(mL)**

VB2 Volume collected: ☐☐ **(mL)**

ID VB1 tube	U	R	I	0	0					
ID VB2 tube	U	R	I	0	0					

Date shipped: ☐☐ / ☐☐ / 20☐☐ (M M / D D / Y Y)

Comments:

None ☐

I certify that informed consent was obtained from this patient for the collection and storage of these specimens.

Coordinator's signature

To be Completed by TATC

Complete all TATC Fields, enter data into the database and file form in the site study binder. Please contact Research Coordinator in case of discrepancies, record explanation, and initial and date any corrections made to this form.

Date received: ☐☐ / ☐☐ / 20☐☐ (M M / D D / Y Y)

Time received: ☐☐:☐☐ (24 hrs) (H H : M M)

Time stored: ☐☐:☐☐ (24 hrs) (H H : M M)

Condition of Samples/Specimens:	VB1	VB2
No Issues (Intact)	☐	☐
Spills/Leakage	☐	☐
Tube Broken/Open	☐	☐
Thawed	☐	☐
Other (specify on back of form)	☐	☐

Volumes: VB1: ☐☐ **(mL)** **VB2:** ☐☐ **(mL)**

Specimen comments:

None ☐

Data entry comments:

None ☐ Data entry complete ☐

Initials of processing tech:

Initials of data entry tech:

MIE Male Urine Specimen Acquisition Tracking Form

MAPP research network

Affix **IE Urine** Collection Kit Barcode here

To be Completed by Collection Site

Complete all fields. Register collection event through DCC web portal. Ship original form with specimen to the TATC. File a copy in the study binder at collection site. **Please sign in the provided box to confirm that informed consent from patient is on file; samples without proper consent cannot be shipped to the TATC.**

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

Research Coordinator ID: ___ ___ ___ ___ (4-digit ID)

Was a urine specimen collected at this visit? ☐1 Yes ☐0 No

Collection date: MM / DD / 20YY

1) Confirm that a specimen was collected, record header information, RC ID, and collection date above. Check kit contents and place the kit barcode in the upper right hand corner of this sheet.
2) Perform Clean-Catch First-Void (VB1) and Mid-Stream (VB2) urine collection using saline wipes and 60 ml urine cups provided. Record collection time and collection volume for each catch type.
3) Invert the urine cups 3 times and transfer the collected urine specimen to the respective 50 ml barcode labeled orange top conical tube provided. Record tube IDs.
4) Immediately store the 50 ml tubes in the -80°C freezer until shipment. Record the time the tubes were placed in the freezer.
5) Perform Clean-Catch First-Void (VB3) urine collection after prostate massage using saline wipes and 60 ml urine cup provided. Record collection time and collection volume.
6) Invert the urine cup 3 times and transfer the collected urine to the 50 ml barcode labeled orange top conical tube provided. Record the tube ID.
7) Immediately store the 50 ml tube in a -80°C freezer until shipment. Record the time the tubes were placed in the freezer.
8) Ship specimens to the TATC and record shipment date.

VB1 & VB2

Collection time: HH:MM (24 hrs) **Time placed in freezer:** HH:MM (24 hrs)

VB1 Volume collected: ___ **(mL)**

VB2 Volume collected: ___ **(mL)**

ID VB1 tube	U	R	I	0	0					
ID VB2 tube	U	R	I	0	0					

VB3

Collection time: HH:MM (24 hrs) **Time placed in freezer:** HH:MM (24 hrs)

VB3 Volume collected: ___ **(mL)**

ID VB3 tube	U	R	I	0	0					

Date shipped: MM / DD / 20YY

Comments:

None ☐

I certify that informed consent was obtained from this patient for the collection and storage of these specimens. Coordinator's signature

To be Completed by TATC

Complete all TATC Fields, enter data into the database and file form in the site study binder. Please contact Research Coordinator in case of discrepancies, record explanation, and initial and date any corrections made to this form.

Date received: MM / DD / 20YY

Time received: HH:MM (24 hrs)

Time stored: HH:MM (24 hrs)

Condition of Samples/Specimens:	VB1	VB2	VB3
No Issues (Intact)	☐	☐	☐
Spills/Leakage	☐	☐	☐
Tube Broken/Open	☐	☐	☐
Thawed	☐	☐	☐
Other (specify on back of form)	☐	☐	☐

Volume: VB1: ___ (mL) VB2: ___ (mL) VB3: ___ (mL)

Specimen comments:

None ☐

Data entry comments:

None ☐ Data entry complete ☐

Initials of processing tech:

Initials of data entry tech:

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

Pressure / Pain Threshold Procedure Results

Research Coordinator completes at the Baseline Contact.*

*This form is also completed at the Six-month and Twelve-month Contacts, if necessary.

1. Were the Pressure/Pain Threshold procedures administered? ❑$_1$ Yes ❑$_0$ No

   If ***NO***, please specify the reason why Pressure/Pain Threshold procedures not administered:

   a. Participant has artificial fingernails ❑$_1$ Yes ❑$_0$ No

   b. Participant's thumb too large ❑$_1$ Yes ❑$_0$ No

   c. Participant has arthritis ❑$_1$ Yes ❑$_0$ No

   d. Other (please specify) _____ ❑$_1$ Yes ❑$_0$ No

2. Research Coordinator ID: ___ ___ ___ ___ (4-digit ID)

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

PROCEDURAL OR UNANTICIPATED PROBLEMS

1. RC ID: ___ ___ ___ ___

Problem #	PUP Code See codes below	Date of Onset MM/DD/YYYY	Treatment for PUP No = 0 Yes = 1
	__ __ __ - __ __	__ __/ __ __/ __ __ __ __	
Comments: [ALL PUPs require a brief narrative explaining type of occurrence (limit to 25 words)]			

Problem #	PUP Code See codes below	Date of Onset MM/DD/YYYY	Treatment for PUP No = 0 Yes = 1
	__ __ __ - __ __	__ __/ __ __/ __ __ __ __	
Comments: [ALL PUPs require a brief narrative explaining type of occurrence (limit to 25 words)]			

PUP Codes:

Specimen collection-related		Procedure-related	
SPC-01	Presyncopal episode or fainting episode	**PRO -01**	Allergic reaction
SPC-02	Severe hematoma	**PRO -02**	Headache/Migraine
SPC-03	Prolonged bleeding	**PRO -03**	Hand pain due to typing/using mouse
SPC-04	Infection at the needle insertion site	**PRO -04**	Thumb pain due to pain pressure procedure
SPC-05	A pregnant or breast feeding woman, excluded from this study per the study protocol, was inadvertently enrolled in the study and specimens were collected.	**MIS-01**	For example, "the phlebotomist was stuck with the needle used to draw the participant's blood" or any other problem not coded elsewhere on this grid
		Protocol Deviation/Violation	
		PDV-01	**Protocol Deviation**
		PDV-02	**Protocol Violation**
		PDV-03	**Both Protocol Deviation and Violation**

Important:

- This CRF must be completed and entered into the database within 72 hours of 'first knowledge' of the "unanticipated problem."
- In accordance with 45 CFR 46, all "unanticipated problems involving risks to subjects or others" must be promptly reported to:
  1. Appropriate institutional officials (e.g., PI and others, prn).
  2. Your IRB (in accordance with their reporting timelines/guidelines).
  3. The Sponsor (for this study, Sponsor notification will occur via regular reports from the SDCC rather than from direct site reporting).

Urological Phenotyping Group,
Case Report Forms for Control Participants

CRFs for Female Participants ONLY

- Female Genitourinary Pain Index (FGUPI)
- Female Sexual Function Index (FSFI)
- Self-Esteem and Relationship Questionnaire, Female Pt.s (FSEAR)

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

FEMALE GENITOURINARY PAIN INDEX

FEMALE PARTICIPANT COMPLETES AT THE BASELINE CONTACT.

Pain or Discomfort

1. In the last week, have you experienced any pain or discomfort in the following areas?
   a. Entrance to vagina ❑1 Yes ❑0 No
   b. Vagina ❑1 Yes ❑0 No
   c. Urethra ❑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 intercourse? ❑1 Yes ❑0 No
   c. Pain or discomfort as your bladder fills? ❑1 Yes ❑0 No
   d. Pain or discomfort relieved by voiding? ❑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

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

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

FEMALE GENITOURINARY PAIN INDEX

FEMALE PARTICIPANT COMPLETES AT THE BASELINE CONTACT.

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

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

Scoring

10. Pain subscale: Total of items 1a, 1b, 1c, 1d, 2a, 2b, 2c, 2d, 3, and 4 = _____ (range 0-23)
11. Urinary subscale: Total of items 5 and 6 = _____ (range 0-10)
12. QOL Impact: Total of items 7, 8, and 9 = _____ (range 0-12)
13. Total score: Sum of subscale scores = _____ (range 0-45)

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

Self-Esteem And Relationship Questionnaire ®

(For Female Participants)

FEMALE PARTICIPANT COMPLETES AT BASELINE, BI-MONTLY, SIX-MONTH, AND TWELVE-MONTH CONTACTS.

During the past 4 weeks:

1. I felt relaxed about initiating sex with my partner
   - ❑1 Almost never/never
   - ❑2 A few times (much less than half the time)
   - ❑3 Sometimes (about half the time)
   - ❑4 Most times (much more than half the time)
   - ❑5 Almost always/always
2. I was satisfied with my sexual performance
   - ❑1 Almost never/never
   - ❑2 A few times (much less than half the time)
   - ❑3 Sometimes (about half the time)
   - ❑4 Most times (much more than half the time)
   - ❑5 Almost always/always
3. I felt that sex could be spontaneous
   - ❑1 Almost never/never
   - ❑2 A few times (much less than half the time)
   - ❑3 Sometimes (about half the time)
   - ❑4 Most times (much more than half the time)
   - ❑5 Almost always/always
4. I was likely to initiate sex
   - ❑1 Almost never/never
   - ❑2 A few times (much less than half the time)
   - ❑3 Sometimes (about half the time)
   - ❑4 Most times (much more than half the time)
   - ❑5 Almost always/always
5. I felt confident about performing sexually
   - ❑1 Almost never/never
   - ❑2 A few times (much less than half the time)
   - ❑3 Sometimes (about half the time)
   - ❑4 Most times (much more than half the time)
   - ❑5 Almost always/always
6. I was satisfied with our sex life
   - ❑1 Almost never/never
   - ❑2 A few times (much less than half the time)
   - ❑3 Sometimes (about half the time)
   - ❑4 Most times (much more than half the time)
   - ❑5 Almost always/always
7. My partner was unhappy with the quality of our sexual relations
   - ❑5 Almost never/never
   - ❑4 A few times (much less than half the time)
   - ❑3 Sometimes (about half the time)
   - ❑2 Most times (much more than half the time)
   - ❑1 Almost always/always
8. I had good self-esteem
   - ❑1 Almost never/never
   - ❑2 A few times (much less than half the time)
   - ❑3 Sometimes (about half the time)
   - ❑4 Most times (much more than half the time)
   - ❑5 Almost always/always

MAPP research network	**Participant ID:** __ __ __ __ __ __	**Pin #** __ __ __ __
	Discovery Site: __ __	**Clinical Center** __ __
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Self-Esteem And Relationship Questionnaire ®

(For Female Participants)

FEMALE PARTICIPANT COMPLETES AT BASELINE, BI-MONTLY, SIX-MONTH, AND TWELVE-MONTH CONTACTS.

9. I was inclined to feel that I am a failure

- ❑5 Almost never/never
- ❑4 A few times (much less than half the time)
- ❑3 Sometimes (about half the time)
- ❑2 Most times (much more than half the time)
- ❑1 Almost always/always

10. I felt confident

- ❑1 Almost never/never
- ❑2 A few times (much less than half the time)
- ❑3 Sometimes (about half the time)
- ❑4 Most times (much more than half the time)
- ❑5 Almost always/always

11. My partner was satisfied with our relationship in general

- ❑1 Almost never/never
- ❑2 A few times (much less than half the time)
- ❑3 Sometimes (about half the time)
- ❑4 Most times (much more than half the time)
- ❑5 Almost always/always

12. I was satisfied with our relationship in general

- ❑1 Almost never/never
- ❑2 A few times (much less than half the time)
- ❑3 Sometimes (about half the time)
- ❑4 Most times (much more than half the time)
- ❑5 Almost always/always

Urological Phenotyping Group,
Case Report Forms for Control Participants

CRFs for Male Participants ONLY

- Male Genitourinary Pain Index (MGUPI)
- International Index of Erectile Function, Short Form (IIEF)
- University of Washington Ejaculatory Function Scale (EFS)
- Self-Esteem and Relationship Questionnaire, Male Pt.s (MSEAR)

MAPP research network	**Participant ID:** __ __ __ __ __ __	**Pin #** __ __ __ __
	Discovery Site: __ __	**Clinical Center** __ __
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MALE GENITOURINARY PAIN INDEX

PARTICIPANT COMPLETES THIS FORM AT THE BASELINE CONTACT.

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
   c. Pain or discomfort as your bladder fills? ❑$_1$ Yes ❑$_0$ No
   d. Pain or discomfort relieved by voiding? ❑$_1$ 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

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

MAPP research network	**Participant ID:** __ __ __ __ __ __	**Pin #** __ __ __ __
	Discovery Site: __ __	**Clinical Center** __ __
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MALE GENITOURINARY PAIN INDEX

PARTICIPANT COMPLETES THIS FORM AT THE BASELINE CONTACT.

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

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

Scoring

10. Pain subscale: Total of items 1a, 1b, 1c, 1d, 2a, 2b, 2c, 2d, 3, and 4 = _____ (range 0-23)
11. Urinary subscale: Total of items 5 and 6 = _____ (range 0-10)
12. QOL Impact: Total of items 7, 8, and 9 = _____ (range 0-12)
13. Total score: Sum of subscale scores = _____ (range 0-45)

MAPP research network	**Participant ID:** __ __ __ __ __ __	**Pin #** __ __ __ __
	Discovery Site: __ __	**Clinical Center** __ __
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International Index of Erectile Function®

PARTICIPANT COMPLETES AT BASELINE, BI-MONTLY, SIX-MONTH, AND TWELVE-MONTH CONTACTS.

Over the past 4 weeks:

1. How often were you able to get an erection during sexual activity?
   - ❑0 No sexual activity
   - ❑1 Almost never/never
   - ❑2 A few times (much less than half the time)
   - ❑3 Sometimes (about half the time)
   - ❑4 Most times (much more than half the time)
   - ❑5 Almost always/always

2. When you had erections with sexual stimulation, how often were your erections hard enough for penetration?
   - ❑0 No sexual activity
   - ❑1 Almost never/never
   - ❑2 A few times (much less than half the time)
   - ❑3 Sometimes (about half the time)
   - ❑4 Most times (much more than half the time)
   - ❑5 Almost always/always

3. When you attempted sexual intercourse, how often were you able to penetrate (enter) your partner?
   - ❑0 Did not attempt intercourse
   - ❑1 Almost never/never
   - ❑2 A few times (much less than half the time)
   - ❑3 Sometimes (about half the time)
   - ❑4 Most times (much more than half the time)
   - ❑5 Almost always/always

4. During sexual intercourse, how often were you able to maintain your erection after you had penetrated (entered) your partner?
   - ❑0 Did not attempt intercourse
   - ❑1 Almost never/never
   - ❑2 A few times (much less than half the time)
   - ❑3 Sometimes (about half the time)
   - ❑4 Most times (much more than half the time)
   - ❑5 Almost always/always

5. During sexual intercourse, how difficult was it to maintain your erection to completion of intercourse?
   - ❑0 Did not attempt intercourse
   - ❑1 Extremely difficult
   - ❑2 Very difficult
   - ❑3 Difficult
   - ❑4 Slightly difficult
   - ❑5 Not difficult

6. How do you rate your confidence that you could get and keep an erection?
   - ❑1 Very low
   - ❑2 Low
   - ❑3 Moderate
   - ❑4 High
   - ❑5 Very high

MAPP research network	**Participant ID:** __ __ __ __ __ __	**Pin #** __ __ __ __
	Discovery Site: __ __	**Clinical Center** __ __
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University of Washington - Ejaculatory Function Scale

Male Participant completes at Baseline, Bi-monthly, Six-month, and Twelve-month Contacts.

INSTRUCTIONS: The following three (3) questions ask about your ejaculatory function and responses during the past 4 weeks because many patients have ejaculatory problems. Please answer the following questions as honestly and clearly as possible. Your responses will be kept completely confidential.

During the past 4 weeks:

1. Pain with ejaculation:
   - ❑$_4$ Extremely
   - ❑$_3$ Quite a bit
   - ❑$_2$ Moderately
   - ❑$_1$ A little bit
   - ❑$_0$ Not at all

2. Premature ejaculation:
   - ❑$_4$ Extremely
   - ❑$_3$ Quite a bit
   - ❑$_2$ Moderately
   - ❑$_1$ A little bit
   - ❑$_0$ Not at all

3. Difficulty in reaching ejaculation:
   - ❑$_4$ Extremely
   - ❑$_3$ Quite a bit
   - ❑$_2$ Moderately
   - ❑$_1$ A little bit
   - ❑$_0$ Not at all

MAPP research network	**Participant ID:** __ __ __ __ __ __	**Pin #** __ __ __ __
	Discovery Site: __ __	**Clinical Center** __ __
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Self-Esteem And Relationship Questionnaire®

(For Male Participants)

MALE PARTICIPANT COMPLETES AT BASELINE, BI-MONTLY, SIX-MONTH, AND TWELVE-MONTH CONTACTS.

During the past 4 weeks:

1. I felt relaxed about initiating sex with my partner
   - ❑1 Almost never/never
   - ❑2 A few times (much less than half the time)
   - ❑3 Sometimes (about half the time)
   - ❑4 Most times (much more than half the time)
   - ❑5 Almost always/always
2. I felt confident that during sex my erection would last long enough
   - ❑1 Almost never/never
   - ❑2 A few times (much less than half the time)
   - ❑3 Sometimes (about half the time)
   - ❑4 Most times (much more than half the time)
   - ❑5 Almost always/always
3. I was satisfied with my sexual performance
   - ❑1 Almost never/never
   - ❑2 A few times (much less than half the time)
   - ❑3 Sometimes (about half the time)
   - ❑4 Most times (much more than half the time)
   - ❑5 Almost always/always
4. I felt that sex could be spontaneous
   - ❑1 Almost never/never
   - ❑2 A few times (much less than half the time)
   - ❑3 Sometimes (about half the time)
   - ❑4 Most times (much more than half the time)
   - ❑5 Almost always/always
5. I was likely to initiate sex
   - ❑1 Almost never/never
   - ❑2 A few times (much less than half the time)
   - ❑3 Sometimes (about half the time)
   - ❑4 Most times (much more than half the time)
   - ❑5 Almost always/always
6. I felt confident about performing sexually
   - ❑1 Almost never/never
   - ❑2 A few times (much less than half the time)
   - ❑3 Sometimes (about half the time)
   - ❑4 Most times (much more than half the time)
   - ❑5 Almost always/always
7. I was satisfied with our sex life
   - ❑1 Almost never/never
   - ❑2 A few times (much less than half the time)
   - ❑3 Sometimes (about half the time)
   - ❑4 Most times (much more than half the time)
   - ❑5 Almost always/always
8. My partner was unhappy with the quality of our sexual relations
   - ❑5 Almost never/never
   - ❑4 A few times (much less than half the time)
   - ❑3 Sometimes (about half the time)
   - ❑2 Most times (much more than half the time)
   - ❑1 Almost always/always

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

Self-Esteem And Relationship Questionnaire®

(For Male Participants)

MALE PARTICIPANT COMPLETES AT BASELINE, BI-MONTLY, SIX-MONTH, AND TWELVE-MONTH CONTACTS.

9. I had good self-esteem
- ❑1 Almost never/never
- ❑2 A few times (much less than half the time)
- ❑3 Sometimes (about half the time)
- ❑4 Most times (much more than half the time)
- ❑5 Almost always/always

10. I felt like a whole man
- ❑1 Almost never/never
- ❑2 A few times (much less than half the time)
- ❑3 Sometimes (about half the time)
- ❑4 Most times (much more than half the time)
- ❑5 Almost always/always

11. I was inclined to feel that I am a failure
- ❑5 Almost never/never
- ❑4 A few times (much less than half the time)
- ❑3 Sometimes (about half the time)
- ❑2 Most times (much more than half the time)
- ❑1 Almost always/always

12. I felt confident
- ❑1 Almost never/never
- ❑2 A few times (much less than half the time)
- ❑3 Sometimes (about half the time)
- ❑4 Most times (much more than half the time)
- ❑5 Almost always/always

13. My partner was satisfied with our relationship in general
- ❑1 Almost never/never
- ❑2 A few times (much less than half the time)
- ❑3 Sometimes (about half the time)
- ❑4 Most times (much more than half the time)
- ❑5 Almost always/always

14. I was satisfied with our relationship in general
- ❑1 Almost never/never
- ❑2 A few times (much less than half the time)
- ❑3 Sometimes (about half the time)
- ❑4 Most times (much more than half the time)
- ❑5 Almost always/always

Non-Urological Phenotyping
Case Report Forms
Control Participants

- Brief Pain Inventory (BPI)
- SF-12
- PANAS
- Hospital Anxiety and Depression Scale (HADS)
- PROMIS - Anger - Short Form - (ANGER)
- PROMIS - Fatigue - Short Form - (FATIGUE)
- PROMIS - Sleep - Short Form - (SLEEP)
- Multiple Ability Self-Report Questionnaire (MASQ)
- Perceived Stress Scale (PSS)
- IPIP
- Thoughts About Symptoms –Catastrophizing Sub-scale (CSQ)
- Beliefs in Pain Control Questionnaire (BPCQ)
- Childhood Traumatic Events Scale (CTES)
- CMSI – Complex Medical Symptoms Inventory (Baseline)
- CMSI – Complex Medical Symptoms Inventory – Fibromyalgia Tender Point
- CMSI – Complex Medical Symptoms Inventory - VDYN
- CMSI – Complex Medical Symptoms Inventory - MI
- CMSI – Complex Medical Symptoms Inventory - TMJ

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

BRIEF PAIN INVENTORY (SHORT FORM) for Female Participants

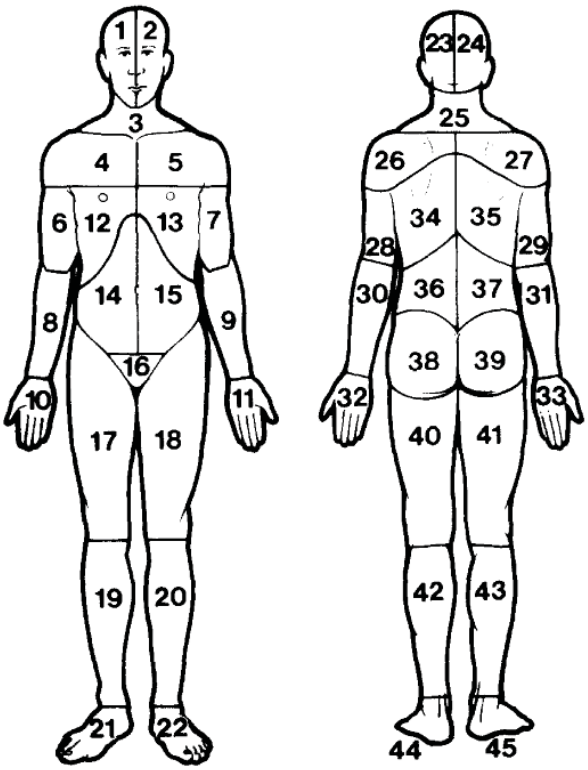
Female Participant completes at Baseline, Bi-monthly, Six-month, and Twelve-month contacts.

1. Throughout our lives, most of us have had pain from time to time (such as minor headaches, sprains, and toothaches). Have you had pain other than these everyday kinds of pain during the last week? ❑$_1$ Yes ❑$_0$ No

2. Check the boxes listed below for each area on the body diagram where you feel pain:

❑ 1 ❑ 2 ❑ 3 ❑ 4 ❑ 5 ❑ 6 ❑ 7 ❑ 8 ❑ 9 ❑10 ❑11 ❑12 ❑13 ❑14 ❑15 ❑16 ❑17 ❑18 ❑19 ❑20 ❑21 ❑22

❑23 ❑24 ❑25 ❑26 ❑27 ❑28 ❑29 ❑30 ❑31 ❑32 ❑33 ❑34 ❑35 ❑36 ❑37 ❑38 ❑39 ❑40 ❑41 ❑42 ❑43 ❑44 ❑45



a. Enter the number here for the area on the body diagram that hurts the most: ___ ___

MAPP research network	**Participant ID:** __ __ __ __ __ __	**Pin #** __ __ __ __
	Discovery Site: __ __	**Clinical Center** __ __
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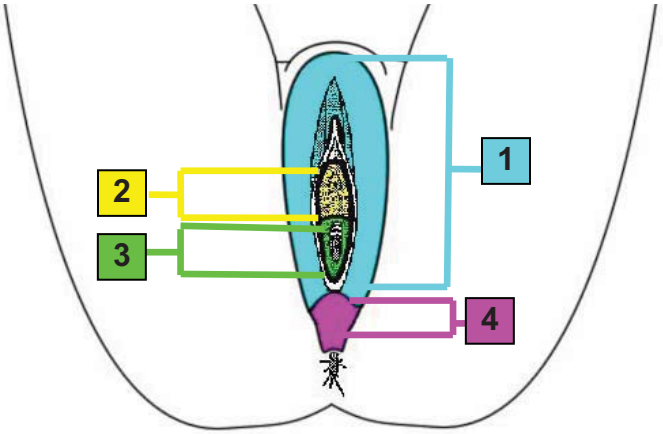
BRIEF PAIN INVENTORY (SHORT FORM) for Female Participants

Female Participant completes at Baseline, Bi-monthly, Six-month, and Twelve-month contacts.

3. Check the boxes listed below for each area on the genital diagram where you feel pain:

1 - ❑1
2 - ❑2
3 - ❑3
4 - ❑4



a. Enter the number here for the area on the genital diagram that hurts the most: ___

4. Please rate your pain by circling the one number that best describes your pain at its ***worst*** in the last week.

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

5. Please rate your pain by circling the one number that best describes your pain at its ***least*** in the last week.

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

6. Please rate your pain by circling the one number that best describes your pain on the ***average.***

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

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

BRIEF PAIN INVENTORY (SHORT FORM) for Female Participants

Female Participant completes at Baseline, Bi-monthly, Six-month, and Twelve-month contacts.

7. Please rate your pain by circling the one number that tells how much pain you have ***right now.***

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

8. What treatments or medications are you receiving for your pain?

_____

_____

_____

9. In the last week, how much relief have pain treatments or medications provided? Please circle the one percentage that most shows how much ***relief*** you have received.

0%	10%	20%	30%	40%	50%	60%	70%	80%	90%	100%
No relief										Complete relief

10. Circle the one number that describes how much, during the past week, pain has interfered with your:

A. General Activity

0	1	2	3	4	5	6	7	8	9	10
Does not interfere										Completely interferes

B. Mood

0	1	2	3	4	5	6	7	8	9	10
Does not interfere										Completely interferes

C. Walking Ability

0	1	2	3	4	5	6	7	8	9	10
Does not interfere										Completely interferes

D. Normal Work (includes both work outside the home and housework)

0	1	2	3	4	5	6	7	8	9	10
Does not interfere										Completely interferes

E. Relations with other people

0	1	2	3	4	5	6	7	8	9	10
Does not interfere										Completely interferes

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

BRIEF PAIN INVENTORY (SHORT FORM) for Female Participants

Female Participant completes at Baseline, Bi-monthly, Six-month, and Twelve-month contacts.

F. Sleep

0	1	2	3	4	5	6	7	8	9	10
Does not interfere										Completely interferes

G. Enjoyment of life

0	1	2	3	4	5	6	7	8	9	10
Does not interfere										Completely interferes

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

BRIEF PAIN INVENTORY (SHORT FORM) for Male Participants

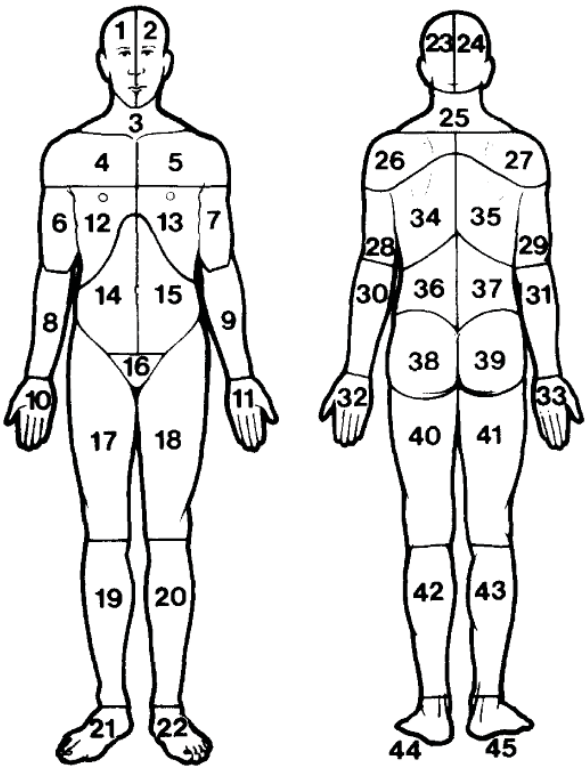
Male Participant completes at Baseline, Bi-monthly, Six-month, and Twelve-month contacts.

1. Throughout our lives, most of us have had pain from time to time (such as minor headaches, sprains, and toothaches). Have you had pain other than these everyday kinds of pain during the last week? ❑$_1$ Yes ❑$_0$ No

2. Check the boxes listed below for each area on the body diagram where you feel pain:

❑ 1 ❑ 2 ❑ 3 ❑ 4 ❑ 5 ❑ 6 ❑ 7 ❑ 8 ❑ 9 ❑10 ❑11 ❑12 ❑13 ❑14 ❑15 ❑16 ❑17 ❑18 ❑19 ❑20 ❑21 ❑22

❑23 ❑24 ❑25 ❑26 ❑27 ❑28 ❑29 ❑30 ❑31 ❑32 ❑33 ❑34 ❑35 ❑36 ❑37 ❑38 ❑39 ❑40 ❑41 ❑42 ❑43 ❑44 ❑45



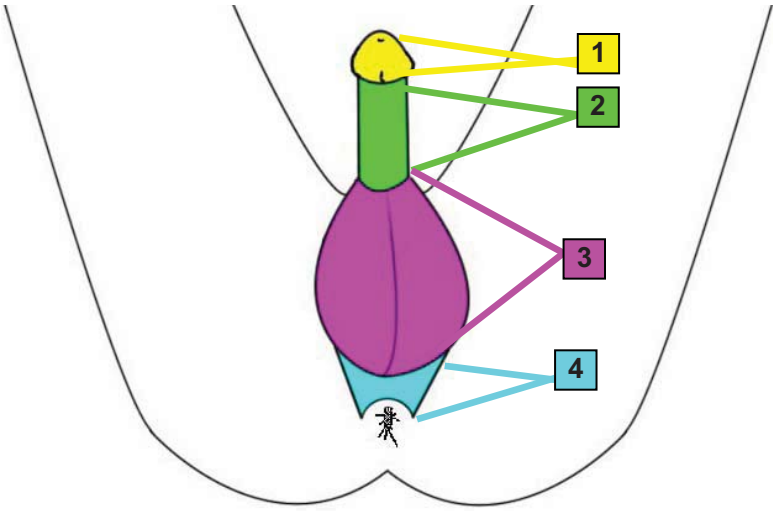
a. Enter the number here for the area on the body diagram that hurts the most: ___ ___

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

BRIEF PAIN INVENTORY (SHORT FORM) for Male Participants

Male Participant completes at Baseline, Bi-monthly, Six-month, and Twelve-month contacts.

3. Check the boxes listed below for each area on the genital diagram where you feel pain:



1 - ❑1

2 - ❑2

3 - ❑3

4 - ❑4

a. Enter the number here for the area on the genital diagram that hurts the most: ___

4. Please rate your pain by circling the one number that best describes your pain at its ***worst*** in the last week.

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

5. Please rate your pain by circling the one number that best describes your pain at its ***least*** in the last week.

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

6. Please rate your pain by circling the one number that best describes your pain on the ***average.***

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

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BRIEF PAIN INVENTORY (SHORT FORM) for Male Participants

Male Participant completes at Baseline, Bi-monthly, Six-month, and Twelve-month contacts.

7. Please rate your pain by circling the one number that tells how much pain you have ***right now.***

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

8. What treatments or medications are you receiving for your pain?

_____

_____

_____

9. In the last week, how much relief have pain treatments or medications provided? Please circle the one percentage that most shows how much ***relief*** you have received.

0%	10%	20%	30%	40%	50%	60%	70%	80%	90%	100%
No relief										Complete relief

10. Circle the one number that describes how much, during the past week, pain has interfered with your:

A. General Activity

0	1	2	3	4	5	6	7	8	9	10
Does not interfere										Completely interferes

B. Mood

0	1	2	3	4	5	6	7	8	9	10
Does not interfere										Completely interferes

C. Walking Ability

0	1	2	3	4	5	6	7	8	9	10
Does not interfere										Completely interferes

D. Normal Work (includes both work outside the home and housework)

0	1	2	3	4	5	6	7	8	9	10
Does not interfere										Completely interferes

E. Relations with other people

0	1	2	3	4	5	6	7	8	9	10
Does not interfere										Completely interferes

BRIEF PAIN INVENTORY (SHORT FORM) for Male Participants

Male Participant completes at Baseline, Bi-monthly, Six-month, and Twelve-month contacts.

F. Sleep

0	1	2	3	4	5	6	7	8	9	10
Does not interfere										Completely interferes

G. Enjoyment of life

0	1	2	3	4	5	6	7	8	9	10
Does not interfere										Completely interferes

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SF-12 – Health Status Questionnaire®

Participant completes at Baseline, Bi-monthly, Six-month, and Twelve-month contacts.

Your Health and Well Being

This survey asks for your views about your health. This information will help keep track of how you feel and how well you are able to do your usual activities. *Thank you for completing this survey!*

For each of the following questions, please mark an ☒ in the one box that best describes your answer.

1. In general, would you say your health is:

Excellent	Very good	Good	Fair	Poor
❑1	❑2	❑3	❑4	❑5

2. The following questions are about activities you might do during a typical day. Does <u>your health now limit you</u> in these activities? If so, how much?

	Yes, limited a lot	Yes, limited a little	No, not limited at all
a. <u>Moderate activities</u>, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf.	❑1	❑2	❑3
b. Climbing <u>several</u> flights of stairs	❑1	❑2	❑3

3. During the past <u>4 weeks</u>, how much of the time have you had any of the following problems with your work or other regular daily activities <u>as a result of your physical health</u>?

	All of the time	Most of the time	Some of the time	A little of the time	None of the time
a. <u>Accomplished less</u> than you would like	❑1	❑2	❑3	❑4	❑5
b. Were limited in the <u>kind</u> of work or other activities	❑1	❑2	❑3	❑4	❑5

4. During the <u>past 4 weeks</u>, how much of the time have you had any of the following problems with your work or other regular daily activities <u>as a result of any emotional problems</u> (such as feeling depressed or anxious)?

	All of the time	Most of the time	Some of the time	A little of the time	None of the time
a. <u>Accomplished less</u> than you would like	❑1	❑2	❑3	❑4	❑5
b. Did work or other activities <u>less carefully than usual</u>	❑1	❑2	❑3	❑4	❑5

5. During the <u>past 4 weeks</u>, how much did <u>pain</u> interfere with your normal work (including both work outside the home and housework)?

Not at all	A little bit	Moderately	Quite a bit	Extremely
❑1	❑2	❑3	❑4	❑5

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SF-12 – Health Status Questionnaire®

Participant completes at Baseline, Bi-monthly, Six-month, and Twelve-month contacts.

6. These questions are about how you feel and how things have been with you during the past 4 weeks. For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks...

	All of the time	Most of the time	Some of the time	A little of the time	None of the time
a. Have you felt calm and peaceful?	❑1	❑2	❑3	❑4	❑5
b. Did you have a lot of energy?	❑1	❑2	❑3	❑4	❑5
c. Have you felt downhearted and depressed?	❑1	❑2	❑3	❑4	❑5

7. During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting friends, relatives, etc.)?

All of the time	Most of the time	Some of the time	A little of the time	None of the time
❑1	❑2	❑3	❑4	❑5

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PANAS

Participant completes this form at Baseline, Six-month, and Twelve-month contacts.

Directions

This scale consists of a number of words that describe different feelings and emotions. Read each item and then circle the appropriate answer next to that word. Indicate to what extent you have felt this way ***during the past week.***

Use the following scale to record your answers.

(1) = Very slightly or not at all (2) = A little (3) = Moderately (4) = Quite a bit (5) = Extremely

	Very slightly or not at all	A little	Moderately	Quite a bit	Extremely
1. Interested	❑1	❑2	❑3	❑4	❑5
2. Distressed	❑1	❑2	❑3	❑4	❑5
3. Excited	❑1	❑2	❑3	❑4	❑5
4. Upset	❑1	❑2	❑3	❑4	❑5
5. Strong	❑1	❑2	❑3	❑4	❑5
6. Guilty	❑1	❑2	❑3	❑4	❑5
7. Scared	❑1	❑2	❑3	❑4	❑5
8. Hostile	❑1	❑2	❑3	❑4	❑5
9. Enthusiastic	❑1	❑2	❑3	❑4	❑5
10. Proud	❑1	❑2	❑3	❑4	❑5
11. Irritable	❑1	❑2	❑3	❑4	❑5
12. Alert	❑1	❑2	❑3	❑4	❑5
13. Ashamed	❑1	❑2	❑3	❑4	❑5
14. Inspired	❑1	❑2	❑3	❑4	❑5
15. Nervous	❑1	❑2	❑3	❑4	❑5
16. Determined	❑1	❑2	❑3	❑4	❑5
17. Attentive	❑1	❑2	❑3	❑4	❑5
18. Jittery	❑1	❑2	❑3	❑4	❑5
19. Active	❑1	❑2	❑3	❑4	❑5
20. Afraid	❑1	❑2	❑3	❑4	❑5

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Hospital Anxiety and Depression Scale (HADS)

Participant completes at Baseline, Bi-monthly, Six-month, and Twelve-month contacts.

Doctors are aware that emotions play an important part in most illnesses. If your doctor knows about these feelings he will be able to help you more.

This questionnaire is designed to help your doctor to know how you feel. Read each item and underline the reply which comes closest to how you have been feeling in the past week.

Don't take too long over your replies; your immediate reaction to each item will probably be more accurate than a long thought-out response.

1. I feel tense or "wound up":

   ❑$_3$ Most of the time
   ❑$_2$ A lot of the time
   ❑$_1$ From time to time, occasionally
   ❑$_0$ Not at all

2. I still enjoy the things I used to enjoy:

   ❑$_0$ Definitely as much
   ❑$_1$ Not quite so much
   ❑$_2$ Only a little
   ❑$_3$ Hardly at all

3. I get a sort of frightened feeling as if something awful is about to happen:

   ❑$_3$ Very definitely and quite badly
   ❑$_2$ Yes, but not too badly
   ❑$_1$ A little, but it doesn't worry me
   ❑$_0$ Not at all

4. I can laugh and see the funny side of things:

   ❑$_0$ As much as I always could
   ❑$_1$ Not quite so much now
   ❑$_2$ Definitely not so much now
   ❑$_3$ Not at all

5. Worrying thoughts go through my mind:

   ❑$_3$ A great deal of the time
   ❑$_2$ A lot of the time
   ❑$_1$ From time to time, but not too often
   ❑$_0$ Only occasionally

6. I feel cheerful:

   ❑$_3$ Not at all
   ❑$_2$ Not often
   ❑$_1$ Sometimes
   ❑$_0$ Most of the time

7. I can sit at ease and feel relaxed:

   ❑$_0$ Definitely
   ❑$_1$ Usually
   ❑$_2$ Not often
   ❑$_3$ Not at all

8. I feel as if I am slowed down:

   ❑$_3$ Nearly all the time
   ❑$_2$ Very often
   ❑$_1$ Sometimes
   ❑$_0$ Not at all

9. I got a sort of frightened feeling like "butterflies" in the stomach:

   ❑$_0$ Not at all
   ❑$_1$ Occasionally
   ❑$_2$ Quite often
   ❑$_3$ Very often

10. I have lost interest in my appearance:

    ❑$_3$ Definitely
    ❑$_2$ I don't take as much care as I should
    ❑$_1$ I may not take quite as much care
    ❑$_0$ I take just as much care as ever

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Hospital Anxiety and Depression Scale (HADS)

Participant completes at Baseline, Bi-monthly, Six-month, and Twelve-month contacts.

11. I feel restless as if I have to be on the move:

- ❑3 Very much indeed
- ❑2 Quite a lot
- ❑1 Not very much
- ❑0 Not at all

12. I look forward with enjoyment to things:

- ❑0 As much as I ever did
- ❑1 Rather less than I used to
- ❑2 Definitely less than I used to
- ❑3 Hardly at all

13. I get sudden feelings of panic:

- ❑3 Very often indeed
- ❑2 Quite often
- ❑1 Not very often
- ❑0 Not at all

14. I can enjoy a good book or radio or TV program:

- ❑0 Often
- ❑1 Sometimes
- ❑2 Not often
- ❑3 Very seldom

15. Total Score: ___ ___

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PROMIS Item Bank v. 1.0

Emotional Distress - Anger – Short Form

Participant completes at Baseline, Bi-monthly, Six-month, and Twelve-month contacts.

Please respond to each item by marking one box per row.

In the past 7 days...

		Never	Rarely	Sometimes	Often	Always
1.	I was irritated more than people knew	❑1	❑2	❑3	❑4	❑5
2.	I made myself angry about something just by thinking about it	❑1	❑2	❑3	❑4	❑5
3.	I felt angry	❑1	❑2	❑3	❑4	❑5
4.	I felt like I was ready to explode	❑1	❑2	❑3	❑4	❑5
5.	I stayed angry for hours	❑1	❑2	❑3	❑4	❑5
6.	I felt angrier than I thought I should	❑1	❑2	❑3	❑4	❑5
7.	I was grouchy	❑1	❑2	❑3	❑4	❑5
8.	I felt annoyed	❑1	❑2	❑3	❑4	❑5

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PROMIS Item Bank v. 1.0

Fatigue - Short Form

Participant completes at Baseline, Bi-monthly, Six-month, and Twelve-month contacts.

Please respond to each question by marking one box per row.

In the past 7 days...

		Never	Rarely	Sometimes	Often	Always
1.	How often did you feel tired?	❑1	❑2	❑3	❑4	❑5
2.	How often did you experience extreme exhaustion?	❑1	❑2	❑3	❑4	❑5
3.	How often did you run out of energy?	❑1	❑2	❑3	❑4	❑5
4.	How often did your fatigue limit you at work (include work at home)?	❑1	❑2	❑3	❑4	❑5
5.	How often were you too tired to think clearly?	❑1	❑2	❑3	❑4	❑5
6.	How often were you too tired to take a bath or shower?	❑1	❑2	❑3	❑4	❑5
7.	How often did you have enough energy to exercise strenuously?	❑1	❑2	❑3	❑4	❑5

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PROMIS Item Bank v. 1.0

Sleep Disturbance - Short Form

Participant completes at Baseline, Bi-monthly, Six-month, and Twelve-month contacts.

Please respond to each item by marking one box per row.

In the past 7 days...

		Not at all	A little bit	Somewhat	Quite a bit	Very much
1.	My sleep was restless	❑1	❑2	❑3	❑4	❑5
2.	I was satisfied with my sleep	❑1	❑2	❑3	❑4	❑5
3.	My sleep was refreshing	❑1	❑2	❑3	❑4	❑5
4.	I had difficulty falling asleep	❑1	❑2	❑3	❑4	❑5

In the past 7 days...

		Never	Rarely	Sometimes	Often	Always
5.	I had trouble staying asleep	❑1	❑2	❑3	❑4	❑5
6.	I had trouble sleeping	❑1	❑2	❑3	❑4	❑5
7.	I got enough sleep	❑1	❑2	❑3	❑4	❑5

In the past 7 days...

		Very poor	Poor	Fair	Good	Very good
8.	My sleep quality was	❑1	❑2	❑3	❑4	❑5

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Multiple Ability Self-Report Questionnaire (MASQ)

Participant completes at Baseline, Six-month, and Twelve-month contacts.

Instructions: Please rate your ability to perform the activities below according to the following five-point scale. Please indicate 1=never, 2=rarely, 3=sometimes, 4=usually, or 5=always.

	Never	Rarely	Sometimes	Usually	Always
1. When talking, I have difficulty conveying precisely what I mean.	❑1	❑2	❑3	❑4	❑5
2. I can follow telephone conversations.	❑1	❑2	❑3	❑4	❑5
3. I find myself searching for the right word to express my thoughts.	❑1	❑2	❑3	❑4	❑5
4. My speech is slow or hesitant.	❑1	❑2	❑3	❑4	❑5
5. I find myself calling a familiar object by the wrong name.	❑1	❑2	❑3	❑4	❑5
6. I find it easy to make sense out of what people say to me.	❑1	❑2	❑3	❑4	❑5
7. People seem to be speaking too fast.	❑1	❑2	❑3	❑4	❑5
8. It is easy for me to read and follow a newspaper story.	❑1	❑2	❑3	❑4	❑5
9. I can easily fit the pieces of a jig-saw puzzle together.	❑1	❑2	❑3	❑4	❑5
10. I am able to follow the visual diagrams that are included in "easy to assemble" products.	❑1	❑2	❑3	❑4	❑5
11. I have difficulty locating a friend in a crowd of people.	❑1	❑2	❑3	❑4	❑5
12. I have difficulty estimating distances (for example; from my house to a house of a relative).	❑1	❑2	❑3	❑4	❑5
13. I get lost when traveling around.	❑1	❑2	❑3	❑4	❑5
14. It is hard for me to read a map to find a new place.	❑1	❑2	❑3	❑4	❑5
15. I forget to mention important issues during conversations.	❑1	❑2	❑3	❑4	❑5
16. I forget important things I was told just a few days ago.	❑1	❑2	❑3	❑4	❑5
17. I am able to recall the details of the evening news report several hours later.	❑1	❑2	❑3	❑4	❑5
18. I forget important events which occurred over the past month.	❑1	❑2	❑3	❑4	❑5
19. I forget the important portions of gossip I have heard.	❑1	❑2	❑3	❑4	❑5
20. I forget to give phone call messages.	❑1	❑2	❑3	❑4	❑5
21. I have to hear or read something several times before I can recall it without difficulty.	❑1	❑2	❑3	❑4	❑5
22. I can recall the names of people who were famous when I was growing up.	❑1	❑2	❑3	❑4	❑5
23. After putting something away for safekeeping, I am able to recall its location.	❑1	❑2	❑3	❑4	❑5

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Multiple Ability Self-Report Questionnaire (MASQ)

Participant completes at Baseline, Six-month, and Twelve-month contacts.

	Never	Rarely	Sometimes	Usually	Always
24. When I first go to a new restaurant, I can easily find my way back to the table when I get up.	❑1	❑2	❑3	❑4	❑5
25. I have difficulty finding stores in a mall even if I have been there before.	❑1	❑2	❑3	❑4	❑5
26. I can easily locate an object that I know is in my closet.	❑1	❑2	❑3	❑4	❑5
27. I have difficulty remembering the faces of the people I have recently met.	❑1	❑2	❑3	❑4	❑5
28. After the first visit to a new place, I can find my way around with little difficulty (e.g. restaurant, department store)	❑1	❑2	❑3	❑4	❑5
29. I remember the pictures that accompany magazine or newspaper articles I have recently read.	❑1	❑2	❑3	❑4	❑5
30. I can easily pick out my coat from among others on a coat rack.	❑1	❑2	❑3	❑4	❑5
31. I can do simple calculations in my head quickly.	❑1	❑2	❑3	❑4	❑5
32. I ask people to repeat themselves because my mind wanders during conversations.	❑1	❑2	❑3	❑4	❑5
33. I am alert to things going on around me.	❑1	❑2	❑3	❑4	❑5
34. I have difficulty sitting still to watch my favorite TV programs.	❑1	❑2	❑3	❑4	❑5
35. I am easily distracted from my work by things going on around me.	❑1	❑2	❑3	❑4	❑5
36. I can keep my mind on more than one thing at a time.	❑1	❑2	❑3	❑4	❑5
37. I can focus my attention on a task for more than a few minutes at a time.	❑1	❑2	❑3	❑4	❑5
38. I find it difficult to keep my train of thought going during a short interruption.	❑1	❑2	❑3	❑4	❑5

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Perceived Stress Scale (PSS)

Participant completes at Baseline, Bi-monthly, Six-month, and Twelve-month contacts.

Instructions: *The questions in this scale ask you about your feelings and thoughts **during the last month.** In each case, you will be asked to indicate your response about **how often** you felt or thought a certain way.*

In the last month, how often have you...	**Never**	**Almost Never**	**Sometimes**	**Fairly Often**	**Very Often**
1. been upset because of something that happened unexpectedly?	❑0	❑1	❑2	❑3	❑4
2. felt that you were unable to control the important things in your life?	❑0	❑1	❑2	❑3	❑4
3. felt nervous and "stressed"?	❑0	❑1	❑2	❑3	❑4
4. felt confident about your ability to handle your personal problems?	❑0	❑1	❑2	❑3	❑4
5. felt that things were going your way?	❑0	❑1	❑2	❑3	❑4
6. found that you could not cope with all the things that you had to do?	❑0	❑1	❑2	❑3	❑4
7. been able to control irritations in your life?	❑0	❑1	❑2	❑3	❑4
8. felt that you were on top of things?	❑0	❑1	❑2	❑3	❑4
9. been angered because of things that were outside of your control?	❑0	❑1	❑2	❑3	❑4
10. felt difficulties were piling up so high that you could not overcome them?	❑0	❑1	❑2	❑3	❑4

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IPIP

Participant completes at the Baseline contact.

Instructions:

The following pages contain phrases describing people's behaviors. Please use the rating scale below to describe how accurately each statement describes you. Describe yourself as you generally are now, not as you wish to be in the future. Describe yourself as you honestly see yourself, in relation to other people you know of the same sex as you are, and roughly your same age. So that you can describe yourself in an honest manner, your responses will be kept in absolute confidence. Please read each statement carefully, and then check the box that corresponds to the accuracy of the statement. Please answer every item.

		Very Inaccurate	Moderately Inaccurate	Neither Accurate Nor Inaccurate	Moderately Accurate	Very Accurate
1	Worry about things.	❑1	❑2	❑3	❑4	❑5
2	Make friends easily.	❑1	❑2	❑3	❑4	❑5
3	Have a vivid imagination.	❑1	❑2	❑3	❑4	❑5
4	Trust others.	❑1	❑2	❑3	❑4	❑5
5	Complete tasks successfully.	❑1	❑2	❑3	❑4	❑5
6	Get angry easily.	❑1	❑2	❑3	❑4	❑5
7	Love large parties.	❑1	❑2	❑3	❑4	❑5
8	Believe in the importance of art.	❑1	❑2	❑3	❑4	❑5
9	Use others for my own ends.	❑1	❑2	❑3	❑4	❑5
10	Like to tidy up.	❑1	❑2	❑3	❑4	❑5
11	Often feel blue.	❑1	❑2	❑3	❑4	❑5
12	Take charge.	❑1	❑2	❑3	❑4	❑5
13	Experience my emotions intensely.	❑1	❑2	❑3	❑4	❑5
14	Love to help others.	❑1	❑2	❑3	❑4	❑5
15	Keep my promises.	❑1	❑2	❑3	❑4	❑5
16	Find it difficult to approach others.	❑1	❑2	❑3	❑4	❑5
17	Am always busy.	❑1	❑2	❑3	❑4	❑5
18	Prefer variety to routine.	❑1	❑2	❑3	❑4	❑5
19	Love a good fight.	❑1	❑2	❑3	❑4	❑5
20	Work hard.	❑1	❑2	❑3	❑4	❑5
21	Go on binges.	❑1	❑2	❑3	❑4	❑5
22	Love excitement.	❑1	❑2	❑3	❑4	❑5
23	Love to read challenging material.	❑1	❑2	❑3	❑4	❑5
24	Believe that I am better than others.	❑1	❑2	❑3	❑4	❑5

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Participant completes at the Baseline contact.

		Very Inaccurate	Moderately Inaccurate	Neither Accurate Nor Inaccurate	Moderately Accurate	Very Accurate
25	Am always prepared.	❑1	❑2	❑3	❑4	❑5
26	Panic easily.	❑1	❑2	❑3	❑4	❑5
27	Radiate joy.	❑1	❑2	❑3	❑4	❑5
28	Tend to vote for liberal political candidates.	❑1	❑2	❑3	❑4	❑5
29	Sympathize with the homeless.	❑1	❑2	❑3	❑4	❑5
30	Jump into things without thinking.	❑1	❑2	❑3	❑4	❑5
31	Fear for the worst.	❑1	❑2	❑3	❑4	❑5
32	Feel comfortable around people.	❑1	❑2	❑3	❑4	❑5
33	Enjoy wild flights of fantasy.	❑1	❑2	❑3	❑4	❑5
34	Believe that others have good intentions.	❑1	❑2	❑3	❑4	❑5
35	Excel in what I do.	❑1	❑2	❑3	❑4	❑5
36	Get irritated easily.	❑1	❑2	❑3	❑4	❑5
37	Talk to a lot of different people at parties.	❑1	❑2	❑3	❑4	❑5
38	See beauty in things that others might not notice.	❑1	❑2	❑3	❑4	❑5
39	Cheat to get ahead.	❑1	❑2	❑3	❑4	❑5
40	Often forget to put things back in their proper place.	❑1	❑2	❑3	❑4	❑5
41	Dislike myself.	❑1	❑2	❑3	❑4	❑5
42	Try to lead others.	❑1	❑2	❑3	❑4	❑5
43	Feel others' emotions.	❑1	❑2	❑3	❑4	❑5
44	Am concerned about others.	❑1	❑2	❑3	❑4	❑5
45	Tell the truth.	❑1	❑2	❑3	❑4	❑5
46	Am afraid to draw attention to myself.	❑1	❑2	❑3	❑4	❑5
47	Am always on the go.	❑1	❑2	❑3	❑4	❑5
48	Prefer to stick with things that I know.	❑1	❑2	❑3	❑4	❑5
49	Yell at people.	❑1	❑2	❑3	❑4	❑5
50	Do more than what's expected of me.	❑1	❑2	❑3	❑4	❑5
51	Rarely overindulge.	❑1	❑2	❑3	❑4	❑5
52	Seek adventure.	❑1	❑2	❑3	❑4	❑5
53	Avoid philosophical discussions.	❑1	❑2	❑3	❑4	❑5

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		Very Inaccurate	Moderately Inaccurate	Neither Accurate Nor Inaccurate	Moderately Accurate	Very Accurate
54	Think highly of myself.	❑1	❑2	❑3	❑4	❑5
55	Carry out my plans.	❑1	❑2	❑3	❑4	❑5
56	Become overwhelmed by events.	❑1	❑2	❑3	❑4	❑5
57	Have a lot of fun.	❑1	❑2	❑3	❑4	❑5
58	Believe that there is no absolute right or wrong.	❑1	❑2	❑3	❑4	❑5
59	Feel sympathy for those who are worse off than myself.	❑1	❑2	❑3	❑4	❑5
60	Make rash decisions.	❑1	❑2	❑3	❑4	❑5
61	Am afraid of many things.	❑1	❑2	❑3	❑4	❑5
62	Avoid contacts with others.	❑1	❑2	❑3	❑4	❑5
63	Love to daydream.	❑1	❑2	❑3	❑4	❑5
64	Trust what people say.	❑1	❑2	❑3	❑4	❑5
65	Handle tasks smoothly.	❑1	❑2	❑3	❑4	❑5
66	Lose my temper.	❑1	❑2	❑3	❑4	❑5
67	Prefer to be alone.	❑1	❑2	❑3	❑4	❑5
68	Do not like poetry.	❑1	❑2	❑3	❑4	❑5
69	Take advantage of others.	❑1	❑2	❑3	❑4	❑5
70	Leave a mess in my room.	❑1	❑2	❑3	❑4	❑5
71	Am often down in the dumps.	❑1	❑2	❑3	❑4	❑5
72	Take control of things.	❑1	❑2	❑3	❑4	❑5
73	Rarely notice my emotional reactions.	❑1	❑2	❑3	❑4	❑5
74	Am indifferent to the feelings of others.	❑1	❑2	❑3	❑4	❑5
75	Break rules.	❑1	❑2	❑3	❑4	❑5
76	Only feel comfortable with friends.	❑1	❑2	❑3	❑4	❑5
77	Do a lot in my spare time.	❑1	❑2	❑3	❑4	❑5
78	Dislike changes.	❑1	❑2	❑3	❑4	❑5
79	Insult people.	❑1	❑2	❑3	❑4	❑5
80	Do just enough work to get by.	❑1	❑2	❑3	❑4	❑5
81	Easily resist temptations.	❑1	❑2	❑3	❑4	❑5
82	Enjoy being reckless.	❑1	❑2	❑3	❑4	❑5

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Participant completes at the Baseline contact.

		Very Inaccurate	Moderately Inaccurate	Neither Accurate Nor Inaccurate	Moderately Accurate	Very Accurate
83	Have difficulty understanding abstract ideas.	❑1	❑2	❑3	❑4	❑5
84	Have a high opinion of myself.	❑1	❑2	❑3	❑4	❑5
85	Waste my time.	❑1	❑2	❑3	❑4	❑5
86	Feel that I'm unable to deal with things.	❑1	❑2	❑3	❑4	❑5
87	Love life.	❑1	❑2	❑3	❑4	❑5
88	Tend to vote for conservative political candidates.	❑1	❑2	❑3	❑4	❑5
89	Am not interested in other people's problems.	❑1	❑2	❑3	❑4	❑5
90	Rush into things.	❑1	❑2	❑3	❑4	❑5
91	Get stressed out easily.	❑1	❑2	❑3	❑4	❑5
92	Keep others at a distance.	❑1	❑2	❑3	❑4	❑5
93	Like to get lost in thought.	❑1	❑2	❑3	❑4	❑5
94	Distrust people.	❑1	❑2	❑3	❑4	❑5
95	Know how to get things done.	❑1	❑2	❑3	❑4	❑5
96	Am not easily annoyed.	❑1	❑2	❑3	❑4	❑5
97	Avoid crowds.	❑1	❑2	❑3	❑4	❑5
98	Do not enjoy going to art museums.	❑1	❑2	❑3	❑4	❑5
99	Obstruct others' plans.	❑1	❑2	❑3	❑4	❑5
100	Leave my belongings around.	❑1	❑2	❑3	❑4	❑5
101	Feel comfortable with myself.	❑1	❑2	❑3	❑4	❑5
102	Wait for others to lead the way.	❑1	❑2	❑3	❑4	❑5
103	Don't understand people who get emotional.	❑1	❑2	❑3	❑4	❑5
104	Take no time for others.	❑1	❑2	❑3	❑4	❑5
105	Break my promises.	❑1	❑2	❑3	❑4	❑5
106	Am not bothered by difficult social situations.	❑1	❑2	❑3	❑4	❑5
107	Like to take it easy.	❑1	❑2	❑3	❑4	❑5
108	Am attached to conventional ways.	❑1	❑2	❑3	❑4	❑5
109	Get back at others.	❑1	❑2	❑3	❑4	❑5
110	Put little time and effort into my work.	❑1	❑2	❑3	❑4	❑5

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Participant completes at the Baseline contact.

	Very Inaccurate	Moderately Inaccurate	Neither Accurate Nor Inaccurate	Moderately Accurate	Very Accurate
111 Am able to control my cravings.	❑1	❑2	❑3	❑4	❑5
112 Act wild and crazy.	❑1	❑2	❑3	❑4	❑5
113 Am not interested in theoretical discussions.	❑1	❑2	❑3	❑4	❑5
114 Boast about my virtues.	❑1	❑2	❑3	❑4	❑5
115 Have difficulty starting tasks.	❑1	❑2	❑3	❑4	❑5
116 Remain calm under pressure.	❑1	❑2	❑3	❑4	❑5
117 Look at the bright side of life.	❑1	❑2	❑3	❑4	❑5
118 Believe that we should be tough on crime.	❑1	❑2	❑3	❑4	❑5
119 Try not to think about the needy.	❑1	❑2	❑3	❑4	❑5
120 Act without thinking.	❑1	❑2	❑3	❑4	❑5

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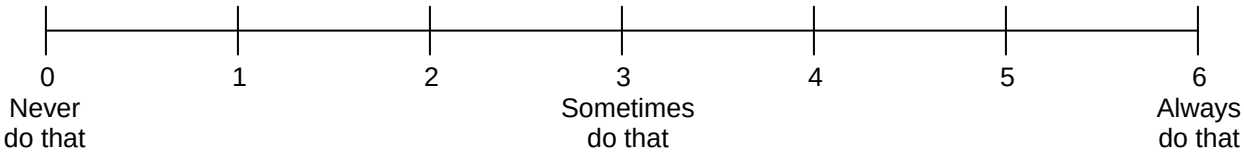
THOUGHTS ABOUT SYMPTOMS (CSQ)

The Participant completes this form at Baseline, Six-Month and Twelve-Month contacts.

Instructions: Individuals who experience pain have developed a number of ways to cope or deal with, their symptoms. These include saying things to themselves when they experience pain, fatigue, etc. or engaging in different activities. Below is a list of things that patients have reported doing when they feel pain. For each activity, I want you to indicate, using the scale below, how much you engage in that activity when you feel pain, where a 0 indicates you never do that when you are experiencing pain, a 3 indicates you sometimes do that when you are experiencing pain, and a 6 indicates you always do that when you are experiencing pain. *Please write the numbers you choose in the blanks beside the activities.* Remember, you can use any point along the scale.



When I feel pain …

____ 1. It is terrible, and I feel it's never going to get any better.

____ 2. It is awful, and I feel that it overwhelms me.

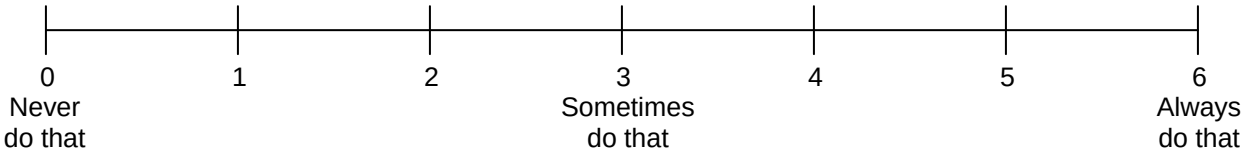
____ 3. I feel my life isn't worth living.

____ 4. I worry all the time about whether it will end.

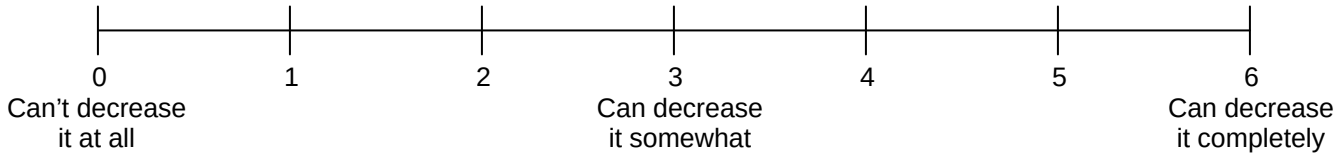
____ 5. I feel I can't stand it anymore.

____ 6. I feel like I can't go on.

7. Based on all the things you do to cope, or deal with your pain, on an average day, how much control do you feel you have over it? Please select the appropriate number. Remember, you can select any number along the scale.



8. Based on all the things you do to cope, or deal with your pain, on an average day, how much are you able to decrease it? Please select the appropriate number. Remember, you can select any number along the scale.



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BELIEFS IN PAIN CONTROL QUESTIONNAIRE (BPCQ)

Participant completes at Baseline, Six-month, and Twelve-month contacts.

Instructions: *Here are some opinions that people sometimes hold about pain. Please read them carefully and indicate how much you agree or disagree with each one by indicating your response for each question. There are no right or wrong answers.*

	Strongly Disagree	Disagree	Mildly Disagree	Mildly Agree	Agree	Strongly Agree
1. If I take good care of myself, I can usually avoid pain.	❑1	❑2	❑3	❑4	❑5	❑6
2. Whether or not I am in pain in the future depends on the skill of the doctors.	❑1	❑2	❑3	❑4	❑5	❑6
3. Whenever I am in pain, it is usually because of something I have done or not done.	❑1	❑2	❑3	❑4	❑5	❑6
4. Being pain-free is largely a matter of luck.	❑1	❑2	❑3	❑4	❑5	❑6
5. No matter what I do, if I am going to be in pain I will be in pain.	❑1	❑2	❑3	❑4	❑5	❑6
6. Whether or not I am in pain depends on what the doctors do for me.	❑1	❑2	❑3	❑4	❑5	❑6
7. I cannot get any help for my pain unless I go to seek medical help.	❑1	❑2	❑3	❑4	❑5	❑6
8. When I am in pain, I know that it is because I have not been taking proper exercise or eating the right food.	❑1	❑2	❑3	❑4	❑5	❑6
9. Whether or not people are in pain is governed by accidental happenings.	❑1	❑2	❑3	❑4	❑5	❑6
10. People's pain results from their own carelessness.	❑1	❑2	❑3	❑4	❑5	❑6
11. I am directly responsible for my pain.	❑1	❑2	❑3	❑4	❑5	❑6
12. Relief from pain is chiefly controlled by the doctors.	❑1	❑2	❑3	❑4	❑5	❑6
13. People who are never in pain are just plain lucky.	❑1	❑2	❑3	❑4	❑5	❑6

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Childhood Traumatic Events Scale

Participant completes at the Baseline contact.

For the following questions, answer each item that is relevant. Be as honest as you can. Each question refers to any event that you may have experienced **prior to the age of 17.**

1. Prior to the age of 17, did you experience a death of a very close friend or family member? ❑$_1$ Yes ❑$_0$ No

   a. If yes, how old were you? ___ ___

   b. If yes, how traumatic was this?

(using a 7-point scale, where 1 = not at all traumatic, 4 = somewhat traumatic, 7 = extremely traumatic)

Not at all traumatic			Somewhat traumatic			Extremely traumatic
❑	❑	❑	❑	❑	❑	❑
1	2	3	4	5	6	7

   c. If yes, how much did you confide in others about this traumatic experience at the time?

   (1 = not at all, 7 = a great deal)

Not at all						A great deal
❑	❑	❑	❑	❑	❑	❑
1	2	3	4	5	6	7

2. Prior to the age of 17, was there a major upheaval between your parents (such as divorce, separation)? ❑$_1$ Yes ❑$_0$ No

   a. If yes, how old were you? ___ ___

   b. If yes, how traumatic was this? (where 7 = extremely traumatic)

Not at all traumatic			Somewhat traumatic			Extremely traumatic
❑	❑	❑	❑	❑	❑	❑
1	2	3	4	5	6	7

   c. If yes, how much did you confide in others? (7 = a great deal)

Not at all						A great deal
❑	❑	❑	❑	❑	❑	❑
1	2	3	4	5	6	7

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Childhood Traumatic Events Scale

Participant completes at the Baseline contact.

3. Prior to the age of 17, did you have a traumatic sexual experience (raped, molested, etc.)? ❑$_1$ Yes ❑$_0$ No

   a. If yes, how old were you? ___ ___

   b. If yes, how traumatic was this? (7 = extremely traumatic)

Not at all traumatic			Somewhat traumatic			Extremely traumatic
❑	❑	❑	❑	❑	❑	❑
1	2	3	4	5	6	7

   c. If yes, how much did you confide in others? (7 = a great deal)

Not at all						A great deal
❑	❑	❑	❑	❑	❑	❑
1	2	3	4	5	6	7

4. Prior to the age of 17, were you the victim of violence (child abuse, mugged or assaulted other than sexual)? ❑$_1$ Yes ❑$_0$ No

   a. If yes, how old were you? ___ ___

   b. If yes, how traumatic was this? (7 = extremely traumatic)

Not at all traumatic			Somewhat traumatic			Extremely traumatic
❑	❑	❑	❑	❑	❑	❑
1	2	3	4	5	6	7

   c. If yes, how much did you confide in others? (7 = a great deal)

Not at all						A great deal
❑	❑	❑	❑	❑	❑	❑
1	2	3	4	5	6	7

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Childhood Traumatic Events Scale

Participant completes at the Baseline contact.

5. Prior to the age of 17, were you extremely ill or injured? ❑$_1$ Yes ❑$_0$ No

   a. If yes, how old were you? ___ ___

   b. If yes, how traumatic was this? (7 = extremely traumatic)

Not at all traumatic			Somewhat traumatic			Extremely traumatic
❑	❑	❑	❑	❑	❑	❑
1	2	3	4	5	6	7

   c. If yes, how much did you confide in others? (7 = a great deal)

Not at all						A great deal
❑	❑	❑	❑	❑	❑	❑
1	2	3	4	5	6	7

6. Prior to the age of 17, did you experience any other major upheaval that you think may have shaped your life or personality significantly? ❑$_1$ Yes ❑$_0$ No

   a. If yes, how old were you? ___ ___

   b. If yes, what was the event? _____

   c. If yes, how traumatic was this? (7 = extremely traumatic)

Not at all traumatic			Somewhat traumatic			Extremely traumatic
❑	❑	❑	❑	❑	❑	❑
1	2	3	4	5	6	7

   d. If yes, how much did you confide in others? (7 = a great deal)

Not at all						A great deal
❑	❑	❑	❑	❑	❑	❑
1	2	3	4	5	6	7

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Recent Traumatic Events Scale

Participant completes at the Baseline contact.

For the following questions, again answer each item that is relevant and again be as honest as you can. Each question refers to any event that you may have experienced **within the last 3 years.**

7. Within the last 3 years, did you experience a death of a very close friend or family member? ❑$_1$ Yes ❑$_0$ No

   a. If yes, how traumatic was this? (1 = not at all traumatic, 7 = extremely traumatic)

Not at all traumatic			Somewhat traumatic			Extremely traumatic
❑	❑	❑	❑	❑	❑	❑
1	2	3	4	5	6	7

   b. If yes, how much did you confide in others about the experience at the time?

   (1 = not at all,7 = a great deal)

Not at all						A great deal
❑	❑	❑	❑	❑	❑	❑
1	2	3	4	5	6	7

8. Within the last 3 years, was there a major upheaval between you and your spouse (such as divorce, separation)? ❑$_1$ Yes ❑$_0$ No

   a. If yes, how traumatic was this? (1 = not at all traumatic, 7 = extremely traumatic)

Not at all traumatic			Somewhat traumatic			Extremely traumatic
❑	❑	❑	❑	❑	❑	❑
1	2	3	4	5	6	7

   b. If yes, how much did you confide in others? (1 = not at all,7 = a great deal)

Not at all						A great deal
❑	❑	❑	❑	❑	❑	❑
1	2	3	4	5	6	7

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Recent Traumatic Events Scale

Participant completes at the Baseline contact.

9. Within the last 3 years, did you have a traumatic sexual experience (raped, molested, etc.)?
   ❑$_1$ Yes
   ❑$_0$ No

   a. If yes, how traumatic was this? (1 = not at all traumatic, 7 = extremely traumatic)

Not at all traumatic			Somewhat traumatic			Extremely traumatic
❑	❑	❑	❑	❑	❑	❑
1	2	3	4	5	6	7

   b. If yes, how much did you confide in others? (1 = not at all,7 = a great deal)

Not at all						A great deal
❑	❑	❑	❑	❑	❑	❑
1	2	3	4	5	6	7

10. Within the last 3 years, were you the victim of violence (other than sexual)?
    ❑$_1$ Yes
    ❑$_0$ No

   a. If yes, how traumatic was this? (1 = not at all traumatic, 7 = extremely traumatic)

Not at all traumatic			Somewhat traumatic			Extremely traumatic
❑	❑	❑	❑	❑	❑	❑
1	2	3	4	5	6	7

   b. If yes, how much did you confide in others? (1 = not at all,7 = a great deal)

Not at all						A great deal
❑	❑	❑	❑	❑	❑	❑
1	2	3	4	5	6	7

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Recent Traumatic Events Scale

Participant completes at the Baseline contact.

11. Within the last 3 years, were you extremely ill or injured? ❑$_1$ Yes ❑$_0$ No

a. If yes, how traumatic was this? (1 = not at all traumatic, 7 = extremely traumatic)

Not at all traumatic			Somewhat traumatic			Extremely traumatic
❑	❑	❑	❑	❑	❑	❑
1	2	3	4	5	6	7

b. If yes, how much did you confide in others? (1 = not at all,7 = a great deal)

Not at all						A great deal
❑	❑	❑	❑	❑	❑	❑
1	2	3	4	5	6	7

12. Within the last 3 years, has there been a major change in the kind of work you do (e.g., a new job, promotion, demotion, lateral transfer)? ❑$_1$ Yes ❑$_0$ No

a. If yes, how traumatic was this? (1 = not at all traumatic, 7 = extremely traumatic)

Not at all traumatic			Somewhat traumatic			Extremely traumatic
❑	❑	❑	❑	❑	❑	❑
1	2	3	4	5	6	7

b. If yes, how much did you confide in others? (1 = not at all,7 = a great deal)

Not at all						A great deal
❑	❑	❑	❑	❑	❑	❑
1	2	3	4	5	6	7

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Recent Traumatic Events Scale

Participant completes at the Baseline contact.

13. Within the last 3 years, did you experience any other major upheaval that you think may have shaped your life or personality significantly?
    - ❑$_1$ Yes
    - ❑$_0$ No

a. If yes, what was the event? _____

b. If yes, how traumatic was this? (1 = not at all traumatic, 7 = extremely traumatic)

Not at all traumatic			Somewhat traumatic			Extremely traumatic
❑	❑	❑	❑	❑	❑	❑
1	2	3	4	5	6	7

c. If yes, how much did you confide in others? (1 = not at all,7 = a great deal)

Not at all						A great deal
❑	❑	❑	❑	❑	❑	❑
1	2	3	4	5	6	7

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COMPLEX MEDICAL SYMPTOMS INVENTORY

Participant completes this form at the Baseline contact.

Instructions: *Please read the following list of symptoms. If you have had any of these symptoms for **at least three (3) months in the past year**, please mark the appropriate box. If you had a symptom for **three (3) months at any other time in your life**, then mark the appropriate box.*

Q#	SYMPTOM	3 months during the last year (12 months) (A)	3 months during your lifetime (B)	*For staff use only*
1	Muscle or joint pain	❑1	❑1	❑1M:FM ❑1M:CFS
2	Morning stiffness	❑1	❑1	
3	Muscle spasms	❑1	❑1	
4	Persistent fatigue not relieved with rest	❑1	❑1	❑1M:CFS
5	Extreme fatigue following exercise or mild exertion	❑1	❑1	
6	Recurrent fevers	❑1	❑1	
7	Dry eyes	❑1	❑1	
8	Dry mouth	❑1	❑1	
9	Fingers turn blue and/or white in the cold	❑1	❑1	
10	Numbness or tingling in arms or legs	❑1	❑1	
11	Shortness of breath during normal activity	❑1	❑1	
12	Impaired memory, concentration or attention	❑1	❑1	
13	Chest pain	❑1	❑1	
14	Palpitations	❑1	❑1	
15	Rapid heart rate	❑1	❑1	
16	Heartburn	❑1	❑1	
17	Vomiting	❑1	❑1	
18	Nausea	❑1	❑1	
19	Abdominal pain or discomfort	❑1	❑1	❑1M:IBS
20	Problems with balance	❑1	❑1	
21	Dizziness	❑1	❑1	
22	Ringing in ears	❑1	❑1	
23	Ear pain	❑1	❑1	❑1M:TMJ

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COMPLEX MEDICAL SYMPTOMS INVENTORY

Participant completes this form at the Baseline contact.

Q#	SYMPTOM	3 months during the last year (12 months) (A)	3 months during your lifetime (B)	*For staff use only*
24	Sensation of ear blockage or fullness	❑1	❑1	
25	Sinus pressure	❑1	❑1	
26	Pelvic/bladder discomfort (pain or pressure)	❑1	❑1	
27	Urinary urgency	❑1	❑1	
28	Urinary frequency, >8/day during waking hours	❑1	❑1	
29	Frequent nocturia (nighttime urination), 3/night	❑1	❑1	
30	Sensation of bladder fullness after urination	❑1	❑1	
31	Jaw and/or face pain	❑1	❑1	❑1M:TMJ
32	Temple pain	❑1	❑1	
33	Pulsating and/or one-sided headache pain or migraines	❑1	❑1	❑1M:MI
34	Pressing/tightening headache pain or tension headaches	❑1	❑1	
35	Sensitivity to certain chemicals, such as perfumes, laundry detergents, gasoline and others	❑1	❑1	
36	Sensitivity to sound	❑1	❑1	
37	Sensitivity to odors	❑1	❑1	
38	Body feeling tender	❑1	❑1	
39	Frequent sensitivity to bright lights	❑1	❑1	
FEMALES ONLY:				
40	Constant burning or raw feeling at the opening of vagina	❑1	❑1	❑1M:VDYN
41	Itching at opening of vagina	❑1	❑1	

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COMPLEX MEDICAL SYMPTOMS INVENTORY

Fibromyalgia, Tender Point Exam - OPTIONAL (Turk)

RESEARCH COORDINATOR ADMINISTERS TO PATIENT AT BASELINE CONTACT, *OPTIONAL*.

Administered by the Research Coordinator as part of the Fibromyalgia CMSI

1. Tender Point exam administered? ❑$_1$ Yes ❑$_0$ No

Tell the participant: "Various areas of your body will be examined for pain. Please say Yes or No if there is any pain when I press a specific point. I want you to rate the intensity of the pain on a scale of 0-10. 0 being no pain and 10 being the worst pain you have ever experienced. Are you ready to begin? *(Answer any questions, repeat the pain scale to the participant after Point 9*

Pressure Point	Pain: Yes or No		Rating (0-10)
a. Point 1 – Forehead, Control	❑$_1$ Yes	❑$_0$ No	_____
b. Point 2 - Right Occiput	❑$_1$ Yes	❑$_0$ No	_____
c. Point 3 - Left Occiput	❑$_1$ Yes	❑$_0$ No	_____
d. Point 4 - Right Trapezius	❑$_1$ Yes	❑$_0$ No	_____
e. Point 5 - Left Trapezius	❑$_1$ Yes	❑$_0$ No	_____
f. Point 6 - Right Supraspinatus	❑$_1$ Yes	❑$_0$ No	_____
g. Point 7 - Left Supraspinatus	❑$_1$ Yes	❑$_0$ No	_____
h. Point 8 - Right Gluteal	❑$_1$ Yes	❑$_0$ No	_____
i. Point 9 - Left Gluteal	❑$_1$ Yes	❑$_0$ No	_____
j. Point 10 - Right Low cervical	❑$_1$ Yes	❑$_0$ No	_____
k. Point 11 - Left Low cervical	❑$_1$ Yes	❑$_0$ No	_____
l. Point 12 - Right Second rib	❑$_1$ Yes	❑$_0$ No	_____
m. Point 13 - Left Second rib	❑$_1$ Yes	❑$_0$ No	_____
n. Point 14 - Right Lateral epicondyle	❑$_1$ Yes	❑$_0$ No	_____
o. Point 15 - Left Lateral epicondyle	❑$_1$ Yes	❑$_0$ No	_____
p. Point 16 - Right Forearm, Control	❑$_1$ Yes	❑$_0$ No	_____
q. Point 17 - Left Thumb, Control	❑$_1$ Yes	❑$_0$ No	_____
r. Point 18 - Right Greater trochanter	❑$_1$ Yes	❑$_0$ No	_____
s. Point 19 - Left Greater trochanter	❑$_1$ Yes	❑$_0$ No	_____
t. Point 20 - Right Knee	❑$_1$ Yes	❑$_0$ No	_____
u. Point 21 - Left Knee	❑$_1$ Yes	❑$_0$ No	_____

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COMPLEX MEDICAL SYMPTOMS INVENTORY

Current Migraine Symptoms (HIS 2nd edition criteria, 2004)

Research Coordinator administers to Patient at Baseline Contact, *if needed.*

1. How long is your typical headache? ***(Choose all that apply)***
   - ❑1 Less than 30 Minutes
   - ❑1 Between 30 Minutes and 4 Hours
   - ❑1 Between 4 Hours and 3 Days? (untreated or unsuccessfully treated)
   - ❑1 Longer than 3 days
2. How often do you have these headaches?
   - ❑0 Never
   - ❑1 Once or twice a year
   - ❑2 Every few months
   - ❑3 Monthly
   - ❑4 Weekly
3. How many severe headaches (lasting more than 4 hours) have you had in the past 6 months?
   - ❑0 None
   - ❑1 1-2
   - ❑2 3-5
   - ❑3 More than 5
4. Do any of the following accompany your typical headache?

a.	Feeling sick to your stomach	❑1 Yes	❑0 No
b.	Vomiting	❑1 Yes	❑0 No
c.	More sensitive to light	❑1 Yes	❑0 No
d.	More sensitive to sound	❑1 Yes	❑0 No
e.	A throbbing feeling in your head	❑1 Yes	❑0 No
f.	Pain on only one side of your head	❑1 Yes	❑0 No
g.	Pain on both sides of your head	❑1 Yes	❑0 No
h.	A preceding warning such as problems with vision, speech, hearing, swallowing, strength or sensation	❑1 Yes	❑0 No ***(If No, skip to Q#4k)***
i.	Does this warning last less than 60 minutes?	❑1 Yes	❑0 No
j.	Do you have a headache less than 60 minutes following the warning?	❑1 Yes	❑0 No
k.	A decrease in your normal daily activity	❑1 Yes	❑0 No
l.	A pressing or tightening feeling	❑1 Yes	❑0 No
m.	Aggravated by routine physical activity	❑1 Yes	❑0 No
n.	Not aggravated by routine physical activity	❑1 Yes	❑0 No
o.	Is the headache pain mild to moderate in intensity?	❑1 Yes	❑0 No
p.	Is the headache pain moderate to severe in intensity?	❑1 Yes	❑0 No

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COMPLEX MEDICAL SYMPTOMS INVENTORY

Current Vulvodynia Symptoms – Females Only

Research Coordinator administers to Patient at Baseline Contact, *if needed.*

1.	On the survey you indicated that you experience constant burning or raw feeling at the opening of the vagina – is this correct?	❑$_1$ Yes	❑$_0$ No
2.	Is your vaginal area tender to touch, or do you experience pain with tampon insertion and/or intercourse?	❑$_1$ Yes	❑$_0$ No
3.	Have these pain symptoms persisted for 3 months or more?	❑$_1$ Yes	❑$_0$ No
4.	Are you experiencing pain currently (w/in the last week)?	❑$_1$ Yes	❑$_0$ No
5.	On the survey you indicated that you experience itching at the opening of the vagina – is this correct?	❑$_1$ Yes	❑$_0$ No
6.	Could this pain be caused by a rash or lesion in the area?	❑$_1$ Yes	❑$_0$ No
7.	Is there a discharge, the onset of which can be associated with the onset of the pain or discomfort?	❑$_1$ Yes	❑$_0$ No
8.	Is this itching and discomfort relieved by the use of anti-candidal therapy (ie Monistat)?	❑$_1$ Yes	❑$_0$ No

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COMPLEX MEDICAL SYMPTOMS INVENTORY

Current TMD Symptoms (TMD/RDC 2002)

RESEARCH COORDINATOR ADMINISTERS TO PATIENT AT BASELINE CONTACT, *IF NEEDED.*

1. Have you had persistent or recurrent pain in the face, jaw, temple, in front of the ear or in the ear in the past month? ❑$_1$ Yes ❑$_0$ No **(Stop)**

2. How would you rate your facial pain right now?

No Pain										Pain as bad as could be
0	1	2	3	4	5	6	7	8	9	10

3. In the past 6 months, how intense was your ***worst*** pain?

No Pain										Pain as bad as could be
0	1	2	3	4	5	6	7	8	9	10

4. In the past 6 months, on the ***average***, how intense was your pain? [That is, your usual pain at times you were experiencing pain.]

No Pain										Pain as bad as could be
0	1	2	3	4	5	6	7	8	9	10

5. About how many days in the past 6 months have you been kept from your usual activities (work, school or housework) because of facial pain? ___ ___ # of Days

6. In the past 6 months, how much has facial pain interfered with your daily activities?

No Interference										Unable to carry on any activities
0	1	2	3	4	5	6	7	8	9	10

7. In the past 6 months, how much has facial pain changed your ability to take part in recreational, social and family activities?

No Change										Extreme change
0	1	2	3	4	5	6	7	8	9	10

8. In the past 6 months, how much has facial pain changed your ability to work (including housework)?

No Change										Extreme change
0	1	2	3	4	5	6	7	8	9	10