Domain	Form Name	Form Code	Latest Version Number
Screening and Enrollment			
	Demographics	**DEMO**	**v1.0.20141027**
	Eligibility	**ELIG2**	**v10.0.20170925**
	Neuroimaging Study Eligibility	**ELIG_SCAN2**	**v2.0.20170925**
	Urine Culture Result	**UCR**	**v2.0.20160606**
	Enrollment	**ENROLL**	**v3.0.20180403**
Urologic CRFs - Females and Males			
Symptoms	Symptom, Healthcare Utilization, And Flare Status Questionnaire	**SYM-Q-Screening** **SYM-Q-Run-In** **SYM-Q-Baseline** **SYM-Q-Follow-Up** **SYM-Q-ATLAS**	**v2.0.20150310** **v2.0.20150303** **v2.0.20151113** **v2.0.20151113** **v2.0.20151113**
	Global Response Assessment	**GRA** **GRA_ATLAS**	**v1.0.20150226** **v1.0.20150225**
	Interstitial Cystitis Symptom Index Interstitial Cystitis Problem Index	**ICINDEX** **ICINDEX-Run-In** **ICINDEX_ATLAS**	**v1.0.20141029** **v1.0.20141025** **v1.0.20150217**
	AUA Symptom Index	**AUASI**	**v2.0.20150226**
	RICE Case Definition Questionnaire	**RICE_Screening** **RICE_Run-In** **RICE_Follow-up** **RICE_ATLAS**	**v1.0.20141027** **v1.0.20141023** **v1.0.20141110** **v1.0.20150212**
	RICE Bladder Symptom Impact	**BSI**	**v2.0.20150512**
Medical History	Medical History	**MEDHX2**	**v2.0.20150825**
	Early In Life Infection History	**EIL-INF**	**v2.0.20150310**
	Family Medical History	**FAMHX**	**v4.0.20161021**
Treatment	Concomitant Medications	**CMED2**	**v2.0.20160502**
	MyMED Treatment Tracking Module	**MyMED**	**v3.0.20170228**
	Antibiotics Treatment History	**ABHX**	**v2.0.20150625**
	Pelvic Therapy History	**PTHX**	**v4.0.20180501**
	Cystoscopy History	**CYSTO-2**	**v2.0.20171018**
Physical Exam	Physical Exam	**EXAM2**	**v2.0.20151019**
	Pelvic Exam	**PEX_Female** **PEX_Female_Procedures (Admin.)** **PEX_Male** **PEX_Male_Procedures (Admin.)**	**v2.0.20171011** **v1.0.20150211** **v2.0.20171011** **v1.0.20150211**
	Brief Clinical Diagnostics for Baseline & Follow-up	**CDX**	**v4.0.20160617**
Study Stop/Withdrawal	Study Stop	**SSTOP**	**v1.0.20141110**
	Consent Withdrawal	**CONWITHDR2**	**v1.0.20150223**
	Reinstatement of Consent	**RECON2**	**v1.0.20150223**
	Consent Change	**CONSENT_CHG**	**v2.0.20190219**

Domain	Form Name	Form Code	Latest Version Number
Urologic CRFs - Females only			
Symptoms	Female Genitourinary Pain Index	**FGUPI**	**v1.0.20141027**
Sexual Function	Female Sexual Function Index	**FSFI-2**	**v1.0.20170131**
	Female Self-Esteem & Relationship Questionnaire	**FSEAR**	**v1.0.20141109**
Urologic CRFs - Males only			
Symptoms	Male Genitourinary Pain Index	**MGUPI**	**v1.0.20141027**
Sexual Function	International Index of Erectile Function	**IIEF**	**v1.0.20141109**
	U. Washington Ejaculatory Function Scale	**EFS**	**v1.0.20141109**
	Male Self-Esteem & Relationship Questionnaire	**MSEAR**	**v1.0.20141109**
Non-Urologic CRFs			
Symptoms			
Pain	BPI (***Body Map***, **Intensity, Interference**)	**BPI2-Female**	**v1.0.20150226**
	BPI (***Body Map***, **Intensity, Interference**)	**BPI2-Male**	**v1.0.20150226**
	PAIN Detect	**PAIN** **PAIN_Run-In** **PAIN_ATLAS**	**v3.0.20190702** **v3.0.20190702** **v3.0.20190702**
	McGill Pain Questionnaire	**MPQ**	**v1.0.20141120**
	Gracely Box Scales	**GBS**	**v1.0.20141120**
Physical Function	WHO Disability Assessment Schedule	**WHODAS** **WHODAS_R.A.**	**v1.0.20150227** **v1.0.20150227**
	SF-12 Health Status Questionnaire	**SF12**	**v1.0.20141109**
	International Physical Activity Questionnaire	**IPAQ**	**v2.0.20170303**
	Work Productivity & Activity Impairment Questionnaire	**WPAI**	**v2.0.20150306**
Mood	PANAS	**PANAS**	**v1.0.20141109**
	Hospital Anxiety and Depression Scale	**HADS**	**v1.0.20141120**
Cognition	Multiple Ability Self-Report Questionnaire	**MASQ**	**v1.0.20141109**
Fatigue	PROMIS - Fatigue - Short Form	**FATIGUE**	**v1.0.20141109**
Sleep	PROMIS - Sleep - Short Form	**SLEEP**	**v1.0.20141109**
Stress	Perceived Stress Scale	**PSS** **PSS_Run-In** **PSS_ATLAS**	**v1.0.20150227** **v1.0.20150227** **v1.0.20150227**
Trait-like Personal Factors			
Personality	Ten-Item Personality Inventory	**TIPI**	**v1.0.20141120**
Catastrophizing	Thoughts About Symptoms	**CSQ**	**v1.0.20141109**
Trauma History	Childhood/Recent Traumatic Events Scale	**CTES** **RTES**	**v1.0.20141109** **v1.0.20150226**

Domain	Form Name	Form Code	Latest Version Number
Co-morbid Diagnostics			
Symptom Test	Complex Medical Symptoms Inventory	CMSI2_Screening CMSI2_Run-In CMSI2_Baseline CMSI2_Follow-Up CMSI2_ATLAS	v3.0.20150708 v2.0.20150708 v2.0.20150708 v2.0.20150708 v2.0.20150708
Syndrome Modules	Fibromyalgia Diagnostic Module (ACR 2010)	CMSI2_FM2	v1.0.20150306
	Chronic Fatigue	CMSI2_CFS2	v1.0.20141110
	Irritable Bowel Syndrome	CMSI2_IBS2	v1.0.20141110
	Vulvodynia	CMSI2_VDYN2	v1.0.20141110
	Migraine	CMSI2_MI2	v1.0.20141110
	Temporomandibular Joint Disorder	CMSI2_TMD2	v1.0.20141110
	Gonzalez TMJD Questionnaire	TMDSI	v1.0.20141120
Specimens and Procedures			
Plasma and DNA	Plasma Specimen Tracking	PTRAC2	v1.0.20150223
Plasma	STIM Tubes Specimen	STIMTR2	v1.0.20150223
Urine	Urine Specimen Tracking	UTRAC2	v1.0.20150223
	Microbiome Universal Urine Specimen Tracking (VB2)	UUMBTR2	v1.0.20150223
	Microbiome Urine Specimen Tracking (Female/Male)	UFMBTR2 UMMBTR2	v1.1.20150526 v1.1.20150526
Rectal & Vaginal Swabs	Rectal Swab Specimen Tracking	RSTRAC2	v1.2.20150629
	Vaginal Swab Specimen Tracking	VSTRAC2	v1.2.20150629
Saliva	Home Saliva Collection, 3 day	S3TRAC2	v1.1.2016520
	Home Saliva Collection, 7 day	S7TRAC2	v1.0.20160411
ATLAS Module Treatment, Time Frame, and Procedures Confirmation			
ATLAS Module Initiation		ATLAS-INIT	v3.0.20180501
ATLAS Module Stop		ATLAS-STOP	v1.0.20150225
Neuroimaging Study Procedures Confirmation And Data Collection			
Neuroimaging Day of Scan MRI Screening Procedures (Administrative)		MR_SCREEN	v1.0.20150227
Neuroimaging Day of Scan Data and Procedures Status Confirmation		NEURO_SCAN2	v5.0.20171026
Neuroimaging Data Collection CRF		NEURO_CRF	v2.0.20150512
Quantitative Sensory Testing Procedures			
Quantitative Sensory Testing Screening		QST_Screen	v1.0.20150212
Quantitative Sensory Testing Procedures & Data Collection Instructions		QST_Instructions	v1.0.20150526
Quantitative Sensory Testing Procedures		QST	v.3.0.20151105
Ad-Hoc Deep Phenotyping Visits			
Ad-Hoc Deep Phenotyping Initiation		DP-INIT	v1.0.20161129
Ad-Hoc Deep Phenotyping Stop		DP-STOP	v1.0.20161129
PRN Documentation			
Procedural or Unanticipated Problems		PUP2	v1.0.20141110
Comments Sheet		COMM	v1.0.20150501

MAPP II Symptom Patterns Study Visit Schedule

Domain	INSTRUMENT	FORM CODE	Total Items	Week 0/ Screening & Elig. Conf.	Post-Screening Online Run-in (Wk.1,2,&3)	Week 4/ Post-Run-in Clinic Visit, Deep Pheno. Neuro. Scans & QST Procs.	Month 3 (Online data)	Month 6 (Clinic) Deep Pheno. Neuro. Scans & QST Procs.	Month 9 (Online data)	Month 12 (Opt.Clinic for Bio-spec.)	Month 15 (Online data)	Month 18 (Clinic) Deep Pheno. Neuro. Scans & QST Procs.	Month 21 (Online data)	Months 24 & 30 (Opt.Clinic for Bio-spec.)	Months 27 & 33 (Online data)	Month 36 (Clinic) Deep Pheno. Neuro. Scans & QST Procs.
				Visit #1, Screening/ Study Entry/ Phenotyping Visit	Weekly Follow-up (for the 3 wk.s post Screening)	Post-Run-in "Baseline" Clinic/ Deep Phenotyping/ Neuroimaging/ QST Clinic Visit	Quarterly Follow-up (Every 3 mon.)	6-month interval Phenotyping Clinic Visit	Quarterly Follow-up	Annual interval Phenotyping (Opt.Clinic) Visit	Quarterly Follow-up	6-month interval Clinic/ Deep Phenotyping/ Neuroimaging/ QST Clinic Visit	Quarterly Follow-up	Annual/ Semi-Annual interval Phenotyping (Opt.Clinic) Visits	Quarterly Follow-up	6-month interval Clinic/ Deep Phenotyping/ Neuroimaging/ QST Clinic Visit
Pre-screening	Pre-screening	PRESCR2	PRN													
Screening Procedures																
Consent	Informed Consent Form	ICF	PRN	X												
Demographics	Demographics	DEMO	12	X												
Symptom Assessment	Symptom, Health Care Utilization & Flare Status Questionnaire for: Screening, Baseline, Run-In, & Follow-up	SYM-Q Screening SYM-Q Run-In SYM-Q Baseline SYM-Q Follow-Up	12	X	X	X	X	X	X	X	X	X	X	X	X	X
	Global Response Assessment	GRA	2		X	X	X	X	X	X	X	X	X	X	X	X
Eligibility*	Eligibility	ELIG2	27	X												
	Neuroimaging Study Eligibility	ELIG_SCAN2	8	X												
	Urine Culture Result	UCR	3	X												
	Enrollment	ENROLL	3	X												
		Grand Total	67	65	14	14	14	14	14	14	14	14	14	14	14	14
Urologic CRFs (Females and Males):																
Symptoms	Interstitial Cystitis Symptom Index	ICINDEX ICINDEX Run-In	4	X	X	X	X	X	X	X	X	X	X	X	X	X
	Interstitial Cystitis Problem Index		4	X	X	X	X	X	X	X	X	X	X	X	X	X
	AUA Symptom Index	AUASI	7			X		X				X				X
	RICE Case Definition Questionnaire	RICE_Screening RICE_Run-In RICE_Follow-up	5	X	X	X	X	X	X	X	X	X	X	X	X	X
	RICE Bladder Symptom Impact	BSI	5			X		X				X				X
Medical History	Medical History	MEDHX2	21	X												
	Early In Life Infection History	EIL-INF	10	X												
	Family Medical History	FAMHX	1	X												
Treatment	Concomitant Medications	CMED2	PRN	X		X		X		X		X		X		X
	Pelvic Therapy History	PTHX	20	X		X		X		X		X		X		X
	My Medications (**Monthly Tx. Tracking**)	MyMED	PRN	X (Intro.)	X	X	X	X	X	X	X	X	X	X	X	X
	ATLAS Module Initiation	ATLAS_INIT	11					PRN	PRN	PRN	PRN	PRN	PRN	PRN	PRN	
	ATLAS Module Stop	ATLAS_STOP	7					PRN	PRN	PRN	PRN	PRN	PRN	PRN	PRN	
	Cystoscopy History	CYSTO	6	X								X				X
	Antibiotic Treatment History	ABHX	2	X				X		X		X		X		X
Physical Exam	Physical Exam	EXAM2	15	X				PRN		PRN		PRN		PRN		PRN
	Pelvic Exam, Female & Male	PEX_Female PEX_Male	9	X								X				
	Brief Clinical Diagnostics for Baseline & Follow-up	CDX	8			X		X		X		X		X		X
Study Stop/Withdrawal	Study Stop	SSTOP	3	PRN	PRN	PRN	PRN	PRN	PRN	PRN	PRN	PRN	PRN	PRN	PRN	X
	Consent Withdrawal	CONWITHDR2	6	PRN	PRN	PRN	PRN	PRN	PRN	PRN	PRN	PRN	PRN	PRN	PRN	PRN
	Reinstatement of Consent	RECON2	2	PRN	PRN	PRN	PRN	PRN	PRN	PRN	PRN	PRN	PRN	PRN	PRN	PRN
		Grand Total:	146	104	13	53	13	55	13	43	13	68	13	43	13	64
Urologic CRFs - Females only																
Symptoms	Female Genitourinary Pain Index	FGUPI	9	X	X	X	X	X	X	X	X	X	X	X	X	X
Sexual Function	Female Sexual Function Index-2	FSFI-2	19			X		X				X				X
	Female Self-Esteem & Relationship Questionnaire	FSEAR	12			X		X				X				X
		Grand Total:	40	9	9	40	9	40	9	9	9	40	9	9	9	40
Urologic CRFs - Males only																
Symptoms	Male Genitourinary Pain Index	MGUPI	9	X	X	X	X	X	X	X	X	X	X	X	X	X
Sexual Function	International Index of Erectile Function	IIEF	6			X		X				X				X
	U. Washington Ejaculatory Function Scale	EFS	3			X		X				X				X
	Male Self-Esteem & Relationship Questionnaire	MSEAR	14			X		X				X				X
		Grand Total:	32	9	9	32	9	32	9	9	9	32	9	9	9	32

Domain	INSTRUMENT	FORM CODE	Total Items	Week 0/ Screening & Elig. Conf.	Post-Screening Online Run-in (Wk.1,2,&3)	Week 4/ Post-Run-in Clinic Visit, Deep Pheno. Neuro. Scans & QST Procs.	Month 3 (Online data)	Month 6 (Clinic) Deep Pheno. Neuro. Scans & QST Procs.	Month 9 (Online data)	Month 12 (Opt.Clinic for Bio-spec.)	Month 15 (Online data)	Month 18 (Clinic) Deep Pheno. Neuro. Scans & QST Procs.	Month 21 (Online data)	Months 24 & 30 (Opt.Clinic for Bio-spec.)	Months 27 & 33 (Online data)	Month 36 (Clinic) Deep Pheno. Neuro. Scans & QST Procs.
				Visit #1, Screening/ Study Entry/ Phenotyping Visit	Weekly Follow-up (for the 3 wk.s post Screening)	Post-Run-in "Baseline" Clinic/ Deep Phenotyping/ Neuroimaging/ QST Clinic Visit	Quarterly Follow-up (Every 3 mon.)	6-month interval Phenotyping Clinic Visit	Quarterly Follow-up	Annual interval Phenotyping (Opt.Clinic) Visit	Quarterly Follow-up	6-month interval Clinic/ Deep Phenotyping/ Neuroimaging/ QST Clinic Visit	Quarterly Follow-up	Annual/ Semi-Annual interval Phenotyping (Opt.Clinic) Visits	Quarterly Follow-up	6-month interval Clinic/ Deep Phenotyping/ Neuroimaging/ QST Clinic Visit
Non-Urologic CRFs																
Symptoms																
Symptom Test	Complex Medical Symptoms Inventory	CMSI2_Screening CMSI2_Run-In CMSI2_Baseline CMSI2_Follow-Up	41	X (3 Mon.last yr.)	X (Weekly)	X (1 Month)	X (3mon.)	X (3 mon.)	X (3mon.)	X (3 mon.)	X (3mon.)	X (3 mon.)	X (3mon.)	X (3 mon.)	X (3mon.)	X (3 mon.)
Syndrome Module	Fibromyalgia	CMSI2-FM2	4	X	X	X	X	X	X	X	X	X	X	X	X	X
Pain & Physical Function	BPI: Body map, Intensity, Interference	BPI2_Female BPI2_Male	10	X	X	X	X	X	X	X	X	X	X	X	X	X
	PAIN Detect	PAIN PAIN Run-In	16	X	X	X	X	X	X	X	X	X	X	X	X	X
	McGill Pain Questionnaire	MPQ	15			X		X				X				X
	Gracely Box Scales	GBS	2			X		X				X				X
Physical Function	WHO Disability Assessment Schedule	WHO-DAS WHO-DAS_R.A.	15	X	X	X	X	X	X	X	X	X	X	X	X	X
	SF-12 Health Status Questionnaire	SF-12	12			X		X		X		X		X		X
	International Physical Activity Questionnaire	IPAQ	7			X		X		X		X		X		X
	Work Productivity & Activity Impairment Questionnaire	WPAI	6			X		X		X		X		X		X
Mood	PANAS	PANAS	20			X		X		X		X		X		X
	Hospital Anxiety and Depression Scale	HADS	14	X	X	X	X	X	X	X	X	X	X	X	X	X
Cognition	Multiple Ability Self-Report Questionnaire	MASQ	38			X		X		X		X		X		X
Fatigue	PROMIS - Fatigue - Short Form	FATIGUE	7	X	X	X	X	X	X	X	X	X	X	X	X	X
Sleep	PROMIS - Sleep - Short Form	SLEEP	8	X	X	X	X	X	X	X	X	X	X	X	X	X
Stress	Perceived Stress Scale	PSS PSS_Run-In	10	X	X	X	X	X	X	X	X	X	X	X	X	X
		Grand Total:	225	125	125	225	125	225	125	208	125	225	125	208	125	225
Trait-like Personal Factors																
	Ten-Item Personality Inventory	TIPI	10			X										
Cat	Thoughts About Symptoms	CSQ	6			X		X		X		X		X		X
Trauma History	Childhood/Recent Traumatic Events Scale	CTES RTES	13			X		X (RTES)				X (RTES)				X (RTES)
		Grand Total:	29			29		19		6		19		6		19
Co-morbid Diagnostics																
Syndrome Modules	Chronic Fatigue	CMSI2-CFS2	19			PRN		PRN				PRN				PRN
	Irritable Bowel Syndrome	CMSI2-IBS2	10			PRN		PRN				PRN				PRN
	Vulvodynia	CMSI2-VDYN2	8			PRN		PRN				PRN				PRN
	Migraine	CMSI2-MI2	19			PRN		PRN				PRN				PRN
	Temporomandibular Joint Disorder	CMSI2-TMD2	8			PRN		PRN				PRN				PRN
	Gonzalez TMJD Questionnaire	TMDSI	3			PRN		PRN				PRN				PRN
		Grand Total:	67			PRN		PRN				PRN				PRN
Specimens and Procedures																
Plasma and DNA	Plasma Specimen Tracking	PTRAC2	PRN			X		X		X		X		X		X
	STIM TUBES	STIMTR2	PRN			X		X				X				X
	Home Saliva Collection	S3TRAC2	PRN			X										
		S7TRAC2	PRN					X								
Urine	Urine Specimen Tracking	UTRAC2	PRN			X		X		X		X		X		X
	Microbiome Spec. (Male/Female)	UMMBTR2 UFMBTR2 UUMBTR2	PRN	X				X		X		X		X		X
Rec./Vag. Swabs	Rectal & Vaginal Swabs	RSTRAC2/VSTRAC2	PRN	X								X				
Neuroimaging Procedures Confirmation		NEURO_SCAN2	8			X		X				X				X
Neuroimaging Data Collection		NEURO_CRF	47			X		X				X				X
Quantitative Sensory Testing Screening		QST_Screen	7	X												
Quantitative Sensory Testing Procedures		QST	12			X		X				X				X
Procedural or Unanticipated Problems		PUP	PRN	PRN	PRN	PRN	PRN	PRN	PRN	PRN	PRN	PRN	PRN	PRN	PRN	PRN
		Grand Total:	74	7		67		67				67				67

MAPP II Symptom Patterns Study: ATLAS Modules 1 and 2
Visit Schedule

Domain	INSTRUMENT	FORM CODE	Total Items	ATLAS Initiation Deep Pheno. Clinic Visit BioSpec., Neuro. Scans & QST Procs.	ATLAS Online Follow-up	ATLAS Online Follow-up	ATLAS Online Follow-up	ATLAS Online Follow-up	ATLAS Online Follow-up	ATLAS Close-out Deep Pheno. Clinic Visit BioSpec., Neuro. Scans & QST Procs.
				ATLAS Week 0 / ATLAS Module Initiation	**ATLAS Week 2 / ATLAS Follow-up**	**ATLAS Week 4 / ATLAS Follow-up**	**ATLAS Week 6 / ATLAS Follow-up**	**ATLAS Week 8 / ATLAS Follow-up**	**ATLAS Week 10 / ATLAS Follow-up**	**ATLAS Week 12 / ATLAS Module Close-out**
ATLAS Modules 1 & 2 Initiation Procedures, Treatment Documentation, and Close-out Procedures	ATLAS Mod.1 & Mod.2 Initiation	ATLAS_INIT	11	X						
	ATLAS1 & 2 Mod.Stop	ATLAS_STOP	7		PRN	PRN	PRN	PRN	PRN	X
Urologic CRFs (Females and Males):										
Symptom Assessment	Symptom, Health Care Utilization & Flare Status Questionnaire for: ATLAS Module	SYM-Q ATLAS	17	X	X	X	X	X	X	X
	Global Response Assessment	GRA_ATLAS	2	X	X	X	X	X	X	X
Symptoms	Interstitial Cystitis Symptom Index	ICINDEX_ATLAS	4	X	X	X	X	X	X	X
	Interstitial Cystitis Problem Index		4	X	X	X	X	X	X	X
	AUA Symptom Index	AUASI	7	X						X
	RICE Case Definition Questionnaire	RICE_ATLAS	5	X	X	X	X	X	X	X
	RICE Bladder Symptom Impact	BSI	5	X						X
Treatment	Concomitant Medications	CMED	PRN	X						X
	Pelvic Therapy History	PTHX	4	X						X
	My Medications (Weekly Tx. Tracking)	MyMED	PRN	X	X	X	X	X	X	X
Physical Diagnostics	Brief Clinical Diagnostics for Baseline & Follow-up	CDX	8	X						X
	Dipstick Urinalysis Result	UAR	4	X						X
	Consent Withdrawal	CONWITHDR	5	PRN	PRN	PRN	PRN	PRN	PRN	PRN
	Reinstatement of Consent	RECON	2	PRN	PRN	PRN	PRN	PRN	PRN	PRN
		Grand Total:	67	67	32	32	32	32	32	67
Urologic CRFs - Females only										
Symptoms	Female Genitourinary Pain Index	FGUPI	9	X	X	X	X	X	X	X
Sexual Function	Female Sexual Function Index 2	FSFI-2	19	X						X
	Female Self-Esteem & Relationship Questionnaire	FSEAR	12	X						X
		Grand Total:	40	40	9	9	9	9	9	40
Urologic CRFs - Males only										
Symptoms	Male Genitourinary Pain Index	MGUPI	9	X	X	X	X	X	X	X
Sexual Function	International Index of Erectile Function	IIEF	6	X						X
	U. Washington Ejaculatory Function Scale	EFS	3	X						X
	Male Self-Esteem & Relationship Questionnaire	MSEAR	14	X						X
		Grand Total:	32	9	9	9	9	9	9	32

Domain	INSTRUMENT	FORM CODE	Total Items	ATLAS Initiation Deep Pheno. Clinic Visit BioSpec., Neuro. Scans & QST Procs.	ATLAS Online Follow-up	ATLAS Online Follow-up	ATLAS Online Follow-up	ATLAS Online Follow-up	ATLAS Online Follow-up	ATLAS Close-out Deep Pheno. Clinic Visit BioSpec., Neuro. Scans & QST Procs.
				ATLAS Week 0 / ATLAS Module Initiation	ATLAS Week 2 / ATLAS Follow-up	ATLAS Week 4 / ATLAS Follow-up	ATLAS Week 6 / ATLAS Follow-up	ATLAS Week 8 / ATLAS Follow-up	ATLAS Week 10 / ATLAS Follow-up	ATLAS Week 12 / ATLAS Module Close-out
Non-Urologic CRFs										
Symptoms										
Symptom Test	Complex Medical Symptoms Inventory	**CMSI2_ATLAS**	41	X	X	X	X	X	X	X
Syndrome Module	Fibromyalgia	**CMSI2-FM2**	4	X	X	X	X	X	X	X
Pain & Physical Function	BPI: Body map, Intensity, Interference	**BPI2_Female** **BPI2_Male**	10	X	X	X	X	X	X	X
	PAIN Detect	**PAIN ATLAS**	16	X	X	X	X	X	X	X
	McGill Pain Questionnaire	**MPQ**	15	X						X
	Gracely Box Scales	**GBS**	2	X						X
Physical Function	WHO Disability Assessment Schedule	**WHO-DAS_R.A.**	15	X	X	X	X	X	X	X
	SF-12 Health Status Questionnaire	**SF-12**	12	X						X
	International Physical Activity Questionnaire	**IPAQ**	7	X						X
	Work Productivity & Activity Impairment Questionnaire	**WPAI**	6	X						X
Mood	PANAS	**PANAS**	20	X						X
	Hospital Anxiety and Depression Scale	**HADS**	14	X	X	X	X	X	X	X
Cognition	Multiple Ability Self-Report Questionnaire	**MASQ**	38	X						X
Fatigue	PROMIS - Fatigue - Short Form	**FATIGUE**	7	X	X	X	X	X	X	X
Sleep	PROMIS - Sleep - Short Form	**SLEEP**	8	X	X	X	X	X	X	X
Stress	Perceived Stress Scale	**PSS_ATLAS**	10	X	X	X	X	X	X	X
		Grand Total:	225	**225**	**125**	**125**	**125**	**125**	**125**	**225**
Trait-like Personal Factors										
Cat	Thoughts About Symptoms	**CSQ**	6	X						X
Trauma History	Recent Traumatic Events Scale	**RTES**	13	X						X
		Grand Total:	19	**19**						**19**
Specimens and Procedures										
Plasma and DNA	Plasma Specimen Tracking	**PTRAC2**	PRN	X						X
	STIM TUBES	**STIMTRAC**	PRN	X						X
Urine	Urine Specimen Tracking	**UTRAC2**	PRN	X						X
	Microbiome Spec. (Male/Female)	**UMMBTRAC** **UFMBTRAC** **UUMBTRAC**	PRN	X						X
Neuroimaging Procedures Confirmation		**NEURO_SCAN2**	8	X						X
Neuroimaging Data Collection		**NEURO_CRF**	47	X						X
Quantitative Sensory Testing Procedures		**QST**	12	X						X
Procedural or Unanticipated Problems		**PUP**	PRN	**PRN**	**PRN**	**PRN**	**PRN**	**PRN**	**PRN**	**PRN**
		Grand Total:	**67**	**67**						**67**

MAPP research network MAPP II SPS	**Participant ID:** __ __ __ __ __ __	**Pin #** __ __ __ __
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	CRF Date: __ __/__ __/__ __ __ __	**Visit #:** __ __

Demographics

RESEARCH COORDINATOR COMPLETES AT **SCREENING WEEK 0** 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 MAPP II SPS	**Participant ID:** __ __ __ __ __ __	**Pin #**	__ __ __ __
	Discovery Site: __ __	**Clinical Center**	__ __
	CRF Date: __ __/__ __/__ __ __ __	**Visit #:**	__ __

MAPP Phase II Eligibility Confirmation

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

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

Inclusion Criteria

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

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

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

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

Diagnosis History (per AUA guidelines)

9. Participant has received a ***clinical diagnosis*** of:

❑1 IC/BPS

❑2 CP/CPPS

❑3 Both IC/BPS and CP/CPPS

❑4 *No **prior clinical diagnosis** of IC/BPS or CP/CPPS available

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

10.	**Clinician familiar with UCPPS criteria confirms Participant meets UCPPS evaluation criteria per-protocol.**	❑1 Yes	❑0 No
	Clinician Initials: _____		

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

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

MAPP research network MAPP II SPS	**Participant ID:** __ __ __ __ __ __	**Pin #** __ __ __ __
	Discovery Site: __ __	**Clinical Center** __ __
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MAPP Phase II Eligibility Confirmation

Research Coordinator completes at **Screening Week 0** 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 is currently undergoing dose titration or medication adjustments for a poorly controlled autoimmune or infectious disorder (such as Crohn's Disease, Ulcerative Colitis, Lupus, Rheumatoid Arthritis, Multiple Sclerosis, or HIV) which in the opinion of the Investigator could impact bladder symptoms. ❑1 Yes ❑0 No
16. Participant has a history of cancer (with the exception of skin cancer). ❑1 Yes ❑0 No

16a. Participant has a history of any pelvic malignancy (e.g. GI, GU, Gyn). ❑1 Yes ❑0 No

16b. Participant is having ongoing systemic treatment/therapy for any type of cancer. ❑1 Yes ❑0 No

17. Participant has current major psychiatric disorder or other psychiatric or medical issues that would interfere with study participation (e.g. dementia, psychosis, upcoming major surgery, etc). ❑1 Yes ❑0 No
18. Participant has severe cardiac, pulmonary, renal, or hepatic disease that in the judgment of the study physician would preclude participation in this study. ❑1 Yes ❑0 No

ALL EXCLUSION CRITERIA RESPONSES MUST BE "NO" FOR THE PARTICIPANT TO BE ELIGIBLE FOR ENROLLMENT IN THE MAPPII SPS STUDY.

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

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

Deferral Criteria – Treatment and history

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

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

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

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

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

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

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

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

MAPP research network MAPP II SPS	**Participant ID:** __ __ __ __ __ __	**Pin #** __ __ __ __
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	CRF Date: __ __/__ __/__ __ __ __	**Visit #:** __ __

MAPP Phase II Eligibility Confirmation

Research Coordinator completes at **Screening Week 0** 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

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

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

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

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

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

Question #25 is a Deferral Criterion for females of childbearing potential *ONLY.*

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

25. Female participant has a positive urine pregnancy test. (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.**

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

Please note:

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

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

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

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

Eligibility Confirmation – MAPP SPS Neuroimaging Study

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

1. Participant agrees to complete Neuroimaging MRI scan and procedures as scheduled for the ***Baseline Week 4 contact***. ❑1 Yes ❑0 No

   If Q.#1 is ***YES***, please continue to Q.#1a.

   If Q.#1 is ***No***, please skip to Q.#1b.

   a. Please confirm date the MRI scan is scheduled for the Baseline Week 4 contact: __ __/__ __/__ __ __ __ (MM DD YYYY)

   b. Did the Participant decline the Neuroimaging study procedures? ❑1 Yes ❑0 No

Exclusion Criteria

2. Participant has CNS Disease, including structural brain abnormalities (e.g., neoplasms, subarachnoid cysts), cerebrovascular disease, ongoing infectious disease (e.g., abscess), history of other neurological disease, including stroke or seizure disorders. ❑1 Yes ❑0 No
3. Participant has claustrophobia: Potential participants will be questioned about possible discomfort with being in an enclosed space (e.g., MRI scanner). Those who report such problems will be excluded. ❑1 Yes ❑0 No
4. Participant has vision or hearing impairments that would impede completion of study procedures. ❑1 Yes ❑0 No
5. Participant has any metal implants, devices, or jewelry that would be unsafe in the MRI, or meets any other exclusionary criteria as specified by the Magnetic Resonance Screening form. ❑1 Yes ❑0 No
   (Please refer to the Magnetic Resonance Screening administrative form: MR_SCREEN.)
6. Participant has an active neurostimulator. ❑1 Yes ❑0 No
9. Participant ineligible due to other reasons. ❑1 Yes ❑0 No

   a. Please specify: _____

   _____

ALL EXCLUSION CRITERIA RESPONSES ABOVE MUST BE "NO" FOR THE PARTICIPANT TO BE ELIGIBLE FOR ENROLLMENT IN THE TRANS-MAPP NEUROIMAGING STUDY

7. Did the participant meet all Eligibility Criteria for the MAPP SPS Neuroimaging Study? ❑1 Yes ❑0 No

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

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

Urine Culture Result - Deferral Criterion for Eligibility Confirmation

Research Coordinator completes at **Screening Week 0**

to confirm negative urine culture results.

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 **6 weeks** 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 MAPP II SPS	**Participant ID:** __ __ __ __ __ __	**Pin #** __ __ __ __
	Discovery Site: __ __	**Clinical Center** __ __
	CRF Date: __ __/__ __/__ __ __ __	**Visit #:** __ __

Enrollment Confirmation

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

1. Did the Participant successfully enroll in the MAPP Symptom Patterns 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 run-in contact: __ __/__ __/__ __ __ __ (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

   ❑9 Participant refused consent for the MAPP Pelvic Exam

   ❑10 Participant refused consent for Neuroimaging procedures

   ❑11 Participant refused consent for Quantitative Sensory Testing

   ❑12 Participant has been deferred

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

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

Symptom, Health Care Utilization, and Flare Status Questionnaire - Screening

RESEARCH COORDINATOR COMPLETES THIS FORM AT **SCREENING WEEK 0** CONTACT.

Pain, Pressure, Discomfort Scale

(*Please note: SYM-Q, Q.#1 is an Eligibility Criterion for ELIG form Q.#8)

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

*Please note: Q.#s 2, 3, & 4 asked for MAPPI have been archived. The following question structure for Q.# 5 through Q.#10 remains the same as for MAPPI for the purposes of question consistency and analyses.

Urologic or Pelvic Pain Symptom Severity Scales

5. Please rate the overall severity of your **URINARY SYMPTOMS 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

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

Symptom, Health Care Utilization, and Flare Status Questionnaire - Screening

RESEARCH COORDINATOR COMPLETES THIS FORM AT **SCREENING WEEK 0** CONTACT.

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

10. Do you know when you had your most recent (or last) menstrual period? ❑1 Yes ❑0 No ❑99 Not Applicable

(Question #10 is for Female Participants *ONLY*. Please record *"99/Not Applicable"* for Male Participants.)

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

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

Symptom, Health Care Utilization, and Flare Status Questionnaire - Screening

RESEARCH COORDINATOR COMPLETES THIS FORM AT **SCREENING WEEK 0** CONTACT.

Flare Status Questions

11. Have you ***ever*** experienced flares of your urologic or pelvic pain symptoms? By this we mean, have you ever experienced symptoms that are much worse than usual? ❑$_1$ Yes ❑$_0$ No

12. 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

If you answered "Yes" to either question 11 or 12 above, please complete the following additional questions about flares.

Flare Interval Questions

13. Now please think about ***all your flares*** in the ***past 3 months***. About how many flares do you think you have had?

- ❑$_0$ No Flares ***in 3 months***
- ❑$_1$ 1 Flare ***in 3 months***
- ❑$_2$ 2 Flares ***in 3 months***
- ❑$_3$ 3 Flares ***(1 per month)***
- ❑$_4$ 2/3 Flares ***per month***
- ❑$_5$ One Flare ***per week***
- ❑$_6$ 2-6 Flares ***per week***
- ❑$_7$ 1 or more Flares ***per day***
- ❑$_{88}$ Don't know

14. Please indicate how long a ***typical flare*** of your urologic or pelvic pain symptoms lasts for you.

- ❑$_1$ Less than one day
- ❑$_2$ About one day
- ❑$_3$ Two days
- ❑$_4$ 3-6 days
- ❑$_5$ One week or more
- ❑$_{88}$ Don't remember

Flare Comparison Questions

15. Considering both your usual urologic/pelvic pain symptoms (***non-flare***) and then considering a typical ***flare*** of these symptoms, please rate **the intensity of pain** associated with each situation.

	No pain										Worst Pain
a. **Non-flare** (Usual urologic/pelvic pain symptoms)	❑ 0	❑ 1	❑ 2	❑ 3	❑ 4	❑ 5	❑ 6	❑ 7	❑ 8	❑ 9	❑ 10
b. **Flare** (Symptoms much worse than usual)	❑ 0	❑ 1	❑ 2	❑ 3	❑ 4	❑ 5	❑ 6	❑ 7	❑ 8	❑ 9	❑ 10

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

Symptom, Health Care Utilization, and Flare Status Questionnaire - Screening

RESEARCH COORDINATOR COMPLETES THIS FORM AT **SCREENING WEEK 0** CONTACT.

16. Considering both your usual **urinary frequency during your waking hours** (***non-flare***) and then considering a typical ***flare*** of these symptoms, please rate your **urinary frequency during your waking hours** associated with each situation.

a. **Non-flare** (Usual urinary frequency during your waking hours)	❑1 6 times or less	❑2 7-10 times	❑3 11-14 times	❑4 15-19 times	❑5 20 times or more
b. **Flare** (Urinary frequency during your waking hours much worse than usual)	❑1 6 times or less	❑2 7-10 times	❑3 11-14 times	❑4 15-19 times	❑5 20 times or more

17. Considering a typical ***flare***, how much does the flare interfere with the following activities?

	No interference										**Worst interference**
a. Routine daily responsibilities	❑ 0	❑ 1	❑ 2	❑ 3	❑ 4	❑ 5	❑ 6	❑ 7	❑ 8	❑ 9	❑ 10
b. Pleasurable activities	❑ 0	❑ 1	❑ 2	❑ 3	❑ 4	❑ 5	❑ 6	❑ 7	❑ 8	❑ 9	❑ 10
c. Sleep	❑ 0	❑ 1	❑ 2	❑ 3	❑ 4	❑ 5	❑ 6	❑ 7	❑ 8	❑ 9	❑ 10

Flare Management Plan Questions ***(Asked ONLY at Screening, Week 0)***

18. In the event of a **flare**, do you have a management plan? ❑1 Yes ❑0 No

If ***YES***, please confirm the management plan(s) below:

a. Oral Medication ❑1 Yes ❑0 No

a.1. Please specify oral medication(s) below:

_____

b. Instillation ❑1 Yes ❑0 No

c. Change volume of intake ❑1 Yes ❑0 No

d. Change diet ❑1 Yes ❑0 No

e. Heat/Cold ❑1 Yes ❑0 No

f. Rest ❑1 Yes ❑0 No

g. Other, **Please specify:** _____ ❑1 Yes ❑0 No

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

Symptom, Health Care Utilization, and Flare Status Questionnaire – Run-In Visits

PARTICIPANT COMPLETES **VIA ONLINE SURVEY** AT **WEEK #S 1, 2, & 3 RUN-IN** CONTACTS.

Pain, Pressure, Discomfort Scale

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 week?

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

*Please note: Q.#s 2, 3, & 4 asked for MAPPI have been archived. The following question structure for Q.# 5 through Q.#10 remains the same as for MAPPI for the purposes of question consistency and analyses.

Urologic or Pelvic Pain Symptom Severity Scales

5. Please rate the overall severity of your **URINARY SYMPTOMS OR PELVIC PAIN SYMPTOMS** over the past week:

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 week:

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

7. Please rate your **MOOD** over the past week:

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

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

Symptom, Health Care Utilization, and Flare Status Questionnaire – Run-In Visits

PARTICIPANT COMPLETES **VIA ONLINE SURVEY** AT **WEEK #S 1, 2, & 3 RUN-IN** CONTACTS.

8. What was your single most bothersome symptom over the past week?
(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 week:

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

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

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

MAPP research network MAPP II SPS	**Participant ID:** __ __ __ __ __ __	**Pin #** __ __ __ __
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	CRF Date: __ __/__ __/__ __ __ __	**Visit #:** __ __

Symptom, Health Care Utilization, and Flare Status Questionnaire – Run-In Visits

PARTICIPANT COMPLETES **VIA ONLINE SURVEY** AT **WEEK #S 1, 2, & 3 RUN-IN** CONTACTS.

Flare Status Questions

11. Have you experienced flares of your urologic or pelvic pain symptoms **in the past week?** By this we mean, have you ever experienced symptoms that are much worse than usual? ❑$_1$ Yes ❑$_0$ No

12. 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

If you answered "Yes" to either question 11 or 12 above, please complete the following question about flares.

Flare Interval Questions

13. Now please think about ***all your flares*** **in the past week**. About how many flares do you think you have had?

❑$_1$ One Flare in the ***past week***
❑$_2$ 2-6 Flares in the ***past week***
❑$_3$ 1 or more Flares ***per day***
❑$_{88}$ Don't know

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

Symptom, Health Care Utilization, and Flare Status Questionnaire - Baseline

PARTICIPANT COMPLETES **VIA ONLINE SURVEY** AT **BASELINE WEEK 4** CONTACT.

Pain, Urgency, Frequency Severity Scale

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

*Please note: Q.#s 2, 3, & 4 asked for MAPPI have been archived. The following question structure for Q.# 5 through Q.#10 remains the same as for MAPPI for the purposes of question consistency and analyses.

Urologic or Pelvic Pain Symptom Severity Scales

5. Please rate the overall severity of your **URINARY SYMPTOMS 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

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

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

Symptom, Health Care Utilization, and Flare Status Questionnaire - Baseline

PARTICIPANT COMPLETES **VIA ONLINE SURVEY** AT **BASELINE WEEK 4** CONTACT.

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

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

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

Symptom, Health Care Utilization, and Flare Status Questionnaire - Baseline

PARTICIPANT COMPLETES **VIA ONLINE SURVEY** AT **BASELINE WEEK 4** CONTACT.

Flare Status Questions

11. Have you experienced flares of your urologic or pelvic pain symptoms in the ***past 3 months***? By this we mean, have you ever experienced symptoms that are much worse than usual? ❑$_1$ Yes ❑$_0$ No

12. 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

If you answered "Yes" to either question 11 or 12 above, please complete the following additional questions about flares.

Flare Interval Questions

13. Now please think about ***all your flares*** in the ***past 3 months***. About how many flares do you think you have had?

- ❑$_0$ No Flares ***in 3 months***
- ❑$_1$ 1 Flare ***in 3 months***
- ❑$_2$ 2 Flares ***in 3 months***
- ❑$_3$ 3 Flares ***(1 per month)***
- ❑$_4$ 2/3 Flares ***per month***
- ❑$_5$ One Flare ***per week***
- ❑$_6$ 2-6 Flares ***per week***
- ❑$_7$ 1 or more Flares ***per day***
- ❑$_{88}$ Don't know

14. Please indicate how long a ***typical flare*** of your urologic or pelvic pain symptoms in the ***past 3 months*** lasted for you.

- ❑$_1$ Less than one day
- ❑$_2$ About one day
- ❑$_3$ Two days
- ❑$_4$ 3-6 days
- ❑$_5$ One week or more
- ❑$_{88}$ Don't remember

MAPP research network MAPP II SPS	**Participant ID:** __ __ __ __ __ __	**Pin #** __ __ __ __
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	CRF Date: __ __/__ __/__ __ __ __	**Visit #:** __ __

Symptom, Health Care Utilization, and Flare Status Questionnaire – Follow-up

PARTICIPANT COMPLETES **VIA ONLINE SURVEY** AT ***ALL*** **CLINIC** AND **ONLINE** FOLLOW-UP CONTACTS.

Pain, Pressure, Discomfort Scale

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

*Please note: Q.#s 2, 3, & 4 asked for MAPPI have been archived. The following question structure for Q.# 5 through Q.#10 remains the same as for MAPPI for the purposes of question consistency and analyses.

Urologic or Pelvic Pain Symptom Severity Scales

5. Please rate the overall severity of your **URINARY SYMPTOMS 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

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

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

Symptom, Health Care Utilization, and Flare Status Questionnaire – Follow-up

PARTICIPANT COMPLETES **VIA ONLINE SURVEY** AT ***ALL*** **CLINIC** AND **ONLINE** FOLLOW-UP CONTACTS.

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

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

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

Symptom, Health Care Utilization, and Flare Status Questionnaire – Follow-up

PARTICIPANT COMPLETES **VIA ONLINE SURVEY** AT ***ALL*** **CLINIC** AND **ONLINE** FOLLOW-UP CONTACTS.

Flare Status Questions

11. Have you experienced flares of your urologic or pelvic pain symptoms in the ***past 3 months***? By this we mean, have you ever experienced symptoms that are much worse than usual? ❑$_1$ Yes ❑$_0$ No

12. 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

If you answered "Yes" to either question 11 or 12 above, please complete the following additional questions about flares.

Flare Interval Questions

13. Now please think about ***all your flares*** in the ***past 3 months***. About how many flares do you think you have had?

- ❑$_0$ No Flares ***in 3 months***
- ❑$_1$ 1 Flare ***in 3 months***
- ❑$_2$ 2 Flares ***in 3 months***
- ❑$_3$ 3 Flares ***(1 per month)***
- ❑$_4$ 2/3 Flares ***per month***
- ❑$_5$ One Flare ***per week***
- ❑$_6$ 2-6 Flares ***per week***
- ❑$_7$ 1 or more Flares ***per day***
- ❑$_{88}$ Don't know

14. Please indicate how long a ***typical flare*** of your urologic or pelvic pain symptoms in the ***past 3 months*** lasted for you.

- ❑$_1$ Less than one day
- ❑$_2$ About one day
- ❑$_3$ Two days
- ❑$_4$ 3-6 days
- ❑$_5$ One week or more
- ❑$_{88}$ Don't remember

Flare Comparison Questions

15. Considering both your usual urologic/pelvic pain symptoms (***non-flare***) and then considering a typical ***flare*** of these symptoms, please rate **the intensity of pain** associated with each situation in the ***past 3 months***.

	No pain										**Worst Pain**
a. **Non-flare** (Usual urologic/pelvic pain symptoms)	❑ 0	❑ 1	❑ 2	❑ 3	❑ 4	❑ 5	❑ 6	❑ 7	❑ 8	❑ 9	❑ 10
b. **Flare** (Symptoms much worse than usual**)**	❑ 0	❑ 1	❑ 2	❑ 3	❑ 4	❑ 5	❑ 6	❑ 7	❑ 8	❑ 9	❑ 10

Symptom, Health Care Utilization, and Flare Status Questionnaire – Follow-up

PARTICIPANT COMPLETES **VIA ONLINE SURVEY** AT ***ALL*** **CLINIC** AND **ONLINE** FOLLOW-UP CONTACTS.

16. Considering both your **urinary frequency during your waking hours** (***non-flare***) and then considering a typical ***flare*** of these symptoms, please rate your **urinary frequency during your waking hours** associated with each situation in the ***past 3 months***.

a. **Non-flare** (Usual urinary frequency during your waking hours)	❑1 6 times or less	❑2 7-10 times	❑3 11-14 times	❑4 15-19 times	❑5 20 times or more
b. **Flare** (Urinary frequency during your waking hours much worse than usual)	❑1 6 times or less	❑2 7-10 times	❑3 11-14 times	❑4 15-19 times	❑5 20 times or more

17. Considering a typical ***flare*** in the ***past 3 months***, how much does the flare interfere with the following activities?

	No interference										**Worst interference**
a. Routine daily responsibilities	❑ 0	❑ 1	❑ 2	❑ 3	❑ 4	❑ 5	❑ 6	❑ 7	❑ 8	❑ 9	❑ 10
b. Pleasurable activities	❑ 0	❑ 1	❑ 2	❑ 3	❑ 4	❑ 5	❑ 6	❑ 7	❑ 8	❑ 9	❑ 10
c. Sleep	❑ 0	❑ 1	❑ 2	❑ 3	❑ 4	❑ 5	❑ 6	❑ 7	❑ 8	❑ 9	❑ 10

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

Symptom, Health Care Utilization, and Flare Status Questionnaire for ATLAS Module

PARTICIPANT COMPLETES **VIA ONLINE SURVEY AT ATLAS WEEK 0** AND EVERY **2 WEEKS** DURING **ATLAS** FOLLOW-UP.

Pain, Pressure, Discomfort Scale

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

*Please note: Q.#s 2, 3, & 4 asked for MAPPI have been archived. The following question structure for Q.# 5 through Q.#10 remains the same as for MAPPI for the purposes of question consistency and analyses.

Urologic or Pelvic Pain Symptom Severity Scales

5. Please rate the overall severity of your **URINARY SYMPTOMS 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

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

MAPP research network MAPP II SPS	**Participant ID:** __ __ __ __ __ __	**Pin #** __ __ __ __
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Symptom, Health Care Utilization, and Flare Status Questionnaire for ATLAS Module

PARTICIPANT COMPLETES **VIA ONLINE SURVEY AT ATLAS WEEK 0** AND EVERY **2 WEEKS** DURING **ATLAS** FOLLOW-UP.

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

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

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

Symptom, Health Care Utilization, and Flare Status Questionnaire for ATLAS Module

PARTICIPANT COMPLETES **VIA ONLINE SURVEY AT ATLAS WEEK 0** AND EVERY **2 WEEKS** DURING **ATLAS** FOLLOW-UP.

Flare Status Questions

11. Have you experienced flares of your urologic or pelvic pain symptoms **in the past 2 weeks?** By this we mean, have you ever experienced symptoms that are much worse than usual?

❑$_1$ Yes ❑$_0$ No

12. 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

If you answered "Yes" to either question 11 or 12 above, please complete the following question about flares.

Flare Interval Questions

13. Now please think about ***all your flares*** in the ***past 2 weeks***. About how many flares do you think you have had?

❑$_1$ One Flare in the ***past 2 weeks***
❑$_2$ 2-6 Flares in the ***past 2 weeks***
❑$_3$ 7-13 Flares in the ***past 2 weeks***
❑$_4$ 1 or more Flares ***per day***
❑$_{88}$ Don't know

14. Please indicate how long a ***typical flare*** of your urologic or pelvic pain symptoms in the ***past 2 weeks*** lasted for you.

❑$_1$ Less than one day
❑$_2$ About one day
❑$_3$ Two days
❑$_4$ 3-6 days
❑$_5$ One week or more
❑$_{88}$ Don't remember

Flare Comparison Questions

15. Considering both your usual urologic/pelvic pain symptoms (***non-flare***) and then considering a typical ***flare*** of these symptoms, please rate **the intensity of pain** associated with each situation in the ***past 2 weeks***.

	No pain										**Worst Pain**
a. **Non-flare** (Usual urologic/pelvic pain symptoms)	❑ 0	❑ 1	❑ 2	❑ 3	❑ 4	❑ 5	❑ 6	❑ 7	❑ 8	❑ 9	❑ 10
b. **Flare** (Symptoms much worse than usual**)**	❑ 0	❑ 1	❑ 2	❑ 3	❑ 4	❑ 5	❑ 6	❑ 7	❑ 8	❑ 9	❑ 10

MAPP research network MAPP II SPS	**Participant ID:** __ __ __ __ __ __	**Pin #** __ __ __ __
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Symptom, Health Care Utilization, and Flare Status Questionnaire for ATLAS Module

PARTICIPANT COMPLETES **VIA ONLINE SURVEY AT ATLAS WEEK 0** AND EVERY **2 WEEKS** DURING **ATLAS** FOLLOW-UP.

16. Considering both your usual **urinary frequency during your waking hours** (***non-flare***) and then considering a typical ***flare*** of these symptoms, please rate your **urinary frequency during your waking hours** associated with each situation in the ***past 2 weeks***.

a. **Non-flare** (Usual urinary frequency during your waking hours)	❑1 6 times or less	❑2 7-10 times	❑3 11-14 times	❑4 15-19 times	❑5 20 times or more
b. **Flare** (Urinary frequency during your waking hours much worse than usual)	❑1 6 times or less	❑2 7-10 times	❑3 11-14 times	❑4 15-19 times	❑5 20 times or more

17. Considering a typical ***flare***, in the ***past 2 weeks*** how much does the flare interfere with the following activities?

	No interference										**Worst interference**
a. Routine daily responsibilities	❑ 0	❑ 1	❑ 2	❑ 3	❑ 4	❑ 5	❑ 6	❑ 7	❑ 8	❑ 9	❑ 10
b. Pleasurable activities	❑ 0	❑ 1	❑ 2	❑ 3	❑ 4	❑ 5	❑ 6	❑ 7	❑ 8	❑ 9	❑ 10
c. Sleep	❑ 0	❑ 1	❑ 2	❑ 3	❑ 4	❑ 5	❑ 6	❑ 7	❑ 8	❑ 9	❑ 10

MAPP research network MAPP II SPS	**Participant ID:** __ __ __ __ __ __	**Pin #** __ __ __ __
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Global Response Assessment (GRA) Questionnaire

Participant completes via Online Survey at
ALL Run-In Contacts, Baseline Week 4, and ALL In-Clinic and Online Follow-up Contacts.
Also completed at **ATLAS Week 0** if an ATLAS Treatment Monitoring Module is initiated.

1. 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

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

- ❑$_1$ Markedly worse
- ❑$_2$ Moderately worse
- ❑$_3$ Slightly worse
- ❑$_4$ No change
- ❑$_5$ Slightly improved
- ❑$_6$ Moderately improved
- ❑$_7$ Markedly improved

MAPP research network MAPP II SPS	**Participant ID:** __ __ __ __ __ __	**Pin #** __ __ __ __
	Discovery Site: __ __	**Clinical Center** __ __
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Global Response Assessment (GRA) Questionnaire for ATLAS Follow-up

Participant completes via Online Survey at
ALL ATLAS Bi-weekly Follow-up Contacts* and *the final ATLAS Clinic Contact

1. 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

2. As compared to when you started your ATLAS treatment, how would you rate your overall symptoms now?

- ❑$_1$ Markedly worse
- ❑$_2$ Moderately worse
- ❑$_3$ Slightly worse
- ❑$_4$ No change
- ❑$_5$ Slightly improved
- ❑$_6$ Moderately improved
- ❑$_7$ Markedly improved

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

Interstitial Cystitis Symptom Index and Problem Index

(O'Leary, Sant, Fowler, Whitmore, Spolarich-Kroll)

THE PARTICIPANT COMPLETES THIS FORM VIA ONLINE SURVEY AT
SCREENING WEEK 0 & BASELINE WEEK 4 CLINIC CONTACTS AND ALL ONLINE & CLINIC FOLLOW-UP 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 MAPP II SPS	**Participant ID:** __ __ __ __ __ __	**Pin #** __ __ __ __
	Discovery Site: __ __	**Clinical Center** __ __
	CRF Date: __ __/__ __/__ __ __ __	**Visit #:** __ __

Interstitial Cystitis Symptom Index and Problem Index

(O'Leary, Sant, Fowler, Whitmore, Spolarich-Kroll)

THE PARTICIPANT COMPLETES THIS FORM VIA ONLINE SURVEY AT ***WEEK 1, 2, & 3 RUN-IN*** CONTACTS.

Interstitial Cystitis Symptom Index:

Q1. During the past **week**, 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 **week**, 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 **week**, 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 **week**, 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 **week**, 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 MAPP II SPS	**Participant ID:** __ __ __ __ __ __	**Pin #** __ __ __ __
	Discovery Site: __ __	**Clinical Center** __ __
	CRF Date: __ __/__ __/__ __ __ __	**Visit #:** __ __

Interstitial Cystitis Symptom Index and Problem Index for ATLAS Module

(O'Leary, Sant, Fowler, Whitmore, Spolarich-Kroll)

PARTICIPANT COMPLETES **VIA ONLINE SURVEY AT ATLAS WEEK 0** AND EVERY **2 WEEKS** DURING **ATLAS** FOLLOW-UP.

Interstitial Cystitis Symptom Index:

Q1. During the past **2 weeks**, 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 **2 weeks**, 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 **2 weeks**, 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 **2 weeks**, 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 **2 weeks**, 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 MAPP II SPS	**Participant ID:** __ __ __ __ __ __	**Pin #** __ __ __ __
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AUA Symptom Score Index

Participant completes via online survey at Baseline Week 4 and Months 6, 18, & 36 clinic 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 MAPP II SPS	**Participant ID:** __ __ __ __ __ __	**Pin #** __ __ __ __
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	CRF Date: __ __/__ __/__ __ __ __	**Visit #:** __ __

AUA Symptom Score Index

Participant completes via online survey at Baseline Week 4 and Months 6, 18, & 36 clinic 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 MAPP II SPS	**Participant ID:** __ __ __ __ __ __	**Pin #**	__ __ __ __
	Discovery Site: __ __	**Clinical Center**	__ __
	CRF Date: __ __/__ __/__ __ __ __	**Visit #:**	__ __

RICE Case Definition Questionnaire for Screening & Eligibility Confirmation

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

Please Note: **RICE_Screening Q.#1** below is ***Eligibility Criteria*** per **ELIG form, Q.#5**.
Also, RICE_Screening Q.#1 must be *Yes* if the answer to SYM-Q Q.#1 is *Yes*.

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 MAPP II SPS	**Participant ID:** __ __ __ __ __ __	**Pin #** __ __ __ __
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RICE Case Definition Questionnaire
For Online Surveys During Run-In Period

Participant completes via Online Survey at **Run-In Weeks 1, 2, & 3**.

1. In the past week, 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 week, 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 week, 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 week (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 MAPP II SPS	**Participant ID:** __ __ __ __ __ __	**Pin #** __ __ __ __
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RICE Case Definition Questionnaire
For Online Surveys During Follow-up

Participant completes via online survey at Baseline Week 4 and ALL Follow-up Contacts

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 MAPP II SPS	**Participant ID:** __ __ __ __ __ __	**Pin #** __ __ __ __
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	CRF Date: __ __/__ __/__ __ __ __	**Visit #:** __ __

RICE Case Definition Questionnaire
For Online Surveys During ATLAS Module

PARTICIPANT COMPLETES **VIA ONLINE SURVEY AT ATLAS WEEK 0** AND EVERY **2 WEEKS** DURING **ATLAS** FOLLOW-UP.

1. In the ***past 2 weeks***, 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 2 weeks***, 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 2 weeks***, 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 2 weeks*** (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 MAPP II SPS	**Participant ID:** __ __ __ __ __ __	**Pin #**	__ __ __ __
	Discovery Site: __ __	**Clinical Center**	__ __
	CRF Date: __ __/__ __/__ __ __ __	**Visit #:**	__ __

RICE – Bladder Symptom Impact Scale

Participant completes via online survey at **Week 4 Baseline** and **Months 6, 18, & 36 Clinic Contacts**

Sometimes medical conditions can make life difficult in a variety of ways and sometimes they don't make that much difference. Using any number from **1** to **7**, where **1** ***is having a very small negative or bad effect*** and **7** ***is having a very large negative or bad effect***, please rate each of the following in terms of how negatively, if at all, your bladder symptoms affect this part of your life. ***If there is no effect, rate it as zero***.

Please rate:

1. **The effect of your bladder symptoms on your ability to carry out your home responsibilities?**
   (1 is a very small negative effect, 7 is a very large negative effect)

	Very small negative effect						***Very large negative effect***
❑	❑	❑	❑	❑	❑	❑	❑
0	1	2	3	4	5	6	7

2. **The effect of your bladder symptoms on your social life?**
   (1 is a very small negative effect, 7 is a very large negative effect)

	Very small negative effect						***Very large negative effect***
❑	❑	❑	❑	❑	❑	❑	❑
0	1	2	3	4	5	6	7

3. **The effect of your bladder symptoms on your feelings of self-worth?**
   (1 is a very small negative effect, 7 is a very large negative effect)

	Very small negative effect						***Very large negative effect***
❑	❑	❑	❑	❑	❑	❑	❑
0	1	2	3	4	5	6	7

4. **The effect of your bladder symptoms on your interest in life?**
   (1 is a very small negative effect, 7 is a very large negative effect)

	Very small negative effect						***Very large negative effect***
❑	❑	❑	❑	❑	❑	❑	❑
0	1	2	3	4	5	6	7

MAPP research network MAPP II SPS	**Participant ID:** __ __ __ __ __ __	**Pin #** __ __ __ __
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RICE – Bladder Symptom Impact Scale

Participant completes via online survey at **Week 4 Baseline** and **Months 6, 18, & 36 Clinic Contacts**

5. **The effect of your bladder symptoms on your energy level?**
   (1 is a very small negative effect, 7 is a very large negative effect)

	Very small negative effect						***Very large negative effect***
❑	❑	❑	❑	❑	❑	❑	❑
0	1	2	3	4	5	6	7

6. **The effect of your bladder symptoms on your moods?**
   (1 is a very small negative effect, 7 is a very large negative effect)

	Very small negative effect						***Very large negative effect***
❑	❑	❑	❑	❑	❑	❑	❑
0	1	2	3	4	5	6	7

MAPP research network MAPP II SPS	**Participant ID:** __ __ __ __ __ __	**Pin #** __ __ __ __
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	CRF Date: __ __/__ __/__ __ __ __	**Visit #:** __ __

Medical History

Research Coordinator completes at Screening Week 0 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

   a. If **YES**, at what age did they first begin? ___ ___ age

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

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

3d. Pelvic floor dysfunction ❑1 Yes ❑0 No ❑88 U/K ❑99 N/A

(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

5a. Vulvodynia ❑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

8a. Orchalgia ❑1 Yes ❑0 No ❑88 U/K ❑99 N/A

Medical History

Research Coordinator completes at Screening Week 0 Contact.

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

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

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

a. Diverticulitis ❑1 Yes ❑0 No ❑88 U/K

b. Irritable Bowel Syndrome ❑1 Yes ❑0 No ❑88 U/K

c. GERD ❑1 Yes ❑0 No ❑88 U/K

d. Constipation ❑1 Yes ❑0 No ❑88 U/K

e. Chronic abdominal pain syndrome ❑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

Medical History

Research Coordinator completes at Screening Week 0 Contact.

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

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

Medical History

Research Coordinator completes at Screening Week 0 Contact.

d. Stroke ❑1 Yes ❑0 No ❑88 U/K

e. Arrhythmia ❑1 Yes ❑0 No ❑88 U/K

f. Palpitations/rapid heart rate ❑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 (If ***Yes***, please see **QST MOP**) ❑1 Yes ❑0 No ❑88 U/K

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

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

c. Rheumatoid arthritis ❑1 Yes ❑0 No ❑88 U/K

d. Osteoarthritis ❑1 Yes ❑0 No ❑88 U/K

QST Screening Criterion (If ***Yes***, please see **QST MOP**)

17c. Do you have any open sores or wounds on either or both of your feet? ❑1 Yes ❑0 No ❑88 U/K

Now I am going to ask some questions about some surgeries that you may have had.

Non-urological Surgeries (Both Men and Women)

17d. Back surgery ❑1 Yes ❑0 No ❑88 U/K

17e. Neck surgery ❑1 Yes ❑0 No ❑88 U/K

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Medical History

Research Coordinator completes at Screening Week 0 Contact.

Urological/Gynecologic Surgeries:

(Women Only)

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

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 MAPP II SPS	**Participant ID:** __ __ __ __ __ __	**Pin #** __ __ __ __
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Early in Life Risk Recommendations – Infection History

HOOTON

PARTICIPANT COMPLETES VIA ONLINE SURVEY AT AT **SCREENING WEEK 0** 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 MAPP II SPS	**Participant ID:** __ __ __ __ __ __	**Pin #** __ __ __ __
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Early in Life Risk Recommendations – Infection History

HOOTON

PARTICIPANT COMPLETES VIA ONLINE SURVEY AT AT **SCREENING WEEK 0** 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 MAPP II SPS		
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Family Medical History Questionnaire

RESEARCH COORDINATOR COMPLETES AT **SCREENING WEEK 0** CONTACT.

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 MAPP II SPS	Participant ID: __ __ __ __ __ __	Pin # __ __ __ __
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Family Medical History Questionnaire

RESEARCH COORDINATOR COMPLETES AT **SCREENING WEEK 0** CONTACT.

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. Also, please note, record only one condition per person per line as shown in the example below.

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)*	*_0_ (No)*		
_2_ (Father)	*_0_ (No)*		*_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	____	____ ____

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 MAPP II SPS	Participant ID: __ __ __ __ __ __ __	Pin # __ __ __ __ __
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Concomitant Medications

Research Coordinator completes this form at **Screening Week 0**, **Baseline Week 4**, **and *ALL* in-clinic Follow-up and ATLAS clinic visits**.

Concomitant Medications data from **MyMED** treatment tracking module

Research Coordinator will also record new medications and/or medication changes on this CRF following any new medications or medication changes reported via the **MyMED** treatment tracking module.

LIST THE MOST RECENT INFORMATION FOR 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	Medication Start Date	Medication Stopped?	For Urologic or Pelvic Pain Symptoms	ATLAS Medication?
__ __ __			__ __/__ __/__ __ __ __	❑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

Administrative

Med. Chg. Updt. Via MyMED 1 = Med. stop 2 = New med.	Date of Medication Change per MyMED	Visit #
❑1 ❑2	__ __/__ __/__ __ __ __	
❑1 ❑2	__ __/__ __/__ __ __ __	
❑1 ❑2	__ __/__ __/__ __ __ __	
❑1 ❑2	__ __/__ __/__ __ __ __	
❑1 ❑2	__ __/__ __/__ __ __ __	
❑1 ❑2	__ __/__ __/__ __ __ __	
❑1 ❑2	__ __/__ __/__ __ __ __	
❑1 ❑2	__ __/__ __/__ __ __ __	

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

Additional comments, if needed:

Line #	Comments
__ __ __	
__ __ __	

MAPP research network MAPP II SPS	**Participant ID:** __ __ __ __ __ __	**Pin #** __ __ __ __
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MyMED Treatment Tracking Module

Participant reviews with RC and RC provides instructions at **Screening Week 0**.
Participant completes via online survey at **Baseline Week 4**
and ***ALL* Clinic** and **Online Follow-up Contacts**

Medication Tracking

1. Have you ***stopped*** taking any of the medications listed below for **urologic or pelvic pain symptoms** in the ***past*** _____ ***(month, week or 2 weeks per Follow-up, Run-In, or ATLAS visit type)***:

Current Medications

Line # (For DMS reference only)	Medication Name (Medication Name data for Medication Tracking Table below pre-populated from "Drug Name" field column on CMED Log.)	Medication Stopped?
__ __ __	_____	❑1 Yes ❑0 No
__ __ __	_____	❑1 Yes ❑0 No
__ __ __	_____	❑1 Yes ❑0 No

2. Have you ***started*** any new medications for **urologic or pelvic pain symptoms** in the ***past*** _____ ***(month, week or 2 weeks per Follow-up, Run-In, or ATLAS visit type)***: ❑1 Yes ❑0 No

Newly Added Medications

Medication Name	Medication Start Date	Medication Stopped?
_____	__ __ / __ __ / __ __ __ __	❑1 Yes ❑0 No
_____	__ __ / __ __ / __ __ __ __	❑1 Yes ❑0 No
_____	__ __ / __ __ / __ __ __ __	❑1 Yes ❑0 No

MAPP research network MAPP II SPS	**Participant ID:** __ __ __ __ __ __	**Pin #** __ __ __ __
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MyMED Treatment Tracking Module

Participant reviews with RC and RC provides instructions at **Screening Week 0**.
Participant completes via online survey at **Baseline Week 4**
and ***ALL* Clinic** and **Online Follow-up Contacts**

Non-Medication Tracking

3. In the past _____ ***(month, week or 2 weeks per Follow-up, Run-In, or ATLAS visit type)*** have you received treatment with or utilized any of the following Non-Medication Therapies? ❑$_1$ Yes ❑$_0$ No

Non-Medication Therapy Name	Non-Medication Therapy Received?	Therapy Ongoing?	For urologic symptoms/ pelvic pain?
Pelvic Physical Therapy (ATLAS therapy)	❑$_1$ Yes ❑$_0$ No	❑$_1$ Yes ❑$_0$ No	❑$_1$ Yes ❑$_0$ No
Cystoscopy with hydrodistension	❑$_1$ Yes ❑$_0$ No	❑$_1$ Yes ❑$_0$ No	❑$_1$ Yes ❑$_0$ No
Botox	❑$_1$ Yes ❑$_0$ No	❑$_1$ Yes ❑$_0$ No	❑$_1$ Yes ❑$_0$ No
Sacral Neuromodulation	❑$_1$ Yes ❑$_0$ No	❑$_1$ Yes ❑$_0$ No	❑$_1$ Yes ❑$_0$ No
Bladder Instillation	❑$_1$ Yes ❑$_0$ No	❑$_1$ Yes ❑$_0$ No	❑$_1$ Yes ❑$_0$ No
Massage	❑$_1$ Yes ❑$_0$ No	❑$_1$ Yes ❑$_0$ No	❑$_1$ Yes ❑$_0$ No
Acupuncture	❑$_1$ Yes ❑$_0$ No	❑$_1$ Yes ❑$_0$ No	❑$_1$ Yes ❑$_0$ No
Counseling/Psychotherapy	❑$_1$ Yes ❑$_0$ No	❑$_1$ Yes ❑$_0$ No	❑$_1$ Yes ❑$_0$ No
Dietary changes	❑$_1$ Yes ❑$_0$ No	❑$_1$ Yes ❑$_0$ No	❑$_1$ Yes ❑$_0$ No
Bladder Training	❑$_1$ Yes ❑$_0$ No	❑$_1$ Yes ❑$_0$ No	❑$_1$ Yes ❑$_0$ No
Heat/Cold	❑$_1$ Yes ❑$_0$ No	❑$_1$ Yes ❑$_0$ No	❑$_1$ Yes ❑$_0$ No
Pelvic floor rehab	❑$_1$ Yes ❑$_0$ No	❑$_1$ Yes ❑$_0$ No	❑$_1$ Yes ❑$_0$ No
Home Exercise/Yoga	❑$_1$ Yes ❑$_0$ No	❑$_1$ Yes ❑$_0$ No	❑$_1$ Yes ❑$_0$ No

MAPP research network MAPP II SPS	**Participant ID:** __ __ __ __ __ __	**Pin #** __ __ __ __
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Antibiotic Treatment History

Research Coordinator completes at **Screening Week 0**, **Month 6**, **Month 18**, and **Month 36** clinic visits.

Research Coordinator will also complete at **Month 12, Month 24,** and **Month 30 *optional clinic visits***.

1. Have you been prescribed and completed taking a course of antibiotics for any **Urinary Tract Infections (UTIs)** in the ***past 6 months***? ❑$_1$ Yes ❑$_0$ No

   a. If ***Yes***, ***how many times*** were you prescribed antibiotics for UTIs in the ***past 6 months***? ___ ___ ❑$_{99}$ Not Applicable

2. Have you been prescribed and completed taking a course of antibiotics for any **other infectons** in the ***past 6 months***? ❑$_1$ Yes ❑$_0$ No

   a. If ***Yes***, ***how many times*** were you prescribed antibiotics for other infections in the ***past 6 months***? ___ ___ ❑$_{99}$ Not Applicable

Reference for ANTIBIOTICS/ANTIFUNGALS reported during MAPP, Phase I:

Miconizole (antifungal)

BactrIm (Antibiotic)

Diflucan (Antifungal)

Fluconazole (Antifungal)

Nitrofurantoin (Antibacterial)

Septra (Antibacterial)

MAPP research network MAPP II SPS	**Participant ID:** __ __ __ __ __ __	**Pin #** __ __ __ __
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	CRF Date: __ __/__ __/__ __ __ __	**Visit #:** __ __

Pelvic Therapy History

Research Coordinator completes at Screening Week 0, Baseline Week 4, and Months 6, 18,& 36 in-clinic Follow-up Visits as well as Months 12, 24, & 30 optional clinic visits to document therapies and for MyMED treatment tracking.

Please complete the table below to confirm oral medications and other therapies received for pelvic symptoms.

Oral Medication Therapies (Targeted ATLAS medications)			
Intervention	**EVER**	**RECENT – 6 months**	**ACTIVE (within month)**
Oral Opioids	❑1 Yes ❑0 No	❑1 Yes ❑0 No	❑1 Yes ❑0 No
Tricyclic Antidepressants	❑1 Yes ❑0 No	❑1 Yes ❑0 No	❑1 Yes ❑0 No
Elmiron (Pentosan polysulfate)	❑1 Yes ❑0 No	❑1 Yes ❑0 No	❑1 Yes ❑0 No
Neuropathic Pain Treatments	❑1 Yes ❑0 No	❑1 Yes ❑0 No	❑1 Yes ❑0 No
Alpha Adrenergic Blockers	❑1 Yes ❑0 No	❑1 Yes ❑0 No	❑1 Yes ❑0 No

Other Therapies			
Intervention	**EVER**	**RECENT – 6 months**	**ACTIVE (within month)**
Pelvic Physical Therapy **(ATLAS therapy)**	❑1 Yes ❑0 No	❑1 Yes ❑0 No	❑1 Yes ❑0 No
Procedures with sedation/anesthesia			
Cysto with or without anesthesia **(ATLAS therapy)**	❑1 Yes ❑0 No	❑1 Yes ❑0 No	❑1 Yes ❑0 No
Botox	❑1 Yes ❑0 No	❑1 Yes ❑0 No	❑1 Yes ❑0 No
Sacral Neuromodulation	❑1 Yes ❑0 No	❑1 Yes ❑0 No	❑1 Yes ❑0 No
Bladder Instillations			
Office-based	❑1 Yes ❑0 No	❑1 Yes ❑0 No	❑1 Yes ❑0 No
Home-based	❑1 Yes ❑0 No	❑1 Yes ❑0 No	❑1 Yes ❑0 No
Physical Therapy			
Pelvic Focus	❑1 Yes ❑0 No	❑1 Yes ❑0 No	❑1 Yes ❑0 No
Generalized	❑1 Yes ❑0 No	❑1 Yes ❑0 No	❑1 Yes ❑0 No
Massage	❑1 Yes ❑0 No	❑1 Yes ❑0 No	❑1 Yes ❑0 No
Acupuncture	❑1 Yes ❑0 No	❑1 Yes ❑0 No	❑1 Yes ❑0 No
Counseling/Psychotherapy	❑1 Yes ❑0 No	❑1 Yes ❑0 No	❑1 Yes ❑0 No
Self-management			
Dietary changes	❑1 Yes ❑0 No	❑1 Yes ❑0 No	❑1 Yes ❑0 No
Bladder Training	❑1 Yes ❑0 No	❑1 Yes ❑0 No	❑1 Yes ❑0 No
Heat/Cold	❑1 Yes ❑0 No	❑1 Yes ❑0 No	❑1 Yes ❑0 No
Pelvic floor rehab	❑1 Yes ❑0 No	❑1 Yes ❑0 No	❑1 Yes ❑0 No
Home Exercise/Yoga	❑1 Yes ❑0 No	❑1 Yes ❑0 No	❑1 Yes ❑0 No
Chiropractic Treatment	❑1 Yes ❑0 No	❑1 Yes ❑0 No	❑1 Yes ❑0 No

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

Cystoscopy History

Clinician completes at **Week 0 Screening Visit**

1. Has the Participant ever had a cystoscopy performed?
   - ❑0 No
   - ❑1 Yes
   - ❑88 Unknown

   If ***Yes***, please proceed to Q.#2.

   If ***No*** or ***Unknown***, please leave the rest of this form blank.

2. If **Yes**, are cystoscopy details available via medical records?
   - ❑0 No
   - ❑1 Yes
   - ❑88 Unknown

   If ***Yes***, please proceed to Q.#3.

   If ***No*** or ***Unknown***, please leave the rest of this form blank.

3. If ***Yes***, which of the following did the participant have?

   a. Office cystoscopy
      - ❑0 No
      - ❑1 Yes
      - ❑88 Unknown

      ai. If ***Yes***, was a Hunner's lesion seen?
      - ❑0 No
      - ❑1 Yes

      aii. If ***Yes***, was the office cystoscopy performed by a member of the MAPP Study team?
      - ❑0 No
      - ❑1 Yes
      - ❑88 Unknown

      aiii. If ***Yes***, date of office cystoscopy: __ __/__ __/__ __ __ __
      mm dd yyyy

      aiv. Comment: _____

      _____

   b. Cystoscopy in the OR ***without*** hydrodistention
      - ❑0 No
      - ❑1 Yes
      - ❑88 Unknown

      bi. If ***Yes***, was a Hunner's lesion seen?
      - ❑0 No
      - ❑1 Yes

      bii. If ***Yes***, were glomerulations seen?
      - ❑0 No
      - ❑1 Yes

Cystoscopy History

Clinician completes at **Week 0 Screening Visit**

biii. If ***Yes***, was the OR cystoscopy performed by a member of the MAPP Study team?
- ❑0 No
- ❑1 Yes
- ❑88 Unknown

biv. If ***Yes***, date of OR cystoscopy __ __/__ __/__ __ __ __ (mm dd yyyy)

bv. Comment: _____

_____

c. Cystoscopy in the OR ***with*** hydrodistention
- ❑0 No
- ❑1 Yes
- ❑88 Unknown

ci. If ***Yes***, was a Hunner's lesion seen?
- ❑0 No
- ❑1 Yes

cii. If ***Yes***, were glomerulations seen?
- ❑0 No
- ❑1 Yes

ciii. If ***Yes***, what was the bladder capacity under anesthesia? ___ ___ ___ cc

civ. If ***Yes***, was the OR cystoscopy performed by a member of the MAPP Study team?
- ❑0 No
- ❑1 Yes
- ❑88 Unknown

cv. If ***Yes***, date of OR cystoscopy __ __/__ __/__ __ __ __ (mm dd yyyy)

cvi. Comment: _____

_____

4. Do medical records indicate that the participant has ever had Hunner's lesions?
- ❑0 No
- ❑1 Yes
- ❑88 Unknown

5. If ***Yes***, is a picture of Hunner's lesion(s) available?
- ❑0 No
- ❑1 Yes
- ❑88 Unknown

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

Physical Exam

MAPP Clinician completes at the **Screening Week 0** Contact in combination with ***Pelvic Exam procedures***.

1. Height:
   a. Feet ___ ___
   b. Inches ___ ___
2. Weight: __ __ __ lbs.
3. Umbilical waist circumference: __ __ __ cm.
4. Blood Pressure:
   a. Systolic (mmHg) __ __ __
   b. Diastolic (mmHg) __ __ __
5. Abdominal exam: ❒1 Normal ❒0 Abnormal ❒99 Not Applicable
   a. If **Abnormal** please specify: _____

Pelvic Exam:

6. External Genitalia: ❒1 Normal ❒0 Abnormal ❒99 Not Applicable
   a. If **Abnormal** please specify: _____

Pelvic Exam procedures: Please proceed to *Pelvic Exam* form *before* completing further physical exam procedures.

7. Were pelvic exam procedures completed ***before*** physical exam procedures below? ❒1 Yes ❒0 No

If ***No***, please confirm why pelvic exam procedures were not completed:

   a. Participant declined pelvic exam procedures ❒1 Yes ❒0 No
   b. Certified clinician not available for pelvic exam procedures at this visit **(Please see MOP for contingency pelvic exam details)** ❒1 Yes ❒0 No
   c. Other (please specify): _____ ❒1 Yes ❒0 No

8. Rectal / Bimanual exam: ❒1 Normal ❒0 Abnormal ❒99 Not Applicable

Men only (Check N/A for women)

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

MAPP research network MAPP II SPS	**Participant ID:** __ __ __ __ __ __	**Pin #** __ __ __ __
	Discovery Site: __ __	**Clinical Center** __ __
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Physical Exam

MAPP Clinician completes at the **Screening Week 0** Contact in combination with ***Pelvic Exam procedures***.

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

13c. Labial/vulvar pain ❒1 Yes ❒0 No ❒99 Not Applicable

13d. Abnormal vaginal discharge ❒1 Yes ❒0 No ❒99 Not Applicable

15. MAPP Clinician or RC ID ___ ___ ___ ___ (4-digit ID)

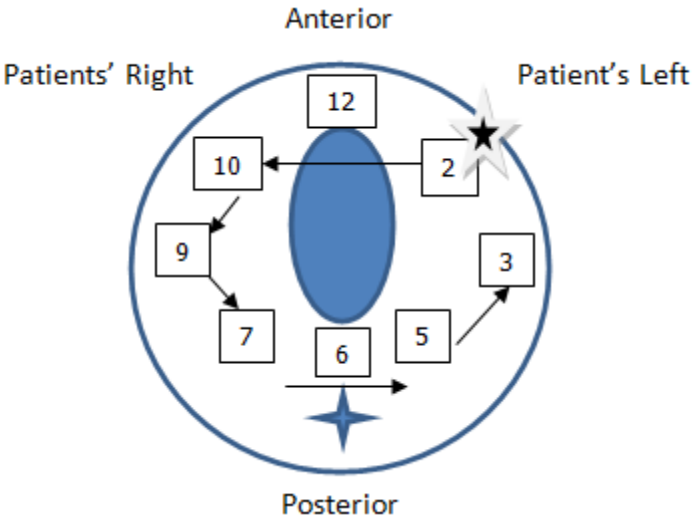
MAPP research network MAPP II SPS	**Participant ID:** __ __ __ __ __ __	**Pin #** __ __ __ __
	Discovery Site: __ __	**Clinical Center** __ __
	CRF Date: __ __/__ __/__ __ __ __	**Visit #:** __ __

Pelvic Exam: Female

MAPP Clinician completes at **Screening Week 0** and at **Month 18 Clinic Contact.**

Smile at patient, and then say the following: "I will be doing a physical examination to determine if there is pain to touch at various points on your body. The exam will include both external touch on your abdomen and perineal region and internal touch of the pelvic muscles. You will feel slight pressure at each site, please let me know if any site that I touch is painful." Exam will be performed in lithotomy position.

1. Suprapubic area pain?	❑0 No	❑1 Yes
2. Perineal body pain? (6:00)	❑0 No	❑1 Yes
3. Anterior levator muscle (2:00)	❑0 No	❑1 Yes
4. Anterior levator muscle (10:00)	❑0 No	❑1 Yes
5. Obturator internus muscle (9:00)	❑0 No	❑1 Yes
6. Posterior levator muscle (7:00)	❑0 No	❑1 Yes
7. Posterior levator muscle (5:00)	❑0 No	❑1 Yes
8. Obturator internus muscle (3:00)	❑0 No	❑1 Yes
9. Did the pelvic examination reproduce your pain or discomfort?	❑0 No	❑1 Yes
10. MAPP Clinician ID	___ ___ ___ ___ (4-digit ID)	



Key for Female Image:

★	**Start palpation at this point, follow arrows for direction of exam**
⬮	**Vaginal opening**
✦	**Anus**
12	**Urethra**
10, 2	**Pubococcygeus (anterior) lateral and posterior to urethra off boney pelvis**
9, 3	**Obturator Internus (lateral)**
6	**Perineal Body (midline between anus and vaginal opening**
7, 5	**Iliococcygeus (posterior) lateral to rectum, distal to coccygeus**

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

Pelvic Exam Procedures: Female

MAPP Clinician refers to the guidelines below at **Screening Week 0** and at **Month 18 Clinic Contact.**

Administrative

Palpation Guidelines: FEMALE

- **Patients will be in the lithotomy position.**
- Legs should be supported and the patient should be asked to relax her legs as much as possible letting the support "hold" her legs.
- A drape will be used to cover the lower limbs for each step of the examination.
- All palpation points will be tested by gradually increasing pressure starting with light to deep touch, taking 2-3 seconds to reach deepest touch, ask for pain response once you have achieved this gradual buildup of pressure. (0.5-1 kg, over a roughly 1 cm^2 area corresponding to the size of a button on your index finger)
- All palpation should be done with the muscles not actively contracting.

1. Supra Pubic Region (Superior to Mons Pubis):
   With your non-dominant hand expose and palpate the mons pubis, next move superiorly to determine the location of the rim of the bony pelvis. Lastly, using your dominant hand palpate the region with two fingers, just superior (3-4 cm, **2 finger width**) above the bony pelvis. (0.5-1 kg/cm^2 of pressure) Return drape to original position.

2. Perineal body: **With a dry glove**, palpate the region between the anus and the vaginal entrance and ask for pain response. (6:00)

For the following palpation sites the sequence of palpation described for a right handed exam and will be as follows**:**

- Start on the left side; first anterior (2:00) and then move to the right side anterior (10:00), follow with right lateral (9:00) and finally right posterior (7:00). Follow this sequence with the rest of the left sided palpation starting posterior and finish with the lateral (3:00) position; avoid rotation of hand as much as possible. Your palpation will start with the hand supinated (palm up) to the pronated position, palm down and internally rotated.
- Left handed examiner will start on the right side following the sequence outlined in reverse.

MAPP research network MAPP II SPS	**Participant ID:** __ __ __ __ __ __	**Pin #** __ __ __ __
	Discovery Site: __ __	**Clinical Center** __ __
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Pelvic Exam Procedures: Female

MAPP Clinician refers to the guidelines below at **Screening Week 0** and at **Month 18 Clinic Contact.**

Administrative

3. Exam Description: Trans vaginal anterior, lateral and posterior palpation sites
    a. Anterior:(Pubococcygeus):
        i. Left: Place gloved finger in vaginal region, at 12:00 position (urethra), pad of finger turned up toward the ceiling, palpate just lateral to the urethra on patient's left side, continue laterally while maintaining contact with the bony pelvis until you reach the 2:00 position. At the 2:00 position, slide palpation point posteriorly off of the bone onto the muscle belly and ask for symptoms. The palpation point should be to the depth of 3-4 cm up to your proximal interphalangeal joint (PIP). (Note: Due to the high frequency of avulsion of the muscle in this region in a parous female, the palpation site may be more lateral and inferior/posterior then in a nulliparous female)
        ii. Right: From the palpation point above, move pad of finger across midline along the bony pelvis until you reach the 10:00 position. At the 10:00 position, slide finger off of the bone onto the muscle belly and ask for symptoms. The palpation point should be to the depth of 3-4 cm up to your proximal interphalangeal joint (PIP). Note: Due to the high frequency of avulsion of the muscle in this region in a parous female, the palpation site may be more lateral and inferior/posterior then in a nulliparous female)

    b. Right lateral pelvic wall muscles (Obturator Internus): Maintaining finger in vagina from the anterior palpation above in 3.a.ii move palpation site laterally and deep toward the bony pelvis to the 9:00 position. Press outward 5-6 cm in depth, (to your metacarpal phalangeal joint (MCP) on the lateral side wall of the pelvis. (Should not be on the bony pelvis but on soft tissue) ask for symptoms. To check for correct placement, ask patient to laterally rotate/abduct right leg outward on non-palpating hand (avoid moving limb into an adducted position). If it is correctly placed, a muscle contraction should be palpated with the internal finger. **Assess for pain when muscle is relaxed.**

    c. Right posterior (Iliococcygeus): While maintaining finger in vagina from the palpation above in 3b, move your palpation inferiorly until you reach the 7:00 position, if you palpate the rectum you have gone too far. (Rectum is the 6:00 position). The point of palpation is at a depth of 5-6 cm up to your metacarpal phalangeal joint (MCP) on soft tissue only, this is not a firm surface (yoga mat on hard wood floor). If the point of palpation feels too firm draw finger out slightly to rest on soft tissue. Ask for pain.

Pelvic Exam Procedures: Female

MAPP Clinician refers to the guidelines below at **Screening Week 0** and at **Month 18 Clinic Contact.**

Administrative

d. Left posterior (Iliococcygeus): While maintaining finger in vagina from the palpation above in 3c, move your palpation site across midline, to the left side of the rectum, until you reach the 5:00 position. The point of palpation is at a depth of 5-6 cm up to your metacarpal phalangeal joint (MCP) and on soft tissue only, this is not a firm surface (yoga mat on hard wood floor). If the point of palpation feels too firm draw finger out slightly to rest on soft tissue. Ask for symptoms.

e. Left lateral pelvic wall muscles (Obturator Internus: OI): Maintaining finger in vagina from the palpation point above in 3d, move palpation site laterally following the brim of the bony pelvis to the 3:00 position. Press outward 5-6 cm in depth on the lateral side wall of the pelvis. The point of palpation is the soft tissue along the lateral pelvic wall, ask for symptoms. To check for correct placement, reach across your body and place non examining hand on the lateral aspect of the left leg, avoid drawing leg inward during this task, ask patient to laterally rotate/abduct the left leg outward on the non-palpating hand, the muscle contraction of the OI should be palpated during this contraction with the internal finger if it is correctly placed. **Assess for pain when muscle is relaxed.**

MAPP research network MAPP II SPS	**Participant ID:** __ __ __ __ __ __	**Pin #** __ __ __ __
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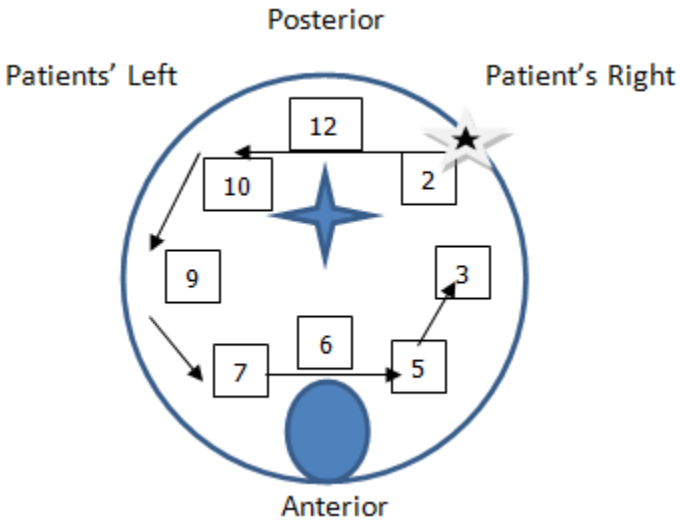
Pelvic Exam: Male

MAPP Clinician completes at **Screening Week 0** and at **Month 18 Clinic Contact.**

Smile at patient, and then say the following: "I will be doing a physical examination to determine if there is pain to touch at various points on your body. The exam will include both external touch on your abdomen and perineal region and internal touch of the pelvic muscles. You will feel slight pressure at each site, please let me know if any site that I touch is painful." Exam will be performed with patient standing, with the upper body bending over the edge of the table (the prostate exam position), prior to the prostate palpation exam.

1. Suprapubic area pain?	❑0 No	❑1 Yes
2. Perineal body pain? (6:00)	❑0 No	❑1 Yes
3. Posterior levator muscle (2:00)	❑0 No	❑1 Yes
4. Posterior levator muscle (10:00)	❑0 No	❑1 Yes
5. Obturator internus muscle (9:00)	❑0 No	❑1 Yes
6. Anterior levator muscle (7:00)	❑0 No	❑1 Yes
7. Anterior levator muscle (5:00)	❑0 No	❑1 Yes
8. Obturator internus muscle (3:00)	❑0 No	❑1 Yes
9. Did the pelvic examination reproduce your pain or discomfort?	❑0 No	❑1 Yes
10. MAPP Clinician ID	___ ___ ___ ___ (4-digit ID)	



Key for Male Image:

★	**Start palpation at this point, follow arrows for direction of exam**
●	**Prostate**
✦	**Anus**
12	**Coccyx**
10, 2	**Iliococcygeus (posterior)**
9, 3	**Obturator Internus (lateral)**
6	**Perineal Body (midline between anus and scrotum**
7, 5	**Pubococcygeus (anterior) lateral to prostate**

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

Pelvic Exam Procedures: Male

MAPP Clinician refers to the guidelines below at **Screening Week 0** and at **Month 18 Clinic Contact.**

Administrative

Palpation Guidelines: **MALE**

- **Palpation of the prostate should be done after the pelvic muscle examination**
- **Patient is standing with the upper body bent over the edge of the examination table (i.e. the usual position for digital rectal/prostate examination)**
- Patients will stand during the abdominal palpation and bent over on to an padded exam table in standing supported prone position for the pelvic floor muscle examination.
- Legs should be as relaxed as possible, allowing support of the table to hold trunk upright. (avoid thigh medial rotation as this will increase tension on the obturator internus muscle)
- All palpation points will be tested by gradually increasing pressure starting with light to deep touch, taking 2-3 seconds to reach deepest touch, ask for pain response once you have achieved this gradual buildup of pressure (0.5-1 kg)
- All palpation should be done with the muscles not actively contracting.

1. Supra Pubic Region (Superior to Mons Pubis):
   With your non-dominant hand expose and palpate the mons pubis, move palpation site superiorly to determine the location of the rim of the bony pelvis. Using your dominant hand, palpate with two fingers the region just superior (3-4 cm, 2 finger breath) above the bony pelvis.

2. Perineal body: With a dry glove, Palpate the region between the anus and the base of the scrotum at the 6:00 position gradually increase pressure and then ask for pain response. (0.5-1 kg)

For the following palpation sites the sequence of palpation will be as follows**:**

- Start on the right posterior site, then move across midline to the left posterior site followed by the left lateral site, left posterior, right posterior site and finally right lateral site; avoid rotation of hand as much as possible. Your palpation will start with the hand supinated (palm up) rotating to the pronated position, palm down and finally slight internally rotated.
- The directions below are written for a right handed examination.
- Left handed examiner will start on the left side following the sequence outlined below in reverse.

Pelvic Exam Procedures: Male

MAPP Clinician refers to the guidelines below at **Screening Week 0** and at **Month 18 Clinic Contact.**

Administrative

3. Exam Description: Trans-anal exam that includes: posterior, left lateral, anterior and then right lateral palpation sites.
    a. Posterior (Illiococcygeus):
        i. Right posterior: Place lubricated gloved finger in anal canal, at 12:00 position (coccyx), pad of finger turned up toward the ceiling, palpate just lateral and distal to the coccyx on the right side of the coccyx, continue laterally with palpation point until you reach the 2:00 position. The point of palpation is slightly distal to the lateral edge of the coccyx at a depth of 5-6 cm up to your metacarpal phalangeal joint (MCP) and on soft tissue only, this is **not** a firm surface (yoga mat on hard wood floor). If the point of palpation feels too firm draw finger out slightly to rest on soft tissue. Gradually build up pressure for 2-3 sec and then ask for presence of pain.
        ii. Left posterior: While maintaining finger in anal canal from the palpation above in 3ai move your palpation site across midline, to the just distal to the left side of the coccyx, until you reach the 10:00 position. The point of palpation is at a depth of 5-6 cm up to your metacarpal phalangeal joint (MCP) and on soft tissue only, this is **not** a firm surface (yoga mat on hard wood floor). If the point of palpation feels too firm draw finger out slightly to rest on soft tissue. Ask for symptoms. Gradually build up pressure for 2-3 sec and then ask for presence of pain.

    b. Left lateral pelvic wall muscles (Obturator Internus): Maintaining finger in anal canal from the posterior palpation above in 3aii move palpation site laterally and deep toward the bony pelvis to the 9:00 position. Press outward 5-6 cm in depth, (to your metacarpal phalangeal joint (MCP) on the lateral side wall of the pelvis. The point of palpation is the soft tissue along the lateral pelvic wall. To check for correct placement, place non examining hand on the lateral aspect of the left leg just above the knee, avoid drawing leg inward during this task, ask patient to laterally rotate/abduct the left leg outward on the non-palpating hand, the muscle contraction of the OI should be palpated during this contraction with the internal finger if it is correctly placed. **Assess for pain when muscle is relaxed.**
    c. Anterior muscles: Pubococcygeus
        i. Left Anterior: from the position in 3b slide pad of finger toward the floor (anterior) to just lateral to the prostrate on the left side at the 7:00 position. The palpation point should be to the depth of 5-6 cm up to your metacarpal phalangeal joint. Assess for pain
        ii. Right Anterior: From the palpation point above, move pad of finger across midline, avoid pressure on the prostrate, until you reach the 5:00 position. Asses for pain.

Pelvic Exam Procedures: Male

MAPP Clinician refers to the guidelines below at **Screening Week 0** and at **Month 18 Clinic Contact.**

Administrative

d. Right lateral pelvic wall muscles (Obturator Internus): Maintaining finger in anal canal from the palpation position above in 3cii move palpation site laterally and deep toward the bony pelvis to the 3:00 position. Press outward 5-6 cm in depth, (to your metacarpal phalangeal joint (MCP) on the lateral side wall of the pelvis. (Should not be on the bony pelvis but on soft tissue) ask for symptoms. To check for correct placement, reach across with other hand, place it on the lateral aspect of the thigh of the right leg just above the knee and ask patient to laterally rotate/abduct right leg outward, avoid moving limb into an adducted position). If it is correctly placed, a muscle contraction should be palpated with the internal finger. **Assess for pain when muscle is relaxed.**

4. The prostate exam can now be performed (prostate enlarged? Irregular? Tender?)

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

Brief Clinical Diagnostics for Baseline and Follow-up

Research Coordinator completes at **Baseline Week 4 and *ALL* in-clinic Follow-up Visits**.

1. Height:
   a. Feet ___ ___
   b. Inches ___ ___
2. Weight: __ __ __ lbs.
3. Umbilical waist circumference: __ __ __ cm.
4. Blood Pressure:
   a. Systolic (mmHg) __ __ __
   b. Diastolic (mmHg) __ __ __

5. Participant currently has a midstream urine culture **(≥100,000 CFU/ml)**, with a single uropathogen. ❑1 Yes ❑0 No

6. Participant reports ***currently*** experiencing a flare of urologic or pelvic pain symptoms per SYM-Q, Question 12 in Participant Survey. ❑1 Yes ❑0 No
   If ***Yes***, please confirm collection of a Flare urine specimen below.
   If ***No***, please record 99 N/A.
   a. Flare urine specimen collected. ❑1 Yes ❑0 No ❑99 N/A
      Please refer to the MOP for guidelines regarding the Flare urine specimen collection and shipment procedures.

7. Research Coordinator confirms Female Participant is ***not*** currently pregnant. ❑1 Yes ❑0 No ❑99 N/A
   Please record 99 – N/A for males & females who are surgically sterile or postmenopausal.

   ***Please note**: If a Female Participant is confirmed pregnant at any time during the study, the Participant *must be withdrawn*. Please see the MOP for guidelines.**

8. Did the Participant withdraw consent for the use of DNA for genetics studies as of this visit? **(If *Yes*, please complete a Withdrawal of Consent CONWTHDR form)** ❑1 Yes ❑0 No
9. Did the Participant agree to be contacted for future studies as of this visit? ❑1 Yes ❑0 No

11. Please confirm which arm was used for the blood specimen collection.
    ❑1 Non-dominant arm
    ❑2 Dominant arm

10. MAPP Clinician or RC ID ___ ___ ___ ___ (4-digit ID)

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

Study Stop Point

Research Coordinator completes at **Month 36** clinic contact
or at final contact if Participant withdraws from the study early.

1. Has the MAPP SPS participant successfully completed the 36-month clinic contact of the Trans-MAPP Symptom Patterns Study? ❑$_1$ Yes ❑$_0$ No

   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 ***final contact***: ___ ___

3. Date that the participant was seen in clinic or logged on to surveys for ***final contact***: __ __/__ __/__ __ __ __ (MM/DD/YYYY)

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

Study Stop Point

Research Coordinator completes at **Month 36** clinic contact
or at final contact if Participant withdraws from the study early.

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 Symptom Patterns 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 Symptom Patterns 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 MAPP II SPS	**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 Trans-MAPP Symptoms Patterns study, complete the Consent Withdrawal Case Report Form (***CONWTHDR2***) 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. Blood specimens ❑1 Yes ❑0 No

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

b. DNA specimens ❑1 Yes ❑0 No

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

c. Urine specimens ❑1 Yes ❑0 No

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

d. Rectal/Vaginal Swab specimens ❑1 Yes ❑0 No

d1. Date of request: __ __/__ __/__ __ __ __ (MM/DD/YYYY)

e. Saliva/cortisol specimens ❑1 Yes ❑0 No

e1. Date of request: __ __/__ __/__ __ __ __ (MM/DD/YYYY)

3. 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. Blood specimens ❑1 Yes ❑0 No

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

b. DNA specimens ❑1 Yes ❑0 No

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

c. Urine specimens ❑1 Yes ❑0 No

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

MAPP research network MAPP II SPS	**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.

d. Rectal/Vaginal Swab specimens ❑1 Yes ❑0 No

d1. Date of confirmation that specimens must be disposed: __ __/__ __/__ __ __ __ (MM/DD/YYYY)

e. Saliva/cortisol specimens ❑1 Yes ❑0 No

e1. Date of confirmation that specimens must be disposed: __ __/__ __/__ __ __ __ (MM/DD/YYYY)

4. 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
5. 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
6. 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
7. Comments:

_____

_____

_____

_____

_____

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

8. 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 Trans-MAPP Symptoms Patterns 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. Blood specimens ❑1 Yes ❑0 No

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

b. DNA specimens ❑1 Yes ❑0 No

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

c. Urine specimens ❑1 Yes ❑0 No

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

d. Rectal/Vaginal Swab specimens ❑1 Yes ❑0 No

d1. Date of confirmation of consent: __ __/__ __/__ __ __ __ (MM/DD/YYYY)

e. Saliva/cortisol specimens ❑1 Yes ❑0 No

e1. Date of confirmation of consent: __ __/__ __/__ __ __ __ (MM/DD/YYYY)

3. Comments:

_____

_____

_____

_____

_____

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

Consent Change Confirmation

RC completes for *ANY* Follow-up Visits at which the participant has changed a consent status.

If there have been no changes in consent this form is not required.

If a participant has changed the consent status for any of the following items, please reconsent the participant according to your institution's IRB guidelines. Please indicate the participant's current consent status for all questions below.

	Does the participant consent to the following items?	
1. DNA for Genetic Studies	❑1 Yes	❑0 No
2. DNA Specimens to be sent to the NIDDK Repository	❑1 Yes	❑0 No
3. Biospecimens	❑1 Yes	❑0 No
a. Blood specimen, plasma	❑1 Yes	❑0 No
ai. Blood specimen, plasma to be sent to the NIDDK Repository	❑1 Yes	❑0 No
b. Stim Tube specimen	❑1 Yes	❑0 No
bi. Stim Tube specimen to be sent to the NIDDK Repository	❑1 Yes	❑0 No
c. Biomarker/Microbiome urine	❑1 Yes	❑0 No
ci. Biomarker/Microbiome urine to be sent to the NIDDK Repository	❑1 Yes	❑0 No
d. Salivary cortisol	❑1 Yes	❑0 No
di. Salivary cortisol to be sent to the NIDDK Repository	❑1 Yes	❑0 No
e. Rectal swabs	❑1 Yes	❑0 No
ei. Rectal swabs to be sent to the NIDDK Repository	❑1 Yes	❑0 No
f. Vaginal swabs	❑1 Yes	❑0 No
fi. Vaginal swabs to be sent to the NIDDK Repository	❑1 Yes	❑0 No
Comments about any biospecimens for which consent status is changed or which should ***not to be sent*** to the NIDDK Repository: _____ _____		
4. Stored samples may be used in future studies for UCPPS or other diseases.	❑1 Yes	❑0 No
5. QST procedures	❑1 Yes	❑0 No
6. Use of medical records to complete required data elements for this research study	❑1 Yes	❑0 No
7. Permission to be re-contacted about future studies of IC, CP, or other chronic pain conditions	❑1 Yes	❑0 No
8. Participation in the MAPP Smartphone Application Assessment	❑1 Yes	❑0 No

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

FEMALE GENITOURINARY PAIN INDEX

Female Participant completes this form at ***ALL* Clinic and Online contacts**.

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

FEMALE GENITOURINARY PAIN INDEX

Female Participant completes this form at ***ALL* Clinic and Online contacts**.

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

Female Sexual Function Index (FSFI)©

Female Participant completes via online survey at **Week 4 Baseline and Months 6, 18, & 36 Follow-up Contacts.**

INSTRUCTIONS: These questions ask about your sexual feelings and responses during the past 4 weeks. Please answer the following questions as honestly and clearly as possible. Your responses will be kept completely confidential. In answering these questions the following definitions apply:

Sexual activity can include caressing, foreplay, masturbation and vaginal intercourse.

Sexual intercourse is defined as penile penetration (entry) of the vagina.

Sexual stimulation includes situations like foreplay with a partner, self-stimulation (masturbation), or sexual fantasy.

CHECK ONLY ONE BOX PER QUESTION.

1. Over the past 4 weeks, how **satisfied** have you been with your overall sexual life?
   - ❑5 Very satisfied
   - ❑4 Moderately satisfied
   - ❑3 About equally satisfied and dissatisfied
   - ❑2 Moderately dissatisfied
   - ❑1 Very dissatisfied

Sexual desire or interest is a feeling that includes wanting to have a sexual experience, feeling receptive to a partner's sexual initiation, and thinking or fantasizing about having sex.

2. Over the past 4 weeks, how **often** did you feel sexual desire or interest?
   - ❑5 Almost always or always
   - ❑4 Most times (more than half the time)
   - ❑3 Sometimes (about half the time)
   - ❑2 A few times (less than half the time)
   - ❑1 Almost never or never

3. Over the past 4 weeks, how would you rate your **level** (degree) of sexual desire or interest?
   - ❑5 Very high
   - ❑4 High
   - ❑3 Moderate
   - ❑2 Low
   - ❑1 Very low or none at all

4. Over the past 4 weeks, did you engage in sexual activity of any kind with a partner and/or by yourself (masturbation)?
   - ❑0 No sexual activity (neither with a partner nor by myself)
   - ❑1 Sexual activity with a partner only
   - ❑2 Sexual activity by myself only
   - ❑3 Sexual activity both with a partner and by myself

Sexual arousal is a feeling that includes both physical and mental aspects of sexual excitement. It may include feelings of warmth or tingling in the genitals, lubrication (wetness), or muscle contractions.

5. Over the past 4 weeks, how **often** did you feel sexually aroused ("turned on") during sexual activity or intercourse?
   - ❑0 No sexual activity
   - ❑5 Almost always or always
   - ❑4 Most times (more than half the time)
   - ❑3 Sometimes (about half the time)
   - ❑2 A few times (less than half the time)
   - ❑1 Almost never or never

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

Female Sexual Function Index (FSFI)©

Female Participant completes via online survey at **Week 4 Baseline and Months 6, 18, & 36 Follow-up Contacts.**

6. Over the past 4 weeks, how would you rate your **level** of sexual arousal ("turn on") during sexual activity or intercourse?
   - ❑0 No sexual activity
   - ❑5 Very high
   - ❑4 High
   - ❑3 Moderate
   - ❑2 Low
   - ❑1 Very low or none at all

7. Over the past 4 weeks, how **confident** were you about becoming sexually aroused during sexual activity or intercourse?
   - ❑0 No sexual activity
   - ❑5 Very high confidence
   - ❑4 High confidence
   - ❑3 Moderate confidence
   - ❑2 Low confidence
   - ❑1 Very low or no confidence

8. Over the past 4 weeks, how **often** have you been satisfied with your arousal (excitement) during sexual activity or intercourse?
   - ❑0 No sexual activity
   - ❑5 Almost always or always
   - ❑4 Most times (more than half the time)
   - ❑3 Sometimes (about half the time)
   - ❑2 A few times (less than half the time)
   - ❑1 Almost never or never

9. Over the past 4 weeks, how **often** did you become lubricated ("wet") during sexual activity or intercourse?
   - ❑0 No sexual activity
   - ❑5 Almost always or always
   - ❑4 Most times (more than half the time)
   - ❑3 Sometimes (about half the time)
   - ❑2 A few times (less than half the time)
   - ❑1 Almost never or never

10. Over the past 4 weeks, how **difficult** was it to become lubricated ("wet") during sexual activity or intercourse?
    - ❑0 No sexual activity
    - ❑1 Extremely difficult or impossible
    - ❑2 Very difficult
    - ❑3 Difficult
    - ❑4 Slightly difficult
    - ❑5 Not difficult

11. Over the past 4 weeks, how often did you **maintain** your lubrication ("wetness") until completion of sexual activity or intercourse?
    - ❑0 No sexual activity
    - ❑5 Almost always or always
    - ❑4 Most times (more than half the time)
    - ❑3 Sometimes (about half the time)
    - ❑2 A few times (less than half the time)
    - ❑1 Almost never or never

12. Over the past 4 weeks, how **difficult** was it to maintain your lubrication ("wetness") until completion of sexual activity or intercourse?
    - ❑0 No sexual activity
    - ❑1 Extremely difficult or impossible
    - ❑2 Very difficult
    - ❑3 Difficult
    - ❑4 Slightly difficult
    - ❑5 Not difficult

Female Sexual Function Index (FSFI)©

Female Participant completes via online survey at **Week 4 Baseline and Months 6, 18, & 36 Follow-up Contacts.**

13. Over the past 4 weeks, when you had sexual stimulation or intercourse, how **often** did you reach orgasm (climax)?
- ❑0 No sexual activity
- ❑5 Almost always or always
- ❑4 Most times (more than half the time)
- ❑3 Sometimes (about half the time)
- ❑2 A few times (less than half the time)
- ❑1 Almost never or never

14. Over the past 4 weeks, when you had sexual stimulation or intercourse, how **difficult** was it for you to reach orgasm (climax)?
- ❑0 No sexual activity
- ❑1 Extremely difficult or impossible
- ❑2 Very difficult
- ❑3 Difficult
- ❑4 Slightly difficult
- ❑5 Not difficult

15. Over the past 4 weeks, how **satisfied** were you with your ability to reach orgasm (climax) during sexual activity or intercourse?
- ❑0 No sexual activity
- ❑5 Very satisfied
- ❑4 Moderately satisfied
- ❑3 About equally satisfied and dissatisfied
- ❑2 Moderately dissatisfied
- ❑1 Very dissatisfied

16. Over the past 4 weeks, how **satisfied** have you been with the amount of emotional closeness during sexual activity between you and your partner?
- ❑0 No sexual activity
- ❑5 Very satisfied
- ❑4 Moderately satisfied
- ❑3 About equally satisfied and dissatisfied
- ❑2 Moderately dissatisfied
- ❑1 Very dissatisfied

17. Over the past 4 weeks, how **satisfied** have you been with your sexual relationship with your partner?
- ❑0 No sexual partner
- ❑5 Very satisfied
- ❑4 Moderately satisfied
- ❑3 About equally satisfied and dissatisfied
- ❑2 Moderately dissatisfied
- ❑1 Very dissatisfied

18. Over the past 4 weeks, how **often** did you experience discomfort or pain <u>during</u> vaginal penetration?
- ❑0 Did not attempt intercourse
- ❑1 Almost always or always
- ❑2 Most times (more than half the time)
- ❑3 Sometimes (about half the time)
- ❑4 A few times (less than half the time)
- ❑5 Almost never or never

19. Over the past 4 weeks, how **often** did you experience discomfort or pain <u>following</u> vaginal penetration?
- ❑0 Did not attempt intercourse
- ❑1 Almost always or always
- ❑2 Most times (more than half the time)
- ❑3 Sometimes (about half the time)
- ❑4 A few times (less than half the time)
- ❑5 Almost never or never

MAPP research network MAPP II SPS	**Participant ID:** __ __ __ __ __ __	**Pin #** __ __ __ __
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Female Sexual Function Index (FSFI)©

Female Participant completes via online survey at **Week 4 Baseline and Months 6, 18, & 36 Follow-up Contacts.**

20. Over the past 4 weeks, how would you rate your **level** (degree) of discomfort or pain during or following vaginal penetration?

- ❑0 Did not attempt intercourse
- ❑1 Very high
- ❑2 High
- ❑3 Moderate
- ❑4 Low
- ❑5 Very low or none at all

21. Over the past 4 weeks, if you did NOT engage in any sexual activity that involved vaginal penetration, please indicate how strongly you agree or disagree with each of the following statements as a reason that you were not sexually active:

	Strongly Agree	**Somewhat Agree**	**Somewhat Disagree**	**Strongly Disagree**
a. No Interest	❑1	❑2	❑3	❑4
b. No sexual partner	❑1	❑2	❑3	❑4
c. Partner unwilling/unable	❑1	❑2	❑3	❑4
d. Pelvic/vaginal pain	❑1	❑2	❑3	❑4
e. Other pain	❑1	❑2	❑3	❑4
f. Bladder, bowel or vaginal problems other than pain	❑1	❑2	❑3	❑4
g. Other health problems	❑1	❑2	❑3	❑4

Thank you for completing this questionnaire

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

Self-Esteem And Relationship Questionnaire ®

(For Female Participants)

FEMALE PARTICIPANT completes via online survey at **Week 4 Baseline and Months 6, 18, & 36 Follow-up 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 MAPP II SPS	**Participant ID:** __ __ __ __ __ __	**Pin #** __ __ __ __
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Self-Esteem And Relationship Questionnaire ®

(For Female Participants)

FEMALE PARTICIPANT completes via online survey at **Week 4 Baseline and Months 6, 18, & 36 Follow-up 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

MAPP research network MAPP II SPS	**Participant ID:** __ __ __ __ __ __	**Pin #** __ __ __ __
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MALE GENITOURINARY PAIN INDEX

Male Participant completes this form via online survey at ***ALL* Clinic and Online contacts**.

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 MAPP II SPS	**Participant ID:** __ __ __ __ __ __	**Pin #** __ __ __ __
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MALE GENITOURINARY PAIN INDEX

Male Participant completes this form via online survey at ***ALL* Clinic and Online contacts**.

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 MAPP II SPS	**Participant ID:** __ __ __ __ __ __	**Pin #** __ __ __ __
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International Index of Erectile Function®

MALE COMPLETES VIA ONLINE SURVEY AT **WEEK 4 BASELINE** AND **MONTHS 6, 18, & 36 FOLLOW-UP 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 MAPP II SPS	**Participant ID:** __ __ __ __ __ __	**Pin #** __ __ __ __
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University of Washington - Ejaculatory Function Scale

Male Participant completes via online survey at **Week 4 Baseline** and **Months 6, 18, & 36** Follow-up 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 MAPP II SPS	**Participant ID:** __ __ __ __ __ __	**Pin #** __ __ __ __
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Self-Esteem And Relationship Questionnaire®

(For Male Participants)

MALE PARTICIPANT COMPLETES VIA ONLINE SURVEY AT **BASELINE WEEK 4 AND MONTHS 6, 18, & 36 FOLLOW-UP 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 MAPP II SPS	**Participant ID:** __ __ __ __ __ __	**Pin #** __ __ __ __
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Self-Esteem And Relationship Questionnaire®

(For Male Participants)

MALE PARTICIPANT COMPLETES VIA ONLINE SURVEY AT **BASELINE WEEK 4 AND MONTHS 6, 18, & 36 FOLLOW-UP 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

MAPP research network MAPP II SPS	**Participant ID:** __ __ __ __ __ __	**Pin #** __ __ __ __
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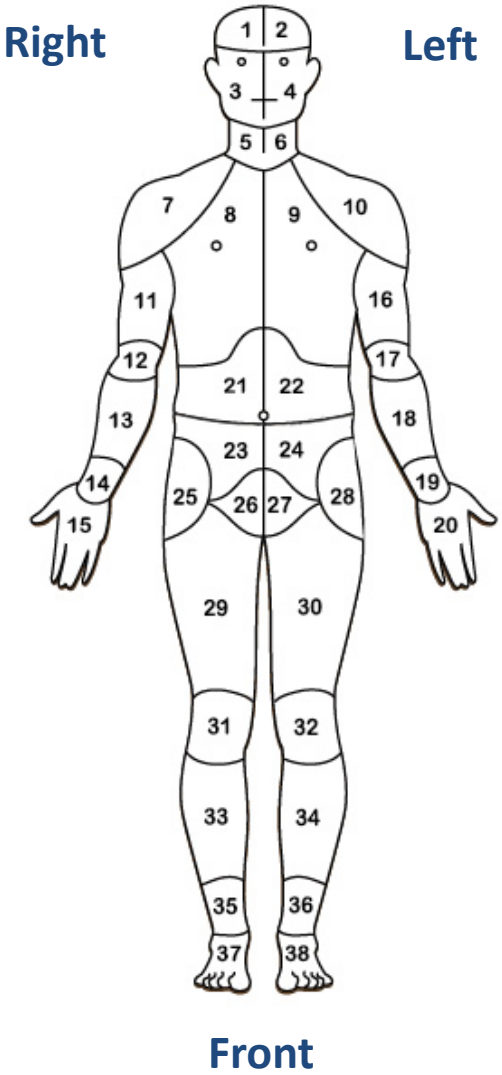
BRIEF PAIN INVENTORY (SHORT FORM) for Female Participants

Female Participant completes via Online Survey at ***ALL* Clinic** and **Online** 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

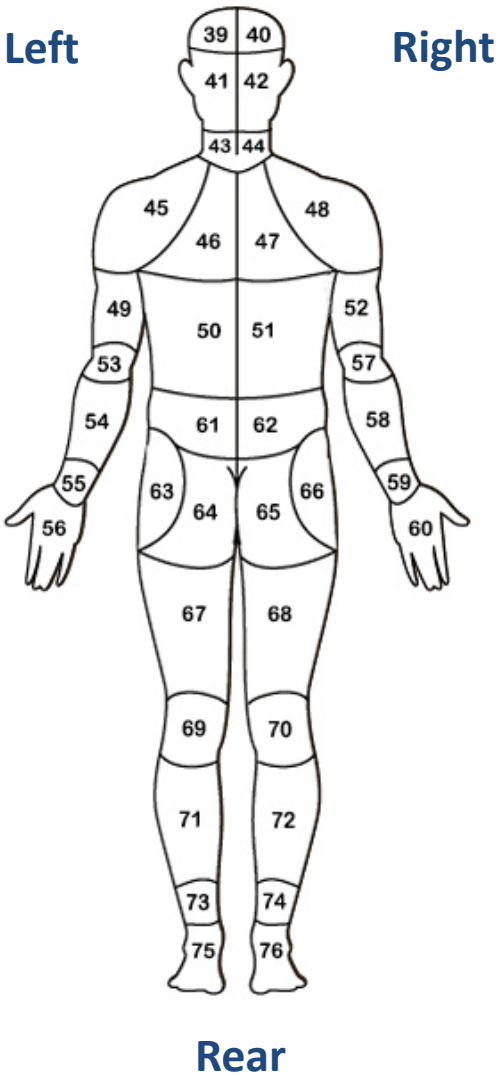
2. Select each area on the body map where you have had pain or tenderness over the ***past 7 days*** and indicate the intensity of pain in that area:

❑$_0$ **No Pain**



Front

❑$_0$ **No Pain**



Rear

a. Select the area on the body map that hurts the most and indicate the intensity of pain in that area. ***(Archived)***

MAPP research network MAPP II SPS	**Participant ID:** __ __ __ __ __ __	**Pin #** __ __ __ __
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BRIEF PAIN INVENTORY (SHORT FORM) for Female Participants

Female Participant completes via Online Survey at ***ALL* Clinic** and **Online** Contacts.

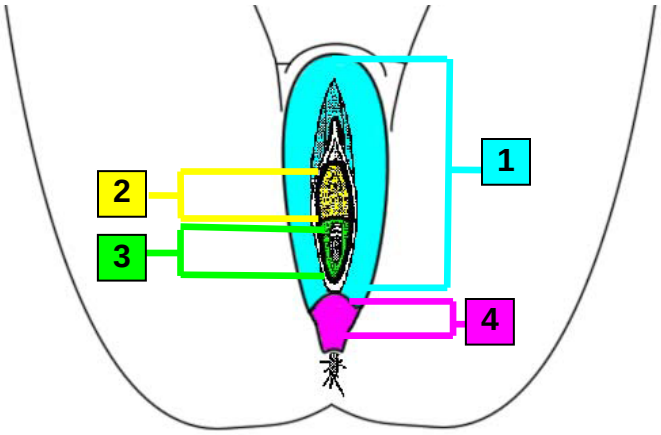
3. Check the boxes listed below for each area on the genital diagram where you feel pain:

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

BRIEF PAIN INVENTORY (SHORT FORM) for Female Participants

Female Participant completes via Online Survey at ***ALL* Clinic** and **Online** 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 Female Participants

Female Participant completes via Online Survey at ***ALL* Clinic** and **Online** 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 MAPP II SPS	**Participant ID:** __ __ __ __ __ __	**Pin #** __ __ __ __
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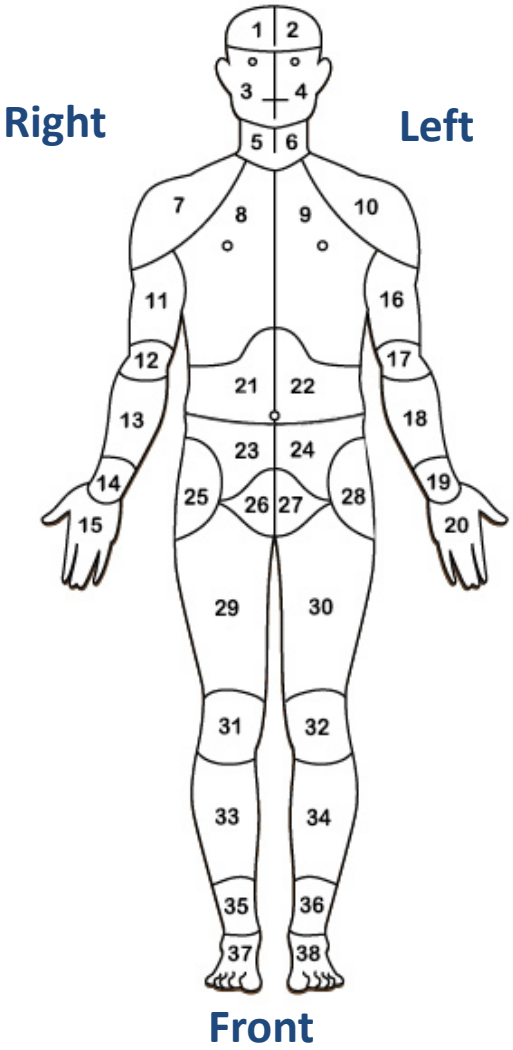
BRIEF PAIN INVENTORY (SHORT FORM) for Male Participants

Male Participant completes via Online Survey at ***ALL*** **Clinic** and **Online** Contacts.

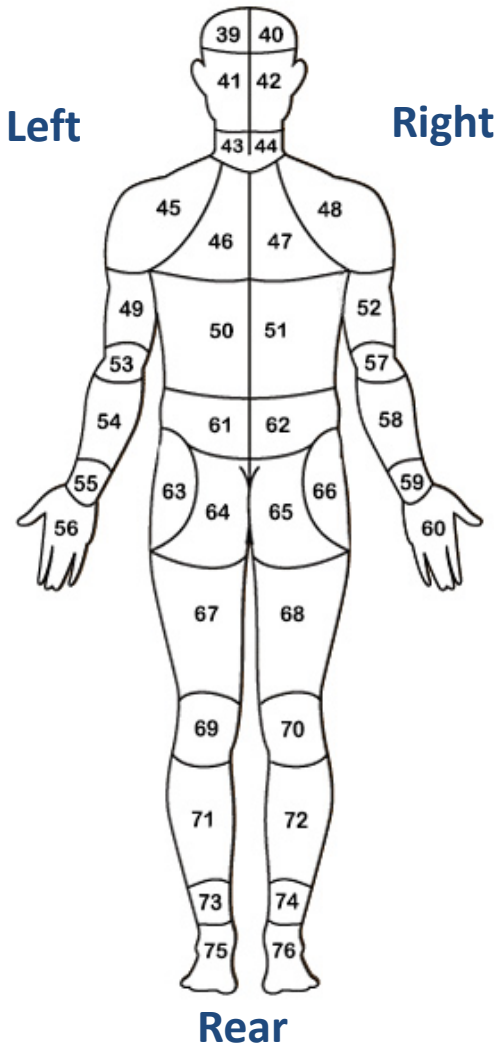
1. Throughout our lives, most of us have had pain from time to time (such as minor headaches, sprains, and toothaches). Have you had pain other than these everyday kinds of pain during the last week? ❑$_1$ Yes ❑$_0$ No

2. Select each area on the body map where you have had pain or tenderness over the ***past 7 days*** and indicate the intensity of pain in that area:

❑$_0$ **No Pain**



❑$_0$ **No Pain**



a. Select the area on the body map that hurts the most and indicate the intensity of pain in that area. ***(Archived)***

MAPP research network MAPP II SPS	**Participant ID:** __ __ __ __ __ __	**Pin #** __ __ __ __
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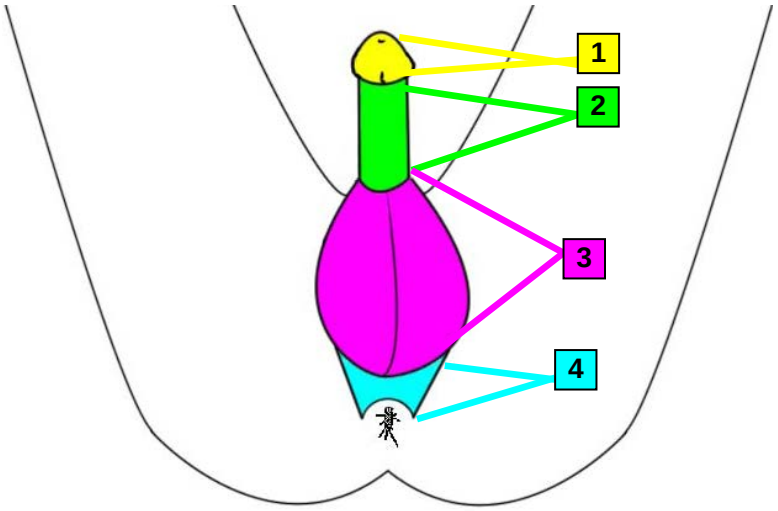
BRIEF PAIN INVENTORY (SHORT FORM) for Male Participants

Male Participant completes via Online Survey at ***ALL* Clinic** and **Online** 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 MAPP II SPS	**Participant ID:** __ __ __ __ __ __	**Pin #** __ __ __ __
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BRIEF PAIN INVENTORY (SHORT FORM) for Male Participants

Male Participant completes via Online Survey at ***ALL* Clinic** and **Online** 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 via Online Survey at ***ALL*** **Clinic** and **Online** 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 MAPP II SPS	**Participant ID:** __ __ __ __ __ __	**Pin #** __ __ __ __
	Discovery Site: __ __	**Clinical Center** __ __
	CRF Date: __ __/__ __/__ __ __ __	**Visit #:** __ __

PAIN *DETECT* for Pelvic Pain

Participant completes via Online Survey at
Screening Week 0, Baseline Week 4, and ***ALL*** Clinic and Online Follow-up Contacts.

Please answer the questions below about your ***pelvic pain***.

1. How would you assess your pelvic pain **now**, at this moment?

None										Max
❑	❑	❑	❑	❑	❑	❑	❑	❑	❑	❑
0	1	2	3	4	5	6	7	8	9	10

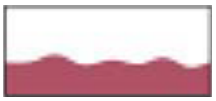
2. How strong was the **strongest** pelvic pain during the past 4 weeks?

None										Max
❑	❑	❑	❑	❑	❑	❑	❑	❑	❑	❑
0	1	2	3	4	5	6	7	8	9	10

3. How strong was the pelvic pain during the past 4 weeks **on average**?

None										Max
❑	❑	❑	❑	❑	❑	❑	❑	❑	❑	❑
0	1	2	3	4	5	6	7	8	9	10

4. **Mark the picture that best describes the course of your pelvic pain:**



Persistent pain with slight fluctuations ❑$_1$

Persistent pain with pain attacks ❑$_2$

Pain attacks without pain between them ❑$_3$

Pain attacks with pain between them ❑$_4$

5. Does your pain radiate to other regions of your body? ❑$_1$ Yes ❑$_0$ No

6. **Do you suffer from a burning sensation (e.g., stinging nettles) in the areas where you feel pelvic pain?**

❑$_0$	❑$_1$	❑$_2$	❑$_3$	❑$_4$	❑$_5$
Never	Hardly noticed	Slightly	Moderately	Strongly	Very Strongly

MAPP research network MAPP II SPS	**Participant ID:** __ __ __ __ __ __	**Pin #** __ __ __ __
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PAIN *DETECT* for Pelvic Pain

Participant completes via Online Survey at
Screening Week 0, Baseline Week 4, and ***ALL*** Clinic and Online Follow-up Contacts.

7. **Do you have a tingling or prickling sensation in the area of your pelvic pain (like crawling ants or electrical tingling)?**

❑0	❑1	❑2	❑3	❑4	❑5
Never	Hardly noticed	Slightly	Moderately	Strongly	Very Strongly

8. **Is light touching (clothing, a blanket) in your pelvic area painful?**

❑0	❑1	❑2	❑3	❑4	❑5
Never	Hardly noticed	Slightly	Moderately	Strongly	Very Strongly

9. **Do you have sudden pain attacks in your pelvic area, like electric shocks?**

❑0	❑1	❑2	❑3	❑4	❑5
Never	Hardly noticed	Slightly	Moderately	Strongly	Very Strongly

10. **Is cold or heat (bath water) in your pelvic area occasionally painful?**

❑0	❑1	❑2	❑3	❑4	❑5
Never	Hardly noticed	Slightly	Moderately	Strongly	Very Strongly

11. **Do you suffer from a sensation of numbness in your pelvic area?**

❑0	❑1	❑2	❑3	❑4	❑5
Never	Hardly noticed	Slightly	Moderately	Strongly	Very Strongly

12. **Does slight pressure in your pelvic area, e.g., with a finger, trigger pain?**

❑0	❑1	❑2	❑3	❑4	❑5
Never	Hardly noticed	Slightly	Moderately	Strongly	Very Strongly

MAPP research network MAPP II SPS	**Participant ID:** __ __ __ __ __ __	**Pin #** __ __ __ __
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PAIN *DETECT* for Pelvic Pain

Participant completes via Online Survey at Weeks 1, 2, & 3 Run-In Contacts.

Please answer the questions below about your ***pelvic pain***.

1. How would you assess your pelvic pain **now**, at this moment?

None										Max
❑	❑	❑	❑	❑	❑	❑	❑	❑	❑	❑
0	1	2	3	4	5	6	7	8	9	10

2. How strong was the **strongest** pelvic pain during the **past week**?

None										Max
❑	❑	❑	❑	❑	❑	❑	❑	❑	❑	❑
0	1	2	3	4	5	6	7	8	9	10

3. How strong was the pelvic pain during the **past week on average**?

None										Max
❑	❑	❑	❑	❑	❑	❑	❑	❑	❑	❑
0	1	2	3	4	5	6	7	8	9	10

4. **Mark the picture that best describes the course of your pelvic pain:**

Persistent pain with slight fluctuations ❑1

Persistent pain with pain attacks ❑2

Pain attacks without pain between them ❑3

Pain attacks with pain between them ❑4

5. Does your pain radiate to other regions of your body? ❑1 Yes ❑0 No

6. **Do you suffer from a burning sensation (e.g., stinging nettles) in the areas where you feel pelvic pain?**

❑0	❑1	❑2	❑3	❑4	❑5
Never	Hardly noticed	Slightly	Moderately	Strongly	Very Strongly

MAPP research network MAPP II SPS	**Participant ID:** __ __ __ __ __ __	**Pin #** __ __ __ __
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PAIN *DETECT* for Pelvic Pain

Participant completes via Online Survey at Weeks 1, 2, & 3 Run-In Contacts.

7. **Do you have a tingling or prickling sensation in the area of your pelvic pain (like crawling ants or electrical tingling)?**

❑0	❑1	❑2	❑3	❑4	❑5
Never	Hardly noticed	Slightly	Moderately	Strongly	Very Strongly

8. **Is light touching (clothing, a blanket) in your pelvic area painful?**

❑0	❑1	❑2	❑3	❑4	❑5
Never	Hardly noticed	Slightly	Moderately	Strongly	Very Strongly

9. **Do you have sudden pain attacks in your pelvic area, like electric shocks?**

❑0	❑1	❑2	❑3	❑4	❑5
Never	Hardly noticed	Slightly	Moderately	Strongly	Very Strongly

10. **Is cold or heat (bath water) in your pelvic area occasionally painful?**

❑0	❑1	❑2	❑3	❑4	❑5
Never	Hardly noticed	Slightly	Moderately	Strongly	Very Strongly

11. **Do you suffer from a sensation of numbness in your pelvic area?**

❑0	❑1	❑2	❑3	❑4	❑5
Never	Hardly noticed	Slightly	Moderately	Strongly	Very Strongly

12. **Does slight pressure in your pelvic area, e.g., with a finger, trigger pain?**

❑0	❑1	❑2	❑3	❑4	❑5
Never	Hardly noticed	Slightly	Moderately	Strongly	Very Strongly

MAPP research network MAPP II SPS	**Participant ID:** __ __ __ __ __ __	**Pin #** __ __ __ __
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PAIN *DETECT* for Pelvic Pain, ATLAS Module

Participant completes via Online Survey for ALL ATLAS Contacts.

Please answer the questions below about your ***pelvic pain***.

1. How would you assess your pelvic pain **now**, at this moment?

None										Max
❑	❑	❑	❑	❑	❑	❑	❑	❑	❑	❑
0	1	2	3	4	5	6	7	8	9	10

2. How strong was the **strongest** pelvic pain during the **past 2 weeks**?

None										Max
❑	❑	❑	❑	❑	❑	❑	❑	❑	❑	❑
0	1	2	3	4	5	6	7	8	9	10

3. How strong was the pelvic pain during the **past 2 weeks on average**?

None										Max
❑	❑	❑	❑	❑	❑	❑	❑	❑	❑	❑
0	1	2	3	4	5	6	7	8	9	10

4. **Mark the picture that best describes the course of your pelvic pain:**

Persistent pain with slight fluctuations ❑$_1$

Persistent pain with pain attacks ❑$_2$

Pain attacks without pain between them ❑$_3$

Pain attacks with pain between them ❑$_4$

5. Does your pain radiate to other regions of your body? ❑$_1$ Yes ❑$_0$ No

6. **Do you suffer from a burning sensation (e.g., stinging nettles) in the areas where you feel pelvic pain?**

❑$_0$	❑$_1$	❑$_2$	❑$_3$	❑$_4$	❑$_5$
Never	Hardly noticed	Slightly	Moderately	Strongly	Very Strongly

MAPP research network MAPP II SPS	**Participant ID:** __ __ __ __ __ __	**Pin #** __ __ __ __
	Discovery Site: __ __	**Clinical Center** __ __
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PAIN *DETECT* for Pelvic Pain, ATLAS Module

Participant completes via Online Survey for ALL ATLAS Contacts.

7. **Do you have a tingling or prickling sensation in the area of your pelvic pain (like crawling ants or electrical tingling)?**

❑0	❑1	❑2	❑3	❑4	❑5
Never	Hardly noticed	Slightly	Moderately	Strongly	Very Strongly

8. **Is light touching (clothing, a blanket) in your pelvic area painful?**

❑0	❑1	❑2	❑3	❑4	❑5
Never	Hardly noticed	Slightly	Moderately	Strongly	Very Strongly

9. **Do you have sudden pain attacks in your pelvic area, like electric shocks?**

❑0	❑1	❑2	❑3	❑4	❑5
Never	Hardly noticed	Slightly	Moderately	Strongly	Very Strongly

10. **Is cold or heat (bath water) in your pelvic area occasionally painful?**

❑0	❑1	❑2	❑3	❑4	❑5
Never	Hardly noticed	Slightly	Moderately	Strongly	Very Strongly

11. **Do you suffer from a sensation of numbness in your pelvic area?**

❑0	❑1	❑2	❑3	❑4	❑5
Never	Hardly noticed	Slightly	Moderately	Strongly	Very Strongly

12. **Does slight pressure in your pelvic area, e.g., with a finger, trigger pain?**

❑0	❑1	❑2	❑3	❑4	❑5
Never	Hardly noticed	Slightly	Moderately	Strongly	Very Strongly

MAPP research network MAPP II SPS	**Participant ID:** __ __ __ __ __ __	**Pin #** __ __ __ __
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Short-Form McGill Pain Questionnaire®

RONALD MELZACK

Participant completes via online survey at **Week 4 Baseline and Months 6, 18, & 36 Follow-up Contacts.**

Instructions: Please indicate whether each of the following words describes your pain, and if it does, please rate the intensity of that particular quality of the pain.

	None	Mild	Moderate	Severe
1. Throbbing	❑0	❑1	❑2	❑3
2. Shooting	❑0	❑1	❑2	❑3
3. Stabbing	❑0	❑1	❑2	❑3
4. Sharp	❑0	❑1	❑2	❑3
5. Cramping	❑0	❑1	❑2	❑3
6. Gnawing	❑0	❑1	❑2	❑3
7. Hot-burning	❑0	❑1	❑2	❑3
8. Aching	❑0	❑1	❑2	❑3
9. Heavy	❑0	❑1	❑2	❑3
10. Tender	❑0	❑1	❑2	❑3
11. Splitting	❑0	❑1	❑2	❑3
12. Tiring-exhausting	❑0	❑1	❑2	❑3
13. Sickening	❑0	❑1	❑2	❑3
14. Fearful	❑0	❑1	❑2	❑3
15. Punishing-cruel	❑0	❑1	❑2	❑3

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Gracely Box Scales

Participant completes via online survey at **Week 4 Baseline and Months 6, 18, & 36 Follow-up Contacts.**

Please rate the UNPLEASANTNESS of ***your symptoms over the last 24 hours*** by indicating any number on this scale. Please read all the words carefully and use them as a guide to where different intensities are located on the scale. Remember you can use any number on the scale including those between the words or above or below the top and bottom word.

20	
19	
18	
17	VERY INTOLERABLE
16	INTOLERABLE
15	
14	
13	VERY DISTRESSING
12	SLIGHTLY INTOLERABLE VERY ANNOYING
11	DISTRESSING
10	VERY UNPLEASANT
9	SLIGHTLY DISTRESSING
8	ANNOYING
7	UNPLEASANT
6	SLIGHTLY ANNOYING
5	SLIGHTLY UNPLEASANT
4	
3	
2	
1	
0	NEUTRAL

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Gracely Box Scales

Participant completes via online survey at **Week 4 Baseline and Months 6, 18, & 36 Follow-up Contacts.**

Please rate the INTENSITY of ***your symptoms over the last 24 hours*** by indicating any number on this scale. Please read all the words carefully and use them as a guide to where different intensities are located on the scale. Remember you can use any number on the scale including those between the words or above or below the top and bottom word.

20	
19	
18	EXTREMELY INTENSE
17	VERY INTENSE
16	INTENSE
15	STRONG
14	
13	SLIGHTLY INTENSE
12	BARELY STRONG
11	MODERATE
10	
9	
8	MILD
7	
6	VERY MILD
5	WEAK
4	VERY WEAK
3	
2	
1	FAINT
0	

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WHODAS 2.0

World Health Organization
Disability Assessment Schedule 2.0

Participant completes via Online Survey at **Screening Week 0**, **Baseline Week 4**, and ***ALL* Clinic** and **Online Follow-up** Contacts.

12-item version, self-administered

This questionnaire asks about difficulties due to health conditions. Health conditions include diseases or illnesses, other health problems that may be short or long lasting, injuries, mental or emotional problems, and problems with alcohol or drugs.

Think back over the past 30 days and answer these questions, thinking about how much difficulty you had doing the following activities. For each question, please select only one response.

In the past 30 days, how much difficulty did you have in:	**None**	**Mild**	**Moderate**	**Severe**	**Extreme or cannot do**
1. Standing for long periods such as 30 minutes?	❑0	❑1	❑2	❑3	❑4
2. Taking care of your household responsibilities?	❑0	❑1	❑2	❑3	❑4
3. Learning a new task, for example, learning how to get to a new place?	❑0	❑1	❑2	❑3	❑4
4. How much of a problem did you have joining in community activities (for example, festivities, religious or other activities) in the same way as anyone else can?	❑0	❑1	❑2	❑3	❑4
5. How much have you been emotionally affected by your health problems?	❑0	❑1	❑2	❑3	❑4
6. Concentrating on doing something for ten minutes?	❑0	❑1	❑2	❑3	❑4
7. Walking a long distance such as a kilometer [or equivalent]?	❑0	❑1	❑2	❑3	❑4
8. Washing your whole body?	❑0	❑1	❑2	❑3	❑4
9. Getting dressed?	❑0	❑1	❑2	❑3	❑4
10. Dealing with people you do not know?	❑0	❑1	❑2	❑3	❑4
11. Maintaining a friendship?	❑0	❑1	❑2	❑3	❑4
12. Your day-to-day work?	❑0	❑1	❑2	❑3	❑4

MAPP research network MAPP II SPS	**Participant ID:** __ __ __ __ __ __	**Pin #** __ __ __ __
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WHODAS 2.0

World Health Organization
Disability Assessment Schedule 2.0

Participant completes via Online Survey at **Screening Week 0**, **Baseline Week 4**, and ***ALL* Clinic** and **Online Follow-up** Contacts.

13. Overall, in the past 30 days, how many days were these difficulties present? ____ ____

14. In the past 30 days, for how many days were you totally unable to carry out your usual activities or work because of any health condition? ____ ____

15. In the past 30 days, not counting the days that you were totally unable, for how many days did you cut back or reduce your usual activities or work because of any health condition? ____ ____

This completes the questionnaire. Thank you.

MAPP research network MAPP II SPS	**Participant ID:** __ __ __ __ __ __	**Pin #** __ __ __ __
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WHODAS 2.0

World Health Organization
Disability Assessment Schedule 2.0
Follow-up Survey for Run-In Contacts & ATLAS Module

PARTICIPANT COMPLETES **VIA ONLINE SURVEY** AT **WEEK #S 1, 2, & 3 RUN-IN** CONTACTS AND FOR ***ALL* ATLAS** CONTACTS IF AN ATLAS MODULE IS INITIATED.

12-item version, self-administered

This questionnaire asks about difficulties due to health conditions. Health conditions include diseases or illnesses, other health problems that may be short or long lasting, injuries, mental or emotional problems, and problems with alcohol or drugs.

Think back **since your last online survey** and answer these questions, thinking about how much difficulty you had doing the following activities. For each question, please select only one response.

Since your last online survey, how much difficulty did you have in:	**None**	**Mild**	**Moderate**	**Severe**	**Extreme or cannot do**
1. Standing for long periods such as 30 minutes?	❑0	❑1	❑2	❑3	❑4
2. Taking care of your household responsibilities?	❑0	❑1	❑2	❑3	❑4
3. Learning a new task, for example, learning how to get to a new place?	❑0	❑1	❑2	❑3	❑4
4. How much of a problem did you have joining in community activities (for example, festivities, religious or other activities) in the same way as anyone else can?	❑0	❑1	❑2	❑3	❑4
5. How much have you been emotionally affected by your health problems?	❑0	❑1	❑2	❑3	❑4
6. Concentrating on doing something for ten minutes?	❑0	❑1	❑2	❑3	❑4
7. Walking a long distance such as a kilometer [or equivalent]?	❑0	❑1	❑2	❑3	❑4
8. Washing your whole body?	❑0	❑1	❑2	❑3	❑4
9. Getting dressed?	❑0	❑1	❑2	❑3	❑4
10. Dealing with people you do not know?	❑0	❑1	❑2	❑3	❑4
11. Maintaining a friendship?	❑0	❑1	❑2	❑3	❑4
12. Your day-to-day work?	❑0	❑1	❑2	❑3	❑4

MAPP research network MAPP II SPS	**Participant ID:** __ __ __ __ __ __	**Pin #** __ __ __ __
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WHODAS 2.0

World Health Organization
Disability Assessment Schedule 2.0
Follow-up Survey for Run-In Contacts & ATLAS Module

PARTICIPANT COMPLETES **VIA ONLINE SURVEY** AT **WEEK #S 1, 2, & 3 RUN-IN** CONTACTS AND FOR ***ALL* ATLAS** CONTACTS IF AN ATLAS MODULE IS INITIATED.

13. Overall, **since your last online survey**, how many days were these difficulties present? ___ ___

14. **Since your last online survey**, for how many days were you totally unable to carry out your usual activities or work because of any health condition? ___ ___

15. **Since your last online survey**, not counting the days that you were totally unable, for how many days did you cut back or reduce your usual activities or work because of any health condition? ___ ___

This completes the questionnaire. Thank you.

MAPP research network MAPP II SPS	**Participant ID:** __ __ __ __ __ __	**Pin #** __ __ __ __
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SF-12 – Health Status Questionnaire®

Participant completes via online survey at **Week 4 Baseline and Months 6, 12, 18, 24, 30, & 36 Follow-up 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 your health now limit you in these activities? If so, how much?

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

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

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

4. During the past 4 weeks, how much of the time have you had any of the following problems with your work or other regular daily activities as a result of any emotional problems (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. Accomplished less than you would like	❑1	❑2	❑3	❑4	❑5
b. Did work or other activities less carefully than usual	❑1	❑2	❑3	❑4	❑5

5. During the past 4 weeks, how much did pain 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

MAPP research network MAPP II SPS	**Participant ID:** __ __ __ __ __ __	**Pin #** __ __ __ __
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SF-12 – Health Status Questionnaire®

Participant completes via online survey at **Week 4 Baseline and Months 6, 12, 18, 24, 30, & 36 Follow-up 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

MAPP research network MAPP II SPS	**Participant ID:** __ __ __ __ __ __	**Pin #** __ __ __ __
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International Physical Activity Questionnaire

Participant completes via online survey at **Week 4 Baseline and Months 6, 12, 18, 24, 30, & 36 Follow-up Contacts**

We are interested in finding out about the kinds of physical activities that people do as part of their everyday lives. The questions will ask you about the time you spent being physically active in the **last 7 days**. Please answer each question even if you do not consider yourself to be an active person. Please think about the activities you do at work, as part of your house and yard work, to get from place to place, and in your spare time for recreation, exercise or sport.

Think about all the **vigorous** activities that you did in the **last 7 days**. **Vigorous** physical activities refer to activities that take hard physical effort and make you breathe much harder than normal. Think *only* about those physical activities that you did for at least 10 minutes at a time.

Please note, the following questions asking about time spent doing activities may be answered with time spent in hours ***or*** minutes ***or*** a combination of each. For example, if an activity takes an hour and a half you may enter **1 hour**, **30 minutes *or* 90 minutes**. If either hours or minutes do not apply, please leave the answer space blank.

1. During the **last 7 days**, on how many days did you do **vigorous** physical activities like heavy lifting, digging, aerobics, or fast bicycling?

   a. _____ **days per week**

   ❑$_0$ No vigorous physical activities → ***Skip to question 3***

2. How much time did you usually spend doing **vigorous** physical activities on one of those days?

   a. _____ **hours per day**

   b. _____ **minutes per day**

   ❑$_{99}$ Don't know/Not sure

Think about all the **moderate** activities that you did in the **last 7 days**. **Moderate** activities refer to activities that take moderate physical effort and make you breathe somewhat harder than normal. Think only about those physical activities that you did for at least 10 minutes at a time.

3. During the **last 7 days**, on how many days did you do **moderate** physical activities like carrying light loads, bicycling at a regular pace, or doubles tennis? Do not include walking.

   a. _____ **days per week**

   ❑$_0$ No moderate physical activities → ***Skip to question 5***

4. How much time did you usually spend doing **moderate** physical activities on one of those days?

   a. _____ **hours per day**

   b. _____ **minutes per day**

   ❑$_{99}$ Don't know/Not sure

SHORT LAST 7 DAYS SELF-ADMINISTERED version of the IPAQ. Revised August 2002.

International Physical Activity Questionnaire

Participant completes via online survey at **Week 4 Baseline and Months 6, 12, 18, 24, 30, & 36 Follow-up Contacts**

Think about the time you spent **walking** in the **last 7 days**. This includes at work and at home, walking to travel from place to place, and any other walking that you might do solely for recreation, sport, exercise, or leisure.

5. During the **last 7 days**, on how many days did you **walk** for at least 10 minutes at a time?

   a. _____ **days per week**

   ❑$_0$ No walking → ***Skip to question 7***

6. How much time did you usually spend **walking** on one of those days?

   a. _____ **hours per day**

   b. _____ **minutes per day**

   ❑$_{99}$ Don't know/Not sure

The last question is about the time you spent **sitting** on weekdays during the **last 7 days**. Include time spent at work, at home, while doing course work and during leisure time. This may include time spent sitting at a desk, visiting friends, reading, or sitting or lying down to watch television.

7. During the **last 7 days**, how much time did you spend **sitting** on a **week day**?

   a. _____ **hours per day**

   b. _____ **minutes per day**

   ❑$_{99}$ Don't know/Not sure

This is the end of the questionnaire, thank you for participating.

SHORT LAST 7 DAYS SELF-ADMINISTERED version of the IPAQ. Revised August 2002.

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Work Productivity and Activity Impairment Questionnaire:

Specific Health Problem V2.0 (WPAI:SHP)

Participant completes via online survey at **Week 4 Baseline and Months 6, 12, 18, 24, 30, & 36 Follow-up Contacts**

The following questions ask about the effect of your PROBLEM on your ability to work and perform regular activities. *Please fill in the blanks or circle a number, as indicated.*

1. Are you currently employed (working for pay)? ❑$_1$ Yes ❑$_0$ No

   *If NO, check "NO" and skip to **question 6**.*

   The next questions are about the **past seven days**, not including today.

2. During the past seven days, how many hours did you miss from work because of problems associated with your PROBLEM? *Include hours you missed on sick days, times you went in late, left early, etc., because of your PROBLEM. Do not include time you missed to participate in this study.*

   ___ ___ HOURS

3. During the past seven days, how many hours did you miss from work because of any other reason, such as vacation, holidays, time off to participate in this study?

   ___ ___ HOURS

4. During the past seven days, how many hours did you actually work?

   _____HOURS *(If **"0"**, skip to **question 6**.)*

5. During the past seven days, how much did your PROBLEM affect your productivity while you were working?

   Think about days you were limited in the amount or kind of work you could do, days you accomplished less than you would like, or days you could not do your work as carefully as usual. If PROBLEM affected your work only a little, choose a low number. Choose a high number if PROBLEM affected your work a great deal.

   Consider only how much PROBLEM affected productivity while you were working.

PROBLEM had no effect on my work										PROBLEM completely prevented me from working
❑	❑	❑	❑	❑	❑	❑	❑	❑	❑	❑
0	1	2	3	4	5	6	7	8	9	10

Reilly MC, Zbrozek AS, Dukes E: The validity and reproducibility of a work productivity and activity impairment measure. PharmacoEconomics 1993; 4(5):353-365.

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Work Productivity and Activity Impairment Questionnaire:

Specific Health Problem V2.0 (WPAI:SHP)

Participant completes via online survey at **Week 4 Baseline and Months 6, 12, 18, 24, 30, & 36 Follow-up Contacts**

SELECT A NUMBER

6. During the past seven days, how much did your PROBLEM affect your ability to do your regular daily activities, other than work at a job?

   By regular activities, we mean the usual activities you do, such as work around the house, shopping, childcare, exercising, studying, etc. Think about times you were limited in the amount or kind of activities you could do and times you accomplished less than you would like. If PROBLEM affected your activities only a little, choose a low number. Choose a high number if PROBLEM affected your activities a great deal.

Consider only how much PROBLEM affected your ability to do your regular daily activities, other than work at a job.

PROBLEM had no effect on my daily activities										PROBLEM completely prevented me from doing my daily activities
❑	❑	❑	❑	❑	❑	❑	❑	❑	❑	❑
0	1	2	3	4	5	6	7	8	9	10

SELECT A NUMBER

WPAI:SHP V2.0 (US English)

Reilly MC, Zbrozek AS, Dukes E: The validity and reproducibility of a work productivity and activity impairment measure. PharmacoEconomics 1993; 4(5):353-365.

MAPP research network MAPP II SPS	**Participant ID:** __ __ __ __ __ __	**Pin #** __ __ __ __
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PANAS

Participant completes via online survey at **Week 4 Baseline and**

Months 6, 12, 18, 24, 30, & 36 Follow-up 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

MAPP research network MAPP II SPS	**Participant ID:** __ __ __ __ __ __	**Pin #** __ __ __ __
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Hospital Anxiety and Depression Scale (HADS)

Participant completes via Online Survey at ***ALL*** Clinic and Online 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

MAPP research network MAPP II SPS	**Participant ID:** __ __ __ __ __ __	**Pin #** __ __ __ __
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Hospital Anxiety and Depression Scale (HADS)

Participant completes via Online Survey at ***ALL*** Clinic and Online 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: ___ ___

MAPP research network MAPP II SPS	**Participant ID:** __ __ __ __ __ __	**Pin #** __ __ __ __
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Multiple Ability Self-Report Questionnaire (MASQ)

Participant completes via online survey at **Week 4 Baseline and Months 6, 12, 18, 24, 30, & 36 Follow-up 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

MAPP research network MAPP II SPS	**Participant ID:** __ __ __ __ __ __	**Pin #** __ __ __ __
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Multiple Ability Self-Report Questionnaire (MASQ)

Participant completes via online survey at **Week 4 Baseline and Months 6, 12, 18, 24, 30, & 36 Follow-up 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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PROMIS Item Bank v. 1.0

Fatigue - Short Form

Participant completes this form via online survey at ***ALL* Clinic and Online 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 this form via online survey at ***ALL* Clinic and Online 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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Perceived Stress Scale (PSS)

Participant completes via Online Survey at
Screening Week 0, Baseline Week 4, and ***ALL*** Clinic and Online Follow-up 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

MAPP research network MAPP II SPS	**Participant ID:** __ __ __ __ __ __	**Pin #** __ __ __ __
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Perceived Stress Scale (PSS)

Participant completes via Online Survey at Weeks 1, 2, & 3 Run-In Contacts.

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

In the last week, 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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Perceived Stress Scale (PSS), ATLAS Module

Participant completes via Online Survey for ALL ATLAS Contacts.

Instructions: *The questions in this scale ask you about your feelings and thoughts **during the last 2 weeks.** In each case, you will be asked to indicate your response about **how often** you felt or thought a certain way.*

In the last 2 weeks, 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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Ten Item Personality Inventory

Participant completes via online survey at **Week 4 Baseline Clinic Contact.**

Here are a number of personality traits that may or may not apply to you.
Please select a number for each statement to indicate the extent to which you agree or disagree with that statement. You should rate the extent to which the pair of traits applies to you, even if one characteristic applies more strongly than the other.

	Disagree strongly	Disagree moderately	Disagree a little	Neither agree nor disagree	Agree a little	Agree moderately	Agree strongly
1. Extraverted, enthusiastic.	❑ 1	❑ 2	❑ 3	❑ 4	❑ 5	❑ 6	❑ 7
2. Critical, quarrelsome.	❑ 1	❑ 2	❑ 3	❑ 4	❑ 5	❑ 6	❑ 7
3. Dependable, self-disciplined.	❑ 1	❑ 2	❑ 3	❑ 4	❑ 5	❑ 6	❑ 7
4. Anxious, easily upset.	❑ 1	❑ 2	❑ 3	❑ 4	❑ 5	❑ 6	❑ 7
5. Open to new experiences, complex.	❑ 1	❑ 2	❑ 3	❑ 4	❑ 5	❑ 6	❑ 7
6. Reserved, quiet.	❑ 1	❑ 2	❑ 3	❑ 4	❑ 5	❑ 6	❑ 7
7. Sympathetic, warm.	❑ 1	❑ 2	❑ 3	❑ 4	❑ 5	❑ 6	❑ 7
8. Disorganized, careless.	❑ 1	❑ 2	❑ 3	❑ 4	❑ 5	❑ 6	❑ 7
9. Calm, emotionally stable.	❑ 1	❑ 2	❑ 3	❑ 4	❑ 5	❑ 6	❑ 7
10. Conventional, uncreative.	❑ 1	❑ 2	❑ 3	❑ 4	❑ 5	❑ 6	❑ 7

TIPI scale scoring (‘‘R’’ denotes reverse-scored items):
Extraversion: 1, 6R
Agreeableness: 2R, 7
Conscientiousness: 3, 8R
Emotional Stability: 4R, 9
Openness to Experiences: 5, 10R

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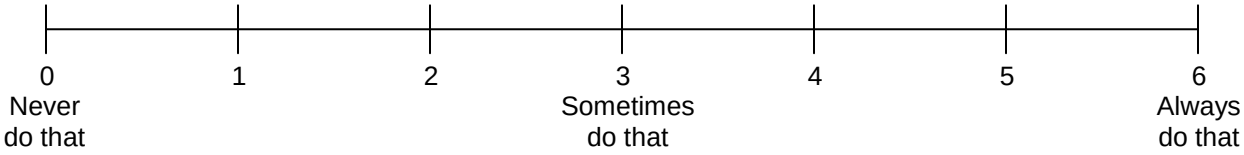
THOUGHTS ABOUT SYMPTOMS (CSQ)

Participant completes via online survey at **Week 4 Baseline and**

Months 6, 12, 18, 24, 30, & 36 Follow-up 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.

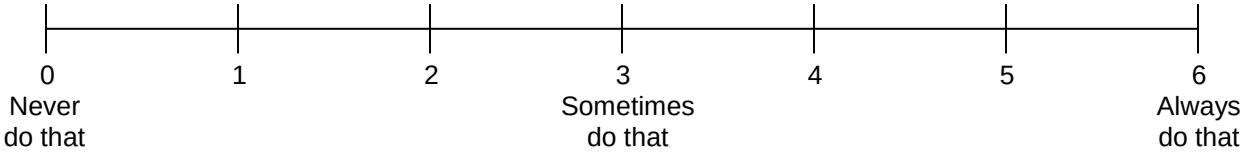
____ 3. I feel my life isn't worth living.

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

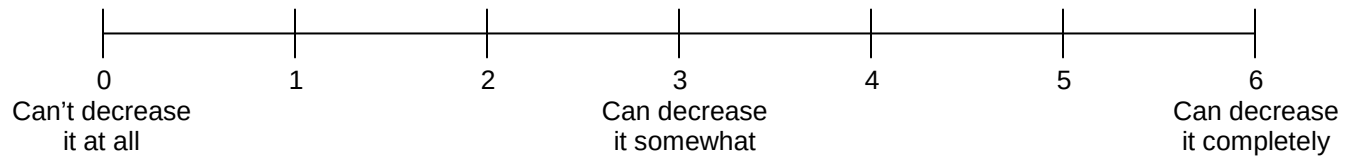
____ 5. I feel I can't stand it anymore.

____ 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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Childhood & Recent Traumatic Events Scale

Childhood Traumatic Events Scale

Participant completes **Childhood Traumatic Events Scale** below via online survey

at **Baseline Week 4** 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 & Recent Traumatic Events Scale

Childhood Traumatic Events Scale

Participant completes **Childhood Traumatic Events Scale** below via online survey

at **Baseline Week 4** 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

Childhood & Recent Traumatic Events Scale

Childhood Traumatic Events Scale

Participant completes **Childhood Traumatic Events Scale** below via online survey

at **Baseline Week 4** 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

Childhood & Recent Traumatic Events Scale

Recent Traumatic Events Scale

Participant completes **Recent Traumatic Events Scale** below via online survey

at **Baseline Week 4** 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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Childhood & Recent Traumatic Events Scale

Recent Traumatic Events Scale

Participant completes **Childhood Traumatic Events Scale** below via online survey

at **Baseline Week 4** 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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Childhood & Recent Traumatic Events Scale

Recent Traumatic Events Scale

Participant completes **Childhood Traumatic Events Scale** below via online survey

at **Baseline Week 4** 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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Childhood & Recent Traumatic Events Scale

Recent Traumatic Events Scale

Participant completes **Childhood Traumatic Events Scale** below via online survey

at **Baseline Week 4** 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

MAPP research network MAPP II SPS	**Participant ID:** __ __ __ __ __ __	**Pin #** __ __ __ __
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Recent Traumatic Events Scale

Participant completes **Recent Traumatic Events Scale** below via online survey at **Month 6, Month 18, and Month 36 Deep Phenotyping Clinic Contacts**.

For the following questions, answer each item that is relevant and be as honest as you can. Each question refers to any event that you may have experienced **since you began participating in this study.**

1. Since you began participating in this study, 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

2. Since you began participating in this study, 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 **Recent Traumatic Events Scale** below via online survey at **Month 6, Month 18, and Month 36 Deep Phenotyping Clinic Contacts**.

3. Since you began participating in this study, 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

4. Since you began participating in this study, 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

MAPP research network MAPP II SPS	**Participant ID:** __ __ __ __ __ __	**Pin #** __ __ __ __
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Recent Traumatic Events Scale

Participant completes **Recent Traumatic Events Scale** below via online survey at **Month 6, Month 18, and Month 36 Deep Phenotyping Clinic Contacts**.

5. Since you began participating in this study, 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

6. Since you began participating in this study, 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 **Recent Traumatic Events Scale** below via online survey at **Month 6, Month 18, and Month 36 Deep Phenotyping Clinic Contacts**.

7. Since you began participating in this study, 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

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

Participant completes via online survey at the Screening Week 0 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 box.*

Q#	SYMPTOM	3 months during the last year (12 months) (A)	*For staff use only*
1	Muscle or joint pain	❑$_1$ Yes ❑$_0$ No	❑$_1$M:FM ❑$_1$M:CFS
2	Morning stiffness	❑$_1$ Yes ❑$_0$ No	
3	Muscle spasms	❑$_1$ Yes ❑$_0$ No	
4	Persistent fatigue not relieved with rest	❑$_1$ Yes ❑$_0$ No	❑$_1$M:CFS
5	Extreme fatigue following exercise or mild exertion	❑$_1$ Yes ❑$_0$ No	
6	Recurrent fevers	❑$_1$ Yes ❑$_0$ No	
7	Dry eyes	❑$_1$ Yes ❑$_0$ No	
8	Dry mouth	❑$_1$ Yes ❑$_0$ No	
9	Fingers turn blue and/or white in the cold	❑$_1$ Yes ❑$_0$ No	
10	Numbness or tingling in arms or legs	❑$_1$ Yes ❑$_0$ No	
11	Shortness of breath during normal activity	❑$_1$ Yes ❑$_0$ No	
12	Impaired memory, concentration or attention	❑$_1$ Yes ❑$_0$ No	
13	Chest pain	❑$_1$ Yes ❑$_0$ No	
14	Palpitations	❑$_1$ Yes ❑$_0$ No	
15	Rapid heart rate	❑$_1$ Yes ❑$_0$ No	
16	Heartburn	❑$_1$ Yes ❑$_0$ No	
17	Vomiting	❑$_1$ Yes ❑$_0$ No	
18	Nausea	❑$_1$ Yes ❑$_0$ No	
19	Abdominal pain or discomfort	❑$_1$ Yes ❑$_0$ No	❑$_1$M:IBS
20	Problems with balance	❑$_1$ Yes ❑$_0$ No	
21	Dizziness	❑$_1$ Yes ❑$_0$ No	
22	Ringing in ears	❑$_1$ Yes ❑$_0$ No	
23	Ear pain	❑$_1$ Yes ❑$_0$ No	❑$_1$M:TMJ
24	Sensation of ear blockage or fullness	❑$_1$ Yes ❑$_0$ No	

MAPP research network MAPP II SPS	**Participant ID:** __ __ __ __ __ __	**Pin #** __ __ __ __
	Discovery Site: __ __	**Clinical Center** __ __
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COMPLEX MEDICAL SYMPTOMS INVENTORY

Participant completes via online survey at the Screening Week 0 contact.

Q#	SYMPTOM	3 months during the last year (12 months) (A)	*For staff use only*
25	Sinus pressure	❑$_1$ Yes ❑$_0$ No	
26	Pelvic/bladder discomfort (pain or pressure)	❑$_1$ Yes ❑$_0$ No	
27	Urinary urgency	❑$_1$ Yes ❑$_0$ No	
28	Urinary frequency, >8/day during waking hours	❑$_1$ Yes ❑$_0$ No	
29	Frequent nocturia (nighttime urination), 3/night	❑$_1$ Yes ❑$_0$ No	
30	Sensation of bladder fullness after urination	❑$_1$ Yes ❑$_0$ No	
31	Jaw and/or face pain	❑$_1$ Yes ❑$_0$ No	❑$_1$M:TMJ
32	Temple pain	❑$_1$ Yes ❑$_0$ No	
33	Pulsating and/or one-sided headache pain or migraines	❑$_1$ Yes ❑$_0$ No	❑$_1$M:MI
34	Pressing/tightening headache pain or tension headaches	❑$_1$ Yes ❑$_0$ No	
35	Sensitivity to certain chemicals, such as perfumes, laundry detergents, gasoline and others	❑$_1$ Yes ❑$_0$ No	
36	Sensitivity to sound	❑$_1$ Yes ❑$_0$ No	
37	Sensitivity to odors	❑$_1$ Yes ❑$_0$ No	
38	Body feeling tender	❑$_1$ Yes ❑$_0$ No	
39	Frequent sensitivity to bright lights	❑$_1$ Yes ❑$_0$ No	
FEMALES ONLY:			
40	Constant burning or raw feeling at the opening of vagina	❑$_1$ Yes ❑$_0$ No	❑$_1$M:VDYN
41	Itching at opening of vagina	❑$_1$ Yes ❑$_0$ No	

MAPP research network MAPP II SPS	**Participant ID:** __ __ __ __ __ __	**Pin #** __ __ __ __
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COMPLEX MEDICAL SYMPTOMS INVENTORY FOR RUN-IN CONTACTS

Participant completes via Online Survey at **Run-In Weeks 1, 2, & 3**.

Instructions: Please read the following list of symptoms. If you have had any of these symptoms ***over the past week,*** please mark the appropriate box.

Q#	SYMPTOM	Over the past week (A)	*For staff use only*
1	Muscle or joint pain	❑$_1$ Yes ❑$_0$ No	❑$_1$M:FM ❑$_1$M:CFS
2	Morning stiffness	❑$_1$ Yes ❑$_0$ No	
3	Muscle spasms	❑$_1$ Yes ❑$_0$ No	
4	Persistent fatigue not relieved with rest	❑$_1$ Yes ❑$_0$ No	❑$_1$M:CFS
5	Extreme fatigue following exercise or mild exertion	❑$_1$ Yes ❑$_0$ No	
6	Recurrent fevers	❑$_1$ Yes ❑$_0$ No	
7	Dry eyes	❑$_1$ Yes ❑$_0$ No	
8	Dry mouth	❑$_1$ Yes ❑$_0$ No	
9	Fingers turn blue and/or white in the cold	❑$_1$ Yes ❑$_0$ No	
10	Numbness or tingling in arms or legs	❑$_1$ Yes ❑$_0$ No	
11	Shortness of breath during normal activity	❑$_1$ Yes ❑$_0$ No	
12	Impaired memory, concentration or attention	❑$_1$ Yes ❑$_0$ No	
13	Chest pain	❑$_1$ Yes ❑$_0$ No	
14	Palpitations	❑$_1$ Yes ❑$_0$ No	
15	Rapid heart rate	❑$_1$ Yes ❑$_0$ No	
16	Heartburn	❑$_1$ Yes ❑$_0$ No	
17	Vomiting	❑$_1$ Yes ❑$_0$ No	
18	Nausea	❑$_1$ Yes ❑$_0$ No	
19	Abdominal pain or discomfort	❑$_1$ Yes ❑$_0$ No	❑$_1$M:IBS
20	Problems with balance	❑$_1$ Yes ❑$_0$ No	
21	Dizziness	❑$_1$ Yes ❑$_0$ No	
22	Ringing in ears	❑$_1$ Yes ❑$_0$ No	
23	Ear pain	❑$_1$ Yes ❑$_0$ No	❑$_1$M:TMJ
24	Sensation of ear blockage or fullness	❑$_1$ Yes ❑$_0$ No	
25	Sinus pressure	❑$_1$ Yes ❑$_0$ No	

MAPP research network MAPP II SPS	Participant ID: __ __ __ __ __ __	Pin # __ __ __ __
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COMPLEX MEDICAL SYMPTOMS INVENTORY FOR RUN-IN CONTACTS

Participant completes via Online Survey at **Run-In Weeks 1, 2, & 3**.

Q#	SYMPTOM	Over the past week (A)	*For staff use only*
26	Pelvic/bladder discomfort (pain or pressure)	❑$_1$ Yes ❑$_0$ No	
27	Urinary urgency	❑$_1$ Yes ❑$_0$ No	
28	Urinary frequency, >8/day during waking hours	❑$_1$ Yes ❑$_0$ No	
29	Frequent nocturia (nighttime urination), 3/night	❑$_1$ Yes ❑$_0$ No	
30	Sensation of bladder fullness after urination	❑$_1$ Yes ❑$_0$ No	
31	Jaw and/or face pain	❑$_1$ Yes ❑$_0$ No	❑$_1$M:TMJ
32	Temple pain	❑$_1$ Yes ❑$_0$ No	
33	Pulsating and/or one-sided headache pain or migraines	❑$_1$ Yes ❑$_0$ No	❑$_1$M:MI
34	Pressing/tightening headache pain or tension headaches	❑$_1$ Yes ❑$_0$ No	
35	Sensitivity to certain chemicals, such as perfumes, laundry detergents, gasoline and others	❑$_1$ Yes ❑$_0$ No	
36	Sensitivity to sound	❑$_1$ Yes ❑$_0$ No	
37	Sensitivity to odors	❑$_1$ Yes ❑$_0$ No	
38	Body feeling tender	❑$_1$ Yes ❑$_0$ No	
39	Frequent sensitivity to bright lights	❑$_1$ Yes ❑$_0$ No	
FEMALES ONLY:			
40	Constant burning or raw feeling at the opening of vagina	❑$_1$ Yes ❑$_0$ No	❑$_1$M:VDYN
41	Itching at opening of vagina	❑$_1$ Yes ❑$_0$ No	

MAPP research network MAPP II SPS	**Participant ID:** __ __ __ __ __ __	**Pin #** __ __ __ __
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COMPLEX MEDICAL SYMPTOMS INVENTORY, BASLINE

Participant completes via online survey at the Baseline Week 4 contact.

Instructions: Please read the following list of symptoms. If you have had any of these symptoms ***over the past month,*** please mark the appropriate box.

Q#	SYMPTOM	Over the past month (A)	*For staff use only*
1	Muscle or joint pain	❑$_1$ Yes ❑$_0$ No	❑$_1$M:FM ❑$_1$M:CFS
2	Morning stiffness	❑$_1$ Yes ❑$_0$ No	
3	Muscle spasms	❑$_1$ Yes ❑$_0$ No	
4	Persistent fatigue not relieved with rest	❑$_1$ Yes ❑$_0$ No	❑$_1$M:CFS
5	Extreme fatigue following exercise or mild exertion	❑$_1$ Yes ❑$_0$ No	
6	Recurrent fevers	❑$_1$ Yes ❑$_0$ No	
7	Dry eyes	❑$_1$ Yes ❑$_0$ No	
8	Dry mouth	❑$_1$ Yes ❑$_0$ No	
9	Fingers turn blue and/or white in the cold	❑$_1$ Yes ❑$_0$ No	
10	Numbness or tingling in arms or legs	❑$_1$ Yes ❑$_0$ No	
11	Shortness of breath during normal activity	❑$_1$ Yes ❑$_0$ No	
12	Impaired memory, concentration or attention	❑$_1$ Yes ❑$_0$ No	
13	Chest pain	❑$_1$ Yes ❑$_0$ No	
14	Palpitations	❑$_1$ Yes ❑$_0$ No	
15	Rapid heart rate	❑$_1$ Yes ❑$_0$ No	
16	Heartburn	❑$_1$ Yes ❑$_0$ No	
17	Vomiting	❑$_1$ Yes ❑$_0$ No	
18	Nausea	❑$_1$ Yes ❑$_0$ No	
19	Abdominal pain or discomfort	❑$_1$ Yes ❑$_0$ No	❑$_1$M:IBS
20	Problems with balance	❑$_1$ Yes ❑$_0$ No	
21	Dizziness	❑$_1$ Yes ❑$_0$ No	
22	Ringing in ears	❑$_1$ Yes ❑$_0$ No	
23	Ear pain	❑$_1$ Yes ❑$_0$ No	❑$_1$M:TMJ
24	Sensation of ear blockage or fullness	❑$_1$ Yes ❑$_0$ No	

MAPP research network MAPP II SPS	**Participant ID:** __ __ __ __ __ __	**Pin #** __ __ __ __
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COMPLEX MEDICAL SYMPTOMS INVENTORY, BASLINE

Participant completes via online survey at the Baseline Week 4 contact.

Q#	SYMPTOM	Over the past month (A)	*For staff use only*
25	Sinus pressure	❑$_1$ Yes ❑$_0$ No	
26	Pelvic/bladder discomfort (pain or pressure)	❑$_1$ Yes ❑$_0$ No	
27	Urinary urgency	❑$_1$ Yes ❑$_0$ No	
28	Urinary frequency, >8/day during waking hours	❑$_1$ Yes ❑$_0$ No	
29	Frequent nocturia (nighttime urination), 3/night	❑$_1$ Yes ❑$_0$ No	
30	Sensation of bladder fullness after urination	❑$_1$ Yes ❑$_0$ No	
31	Jaw and/or face pain	❑$_1$ Yes ❑$_0$ No	❑$_1$M:TMJ
32	Temple pain	❑$_1$ Yes ❑$_0$ No	
33	Pulsating and/or one-sided headache pain or migraines	❑$_1$ Yes ❑$_0$ No	❑$_1$M:MI
34	Pressing/tightening headache pain or tension headaches	❑$_1$ Yes ❑$_0$ No	
35	Sensitivity to certain chemicals, such as perfumes, laundry detergents, gasoline and others	❑$_1$ Yes ❑$_0$ No	
36	Sensitivity to sound	❑$_1$ Yes ❑$_0$ No	
37	Sensitivity to odors	❑$_1$ Yes ❑$_0$ No	
38	Body feeling tender	❑$_1$ Yes ❑$_0$ No	
39	Frequent sensitivity to bright lights	❑$_1$ Yes ❑$_0$ No	
FEMALES ONLY:			
40	Constant burning or raw feeling at the opening of vagina	❑$_1$ Yes ❑$_0$ No	❑$_1$M:VDYN
41	Itching at opening of vagina	❑$_1$ Yes ❑$_0$ No	

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

Participant completes via online survey for ***ALL* Follow-up and Clinic Contacts**.

Instructions: Please read the following list of symptoms. If you have had any of these symptoms ***over the past 3 months*** please mark the appropriate box.

Q#	SYMPTOM	Over the past 3 months (A)	*For staff use only*
1	Muscle or joint pain	❑$_1$ Yes ❑$_0$ No	❑$_1$M:FM ❑$_1$M:CFS
2	Morning stiffness	❑$_1$ Yes ❑$_0$ No	
3	Muscle spasms	❑$_1$ Yes ❑$_0$ No	
4	Persistent fatigue not relieved with rest	❑$_1$ Yes ❑$_0$ No	❑$_1$M:CFS
5	Extreme fatigue following exercise or mild exertion	❑$_1$ Yes ❑$_0$ No	
6	Recurrent fevers	❑$_1$ Yes ❑$_0$ No	
7	Dry eyes	❑$_1$ Yes ❑$_0$ No	
8	Dry mouth	❑$_1$ Yes ❑$_0$ No	
9	Fingers turn blue and/or white in the cold	❑$_1$ Yes ❑$_0$ No	
10	Numbness or tingling in arms or legs	❑$_1$ Yes ❑$_0$ No	
11	Shortness of breath during normal activity	❑$_1$ Yes ❑$_0$ No	
12	Impaired memory, concentration or attention	❑$_1$ Yes ❑$_0$ No	
13	Chest pain	❑$_1$ Yes ❑$_0$ No	
14	Palpitations	❑$_1$ Yes ❑$_0$ No	
15	Rapid heart rate	❑$_1$ Yes ❑$_0$ No	
16	Heartburn	❑$_1$ Yes ❑$_0$ No	
17	Vomiting	❑$_1$ Yes ❑$_0$ No	
18	Nausea	❑$_1$ Yes ❑$_0$ No	
19	Abdominal pain or discomfort	❑$_1$ Yes ❑$_0$ No	❑$_1$M:IBS
20	Problems with balance	❑$_1$ Yes ❑$_0$ No	
21	Dizziness	❑$_1$ Yes ❑$_0$ No	
22	Ringing in ears	❑$_1$ Yes ❑$_0$ No	
23	Ear pain	❑$_1$ Yes ❑$_0$ No	❑$_1$M:TMJ
24	Sensation of ear blockage or fullness	❑$_1$ Yes ❑$_0$ No	

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

Participant completes via online survey for ***ALL* Follow-up and Clinic Contacts**.

Q#	SYMPTOM	Over the past 3 months (A)	*For staff use only*
25	Sinus pressure	❑$_1$ Yes ❑$_0$ No	
26	Pelvic/bladder discomfort (pain or pressure)	❑$_1$ Yes ❑$_0$ No	
27	Urinary urgency	❑$_1$ Yes ❑$_0$ No	
28	Urinary frequency, >8/day during waking hours	❑$_1$ Yes ❑$_0$ No	
29	Frequent nocturia (nighttime urination), 3/night	❑$_1$ Yes ❑$_0$ No	
30	Sensation of bladder fullness after urination	❑$_1$ Yes ❑$_0$ No	
31	Jaw and/or face pain	❑$_1$ Yes ❑$_0$ No	❑$_1$M:TMJ
32	Temple pain	❑$_1$ Yes ❑$_0$ No	
33	Pulsating and/or one-sided headache pain or migraines	❑$_1$ Yes ❑$_0$ No	❑$_1$M:MI
34	Pressing/tightening headache pain or tension headaches	❑$_1$ Yes ❑$_0$ No	
35	Sensitivity to certain chemicals, such as perfumes, laundry detergents, gasoline and others	❑$_1$ Yes ❑$_0$ No	
36	Sensitivity to sound	❑$_1$ Yes ❑$_0$ No	
37	Sensitivity to odors	❑$_1$ Yes ❑$_0$ No	
38	Body feeling tender	❑$_1$ Yes ❑$_0$ No	
39	Frequent sensitivity to bright lights	❑$_1$ Yes ❑$_0$ No	
FEMALES ONLY:			
40	Constant burning or raw feeling at the opening of vagina	❑$_1$ Yes ❑$_0$ No	❑$_1$M:VDYN
41	Itching at opening of vagina	❑$_1$ Yes ❑$_0$ No	

MAPP research network MAPP II SPS	**Participant ID:** __ __ __ __ __ __	**Pin #** __ __ __ __
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COMPLEX MEDICAL SYMPTOMS INVENTORY FOR ATLAS CONTACTS

Participant completes via Online Survey at **ALL ATLAS Contacts**.

Instructions: Please read the following list of symptoms. If you have had any of these symptoms ***over the past 2 weeks,*** please mark the appropriate box.

Q#	SYMPTOM	Over the past 2 weeks (A)	*For staff use only*
1	Muscle or joint pain	❑$_1$ Yes ❑$_0$ No	❑$_1$M:FM ❑$_1$M:CFS
2	Morning stiffness	❑$_1$ Yes ❑$_0$ No	
3	Muscle spasms	❑$_1$ Yes ❑$_0$ No	
4	Persistent fatigue not relieved with rest	❑$_1$ Yes ❑$_0$ No	❑$_1$M:CFS
5	Extreme fatigue following exercise or mild exertion	❑$_1$ Yes ❑$_0$ No	
6	Recurrent fevers	❑$_1$ Yes ❑$_0$ No	
7	Dry eyes	❑$_1$ Yes ❑$_0$ No	
8	Dry mouth	❑$_1$ Yes ❑$_0$ No	
9	Fingers turn blue and/or white in the cold	❑$_1$ Yes ❑$_0$ No	
10	Numbness or tingling in arms or legs	❑$_1$ Yes ❑$_0$ No	
11	Shortness of breath during normal activity	❑$_1$ Yes ❑$_0$ No	
12	Impaired memory, concentration or attention	❑$_1$ Yes ❑$_0$ No	
13	Chest pain	❑$_1$ Yes ❑$_0$ No	
14	Palpitations	❑$_1$ Yes ❑$_0$ No	
15	Rapid heart rate	❑$_1$ Yes ❑$_0$ No	
16	Heartburn	❑$_1$ Yes ❑$_0$ No	
17	Vomiting	❑$_1$ Yes ❑$_0$ No	
18	Nausea	❑$_1$ Yes ❑$_0$ No	
19	Abdominal pain or discomfort	❑$_1$ Yes ❑$_0$ No	❑$_1$M:IBS
20	Problems with balance	❑$_1$ Yes ❑$_0$ No	
21	Dizziness	❑$_1$ Yes ❑$_0$ No	
22	Ringing in ears	❑$_1$ Yes ❑$_0$ No	
23	Ear pain	❑$_1$ Yes ❑$_0$ No	❑$_1$M:TMJ
24	Sensation of ear blockage or fullness	❑$_1$ Yes ❑$_0$ No	
25	Sinus pressure	❑$_1$ Yes ❑$_0$ No	

MAPP research network MAPP II SPS	**Participant ID:** __ __ __ __ __ __	**Pin #** __ __ __ __
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COMPLEX MEDICAL SYMPTOMS INVENTORY FOR ATLAS CONTACTS

Participant completes via Online Survey at **ALL ATLAS Contacts**.

Q#	SYMPTOM	Over the past 2 weeks (A)	*For staff use only*
26	Pelvic/bladder discomfort (pain or pressure)	❑$_1$ Yes ❑$_0$ No	
27	Urinary urgency	❑$_1$ Yes ❑$_0$ No	
28	Urinary frequency, >8/day during waking hours	❑$_1$ Yes ❑$_0$ No	
29	Frequent nocturia (nighttime urination), 3/night	❑$_1$ Yes ❑$_0$ No	
30	Sensation of bladder fullness after urination	❑$_1$ Yes ❑$_0$ No	
31	Jaw and/or face pain	❑$_1$ Yes ❑$_0$ No	❑$_1$M:TMJ
32	Temple pain	❑$_1$ Yes ❑$_0$ No	
33	Pulsating and/or one-sided headache pain or migraines	❑$_1$ Yes ❑$_0$ No	❑$_1$M:MI
34	Pressing/tightening headache pain or tension headaches	❑$_1$ Yes ❑$_0$ No	
35	Sensitivity to certain chemicals, such as perfumes, laundry detergents, gasoline and others	❑$_1$ Yes ❑$_0$ No	
36	Sensitivity to sound	❑$_1$ Yes ❑$_0$ No	
37	Sensitivity to odors	❑$_1$ Yes ❑$_0$ No	
38	Body feeling tender	❑$_1$ Yes ❑$_0$ No	
39	Frequent sensitivity to bright lights	❑$_1$ Yes ❑$_0$ No	
FEMALES ONLY:			
40	Constant burning or raw feeling at the opening of vagina	❑$_1$ Yes ❑$_0$ No	❑$_1$M:VDYN
41	Itching at opening of vagina	❑$_1$ Yes ❑$_0$ No	

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

Fibromyalgia Symptoms Modified (ACR 2010 Fibromyalgia Diagnostic Criteria)

Participant completes via online survey at ***ALL* Clinic, Online, and ATLAS Contacts.**

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 MAPP II SPS	**Participant ID:** __ __ __ __ __ __	**Pin #** __ __ __ __
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COMPLEX MEDICAL SYMPTOMS INVENTORY

Current Chronic Fatigue Symptoms (Fukuda 1994 criteria)

RESEARCH COORDINATOR ADMINISTERS TO PARTICIPANT AT BASELINE WEEK 4 AND MONTHS 6, 18, & 36 CLINIC CONTACTS, *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 MAPP II SPS	**Participant ID:** __ __ __ __ __ __	**Pin #** __ __ __ __
	Discovery Site: __ __	**Clinical Center** __ __
	CRF Date: __ __/__ __/__ __ __ __	**Visit #:** __ __

COMPLEX MEDICAL SYMPTOMS INVENTORY

Current Chronic Fatigue Symptoms (Fukuda 1994 criteria)

RESEARCH COORDINATOR ADMINISTERS TO PARTICIPANT AT BASELINE WEEK 4 AND MONTHS 6, 18, & 36 CLINIC CONTACTS, *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 MAPP II SPS	**Participant ID:** __ __ __ __ __ __	**Pin #** __ __ __ __
	Discovery Site: __ __	**Clinical Center** __ __
	CRF Date: __ __/__ __/__ __ __ __	**Visit #:** __ __

COMPLEX MEDICAL SYMPTOMS INVENTORY

Current IBS Symptoms (Rome III Criteria)

RESEARCH COORDINATOR ADMINISTERS TO PARTICIPANT AT BASELINE WEEK 4 AND MONTHS 6, 18, & 36 CLINIC CONTACTS, *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 MAPP II SPS	**Participant ID:** __ __ __ __ __ __	**Pin #** __ __ __ __
	Discovery Site: __ __	**Clinical Center** __ __
	CRF Date: __ __/__ __/__ __ __ __	**Visit #:** __ __

COMPLEX MEDICAL SYMPTOMS INVENTORY

Current IBS Symptoms (Rome III Criteria)

RESEARCH COORDINATOR ADMINISTERS TO PARTICIPANT AT BASELINE WEEK 4 AND MONTHS 6, 18, & 36 CLINIC CONTACTS, *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 MAPP II SPS	**Participant ID:** __ __ __ __ __ __	**Pin #** __ __ __ __
	Discovery Site: __ __	**Clinical Center** __ __
	CRF Date: __ __/__ __/__ __ __ __	**Visit #:** __ __

COMPLEX MEDICAL SYMPTOMS INVENTORY

Current Vulvodynia Symptoms – Females Only

RESEARCH COORDINATOR ADMINISTERS TO PARTICIPANT AT BASELINE WEEK 4 AND MONTHS 6, 18, & 36 CLINIC CONTACTS, *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

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

COMPLEX MEDICAL SYMPTOMS INVENTORY

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

RESEARCH COORDINATOR ADMINISTERS TO PARTICIPANT AT BASELINE WEEK 4
AND MONTHS 6, 18, & 36 CLINIC CONTACTS, *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

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

COMPLEX MEDICAL SYMPTOMS INVENTORY

Current TMD Symptoms (TMD/RDC 2002)

RESEARCH COORDINATOR ADMINISTERS TO PARTICIPANT AT BASELINE WEEK 4 AND MONTHS 6, 18, & 36 CLINIC CONTACTS, *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

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

Temporomandibular Pain Disorder Screening Instrument

Yoly M. Gonzalez; Eric Schiffman; Sharon M. Gordon; Bradley Seago; Edmond L. Truelove; Gary Slade; Richard Ohrbach

RESEARCH COORDINATOR ADMINISTERS TO PARTICIPANT AT BASELINE WEEK 4 AND MONTHS 6, 18, & 36 CLINIC CONTACTS, *IF NEEDED.*

1. In the last 30 days, on average, how long did any pain in your jaw or temple area on either side last?
   - ❑$_0$ No pain
   - ❑$_1$ From very brief to more than a week, but it does stop
   - ❑$_2$ Continuous

2. In the last 30 days, have you had pain or stiffness in your jaw on awakening? ❑$_1$ Yes ❑$_0$ No

3. In the last 30 days, did the following activities change any pain (that is,make it better or make it worse) in your jaw or temple area on either side?
   a. Chewing hard or tough food ❑$_1$ Yes ❑$_0$ No
   b. Opening your mouth or moving your jaw forward or to the side ❑$_1$ Yes ❑$_0$ No
   c. Jaw habits such as holding teeth together, clenching, grinding or chewing gum ❑$_1$ Yes ❑$_0$ No
   d. Other jaw activities such as talking, kissing or yawning ❑$_1$ Yes ❑$_0$ No

Items **1** through **3A** constitute the **short version** of the screening instrument.
Items **1** through **3D** constitute the **long version**.
A "**No**" response receives **0** points, a "**Yes**" response **1** point and a "**Continuous**" response **2** points.

MAPP research network
MAPP II SPS

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.

If a STIM tube collection is performed at this visit, please collect the TruCulture tubes **before collecting the ACD tube provided in this kit**

1) Store the tube at 4°C until shipment and record the time the tube was stored at 4°C.
2) 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)
- ☐ Hemolyzed
- ☐ Spills/Leakage
- ☐ Tube Broken/Open
- ☐ Warm
- ☐ Other:

# of plasma aliquots made:

ID first tube	P	L	A	0	0					
ID last tube	P	L	A	0	0					
Vol (µL): _____ ID Buffy coat	B	C	O	0	0					

Specimen comments:

None ☐

Data entry comments:

None ☐ Data entry complete ☐

Initials of processing tech:

Initials of data entry tech:

MAPP research network
MAPP II SPS

STIM Tube Acquisition Tracking Form

Affix 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 #:	___ ___ ___ ___	Research Coordinator ID: ___ ___ ___ ___ (4-digit ID
Discovery Site:	___ ___	Clinical Center:	___ ___	Were blood specimens collected at this visit? ☐ Yes ☐ No
CRF Date:	___ ___ / ___ ___ / ___ ___ ___ ___	Visit #:	___ ___	

Tube thaw date: ☐☐ / ☐☐ / 20☐☐ (M M / D D / Y Y)

Tube thaw time: ☐☐ : ☐☐ (24 hrs) (H H : M M)

Tube thaw method (choose one)**:**

☐ **Overnight at 4°C**

☐ **One hour at room temp**

Time placed at room T: ☐☐ : ☐☐ (24 hrs) (H H : M M)

1) Record header information above.
2) Bring TruCulture tubes to room temperature prior to venipuncture.
3) Record the thaw date, thaw time, thaw method, and time at room temperature.
4) Perform venipuncture using TruCulture tubes according to the TruCulture Instructions document provided in the kit.
5) **Always collect the TruCulture tubes before any other blood collections.**
6) Collect tubes in the following order
    1) LPS-1
    2) FLS-1
    3) NULL
7) Record date and time of collection, and the tube LOT numbers.
8) Sign next to the yellow box to certify that consent was obtained for the specimen.
9) Barcode each TruCulture tube with the barcodes included in this kit placing the LPS-1 label on the LPS-1 tube, the FLS-1 label on the FLS-1 tube, and the NULL label on the NULL tube.
10) Incubate specimen with the cap up in a heating block at 37°C and record time placed in the block.
11) Process specimen 24 hours from collection time according to the TruCulture Instructions and record processing information on the back of this form.

TruCulture Tubes collected:

LPS-1 ☐ Yes ☐ No

LPS-1 LOT # ___ ___ ___ ___ ___ ___ ___

FLS-1 ☐ Yes ☐ No

FLS-1 LOT # ___ ___ ___ ___ ___ ___ ___

NULL ☐ Yes ☐ No

NULL LOT # ___ ___ ___ ___ ___ ___ ___

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

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

Time placed at 37°C: ☐☐ : ☐☐ (24 hrs) (H H : M M)

Comments:

☐ None

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

Coordinator's signature Date

Begin processing 24 hours after 37°C incubation start time

Use the back of this form to record processing information

STIM Tube Processing Tracking Form

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

Time removed from 37^{0}C block: ☐☐ : ☐☐ (24 hrs) (H H : M M)

Time placed at -80^{0}C: ☐☐ : ☐☐ (24 hrs) (H H : M M)

Affix **LPS-1** TruCulture Tube Barcode Here	Affix **FLS-1** TruCulture Tube Barcode Here	Affix **NULL** TruCulture Tube Barcode Here
LPS-1 TruCulture Tube	FLS-1 TruCulture Tube	NULL TruCulture Tube

1) Remove the TruCulture tubes from the heating block
2) Process the TruCulture tubes according to steps 12-14 of TruCulture Instructions document provided in the kit.
3) Cap the TruCulture tubes securely.
4) Immediately store the specimens upright at -80^{0}C and record the time stored.
5) Store until shipment to the TATC.
6) Ship to the TATC per packaging and shipment protocol.

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

Comments:

☐ None

Processing 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 Specimens:	LPS	FLS	NULL
No Issues (Intact)	☐	☐	☐
Spills/Leakage	☐	☐	☐
Tube Broken/Open	☐	☐	☐
Thawed	☐	☐	☐
Other (specify in comments)	☐	☐	☐

Specimen comments:

☐ None

Data entry comments:

☐ None ☐ Data entry complete

Initials of processing tech:

Initials of data entry tech:

RBM

Instructions for using TruCulture™ tubes

Follow standard blood draw procedures and blood borne pathogen safety guidelines as recommended by the American Society of Clinical Pathology (ASCP).

The following procedure can be viewed at: http://www.edigmbh.de/ilcs_e.html under the section: "Watch our ILCS-Video"

1. Thaw the required number of TruCulture™ tubes overnight at 1 – 8 °C or sometime prior to blood draw at room temperature (never thaw the tubes at >37°C).

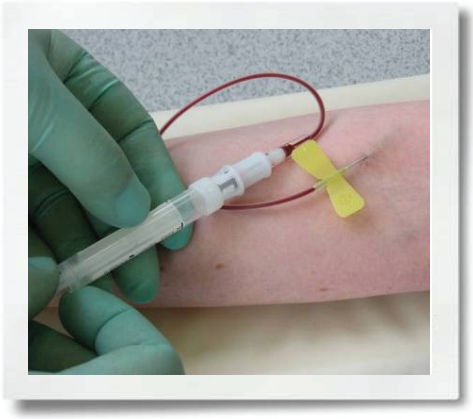
2. Allow tubes to adjust to room temperature.

3. Label the tubes as appropriate; e.g. patient/donor, sample no., date and time of blood sampling (i.e. culture initiation).

4. Prior to drawing blood, press the plunger into the TruCulture™ tube until it stops.

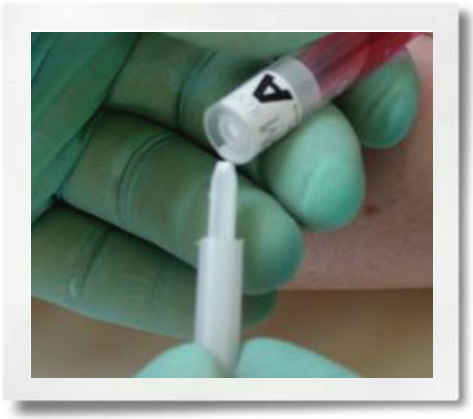
5. Use a "Multifly" (butterfly) needle system and connect its adaptor to the front end of an empty Monovette® syringe and lock it by turning clockwise.

6. Puncture the vein, ensure the cannula position is safe and the blood flows easily. Draw just enough blood to fill the tubing system of the butterfly needle set completely. [picture 1]



picture 1

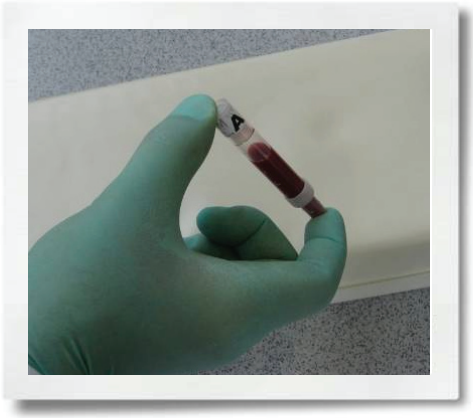
When other blood tubes are to be drawn with the same phlebotomy, make sure that the TruCulture™ tubes are always the FIRST to be filled with blood.



picture 2

7. **STARTING THE CULTURES**. Replace the empty Monovette® syringe with the first TruCulture™ tube. **Fill it slowly** with blood by pulling the plunger **gradually** until it snaps into its final position (with a gentle click), then **wait for at least 5 seconds** until the blood volume shows no further increase.

8. Disconnect the TruCulture™ tube from the butterfly adaptor and **gently** mix the tube contents by inverting 3 times end over end; **avoid foaming**. Break away the plunger close to the rear end of the TruCulture™ tube. [picture 2] Remove any blood remaining in the tube-cap by gently tapping the TruCulture™ tube on the bench top. Place in 37°C block thermostat with the tube-cap end pointing up. [pictures 3 and 4]



picture 3

9. By repeating steps 7 and 8, fill additional TruCulture™ tubes (if required).

10. Remove the needle from the vein and halt the bleeding appropriately.

11. Incubate all TruCulture™ tubes at 37°C in the block thermostat (or equivalent) for a defined period of time. Any deviations should be noted. As such, it is strongly recommended that the exact time of culture initiation (i.e. the time of the blood draw) be recorded on each of the tubes.

12. **STOPPING THE CULTURES**. Assemble the "seraplas filters" (valve separators); insert the sticks with their small "nose" into the little slot ("rear" end) [step 1, picture 5] of the separator and lock them with a counter-clockwise turn [step 2, picture 5]. Next, **carefully** remove the TruCulture™ tubes from the incubator – **avoid shaking**. Remove the screw cap from each tube and **slowly** insert the valve separator until it is about 5 mm (1/4") above the sediment level. It is important to keep the TruCulture™ tubes in an upright position during this procedure. [pictures 5 - 7]

13. Disconnect and remove the sticks from the separators with a counter-clockwise turn; the septum stays in the TruCulture™ tube. [picture 8] Finally, close the TruCulture™ tubes with the screw caps (hand-tight).

14. Freeze the TruCulture™ tubes (-20°C) immediately in an upright position.

15. Tubes should be shipped on dry ice in an upright position. Avoid styrofoam racks.

In case of any questions in Europe contact:
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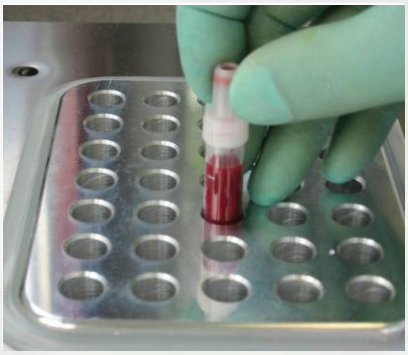
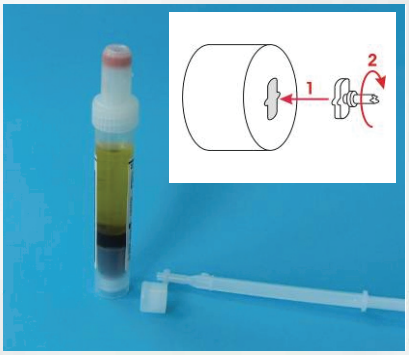
phone: +49 (0) 71 21 – 43 41 03
eMail: info@edigmbh.de

In case of any questions in North America contact:
RBM
phone: (512) 835-8026
eMail: info@rbmmaps.com

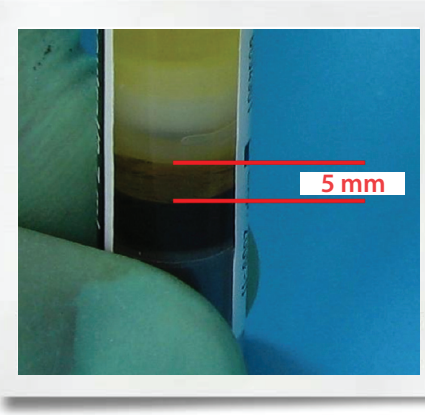


picture 4



picture 5

picture 6



picture 7

picture 8

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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					
ID last tube	U	R	I	0	0					

Specimen comments:

None ☐

Data entry comments:

None ☐ Data entry complete ☐

Initials of processing tech:

Initials of data entry tech:

Biomarker Urine Collection
Clean-Catch Mid-Stream Procedure for Women

Barcoded sterile 90mL urine cup

3 antiseptic wipes

1. Wash hands thoroughly.
2. Remove the lid of the cup, being careful not to touch the inside of the lid or the inside of the cup.
3. Stand in a squatting position over the toilet.
4. Separate the folds of skin around the urinary opening.
5. Cleanse the area on left and right side and around the opening with the wipes, using a fresh wipe for each area and wiping from front to back.
6. Discard the used wipes.
7. Keeping the skin folds separated, void into the toilet for a few seconds.
8. Touching only the outside of the urine cup and without letting it touch the genital area, bring the urine cup into the urine stream until the 90mL cup is filled or voiding stops.
9. Void the remainder of urine into the toilet.
10. Cover the specimen with the lid touching only the outside surfaces of the lid and cup.
11. Clean any urine spilled on the outside of the cup with a clean wipe.
12. Wash hands.
13. Give specimen to clinic staff.

Biomarker Urine Collection
Clean-Catch Mid-Stream Procedure for Men

Barcoded sterile 90mL urine cup

3 antiseptic wipes

1. Wash hands thoroughly.
2. Remove the lid of the cup, being careful not to touch the inside of the lid or the inside of the cup.
3. Cleanse the end of the penis with the wipe provided, beginning at the urethral opening and working away from it in a circular motion (the foreskin of an uncircumcised male must first be retracted). Repeat the procedure with a clean wipe.
4. Discard the used wipes.
5. Keeping the foreskin retracted, void into the toilet for a few seconds.
6. Touching only the outside of the urine cup and without letting it touch the penis, bring the urine cup into the urine stream until the 90mL urine cup is filled or voiding stops.
7. Void the remainder of urine into the toilet.
8. Cover the specimen with the lid touching only the outside surfaces of the lid and cup.
9. Clean any urine spilled on the outside of the cup with a clean wipe.
10. Wash hands.
11. Give specimen to clinic staff.

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UMB Universal Urine Specimen Acquisition Tracking Form

Affix
MB 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 Mid-Stream (VB2) urine collection using saline wipes and 60 ml urine cup provided. Record collection time and collection volume.
3) If appropriate, perform urinalysis in a urinalysis tube using a dipstick and record the results, then discard urinalysis tube.
4) Invert the urine cups 3 times and transfer urine specimen to the orange top 50 ml labeled conical tube provided.
5) Immediately store the 50 ml tube in a -80°C freezer until shipment. Record the time the tube was placed in the freezer.
6) Ship specimen to the TATC and record shipment date.

VB2

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

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

VB2 Volume: ☐☐ **(mL)**

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

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 Sample/Specimen:	**VB2**
No Issues (Intact)	☐
Spills/Leakage	☐
Tube Broken/Open	☐
Thawed	☐
Other (specify on back of form)	☐

Volume: VB2: ☐☐ **(mL)**

Specimen comments:

None ☐

Data entry comments:

None ☐ Data entry complete ☐

Initials of processing tech:

Initials of data entry tech:

Urine Collection
Clean-Catch Mid-Stream Procedure for Women

Barcoded sterile 60mL urine cup

3 Saline wipes

1. Wash hands thoroughly.
2. Remove the lid of the cup, being careful not to touch the inside of the lid or the inside of the cup.
3. Stand in a squatting position over the toilet.
4. Separate the folds of skin around the urinary opening.
5. Cleanse the area on left and right side and around the opening with the wipes, using a fresh wipe for each area and wiping from front to back.
6. Discard the used wipes.
7. Keeping the skin folds separated, void into the toilet for a few seconds.
8. Touching only the outside of the urine cup and without letting it touch the genital area, bring the urine cup into the urine stream filling it only to the mark on the cup (~40mL).
9. Void the remainder of urine into the toilet.
10. Cover the specimen with the lid touching only the outside surfaces of the lid and cup.
11. Clean any urine spilled on the outside of the cup with a clean wipe.
12. Wash hands.
13. Give specimen to clinic staff.

Urine Collection
Clean-Catch Mid-Stream Procedure for Men

Barcoded sterile 60mL urine cup

3 Saline wipes

1. Wash hands thoroughly.
2. Remove the lid of the cup, being careful not to touch the inside of the lid or the inside of the cup.
3. Cleanse the end of the penis with the wipe provided, beginning at the urethral opening and working away from it in a circular motion (the foreskin of an uncircumcised male must first be retracted). Repeat the procedure with a clean wipe.
4. Discard the used wipes.
5. Keeping the foreskin retracted, void into the toilet for a few seconds.
6. Touching only the outside of the urine cup and without letting it touch the penis, bring the urine cup into the urine stream filling it only to the mark on the cup (~40mL).
7. Void the remainder of urine into the toilet.
8. Cover the specimen with the lid touching only the outside surfaces of the lid and cup.
9. Clean any urine spilled on the outside of the cup with a clean wipe.
10. Wash hands.
11. Give specimen to clinic staff.

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F MB Female Urine Specimen Acquisition Tracking Form

Affix
MB 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) If appropriate, perform urinalysis on VB2 in a urinalysis tube using a dipstick and record the results, then discard urinalysis tube.
4) Invert the urine cups 3 times and transfer each urine specimen to the respective orange top 50 ml labeled conical tube provided.
5) Immediately store the 50 ml tubes in a -80°C freezer until shipment. Record the time the tubes were placed in the freezer.
6) 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: ☐☐ **(mL)**

VB2 Volume: ☐☐ **(mL)**

☐ **Urinalysis (VB2)**

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

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:

Female Urine Specimen Collection
Clean-Catch First-Stream and Mid-Stream Procedure

2 Barcoded sterile 60mL urine cups

- First void cup has a Yellow(VB1) sticker
- Mid-stream cup has a Green(VB2) sticker

4 Saline wipes

1. Wash hands thoroughly.
2. Remove the lids of the cups with the yellow(VB1) and green(VB2) stickers, being careful not to touch the inside of the lids or the inside of the cups throughout the rest of the urine collection.
3. Stand in a squatting position over the toilet.
4. Separate the folds of skin around the urinary opening.
5. Cleanse the area on left and right side and around the opening with the wipes, using a fresh wipe for each area and wiping from front to back.
6. Discard the used wipes.
7. Keep the skin folds separated.
8. Touching only the outside of the cup and without letting it touch the genital area collect the initial stream of urine in the urine cup with the yellow(VB1) sticker filling it only to the mark on the cup (~20mL).
9. Without stopping the flow of urine, bring the urine cup with the green(VB2) sticker into the urine stream filling it only to the mark on the cup (~40mL).
10. Void the remainder of urine into the toilet.
11. Cover the specimens with the lids touching only the outside surfaces of the lids and cups.
12. Clean any urine spilled on the outside of the cups with a clean wipe.
13. Wash hands.
14. Give specimen to clinic staff.

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MB Male Urine Specimen Acquisition Tracking Form

Affix **MB 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☐☐ (MM / DD / YY)

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) If appropriate, perform urinalysis on VB2 in a urinalysis tube using a dipstick and record the results, then discard urinalysis tube.
4) Invert the urine cups 3 times and transfer the collected urine specimen to the respective 50 ml barcode labeled orange top conical tube provided.
5) Immediately store the 50 ml tubes in the -80°C freezer until shipment. Record the time the tubes were placed in the freezer.
6) 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.
7) Invert the urine cup 3 times and transfer the collected urine to the 50 ml barcode labeled orange top conical tube provided.
8) Immediately store the 50 ml tube in a -80°C freezer until shipment. Record the time the tubes were placed in the freezer.
9) Ship specimens to the TATC and record shipment date.

VB1 & VB2

Collection time: ☐☐:☐☐ (24 hrs) (HH:MM)

Time placed in freezer: ☐☐:☐☐ (24 hrs) (HH:MM)

VB1 Volume: ☐☐ **(mL)**

VB2 Volume: ☐☐ **(mL)**

VB3

Collection time: ☐☐:☐☐ (24 hrs) (HH:MM)

Time placed in freezer: ☐☐:☐☐ (24 hrs) (HH:MM) **VB3 Volume:** ☐☐ **(mL)**

☐ **Urinalysis (VB2)**

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

Date shipped: ☐☐ / ☐☐ / 20☐☐ (MM / DD / YY)

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☐☐ (MM / DD / YY)

Time received: ☐☐:☐☐ (24 hrs) (HH:MM)

Time stored: ☐☐:☐☐ (24 hrs) (HH:MM)

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:

Male Urine Specimen Collection
Clean-Catch First-Stream and Mid-Stream Procedure

2 Barcoded sterile 60mL urine cups

- First void cup has a Yellow(VB1) sticker
- Mid-stream cup has a Green(VB2) sticker

4 Saline wipes

1. Wash hands thoroughly.
2. Remove the lids of the cups with the yellow(VB1) and green(VB2) stickers, being careful not to touch the inside of the lids or the inside of the cups throughout the rest of the urine collection.
3. Cleanse the end of the penis with the wipe provided, beginning at the urethral opening and working away from it in a circular motion (the foreskin of an uncircumcised male must first be retracted). Repeat the procedure with a clean wipe.
4. Discard the used wipes.
5. Keep the foreskin retracted.
6. Touching only the outside of the cup and without letting it touch the penis collect the initial stream of urine in the urine cup with the yellow(VB1) sticker filling it only to the mark on the cup (~20mL).
7. Without stopping the flow of urine, bring the urine cup with the green(VB2) sticker into the urine stream filling it only to the mark on the cup (~40mL)
8. Void the remainder of urine into the toilet.
9. Cover both specimens with the lids touching only the outside surfaces of the lids and cups.
10. Clean any urine spilled on the outside of the cups with a clean wipe.
11. Wash hands.
12. Give specimen to clinic staff.

Male Urine Specimen Collection
Clean-Catch First-Stream Procedure after Prostatic Massage

Barcoded sterile 60mL urine cup

- First void post prostate massage cup has a Blue(VB3) sticker

3 Saline wipes

1. After your doctor has performed a prostate massage, wash hands thoroughly.
2. Remove the lid of the cup with the blue(VB3) sticker being careful not to touch the inside of the lid or the inside of the cup throughout the rest of the urine collection.
3. As before, cleanse the end of the penis with the wipe provided, beginning at the urethral opening and working away from it in a circular motion (the foreskin of an uncircumcised male must first be retracted). Repeat the procedure with a clean wipe.
4. Keep the foreskin retracted.
5. Touching only the outside of the cup and without letting it touch the penis collect the initial stream of urine in the urine cup with the blue(VB3) sticker filling it only to the mark on the cup (~20mL).
6. Void the remainder of urine into the toilet.
7. Cover the specimen with the lid touching only the outside surfaces of the lid and cup.
8. Clean any urine spilled on the outside of the cup with a clean wipe.
9. Wash hands.
10. Give specimen to clinic staff.

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MAPP II SPS

Rectal Swab Specimen Acquisition Tracking Form

Affix **Rectal 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 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 #:**	__ __ __ __	**Research Coordinator ID:** ___ ___ ___ ___ (4-digit ID)
Discovery Site:	__ __	**Clinical Center:**	__ __	
CRF Date:	__ __/__ __/__ __ __ __	**Visit #:**	__ __	**Were swab specimens 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 -80°C: ☐☐ : ☐☐ (24 hrs) (H H : M M)

1) Confirm that a specimen was collected, record header information, RC ID, and collection date and time above. Check kit contents and place the kit barcode in the upper right hand corner of this sheet.
2) Collect 3 rectal swabs and place all 3 swabs into the pre-labeled, sterile swab tube containing buffer.
3) Mix briefly, and visually confirm that the samples on the swab tips are in direct contact with the buffer.
4) Stand the tube upright for 5 minutes to ensure the swabs absorb the buffer before freezing.
5) Store the tube upright at -80°C until shipment and record the time the tube was stored at -80°C.
6) Ship the 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)

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

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

# of rectal swabs received:

Tube ID | R | S | W | 0 | 0 | | | | | |

Specimen comments:

None ☐

Data entry comments:

None ☐ Data entry complete ☐

Initials of processing tech:

Initials of data entry tech:

Vaginal Swab Specimen Acquisition Tracking Form

Affix **Vaginal 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 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 #:**	__ __ __ __	**Research Coordinator ID:** ___ ___ ___ ___ (4-digit ID)	
Discovery Site:	__ __	**Clinical Center:**	__ __		
CRF Date:	__ __/__ __/__ __ __ __	**Visit #:**	__ __	**Were swab specimens 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 -80°C: ☐☐ : ☐☐ (24 hrs) (H H : M M)

1) Confirm that a specimen was collected, record header information, RC ID, and collection date and time above. Check kit contents and place the kit barcode in the upper right hand corner of this sheet.
2) Collect 3 vaginal swabs and place all 3 swabs into the pre-labeled, sterile swab tube containing buffer solution.
3) Mix briefly, and visually confirm that the samples on the swab tips are in direct contact with the buffer solution.
4) Stand the tube upright for 5 minutes to ensure the swabs absorb the buffer solution before freezing.
5) Store the tube upright at -80°C until shipment and record the time the tube was stored at -80°C.
6) Ship the 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)

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

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

# of vaginal swabs received:

Tube ID | V | S | W | 0 | 0 | | | | | |

Specimen comments:

None ☐

Data entry comments:

None ☐ Data entry complete ☐

Initials of processing tech:

Initials of data entry tech:

MAPP research network
MAPP II SPS

PID: ___ ___ ___ ___ ___ ___

Discovery Site: ___ ___

3 Day Salivette Collection Tracking Form

Collection Instructions (also see detailed instructions on reverse page):

1. Collect 2 samples a day for 3 days according to the salivette instructions on the back of this form
2. Record the collection date and time (highlighted in pink) for every sample on this form
3. Refrigerate all salivettes in the refrigerator until you return them in the pre-labeled envelope included in the kit.

Affix **Salivette** Collection Kit Barcode here

AM Day 1

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

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

AM Collection time: ☐☐ : ☐☐ (H H : M M)

☐ Not Collected

Affix **Salivette** Barcode here

PM Day 1

PM Collection time: ☐☐ : ☐☐ (H H : M M)

☐ Not Collected

Affix **Salivette** Barcode here

AM Day 2

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

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

AM Collection time: ☐☐ : ☐☐ (H H : M M)

☐ Not Collected

Affix **Salivette** Barcode here

PM Day 2

PM Collection time: ☐☐ : ☐☐ (H H : M M)

☐ Not Collected

Affix **Salivette** Barcode here

AM Day 3

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

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

AM Collection time: ☐☐ : ☐☐ (H H : M M)

☐ Not Collected

Affix **Salivette** Barcode here

PM Day 3

PM Collection time: ☐☐ : ☐☐ (H H : M M)

☐ Not Collected

Affix **Salivette** Barcode here

To be Completed by TATC

Complete all fields, enter data into the database and file form in the participant file. 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)

Specimen comments:

☐ None

Data entry comments:

☐ None ☐ Data entry complete

Initials of processing tech:

Initials of data entry tech:

SALIVETTE INSTRUCTIONS

You will be collecting 2 saliva samples a day for 3 days. It is important that you refrain from eating, consuming any caffeine or drinks such as milk or orange juice, and exercising for the 30 minutes prior to collecting the sample.

DAILY COLLECTION SCHEDULE

Please note that the collection tubes are labeled with the day and time of day that the saliva sample should be collected (ex. AM Day 1 & PM Day 1). Please be sure to use the appropriate tube for each collection.

- **AM**- The first sample is collected immediately upon waking (between 4am and 9am). Collect this sample BEFORE breakfast, drinking coffee and brushing your teeth.

- **PM**- The second sample is collected at bedtime (between 8pm and midnight) BEFORE brushing your teeth. (Please allow 30 minutes after eating)

1. Pop the plastic cap off of the plastic tube and remove the cotton swab.
2. Place cotton swab in your mouth for one to two minutes. You can gently chew on it to increase your flow of saliva.
3. When the cotton swab is soaked with saliva, place it back into its container and close the cap tightly.

Please note that your tubes may appear slightly different from the ones pictured here

4. Please write the date and time on the tracking form provided with the collection kit. If you happen to miss a scheduled collection, record the **actual** date and time (highlighted in pink) the sample was collected.
5. If no sample was collected, mark the "not collected" checkbox for that collection.
6. Store the salivettes in the refrigerator at the end of each collection in the zipper bag provided.

Salivette Sample Shipping

1. Once all samples have been completed at the end of the 3 day period seal the zipper bag full of collected salivettes and place them along with this completed tracking form in the pre-addressed envelope included with your kit. Place any unused tubes or materials in the envelope.
2. Seal the envelope.
3. Drop off the pre-addressed envelope in the nearest US Postal Service mail box. Please go to the US Postal service website (www.usps.com) if you have problems locating a drop-off location.

MAPP Research Coordinator Contact Information:

DO NOT write your name, address, phone number, or any personal information on any of the forms, supplies, or shipping materials provided.

MAPP research network
MAPP II SPS

PID: ___ ___ ___ ___ ___ ___

Discovery Site: ___ ___

7 Day Salivette Collection Tracking Form

Collection Instructions (also see detailed instructions on page 3):

1. Collect 2 samples a day for 7 days according to the salivette instructions on page 3 of this form
2. Record the collection date and time (highlighted in pink) of every sample on this form
3. Refrigerate all salivettes in the refrigerator until you return them in the pre-labeled envelope included in the kit.

Affix **Salivette** Collection Kit Barcode here

Scheduled Collection date: ☐☐/☐☐/20☐☐ (M M D D Y Y) **Actual Collection date:** ☐☐/☐☐/20☐☐ (M M D D Y Y) AM Day 1 **AM Collection time:** ☐☐:☐☐ (H H M M)	☐ Not Collected Affix **Salivette** Barcode here	PM Day 1 **PM Collection time:** ☐☐:☐☐ (H H M M)	☐ Not Collected Affix **Salivette** Barcode here
Scheduled Collection date: ☐☐/☐☐/20☐☐ (M M D D Y Y) **Actual Collection date:** ☐☐/☐☐/20☐☐ (M M D D Y Y) AM Day 2 **AM Collection time:** ☐☐:☐☐ (H H M M)	☐ Not Collected Affix **Salivette** Barcode here	PM Day 2 **PM Collection time:** ☐☐:☐☐ (H H M M)	☐ Not Collected Affix **Salivette** Barcode here
Scheduled Collection date: ☐☐/☐☐/20☐☐ (M M D D Y Y) **Actual Collection date:** ☐☐/☐☐/20☐☐ (M M D D Y Y) AM Day 3 **AM Collection time:** ☐☐:☐☐ (H H M M)	☐ Not Collected Affix **Salivette** Barcode here	PM Day 3 **PM Collection time:** ☐☐:☐☐ (H H M M)	☐ Not Collected Affix **Salivette** Barcode here
Scheduled Collection date: ☐☐/☐☐/20☐☐ (M M D D Y Y) **Actual Collection date:** ☐☐/☐☐/20☐☐ (M M D D Y Y) AM Day 4 **AM Collection time:** ☐☐:☐☐ (H H M M)	☐ Not Collected Affix **Salivette** Barcode here	PM Day 4 **PM Collection time:** ☐☐:☐☐ (H H M M)	☐ Not Collected Affix **Salivette** Barcode here

MAPP research network
MAPP II SPS

PID: ___ ___ ___ ___ ___ ___

Discovery Site: ___ ___

7 Day Salivette Collection Tracking Form

Page 2

Affix **Salivette** Collection Kit Barcode here

AM Day 5

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

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

AM Collection time: ☐☐ : ☐☐ (H H : M M)

☐ Not Collected

Affix **Salivette** Barcode here

PM Day 5

PM Collection time: ☐☐ : ☐☐ (H H : M M)

☐ Not Collected

Affix **Salivette** Barcode here

AM Day 6

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

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

AM Collection time: ☐☐ : ☐☐ (H H : M M)

☐ Not Collected

Affix **Salivette** Barcode here

PM Day 6

PM Collection time: ☐☐ : ☐☐ (H H : M M)

☐ Not Collected

Affix **Salivette** Barcode here

AM Day 7

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

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

AM Collection time: ☐☐ : ☐☐ (H H : M M)

☐ Not Collected

Affix **Salivette** Barcode here

PM Day 7

PM Collection time: ☐☐ : ☐☐ (H H : M M)

☐ Not Collected

Affix **Salivette** Barcode here

To be Completed by TATC

Complete all fields, enter data into the database and file form in the participant file. 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)

Specimen comments:

☐ None

Data entry comments:

☐ None ☐ Data entry complete

Initials of processing tech:

Initials of data entry tech:

MAPP research network
MAPP II SPS

SALIVETTE INSTRUCTIONS

You will be collecting 2 saliva samples a day for 7 days. It is important that you refrain from eating, consuming any caffeine or drinks such as milk or orange juice, and exercising for the 30 minutes prior to collecting the sample.

DAILY COLLECTION SCHEDULE

Please note that the collection tubes are labeled with the day and time of day that the saliva sample should be collected (ex. AM Day 1 & PM Day 1). Please be sure to use the appropriate tube for each collection.

- **AM**- The first sample is collected immediately upon waking (between 4am and 9am). Collect this sample BEFORE breakfast, drinking coffee and brushing your teeth.

- **PM**- The second sample is collected at bedtime (between 8pm and midnight) BEFORE brushing your teeth. (Please allow 30 minutes after eating)

1. Pop the plastic cap off of the plastic tube and remove the cotton swab.
2. Place cotton swab in your mouth for one to two minutes. You can gently chew on it to increase your flow of saliva.
3. When the cotton swab is soaked with saliva, place it back into its container and close the cap tightly.

Please note that your tubes may appear slightly different from the ones pictured here

4. **Please write the date and time** (highlighted in pink) **on the tracking form provided with the collection kit**. If you happen to miss a scheduled collection, record the **actual** date and time the sample was collected.
5. If no sample was collected, mark the "not collected" checkbox for that collection.
6. Store the salivettes in the refrigerator at the end of each collection in the zipper bag provided.

Salivette Sample Shipping

1. Once all samples have been completed at the end of the 7 day period seal the zipper bag full of collected salivettes and place them along with all 3 pages of the completed tracking form in the pre-addressed envelope included with your kit. Place any unused tubes or materials in the envelope.
2. Seal the envelope.
3. Drop off the pre-addressed envelope in the nearest US Postal Service mail box. Please go to the US Postal service website (www.usps.com) if you have problems locating a drop-off location.

MAPP Research Coordinator Contact Information:

DO NOT write your name, address, phone number, or any personal information on any of the forms, supplies, or shipping materials provided.

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

ATLAS Module Initiation

Research Coordinator completes to record ATLAS Module details
at the time a Participant reports the projected start of a targeted ATLAS treatment.

1. Date of initial ATLAS clinic visit and procedures*: __ __/__ __/__ __ __ __
   MM DD YYYY

*** Please note:** The date of the initial ATLAS clinic visit serves as the initiation date for ATLAS data collection for Deep Phenotyping and bi-weekly follow-up via the online Participant Survey.

2. Initial ATLAS clinic visit designation:

   (Please indicate the corresponding clinic visit from the Visit Schedule if the first ATLAS clinic visit coincides with an established clinic visit)

   ❑1 ATLAS Baseline Visit only
   ❑2 6 Month Visit
   ❑3 12 Month Visit
   ❑4 18 Month Visit
   ❑5 24 Month Visit
   ❑6 30 Month Visit

3. Procedures completed at ATLAS Baseline Visit:

   a. Biospecimen collection ❑1 Yes ❑0 No
   b. Deep phenotyping data collection ❑1 Yes ❑0 No
   c. Neuroimaging ❑1 Yes ❑0 No
   d. QST ❑1 Yes ❑0 No

4. Please record the type of targeted ATLAS treatment to be initiated:

   ❑1 Opioid
   ❑2 Tricyclic
   ❑3 Pelvic Floor Physical Therapy
   ❑4 Alphablockers ***(Men only)***
   ❑5 Elmiron
   ❑6 Neuropathic pain treatment
   ❑7 Cystoscopy w/ hydrodistention

5. Please record the treatment initiation details below for the targeted ATLAS treatment:

Treatment Code # (from Medication Reference Tool)	Treatment Name	Typical Daily Dose	Unit	
_____	_____	_____	❑1 mg ❑2 ml/cc ❑3 tablets	❑4 capsules ❑5 tbsp ❑98 other

6. Reason for ATLAS treatment module initiation

   a. Usual urologic/pelvic pain symptoms (***non-flare***) ❑1 Yes ❑0 No
   b. Worse than usual urologic/pelvic pain symptoms (***flare***) ❑1 Yes ❑0 No
   c. Dissatisfied with current UCPPS treatment ❑1 Yes ❑0 No
   d. Other, specify: _____ ❑1 Yes ❑0 No

7. Date of treatment change: __ __/__ __/__ __ __ __
   MM DD YYYY

8. Date of first ATLAS online survey: __ __/__ __/__ __ __ __
   MM DD YYYY

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

ATLAS Module Initiation

Research Coordinator completes to record ATLAS Module details
at the time a Participant reports the projected start of a targeted ATLAS treatment.

9. Date of projected ATLAS module completion: __ __/__ __/__ __ __ __
   MM DD YYYY

10. Final ATLAS clinic visit designation:

    (Please indicate the corresponding clinic visit from the Visit Schedule if a final ATLAS clinic visit coincides with an established clinic visit)

    - ❑1 ATLAS Wk. 12 Visit only
    - ❑2 12 Month Visit
    - ❑3 18 Month Visit
    - ❑4 24 Month Visit
    - ❑5 30 Month Visit

11. RC ID ___ ___ ___ ___ (4-digit ID)

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

ATLAS Module Stop

Research Coordinator completes to record ATLAS Module details at ATLAS Week 12
or at the last completed ATLAS contact if a Participant discontinues the Module prior to ATLAS Week 12.

1. Did the Participant successfully complete the 12-week ATLAS treatment assessment module? ❑1 Yes ❑0 No

   If ***NO***, reason(s) for ATLAS module discontinuation:

   a. Participant chose to stop ATLAS due to lack of treatment response ❑1 Yes ❑0 No
   b. Treatment side effects ❑1 Yes ❑0 No
   c. Participant chose to stop ATLAS due to symptom improvement ❑1 Yes ❑0 No
   d. No longer willing/interested in participating in ATLAS ❑1 Yes ❑0 No
   e. Medical condition/event ❑1 Yes ❑0 No
   f. Physician's discretion ❑1 Yes ❑0 No
   g. Other (specify): _____ ❑1 Yes ❑0 No

2. Date of final ATLAS contact*: __ __/__ __/__ __ __ __
   MM DD YYYY

*** Please note:** The date of the final ATLAS contact serves as the stop date for the ATLAS module and allows for continuation of quarterly and semi-annual follow-up and data collection via the online Participant Survey.

3. Final ATLAS contact designation:

   (Please indicate the corresponding contact from the Visit Schedule if the final ATLAS contact coincides with an established clinic visit)

   ❑1 ATLAS Wk. 12 Visit only
   ❑2 12 Month Visit
   ❑3 18 Month Visit
   ❑4 24 Month Visit
   ❑5 30 Month Visit
   ❑6 ATLAS STOP ***prior to Wk.12***

   a. If the ATLAS module was stopped ***prior to Week 12***, please confirm the final completed ATLAS contact below:

❑1	❑2	❑3	❑4	❑5	❑6
ATLAS Week 0	ATLAS Week 2	ATLAS Week 4	ATLAS Week 6	ATLAS Week 8	ATLAS Week 10

4. Please record the treatment details below for the targeted ATLAS treatment:

Treatment Code # (from Medication Reference Tool)	Treatment Name	Typical Daily Dose	Unit	
_____	_____	_____	❑1 mg ❑2 ml/cc ❑3 tablets	❑4 capsules ❑5 tbsp ❑98 other

5. How satisfied was the Participant with this ATLAS treatment?

❑1	❑2	❑3	❑4	❑5
Very dissatisfied	Moderately dissatisfied	About equally satisfied and dissatisfied	Moderately Satisfied	Very satisfied

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

ATLAS Module Stop

Research Coordinator completes to record ATLAS Module details at ATLAS Week 12
or at the last completed ATLAS contact if a Participant discontinues the Module prior to ATLAS Week 12.

6. Procedures completed at ATLAS Week 12 clinic visit:
   a. Biospecimen collection ❑$_1$ Yes ❑$_0$ No ❑$_{99}$ N/A
   b. Deep phenotyping data collection ❑$_1$ Yes ❑$_0$ No ❑$_{99}$ N/A
   c. Neuroimaging ❑$_1$ Yes ❑$_0$ No ❑$_{99}$ N/A
   d. QST ❑$_1$ Yes ❑$_0$ No ❑$_{99}$ N/A

7. RC ID ___ ___ ___ ___ (4-digit ID)

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

MAGNETIC RESONANCE (MR) ENVIRONMENT SCREENING
(Administrative form)

RC completes this form with Participant at **Baseline Week 4**
and reviews at each Deep Phenotyping Follow-up and ATLAS visit before the MRI scan.

The MR system has a very strong magnetic field that may be hazardous to individuals entering the MR environment or MR system room if they have certain metallic, electronic, magnetic, or mechanical implants, devices, or objects. Therefore, all individuals are required to fill out this form BEFORE entering the MR environment or MR system room. Be advised, the MR system magnet is ALWAYS on.

1. Have you had prior surgery or an operation (e.g., arthroscopy, endoscopy, etc.) of any kind? ❑$_1$ Yes ❑$_0$ No

   If **Yes**, please indicate date and type of surgery:

   a. Date __ __ / __ __ / __ __ __ __

   b. Type of surgery:

   _____

2. Have you had an injury to the eye involving a metallic object (e.g., metallic slivers, foreign body)? ❑$_1$ Yes ❑$_0$ No

   a. If yes, please describe:

   _____

3. Have you ever been injured by a metallic object or foreign body (e.g., BB, bullet, shrapnel, etc.)? ❑$_1$ Yes ❑$_0$ No

   a. If yes, please describe:

   _____

4. Are you pregnant or suspect that you are pregnant? ❑$_1$ Yes ❑$_0$ No

WARNING: Certain implants, devices, or objects may be hazardous to you in the MR environment or MR system room. Do not enter the MR environment or MR system room if you have any question or concern regarding an implant, device, or object.

5. **Please indicate if you have any of the following:**

a. Aneurysm clip(s)	❑$_1$ Yes	❑$_0$ No	j. Implanted drug infusion device	❑$_1$ Yes	❑$_0$ No
b. Cardiac pacemaker	❑$_1$ Yes	❑$_0$ No	k. Any type of prosthesis or implant	❑$_1$ Yes	❑$_0$ No
c. Implanted cardioverter defibrillator (ICD)	❑$_1$ Yes	❑$_0$ No	l. Artificial or prosthetic limb	❑$_1$ Yes	❑$_0$ No
d. Electronic implant or device	❑$_1$ Yes	❑$_0$ No	m. Any metallic fragment or foreign body	❑$_1$ Yes	❑$_0$ No
e. Magnetically-activated implant or device	❑$_1$ Yes	❑$_0$ No	n. Any external or internal metallic object	❑$_1$ Yes	❑$_0$ No
f. Neurostimulation system	❑$_1$ Yes	❑$_0$ No	o. Hearing aid	❑$_1$ Yes	❑$_0$ No
g. Spinal cord stimulator	❑$_1$ Yes	❑$_0$ No	p. Other implant (Please specify)	❑$_1$ Yes	❑$_0$ No
h.Cochlear implant or implanted hearing aid	❑$_1$ Yes	❑$_0$ No	_____		
i. Insulin or infusion pump	❑$_1$ Yes	❑$_0$ No			

IMPORTANT INSTRUCTIONS

Remove all metallic objects before entering the MR environment or MR system room including hearing aids, beeper, cell phone, keys, eyeglasses, hair pins, barrettes, jewelry (including body piercing jewelry), watch, safety pins, paperclips, money clip, credit cards, bank cards, magnetic strip cards, coins, pens, pocket knife, nail clipper, steel-toed boots/shoes, and tools. Loose metallic objects are especially prohibited in the MR system room and MR environment.
Please consult the MRI Technologist or Radiologist if you have any question or concern BEFORE you enter the MR system room.

Participant:

6. I attest that the above information is correct to the best of my knowledge. I have read and understand the entire contents of this form and have had the opportunity to ask questions regarding the information on this form. ❑$_1$ Yes ❑$_0$ No

Form Information Reviewed By: Print name:_____ Signature:_____

□ MRI Technologist □ Radiologist □ Other

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

Neuroimaging Day of Scan Data and Procedures Status Confirmation

Research Coordinator completes on day of Neuroimaging Study scan
at **Baseline Week 4** and **Months 6, 18, & 36** Clinic Visits.
RC also completes at **ATLASI** Visits **61 & 67** and **ATLASII** Visits **71 & 77**.

1. Did the Participant have a Neuroimaging scan at this visit? ❑1 Yes ❑0 No

   If **No**, please complete question 1a. below and leave the rest of this form blank.
   If **Yes**, please continue to question 2 and complete the rest of this form.

   a. If **No**, confirm the reason why the Participant did not have a Neuroimaging scan at this visit:
   - ❑1 Participant not available
   - ❑2 Scan facility not available
   - ❑3 Scan Visit out of window
   - ❑98 Other (specify)

   _____

2. Does the Participant still meet all Eligibility Criteria for the Trans-MAPP Neuroimaging Study at the time of this visit? * ❑1 Yes ❑0 No

(* Please note, eligibility is documented at Screening Week 0 on the ELIG_SCAN CRF and per the guidelines of the MRI_SCREEN administrative form. Eligibility is confirmed on the day of the MRI scan by answering Question #2 above. Additional screening for eligibility is done on the day of the MRI scan per the guidelines of the MRI_SCREEN administrative form and any other applicable Magnetic Resonance screening procedures per the institution performing the MRI scan.)

3. Research Coordinator confirms Female Participant is not currently pregnant. ❑1 Yes ❑0 No ❑99 N/A
   Please record 99 – N/A for males & females who are surgically sterile or postmenopausal.

4. Please confirm Trans-MAPP SPS Study Clinic Visit for which the scan was completed
   - ❑1 Baseline Week 4
   - ❑2 Month 6 clinic visit
   - ❑3 Month 18 clinic visit
   - ❑4 Month 36 clinic visit
   - ❑_ ATLAS Initiation clinic visit
   - ❑_ ATLAS Stop clinic visit
   - ❑_ Ad Hoc DP clinic visit

5. Please record the date the scan was completed: __ __/__ __/__ __ __ __
   MM DD YYYY

9. Did the participant report taking any medication(s) for stress or anxiety symptoms at the time of this visit? ❑1 Yes ❑0 No

   If ***Yes to Q.#9:***

   a. Did the participant report taking medication(s) for stress/anxiety related to ***medical procedures in general***? ❑1 Yes ❑0 No

   b. Did the participant report taking medication(s) for stress/anxiety related to ***the MRI (or other MAPP-specific) procedure(s)***? ❑1 Yes ❑0 No

   c. Please record below the medication(s) taken for stress or anxiety symptoms:

   _____

   _____

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

Neuroimaging Day of Scan Data and Procedures Status Confirmation

Research Coordinator completes on day of Neuroimaging Study scan
at **Baseline Week 4** and **Months 6, 18, & 36** Clinic Visits.
RC also completes at **ATLASI** Visits **61 & 67** and **ATLASII** Visits **71 & 77**.

6. Were ***ALL*** Neuroimaging procedures completed during the scan? ❑1 Yes ❑0 No

   If **Q.#6** is ***No***, please confirm the Neuroimaging procedures completed during the scan:

   a. Water ingestion procedures ❑1 Yes ❑0 No

   b. 10 minute resting state fMRI with full bladder (RS1) ❑1 Yes ❑0 No

   c. 10 minute resting state fMRI with empty bladder (RS2) ❑1 Yes ❑0 No

   d. 3D-T1 structural scan ❑1 Yes ❑0 No

   e. DTI scan ❑1 Yes ❑0 No

7. Was the Neuroimaging data successfully uploaded to UCLA? ❑1 Yes ❑0 No

   a. Please confirm the date the scan was successfully uploaded to UCLA __ __/__ __/__ __ __ __
   MM DD YYYY

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

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

Neuroimaging Data Collection CRF

For ***SPS Pt.s*** Research Coordinator completes on day of Neuroimaging scan at **Baseline Week 4** and **Months 6, 18, & 36** Clinic Visits.
RC also completes at **ATLASI** Visits **61 & 67** and **ATLASII** Visits **71 & 77**.

For ***Neuroimaging Control Pts*.** RC completes at **Screening/Eligibility Visit & Follow-up, Month 5 Visit.**

1. First Void completed?	❑$_1$ Yes ❑$_0$ No
a. If ***No***, please explain: _____	
2. First Void Time:	___ ___ : ___ ___ (HH : MM)
3. First Void Volume:	___ ___ ___ (cc)

4. Water ingestion completed?	❑$_1$ Yes ❑$_0$ No
a. If ***No***, please explain: _____	
5. Water drink start time:	___ ___ : ___ ___ (HH : MM)
6. Water drink end time:	___ ___ : ___ ___ (HH : MM)
7. Volume of ingested water:	___ ___ ___ (cc)

8. 0-min Post Ingestion procedures completed?	❑$_1$ Yes ❑$_0$ No
a. If ***No***, please explain: _____	
9. 0-min Post Ingestion Time:	___ ___ : ___ ___ (HH : MM)
10. 0-min Post Ingestion Pain:	___ ___ (0-10)
11. 0-min Post Ingestion Urgency:	___ ___ (0-10)

12. 20-min Post Ingestion procedures completed?	❑$_1$ Yes ❑$_0$ No
a. If ***No***, please explain: _____	
13. 20-min Post Ingestion Time:	___ ___ : ___ ___ (HH : MM)
14. 20-min Post Ingestion Pain:	___ ___ (0-10)
15. 20-min Post Ingestion Urgency:	___ ___ (0-10)

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

Neuroimaging Data Collection CRF

For ***SPS Pt.s*** Research Coordinator completes on day of Neuroimaging scan
at **Baseline Week 4** and **Months 6, 18, & 36** Clinic Visits.
RC also completes at **ATLASI** Visits **61 & 67** and **ATLASII** Visits **71 & 77**.

For ***Neuroimaging Control Pts*.** RC completes at **Screening/Eligibility Visit & Follow-up, Month 5 Visit.**

16. RS1 procedures completed? ❑$_1$ Yes ❑$_0$ No
    a. If ***No***, please explain: _____
17. Pre-RS1 Time: ___ ___ : ___ ___ (HH : MM)
18. Pre-RS1 Pain: ___ ___ (0-10)
19. Pre-RS1 Urgency: ___ ___ (0-10)
20. Post-RS1 Time: ___ ___ : ___ ___ (HH : MM)
21. Post-RS1 Pain: ___ ___ (0-10)
22. Post-RS1 Urgency: ___ ___ (0-10)
23. Post-RS1: RS1 acquisition successful? ❑$_1$ Yes ❑$_0$ No
    a. If ***No***, please explain: _____

24. Post-RS1: Did the participant go to sleep: ❑$_1$ Yes ❑$_0$ No
25. Post-RS1 Void completed? ❑$_1$ Yes ❑$_0$ No
    a. If ***No***, please explain: _____
26. Post-RS1 Void Time: ___ ___ : ___ ___ (HH : MM)
27. Post-RS1 Void Volume: ___ ___ ___ (cc)

28. RS2 procedures completed? ❑$_1$ Yes ❑$_0$ No
    a. If ***No***, please explain: _____
29. Pre-RS2 Time: ___ ___ : ___ ___ (HH : MM)
30. Pre-RS2 Pain: ___ ___ (0-10)
31. Pre-RS2 Urgency: ___ ___ (0-10)

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

Neuroimaging Data Collection CRF

For ***SPS Pt.s*** Research Coordinator completes on day of Neuroimaging scan
at **Baseline Week 4** and **Months 6, 18, & 36** Clinic Visits.
RC also completes at **ATLASI** Visits **61 & 67** and **ATLASII** Visits **71 & 77**.

For ***Neuroimaging Control Pts*.** RC completes at **Screening/Eligibility Visit & Follow-up, Month 5 Visit.**

32. Post-RS2 Time: ___ ___ : ___ ___ (HH : MM)
33. Post-RS2 Pain: ___ ___ (0-10)
34. Post-RS2 Urgency: ___ ___ (0-10)
35. Post-RS2: Did the participant go to sleep: ❑$_1$ Yes ❑$_0$ No
36. Post-RS2: RS2 acquisition successful? ❑$_1$ Yes ❑$_0$ No
    a. If ***No***, please explain: _____

37. Post-T1 procedures completed? ❑$_1$ Yes ❑$_0$ No
    a. If ***No***, please explain: _____
38. Post-T1 Time: ___ ___ : ___ ___ (HH : MM)
39. Post-T1 Pain: ___ ___ (0-10)
40. Post-T1 Urgency: ___ ___ (0-10)
41. Post-T1: T1 acquisition successful? ❑$_1$ Yes ❑$_0$ No
    a. If ***No***, please explain: _____

42. Post-DTI procedures completed? ❑$_1$ Yes ❑$_0$ No
    a. If ***No***, please explain: _____
43. Post-DTI Time: ___ ___ : ___ ___ (HH : MM)
44. Post-DTI Pain: ___ ___ (0-10)
45. Post-DTI Urgency: ___ ___ (0-10)
46. Post-DTI: DTI acquisition successful? ❑$_1$ Yes ❑$_0$ No
    a. If ***No***, please explain: _____

47. Protocol Deviations? ❑$_1$ Yes ❑$_0$ No
    a. If ***Yes***, please explain: _____
    _____

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

Quantitative Sensory Testing Screening

RC completes at **Screening Week 0** to instruct Participant and confirm QST procedures for **Baseline Week 4**.

QST pre-procedure notes and instructions:

- Please refer to the QST Manual of Procedures for important details to be reviewed prior to administering QST procedures. Review history and details regarding artificial fingernails, peripheral neuropathy, and the presence of open wounds on feet and record the details in the pre-procedure diagnostic section below.
- Request that the Participant wear comfortable loose-fitting clothing for the QST procedures. If necessary, provide a gown if clothing is not comfortable enough to wear during QST procedures.
- Notify the Participant that both legs up to the knee, both forearms up to the elbow, the neck and shoulder area, and the lower front waistline area will be exposed for testing. The feet up to the ankle will be submersed in a water bath.
- Please instruct the Participant to void before QST procedures.

QST pre-procedure diagnostic questions

1. Artificial fingernails status and history for **MAST** procedures

   Please see the QST MOP section regarding artificial fingernails and review with the Participant ***prior to completing MAST procedures***.

   a. Participant has artificial fingernails — ❑$_1$ Yes ❑$_0$ No ❑$_{99}$ NA

      i. If ***Yes***, Participant agrees to continue wearing artificial fingernails for the full duration of the MAPPII SPS Study — ❑$_1$ Yes ❑$_0$ No ❑$_{99}$ NA

   b. Has Participant ***discontinued*** wearing artificial fingernails less than six months prior to enrolling in the MAPP Symptom Patterns Study? — ❑$_1$ Yes ❑$_0$ No ❑$_{99}$ NA

      If ***Yes***, ***skip MAST procedures until after Pt. has been without artificial fingernails for at least six months***.

---

2. Peripheral neuropathy for **MAST** & **Conditioned Pain Modulation** procedures

   Please see the QST MOP section regarding peripheral neuropathy and review with the Participant ***prior to completing MAST and CPM procedures***.

   a. Participant has peripheral neuropathy in **hands** which would interfere with **MAST** results. — ❑$_1$ Yes ❑$_0$ No

      If ***Yes***, ***skip MAST procedures***.

   b. Participant has peripheral neuropathy in **fee**t which would interfere with **Conditioned Pain Modulation** results. — ❑$_1$ Yes ❑$_0$ No

      If ***Yes***, ***skip CPM procedures***.

---

3. Open wounds on feet for **Conditioned Pain Modulation** procedures

   Please see the QST MOP section regarding open wounds on feet and review with the Participant ***prior to completing CPM procedures***.

   a. Participant has open wound(s) on dominant foot requiring non-dominant foot to be used for CPM testing. — ❑$_1$ Yes ❑$_0$ No

   b. Participant has open wound(s) on both feet requiring CPM testing to be skipped at the Baseline Week 4 visit. — ❑$_1$ Yes ❑$_0$ No

4. Has the Participant reviewed and consented to **MAST** procedures? — ❑$_1$ Yes ❑$_0$ No

5. Has the Participant reviewed and consented to **Segmental/Regional Mechanical Sensitivity** procedures? — ❑$_1$ Yes ❑$_0$ No

6. Has the Participant reviewed and consented to **Temporal Summation** procedures? — ❑$_1$ Yes ❑$_0$ No

7. Has the Participant reviewed and consented to **Conditioned Pain Modulation** procedures? — ❑$_1$ Yes ❑$_0$ No

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

Quantitative Sensory Testing Procedures Instructions

Administrative

RC completes at Baseline Week 4 and Months 6, 18, & 36 Clinic Visits.
RC also completes at **ATLASI** Visits 61 & 67 and **ATLASII** Visits 71 & 77.

QST CRF notes and procedural instructions

QST CRF notes and instructions:

- The Core QST Battery consists of the four separate QST measures as indicated at each section heading in bold **Roman numerals** on the QST CRF.
- **Section I, MAST** test results are captured electronically and are uploaded to the central MAST database.
- Data collection variables for **Sections II, III, and IV** are recorded on the QST CRF and entered on the electronic QST form in the Data Management System.
- All pain intensity ratings recorded on the QST CRF use a 0-100 numerical rating scale.

QST pre-procedure notes and instructions:

- Please refer to the QST Manual of Procedures for important details to be reviewed prior to administering QST procedures. Review history and details regarding artificial fingernails, peripheral neuropathy, and the presence of open wounds on feet and record the details in the pre-procedure diagnostic section of the QST CRF.
- Confirm Participant is wearing comfortable loose-fitting clothing for the QST procedures. If necessary, provide a gown if clothing is not comfortable enough to wear during QST procedures.
- Please be sure Participant has voided and is comfortable prior to QST procedures.
  Participant may void during QST procedures if necessary

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

Quantitative Sensory Testing Procedures

RC completes at Baseline Week 4 and Months 6, 18, & 36 Clinic Visits.
RC also completes at **ATLASI** Visits 61 & 67 and **ATLASII** Visits 71 & 77.

QST pre-procedure diagnostic questions

1d. Please confirm the Participants ***dominant*** thumb: ❑1 Right ❑2 Left

1. Artificial fingernails status and history for **MAST** procedures

   Please see the QST MOP section regarding artificial fingernails and review with the Participant ***prior to completing MAST procedures***.

   a. Participant has artificial fingernails ❑1 Yes ❑0 No ❑99 NA

      i. If ***Yes***, Participant agrees to continue wearing artificial fingernails for the full duration of the MAPPII SPS Study ❑1 Yes ❑0 No ❑99 NA

   b. Has Participant ***started*** wearing artificial fingernails since previous clinic visit QST procedures? ❑1 Yes ❑0 No ❑99 NA

      If ***Yes***, ***skip MAST procedures***. Data analysis will not be possible.

   c. Has Participant ***discontinued*** wearing artificial fingernails since previous clinic visit QST procedures? ❑1 Yes ❑0 No ❑99 NA

      If ***Yes***, ***skip MAST procedures***. Data analysis will not be possible.

---

2. Peripheral neuropathy for **MAST** & **Conditioned Pain Modulation** procedures

   Please see the QST MOP section regarding peripheral neuropathy and review with the Participant ***prior to completing MAST and CPM procedures***.

   a. Participant has peripheral neuropathy in **hands** which would interfere with **MAST** results. ❑1 Yes ❑0 No

      If ***Yes***, ***skip MAST procedures***.

   b. Participant has peripheral neuropathy in **fee**t which would interfere with **Conditioned Pain Modulation** results. ❑1 Yes ❑0 No

      If ***Yes***, ***skip CPM procedures***.

   c. Participant reports sensory abnormalities in either the hands or the feet but does not have diagnosed upper or lower extremity neuropathy, respectively. ❑1 Yes ❑0 No

      i. If **Yes**, please describe these abnormalities in the space below, but conduct all QST procedures as normal.

_____

_____

_____

---

3. Open wounds on feet for **Conditioned Pain Modulation** procedures

   Please see the QST MOP section regarding open wounds on feet and review with the Participant ***prior to completing CPM procedures***.

   a. Participant has open wound(s) on **non-dominant** foot requiring **dominant** foot to be used for CPM testing. ❑1 Yes ❑0 No

   b. Participant has open wound(s) on **both feet** requiring CPM testing to be skipped at this visit. ❑1 Yes ❑0 No

Quantitative Sensory Testing Procedures

RC completes at Baseline Week 4 and Months 6, 18, & 36 Clinic Visits.
RC also completes at **ATLASI** Visits 61 & 67 and **ATLASII** Visits 71 & 77.

Section I: Generalized Mechanical Sensitivity (MAST Test)

4. Was MAST familiarization protocol conducted (testing non-dominant thumb)? ❑1 Yes ❑0 No
   If **No**, please confirm why the non-dominant thumb was not tested.

   If ***Yes***, please leave the section below blank and proceed to **Q.#5**

   a. Non-dominant thumb is malformed, significantly injured, or missing requiring dominant thumb to be used for MAST familiarization. ❑1 Yes ❑0 No
   b. Participant has peripheral neuropathy in non-dominant thumb requiring dominant thumb to be used for MAST familiarization. ❑1 Yes ❑0 No
   c. Other (please specify) _____ ❑1 Yes ❑0 No

5. Were the MAST test procedures completed (testing dominant thumb)? ❑1 Yes ❑0 No

   If ***No***, please confirm why the MAST procedures were not completed.

   If ***Yes***, please leave the section below blank and proceed to **Q.#6.**

   a. Participant declined MAST procedures ❑1 Yes ❑0 No
   b. Participant's thumb too large ❑1 Yes ❑0 No
   c. Participant's hand too small ❑1 Yes ❑0 No
   d. Equipment/Technical Malfunction ❑1 Yes ❑0 No
   e. Other (please specify) _____ ❑1 Yes ❑0 No

6. Was the Participant's dominant thumb tested? ❑1 Yes ❑0 No
   If **No**, please confirm why the dominant thumb was not tested.

   a. Dominant thumb is malformed, significantly injured, or missing requiring non-dominant thumb to be used for MAST procedure. ❑1 Yes ❑0 No
   b. Participant has peripheral neuropathy in dominant thumb requiring non-dominant thumb to be used for MAST procedure. ❑1 Yes ❑0 No
   c. Other (please specify) _____ ❑1 Yes ❑0 No

7. Was MAST test procedure data successfully recorded to the MAST equipment and uploaded to the central MAST database? ❑1 Yes ❑0 No ❑99 NA

   Please record ***99/NA*** if MAST procedures were not completed.

   Please complete **Q.#7a.** below if **Q.#7** is ***No*** and MAST data was not successfully recorded and/or uploaded.

   a. Reason MAST data not recorded and/or uploaded:

   _____

Quantitative Sensory Testing Procedures

RC completes at Baseline Week 4 and Months 6, 18, & 36 Clinic Visits.
RC also completes at **ATLASI** Visits 61 & 67 and **ATLASII** Visits 71 & 77.

Section II: Segmental/Regional Mechanical Sensitivity (Algometer Test)

8. Was the **Algometer Familiarization Protocol** conducted? ❑1 Yes ❑0 No

   If **Algometer Familiarization Protocol** was ***NOT*** completed, please confirm reasons below

   a. Participant declined procedure ❑1 Yes ❑0 No

   b. Procedure too painful/uncomfortable ❑1 Yes ❑0 No

   c. Other (please specify) _____ ❑1 Yes ❑0 No

9. Were ***ALL* Segmental/Regional Mechanical Sensitivity** procedures completed? ❑1 Yes ❑0 No

   If **Q.#9** is **No**, please confirm which procedures were completed, which procedures were not completed, and reasons for procedures not completed.

   a. **Dominant forearm** (control) procedures completed? ❑1 Yes ❑0 No

      i. 2 kg __ __ __ (0 – 100) ❑99 **Not done**

      ii. 2 kg __ __ __ (0 – 100) ❑99 **Not done**

      iii. ***4 kg*** __ __ __ ***(0 – 100)*** ❑99 **Not done**

      iv. 2 kg __ __ __ (0 – 100) ❑99 **Not done**

      v. ***4 kg*** __ __ __ ***(0 – 100)*** ❑99 **Not done**

      vi. ***4 kg*** __ __ __ ***(0 – 100)*** ❑99 **Not done**

      vii. ***Calculated mean of 3 ratings of 2 kg to be generated by Biostatistics.***

      viii. ***Calculated mean of 3 ratings of 4 kg to be generated by Biostatistics.***

   If **Dominant forearm** procedures were ***NOT*** completed, please confirm reasons below

      ix. Procedure stopped early ❑1 Yes ❑0 No

      x. Procedure too painful/uncomfortable ❑1 Yes ❑0 No

      xi. Other (please specify) _____ ❑1 Yes ❑0 No

Quantitative Sensory Testing Procedures

RC completes at Baseline Week 4 and Months 6, 18, & 36 Clinic Visits.
RC also completes at **ATLASI** Visits 61 & 67 and **ATLASII** Visits 71 & 77.

b. **Suprapubic** procedures completed? ❑1 Yes ❑0 No

i. 2kg __ __ __ (0 – 100) ❑99 **Not done**

ii. 2kg __ __ __ (0 – 100) ❑99 **Not done**

iii. ***4***kg __ __ __ ***(0 – 100)*** ❑99 **Not done**

iv. 2kg __ __ __ (0 – 100) ❑99 **Not done**

v. ***4***kg __ __ __ ***(0 – 100)*** ❑99 **Not done**

vi. ***4***kg __ __ __ ***(0 – 100)*** ❑99 **Not done**

vii. ***Calculated mean of 3 ratings of 2 kg to be generated by Biostatistics.***

viii. ***Calculated mean of 3 ratings of 4 kg to be generated by Biostatistics.***

If **– Suprapubic** procedures were ***NOT*** completed, please confirm reasons below

ix. Bladder pain/discomfort too severe for procedures ❑1 Yes ❑0 No

x. Procedure stopped early ❑1 Yes ❑0 No

xi. Procedure too painful/uncomfortable ❑1 Yes ❑0 No

xii. Other (please specify) _____ ❑1 Yes ❑0 No

c. **Pressure Pain Threshold –** Trapezius threshold familiarization completed? ❑1 Yes ❑0 No

i. Threshold 1 - Left __ __ . __ (kg) ❑99 **Not done**

ii. Threshold 2 - Right __ __ . __ (kg) ❑99 **Not done**

iii. Threshold 3 - Left __ __ . __ (kg) ❑99 **Not done**

iv. Threshold 4 - Right __ __ . __ (kg) ❑99 **Not done**

v. ***Calculated mean of 4 ratings to be generated by Biostatistics.***

If **Pressure Pain Threshold – Trapezius** (control) procedures were ***NOT*** completed, please confirm reasons below

vi. Procedure stopped early ❑1 Yes ❑0 No

vii. Procedure too painful/uncomfortable ❑1 Yes ❑0 No

viii. Other (please specify)_____ ❑1 Yes ❑0 No

Quantitative Sensory Testing Procedures

RC completes at Baseline Week 4 and Months 6, 18, & 36 Clinic Visits.
RC also completes at **ATLASI** Visits 61 & 67 and **ATLASII** Visits 71 & 77.

Section III: Temporal Summation (PinPrick Test)

10. Was the **Temporal Summation Familiarization Protocol** conducted? ❑1 Yes ❑0 No

If **Temporal Summation Familiarization Protocol** was ***NOT*** completed, please confirm reasons below

i. Participant declined procedure ❑1 Yes ❑0 No

ii. Procedure too painful/uncomfortable ❑1 Yes ❑0 No

iii. Other (please specify) _____ ❑1 Yes ❑0 No

11. Were ***ALL*** **Temporal Summation** procedures completed? ❑1 Yes ❑0 No

If **Q.#11** is **No**, please confirm which procedures were completed, which procedures were not completed, and reasons for procedures not completed.

a. **Dominant Forearm (256 mN stimulator)** procedures completed? ❑1 Yes ❑0 No

i. Rating 1a – Single Stimulus __ __ __ (0 – 100) ❑99 **Not done**

ii. Rating 1b – 10 Stimuli __ __ __ (0 – 100) ❑99 **Not done**

iii. Rating 2a – Single Stimulus __ __ __ (0 – 100) ❑99 **Not done**

iv. Rating 2b – 10 Stimuli __ __ __ (0 – 100) ❑99 **Not done**

v. Rating 3a – Single Stimulus __ __ __ (0 – 100) ❑99 **Not done**

vi. Rating 3b – 10 Stimuli __ __ __ (0 – 100) ❑99 **Not done**

vii. Calculated WUR (mean of a.ii, a.iv.,a.vi. / mean of a.i., a.iii., a.v.) to be generated by Biostatistics.

viii. After-sensation rating 15 s __ __ __ (0 – 100) ❑99 **Not done**

ix. After-sensation 30 s __ __ __ (0 – 100) ❑99 **Not done**

If **Dominant Forearm (256 mN stimulator)** procedures were ***NOT*** completed, please confirm reasons below

x. Procedure stopped early ❑1 Yes ❑0 No

xi. Procedure too painful/uncomfortable ❑1 Yes ❑0 No

xii. Other (please specify) _____ ❑1 Yes ❑0 No

Quantitative Sensory Testing Procedures

RC completes at Baseline Week 4 and Months 6, 18, & 36 Clinic Visits.
RC also completes at **ATLASI** Visits 61 & 67 and **ATLASII** Visits 71 & 77.

b. **Suprapubic (256 mN stimulator)** procedures completed? ❑1 Yes ❑0 No

i. Rating 1a – Single Stimulus __ __ __ (0 – 100) ❑99 **Not done**

ii. Rating 1b – 10 Stimuli __ __ __ (0 – 100) ❑99 **Not done**

iii. Rating 2a – Single Stimulus __ __ __ (0 – 100) ❑99 **Not done**

iv. Rating 2b – 10 Stimuli __ __ __ (0 – 100) ❑99 **Not done**

v. Rating 3a – Single Stimulus __ __ __ (0 – 100) ❑99 **Not done**

vi. Rating 3b – 10 Stimuli __ __ __ (0 – 100) ❑99 **Not done**

vii. Calculated WUR (mean of b.ii, b.iv.,b.vi. / mean of b.i., b.iii., b.v.) to be generated by Biostatistics.

viii. After-sensation rating - 15 s __ __ __ (0 – 100) ❑99 **Not done**

ix. After-sensation rating - 30 s __ __ __ (0 – 100) ❑99 **Not done**

If **Suprapubic (256 mN stimulator)** procedures were ***NOT*** completed, please confirm reasons below

x. Procedure stopped early ❑1 Yes ❑0 No

xi. Procedure too painful/uncomfortable ❑1 Yes ❑0 No

xii. Other (please specify) _____ ❑1 Yes ❑0 No

IV. Conditioned Pain Modulation

12. Were ***ALL*** **Conditioned Pain Modulation** procedures completed? ❑1 Yes ❑0 No

If **Q.#12** is **No**, please confirm which procedures were completed, which procedures were not completed, and reasons for procedures not completed.

a. ***Note: Original Q.#12a. section removed per confirmation from QST working group.**

b. **Test Stimulus Calibration**

i. Initial Pain40 pressure __ __ . __ __ (kg)

ii. Initial Pain40 pre-test rating __ __ __ (0 – 100)

iii. Final adjusted Pain40 Pressure __ __ . __ __ (kg) ❑99 **N/A**

iv. Final adjusted Pain40 pre-test rating __ __ __ (0 – 100) ❑99 **N/A**

v. Number of adjustments required __ __ ❑99 **N/A**

Quantitative Sensory Testing Procedures

RC completes at Baseline Week 4 and Months 6, 18, & 36 Clinic Visits.
RC also completes at **ATLASI** Visits 61 & 67 and **ATLASII** Visits 71 & 77.

c. **Test Stimulus Alone (30-s, dominant thumb, Pain40 pressure)** procedures completed? ❑1 Yes ❑0 No

i. Rating 1 - 10 s __ __ __ (0 – 100) ❑99 **Not done**

ii. Rating 2 - 20 s __ __ __ (0 – 100) ❑99 **Not done**

iii. Rating 3 - 30 s __ __ __ (0 – 100) ❑99 **Not done**

iv. Calculated mean of 3 test stimulus ratings to be generated by Biostatistics.

v. Calculated Pressure Summation (c.iii. - c.i.) to be generated by Biostatistics.

If **Test Stimulus Alone (30-s, Pain40 thumb pressure)** procedures were ***NOT*** completed, please confirm reasons below

vi. Procedure stopped early ❑1 Yes ❑0 No

vii. Procedure too painful/uncomfortable ❑1 Yes ❑0 No

viii. Other (please specify) _____ ❑1 Yes ❑0 No

d. **Test Stimulus + Neutral Conditioning Stimulus (60-s, 32 °C neutral foot bath, non-dominant foot)** procedures completed? ❑1 Yes ❑0 No

i. Ratings of Neutral Conditioning Stimulus (foot bath)

1. Rating 2 - 10 s __ __ __ (0 – 100) ❑99 **Not done**
2. Rating 3 - 25 s __ __ __ (0 – 100) ❑99 **Not done**
3. Rating 4 - 60 s __ __ __ (0 – 100) ❑99 **Not done**
4. ***Calculated mean of 3 ratings to be generated by Biostatistics.***

ii. Ratings of Test Stimulus (thumb)

1. Rating 1 – 40 s __ __ __ (0 – 100) ❑99 **Not done**
2. Rating 2 – 50 s __ __ __ (0 – 100) ❑99 **Not done**
3. Rating 3 – 60 s __ __ __ (0 – 100) ❑99 **Not done**
4. ***Calculated mean of 3 test stimulus ratings to be generated by Biostatistics.***

If **Test Stimulus + Neutral Conditioning Stimulus (60-s, neutral foot bath)** procedures were ***NOT*** completed, please confirm reasons below

iii. Procedure stopped early ❑1 Yes ❑0 No

iv. Procedure too painful/uncomfortable ❑1 Yes ❑0 No

v. Other (please specify) _____ ❑1 Yes ❑0 No

Quantitative Sensory Testing Procedures

RC completes at Baseline Week 4 and Months 6, 18, & 36 Clinic Visits.
RC also completes at **ATLASI** Visits 61 & 67 and **ATLASII** Visits 71 & 77.

e. **Painful Conditioning Stimulus Calibration**

i. Initial hot water temperature: (°C) __ __ . __ (°C)

ii. Initial hot water rating __ __ __ (0 – 100)

iii. Final adjusted water temperature (46.5 °C max) __ __ . __ (°C) ❑99 **N/A**

iv. Final adjusted rating __ __ __ (0 – 100 ❑99 **N/A**

v. Number of adjustments required __ __ ❑99 **N/A**

vi. Was the immersion circulator repositioned to provide direct water flow onto foot? ❑1 Yes ❑0 No

f. **Test Stimulus + Painful Conditioning Stimulus (60-s, hot foot bath, non-dominant foot)** procedures completed? ❑1 Yes ❑0 No

i. Ratings of Painful Conditioning Stimulus (foot bath)

1. Rating 2 - 10 s __ __ __ (0 – 100) ❑99 **Not done**
2. Rating 3 - 25 s __ __ __ (0 – 100) ❑99 **Not done**
3. Rating 4 - 60 s __ __ __ (0 – 100) ❑99 **Not done**
4. ***Calculated mean of 3 ratings to be generated by Biostatistics.***

ii. Ratings of Test Stimulus (thumb)

1. Rating 1 – 40 s __ __ __ (0 – 100) ❑99 **Not done**
2. Rating 2 – 50 s __ __ __ (0 – 100) ❑99 **Not done**
3. Rating 3 – 60 s __ __ __ (0 – 100) ❑99 **Not done**
4. ***Calculated mean of 3 test stimulus ratings to be generated by Biostatistics.***

If **Test Stimulus + Painful Conditioning Stimulus (60-s, hot foot bath)** procedures were ***NOT*** completed, please confirm reasons below

iii. Procedure stopped early ❑1 Yes ❑0 No

iv. Procedure too painful/uncomfortable ❑1 Yes ❑0 No

v. Other (please specify) _____ ❑1 Yes ❑0 No

g. ***CPM Magnitude*** *(calculated variables)*

i. Neutral (Sham) Conditioning (d.ii.4. – c.iv.) __ __ __ (0 – ±100) ***to be generated by Biostatistics.***

ii. Painful Conditioning (f.ii.4. - c.iv.) __ __ __ (0 – ±100) ***to be generated by Biostatistics.***

iii. CPM relative effect (f.ii.4. – d.ii.4) __ __ __ (0 – ±100) ***to be generated by Biostatistics.***

13. Comments: _____

_____

_____

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

Ad-Hoc Deep Phenotyping Visit Initiation

Research Coordinator completes to record details for an ad-hoc Deep Phenotyping clinic visit in the event that a regularly scheduled Deep Phenotyping clinic visit was missed.

*** Please note:** The date of the ad-hoc Deep Phenotyping clinic visit as recorded in the CRF Date on this form serves as the initiation date for Participant Survey data collection at this ad-hoc Deep Phenotyping clinic visit.

---

1. MAPPII SPS Deep Phenotyping clinic visit for which this ad-hoc Deep Phenotyping clinic visit will serve as a substitute:

   ❑1 6 Month Visit **(Ad-hoc V.#81)**
   ❑2 18 Month Visit **(Ad-hoc V.#82)**
   ❑3 36 Month Visit **(Ad-hoc V.#83)**

2. Reason for ad-hoc Deep Phenotyping visit initiation

   a. Participant missed originally scheduled Deep Phenotyping visit ❑1 Yes ❑0 No

   b. Other (specify): _____

      _____

3. RC ID ___ ___ ___ ___ (4-digit ID)

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

Ad-Hoc Deep Phenotyping Visit Stop

Research Coordinator completes to record details for an ad-hoc Deep Phenotyping clinic visit in the event that a regularly scheduled Deep Phenotyping clinic visit was missed.

*** Please note:** The CRF Date on this form serves as the **stop date** for the ad-hoc Deep Phenotyping clinic visit. Once this CRF is saved in the DMS, the original MAPPII SPS visit schedule will apply for all subsequent visits from this CRF Date.

1. Did the Participant successfully complete the ad-hoc Deep Phenotyping clinic visit? ❑1 Yes ❑0 No

   If ***NO***, reason(s) for incomplete ad-hoc Deep Phenotyping clinic visit:

   a. Participant not seen at this visit ❑1 Yes ❑0 No
   b. Participant chose to withdraw at this visit ❑1 Yes ❑0 No
   c. Medical condition/event ❑1 Yes ❑0 No
   d. Other (specify): _____ ❑1 Yes ❑0 No

2. Procedures completed at this ad-hoc Deep Phenotyping clinic visit:

   a. Biospecimen collection ❑1 Yes ❑0 No
   b. Deep phenotyping data collection ❑1 Yes ❑0 No
   c. Neuroimaging ❑1 Yes ❑0 No
   d. QST ❑1 Yes ❑0 No

3. Comments: _____

   _____

   _____

4. RC ID ___ ___ ___ ___ (4-digit ID)

MAPP research network MAPP II SPS	**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).

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

Comments Sheet

Administrative

Use the table below to list comments for a Visit or a CRF

Visit # / CRF Question	Comment