# **Enrollment Assessment**

Ν	Month Day Yea	r						
#	Field Name	Lookup S	et 7	Гуре	Lengt	n Ra	ange Ch	ecks
1	DateScreen		DAT	TETIME		No	o range ch	necks
	ubject irst Name			Last Nam	e			
			up Set	Тур	e	Leng	th Ran	ge Checks
#	Field Nan	ie Look	up sei	- J P				
# 1			up set	NVARC		50	No ra	ange checks
1	PatientFirstN	ame		• •	HAR	50 50		ange checks
1 2 M #	PatientFirstN PatientLastN Iedical Record N	ame ame Jumber J <b>ame</b>	Looku	NVARC NVARC	HAR HAR Type	50	No ra	ange checks Range Checks
1 2 M	PatientFirstN PatientLastN Iedical Record N	ame ame Jumber J <b>ame</b>	-	NVARC NVARC	HAR HAR	50	No ra	ange checks
1 2 M 	PatientFirstN PatientLastN Iedical Record N	ame ame Jumber J <b>ame</b>	-	NVARC NVARC	HAR HAR Type	50	No ra	ange checks Range Checks
1 2 M 	PatientFirstN PatientLastN PatientLastN Field N MedicalReco fedical Provider	ame	Looku	NVARC NVARC	HAR HAR Type	50 IAR	No ra	ange checks Range Checks No range checks

#	Field Name	Lookup Set	Туре	Length	Range Checks
1	DateOfBirth		DATETIME		No range checks

Sex: (an answer is required before the patient can appear as Eligible)

- 0 ---
- O Male
- Female

#	Field Name		Lo	ookup Set	Туре	Length	Range Checks
		Name Gene		mt <i>SASFmt:</i>			
1	Gender	Val	Text	Culture Suppression	SMALLINT		No range checks
		-1					checks
		1	Male				
		2	Female				

Race (select all that apply):

**—**…

3

- American Indian or Alaska Native
- ---- Asian/Asian American
- Black or African American
- ---- Native Hawaiian or other Pacific Islander
- White
- ---- Other
- 🛄 🔲 Unknown

#	Field Name		Lookup Set		Туре	Length	Range Checks
1	Race	Nam	e: Race SASFmt: Race	NVARCHAR	200	No range	
		Val	Text	Culture Suppression			checks
		-1					
		1	American Indian or Alaska Native				
		2	Asian/Asian American				
		3	Black or African American				

4	Native Hawaiian or other Pacific Islander		
5	White		
6	Other		
97	Unknown		

Ethnicity:

O ---

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- O Hispanic or Latino
- Not Hispanic or Latino
- Unknown

#	Field Name		Lookup S	Set	Туре	Length	Range Checks
		Nam	e: \$EthHisp SASFmt	: \$EthHisp			
		Val	Text	Culture Suppression			
		-1					No range
1	Ethnicity	1	Hispanic or Latino		SMALLINT		checks
		2	Not Hispanic or Latino				
		3	Unknown				

Education:

O ---

- Less than HS diploma/GED
- HS diploma/GED
- Some college or tech school, no degree
  - Associate's degree
  - O Bachelor's degree
  - Graduate degree
  - Unknown

#	Field Name	Lookup Set	Туре	Length	Range Checks
1	Education	Name: Education SASFmt: Education	SMALLINT		No range
					checks

Val	Text	Culture Suppression		
-1				
1	Less than HS diploma/GED			
2	HS diploma/GED			
3	Some college or tech school, no degree			
4	Associate's degree			
5	Bachelor's degree			
6	Graduate degree			
97	Unknown			

- Employment: --Employed part-time Employed full-time Unemployed (looking for work) Not employed (not looking for work, includes stay-at-home, retired) Unknown

#	Field Name		Lookup Set		Туре	Length	Range Checks
1	1 EmplymentStat		e: EmplStat SASFmt: ]	EmplStat	SMALLINT		No range
		Val	Text	Culture Suppression			checks
		-1					
		1	Employed part-time				
		2	Employed full-time				
		3	Unemployed (looking for work)				
		4	Not employed (not looking for work, includes stay-at- home, retired)				
		97	Unknown				

- Marital Status:
- 0 --
- O Married/civil union

- Marned civil union
  Living with a partner
  Separated or divorced
  Widowed
  Single, never married
  Unknown

#	Field Name		Lookup	Set	Туре	Length	Range Checks
		Nam	e: MariStat SASFmi	t: MariStat			
		Val	Text	Culture Suppression			
		-1					
		1	Married/civil union				
1	MaritalStat	2	Living with a partner		SMALLINT		No range checks
		3	Separated or divorced				
		4	Widowed				
		5	Single, never married				
		97	Unknown				

Is this patient being screened for the Neuroimaging Sensory and Testing protocol only?

0 ---

8

- O No
- Yes

#	Field Name		Ι	Lookup Set	Туре	Length	Range Checks
1	ScreenNIOnly	Nam	e: Yesl	No SASFmt: YesNo	SMALLINT		No range checks
		Val	Text	Culture Suppression			
		-1					

0	No		
1	Yes		

Is this a previously/currently enrolled LURN Observational patient?

- 0 --
- YesNo

#	Field Name		Ι	ookup Set	Туре	Length	Range Checks
	PreviousPatient	Name: NoYes SASFmt: NoYes					
1		Val	Text	Culture Suppression	SMALLINT		No range
1		-1			SWALLINT		checks
		1	Yes				
		0	No				

10

If yes, please specify patient's existing LURN Study ID:

#	Field Name	Lookup Set	Туре	Length	Range Checks
1	PrevStudyID		NVARCHAR	5	No range checks

B. Inclusion Criteria

Is the participant presenting for new or returning patient visits for evaluation of treatment of LUTS to one of the LURN physicians?

O --

1

- No
  Yes, new patient
  Yes, returning patient
- O Unknown

#	Field Name	Lookup Set	Туре	Length	Range Checks
1	NewPat	<i>Name:</i> PatientNewRet <i>SASFmt:</i> PatientNewRet	SMALLINT		No range checks

Val	Text	Culture Suppression	
-1			
0	No		
1	Yes, new patient		
3	Yes, returning patient		
2	Unknown		

- Is the participant 18 years of age or older? 0 ---
- No

- Field # Lookup Set Туре Length **Range Checks** Name Name: \$Edema SASFmt: \$Edema Culture Val || Text Suppression No range 1 PatAdult -1 **SMALLINT** -checks 0 No 1 Yes 2 Unknown
- Does the participant have the ability to give informed consent?
- 0 ---
- No
- Yes
- Unknown

;	#	Field Name		L	ookup Set	Туре	Length	Range Checks
	1	PatConsent	Name	e: \$Edem	a <i>SASFmt:</i> \$Edema	SMALLINT		No range checks
			Val	Text	Culture Suppression			

2

- Yes
  - Unknown

-1			
0	No		
1	Yes		
2	Unknown		

Does the participant have the ability to complete self-reported questionnaires electronically? ○ ---

4

- No Yes
- Unknown

#	Field Name		Loo	kup Set	Туре	Length	Range Checks
	PatQuesElec	Name: \$Edema SASFmt: \$Edema					
		Val	Text	Culture Suppression			No range checks
1		-1			SMALLINT		
		0	No				
		1	Yes				
		2	Unknown		j		

# C. Exclusion Criteria

Does the participant have gross hematuria?

- O ---
- No Yes

Unknown

#	Field Name		Lool	cup Set	Туре	Length	Range Checks
1	PatHematuria	Nam	e: \$Edema S	SMALLINT		No range checks	
		Val	Text	Culture Suppression			
		-1					

0	No		
1	Yes		
2	Unknown		

Does the participant have significant neurologic disease or injury? (Alzheimer's dementia, Parkinson's disease, spinal cord injury, multiple sclerosis, etc.)

- 2 One Section Contract Contrac

#	Field Name		Loo	kup Set	Туре	Length	Range Checks
		Nam	e: \$Edema S	SASFmt: \$Edema			
	PatNeurDis	Val Text		Culture Suppression			
1		-1			SMALLINT		No range checks
		0         No           1         Yes					
		2	Unknown				

3 Is the participant's primary complaint pelvic pain? 3 No Yes Unknown

#	Field Name		Loo	kup Set	Туре	Length	Range Checks
1	PatPelPain	Nam	e: \$Edema S	SASFmt: \$Edema	SMALLINT		No range checks
		Val	Text	Culture Suppression			
		-1					
		0	No				
		1	Yes				

2

Has the participant been diagnosed with interstitial cystitis, chronic prostatitis, or chronic orchialgia?

- No
- Yes
- O Unknown

#	Field Name		Look	cup Set	Туре	Length	Range Checks
		Name: \$Edema SASFmt: \$Edema					
		Val	Text	Culture Suppression			
1	PatCisProsOrch	-1			SMALLINT		No range checks
		0	No				
		1 Yes					
		2	Unknown				

Has the participant had a pelvic or endoscopic GU surgery within the past 6 months? (Not including diagnostic cystoscopy)

O ---

5

- No
- Yes
- Unknown

#	Field Name		Loo	kup Set	Туре	Length	Range Checks
		Nam	e: \$Edema S	SASFmt: \$Edema	SMALLINT		No range checks
		Val	Text	Culture Suppression			
1	PatGUSurg	-1					
		0	No				
		1	Yes				
		2	Unknown				

-No
Yes
Unknown

#	Field Name		Looki	ıp Set	Туре	Length	Range Checks
		<i>Name:</i> \$Edema <i>SASFmt:</i> \$Edema					
		Val	Text	Culture Suppression			No range
1	PatSympUrethStric	-1			SMALLINT		checks
		0	No				
		1	Yes				
			Unknown				

Does the participant have a history of lower urinary tract or pelvic malignancy?

Does the part
-No
Yes
Unknown

#	Field Name		Look	up Set	Туре	Length	Range Checks
		Name: \$Edema SASFmt: \$Edema					
		Val	Text	Culture Suppression			
1	PatHxLUTPMalig	-1			SMALLINT		No range checks
		0	No				
		1	Yes				
		2	Unknown				

Is the participant currently undergoing chemotherapy or other cancer therapy?

- In the period
  In the period
  No
  Yes

8

YesUnknown

#	Field Name		Look	sup Set	Туре	Length	Range Checks
		Nam	e: \$Edema S	SASFmt: \$Edema			
		Val	Text	Culture Suppression			
1	PatCancerTher	-1			SMALLINT		No range checks
		0	No				
		1	Yes				
		2	Unknown				

Does the participant have a pelvic device or implant complication? (e.g. sling or mesh complications) 0 ---

- No Yes
- O Unknown

#	Field Name		Lool	Туре	Length	Range Checks	
		Name: \$Edema SASFmt: \$Edema					
		Val	Text	Culture Suppression			
1	PatImpCompl	-1			SMALLINT		No range checks
		0	No				
		1	Yes				
		2	Unknown				

Does the participant currently have a functioning neurostimulator?

10

- Does the part
  -No
  Yes
  Unknown

#	Field Name	Lookup Set	Туре	Length	Range Checks
1	NeuroStimulator	Name: \$Edema SASFmt: \$Edema	SMALLINT		No range

				checks
Val	Text	Culture Suppression		
-1				
0	No			
1	Yes			
2	Unknown			

Has the participant had a Botox injection to the bladder or pelvic structures within the past 12 months? 11 No Ves Unknown

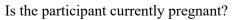
#	Field Name		Loo	kup Set	Туре	Length	Range Checks
	PatBotox	Name: \$Edema SASFmt: \$Edema					
		Val	Text	Culture Suppression			No range checks
1		-1			SMALLINT		
		0	No				
		1	Yes				
		2	Unknown				

Has the participant had a prostate biopsy in the past 3 months?

- Inas the partie
  Inas the partie
  No
  Yes
  Unknown

#	Field Name		Loo	kup Set	Туре	Length	Range Checks
1	PatProsBx	Name	e: \$Edema S	SASFmt: \$Edema	SMALLINT		No range checks
		Val	Text	Culture Suppression			
		-1					

0	No		
1	Yes		
2	Unknown		



- O ---
- No Yes
- Unknown

#	Field Name		Loo	kup Set	Туре	Length	Range Checks
	PatPreg	Name	e: \$Edema S	SASFmt: \$Edema			
		Val	Text	Culture Suppression			
1		-1			SMALLINT		No range checks
		0	No				
		1	Yes				
		2	Unknown				

Does the participant have a history of cystitis caused by tuberculosis, radiation therapy, or Cytoxan / cyclophosphamide therapy?

O ---

- No
- Yes
- O Unknown

#	Field Name		Lool	kup Set	Туре	Length	Range Checks
1	PatHxCystitis	Nam	e: \$Edema S	SMALLINT		No range checks	
		Val	Text	Culture Suppression			
		-1					
		0	No				
		1	Yes				

14

2

Has the participant had an augmentation cystoplasty or cystectomy?

0 ---

15

- No

YesUnknown

#	Field Name	Lookup Set			Туре	Length	Range Checks
		Name: \$Edema SASFmt: \$Edema					
		Val	Text	Culture Suppression			
1	PatCysPlasEctomy	-1			SMALLINT		No range checks
		0	No				
		1	Yes				
		2	Unknown				

Does the participant have a urinary tract fistula?

Does the participation
-No
Yes
Unknown

#	Field Name		Loo	kup Set	Туре	Length	Range Checks
		Nam	e: \$Edema S	SASFmt: \$Edema			
		Val	Text	Culture Suppression			
1	l PatUTFist	-1			SMALLINT		No range checks
		0	No				
		1 Yes					
		2	Unknown				

Does the participant currently have a major psychiatric disorder or other psychiatric or medical issues that 17 would interfere with study participation? (e.g. dementia, psychosis, etc.)

No
Yes
Unknown

#	Field Name		Loo	kup Set	Туре	Length	Range Checks	
		Nam	e: \$Edema S	SASFmt: \$Edema				
		Val	Text	Culture Suppression				
1	PatPsychDis	-1			SMALLINT		No range checks	
		0	No					
		1	Yes					
		2	Unknown					

Is the participant unable to relay valid information, actively participate in the study, or provide informed consent? (Includes uncontrolled psychiatric disease)

0 ---

18

- NoYesUnknown

#	Field Name		Looki	ıp Set	Туре	Length	Range Checks
		<i>Nam</i> \$Ede	e: \$Edema \$ ma				
		Val	Text	Culture Suppression			No range
1	PatUnableRelayInfo	-1			SMALLINT		checks
		0	No				
		1	Yes				
		2	Unknown				

Does the participant have a difficulty reading or communicating in English? ---No

#	Field Name		Loo	kup Set	Туре	Length	Range Checks
		Nam	e: \$Edema S	SASFmt: \$Edema			
		Val	Text	Culture Suppression			
1	PatDiffEng	-1			SMALLINT		No range checks
		0 No					
		1	1 Yes				
		2 Unknown					

# D. Deferral Criteria

Does the participant have microscopic hematuria?

- 0 ---
- No

1

- Yes
- Unknown

#	Field Name		Look	Туре	Length	Range Checks	
			e: \$Edema S				
		Val	Text	Culture Suppression			
1	PatMicroHematura	-1			SMALLINT		No range checks
		0	No				
		1	Yes				
		2	Unknown				

Does the participant have a positive urine culture?

0 ---

2

○ No

#	Field Name		Look	sup Set	Туре	Length	Range Checks
		Nam	e: \$Edema S	SASFmt: \$Edema			
		Val	Text	Culture Suppression			
1	PatPasUrinCult	-1			SMALLINT		No range checks
		0	No				
		1	Yes				
		2	Unknown				

Has the participant had a pregnancy in the past 6 months?

- 0 ---
- No

3

- O Yes
- O Unknown

#	Field Name	Lookup Set			Туре	Length	Range Checks
		Nam	e: \$Edema S	SASFmt: \$Edema			
		Val	Text	Culture Suppression			
1	PatPregSixMon	-1			SMALLINT		No range checks
		0	No				
		1	Yes				
		2	Unknown				

Does the participant currently have a sexually transmitted infection?

- 0 ---
- No

- Yes
- O Unknown

	Name				
		Name: \$Edem	a <i>SASFmt:</i> \$Edema		
		Val Text	Culture Suppression		
1	1 PatInfect	-1		SMALLINT	No range checks
		0 No			
		1 Yes			
		2 Unknow	n		

E. Consent Questions

1

1

Date consented or refused consent:

Month Day Year

#	Field Name	Lookup Set	Туре	Length	Range Checks
1	ConsentDate		DATETIME		No range checks

Did the patient consent to the study?

- O ---
- No
- Yes

#	Field Name		Ι	Lookup Set	Туре	Length	Range Checks
		Nam	e: Yesl	No SASFmt: YesNo			
		Val	Text	Culture Suppression			
1	Consent	-1			SMALLINT		No range checks
		0	No				
		1	Yes				

Did the patient consent to provide biospecimens?

- No
- Yes

#	Field Name		Ι	Lookup Set	Туре	Length	Range Checks
		Name: YesNo SASFmt: YesNo					
		Val	Text	Culture Suppression			
1	ConBioSp	-1			SMALLINT		No range checks
		0	No				
		1	Yes				

Did the patient consent to provide blood for DNA?

- No
- Yes

#	Field Name	Lookup Set		Туре	Length	Range Checks	
		Name: YesNo SASFmt: YesNo					
		Val	Text	Culture Suppression			
1	ConBlood	-1			SMALLINT		No range checks
		0	No				
		1	Yes				

If the patient didn't consent to the whole study (including biospecimens and DNA), provide reason(s) why:

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4

- Not interested
- Too much effort to get to center
- Transportation issues
- Child care issues
- Work-related issues
- Financial hardship
- Did not want to be catheterized
- Did not want to fill out PROs
- ---- Not approached
- Unwilling to delay start of new treatment
- Other (specify)

#	Field Name	Lookup Set	Туре	Length	Range Checks

1	EligNoCons	Nam	e: EligNoCons SASFmt:	EligNoCons	NVARCHAR	100	No range
		Val	Text	Culture Suppression			checks
		-1					
		1	Not interested				
		2	Too much effort to get to center				
		3	Transportation issues				
		4	Child care issues				
		5	Work-related issues				
		6	Financial hardship				
		7	Did not want to be catheterized				
		8	Did not want to fill out PROs				
		9	Did not want to provide biospecimens and/or blood for DNA				
		10	Not approached				
		12	Unwilling to delay start of new treatment				
		13	Did not want to have an MRI				
		14	Did not want to undergo auditory testing				
		15	Did not want to undergo sensory testing				
		11	Other (specify)				

If the patient was not approached, provide reason(s) why:

**\_**...

5

Demonstrated past non-compliance or non-adherence to medical visits or therapy Barriers to obtaining informed consent (e.g. dementia, language, other)

---- Not approached per treating physician

Other, specify (with textbox)

#	Field Name		Lookup Set		Туре	Length	Range Checks
		<i>Name:</i> PatNotAppRea <i>SASFmt:</i> PatNotAppRea					
		Val	Text	Culture Suppression			
		-1					
1	PatNotAppRea	1	Demonstrated past non-compliance or non-adherence to medical visits or therapy		NVARCHAR	100	No range
		2	Barriers to obtaining informed consent (e.g. dementia, language, other)				checks
		3	Not approached per treating physician				
		4	Other, specify (with textbox)				

### F. Contact Information

1

Street Address:

City:

#	Field Name	Lookup Set	Туре	Length	Range Checks
1	Address		NVARCHAR	50	No range checks

#	Field Name	Lookup Set	Туре	Length	Range Checks

State:

3

#	Field Name	Lookup Set	Туре	Length	Range Checks
1	State		NVARCHAR	50	No range checks

4

Zip code:

#	Field Name	Lookup Set	Туре	Length	Range Checks
1	Zipcode		NVARCHAR	50	No range checks

5

Primary Phone Number:

#	Field Name	Lookup Set	Туре	Length	Range Checks
1	PrimPhone		NVARCHAR	50	No range checks

6

Secondary Phone Number:

#	Field Name	Lookup Set	Туре	Length	Range Checks
1	SecPhone		NVARCHAR	50	No range checks

7

E-mail Address:

#	Field Name	Lookup Set	Туре	Length	Range Checks
1	Email		NVARCHAR	500	No range checks