

Neuroimaging Eligibility and Consent

A. Inclusion Criteria

1

Date screened

Month Day Year

#	Field Name	Lookup Set	Type	Length	Range Checks
1	DateScreen		DATETIME		No range checks

2

Does the participant have symptoms of urgency, with or without incontinence, consistent with the definition of overactive bladder?

--
 No
 Yes

#	Field Name	Lookup Set	Type	Length	Range Checks												
1	PartSymptoms	<p><i>Name: YesNo SASFmt: YesNo</i></p> <table border="1"> <thead> <tr> <th>Val</th> <th>Text</th> <th>Culture Suppression</th> </tr> </thead> <tbody> <tr> <td>-1</td> <td>--</td> <td></td> </tr> <tr> <td>0</td> <td>No</td> <td></td> </tr> <tr> <td>1</td> <td>Yes</td> <td></td> </tr> </tbody> </table>	Val	Text	Culture Suppression	-1	--		0	No		1	Yes		SMALLINT		No range checks
Val	Text	Culture Suppression															
-1	--																
0	No																
1	Yes																

3

Did the participant answer "Sometimes," "Often," or "Always" on question 6 of the LUTS tool - 1 month version?

--
 No
 Yes

#	Field Name	Lookup Set	Type	Length	Range Checks						
1	PartLUTS6	<p><i>Name: YesNo SASFmt: YesNo</i></p> <table border="1"> <thead> <tr> <th>Val</th> <th>Text</th> <th>Culture Suppression</th> </tr> </thead> <tbody> <tr> <td></td> <td></td> <td></td> </tr> </tbody> </table>	Val	Text	Culture Suppression				SMALLINT		No range checks
Val	Text	Culture Suppression									

		-1	--				
		0	No				
		1	Yes				

4

What did the participant answer on question 16b of the LUTS tool - 1 month version?

-
- "Sometimes," "Often," or "Always"
- "Never" or "Rarely"

#	Field Name	Lookup Set			Type	Length	Range Checks												
1	PartLutsNIGroup	<i>Name:</i> PartLutsNIGroup <i>SASFmt:</i> PartLutsNIGroup <table border="1"> <thead> <tr> <th>Val</th> <th>Text</th> <th>Culture Suppression</th> </tr> </thead> <tbody> <tr> <td>-1</td> <td>--</td> <td></td> </tr> <tr> <td>1</td> <td>"Sometimes," "Often," or "Always"</td> <td></td> </tr> <tr> <td>2</td> <td>"Never" or "Rarely"</td> <td></td> </tr> </tbody> </table>			Val	Text	Culture Suppression	-1	--		1	"Sometimes," "Often," or "Always"		2	"Never" or "Rarely"		SMALLINT		No range checks
Val	Text	Culture Suppression																	
-1	--																		
1	"Sometimes," "Often," or "Always"																		
2	"Never" or "Rarely"																		

B. Exclusion Criteria

1

Did the participant answer "Never" or "Rarely" on question 6 of the LUTS tool - 1 month version?

-
- No
- Yes

#	Field Name	Lookup Set			Type	Length	Range Checks												
1	PartLuts62	<i>Name:</i> YesNo <i>SASFmt:</i> YesNo <table border="1"> <thead> <tr> <th>Val</th> <th>Text</th> <th>Culture Suppression</th> </tr> </thead> <tbody> <tr> <td>-1</td> <td>--</td> <td></td> </tr> <tr> <td>0</td> <td>No</td> <td></td> </tr> <tr> <td></td> <td></td> <td></td> </tr> </tbody> </table>			Val	Text	Culture Suppression	-1	--		0	No					SMALLINT		No range checks
Val	Text	Culture Suppression																	
-1	--																		
0	No																		

		1	Yes			
--	--	---	-----	--	--	--

2

Is the participant unable to schedule a neuroimaging and sensory testing visit within four weeks of the questionnaire data and biospecimens collection of the Observational Cohort Study?

-
- No
- Yes

#	Field Name	Lookup Set			Type	Length	Range Checks												
1	UnableSched	<i>Name: YesNo SASFmt: YesNo</i> <table border="1"> <tr> <th>Val</th> <th>Text</th> <th>Culture Suppression</th> </tr> <tr> <td>-1</td> <td>--</td> <td></td> </tr> <tr> <td>0</td> <td>No</td> <td></td> </tr> <tr> <td>1</td> <td>Yes</td> <td></td> </tr> </table>			Val	Text	Culture Suppression	-1	--		0	No		1	Yes		SMALLINT		No range checks
Val	Text	Culture Suppression																	
-1	--																		
0	No																		
1	Yes																		

3

Is the participant left-handed?

-
- No
- Yes

#	Field Name	Lookup Set			Type	Length	Range Checks												
1	LeftHanded	<i>Name: YesNo SASFmt: YesNo</i> <table border="1"> <tr> <th>Val</th> <th>Text</th> <th>Culture Suppression</th> </tr> <tr> <td>-1</td> <td>--</td> <td></td> </tr> <tr> <td>0</td> <td>No</td> <td></td> </tr> <tr> <td>1</td> <td>Yes</td> <td></td> </tr> </table>			Val	Text	Culture Suppression	-1	--		0	No		1	Yes		SMALLINT		No range checks
Val	Text	Culture Suppression																	
-1	--																		
0	No																		
1	Yes																		

4

Does the participant have a CNS disease including structural brain abnormalities (e.g., neoplasms, subarachnoid cysts), cerebrovascular disease, ongoing infectious disease (e.g., abscess), or a history of other neurological disease including stroke or seizure disorders?

-
- No
- Yes

#	Field Name	Lookup Set			Type	Length	Range Checks
---	------------	------------	--	--	------	--------	--------------

1	CNSDisease	<i>Name: YesNo SASFmt: YesNo</i>			SMALLINT	No range checks
		Val	Text	Culture Suppression		
		-1	--			
		0	No			
		1	Yes			

5

Does the participant have claustrophobia or discomfort with enclosed spaces?

-
- No
- Yes

#	Field Name	Lookup Set			Type	Length	Range Checks
1	Claustro	<i>Name: YesNo SASFmt: YesNo</i>			SMALLINT		No range checks
		Val	Text	Culture Suppression			
		-1	--				
		0	No				
		1	Yes				

6

Does the participant have vision or hearing impairments that would impede completion of study procedures?

-
- No
- Yes

#	Field Name	Lookup Set			Type	Length	Range Checks
1	VisionHear	<i>Name: YesNo SASFmt: YesNo</i>			SMALLINT		No range checks
		Val	Text	Culture Suppression			
		-1	--				
		0	No				
		1	Yes				

- 7 Does the participant have metal implants, devices, or jewelry that would be unsafe in the MRI, or meet any other exclusionary criteria as specified by your site's MRI Screening form?
- - No
 - Yes

#	Field Name	Lookup Set	Type	Length	Range Checks	
1	Implants	<i>Name: YesNo SASFmt: YesNo</i>			SMALLINT	No range checks
		Val	Text	Culture Suppression		
		-1	--			
		0	No			
		1	Yes			

- 8 Does the participant have current, habitual, or previous use (within the last 12 months) of artificial nails, nails enhancements, or nail extensions that cover any portion of the thumbnail? (Occasional use may be permissible.)
- - No
 - Yes

#	Field Name	Lookup Set	Type	Length	Range Checks	
1	ArtNails	<i>Name: YesNo SASFmt: YesNo</i>			SMALLINT	No range checks
		Val	Text	Culture Suppression		
		-1	--			
		0	No			
		1	Yes			

- 9 Does the participant have Menière's disease or the use of a hearing aid in either ear?
- - No
 - Yes

#	Field Name	Lookup Set	Type	Length	Range Checks	
1	MeniereDis	<i>Name: YesNo SASFmt: YesNo</i>			SMALLINT	No range checks

	Val	Text	Culture Suppression		
	-1	--			
	0	No			
	1	Yes			

10

Has the participant used opioids, including tramadol, and sedatives, including benzodiazepines, without a 1-week washout period before the day of testing?

-
- No
- Yes

#	Field Name	Lookup Set			Type	Length	Range Checks												
1	Opiads	<i>Name: YesNo SASFmt: YesNo</i> <table border="1"> <tr> <td>Val</td> <td>Text</td> <td>Culture Suppression</td> </tr> <tr> <td>-1</td> <td>--</td> <td></td> </tr> <tr> <td>0</td> <td>No</td> <td></td> </tr> <tr> <td>1</td> <td>Yes</td> <td></td> </tr> </table>			Val	Text	Culture Suppression	-1	--		0	No		1	Yes		SMALLINT		No range checks
Val	Text	Culture Suppression																	
-1	--																		
0	No																		
1	Yes																		

C. Deferral Criteria

1

Does the participant have microscopic hematuria?

-
- No
- Yes

#	Field Name	Lookup Set			Type	Length	Range Checks												
1	MicroHema	<i>Name: YesNo SASFmt: YesNo</i> <table border="1"> <tr> <td>Val</td> <td>Text</td> <td>Culture Suppression</td> </tr> <tr> <td>-1</td> <td>--</td> <td></td> </tr> <tr> <td>0</td> <td>No</td> <td></td> </tr> <tr> <td>1</td> <td>Yes</td> <td></td> </tr> </table>			Val	Text	Culture Suppression	-1	--		0	No		1	Yes		SMALLINT		No range checks
Val	Text	Culture Suppression																	
-1	--																		
0	No																		
1	Yes																		

2

Was the participant's urine culture positive?

- No
 Yes

#	Field Name	Lookup Set	Type	Length	Range Checks												
1	UrineCult	<i>Name: YesNo SASFmt: YesNo</i> <table border="1"> <thead> <tr> <th>Val</th> <th>Text</th> <th>Culture Suppression</th> </tr> </thead> <tbody> <tr> <td>-1</td> <td>--</td> <td></td> </tr> <tr> <td>0</td> <td>No</td> <td></td> </tr> <tr> <td>1</td> <td>Yes</td> <td></td> </tr> </tbody> </table>	Val	Text	Culture Suppression	-1	--		0	No		1	Yes		SMALLINT		No range checks
Val	Text	Culture Suppression															
-1	--																
0	No																
1	Yes																

3

Does the participant have a current sexually transmitted infection?

- No
 Yes

#	Field Name	Lookup Set	Type	Length	Range Checks												
1	SexTrans	<i>Name: YesNo SASFmt: YesNo</i> <table border="1"> <thead> <tr> <th>Val</th> <th>Text</th> <th>Culture Suppression</th> </tr> </thead> <tbody> <tr> <td>-1</td> <td>--</td> <td></td> </tr> <tr> <td>0</td> <td>No</td> <td></td> </tr> <tr> <td>1</td> <td>Yes</td> <td></td> </tr> </tbody> </table>	Val	Text	Culture Suppression	-1	--		0	No		1	Yes		SMALLINT		No range checks
Val	Text	Culture Suppression															
-1	--																
0	No																
1	Yes																

4

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

- No
 Yes

#	Field Name	Lookup Set	Type	Length	Range Checks						
1	Preg6mnth	<i>Name: YesNo SASFmt: YesNo</i> <table border="1"> <thead> <tr> <th>Val</th> <th>Text</th> <th>Culture Suppression</th> </tr> </thead> <tbody> <tr> <td>-1</td> <td>--</td> <td></td> </tr> </tbody> </table>	Val	Text	Culture Suppression	-1	--		SMALLINT		No range checks
Val	Text	Culture Suppression									
-1	--										

		0	No			
		1	Yes			

D. Consent Questions

1 Date of consent or refusal

Month Day Year

#	Field Name	Lookup Set	Type	Length	Range Checks
1	DateConsentRefuse		DATETIME		No range checks

2 Did the patient consent to the study?
 --
 No
 Yes

#	Field Name	Lookup Set	Type	Length	Range Checks												
1	ConsentYN	<i>Name: YesNo SASFmt: YesNo</i> <table border="1" style="width: 100%; border-collapse: collapse;"> <tr> <td>Val</td> <td>Text</td> <td>Culture Suppression</td> </tr> <tr> <td>-1</td> <td>--</td> <td></td> </tr> <tr> <td>0</td> <td>No</td> <td></td> </tr> <tr> <td>1</td> <td>Yes</td> <td></td> </tr> </table>	Val	Text	Culture Suppression	-1	--		0	No		1	Yes		SMALLINT		No range checks
Val	Text	Culture Suppression															
-1	--																
0	No																
1	Yes																

3 If the patient didn't consent to the study, provide reason(s) why:

-
- 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
 - Did not want have an MRI
 - Did not want to undergo auditory testing
 - Did not want to undergo sensory testing

- Not approached
- Other (specify)

#	Field Name	Lookup Set	Type	Length	Range Checks																																													
1	ReasonNoConsent	<p><i>Name:</i> NIREasonNoConsent <i>SASFmt:</i> NIREasonNoConsent</p> <table border="1" data-bbox="560 451 1052 1984"> <thead> <tr> <th>Val</th> <th>Text</th> <th>Culture Suppression</th> </tr> </thead> <tbody> <tr> <td>-1</td> <td>--</td> <td></td> </tr> <tr> <td>1</td> <td>Not interested</td> <td></td> </tr> <tr> <td>2</td> <td>Too much effort to get to center</td> <td></td> </tr> <tr> <td>3</td> <td>Transportation issues</td> <td></td> </tr> <tr> <td>4</td> <td>Child care issues</td> <td></td> </tr> <tr> <td>5</td> <td>Work-related issues</td> <td></td> </tr> <tr> <td>6</td> <td>Financial hardship</td> <td></td> </tr> <tr> <td>7</td> <td>Did not want to be catheterized</td> <td></td> </tr> <tr> <td>8</td> <td>Did not want to fill out PROs</td> <td></td> </tr> <tr> <td>9</td> <td>Did not want have an MRI</td> <td></td> </tr> <tr> <td>10</td> <td>Did not want to undergo auditory testing</td> <td></td> </tr> <tr> <td>11</td> <td>Did not want to undergo sensory testing</td> <td></td> </tr> <tr> <td>12</td> <td>Not approached</td> <td></td> </tr> <tr> <td>13</td> <td>Other (specify)</td> <td></td> </tr> </tbody> </table>	Val	Text	Culture Suppression	-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 have an MRI		10	Did not want to undergo auditory testing		11	Did not want to undergo sensory testing		12	Not approached		13	Other (specify)		NVARCHAR	100	No range checks
Val	Text	Culture Suppression																																																
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11	Did not want to undergo sensory testing																																																	
12	Not approached																																																	
13	Other (specify)																																																	

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



- 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)

4

#	Field Name	Lookup Set	Type	Length	Range Checks															
1	ReasonNotAppro	<p><i>Name:</i> ReasonNotAppro <i>SASFmt:</i> ReasonNotAppro</p> <table border="1"> <thead> <tr> <th>Val</th> <th>Text</th> <th>Culture Suppression</th> </tr> </thead> <tbody> <tr> <td>1</td> <td>Demonstrated past non-compliance or non-adherence to medical visits or therapy</td> <td></td> </tr> <tr> <td>2</td> <td>Barriers to obtaining informed consent (e.g. dementia, language, other)</td> <td></td> </tr> <tr> <td>3</td> <td>Not approached per treating physician</td> <td></td> </tr> <tr> <td>4</td> <td>Other (specify)</td> <td></td> </tr> </tbody> </table>	Val	Text	Culture Suppression	1	Demonstrated past non-compliance or non-adherence to medical visits or therapy		2	Barriers to obtaining informed consent (e.g. dementia, language, other)		3	Not approached per treating physician		4	Other (specify)		NVARCHAR	100	No range checks
Val	Text	Culture Suppression																		
1	Demonstrated past non-compliance or non-adherence to medical visits or therapy																			
2	Barriers to obtaining informed consent (e.g. dementia, language, other)																			
3	Not approached per treating physician																			
4	Other (specify)																			

E. Questionnaire Complete

Questionnaire Complete

-
- Yes

E1

#	Field Name	Lookup Set	Type	Length	Range Checks
1	CenterComplete	<i>Name:</i> QuestComp <i>SASFmt:</i>	SMALLINT		No range

QuestComp

checks

Val	Text	Culture Suppression
-1	--	
1	Yes	
