

Control 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 Is the person 18 years of age or older?
 --
 No
 Yes

#	Field Name	Lookup Set	Type	Length	Range Checks												
1	Over18	<i>Name: YesNo SASFmt: YesNo</i> <table border="1" style="width: 100%; border-collapse: collapse;"> <tr> <td style="width: 10%;">Val</td> <td style="width: 10%;">Text</td> <td style="width: 80%;">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 Did the person answer "1-3 times a day" or "4 to 7 times a day" on question 2 of the LUTS tool - 1 month version?
 --
 No
 Yes

#	Field Name	Lookup Set	Type	Length	Range Checks			
1	Answer1to3timesQ2LUTS	<i>Name: YesNo SASFmt: YesNo</i> <table border="1" style="width: 100%; border-collapse: collapse;"> <tr> <td style="width: 10%;">Val</td> <td style="width: 10%;">Text</td> <td style="width: 80%;">Culture</td> </tr> </table>	Val	Text	Culture	smallint		No range checks
Val	Text	Culture						

			Suppression		
	-1	--			
	0	No			
	1	Yes			

4

Did the person answer "None" or "1 time a night" on question 3 of the LUTS tool - 1 month version?

-
- No
- Yes

#	Field Name	Lookup Set	Type	Length	Range Checks												
1	AnswerNonetoQ3LUTS	<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																

5

Did the person answer "never" or "rarely" on all other questions of the LUTS tool - 1 month version?

-
- No
- Yes

#	Field Name	Lookup Set	Type	Length	Range Checks												
1	AnswerNorROtherLUTS	<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																

6

Did the person have an AUA Symptom Index score between 0 and 7 (inclusive)?

-
- No
- Yes

#	Field Name	Lookup Set	Type	Length	Range Checks												
1	AUASympton	<p><i>Name: YesNo SASFmt: YesNo</i></p> <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																

7

Did the person have a normal urinalysis?

-
- No
- Yes

#	Field Name	Lookup Set	Type	Length	Range Checks												
1	NormalUrinalysis	<p><i>Name: YesNo SASFmt: YesNo</i></p> <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																

B. Exclusion Criteria

1

Does the person have gross hematuria?

-
- No
- Yes

#	Field Name	Lookup Set	Type	Length	Range Checks

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

2

Does the person have significant neurologic disease or injury? (Cerebral vascular accident with residual defect, Alzheimer's disease, dementia, Parkinson's disease, traumatic brain injury, spinal cord injury, complicated spinal surgery, multiple sclerosis. etc.)

-
- No
- Yes

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

3

Is the person's primary complaint pelvic pain?

-
- No
- Yes

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

- 4 Has the person been diagnosed with interstitial cystitis, chronic prostatitis, or chronic orchialgia?
- - No
 - Yes

#	Field Name	Lookup Set	Type	Length	Range Checks												
1	InterstitialCyt	<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																

- 5 Has the person had a pelvic or endoscopic GU surgery within the past 6 months? (Not including diagnostic cystoscopy)
- - No
 - Yes

#	Field Name	Lookup Set	Type	Length	Range Checks												
1	PelvicEndo	<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																

- 6 Does the person have an ongoing symptomatic urethral stricture?
- - No
 - Yes

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

	-1	--	
	0	No	
	1	Yes	

7

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

-
- No
- Yes

#	Field Name	Lookup Set	Type	Length	Range Checks												
1	LowUrinTracMal	<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																

8

Is the person currently undergoing chemotherapy or other cancer therapy?

-
- No
- Yes

#	Field Name	Lookup Set	Type	Length	Range Checks												
1	ChemoTherapy	<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																

9

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

-
- No
- Yes

--	--	--	--	--

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

10

Has the person had a Botox injection to the bladder or pelvic structures within the past 12 months?

-
- No
- Yes

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

11

Does the person currently have a functioning neurostimulator?

-
- No
- Yes

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

12

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

- No
 Yes

#	Field Name	Lookup Set	Type	Length	Range Checks												
1	ProstratreBio	<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																

13

Is the person currently pregnant?

- No
 Yes

#	Field Name	Lookup Set	Type	Length	Range Checks												
1	CurPreg	<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																

14

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

- No
 Yes

#	Field Name	Lookup Set	Type	Length	Range Checks						
1	HisCystitis	<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></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			

15

Has the person had an augmentation cystoplasty or cystectomy?

-
- No
- Yes

#	Field Name	Lookup Set			Type	Length	Range Checks												
1	AugmentCyst	<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																		

16

Does the person have a urinary tract fistula?

-
- No
- Yes

#	Field Name	Lookup Set			Type	Length	Range Checks												
1	UrinTractFistula	<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																		

17

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

-
- No
- Yes

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

18

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

- No
 Yes

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

19

Does the person have a difficulty reading or communicating in English?

- No
 Yes

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

20

Does the person have a clinical diagnosis of overactive bladder (OAB)?

-
- No
- Yes

#	Field Name	Lookup Set	Type	Length	Range Checks												
1	ClinicalDiagOverAct	<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																

21

Is the person currently using medication for LUTS/LUTD (e.g., anti-cholinergics, beta-agonists, alpha-agonists, 5-alpha-reductases, or PDE5-inhibitors for urinary problems)?

-
- No
- Yes

#	Field Name	Lookup Set	Type	Length	Range Checks												
1	UsingMeds	<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																

22

Does the person have a history of incomplete bladder emptying?

-
- No
- Yes

#	Field Name	Lookup Set	Type	Length	Range Checks			
1	PostVoidResid	<i>Name: YesNo SASFmt: YesNo</i> <table border="1"> <tr> <td>Val</td> <td>Text</td> <td></td> </tr> </table>	Val	Text		smallint		No range checks
Val	Text							

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

23

Is the person left-handed?

-
- No
- Yes

#	Field Name	Lookup Set			Type	Length	Range Checks												
1	LeftHanded	<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																		

24

Does the person 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> <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																		

25

Does the person have individual or discomfort with enclosed spaces?

-

- No
- Yes

#	Field Name	Lookup Set	Type	Length	Range Checks												
1	DiscomEnclosed	<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																

26

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

-
- No
- Yes

#	Field Name	Lookup Set	Type	Length	Range Checks												
1	VisionHearImped	<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																

27

Does the person have metal implants, devices, or jewelry that would be unsafe in the MRI, or meets any other exclusionary criteria as specified by your site's MRI Screening form?

-
- No
- Yes

#	Field Name	Lookup Set	Type	Length	Range Checks									
1	MetalImplants	<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></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			

28

Does the person 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	ArtificialNails	<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																		

29

Does the person 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	MenieresDis	<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																		

30

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

31

Has the person previously received treatment for LUTS/LUTD?

-
- No
- Yes

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

32

Does the person have a positive urinalysis or positive urine culture?

-
- No
- Yes

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

33

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

-
- No
- Yes

#	Field Name	Lookup Set			Type	Length	Range Checks
1	PregPas6Mos	<i>Name: YesNo SASFmt: YesNo</i>			smallint		No range checks
		Val	Text	Culture Suppression			
		-1	--				
		0	No				
		1	Yes				

34

Does the person have a current sexually transmitted infection?

-
- No
- Yes

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

35

Has the person reported or been treated for a urinary tract infection in the past 90 days?

-
- No
- Yes

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

	-1	--			
	0	No			
	1	Yes			

36

Has the person had medical expulsive therapy for symptomatic kidney or ureteral stone within 90 days?

-
- No
- Yes

#	Field Name	Lookup Set			Type	Length	Range Checks												
1	ExpulsiveTherapy	<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. Demographic Categories

1

Does this person fit into the remaining demographic categories needed for the Neuroimaging study?

-
- No
- Yes

#	Field Name	Lookup Set			Type	Length	Range Checks												
1	FitDemogNI	<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

Does this person fit into the remaining demographic categories needed for the Biomarker Pilot study?

-
- No
- Yes

#	Field Name	Lookup Set	Type	Length	Range Checks												
1	FitDemogBioP	<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																

D. Consent Questions

Date of consent or refusal

1

Month Day Year

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

Did the person consent to the study?

2

-
- No, neither
- Yes, Neuroimaging
- Yes, Biomarker Pilot only

#	Field Name	Lookup Set	Type	Length	Range Checks												
1	ConsentYN	<i>Name: YNNIBio SASFmt: YNNIBio</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>1</td> <td>No, neither</td> <td></td> </tr> <tr> <td></td> <td></td> <td></td> </tr> </table>	Val	Text	Culture Suppression	-1	--		1	No, neither					smallint		No range checks
Val	Text	Culture Suppression															
-1	--																
1	No, neither																

	2	Yes, Neuroimaging			
	3	Yes, Biomarker Pilot only			

3

Did the person consent to provide biospecimens?

-
- No
- Yes

#	Field Name	Lookup Set			Type	Length	Range Checks												
1	ConsentBio	<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

Did the person consent to provide blood for DNA?

-
- No
- Yes

#	Field Name	Lookup Set			Type	Length	Range Checks												
1	ConsentDNA	<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																		

5

If the person 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 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	NoConsentReason	<i>Name:</i> CGReasonNoConsent <i>SASFmt:</i> CGReasonNoConsent <table border="1" style="margin-top: 10px; width: 100%;"> <thead> <tr> <th>Val</th> <th>Text</th> <th>Culture Suppression</th> </tr> </thead> <tbody> <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>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	Not interested		2	Too much effort to get to center		3	Transportation issues		4	Child care issues		5	Work-related issues		6	Financial hardship		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	200	No range checks
Val	Text	Culture Suppression																																										
1	Not interested																																											
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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)																																											

If the person 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)

6

#	Field Name	Lookup Set	Type	Length	Range Checks															
1	NotApproReason	<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	200	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
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1	CenterComplete	<i>Name:</i> QuestComp <i>SASFmt:</i> QuestComp			SMALLINT	No range checks
		Val	Text	Culture Suppression		
		-1	--			
		1	Yes			
