

## SECTION A: GENERAL STUDY INFORMATION FOR OFFICE USE ONLY:

A1. STUDY ID#:

LABEL

A2. VISIT # BASELINE SCREENING .....SCRN

A3. DATE INTERVIEW COMPLETED: \_\_\_\_ / \_\_\_\_ / \_\_\_\_  
MONTH DAY YEAR

A4. INTERVIEWER INITIALS: \_\_\_\_

A5. CONSENT OBTAINED? YES..... 1

NO ..... 2

## SECTION B: ELIGIBILITY AND RELATED HEALTH CONDITIONS

This section includes questions about your general health, and conditions you may have had earlier in your life, or conditions that you have now.

SOURCE CODES: 1 = PATIENT; 2 = MEDICAL RECORD; 3 = BOTH PT & RECORD, 4 = SITE PI, 5 = PT REPORT AND SENT FOR MR. ↓

DOES THE PATIENT REPORT OR IS THERE EVIDENCE OF ANY OF THE FOLLOWING CONDITIONS?		YES	NO	a. SOURCE CODE
B1.	Do you <b>consistently</b> use a wheel chair to get around?	1	2	
B2.	Have you <b>ever</b> had bladder or pelvic cancer?	1	2	
B3.	Have you <b>ever</b> had pelvic radiation therapy for any reason?	1	2	
B4.	Do you <b>currently</b> use a catheter to empty your bladder?	1	2	
B5.	Do you have urethral diverticulum (pocket or outpouching in the urethra)?	1	2	
B6.	Have you <b>ever</b> had augmentation cystoplasty (surgical expansion of the bladder) or an artificial urethral sphincter?	1	2	
B7.	Have you <b>ever</b> received neuromodulation for pelvic indications?	1	2	
B8.	Have you been diagnosed with gastric retention?	1	2	
B9.	Do you have Parkinson's Disease?	1	2	
B10.	Do you have Multiple Sclerosis?	1	2	
B11.	Do you have spina bifida?	1	2	
B12.	Have you ever had a spinal cord injury or trauma?	1	2	

B13. ANY "YES" CODES TO ITEMS B1 – B12?

YES..... 1 → INELIGIBLE

NO ..... 2

B14. DOES THE PATIENT REPORT OR IS THERE EVIDENCE OF GLAUCOMA? ASK,

Do you have glaucoma?

- YES..... 1    ➔ OPTHAMOLOGIST MUST BE CONSULTED FOR  
CLEARANCE TO PARTICIPATE IN TRIAL
- NO..... 2    ➔ SKIP TO B15

B15. DOES THE PATIENT REPORT OR IS THERE EVIDENCE OF CONGESTIVE HEART FAILURE? ASK,

Do you have congestive heart failure?

- YES..... 1    ➔ BE SURE TO CHECK MD DETERMINATION OF WHETHER  
THIS CONDITION IS WELL-MANAGED ON F204
- NO..... 2    ➔ SKIP TO B16

B16. DOES THE PATIENT REPORT OR IS THERE EVIDENCE OF DIABETES? ASK,

Do you have diabetes?

- YES..... 1    ➔ BE SURE TO CHECK MD DETERMINATION OF WHETHER  
THIS CONDITION IS WELL-MANAGED ON F204
- NO..... 2    ➔ SKIP TO B17

B17. WHAT IS THE PATIENT’S MENOPAUSE STATUS? ASK,

Do you currently consider yourself to be pre-menopausal, post-menopausal or somewhere in between (peri-menopausal)? (PROBE: Menopausal is defined as not having had a menstrual period for the past 12 months.)

- PRE-MENOPAUSAL ..... 1
- POST-MENOPAUSAL ..... 2
- SOMEWHERE IN-BETWEEN ..... 3
- NOT SURE ..... 4

SECTION C: MEDICAL, SURGICAL OR BEHAVIORAL TREATMENT FOR INCONTINENCE

C1. DOES THE PATIENT REPORT OR IS THERE EVIDENCE OF ANY SURGERY FOR INCONTINENCE, VAGINAL, BLADDER OR PROLAPSE IN THE LAST 6 MONTHS? ASK,

Have you had any pelvic, rectal, incontinence, vaginal, bladder or prolapse surgery in the past 6 months?  
REFER TO ATTACHMENT A FOR LIST OF SURGERIES.

YES..... 1 →INELIGIBLE\*

NO..... 2

\*THE PATIENT MAY BE ELIGIBLE AT A LATER DATE.

C2. DOES THE PATIENT REPORT OR IS THERE EVIDENCE OF ANY SURGERY FOR PELVIC, RECTAL, INCONTINENCE, VAGINAL, BLADDER OR PROLAPSE? ASK,

Have you ever had any other pelvic, rectal, incontinence, vaginal, bladder or prolapse surgery? REFER TO ATTACHMENT A FOR A LIST OF SURGERIES.

YES..... 1

NO..... 2 → SKIP TO C4

C3. RECORD NAMES, CODES AND DATES OF ANY PELVIC, RECTAL, INCONTINENCE, VAGINAL, BLADDER OR PROLAPSE SURGERIES. SAY,

Tell me a little bit more about the surgeries you've had.

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	a.	b.	c.	d.	e.
	NAME OF SURGERY	SURGICAL CODE	SPECIFY (IF SURGICAL CODE = 07)	YEAR OF SURGERY	SOURCE CODE†
1.				_____	
2.				_____	
3.				_____	
4.				_____	
5.				_____	
6.				_____	
7.				_____	

C4. DOES THE PATIENT REPORT OR IS THERE EVIDENCE OF TREATMENT OF VAGINAL PROLAPSE WITH A PESSARY OR INCONTINENCE DISH THAT HAS NOT BEEN STABLE FOR THE PAST 3 MONTHS? ASK,

Do you use a vaginal pessary or incontinence dish to manage a prolapse?

- YES..... 1
- NO..... 2    ➔ SKIP TO C5

C4a. Has your treatment with a pessary or incontinence dish been stable for at least 3 months?

- YES..... 1
- NO..... 2    ➔ INELIGIBLE\*

\*THE PATIENT MAY BE ELIGIBLE AT A LATER DATE.

C5. DOES THE PATIENT REPORT OR IS THERE EVIDENCE OF HYPERSENSITIVITY TO THE STUDY DRUG? ASK,

Have you ever experienced hypersensitivity to Detrol?

- YES..... 1    ➔ INELIGIBLE
- NO..... 2

C6. DOES THE PATIENT REPORT OR IS THERE EVIDENCE OF ANY **NON-SURGICAL** TREATMENT FOR URINARY INCONTINENCE? ASK,

Have you ever received any **non-surgical** treatment for your urinary incontinence, such as medication, or behavioral or biofeedback treatment of at least 2 months duration? REFER TO ATTACHMENT A FOR A LIST OF TREATMENTS.

YES..... 1

NO..... 2 ➔ **SKIP TO C8**

C7. RECORD THE NAMES, CODES AND DATES OF ALL NON-SURGICAL TREATMENTS FOR UI. SAY,

Tell me a little bit more about that / those... (non-surgical treatments for urinary incontinence)

**SOURCE CODES:** 1 = PATIENT; 2 = MEDICAL RECORD; 3 = BOTH PT & RECORD, 4 = SITE PL., 5 = PT REPORT AND SENT FOR MR ↓

	a.	b.	c.	d.
	TYPE OF TREATMENT	TREATMENT CODE	DATES OF TREATMENT	SOURCE CODE†
1.			FROM: ____ / ____ / ____ TO: ____ / ____ / ____	
2.			FROM: ____ / ____ / ____ TO: ____ / ____ / ____	
3.			FROM: ____ / ____ / ____ TO: ____ / ____ / ____	
4.			FROM: ____ / ____ / ____ TO: ____ / ____ / ____	
5.			FROM: ____ / ____ / ____ TO: ____ / ____ / ____	

C8. DOES THE PATIENT REPORT OR IS THERE EVIDENCE OF ANY PREVIOUS BEHAVIORAL OR BIOFEEDBACK TREATMENT OF > 2 MONTHS DURATION WITHIN THE PAST TWO YEARS?

YES..... 1 ➔ **INELIGIBLE**

NO..... 2

## SECTION D: ELIGIBILITY SUMMARY

D1. DOES THE PATIENT MEET ALL ELIGIBILITY CRITERIA AS REQUIRED IN THIS FORM?

(REVIEW CODES TO ITEMS B13, C1, C4a, C5, AND C8)

YES..... 1 ➔ **CONTINUE SCREENING**

NO..... 2 ➔ **INELIGIBLE; END SCREENING**

## Attachment A

PELVIC SURGERY CODES	
01	Anterior repair
02	Anterior repair, Kelly plication, suburethral plication
03	Cesarean delivery
04	Collagen injection
05	Durasphere injection
06	Hysterectomy
07	Laparoscopy
08	Marshall-Marchetti-Krantz (MMK) bladder suspension
09	Needle suspensions: Raz, Pereyra, Gittes
10	Burch colposuspension
11	Posterior repair
12	Removal of an ectopic pregnancy
13	Removal of an ovarian cyst
14	Removal of both ovaries
15	Removal of one ovary
16	Sling procedure
17	Supracervical hysterectomy
18	Tubal ligation
88	UNKNOWN TYPE
99	OTHER

TREATMENT CODES	
40	Medicine (drug treatment)
41	Bladder training (including behavior changes involving the timing of urination or changes in fluid intake)
42	Pelvic muscle exercises (Kegel exercises)
43	Electrical stimulation
44	Electromagnetic therapy
45	Biofeedback
46	Acupuncture or other alternative medicine techniques
47	Vaginal device
49	UNKNOWN TYPE

COLON AND RECTAL SURGERY CODES	
20	AP resection
21	Low anterior resection of the colon
22	Repair of the anal sphincter
23	Colectomy
24	Hemorrhoidectomy
25	Rectopexy
26	Sigmoidopexy
27	Ripstein procedure
28	UNKNOWN TYPE
29	OTHER