F204: Baseline History and Physical Exam, version 03/29/05 (B)

UITN BE-DRI

Section A: General Study Information for Office Use Only:

A1. Study ID#: Label

A2. Visit # Baseline Screening..... SCRN

SECTION B: ANTHROPOMETRIC MEASURES AND BLOOD PRESSURE

B1. Height: ____ ____ **inches**

B2. Weight: ____ ____ ____ **lbs**

B3. Systolic BP: ____ ____ ____

B4. Diastolic BP: ____ ____ ____

SECTION C: DIRECTED NEUROLOGICAL AND RECTAL EXAM

C1. Deep Tendon Reflex Knee..... Normal ..... 1 Abnormal 2

C2. Perineal Sensation..... Normal ..... 1 Decreased..... 2

C3. Anal Sphincter Voluntary Contractions..... Normal ..... 1 Decreased..... 2

C4. Date exam completed: ___ ___ / ___ ___ / ___ ___ ___ ___ (Month / Day / Year) C5. Directed neuro examiner's initials: ___ ___ ___

C6. Date abstract completed: ___ ___ / ___ ___ / ___ ___ ___ ___ (Month / Day / Year) C7. Abstractor's initials: ___ ___ ___

C8. Was there evidence of fecal impaction on rectal examination?

Yes ..... 1 ➔ **INELIGIBLE***

No..... 2

***THE PATIENT MAY BE ELIGIBLE IF INCONTINENCE PERSISTS AFTER IMPACTION IS MANAGED.**

C9. Date rectal exam completed: ___ ___ / ___ ___ / ___ ___ ___ ___ (Month / Day / Year) C10. Examiner's initials: ___ ___ ___

C11. Date abstract completed: ___ ___ / ___ ___ / ___ ___ ___ ___ (Month / Day / Year) C12. Abstractor's initials: ___ ___ ___

SECTION D: PUBOCOCCYGEUS CONTRACTION ASSESSMENT

	PARAMETER	RATING DESCRIPTION	
D1.	Pressure	No response; cannot perceive on finger surface..... 1 Weak squeeze; felt as a flick at various points along finger surface; not all the way around..... 2 Moderate squeeze; felt all the way around finger surface.... 3 Strong squeeze 4	➔ **INELIGIBLE**
D2.	Duration	_____ _____ • _____ seconds	
D3.	Displacement of vertical plane	None ..... 1 Fingertips may move anteriorly (pushed up by muscle bulk) ..... 2 Whole length of fingers move anteriorly ..... 3 Whole fingers move anteriorly; are gripped and pulled in... 4	

D4. Based on this PC Assessment, is the woman **eligible** to continue with the screening assessment (D1>1)?

YES..... 1

NO..... 2 ➔ **INELIGIBLE**

D5. Date PC assessment completed: ___ ___ / ___ ___ / ___ ___ ___ ___ (Month / Day / Year)

D6. PC assessment examiner's initials: ___ ___ ___

D7. Date abstract completed: ___ ___ / ___ ___ / ___ ___ ___ ___ (Month / Day / Year)

D8. Abstractor's initials: ___ ___ ___

SECTION E: PELVIC ORGAN PROLAPSE QUANTIFICATION EXAM

	POINT	[DESCRIPTION]	RECORD VALUE	RANGE	NA
E1.	**Aa**	anterior wall 3 cm from external urethral meatus.....	____ ____ ____ . ____	-03 to +03	
E2.	**Ba**	most dependent part of anterior wall	____ ____ ____ . ____	-03 to +TVL	
E3.	**C**	cervix or vaginal cuff.....	____ ____ ____ . ____	± TVL	
E4.	**D**	posterior fornix (if no prior total hyst).....	____ ____ ____ . ____	± TVL	888
E5.	**Ap**	posterior wall 3 cm from hymen.....	____ ____ ____ . ____	-03 to +03	
E6.	**Bp**	most dependent part of posterior wall.....	____ ____ ____ . ____	-03 to +TVL	
E7.	**GH**	genital hiatus (mid urethral meatus to vaginal introitus posterior Fourchette).....	____ ____ ____ . ____	no limit	
E8.	**PB**	perineal body (vaginal introitus posterior Fourchette to mid-anal opening).....	____ ____ ____ . ____	no limit	
E9.	**TVL**	total vaginal length.....	____ ____ ____ . ____	no limit	

E10. Date POP-Q completed: ___ ___ / ___ ___ / ___ ___ ___ ___ (Month / Day / Year)

E11. POP-Q examiner's initials: ___ ___ ___

E12. Date abstract completed: ___ ___ / ___ ___ / ___ ___ ___ ___ (Month / Day / Year)

E13. Abstractor's initials: ___ ___ ___

SECTION F: PVR

F1. Post void residual: **____ ____ ____ ml** ➔ **INELIGIBLE IF PVR > 150 ML**

F2. Date PVR measured: ___ ___ / ___ ___ / ___ ___ ___ ___ (Month / Day / Year)

F3. Abstractor's initials: ___ ___ ___

SECTION G: URINALYSIS

G1. Does urinalysis show evidence of hematuria (defined as a positive dipstick and >5 RBC/high power field or a micro result of >5 RBC/high power field) **in the absence of** a negative cystoscopy, upper urinary tract imaging and urine cytology workup within the past 5 years?

YES ..... 1 ➔ **INELIGIBLE***

NO 2

***THE PATIENT MAY BE ELIGIBLE IF INCONTINENCE PERSISTS AFTER HEMATURIA IS TREATED.**

G2. Date urinalysis completed: __ __ / __ __ / __ __ __ __ (Month / Day / Year)

G3. UITN MD Investigator or "Designee" initials: ___ ___ ____

SECTION H: UTI

H1. Is the patient currently being treated for a UTI (Patient must be >7 days post-treatment and all symptoms of UTI must be resolved per UITN MD Investigator judgement)?

YES ..... 1 ➔ **INELIGIBLE***

NO 2

***THE PATIENT MAY BE ELIGIBLE IF INCONTINENCE PERSISTS AFTER INFECTION IS RESOLVED.**

H2. Date of assessment: ___ ___ / ___ ___ / ___ ___ ___ ___ (Month / Day / Year)

H3. UITN MD Investigator or "Designee" initials: ___ ___ ___

SECTION I : HISTORY AND PHYSICAL EXAMINATION BY UITN MD INVESTIGATOR OR DESIGNEE

The UITN MD Investigator or "Designee" must perform a history and physical examination.

	IS THERE ANY EVIDENCE OF THE FOLLOWING SYMPTOMS OR CONDITIONS?:	YES	NO
I1.	Uncontrolled or poorly controlled diabetes	1	2
I2.	Decompensated congestive heart failure	1	2
I3.	Glaucoma without clearance from ophthalmologist	1	2
I4.	Any other uncontrolled medical condition	1↓	2
	If yes, specify: _____		
I5.	History of bladder or pelvic cancer	1	2
I6.	History of pelvic radiation therapy	1	2
I7.	Current use of a catheter to empty the bladder	1	2
I8.	Urethral diverticulum, current or previous (i.e. repaired)	1	2
I9.	Prior augmentation cystoplasty or an artificial urethral sphincter	1	2
I10.	Gastric retention	1	2
I11.	Any incontinence, vaginal, bladder or prolapse surgery within the past 6 months	1	2
I12.	Current or recent (<6 months post-partum) pregnancy	1	2
I13.	Systemic disease known to affect bladder function (e.g. Parkinson's disease, multiple sclerosis, spina bifida, spinal cord injury or trauma)	1	2

I14.	Is the patient non-ambulatory?	1	2

I15.	Are there any other conditions or symptoms that should be noted for this patient?	1↓	2
	If yes, describe: _____		

I16. Based upon your history and physical examination of the patient, is she eligible to participate in the BE-DRI Trial? (Any yes response in Section I may render the patient ineligible).

YES..... 1

NO ..... 2 ➔ **INELIGIBLE**

I17. UITN MD Investigator or "Designee" Signature: _____ I18.Date: ___ ___ / ___ ___ / ___ ___ ___ ___
Month Day Year

SECTION J: ELIGIBILITY SUMMARY

J1. Does the patient meet all eligibility criteria as required in this form?

(Review codes to items C8, D4, F1, G1, H1 and I16)

YES..... 1 ➔ **CONTINUE SCREENING**

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

J2. Date eligibility determination completed: ___ ___ / ___ ___ / ___ ___ ___ ___
Month Day Year

J3. Initials of person completing eligibility determination: ____ ____ ____

J4. What is the earliest completion date of any measure on this Data Form? ___ ___ / ___ ___ / ___ ___ ___ ___
Month Day Year