

Section A: General Study Information for Office Use Only:

A1. Study ID#:

Label

A2. Visit # Baseline Screening..... SCR N

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 → INELIGIBLE
	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
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.	<u>Current</u> use of a catheter to empty the bladder	1	2
I8.	Urethral diverticulum, <u>current or previous</u> (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 <u>within the past 6 months</u>	1	2
I12.	<u>Current or recent</u> (<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