

SECTION A: GENERAL STUDY INFORMATION FOR OFFICE USE ONLY

A1. Study ID#: A2. Visit # Baseline TBAS
 A3. ARE THESE REPEAT MEASURES DUE TO PREVIOUSLY EXPIRED MEASURES? YES 1 NO 2

SECTION B: ANTHROPOMETRIC MEASURES

B1. Height: _____ inches B2. Weight: _____ lbs

SECTION C: NEURO MUSCULAR EXAM

Neuro Assessment

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

NOTE TO EXAMINER: Complete C4 after you interview the patient and complete the neuromuscular exam.

Pain Assessment

C4. Is there evidence of palpable pain in the location of the ...

	YES	NO
a. ...lower abdomen, right side?.....	1	2
b. ...lower abdomen, left side?.....	1	2
c. ...inner thigh, right side?.....	1	2
d. ...inner thigh, left side?.....	1	2
e. ...vagina (inside), right side?.....	1	2
f. ...vagina (inside), left side?.....	1	2
g. ...vulva, right side?.....	1	2
h. ...vulva, left side?.....	1	2
i. ...lower back, right side?.....	1	2
j. ...lower back, left side?.....	1	2
k. ...front leg, right side?.....	1	2
l. ...front leg, left side?.....	1	2
m. ...back leg or buttocks, right side?.....	1	2
n. ...back leg or buttocks, left side.....	1	2

Pubococcygeus Contraction Assessment

PARAMETER	RATING DESCRIPTION
C5. 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
C6. Duration	_____ • _____ seconds
C7. 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

C8. Date Neuro-Muscular Exam Completed: _____ / _____ / _____
Month Day Year

C9. Examiner's ID: _____

C10. Date Abstract Completed: _____ / _____ / _____
Month Day Year

C11. Abstractor's ID: _____

SECTION D: PELVIC ORGAN PROLAPSE QUANTIFICATION EXAM

POINT	[DESCRIPTION]	RECORD VALUE	RANGE	NA
D1.	Aa anterior wall 3 cm from external urethral meatus	_____ . _____	-03 to +03	
D2.	Ba most dependent part of anterior wall	_____ . _____	-03 to +TVL	
D3.	C cervix or vaginal cuff.....	_____ . _____	± TVL	
D4.	D posterior fornix (if no prior total hyst).....	_____ . _____	± TVL	888
D5.	Ap posterior wall 3 cm from hymen.....	_____ . _____	-03 to +03	
D6.	Bp most dependent part of posterior wall.....	_____ . _____	-03 to +TVL	
D7.	GH genital hiatus (mid urethral meatus to vaginal introitus posterior Fourchette).....	_____ . _____	no limit	
D8.	PB perineal body (vaginal introitus posterior Fourchette to mid-anal opening)	_____ . _____	no limit	
D9.	TVL total vaginal length.....	_____ . _____	no limit	

D10. Record prolapse Stage:
 Stage 0 or I..... 1 [D2, D3, D6: all < -1]
 Stage II or higher 2 [D2, D3, D6: any ≥ -1]

Stage 0 Point Aa, Ap, Ba, & Bp are all at -3cm and either point C or D is at ≤ -(TVL-2) cm
Stage I The criteria for Stage 0 are not met and the leading edge of prolapse is < -1 cm

Stage II Leading edge of prolapse is ≥ -1 cm but ≤ +1 cm
Stage III Leading edge of prolapse is > + 1 cm but < +(TVL-2) cm
Stage IV Leading edge of prolapse is ≥ +(TVL-2) cm
TVL Total vaginal length in centimeters in Stages O, III and IV.

D11. Date POPQ Completed: ____ / ____ / ____ D12. Examiner's ID: ____
Month Day Year
 D13. Date Abstract Completed: ____ / ____ / ____ D14. Abstractor's ID: ____
Month Day Year

SECTION E: HISTORY AND PHYSICAL EXAMINATION BY TOMUS MD INVESTIGATOR

The TOMUS MD Investigator must review all baseline data forms and complete or review history and physical exam data prior to completing Section E.

<u>Based on your clinical judgment, is there evidence of the following symptoms or conditions?</u>		YES	NO
E1.	Non-ambulatory? (ambulation with assistive devices is not an exclusion)	1	2
E2.	History of lower urinary tract cancer?	1	2
E3.	Pelvic irradiation, current or previous?	1	2
E4.	Current chemotherapy?	1	2
E5.	Systemic disease known to affect bladder function (e.g. Parkinson’s disease, multiple sclerosis, spina bifida, spinal cord injury or trauma)?	1	2
E6.	Prior augmentation cystoplasty or an artificial urethral sphincter?	1	2
E7.	Urethral diverticulum, <u>current or previous</u> (i.e. repaired)?	1	2
E8.	Current use of a catheter to empty the bladder?	1	2
E9.	Implanted nerve stimulators for urinary symptoms?	1	2
E10.	History of synthetic sling for SUI?	1	2
E11.	Currently or recently pregnant (<12 months post-partum)?	1	2
E12.	Laparoscopic or open pelvic surgery <3 months?	1	2
E13.	Current evaluation or treatment for chronic pelvic pain (painful bladder syndrome)?	1	2
E14.	ASA Class IV?	1	2
E15.	Current urinary tract infection?	1	2
E16.	Previous placement of synthetic mesh on a vaginal approach to reconstructive surgery?	1	2
E17.	Does the patient need concomitant surgery requiring an abdominal incision, use of a graft material in the anterior compartment or any use of synthetic graft material?	1	2

E18. Based upon your evaluation of the patient, is she eligible to participate in TOMUS and receive either study surgical procedure? (Any yes response in Section E may render the patient ineligible).

- YES 1
- NO 2 → **INELIGIBLE**

E19. TOMUS MD Investigator Signature: _____

E19a. Initials of Person Who Signed in E19: _____

E20. Date: ____ / ____ / ____
Month Day Year

E21. What is the earliest completion date of any measure on this Data Form? ____ / ____ / ____
Month Day Year