

F304: Baseline Physical Exam, version 11/12/07 (B)

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

REPEAT MEAS	Frequency	Percent	Cum Freq	Cum Percent
1	5	0.84	5	0.84
2	592	99.16	597	100.00

SECTION B: ANTHROPOMETRIC MEASURES

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

Analysis Variable : HEIGHT								
N	N Miss	Mean	SD	Minimum	Lower Quartile	Median	Upper Quartile	Maximum
592	0	64.2	2.7	47.0	62.0	64.0	66.0	74.0

HEIGHT	Frequency	Percent	Cum Freq	Cum Percent
-9	5	100.00	5	100.00

Analysis Variable : WEIGHT								
N	N Miss	Mean	SD	Minimum	Lower Quartile	Median	Upper Quartile	Maximum
596	0	178.0	42.2	88.0	148.0	170.0	202.0	343.0

WEIGHT	Frequency	Percent	Cum Freq	Cum Percent
-9	1	100.00	1	100.00

SECTION C: NEURO MUSCULAR EXAM

Neuro Assessment

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

Because the frequency of at least one category is very low, the variable was not included in the dataset

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

Because the frequency of at least one category is very low, the variable was not included in the dataset

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

ANAL_SPHINC	Frequency	Percent	Cum Freq	Cum Percent
-9	2	0.34	2	0.34
1	559	93.63	561	93.97
2	36	6.03	597	100.00

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

PAIN_ABD_R	Frequency	Percent	Cum Freq	Cum Percent
1	19	3.18	19	3.18
2	578	96.82	597	100.00

b. ...lower abdomen, left side?.....

1 2

PAIN_ABD_L	Frequency	Percent	Cum Freq	Cum Percent
1	16	2.68	16	2.68
2	581	97.32	597	100.00

c. ...inner thigh, right side?.....

1 2

Because the frequency of at least one category is very low, the variable was not included in the dataset

d. ...inner thigh, left side?.....

1 2

Because the frequency of at least one category is very low, the variable was not included in the dataset

e. ...vagina (inside), right side?.....

1 2

PAIN_VAG_R	Frequency	Percent	Cum Freq	Cum Percent
1	16	2.68	16	2.68
2	581	97.32	597	100.00

f. ...vagina (inside), left side?.....

1 2

PAIN_VAG_L	Frequency	Percent	Cum Freq	Cum Percent
1	21	3.52	21	3.52
2	576	96.48	597	100.00

g. ... vulva, right side?.....

1 2

Because the frequency of at least one category is very low, the variable was not included in the dataset

h. ...vulva, left side?.....

1 2

Because the frequency of at least one category is very low, the variable was not included in the dataset

i. ...lower back, right side?.....

1 2

PAIN_BACK_R	Frequency	Percent	Cum Freq	Cum Percent
1	30	5.03	30	5.03
2	567	94.97	597	100.00

j. ...lower back, left side? 1 2

PAIN_BACK_L	Frequency	Percent	Cum Freq	Cum Percent
1	30	5.03	30	5.03
2	567	94.97	597	100.00

k. ...front leg, right side? 1 2

Because the frequency of at least one category is very low, the variable was not included in the dataset

l. ...front leg, left side? 1 2

Because the frequency of at least one category is very low, the variable was not included in the dataset

m. ...back leg or buttocks, right side? 1 2

Because the frequency of at least one category is very low, the variable was not included in the dataset

n. ...back leg or buttocks, left side 1 2

Because the frequency of at least one category is very low, the variable was not included in the dataset

TOMMUS

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

PC PRES	Frequency	Percent	Cum Freq	Cum Percent
.	2	.	.	.
1	42	7.06	42	7.06
2	244	41.01	286	48.07
3	220	36.97	506	85.04
4	89	14.96	595	100.00

Frequency Missing = 2

C6. Duration _____ • _____ seconds

Analysis Variable : PC_DUR								
N	N Miss	Mean	SD	Minimum	Lower Quartile	Median	Upper Quartile	Maximum
594	0	7.6	6.0	0.0	4.0	6.7	10.0	46.2

PC_DUR	Frequency	Percent	Cum Freq	Cum Percent
-9	3	100.00	3	100.00

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

PC DIS	Frequency	Percent	Cum Freq	Cum Percent
.	2	.	.	.
1	84	14.12	84	14.12
2	268	45.04	352	59.16
3	164	27.56	516	86.72
4	79	13.28	595	100.00

Frequency Missing = 2

C8. Date Neuro-Muscular Exam Completed: _____ / _____ / _____ C9. Examiner's ID: _____
 Month Day Year

Affix ID Label Here

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

C11. Abstractor's ID: ___

TOMMUS

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																																									
<table border="1"> <thead> <tr> <th colspan="10">Analysis Variable : POPQ_AA</th> </tr> <tr> <th>N</th> <th>N Miss</th> <th>Mean</th> <th>SD</th> <th>Minimum</th> <th>Lower Quartile</th> <th>Median</th> <th>Upper Quartile</th> <th>Maximum</th> <th></th> </tr> </thead> <tbody> <tr> <td>597</td> <td>0</td> <td>-1.37</td> <td>1.31</td> <td>-3</td> <td>-2</td> <td>-2</td> <td>-1</td> <td>3</td> <td></td> </tr> </tbody> </table>					Analysis Variable : POPQ_AA										N	N Miss	Mean	SD	Minimum	Lower Quartile	Median	Upper Quartile	Maximum		597	0	-1.37	1.31	-3	-2	-2	-1	3											
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D2.	Ba most dependent part of anterior wall	-03 to +TVL																																									
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D3.	C cervix or vaginal cuff	± TVL																																									
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597	0	-6.45	3.4	-12	-8	-7	-6	14																																				
D4.	D posterior fornix (if no prior total hyst)	± TVL	888																																								
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D5.	Ap posterior wall 3 cm from hymen	-03 to +03																																									
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597	0	-1.97	1.2	-3	-3	-2	-2	3																																				
D6.	Bp most dependent part of posterior wall	-03 to +TVL																																									
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597	0	-1.91	1.4	-3	-3	-2	-2	14																																				
D7.	GH genital hiatus (mid urethral meatus to vaginal introitus posterior Fourchette)	_____ . _____	no limit																																									

Analysis Variable : POPQ GH								
N	N Miss	Mean	SD	Minimum	Lower Quartile	Median	Upper Quartile	Maximum
597	0	3.5	1.0	1.5	3.0	3.0	4.0	9.0

D8. **PB** perineal body (vaginal introitus posterior Fourchette to mid-anal opening) _____ . _____ no limit

Analysis Variable : POPQ PB								
N	N Miss	Mean	SD	Minimum	Lower Quartile	Median	Upper Quartile	Maximum
597	0	3.5	1.1	0.5	3.0	3.5	4.0	7.5

D9. **TVL** total vaginal length _____ . _____ no limit

Analysis Variable : POPQ TVL								
N	N Miss	Mean	SD	Minimum	Lower Quartile	Median	Upper Quartile	Maximum
597	0	9.5	1.4	4.0	9.0	10.0	10.0	20.0

D10. Record prolapse Stage:

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

PRO_STAGE	Frequency	Percent	Cum Freq	Cum Percent
1	267	44.72	267	44.72
2	330	55.28	597	100.00

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.

Based on your clinical judgment, is there evidence of the following symptoms or conditions?		YES	NO										
E1.	Non-ambulatory? (ambulation with assistive devices is not an exclusion) <table border="1"> <thead> <tr> <th>NON_AM B</th> <th>Frequency</th> <th>Percent</th> <th>Cum Freq</th> <th>Cum Percent</th> </tr> </thead> <tbody> <tr> <td>2</td> <td>597</td> <td>100.00</td> <td>597</td> <td>100.00</td> </tr> </tbody> </table>	NON_AM B	Frequency	Percent	Cum Freq	Cum Percent	2	597	100.00	597	100.00	1	2
NON_AM B	Frequency	Percent	Cum Freq	Cum Percent									
2	597	100.00	597	100.00									
E2.	History of lower urinary tract cancer? <table border="1"> <thead> <tr> <th>UT_CANCER</th> <th>Frequency</th> <th>Percent</th> <th>Cum Freq</th> <th>Cum Percent</th> </tr> </thead> <tbody> <tr> <td>2</td> <td>597</td> <td>100.00</td> <td>597</td> <td>100.00</td> </tr> </tbody> </table>	UT_CANCER	Frequency	Percent	Cum Freq	Cum Percent	2	597	100.00	597	100.00	1	2
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E3.	Pelvic irradiation, current or previous? <table border="1"> <thead> <tr> <th>PELV_IRRAD</th> <th>Frequency</th> <th>Percent</th> <th>Cum Freq</th> <th>Cum Percent</th> </tr> </thead> <tbody> <tr> <td>2</td> <td>597</td> <td>100.00</td> <td>597</td> <td>100.00</td> </tr> </tbody> </table>	PELV_IRRAD	Frequency	Percent	Cum Freq	Cum Percent	2	597	100.00	597	100.00	1	2
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E4.	Current chemotherapy? <table border="1"> <thead> <tr> <th>CHEMO</th> <th>Frequency</th> <th>Percent</th> <th>Cum Freq</th> <th>Cum Percent</th> </tr> </thead> <tbody> <tr> <td>2</td> <td>597</td> <td>100.00</td> <td>597</td> <td>100.00</td> </tr> </tbody> </table>	CHEMO	Frequency	Percent	Cum Freq	Cum Percent	2	597	100.00	597	100.00	1	2
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2	597	100.00	597	100.00									
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? <table border="1"> <thead> <tr> <th>AUG_CST</th> <th>Frequency</th> <th>Percent</th> <th>Cum Freq</th> <th>Cum Percent</th> </tr> </thead> <tbody> <tr> <td>2</td> <td>597</td> <td>100.00</td> <td>597</td> <td>100.00</td> </tr> </tbody> </table>	AUG_CST	Frequency	Percent	Cum Freq	Cum Percent	2	597	100.00	597	100.00	1	2
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2	597	100.00	597	100.00									
E7.	Urethral diverticulum, <u>current or previous</u> (i.e. repaired)? <table border="1"> <thead> <tr> <th>URETH_DIV</th> <th>Frequency</th> <th>Percent</th> <th>Cum Freq</th> <th>Cum Percent</th> </tr> </thead> <tbody> <tr> <td>2</td> <td>597</td> <td>100.00</td> <td>597</td> <td>100.00</td> </tr> </tbody> </table>	URETH_DIV	Frequency	Percent	Cum Freq	Cum Percent	2	597	100.00	597	100.00	1	2
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E8.	Current use of a catheter to empty the bladder? <table border="1"> <thead> <tr> <th>CURR_CATH</th> <th>Frequency</th> <th>Percent</th> <th>Cum Freq</th> <th>Cum Percent</th> </tr> </thead> <tbody> <tr> <td>2</td> <td>597</td> <td>100.00</td> <td>597</td> <td>100.00</td> </tr> </tbody> </table>	CURR_CATH	Frequency	Percent	Cum Freq	Cum Percent	2	597	100.00	597	100.00	1	2
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E9.	Implanted nerve stimulators for urinary symptoms? <table border="1"> <thead> <tr> <th>NERVE_STIM</th> <th>Frequency</th> <th>Percent</th> <th>Cum Freq</th> <th>Cum Percent</th> </tr> </thead> <tbody> <tr> <td>2</td> <td>597</td> <td>100.00</td> <td>597</td> <td>100.00</td> </tr> </tbody> </table>	NERVE_STIM	Frequency	Percent	Cum Freq	Cum Percent	2	597	100.00	597	100.00	1	2
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2	597	100.00	597	100.00									
E10.	History of synthetic sling for SUI? <table border="1"> <thead> <tr> <th>SYN_SLING</th> <th>Frequency</th> <th>Percent</th> <th>Cum Freq</th> <th>Cum Percent</th> </tr> </thead> <tbody> <tr> <td>2</td> <td>597</td> <td>100.00</td> <td>597</td> <td>100.00</td> </tr> </tbody> </table>	SYN_SLING	Frequency	Percent	Cum Freq	Cum Percent	2	597	100.00	597	100.00	1	2
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E11.	Currently or recently pregnant (<12 months post-partum)? <table border="1"> <thead> <tr> <th>CURR_PREG</th> <th>Frequency</th> <th>Percent</th> <th>Cum Freq</th> <th>Cum Percent</th> </tr> </thead> <tbody> <tr> <td>2</td> <td>597</td> <td>100.00</td> <td>597</td> <td>100.00</td> </tr> </tbody> </table>	CURR_PREG	Frequency	Percent	Cum Freq	Cum Percent	2	597	100.00	597	100.00	1	2
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2	597	100.00	597	100.00									

Affix ID Label Here

E12.	Laparoscopic or open pelvic surgery <3 months?		1	2															
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2	597	100.00	597	100.00															
E13.	Current evaluation or treatment for chronic pelvic pain (painful bladder syndrome)?		1	2															
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E14.	ASA Class IV?		1	2															
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2	597	100.00	597	100.00															
E15.	Current urinary tract infection?		1	2															
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2	597	100.00	597	100.00															
E16.	Previous placement of synthetic mesh on a vaginal approach to reconstructive surgery?		1	2															
	<table border="1"> <thead> <tr> <th>PREV_MESH</th> <th>Frequency</th> <th>Percent</th> <th>Cum Freq</th> <th>Cum Percent</th> </tr> </thead> <tbody> <tr> <td>.</td> <td>439</td> <td>.</td> <td>.</td> <td>.</td> </tr> <tr> <td>2</td> <td>158</td> <td>100.00</td> <td>158</td> <td>100.00</td> </tr> </tbody> </table> <p style="text-align: center;">Frequency Missing = 439</p>	PREV_MESH	Frequency	Percent	Cum Freq	Cum Percent	.	439	.	.	.	2	158	100.00	158	100.00			
PREV_MESH	Frequency	Percent	Cum Freq	Cum Percent															
.	439	.	.	.															
2	158	100.00	158	100.00															
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															
	<table border="1"> <thead> <tr> <th>CONCOM_SURG</th> <th>Frequency</th> <th>Percent</th> <th>Cum Freq</th> <th>Cum Percent</th> </tr> </thead> <tbody> <tr> <td>2</td> <td>597</td> <td>100.00</td> <td>597</td> <td>100.00</td> </tr> </tbody> </table>	CONCOM_SURG	Frequency	Percent	Cum Freq	Cum Percent	2	597	100.00	597	100.00								
CONCOM_SURG	Frequency	Percent	Cum Freq	Cum Percent															
2	597	100.00	597	100.00															

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**

Because the frequency of at least one category is very low, the variable was not included in the dataset

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