Form 55: Follow-Up Urodynamic Studies, Version 10/07/04 (C)

Section A: General Study Information for Office Use Only:

A1. Study ID#: Label

A2. Visit # F/U 24 MONTHS FU24
FAILURE .....FAIL
OTHER: ____ ____ ____ ____

SECTION B: NON-INSTRUMENTED UROFLOWMETRY (NIF)

B1. Maximum flow rate: ____ ____ . ____ **ml/sec**

B2. Mean flow rate: ____ ____ . ____ **ml/sec**

B3. Classify the flow pattern of the urine stream:

Normal (continuous, smooth, arc-shaped signal with high amplitude) 1

Abnormal 2

B4. Time to maximum flow: ____ ____ ____ . ____ **sec**

B5. Voided volume: ____ ____ ____ **ml**

(If voided volume is < 150 ml, NIF must be repeated at another time.
Data recorded in Section B should be from the NIF with the greater voided volume.)

B5a. Is the NIF from a spontaneous or a mechanical fill? Spontaneous fill 1

Mechanical fill 2

B6. Post void residual: ____ ____ ____ **ml**

B7. Are any NIF data points missing? Yes 1

No.....2 ➔ **SKIP TO B8**

B7a. Describe: _____

_____

B8. NIF test date: ___ ___ / ___ ___ / ___ ___ ___ ___
Month Day Year

B9. NIF Tester's Initials: ___ ___ ___

B10. NIF abstraction date: ___ ___ / ___ ___ / ___ ___ ___ ___
Month Day Year

B11. UITN Reviewer's Initials: ____ ____ ____
(REVIEWER MUST = UITN CERTIFIED SURGEON.
IF REVIEWER = TESTER, CODE –3)

B12. Equipment BCC Registration ID#: ___ ___ ___ / ___ ___

SECTION C: PATIENT POSITION AND CATHETER USED

C1. In what position was the CMG completed?

Freestanding, weight bearing (protocol)..... 1 ➔ **SKIP TO C2**

Leaning..... 2

Supine..... 3

Sitting upright..... 4

Sitting at 45º angle..... 5

C1a. Why not freestanding? _____

C2. Catheter diameter:

< 8 French ..... 1 ➔ **SKIP TO SECTION D**

8 French..... 2 ➔ **SKIP TO SECTION D**

> 8 French 3

C2a. Specify catheter diameter: ____ ____ **F**

C2b. Why not ≤ 8 French? _____

SECTION D: CMG VALIDITY, PRESSURES AND VOLUME MEASUREMENTS

CMG pressure measurements will be considered invalid for several reasons; most are listed below. You may also determine CMG pressure values invalid for other reasons. Please review the CMG and **code yes or no to each of the following questions,** then follow the skip directives to complete your review.

D1.	Are the signals legible?	Yes (1)	No (2)*
D2.	Were the catheters zeroed **to atmosphere** prior to the start of filling?	Yes (1)	No (2)*
D3.	Was the **Pves** measuring system functioning properly at **CMG baseline**?	Yes (1)	No (2)*
D4.	Was the **Pabd** measuring system functioning properly at **CMG baseline**?	Yes (1)	No (2)*
D5.	Are there any other reasons you consider the CMG invalid?	Yes (1)*	No (2)
D5a.	If Yes, describe_____		

D6. WERE THERE ANY INVALID CONDITIONS FOR THE CMG?

[Code D6 Yes (1) if you circled a code in any gray box above.]

Yes..... 1 ➔ **IF YES, write '*invalid*' in the data fields for all CMG pressure values but record values for all other data points.**

No 2

D7. P**ves** at baseline: ____ ____ ____ **cm H_2O**

D8. P**abd** at baseline: ____ ____ ____ **cm H_2O**

D9. P**det** at baseline: ____ ____ ____ **cm H_2O**

D10. Bladder **volume** at first desire to void: _____ _____ _____ **ml**

D11. Bladder **volume** at strong desire to void: _____ _____ _____ **ml**

PROLAPSE STATUS

D12. Is there a Stage III or IV anterior prolapse? YES ..... 1 ➔ **SKIP TO D15**

NO 2

LPP MEASURES FOR PATIENT WITHOUT ANTERIOR PROLAPSE STAGE III OR IV

D13. Did leakage occur with Valsalva? * Yes 1

No ..... 2 ➔ **SKIP TO D20**

* *To code this item YES, leakage must occur with Valsalva at least twice at the same volume level.*

D14. At what volume? ____ ____ ____ **ml**

D14a. Raw Pves at **1st** leakage: ____ ____ ____ **cm H_2O**

D14b. Raw Pves at **2nd** leakage: ____ ____ ____ **cm H_2O**

D14c. Raw Pves at **3rd** leakage: ____ ____ ____ **cm H_2O**

➔ **SKIP TO D21** if leakage occurs at least twice at the same volume with Valsava maneuvers

LPP MEASURES FOR PATIENT WITH ANTERIOR PROLAPSE STAGE III OR IV

D15. Did leakage occur with Valsalva **without reduction**? * Yes 1

No ..... 2 ➔ **SKIP TO D17**

* *To code this item YES, leakage must occur with Valsalva at least twice at the same volume level.*

D16. At what volume? ____ ____ ____ **ml**

D16a. Raw Pves at **1st** leakage: ____ ____ ____ **cm H_2O**

D16b. Raw Pves at **2nd** leakage: ____ ____ ____ **cm H_2O**

D16c. Raw Pves at **3rd** leakage: ____ ____ ____ **cm H_2O**

➔ Leakage must occur at least twice with Valsalva maneuvers at the same volume

MEASURES COMPLETED AFTER PROLAPSE REDUCTION

D17. Specify how the prolapse was reduced:

Gauze vaginal packing ..... 1➔ **SKIP TO D18**

Sponge stick ..... 2➔ **SKIP TO D18**

Pessary ..... 3➔ **SKIP TO D17a**

Speculum ..... 4➔ **SKIP TO D17c**

Other ..... 99 ⬇

Specify: _____ ➔ **SKIP TO D17c**

D17a. Specify pessary size: _____

D17b. Specify pessary type: _____

D17c. Why wasn't gauze vaginal packing or sponge stick used?_____

_____

D18. Did leakage occur with Valsalva **with reduction? *** Yes 1

No..... 2 ➔ **SKIP TO D20**

> ***** *To code this item YES, leakage must occur with Valsalva at least twice at the same volume level.*

D19. At what volume? ____ ____ ____ **ml**

D19a. Raw Pves at **1st** leakage: ____ ____ ____ **cm H_2O**

D19b. Raw Pves at **2nd** leakage: ____ ____ ____ **cm H_2O**

D19c. Raw Pves at **3rd** leakage: ____ ____ ____ **cm H_2O**

➔ **SKIP TO D21** if leakage occurs at least twice at the same volume with Valsalva maneuvers

D20. Did leakage occur with cough at MCC? Yes 1

No 2

D21. Bladder volume at MCC: ____ ____ ____ **ml**

D21a. P**ves** at MCC: ____ ____ ____ **cm H_2O**

D21b. P**abd** at MCC: ____ ____ ____ **cm H_2O**

D22. Was there detrusor overactivity? Yes..... 1 No ..... 2➔ **SKIP TO E1**

Record volume at each occurrence of detrusor overactivity and indicate if overactivity was associated w/ leakage.

	Occurrence	**Recorded Volume**		**Leakage?**	
D22a.	Occurrence 1:	____ ____ ____ ____ **ml**	YES.....1	NO.....2	
D22b.	Occurrence 2:	____ ____ ____ ____ **ml**	YES.....1	NO.....2	
D22c.	Occurrence 3:	____ ____ ____ ____ **ml**	YES.....1	NO.....2	

SECTION E: PRESSURE FLOW STUDY (PFS)

PFS pressure measurements will be considered invalid for several reasons; most are listed below. You may also determine PFS pressure values invalid for other reasons. Please review the PFS signals and **code yes or no to each of the following questions** then follow the skip directives to complete your review.

E1.	Are the signals legible?	Yes (1)	No (2)*
E2.	Were the catheters zeroed **to atmosphere** prior to the start of filling?	Yes (1)	No (2)*
E3.	Did the patient sit to void?.....	Yes (1)	No (2)*
E4.	Were transducers adjusted after the patient changed her position?	Yes (1)	No (2)*
E5.	Was the PFS baseline interpretable?	Yes (1)	No (2)*
E6.	Was the **Pves** measuring system functioning properly at **baseline**?.....	Yes (1)	No (2)*
E7.	Was the **Pabd** measuring system functioning properly at **baseline**?.....	Yes (1)	No (2)*
E8.	Did the patient void?	Yes (1)	No (2)*
E9.	Was the **Pves** measuring system functioning properly at **Qmax**?.....	Yes (1)	No (2)*
E10.	Was the **Pabd** measuring system functioning properly at **Qmax**?.....	Yes (1)	No (2)*
E11.	Are there any other reasons you consider the PFS invalid?.....	Yes (1)*	No (2)
	E11a.	If Yes, describe_____	

***E12.** WERE THERE ANY INVALID CONDITIONS FOR THE PFS?

[Code E12 Yes (1) if you circled a code in any gray box above.]

Yes..... 1 ➔ **If YES, skip to E17, complete E17 through E20, then skip to E26.** ★

No..... 2

E13. Did the patient cough before the void? Yes. ..... 1 No ..... 2➔ **IF NO, SKIP TO E15**

E14. Was there 70% concordance between the Pves and Pabd pre-void cough spike? Yes ..... 1 No 2

E15. **PFS BASELINE PRESSURES:** Read baseline pressure values after patient sits to void, the adjustment of transducers and pre-void cough. Take readings from a stable, flat Pves and Pabd signal. Typically, this measurement occurs a few or several seconds before flow and prior to any vesical or abdominal pressure increase associated with the beginning of the void.

E15a. Pves at PFS **baseline**: ____ ____ ____

E15b. Pabd at PFS **baseline**: ____ ____ ____

E15c. Pdet at PFS **baseline**: ____ ____ ____

E16. **PRESSURES AT MAX FLOW (Qmax)**

E16a. Pves at **Qmax**: ____ ____ ____

E16b. Pabd at **Qmax**: ____ ____ ____

E16c. Pdet at **Qmax**: ____ ____ ____

E17. Max flow rate: _____ _____

E18. Time to max flow: _____ _____

E19. Voided volume: _____ _____ _____

If the patient cannot void [E8=2 (No)], write "***missing***" for E17-E20 and skip to E26.

E20. Did the urethral sphincter relax during voiding?

Yes 1

No 2

Perineal surface EMG electrodes weren't used 3

Cannot determine, EMGs not functioning or results not conclusive 4

★ ***Skip E21 – E24 if the study is invalid per your 'Yes' response to E12.***

E21. Voiding Mechanism:

Detrusor: ≥ 5cm increase in Pves and ≤ 5 cm increase in Pabd 1

Abdominal: ≥5 cm increase in Pabd during flow, mirrored by the Pves signal, with no suggestion of a detrusor component 2

Mixed: ≥ 5 cm increase in Pabd and Pdet during the flow study 3

Urethral relaxation: < 5 cm increase in Pves and Pabd 4

Uninterpretable 5

E22. Did the patient cough after the void? Yes ..... 1 No ..... 2 ➔ **SKIP TO E26**

E23. Was the **Pves signal** functioning during the post void cough? Yes ..... 1 No 2

E24. Was the **Pabd signal** functioning during the post void cough? Yes ..... 1 No 2

E26. CMG test date: ___ ___ / ___ ___ / ___ ___ ___ ___ (Month / Day / Year)

E27. CMG Tester's initials: ___ ___ ___

E28. PFS test date ___ ___ / ___ ___ / ___ ___ ___ ___ (Month / Day / Year)

E29. PFS Tester's initials: ___ ___ ___ (IF PFS TESTER = CMG TESTER, CODE -3)

E30. Abstraction date: ___ ___ / ___ ___ / ___ ___ ___ ___ (Month / Day / Year)

E31. MD Reviewer's initials: ___ ___ ___ (REVIEWER MUST = UITN CERTIFIED SURGEON. IF REVIEWER = EXAMINER FOR BOTH, CODE –3)

E32. Equipment BCC registration ID#: ___ ___ ___ / ___ ___