Question by Question Specifications Guide
Form 52: Follow-Up Physician Assessment
Version 06/07/05 (B)

I. Purpose

The purpose of this Data Form is for the study surgeon to document any evidence (e.g. patient's history, MR, etc.) or patient report of (e.g. FM51), pain, urinary retention (defined as catheter use or use of medication to enhance voiding or PVR >150cc), vaginal prolapse, de novo urge incontinence, persistent urge incontinence, stress urinary incontinence, or any other complaint or event related to the study surgery (for guidance re: reportable adverse events, refer to FMs 91 and 71).

II. Administration

A. Windows for Follow-up Visits

The visit window is defined as the period of time in which measures for a specific study event should be completed. In the best of circumstances, measures completed for a study visit are collected in a single session, but this is not always practical. With this objective in mind, we have established visit windows for each of the follow-up visit events. Review the "Visit Windows" document published in the Data Management Manual and on the website for information about how target windows are established.

B. Source and Method of Data Form Completion

The "Follow-Up Physician Assessment" Data Form must be completed by the UITN-certified surgeon who completed the patient's surgery. This requirement is meant to ensure that complications and Adverse Events are recorded as accurately as possible, thereby providing the highest quality data for the UITN's Data and Safety Monitoring Board.

C. Materials needed:

- Patient's Visit Control Sheet (VCS) for the current visit
- Data Form 52 with ID labels attached
- Completed Data Form 51 (for reference)
- Blank copy of FM93 (in case there are reinterventions or treatments to document)
- Blank copies of FMs 91 and 71 (in case there are any reportable adverse events to document)
- Medical record (for reference)

III. Section by Section Review for Form 52

Section A. General Information

A1. **Study ID Number:** Affix the patient ID label in the spaces provided in the A1 field and at the top of subsequent pages on the Data Form. Avoid handwriting ID numbers. Check carefully to be sure the ID number matches the ID number on the patient's Visit Control Sheet.

A2. **Visit Number:** Circle the correct visit code for the event. If this Data Form is being completed as part of a scheduled UITN study visit, circle the correct visit code. If it is being completed solely because of a treatment failure, circle "FAIL."

A3. **Date Form Completed:** Record the date that the form is being completed. Use the mm/dd/yyyy format.

A4. **Initials of Person Completing this Form:** The surgeon completing this Data Form should enter his/her initials. Enter the first initial in the first space provided, middle initial in the second space provided and last initial in the third space provided. If the surgeon does not have a middle initial, strike a dash in the second space. If the surgeon's last name is hyphenated or if s/he has 2 last names, enter the initial of the first last name in the third space.

Section B: Patient Complications or Symptoms

B1. **Pain related to UITN index surgery?** Review Data Form 51, which was completed through patient interview and medical record abstraction. Given that information and data in the patient's MR, indicate whether there is any evidence that the patient is experiencing pain that she feels is related to her UITN index surgery. Circle "1" (YES) or "2" (NO), and follow the skip pattern on the Data Form.

B1a. **Judgment of the cause of pain?** If B1 was "Yes," the surgeon should indicate whether s/he feels that the patient's pain is actually related to her index surgery for urinary incontinence. Circle "1" (YES) or "2" (NO), and follow the skip pattern on the Data Form.

B1b. **Treatment(s) for pain?** Indicate whether or not the patient received or is receiving any treatment(s) for her reported pain since her last study visit. Circle "1" (YES) or "2" (NO), and follow the skip pattern on the Data Form.

B1c. **Describe any treatments for pain:** Describe any treatment(s) that were or are being administered for pain resulting from the patient's index surgery since her last study visit.

PAIN FROM THE INDEX SURGERY IS CONSIDERED A COMPLICATION, NOT A REPORTABLE ADVERSE EVENT.

B2a-e. **Evidence of urinary retention, vaginal prolapse, de novo UI, persistent UI and/or stress UI?** Based on a review of the patient's medical history and Data Form 51, indicate whether or not there is new or continuing evidence of urinary retention (defined as catheter use or use of medication to enhance voiding or PVR >150cc), vaginal prolapse, de novo UI, persistent UI and/or stress UI. Circle "1" (YES) or "2" (NO) for each item.

B3. **Did you code "YES" to any of B2a-e?** Indicate whether or not "YES" was coded for any of the items in B2a-e. If "NO," follow the skip pattern on the Data Form.

B4. **Treatments for conditions reported in B2a-e?** Indicate whether the patient received or is receiving new or continuing treatment(s) for any of the items in B2a-e since her last study visit. Circle "1" (YES) or "2" (NO). If "YES," the surgeon is required to complete a "Data Form 93: Reintervention or Treatment" in order to document this/these treatment(s).

B5. **Is this Form being completed as part of the FU30 visit or beyond?** Indicate whether this FM52 is being completed as part of the FU30 visit or beyond. If no, skip to B7.

B6. **Does the patient report or is there any new evidence of any of the following reportable E-SISTEr adverse events since the last visit:** For patients at FU30 and beyond, indicate whether there is any new evidence of any reportable E-SISTEr adverse events. For all "YES" answers, you must complete a Form 71: E-SISTEr Adverse Event. Please note, in E-SISTEr, "recurrent cystitis" is the reportable AE (i.e. as opposed to reporting every occurrence of "cystitis" in SISTEr). As "recurrent cystitis" is defined as ≥2 occurrences in a 6 month period, please review the past visit's FM52 and associated source documents.

B7. **Evidence or patient report of any other symptom or complication related to the UITN surgery? For patients at all visits, i**ndicate whether the patient reported or there is any evidence of any other symptom or complication related to the UITN surgery. Circle "1" (YES) or "2" (NO). If "NO," the form is complete. If "YES" please complete a Form 91:Adverse Event or Form 71:E-SISTEr Adverse Event as necessary.

B7a. **Describe any other symptom or complication related to the UITN surgery:** Describe any other symptom or complication related to the UITN surgery on the lines provided.