Question by Question Specifications Guide
Form 60: 24 Month Physical Systems Update
Version 08/04/03 (A)_revised 11/24/03

I. Purpose

The primary aim of this Data Form is to record the patient's height and weight at 24 Months and at the time of surgical retreatment for SUI, and to capture any newly diagnosed health conditions the patient may have.

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 for UITN patients. With this in mind, we have established visit windows for each of the studies' follow-up visit events. Review the "Visit Windows" document published in the Data Management Manual and on the web for information about how target windows are established.

B. Source of Data

Data gathered for this Data Form may be gathered by interview and medical record review. Regardless of the source, all data must be gathered by UITN research staff certified and registered with the BCC. When medical records are used for data elements within Form 60, the medical record numbers must be recorded on the patient's Visit Control Sheet and source documentation must be readily available for a data audit as required.

C. Certification of UITN Interviewers and Data Collectors

Interviewers and data collectors must by certified by and registered with the BCC as a UITN Interviewer / Data Collector. The obligations of certification are documented in the QC Plan. Data gathered by non-certified persons may not be entered into the UITN DMS.

D. Materials needed:

- Patient's Visit Control Sheet (VCS) for the FU24 or FAIL visit
- Form 60 with ID labels attached;
- Patient's medical record(s)

III. Section by Section Review for Form 60

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 in the data from. Avoid handwriting ID numbers.

A2. **Visit Number**: Circle the correct visit code for the event. If Form 60 is completed at the time of the 24-month follow-up study visit, circle FU24. Form 60 is will be required **prior** to the 24-month visit only if a patient receives surgical retreatment for SUI; when Form 60 is completed prior to surgical re-treatment for SUI, circle FAIL.

A3. **Date interview completed**: Record the date you complete the interview. Use the mm/dd/yyyy format.

A4. **Interviewer's Initials**: The person completing the interview should record his/her initials in this data field. All Interviewers/Data Collectors must be certified by and registered with the BCC. Data submitted by non-certified individuals should not be data entered into the UITN DMS. Enter first initial in the first space provided, middle initials in the second space provided and last initial in the third space provided. If you don't have a middle initial, strike a dash in the second space. If your last name is hyphenated or if you have 2 last names, enter the initials of the first last name in the third space.

A5. **Which version of this form was used?:** Record which language version of the form was used to complete the Physical Systems Update Data Form.

Section B: Anthropometric Measures

B1. **Height in Inches:** Ask the patient to remove her shoes. Record the patient's height to the nearest whole inch. If the patient's height falls exactly between two whole numbers, round up to the next higher inch.

Examples: If the patient's height is >65 inches but <65½ inches, record as 65 inches.
If the patient's height is exactly 65½ inches, record as 66 inches.
If the patient's height is >65½ inches but <66 inches, record as 66 inches.

B2. **Weight in Pounds:** Have the patient remain clothed, but ask her to remove her shoes. Record the patient's weight to the nearest whole pound. If the patient's weight falls exactly between two whole numbers, round up to the next higher pound.

Examples: If the patient's weight is >140 pounds but <140½ pounds, record as 140 pounds.
If the patient's weight is exactly 140½ pounds, record as 141 pounds.
If the patient's weight is >140½ pounds but <141 pounds, record as 141 pounds.

Section C: Newly Diagnosed Health Conditions

B1 – B12: **Newly diagnosed health conditions**: These data can be obtained through direct interview with the patient and through abstraction of the patient's medical records. Definitive data may be required for select items where indicated. Ask the question of the patient as written. Interviewers may probe to gather accurate information. Code yes or no for each item.

B1-12a: **Source codes**: Record the source for the data recorded here. If the only source of information is the patient, record 1 as the source code in the last column of this table. If the only source of information for the data is the medical record, record 2 as the source code. If the source for the data is **both** the patient and the medical record and there is agreement between these sources, record 3 as the source code. If the patient report contradicts information found in the medical record, a CTC PI must arbitrate the final code for the data; use the source code of 4 for these cases. If the source of information for the data is the patient and a medical record has been sent for, record 5 as the source code. This code will prompt a pending edit that must be resolved when the medical record arrives, when it should then be changed to 3; or if the medical record proves to be unattainable, when it should be changed to 1.
If medical record(s) are used for any of these items, the medical record numbers must be recorded on the patient's Visit Control Sheet and source documentation must be readily available for a data audit as required.