Question by Question Specifications Guide
Form 04: Baseline Physical Exam
Version 07/01/02 (A)

I. Purpose

The purpose of the of the physical exam is to determine eligibility for the study and to collect data regarding type and severity of UI, risk factors for UI, and pelvic/other comorbidities.

II. Administration

A. Window for Re-Screening of Patients

If more than 6 months transpires between determination of eligibility and surgery, specified measures must be repeated to ensure current eligibility for the trial as well as to obtain current baseline values for critical measures that would be subject to change over a 6-month period. Therefore, the UITN Steering Committee established the following rule:

The following Physical Exam measures must be repeated if more than 6 months elapses between the date of completion of the measure and the date of surgery:

1) POP-Q Examination (Section E)
2) All other eligibility criteria that might be subject to change over a 6-month period including:
   - ASA classification status (Section G)
   - Candidate for harvesting of autologous rectus fascia graft (Section G)
   - Evidence of urethral diverticulum (Section G)
   - Evidence of prior augmentation cystoplasty or artificial sphincter (Section G)
   - Evidence of current pregnancy status (Section G)

B. Timing

In most instances, the Data Form will be completed after the physical exam has been conducted. Please refer to the Field Design. Therefore, data will be abstracted from the medical record. The Data Form can also be completed by the examiner after conducting the exam.

C. Source

These data may be abstracted from medical records provided all measures/exams are completed in accordance with the UITN protocol and conducted by UITN certified examiners.

D. Certification of UITN Examiners and Data Collectors

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

E. Materials Needed:

- Reflex hammer and accessories
- Stop watch accurate to a tenth of a second
- Small hand-held mirror
- Clear plastic ruler
- Graduated ring forceps
- Bivalve speculum
- Sims speculum
- Robinson Pocket goniometer (7.25", 180º with a 5º increment)

III. Section by Section Review

Section A: General Study Information

A1. **Study ID Number:** Affix the patient ID label in the spaces provided in the A1 field and in the upper right-hand corner of each page of the Data Form. At all costs, avoid handwriting ID numbers. Transcription errors are very common when transcribing long numbers, and errors in an eight ID usually cannot be corrected. Furthermore, handwritten numbers are often illegible. Most research studies will not accept handwritten IDs, making the data gathered on such Data Forms unusable.

A2. **Visit Number:** The visit number is pre-coded for Data Form 04 which will always be Visit **BASE**. This Data Form is to be completed at the baseline visit.

A3. **Is this a repeat measure?:** If more than 6 months transpires between determination of eligibility and surgery, the following measures must be repeated to ensure current eligibility for the trial as well as to obtain current baseline values for critical measures that would be subject to change over a 6-month period.

1) POP-Q examination (Section E),
2) All other PE eligibility criteria that might be subject to change over a 6-month period including:
   - ASA classification (Section G)
   - Candidate for harvesting of autologous rectus fascia graft (Section G)
   - Evidence of urethral diverticulum, (Section G)
   - Evidence of prior augmentation cystoplasty or artificial sphincter (Section G)
   - Evidence of current pregnancy (Section G)
3) Eligibility summary (Section H)

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 <u>exactly</u> 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: Directed Neurological Exam

A directed neurological exam is performed to assess any abnormalities of the sensory, motor, and reflex functions of deep tendon knee reflexes, perineal sensation, and anal sphincter voluntary contractions.

C1. **Deep Tendon Reflex Knee:** Deep tendon reflexes will be coded for the lower extremities only. The knee jerk reflex is mediated by the L3 and L4 nerve roots, mainly L4. Insult to the cerebellum may lead to pendular reflexes. Pendular reflexes are best observed when the patient's lower legs are allowed to hang and swing freely off of the end of an examining table. Record whether reflexes were "normal" or "abnormal."

C2. **Perineal Sensation:** With the patient in the dorsal lithotomy position, the S2-S4 segments are touched softly with a broken Q-Tip on the left and right side of the perineum separately. Indicate whether sensation was "normal" or "decreased."

C3. **Anal Sphincter Voluntary Contractions:** Contraction of the external anal sphincter and puborectalis muscles is assessed by using a four point scale for pressure and duration while a single index finger is inserted 4-6 cm into the anal canal. The patient should be instructed to contract the muscles she would use if she were trying to hold in gas. Indicate whether the contractions were found to be "normal" or "decreased."

C4. **Date Exam Completed:** Record the date on which the Directed Neurological Exam was completed. All dates must be in the format of mm/dd/yyyy.

C5. **Directed Neuro Examiner's Initials:** Enter the initials of the examiner who conducted the Directed Neurological Exam. 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 examiner doesn't have a middle initial, strike a dash in the second space. If the examiner's last name is hyphenated or s/he has 2 last names, enter the initials of his/her first last name in the third space.

C6. **Date Abstract Completed**: Record the date on which the abstraction was completed. All dates must be in the format of mm/dd/yyyy.

C7. **Abstractor's Initials**: Enter the initials of the person abstracting the data. If the examiner is filling out this Data Form, code "–3" for this item. 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 abstractor doesn't have a middle initial, strike a dash in the second space. If the abstractor's last name is hyphenated or s/he has 2 last names, enter the initials of his/her first last name in the third space.

Section D: Pubococcygeus Contraction Assessment

This procedure is an adaptation of a test described by Brink, Sampselle, Wells, Diokno, and Gillis (1989). Refer to the Physical Examination Procedures Manual located in the Manual of Operations for details of how to perform this procedure.

D1. **Pressure:** Record according to codes provided directly on the Data Form. More specifically:

1 = No response; cannot perceive on finger surface
2 = Weak squeeze; felt as a flick at various points along the finger surface; not all the way around
3 = Moderate squeeze; felt all the way around finger surface
4 = Strong squeeze

D2. **Duration**: Record the duration of the contraction accurate to a tenth of a second.

D3. **Displacement of vertical plane**: Record according to codes provided directly on the Data Form. More specifically:

1 = None
2 = Fingertips may move anteriorly (pushed up by muscle bulk)
3 = Whole length of fingers move anteriorly
4 = Whole fingers move anteriorly; are gripped and pulled in

D4. **Date PC Assessment Completed:** Record the date on which the PC Exam was completed. All dates must be in the format of mm/dd/yyyy.

D5. **PC Assessment Examiner's Initials:** Enter the initials of the examiner who conducted the PC Assessment. 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 examiner doesn't have a middle initial, strike a dash in the second space. If the examiner's last name is hyphenated or s/he has 2 last names, enter the initials of his/her first last name in the third space.

D6. **Date Abstract Completed**: Record the date on which the abstraction was completed. All dates must be in the format of mm/dd/yyyy.

D7. **Abstractor's Initials**: Enter the initials of the person abstracting the data. If the examiner is filling out this Data Form, code "–3" for this item. 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 abstractor doesn't have a middle initial, strike a dash in the second space. If the abstractor's last name is hyphenated or s/he has 2 last names, enter the initials of his/her first last name in the third space.

Section E: Pelvic Organ Prolapse Quantification Exam (POP-Q)

This procedure will be performed according to the guidelines established by the International Continence Society (Bump et al., 1996) and will be standardized as demonstrated in a videotape produced by Duke University Medical Center ("Pelvic Organ Prolapse Quantification Exam"). Examiners must be certified by and registered with the UITN BCC at NERI (the specific certification obligations are documented in the QC Plan in the Manual of Operations). Refer to the Physical Examination Procedures Manual located in the Manual of Operations for details of how to perform this procedure.

E1-E9. **Points Aa, Ba, C, D, Ap, Bp, GH, PB, TVL:** Document the position or length of each of the nine anatomic landmarks in the "Record Value" column of the table to the tenth of a centimeter. The convention for recording these values is: a positive or negative sign recorded in the first space available in the "Record Value" column, followed by any necessary leading zeroes, and then followed by the actual value. For example, "-3" should be recorded as – 0 3.0; "+3" should be recorded as + 0 3.0. A description of the measure and the accepted range of values is included in the table as a memory aid. Point D is omitted (N/A) for any patient who has had their cervix removed as part of a total hysterectomy. In such cases, circle code "888". Also, be sure that the date of the hysterectomy was properly recorded in Data Form 02.

E10. **Indicate the Stage of Prolapse:** Circle the appropriate Stage according to the staging system summarized at the bottom of the page.

E11. **Date POP-Q Exam Completed:** Record the date on which the POP-Q Exam was completed. All dates must be in the format of mm/dd/yyyy.

E12. **POP-Q Examiner's Initials:** Enter the initials of the examiner who conducted the POP-Q Exam. 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 examiner doesn't have a middle initial, strike a dash in the second space. If the examiner's last name is hyphenated or s/he has 2 last names, enter the initials of his/her first last name in the third space.

E13. **Date Abstract Completed**: Record the date on which the abstraction was completed. All dates must be in the format of mm/dd/yyyy.

E14. **Abstractor's Initials**: Enter the initials of the person abstracting the data. If the examiner is filling out this Data Form, code "–3" for this item. 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 abstractor doesn't have a middle initial, strike a dash in the second space. If the abstractor's last name is hyphenated or s/he has 2 last names, enter the initials of his/her first last name in the third space.

Section F: Urethral Hypermobility (Q-Tip Test)

Refer to the Physical Examination Procedures Manual located in the Manual of Operations for details of how to perform this procedure.

F1. **Resting Angle:** Record the resting angle.

F2. **Angle at maximum straining:** Record the angle at maximum straining.

NOTE: If F1 and F2 are ≤ 30°, the patient is ineligible.

F3. **Based on this Q-Tip test, is the woman eligible to continue with the screening assessment?:** Indicate "Yes" or "No".

F4. **Date Exam Completed:** Record the date on which the Q-Tip Test was completed. All dates must be in the format of mm/dd/yyyy.

F5. **Q-Tip Test Examiner's Initials:** Enter the initials of the examiner who completed the Q-Tip Test. 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 examiner doesn't have a middle initial, strike a dash in the second space. If the examiner's last name is hyphenated or s/he has 2 last names, enter the initials of his/her first last name in the third space.

F6. **Date Abstract Completed**: Record the date on which the abstraction was completed. All dates must be in the format of mm/dd/yyyy.

F7. **Abstractor's Initials**: Enter the initials of the person abstracting the data. If the examiner is filling out this Data Form, code "–3" for this item. 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 abstractor doesn't have a middle initial, strike a dash in the second space. If the abstractor's last name is hyphenated or s/he has 2 last names, enter the initials of his/her first last name in the third space.

Section G: ASA Assessment and Other Eligibility Considerations

G1. **Based on your clinical judgment, is the patient ASA Class I, II, or III?:** Indicate "Yes" or "No" based on your clinical judgment. Note: If the answer is "No," the patient is ineligible. Please refer to Appendix A for ASA Class definitions.

G2. **Based on your examination, will it be possible to harvest the autologous rectus fascia for a sling procedure?:** Indicate "Yes" or "No" based on your clinical judgment. Note: If the answer is "No," the patient is ineligible.

G3a-c. **Based on your examination, is there evidence of…:** Indicate "Yes" or "No" to subparts a-c.

G4. **Did you code "Yes" to any of the items in G3?:** Indicate "Yes" or "No." NOTE: If the answer is "Yes," the patient is ineligible.

G5. **Date Assessment Completed:** Record the date on which this assessment was completed. All dates must be in the format of mm/dd/yyyy.

G6. **ASA/Eligibility Examiner's Initials:** Enter the initials of the person who confirmed ASA class and "other eligibility items." 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 person doesn't have a middle initial, strike a dash in the second space. If the person's last name is hyphenated or s/he has 2 last names, enter the initials of his/her first last name in the third space.

G7. **Date Abstract Completed**: Record the date on which the abstraction was completed. All dates must be in the format of mm/dd/yyyy.

G8. **Abstractor's Initials**: Enter the initials of the person abstracting the data. If the person named in H5 is the person filling out this Data Form, code "–3" for this item. 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 abstractor doesn't have a middle initial, strike a dash in the second space. If the abstractor's last name is hyphenated or s/he has 2 last names, enter the initials of his/her first last name in the third space.

Section H: Eligibility Summary

H1. **Does the patient meet all eligibility criteria as required in this form? (Review codes to items F1, F2, F3, G1, G2, G3 and G4):** Review the specified codes to ascertain if the patient is still eligible to continue with the screening measures. Code "Yes" or "No" to this question. If the patient meets all eligibility criteria in this Data Form, indicate "Yes" and continue with the screening measures. If "No," the patient is ineligible and no further screening measures should be completed.

H2. **Date eligibility determination completed**: Record the date on which the eligibility determination was completed. All dates must be in the format of mm/dd/yyyy.

H3. **Initials of person completing eligibility determination**: Enter the initials of the person who completed the eligibility determination in H1. 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 person doesn't have a middle initial, strike a dash in the second space. If the person's last name is hyphenated or s/he has 2 last names, enter the initials of his/her first last name in the third space.

APPENDIX A

Reference: Composite from different editions of the *Textbook of Surgery* (Sabiston, David C., *Textbook of Surgery*. Philadelphia: W.B. Saunders Company).

CLASS	DESCRIPTION
ASA I	Healthy individual *with no systemic disease*, undergoing elective surgery. Patient not at extremes of age. (*Note:* Age is often ignored as affecting operative risk; however, in practice, patients at either extreme of age are thought to represent increased risk.)
ASA II	Individual with *one system, well-controlled disease*. Disease does not affect daily activities. Other anesthetic risk factors, including mild obesity, alcoholism, and smoking can be incorporated at this level.
ASA III	Individual with *multiple system disease or well-controlled major system disease*. Disease status limits daily activity. However, there is no immediate danger of death from any individual disease.
ASA IV	Individual with *severe, incapacitating disease*. Normally, disease state is poorly controlled or end-stage. Danger of death due to organ failure is always present.
ASA V	Patient who is in *imminent danger of death*. Operation deemed to be a last resort attempt at preserving life. Patient not expected to live through the next 24 hours. In some cases, the patient may be relatively healthy prior to catastrophic event which led to the current medical condition.