BE-DRI

Question by Question Specifications Guide
Form 204: Baseline History and Physical Exam
Version 03/29/05 (B)

I. Purpose

The purpose of the history and physical exam is to determine eligibility for the study as well as to collect some baseline physical data for comparison with follow-up data.

I. Administration

A. Window for Re-Screening of Patients

If more than 3 months transpires between determination of eligibility and randomization, all 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 3-month period.

B. Timing & Source

In most instances, the Data Form will be completed after the physical exam has been conducted. Therefore, data will be abstracted from the medical record. The Data Form can also be completed by the examiner after conducting the exam. Regardless, proper source documentation of these data must be maintained.

C. Certification of UITN Examiners and Data Collectors

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

D. 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

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.

A2. **Visit Number:** The visit number is pre-coded for F204, as it will always be Visit **SCRN**.

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: Directed Neurological Exam and Rectal Exam

Description: 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. A rectal exam is completed to check for fecal impaction.

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 in the format of mm/dd/yyyy.

C5. **Directed Neuro Examiner's Initials:** Enter the initials of the examiner. 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 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.

C8. **Fecal Impaction:** The examiner should check for fecal impaction and code accordingly. If evidence of fecal impaction, code yes. The patient will be ineligible but may be re-screened after the impaction is treated and resolved.

C9. **Date Exam Completed:** Record the date in the format of mm/dd/yyyy.

C10. **Examiner's Initials:** See description for C5 on page 2 of this QxQ.

C11. **Date Abstract Completed**: Record the date in the format of mm/dd/yyyy.

C12. **Abstractor's Initials**: See description for C7 on page 3 of this QxQ.

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:** Circle the number that corresponds to the appropriate description.

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

D3. **Displacement of vertical plane**: Circle the number that corresponds to the appropriate description.

D4. **Eligible by PC Assessment**: To be eligible, the pressure measure in D1 must be >1. If not, code no and patient is ineligible.

D5. **Date PC Assessment Completed:** Record the date in the format of mm/dd/yyyy.

D6. **PC Assessment Examiner's Initials:** See description for C5 on page 2 of this QxQ.

D7. **Date Abstract Completed**: Record the date in the format of mm/dd/yyyy.

D8. **Abstractor's Initials**: See description for C7 on page 3 of this QxQ.

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"). POP-Q 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 202.

E10. **Date POP-Q Exam Completed:** Record the date in the format of mm/dd/yyyy.

E11. **POP-Q Examiner's Initials:** See description for C5 on page 2 of this QxQ.

E12. **Date Abstract Completed**: Record the date in the format of mm/dd/yyyy.

E13. **Abstractor's Initials**: See description for C7 on page 3 of this QxQ.

Section F: PVR

F1. **PVR:** Record the PVR in mls as measured by the Investigator's choice of method. If PVR is >150 ml, patient is ineligible.

F2. **Date PVR Measured**: Record the date in the format of mm/dd/yyyy.

F3. **Abstractor's Initials**: See description for C7 on page 3 of this QxQ.

Section G: Urinalysis

A urinalysis will be conducted to check for hematuria (refer to protocol section C.3.1 for the definition of hematuria).

G1. **Evidence of Hematuria:** Circle appropriate response. If yes, patient is ineligible, but can be rescreened at a later date.

G2. **Date Urinalysis Completed:** Record the date in the format of mm/dd/yyyy.

G3. **UITN MD or "Designee" Initials:** Enter the initials of the UITN MD or designee who reviewed the results of the urinalysis. 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 MD or designee does not have a middle initial, strike a dash in the second space. If the MD or designee'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: UTI

A patient with a urinary tract infection at the time of baseline screening is ineligible.

H1. If the patient has a UTI (defined per protocol as "ongoing treatment for UTI"), code yes; such patients are ineligible but may be rescreened after the infection is resolved (i.e. >7 days post-treatment and all symptoms of UTI determined to be resolved per UITN MD Investigator judgment).

H2. **Date of Assessment:** Record the date in the format of mm/dd/yyyy.

H3. **UITN MD or "Designee" Initials:** Enter the initials of the UITN MD or designee who assessed the patient for a UTI. 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 MD or designee does not have a middle initial, strike a dash in the second space. If the MD or designee'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 I: History and Physical Examination

A history and physical examination must be completed by a certified UITN MD Investigator or designee.
This UITN MD Investigator or designee must then complete section I, all of which are eligibility criteria for study participation.

I1-I14. **Evidence of Symptoms or Conditions:** If the physical exam or medical history provides evidence of any of the listed conditions, code yes. A yes code to any of items I1-I14 renders the patient ineligible.

I15. If there is evidence of a condition not included in items I1-I14 that is of clinical significance, code yes and record a description in the space provided.

I16. **Assessment of Eligibility:** Review the codes for items I1-I15. Any yes code may render the patient ineligible. If eligible, code yes,. If ineligible, code no.

I17. **UITN MD Investigator or "Designee" Signature**: The certified UITN MD Investigator or designee completing the history and physical exam must sign the form in the space indicated.

I18. **Date of Signature:** The certified UITN MD Investigator or designee completing the history and physical exam must record the date on which these measures were completed, using the format of mm/dd/yyyy.

Section J: Eligibility Summary

J1. **Does the patient meet all eligibility criteria in this form:** Review codes to items C8, D4, F1, G1, H1, and I16 to ascertain if the patient is still eligible to continue with the baseline measures. If the patient meets all eligibility criteria in this Data Form, indicate

"Yes" and continue with the baseline measures. If "No," the patient is ineligible and no further measures should be completed.

J2. **Date eligibility determination completed**: Record the date in the format of mm/dd/yyyy.

J3. **Initials of person completing eligibility determination**: Enter the initials of the person who completed the eligibility determination in J1; this person needs to be one of the following: UITN BE-DRI certified Interviewer/Data Collector, Physical Examiner or MD Investigator. 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.

J4. **Earliest completion date of any measure on this form (Review dates in items C4, C9, D5, E10, F2, G2, H2, and I18)**: Record the earliest date on which any of the tests documented on this form were completed. All dates must be in the format of mm/dd/yyyy.