BE-DRI
Question by Question Specifications Guide
Form 202: Preliminary Screening Part II
Version 03/04/05 (B)

I. Purpose

The purpose of the **Preliminary Screening Part II** Data Form is to collect information about health conditions and medical, surgical or behavioral treatments for incontinence that will determine eligibility for study participation.

II. Administration

A. Materials Needed

- Form 202 with ID labels attached;
- Surgical and Treatment Codes (Attachment A to F202); and,
- All patient medical record(s) required to complete eligibility screening in Part II.

B. Window for Re-Screening of Patients

If more than 3 months transpires between completion of screening measures and randomization, all baseline measures must be repeated to ensure current eligibility for the trial as well as to obtain current values for critical measures that would be subject to change over a 3 month period.

C. Source of Data

Data for Part II of the Preliminary Screening 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 02, source documentation must be readily available for a data audit as required.

III. Section by Section Review for Form 202

Section A. General Information

A1. **Study ID Number**: Affix the patient ID label in the space provided in the A1 field and at the top of each subsequent page of the Data Form. Avoid handwriting ID numbers. Check carefully to be sure the ID number matches that recorded on the Confidential ID Assignment Log, F200 and the Visit Control Sheet.

A2. **Visit Number**: The visit number for Form 202 is pre-coded as Visit = SCRN.

A3. **Date Interview Completed**: Record the date the interview was completed using the mm/dd/yyyy format.

A4. **Interviewer's Initials**: The person completing the interview should record his/her initials in this data field. Enter first initial in the first space provided, middle initial in the second space provided, and last initial in the third space provided. If there is not a middle initial to record, strike a dash in the second space. If the last name is hyphenated or if there are 2 last names, enter the initials of the first last name in the third space.

A5. **Consent obtained**: Confirm that consent has been obtained from the patient. At a minimum, a screening consent form must be signed prior to the conduct of the Preliminary Screening measures. The DMS will not allow data entry without verification of completion of consent procedures.

Section B: Eligibility and Related Health Conditions

Description: These questions ask about specific eligibility criteria as well as about other health conditions and previous treatments.

B1 – B12: **Other 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. All eligibility items must be coded; a patient is considered ineligible if any of these codes are missing.

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. If the only source of information for the data is the medical record, record 2. 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 such cases. If the source of information 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.

B13: **Summary of Eligibility**: Code this item accordingly and follow the skip pattern on the form. If any of the conditions are coded yes, the patient is ineligible; this interview form should be finished, but no additional screening measures completed.

B14: **Glaucoma:** If the patient reports that she has glaucoma, an ophthalmologist must be consulted for clearance to participate in the study. This clearance is necessary because the study drug might result in a worsening of narrow angle glaucoma.

B15-B16: **Congestive Heart Failure and Diabetes:** If the patient reports that she has congestive heart failure or diabetes, the condition must be confirmed to be "well managed" in order for her to participate in the study. To confirm such information, check F204, Section I for the physician's determination. If the condition is not judged to be well managed, the patient is

ineligible. She can be re-screened when the condition is stable.

B17: **Menopause status**: Obtain this information through interview with the patient and medical record abstraction, and code the item accordingly. Menopausal is defined as not having had a menstrual period for the past 12 months.

Section C: Medical, Surgical or Behavioral Treatment for Incontinence

C1: **History of incontinence, vaginal, bladder, or prolapse surgery in the past 6 months**: Ask the patient the question as written and review available medical records. If there is any doubt as to the accuracy of the information, additional records may be required to code these data with certainty. You can also read to the patient the list of surgeries noted in the Data Form's Attachment A to prompt information regarding recent surgery. Code the item accordingly. If yes, the patient is not eligible at this time; finish this form as the final screening task. The patient may be rescreened at a later date.

C2: H**istory of any pelvic, rectal, incontinence, vaginal, bladder, or prolapse surgery**: If the patient reports that she had one or more of these surgeries greater than 6 months ago, code yes and proceed to C3. If not, code no and skip to C4.

C3a-e: **Surgeries by (a) name, (b) surgical code, (c) specify, (d) date, (e) source code**: Please be sure to spell the surgery correctly. For item b, you will need to refer to the surgical codes listed in the Data Form's Attachment A. Item (c) is used to further describe a laparoscopic surgery. For example, if the woman reports a laparoscopic tubal ligation, code 07 for item (b) and write "tubal ligation" for item (c). If the surgery was not laparoscopic and item (b) is coded as anything other than 07, record the code in item (b) and leave item (c) blank. For item d, solicit from the patient and use medical records to get date information. Finally, for item e, follow the source code instructions as described on page 2 of this QxQ.

Seven fields are available to record up to 7 different surgeries. This section is programmed as a repeating segment in the DMS and will accept any number of different surgeries; therefore, if you have more than 7 to record, please continue the documentation on the backside of the form, making sure to provide information for each column (a-e). Simply leave the next line on the form blank if there are no more surgeries to record.

C4-C4a: **Treatment of vaginal prolapse with a pessary or incontinence dish:** If the patient reports that she has no prolapse or does not use a pessary or incontinence dish for the treatment of prolapse, code no and skip to C5. If yes, proceed to C4a to determine if use of the pessary or incontinence dish has been stable, i.e., not changed in the past 3 months. If not stable for at least 3 months, code no and finish completion of the form; the patient is ineligible, but can be re-screened at a later date.

C5: **Sensitivity to study drug:** If patient reports that she has previously taken Detrol and had a hypersensitive reaction, code yes and patient is ineligible.

C6: **History of ANY Non-Surgical Treatments for UI:** Ask the patient the question as written and review available medical records. If there is any doubt as to the accuracy of the information, additional records may be required to code these data with certainty. You can also read to the patient the list of treatments noted in the Data Form's Attachment A to prompt information regarding past treatments. Code the item accordingly. If there have never been any non-surgical treatments for UI, code no and skip to Section D. If the patient reports or there is evidence of non-surgical treatments, record each by name, treatment code, date of treatment and source.

C7a-d: **Treatments by (a) name, (b) treatment code, (c) date and (d) source code**: Please be sure to spell the treatment name correctly. For item b, you will need to refer to the treatment codes listed in the Data Form's Attachment A. For item c, solicit from the patient and use medical records to get date information. Finally, for item d, follow the source code instructions as described on page 2 of this QxQ.

The types of treatments are of obvious interest to the Investigators, so every reasonable effort should be made to obtain the most accurate data available. Probe to get the most accurate dates possible. At a minimum, aim to get accuracy for month and year. Prompt women by asking about their age at the time of treatment to get accuracy in the year of treatment. Ask about seasons to hone in on the month. Interviewers may also probe for month by asking about the season when the treatments began/ended. Probe for a response of early, mid or late season. Therefore, since winter season begins in December, spring in March, summer in June and fall in September, you would code these months as the month for an '*early season*' response and use the next subsequent month for a '*mid season*' response and so on. If a patient remembers that her treatments began in early fall of 2000, you would code this as September, 2000. Mid fall would be coded as October, late fall as November. Do not record missing elements in the date. For example, if after careful probing, you conclude that the most accurate date for acupuncture treatment received specifically for UI was early fall of 1999, record this as 09/__ __/1999, i.e. leave the day field blank.

C8: **Previous behavioral or biofeedback treatment:** Code this item accordingly. If the patient reports that she has received behavioral or biofeedback treatment for > than 2 months duration within the past two years, she is ineligible.

Section D: Summary of Eligibility Status

Review items B13, C1, C4a, C5 and C8 to ascertain if the patient is still eligible to continue with screening, and then code yes or no to this question. If the patient meets all eligibility criteria in this Data Form, continue with screening measures. If not, no further measurements should be completed.