Question by Question Specifications Guide
Form 31: 3 Month Follow-Up Assessment, Part I
Version 07/01/02 (A)

I. Purpose

Data will be collected on all UITN patients 3 months following their UITN surgery to gather information related to the patient's post-operative recovery including untoward outcomes that may arise secondary to the anti-incontinence surgery. Data Form 31 is used specifically for the collection of data that can be gathered through self-report interview (Section B) and/or minimal medical record abstraction (Sections C, D and E). Any adverse events or untoward outcomes that occur between the time of the 6 Week Visit and up to the 3 Month Visit must be documented appropriately on the 3 Month Follow-Up Data Forms.

II. Administration

A. Window for the 3 Month Follow-up Visit

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.

The **primary milestone** for creation of the follow-up visit windows is the date of randomization, which in all cases should be equal to the date of the patient's UITN surgery. The **target date** for the 3 month follow-up visit is programmed to be exactly 91 days (13 weeks x 7 days) following the date of randomization. The **visit window** for the 3 month visit is defined as the target date ±2 weeks. Therefore, the **3 month follow-up visit window** is between 11 and 15 weeks following the date of randomization; or between 77 days and 105 days following the date of randomization. The patient's 3 month target date and the 3 month visit window will be printed on the patient's 3 month Visit Control Sheet (VCS) for easy reference. This visit window should be considered the target window within which Study Coordinators should aim to start and end follow-up visit measurements.

B. Source of Data

1. Section B: The Interview: The patient is considered the source for data collected in Section B. All elements in Section B must be collected directly from the patient by formal research interview by a certified UITN Interviewer/Data Collector. Data are recorded simultaneous to the conduct of the research interview.

2. Sections C, D and E: Data gathered in Section C and D may be gathered by interview and medical record review. Regardless of the source, all data must be gathered by a certified UITN Interviewer/Data Collector. When medical records are used for data elements in Sections C, D and E, the source documentation must be readily available for a data audit as required. Sites may use the patient's Visit Control Sheet to maintain a master log of all source documents used for UITN Data Forms.

C. Certification of UITN Interviewers and Data Collectors

Interviewers and data collectors must be 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 3 Month Visit Control Sheet (VCS)
- Form 31 with ID labels attached;
- Patient's medical record(s), depending upon answers to questions in Sections C, D and E

III. Section by Section Review for Form 31

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 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**: The visit number for Form 31 is pre-coded as Visit = F/U 3 months, the 3 month post-operative visit.

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 initial 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. **Interview type**: Circle the code that describes the interview type. The data may be gathered in-person or on the telephone.

A6. **Which version of this form was used?** Record which language version of the form was used to complete the Interview.

Section B: The MESA Interview

Administration: The MESA is a critical measure for the UITN Trial. It is first used to ascertain if a patient has predominant stress urinary incontinence, an essential eligibility criterion. The MESA is also used to determine treatment success or failure following the UITN surgery. Therefore, this instrument will always be administered by a certified UITN interviewer.

Instructions: Read the introduction provided in the data form exactly as written. The response scale for the MESA questions is a four-point scale where '*Never'* is coded as 0; '*Rarely'* is coded as 1, '*Sometimes'* is coded as 2 and '*Often'* is coded as 3. There is no scoring for the follow-up MESA.

MESA Part I: Stress Incontinence:

Read the introduction and the questions to the patient precisely.

B1–B9. **Stress Symptoms**: The Interviewer should read the questions precisely as written on the Data Form. The response choices must be read aloud for **every question** to be certain the patient selects from all of the available responses. An example of this follows:

Interviewer "*Does coughing gently cause you to lose urine? Would you say never, rarely, sometimes or often?"*

Interviewer "*Does coughing hard cause you to lose urine? Would you say never, rarely, sometimes or often?"*

Interviewer "*Does sneezing cause you to lose urine? .... Never, rarely, sometime or often?"*

Interviewer "*Does lifting things cause you to lose urine? ... Never, rarely, sometime or often?"*

It is very common for women to respond to the MESA questions using terms not among the standard choices given in this measure. For example, a woman may respond, "*Oh that happens to me all the time*." Or "*That happens frequently*." In all cases, the Interviewer should repeat the standardized choice categories from the measure, i.e. "*So, would you say never, rarely, sometimes or often?*" Furthermore, **the Interviewer should not code a '*no*' response as '*never*' (code 0)**. The Interviewer should repeat the response choices and ask the patient to select from among **all** the choices. In such instances, it is not uncommon for a woman to make a final choice of "*rarely"* when asked to select from the full range of choices.

B7. **Walking briskly**: If a patient reports she never walks briskly or jogs, you should prompt her by saying, "*Does walking or moving at a pace that is faster than your usual pace cause you to lose urine?"*
In Spanish, ask: *"¿Al caminar o moverse más rápido de lo usual tiene escapes de orina?"*

B8. **Straining**: If a patient reports she is never constipated you should prompt her by saying, "*Do other types of straining, such as opening a tightly closed food container or jar cause you to lose urine?*"
In Spanish, ask: " *¿Tiene escapes de orina cuando se esfuerza de otras formas, tales como cuando abre la tapa de un frasco o envase que esta dura?"*

MESA Part II: Urge Incontinence:

Be sure to read the introduction and the questions to the patient precisely as they are written.

B10-B15. **Urge Symptoms**: The Interviewer should read the questions precisely as written in the Data Form. The response choices should also be read aloud for **every question** to be certain the patient selects from all of the available responses.

As a reminder, it is very common for a woman to respond to the MESA questions using terms not among the standard choices given in this measures. For example, a woman may respond, "*Oh that happens to me all the time*." Or "*That happens frequently*." In all cases, Interviewers should repeat the standardized choice categories from the measure, i.e. "*So, would you say never, rarely, sometimes or often?*" Furthermore, **the Interviewer should not code a '*no*' response as '*never*' (code 0)**. The Interviewer should repeat the response choices and ask the patient to select from among **all** the choices. In such instances, it is not uncommon for a woman to make a final choice of "*rarely"* when asked to select from the full range of choices.

B13. **Washing Hands**: A patient may report even the sound of running water may cause her to lose urine. This can be taken as the equivalent to the washing hands stimulus.

B14. **Cold Weather**: Dr. Diokno, co-developer of the MESA scale and PI of the UITN Beaumont Hospital CTC, reports that some women who live in warmer climates have asked for clarification for this item. If a woman responds, "*I never experience cold weather*." You can probe, "*Have you ever lost urine when you*

entered the freezer section of the grocery store, or when you entered a very cold, air conditioned building?"
In Spanish, ask: *"¿Ha tenido escapes de orina al entrar a la sección de congelados del supermercado, o cuando entra a un edificio con aire acondicionado muy frio?"*

Assessment of Other Physical Symptoms

C1. **Increased Frequency**: Ask the question as written and code the answer accordingly.

C2a-g. **Physical accommodations for urination**: This question is meant to capture physical accommodations that the patient might make to facilitate complete bladder emptying. Ask the patient if she **currently** has to make any of the listed accommodations to urinate. Code "yes" or "no" for every accommodation listed.

C2h. If the patient reports she currently makes any accommodation not included on the list, code "yes" for C2g and describe the accommodation in the text field provided.

C3. **Bothered by changes**: Ask the question as written, and code accordingly.

C4. **Urine stream:** This question is meant to capture the character of the patient's urine stream since surgery. Get the patient to describe her **current** urine stream by asking her to respond "yes" or "no" for each of the urine stream descriptives listed. Code "yes" or "no" for every descriptive listed.

C4g. If the patient uses any other descriptive not included on the list, code "yes" for C4f and write the descriptive in the text field provided.

C5. **Time it takes to urinate**: Ask the question as written and code accordingly.

Symptoms of Bowel Incontinence

C6. **Use of stool softeners**: Ask the question as written and code accordingly.

C7. **Straining**: Ask the question as written. Follow the skip pattern on the Data Form.

C7a. **Frequency of straining**: For patients who report "yes" to straining in QC7, ascertain frequency information using the pre-coded responses provided.

C8. **Leaking Gas**: Ask the question as written and follow the skip pattern on the Data Form.

C8a. **Frequency of leaking gas**: For patients who report "yes" to QC8, ascertain frequency information using the pre-coded responses provided.

C9. **Leaking liquid stool**: Ask the question as written and follow the skip pattern on the Data Form.

C9a. **Frequency of leaking liquid stool**: For patients who report "yes" to QC9, ascertain frequency information using the pre-coded responses provided.

C10. **Leaking solid stool**: Ask the question as written and follow the skip pattern on the Data Form.

C10a. **Frequency of Leaking Solid Stool**: For patients who report "yes" to QC10, ascertain frequency information using the pre-coded responses provided.

Status of Pain and Pain Management

D1. **Any medication(s) for pain related to UITN surgery?** Ask the patient if she is taking any medication for pain related to her UITN surgery. Be sure to ask about any pain meds she reported taking at the 6 week follow-up visit, which are listed on the 3 Month VCS. Code the answer accordingly and follow the skip pattern on the Data Form.

D2. **Do you have physical pain related to UITN surgery?** This question will only be asked of patients who report no pain medication taken for pain related to their UITN surgery.

D3. **Pain rating**: This question will be asked of all patients who report any pain that they feel is directly related to their UITN surgery.

Status of Return to Normal Activities

D4. **Return to full normal activities since surgery**: Ask the question as written, and code the patient's response accordingly. Follow the skip pattern on the Data Form.

D5. **Time it took to return to full normal activities**: Ask the question as written, and record the number of days in the field provided. If the woman is retired or unemployed, code -1 (N/A) in the field.

D6. **Number of <u>paid</u> workdays taken**: Ask the patient how many paid workdays she took off after surgery. If she works but took no <u>paid</u> workdays off, code 00. If she took no paid workdays because she is either unemployed or retired, code -1 (N/A).

<u>Section E: Other Treatments/Health Services Utilization</u>

We will gather data related to: visits to a physician (NP or PA) for urinary symptoms, UITN surgery or any other reason, visits to an emergency room, new non-surgical treatment for UI, new abdominal or pelvic surgeries, and other hospitalizations that have occurred since the patient's 6 Week Visit. Obtain this information through interview with the patient and medical record abstraction. Interviewers should probe to gather accurate information. For example if a patient reports she visited the doctor 2 times since surgery but only one visit is documented in **your** medical record, you should prompt the patient by saying, "I only find evidence of one visit, but I do see a note from a telephone conversation you had with Dr. Brown. Is that what you are remembering?" In this example, a patient might say, "Oh yes, that's right, I spoke with him first, then a week later I came in to see him." Or, the patient might say, "No, actually I did see Dr. Brown once, but I sprained my ankle just last Monday and I saw an orthopedist for it yesterday." The patient might also mix physician visits and emergency room visits. Probe thoroughly and record the information in the appropriate sections.

E1. **Physician Visits related to surgery or urinary symptoms**: These data can be obtained through direct interview with the patient **and** through abstraction of information from the patient's medical records. Ask the question of the patient as written. Interviewers should probe to gather accurate information.

E2. **Dates of and reasons for any MD (NP or PA) Visits for urinary symptoms or surgery**: Record the date (approximate if necessary) and reason for the visit in the text fields provided. A **diagnosis is preferred** over information regarding presenting symptoms at the time of the visit. This data field is a

repeating segment. You may record as many physician visits as the patient reports. Record any additional visits on the reverse side of this page of the Data Form.

E2c: **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's self-report contradicts information found in the medical record, probe thoroughly to get the most accurate information possible. 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 data are gathered from medical records, use the Visit Control Sheet for the 3 Month visit to record any **new** medical record numbers. Additionally, these medical records/source documents must be readily available at the time of an audit.

E3. **Physician Visits for any other reason**: These data can be obtained through direct interview with the patient **and** through abstraction of information from the patient's medical records. Ask the question of the patient as written. Interviewers should probe to gather accurate information.

E4. **Dates of and reasons for any MD (NP or PA) Visits for any other reason**: Record the date (approximate if necessary) and reason for the visit in the text fields provided. A **diagnosis is preferred** over information regarding presenting symptoms at the time of the visit. This data field is a repeating segment. You may record as many physician visits as the patient reports. Record any additional visits on the reverse side of this page of the Data Form.

E4c: **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's self-report contradicts information found in the medical record, probe thoroughly to get the most accurate information possible. 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 data are gathered from medical records, use the Visit Control Sheet for the 3 Month visit to record any **new** medical record numbers. Additionally, these medical records/source documents must be readily available at the time of an audit.

E5: **Ongoing non-surgical treatment for UI**: These data can be obtained through direct interview with the patient **and** through abstraction of information from the patient's medical records. Ask the question of the patient as written. Interviewers should probe to gather accurate information.

E6: **Type of treatment, treatment code, dates of treatment:** For this item, you will need to refer to the Treatment Codes Table included in Attachment C. Record each treatment by name and treatment code as listed in the Treatment Code Table. Make sure all treatments are spelled correctly and match the codes listed in the Code Table.

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. Solicit or obtain the approximate start and end dates for each treatment type. Probe to get the most accurate dates possible.

E6b. **Treatment Code 58, UNKNOWN TYPE**: If the patient reports she has had non-surgical treatments for UI but cannot accurately report or describe sufficiently to allow for accurate coding of the treatment type by name AND you cannot find documentation in the medical record, record the treatment code as code, 58, UNKNOWN TYPE.

Medication: If the patient reports or there is evidence of medications used for the treatment of UI, these medications must also be recorded in the Med Audit (Form 03) for the 3 Month Visit.

E6d. **Source codes**: Record the source code in the last column. 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's self-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 data are gathered from medical records, use the Visit Control Sheet for the 3 Month visit to record any **new** medical record numbers. Additionally, these medical records/source documents must be readily available at the time of an audit.

E7: **Emergency Room Visits**: These data can be obtained through direct interview with the patient **and** through abstraction of information from the patient's medical records. Ask the question of the patient as written. Interviewers should probe to gather accurate information. **Note:** It is not necessary to include ER visits that resulted in hospitalization. These will be captured in Item E11. Only include ER visits which did **not** result in hospital admission.

E8: **Dates of and reasons for ER Visits:** Record the date (approximate if necessary) and reason for the visit in the text fields provided. A **diagnosis is preferred** over information regarding presenting symptoms at the time of the visit. This data field is a repeating segment. You may record as many ER visits as the patient reports. Record any additional visits on the reverse side of this page of the Data Form.

E8c: **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's self-report contradicts information found in the medical record, probe thoroughly to get the most accurate information possible. 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 data are gathered from medical records, use the Visit Control Sheet for the 3 Month visit to record any **new** medical record numbers. Additionally, these medical records/source documents must be readily available at the time of an audit.

E9: **New abdominal or pelvic surgeries since the 6 Week follow-up visit**: These data can be obtained through direct interview with the patient **and** through the abstraction of information from the patient's medical records. Ask the question of the patient as written. Interviewers should probe to gather accurate information.

E10a-e: **Surgeries by name (a), surgical code (b), specify if surg code = 07 (laparoscopy) (c), date of surgery (d) and source code (e)**: For this item, you will need to refer to the Pelvic Surgery Codes included in Attachment C. Record each surgery by name and surgical code as listed in the Pelvic Surgery Code Table. Make sure all surgeries are spelled correctly and match the codes as listed in the Code Table. Item (c) is used to further describe a laparoscopic surgery. If a woman had a laparoscopy, specify the purpose of the laparoscopic procedure in item (c). For example, if a 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.

Solicit from the patient and use the medical records to record the dates of all other pelvic surgeries ever performed. The types of surgery and accurate dates are of obvious interest to the Investigators, so every reasonable effort should be made to obtain the most accurate data available.

b. **Surgical Code 38, UNKNOWN TYPE**: If the patient reports she had a pelvic surgery but cannot accurately report or describe sufficiently to allow accurate coding of the surgery type by name AND you cannot find documentation in the medical record, record the surgical code as code, 38, UNKNOWN TYPE.

e. **Source codes**: Record the source code in the last column. 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's self-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 data are gathered from medical records, use the Visit Control Sheet for the 3 Month visit to record any **new** medical record numbers. Additionally, these medical records/source documents must be readily available at the time of an audit.

E11: **Any other hospitalizations**: These data can be obtained through direct interview with the patient **and** through abstraction of information from the patient's medical records. Ask the question of the patient as written. Interviewers should probe to gather accurate information. Note: It is not necessary to include any hospitalizations that have been captured in previous items. For example, if a woman reported a new pelvic surgery since her 6 week visit in Item E10, do not record the hospitalization for that item here.

E12: **Dates of and reasons for any other hospitalizations**: Record the date (approximate if necessary) and reason for the hospitalization in the text fields provided. A **diagnosis is preferred** over information regarding presenting symptoms at the time of the hospitalization. This data field is a repeating segment. You may record as many hospitalizations as the patient reports. Record any additional hospitalizations on the reverse side of this page of the Data Form.

E12c: **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's

self- report contradicts information found in the medical record, probe thoroughly to get the most accurate information possible. 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 data are gathered from medical records, use the Visit Control Sheet for the 3 Month visit to record any **new** medical record numbers. Additionally, these medical records/source documents must be readily available at the time of an audit.

Use of Antibiotics

E13. **Antibiotic use since the 6 Week follow-up visit:** These data can be obtained through direct interview with the patient **and** through abstraction of information from the patient's medical records. Ask the question of the patient as written. Interviewers should probe to gather accurate information. The patient's medications reported at the 6 Week follow-up visit are listed on her 3 Month VCS. If she was taking an antibiotic at the time of the 6 Week visit, ask the patient about it specifically. Code the item and follow the skip pattern on the Data Form.

E14. **Antibiotics by name including/strength per Rx'd dose/days taken/current use**: If the patient reports she has taken or is currently taking any antibiotics since the 6 Week follow-up visit, record them here. Record the medication by full name including strength and unit dose and the total number of days taken. Record if the patient is still taking the antibiotic and document the reason why this medication was prescribed. This data field is a repeating segment. You may record as many antibiotics as the patient reports having taken since the 6 Week Visit. If there are more than 3 medications to record, document them on the reverse side of this page of the Data Form.

E14d. **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's self-report contradicts information found in the medical record, probe thoroughly to get the most accurate information possible. 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 data are gathered from medical records, use the Visit Control Sheet for the 3 Month visit to record any **new** medical record numbers. Additionally, these medical records/source documents must be readily available at the time of an audit.

Summary of Adverse Events/Untoward Outcomes

F1. **Summary of Adverse Events/Untoward Outcomes:** If the patient reports hospitalizations, ER visits, surgeries or any other event or untoward outcome which has occurred since the 6 Week Visit, this item should be coded "yes" and this event or outcome should be appropriately documented on Form 32. If the event or outcome also qualifies as a "reportable" Adverse Event (as described in the protocol and the QxQ for Data Form 91), be sure to complete and submit an Adverse Event Form according to the procedures outlined in the QxQ for Data Form 91.