Question by Question Specifications Guide
Forms 01 and 02: Preliminary Screening Parts I and II
Version 07/01/02 (A)

I. Purpose

The primary aim of this randomized clinical trial is to compare the Burch modified Tanagho and autologous fascia sling procedures for overall treatment success and stress-related symptoms in women with predominant stress urinary incontinence. The study population will consist of women, 21 years of age or older who have been diagnosed with predominant stress urinary incontinence.

The purpose of the Preliminary Screening data forms is to confirm that a woman meets eligibility criteria to participate in the study through the collection of data that can be gathered through self-report interview and/or minimal medical record abstraction.

The eligibility criteria contained in the **Preliminary Screening Part I** include confirmation of:

- predominant stress incontinence as evidenced by a MESA stress symptom score (percent of total possible stress score) greater than a MESA urge symptom score (percent of total possible urge score);
- stress-type urinary incontinence symptoms of $\geq$3 months duration;
- no current or recent pregnancy (must be $\geq$ 12-months post-partum);
- no intention to become pregnant in the next 2 years; and
- availability to complete at least 2 years of follow-up measurements.

Part II of the Preliminary Screening is designed to rule-out women who have any one of several exclusionary conditions including:

- a lifetime history of cancer of the lower urinary tract, pelvic radiation for any reason, augmentation cystoplasty or artificial urethral sphincter;
- current chemotherapy or radiation treatment for any reason;
- systemic diseases known to affect the bladder function (i.e., Parkinson's disease, multiple sclerosis, spina bifida, spinal cord injury or trauma);
- current use of a catheter to empty bladder;
- urethral diverticulum;
- implanted nerve stimulators; or
- a recent history of pelvic surgery, i.e. **open** pelvic surgery < 6 months or **endoscopic** pelvic surgery < 6 weeks

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 Preliminary Screening measures must be repeated if more than 6 months elapses between the date of completion of the measure and the date of surgery:

1) The MESA assessment (Data Form 01, Sections C and D), and
2) All other eligibility criteria that might be subject to change over a 6-month period including:
    - Current UTI
    - Pregnancy status (Data Form 01, Section F),
    - Recent diagnosis of lower urinary tract cancer, Parkinson's Disease, multiple sclerosis, spinal cord injury or trauma (Data Form 02, Section B)
    - Report or evidence of urethral diverticulum, prior augmentation cystoplasty or artificial sphincter (Data Form 02, Section B),
    - Current intermittent catheterization (Data Form 02, Section B),
    - Current cancer chemotherapy or radiation therapy (Data Form 02, Section B),
    - Recent pelvic surgery (Data Form 02, Section C)
3) The Eligibility Summary (Form 01, Section H and Form 02, Section D)

B. Timing of the UITN Preliminary Screening

In most instances, Study Staff will complete the UITN screening measures to confirm eligibility **after** a Study Surgeon has made a clinical determination that the woman is a surgical candidate for both the Burch and the sling procedures. See the Field Design, Attachment A.

C. Consent Procedures

Consent procedures must be completed prior to the conduct of any UITN data collection or measurements. Sites may conduct a two-level consent process, i.e., first completing a written consent to conduct **screening** measurements, and secondly, for **only** those patients who meet the preliminary eligibility criteria, a second written consent procedure to enroll patients for the full study including randomization and surgery.

D. Source of Data

1. Preliminary Screening, Part I:

The patient is considered the source for data collected in Part I of the Preliminary Screening. Data Form 01 is the source document. All elements in Part I must be collected directly from the patient by formal research interview by a certified UITN Interviewer. Data are recorded simultaneous to the conduct of the research interview.

2. Preliminary Screening, Part II:

Data gathered 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, 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.

E. 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.

F. Materials needed:

- Form 01 with ID labels attached;
- Form 02;
- Adhesive-backed ID labels available for attaching to Form 02 in the event that the patient meets eligibility requirements in Part I;
- the Surgical and Treatment Codes (herein as Attachment C); and,
- all patient medical record(s) required to complete eligibility screening in Part II.

III. Section by Section Review for Forms 01

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. Check carefully to be sure the ID number matches the ID number on the patient's Locator Information Form, Form 00 and the Visit Control Sheet.

A2. **Visit Number**: The visit number for Form 01 is pre-coded as Visit = BASE, the **Baseline** Eligibility Screening 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 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. **Consent obtained**: Confirm that consent has been obtained from the patient here. At a minimum, a screening consent must be completed prior to the conduct of the Preliminary Screening measures. The DMS will not allow data entry of data without verification of completion of consent procedures.

A6. **Which version of this form was used?:** Record which language version of the form was used to complete the Preliminary Screening Part I.

A7. **Is this a repeat measure?:** If more than 6 months transpires between determination of eligibility and surgery, the MESA assessment (Sections C and D), items related to pregnancy status (Section F), and the eligibility summary (Section H) must be repeated. Items that may be repeated are identified in the form with a * in front of each item number.

Form 01: Preliminary Screening Part I

In addition to the eligibility data described above, the following baseline data are gathered in Part I:

- Sociodemographic data including ethnicity, race, education, marital status, employment and income;
- Pregnancy history;
- Lifetime and current smoking habits, and
- Current symptoms associated with bowel incontinence.

Remember, in **all** cases, the patient is considered the source for data collected in Part I of the Preliminary Screening. All elements in Part I must be collected directly from the patient by formal research interview by a certified UITN Interviewer.

Section B: Sociodemographic Information

Description: Standard sociodemographic information, including ethnicity, race, education, marital status, and employment are gathered by self-report in Section B of the Preliminary Screening (Form 01).

For ethnicity and racial designations, the Office of Management and Budget (OMB) Directive No. 15 defines minimum standards for maintaining, collecting and presenting data on race and Hispanic ethnicity for all federal reporting. NIH is required to use these definitions to allow comparisons to other federal databases, especially the census and national health databases.

When an investigator is to collect data on respondent's race and ethnicity, these categories shall be used. Using respondent self-report or self-identification to collect an individual's data on ethnicity and race, investigators should use two separate questions, with ethnicity information collected first, followed by the option to select more than one racial designation. Respondents shall be offered the opportunity to select more than one racial designation. The following definitions apply for **Hispanic ethnicity:**

- **Hispanic or Latino** including persons of Cuban, Mexican, Puerto Rican, South or Central American, or other Spanish culture or origin, regardless of race.

- **Not Hispanic or Latino**: Alternately, persons may report ethnic affiliation as **not Hispanic or Latino.**

The following definitions apply for **racial** categories.

- **White** - a person having origins in any of the original peoples of Europe, the Middle East, or North Africa.

  NIH recognizes the diversity of the U.S. population and that changing demographics are reflected in the changing racial and ethnic composition of the population. The terms "minority groups" and "minority subpopulations" are meant to be inclusive, rather than exclusive, of differing racial and ethnic categories.

- **Black or African American** - a person having origins in any of the black racial groups of Africa. Terms such as "Haitian" or "Negro" can be used in addition to "Black or African American."

- **Asian** - a person having origins in any of the original peoples of the Far East, Southeast Asia, or the Indian subcontinent including, for example, Cambodia, China, India, Japan, Korea, Malaysia, Pakistan, the Philippine Islands, Thailand, and Vietnam. (Note: Individuals from the Philippine Islands have been recorded as Pacific Islanders in previous data collection strategies.)

- **Native Hawaiian or Other Pacific Islander** - a person having origins in any of the original peoples of Hawaii, Guam, Samoa, or other Pacific Islands.

- **American Indian or Alaska Native** - a person having origins in any of the original peoples of North, Central, or South America, and who maintains tribal affiliations or community attachment.

Socioeconomic status will be measured with the Nam-Power Socioeconomic Index (Nam & Power, 1983), which ranks primary occupation on a rank of 1-100, based on the median level of education and median income associated with that occupation as derived from census data.

Item-by-Item Specifications

B1 - 2. **Ethnicity and Race**: Ask these two questions as written on the data form. The race question is written in such a way as to comply with the federal mandate that requires investigators to allow all research participants to choose more than one racial category. Therefore, interviewers must read every race choice aloud and code yes (1) or no (2) for each racial category B2a-e.

Definitions: According to the US Census bureau, ethnicity in the US is defined as either Hispanic/Latino or NON-Hispanic/Latino (common cultural background). Race is defined as Caucasian, Asian, Black, etc. (common genetic background).

B2f. **WAS ANY OTHER MENTIONED?:** Note this choice appears in capital font. This indicates that it should not be read aloud to the patient but may be used if the patient mentions any racial category which is not listed above. Also, if the patient cannot or will not select from the choices offered after prompting, the interviewer can prompt her by saying,

> *"Let me assure you that eligibility for this study is not based on race. The federal government wants to be sure that women from all racial groups are invited to participate in research studies conducted using federal monies, and this is the way we report back to them about who is participating in **this** study. We will be asking the same question of all patients in this study."*

Ultimately, a patient can refuse to answer any question, but we hope that, with proper prompting, we can avoid or minimize missing data.

B2g. **Primary racial background**: Ask the B2g question of any patient who responds '***yes***' to more than one racial category. Circle the code the patient chooses as her primary racial background.

B3. **Education**: The objective of this question is to obtain the highest grade or level of school the patient has completed. For example, if the patient dropped out of high school in the 12th grade and never finished high school, then the interviewer would code this item as code 1; LESS THAN HIGH SCHOOL. But, if the patient reports that she never finished high school but later received a GED (high school equivalency degree), this item should be coded, code 2; COMPLETED HIGH SCHOOL OR GED. Code only one response. Probe as necessary. Use the margin on the left of the response choices to make notes on the patient's responses.

B4. **Current Marital Status**: This question asks for the patient's current marital status. Ask the question as written and read the response choices listed. Code only one response. If the patient responds she is '*single, never married,'* skip to item B7.

B5 & B7. **Patient's occupation**: Ask the primary question to determine if the patient ever worked for pay. This includes any full or part-time work. Skip B5 (patient occupation) and B6 (spouse / partner occupation)

for any patient who reports her marital status as, '*single, never married.'* If you follow the skip pattern as directed, you will collect the patient occupation data in items B7 and B7a.

B5a & B7a. **Occupation category**: Solicit from the subject a description of the work or occupation she held for the longest period of time. Probe **thoroughly** to get as precise a description as possible. For example, if the subject says, "I worked at the Ford Plant for 25 years," probe, "Tell me more about the type of work you did there for the **longest** period of time." Review the Nam -Power occupation categories to get a better appreciation for the occupation categories we are aiming to get. (See Attachment B) Other examples of incomplete descriptions include:

- Military
- Self-employed
- Owner
- Restaurant work
- Sales
- Banking

B5b & B7b. **Occupation code:** Record the Nam-Powers Occupation score using the **scores** listed in Attachment B.

B6. **Spouse's/partner's occupation**: Ask the primary question to determine if the patient's spouse / partner ever worked for pay. This includes any full or part-time work. If the patient reports more than one spouse or partner during her lifetime, instruct her to answer the question using the relationship of longest duration, not necessarily the most recent.

B6a. **Occupation category**: Solicit from the patient a description of the work or occupation her spouse / partner held for the **longest** period of time. Probe **thoroughly** to get as precise a description as possible. For example, if the patient says, "He retired from the Military after 20 years," probe, "Tell me more about the type of work your husband did for the **longest** period of time while he was in the military."

B6b. **Occupation code:** Record the Nam-Powers Occupation score using the **scores** listed in Attachment B.

B7. **Patient Occupation**: B7 and B7a will be asked of those women who report their marital status (in B4) as *single, never married*. See the description for these question in B5 and B5a above.

Section C and D: Predominant Stress Incontinence of 3 months or more duration

Description: Self-reported symptoms of urinary incontinence will be collected using selected items regarding stress and urge type urinary incontinence symptoms taken from the questionnaire for the MESA (Medical, Epidemiologic, and Social Aspects of Aging) Project conducted at the University of Michigan (Herzog, Diokno, Brown, Normolle, & Brock, 1990).

The questions solicit the patient's description of how her urine loss usually occurs. Questions referring to loss of urine at times of exertion such as laughing, sneezing, lifting, or bending over define stress incontinence. Questions referring to urine loss preceded by an urge to void, or uncontrollable voiding with little or no warning defines urge incontinence. Symptoms associated with urine loss of both urge and stress types define "mixed" incontinence. **For purposes of this trial, predominant stress incontinence is defined as the percent of stress-type symptoms > the percent of urge-type symptoms**. Agreement between the MESA questions and clinician's assessment has been reported as 87% for women (Herzog et al., 1990). The authors further reported that self-reported stress-type symptoms had an accuracy of 69% in predicting urodynamically a diagnosis of stress incontinence.

Administration: The MESA is a critical measure for the UITN Trial. It is first used to ascertain if a patient has predominant stress incontinence, an essential eligibility criterion. The MESA will also be used to determine treatment success or failure for the UITN Trial. Therefore, it 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.

Section C: **MESA Part I: Stress Incontinence**:

Read the introduction and the questions to the patient precisely.

C1 – C 9. **Stress 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. 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.

C7. **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?"*

C8. **Straining**: If a patient reports she is never constipated you should prompt her by saying, "*Does 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?"*

C10. **Any SUI symptoms?** If the patient answers *never* to **every** item in the Part I: C1-C9, the patient is ineligible and the interviewer should end the interview and follow the skip pattern on the form.

C11. **Duration of SUI symptoms**: The patient must report SUI symptoms of 3 months duration or longer to be eligible for the Trial. Ask the question as written. If the patient responds '***no'*** to the question, circle code 2 (No) and end the interview following the skip pattern on the form. The patient may be re-screened if her symptoms persist for longer than 3 months. In such cases, the patient will be assigned a new ID number when she returns for the re-screening.

C12. **Onset of SUI symptoms**: Ask the question as written. Record the patient's response by month and year. If the patient's response is vague, probe for year by asking age of onset and working from there. Associations with other life milestones may also prompt memory, e.g. years married, children's ages, etc. Interviewers may also probe for month by asking about the season when the symptoms first began. 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. So, if a patient remembers that her symptoms began in early fall of 2000 you would code this as September, 2000. Mid fall would be coded as October, late fall as November.

C13. **Stress Symptoms Score**: Go back to Part I and determine the Stress Symptoms Score. Tally the column totals and grand total and record this number in the C13 field. The maximum number of points in the Stress Symptoms scale is 27, i.e. 3 points for each of the 9 stress questions. **If the patient fails to respond to any of the Stress items for any reason, the Study Coordinator should contact the BCC after completion of the interview for direction on determination of the Stress Symptoms score.**

C14. **Stress Index**: Use the Stress Symptoms score in C13 to determine the Stress Index using the Look-Up Table provided in the data form. Record the Index in the space provided.

Section D: **MESA Part II: Urge Incontinence**:

Read the introduction and the questions to the patient precisely.

D1 – D6. **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 <u>not</u> 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.

D4. **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.

D5. **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?"*

D7: **Urge Symptoms Score**: Go back to Part II and determine the Urge Symptoms Score. Tally the column totals and grand total and record this number in the D7 field. The maximum number of points in the Urge Symptoms Scale is 18, i.e. 3 points for each of the 6 urge questions. **If the patient fails to respond to any**

of the Urge questions for any reason, the Study Coordinator should contact the BCC after completion of the interview for direction on determination of the Urge Symptoms score.

D8. **Urge Index**: Use the Urge Symptoms score in D7 to determine the Urge Index using the Look-Up Table provided in the data form. Record the Urge Index in the space provided.

MESA Worksheet: The MESA Worksheet is provided to simplify your work in the determination of MESA eligibility. Record the results of the Stress Index (C14) and the Urge Index (D8) in the appropriate boxes in the worksheet. (NOTE: These data will not be data entered again from this field as they are already captured at the C14 and D8 fields.)

D9. **Predominant Stress Incontinence**: Compare the Stress Index to the Urge Index and code D9 accordingly. If the Stress Index is > the Urge Index, the patient is eligible to continue with the screening measures. If not, the patient is ineligible by MESA and the interviewer can end the interview. The patient may be referred for treatment of her urge incontinence and be re-screened for eligibility at a later date. Follow the skip patterns as directed on the form. (NOTE: While it is acceptable to complete the patient interview prior to completing the MESA scoring, the DMS will not allow data entry of data beyond this point for patients who are ineligible by MESA.)

Section E: Physical Accommodations and Character of Urine Stream

E1a-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 the listed accommodation to urinate. Code yes or no for every accommodation listed.

E1h. If the patient reports she currently makes any accommodation not included on the list, code yes for E1g and describe the accommodation in the text field provided.

E2. **Urine stream:** This question is meant to capture the character of the patient's urine stream. 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.

E2g. If the patient uses any other descriptive not included on the list, code yes for E2f and write the descriptive in the text field provided.

Section F: Pregnancy and Future Availability

Description: Women will be excluded if they are currently pregnant, if they intend to become pregnant in the next 2 years, or if they are < 12-months post-partum. In addition, women must be available to complete, at a minimum, 24 months of follow-up visits according to the prescribed study visit schedule, i.e. post-operatively at 6 weeks, 3 months, 6 months and then every 6 months thereafter through to at least the 24 month post-op anniversary visit.

F1. **Currently pregnant**: Ask the question as written. Code per the patient's response. If the woman reports she is currently pregnant or intends to become pregnant in the next 2 years, or if she refuses to answer this item, she is ineligible. The interviewer should end the interview and follow the skip patterns as directed on the data form.

F2. **Ever pregnant**: Ask the question and code accordingly. If the woman responds '*no*', skip to item F8.

F3. **Date of most recent pregnancy**: Record the month, day and year of the woman's most recent pregnancy that was greater than 20 weeks in length. Use the mm/dd/yyyy format. Probe to get as accurate a date as possible. If the woman can refer to records at home to get the precise date, make arrangements to call her at home to get the accurate date. This is an eligibility item; patient eligibility cannot be determined if this item is missing.

F4. **Post-partum ≥ 12 months ago**? The woman must be ≥ 12 months post partum to be eligible for participation in the UITN study. Refer to the date recorded in F3 and code this item accordingly. If the date in F3 is missing, you may continue with the screening measures but make arrangements to obtain the accurate information in F3 as soon as possible. Burdensome measures should not be completed if there is any doubt that the patient will not meet this criterion.

F5. **Times ever pregnant**: Record the number of times the woman reports having ever been pregnant. Count all pregnancies including miscarriages and abortions. Use leading zeros as necessary.

F6. **Number of vaginal deliveries**: Record the number of pregnancies (from F5) that were vaginal deliveries. If none of the woman's pregnancies were vaginal deliveries, code 00 and skip to F8.

F7. **Weight of largest baby delivered vaginally**. Record weight as reported by the patient, i.e. as American measure or metric measure. Record American weight in whole pounds and ounces. Record metric weight in whole grams. Round up at .5 or greater.

F8. **Schedule/Availability**: Ask the question as written in the data form. Ascertain if the woman is likely to still live in the area for the next 2 years. Use a multi-year calendar to aid in this determination. If the woman frequently resides in a second location, e.g. south in the winter or north in the summer, determine if her living arrangement will allow follow-ups on study schedule. If not, the woman is not eligible for enrollment. Code the outcome of this determination and end the interview following the skip patterns on the form.

Section G: Other Medical History

Cigarette Smoking

Description: Cigarette smoking has been associated with several health conditions.

G1. **Smoking**: This question is the lead question to inspire a more complete history of current and lifetime smoking history as necessary. Ask the question as written on the data form and follow the skip pattern on

the form. If the woman responds, '*no'*, skip to G7. A 'y*es'* response will prompt you to complete the smoking history questions that follow.

G2. **Age when first smoked regularly**: Ask the question as written and record the woman's response in whole numbers. If the woman reports that she never smoked **regularly**, circle the –1 code and skip to G7.

G3. **Overall average of cigarettes per day**: Ask the question as written and record the number of cigarettes smoked per day. Emphasize the first part of the question, "*During the entire time that you smoked….*", especially for a current smoker who may have reduced her cigarettes/day average significantly in recent years. Remind the patient that we are interested in the number of **cigarettes** smoked per day rather than **packs per day**.

G4. **Still smoking**: Ask the question as written. Skip to G6 if the woman responds '*no'* to this question.

G5. **Current average:** This question will be asked of all current smokers. This number may differ from the overall average reported in G3 above. Emphasize that this question is asking specifically about "*…number of cigarettes per day that you **now** smoke."*

G6. **Age when quit**: Ask this question of women who report that they have quit smoking.

Symptoms of Bowel Incontinence

Description: Urinary incontinence is sometimes associated with bowel incontinence. Questions G7 – G10 collect data on the extent of this problem.

G7. **Straining**: Ask this question as written. Follow the skip patterns on the form.

G7a. **Frequency of straining**: For patients who report any straining, ascertain frequency using the pre-coded frequency responses provided.

G8. **Leaking Gas**: Ask this question as written. Follow the skip patterns on the form.

G8a. **Frequency of leaking gas**: For patients who report any symptom of leaking gas, ascertain frequency using the pre-coded frequency responses provided.

G9. **Leaking liquid stool**: Ask this question as written. Follow the skip patterns on the form.

G9a: **Frequency of leaking liquid stool**: For patients who report any symptom of leaking liquid stool, ascertain frequency using the pre-coded frequency responses provided.

G10. **Leaking solid stool**: Ask this question as written. Follow the skip patterns on the form.

G10a. **Frequency of Leaking Solid Stool**: For patients who report any symptom of leaking solid stool, ascertain frequency using the pre-coded frequency responses provided.

Section H: Summary of Eligibility Status

Review codes to items C10, C11, D9, E1, E4: and E8 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, continue with the screening measures. If not, no further measurements should be completed.

Form 02: Preliminary Screening Part II

Part II of the Preliminary Screening is designed to rule-out women who have any one of several exclusionary conditions including:

- a lifetime history of cancer of the lower urinary tract, pelvic radiation for any reason, augmentation cystoplasty or artificial urethral sphincter;
- current chemotherapy or radiation treatment for any reason;
- systemic diseases known to affect the bladder function (i.e., Parkinson's disease, multiple sclerosis, spina bifida, spinal cord injury or trauma);
- current use of a catheter to empty bladder;
- urethral diverticulum;
- implanted nerve stimulators; or
- a recent history of pelvic surgery, i.e. **open** pelvic surgery < 6 months or **endoscopic** pelvic surgery < 6-weeks

In addition to these eligibility data, the following baseline data are gathered in Part II:

- History of diabetes,
- History of recent, recurring urinary tract infections (UTIs),
- Menopausal status,
- Current use of ERT, and
- History of prior surgical, medical or behavioral treatment for urinary incontinence

Remember, data gathered 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.

III. Section by Section Review for Forms 02

Section A. General Information

A1. **Study ID Number**: Affix the patient ID label in the spaces provided in the A1 field and on subsequent pages of the form. Avoid handwriting ID numbers. Check carefully to be sure the ID number matches the ID number on the Patient's Locator Form, Form 00 and the patient's Visit Control Sheet.

A2. **Visit Number**: Form 02 will always be identified as Visit = BASE, the **Baseline** Eligibility Screening Visit.

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

A4. **Interviewer's initials**: The person completing the interview /record abstract 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 entered in to 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.

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A5. **Consent obtained**: Confirm that consent has been obtained from the subject here. At a minimum, a screening consent must be completed prior to the conduct of the Preliminary Screening measures. The DMS will not allow data entry of data prior to the completion of consenting procedures.

A6. **Which version of this form was used?:** Record which language version of the form was used to complete the Preliminary Screening Part II.

A7. **Is this a repeat measure?** If more than 6 months transpires between determination of eligibility and surgery, the following items must be repeated: Section B, items C1 – C3 and D1.

Section B: Eligibility and Other 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 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.

B13: **Summary of Eligibility of the Other Conditions**: Were any of the other eligibility conditions items coded yes? Code this item accordingly and follow the skip pattern on the form. If any of the conditions are coded yes, the patient is ineligible, and no additional screening measures should be completed.

B14 and 15: **Diabetes and recent, recurring UTIs**: Obtain this information through interview with the patient and medical record abstraction. Use the question text in the data from for interviews. Code the item yes or no accordingly.

a. **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 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.

B16: **Menopause status**: Obtain this information through interview with the patient and medical record abstraction. Menopausal is defined as not having had a menstrual period for the past 12 months. Code this item accordingly. If the patient is pre-menopausal, skip to Section C.

B17: **HRT**: Ask this question of all women who report they are peri-menopausal or post-menopausal. We will also collect this information for women who report they are not sure of their menopausal status.

B17a-f: Ask each question. Code a yes or a no for each item. Even if a woman reports she only uses the patch, ask each item of the woman separately. This information may also be obtained through medical record abstraction. Use the question text in the data form for interviews. Code the item yes or no accordingly.

i. **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 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 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.

Section C: Medical, Surgical or Behavioral Treatment for Incontinence

Description: Prior to this surgery, a patient might have received other types of surgery, behavioral treatments such as pelvic floor exercises or biofeedback, or taken medications to treat her incontinence. This data will be collected to investigate if there is an effect of this treatment on the outcome of surgery performed in this study.

Recent History of Pelvic Surgery

Items C1 – C3 are items of eligibility determination. 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.

C1: **Recent history of pelvic surgery**: Code the item accordingly. You can read to the patient the list of surgeries from the Pelvic Surgery Code Table in Attachment C to prompt the patient regarding recent pelvic surgery. The Code Table is also attached to the data form. If there have not been any pelvic surgeries in the last 6-months, code no and skip to C3. Disqualifying surgeries include open-pelvic surgery performed in the last 6 months and endoscopic pelvic surgery performed in the last 6 weeks. If there have been **any** pelvic surgeries in the last 6 months, code yes and complete item C2.

C2a-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 listed in the Pelvic Surgery Code Table. Make sure all surgeries are spelled correctly and match the codes listed in the Code Table. Item (c) is used to further describe a laparoscopic surgery. If the woman had a laparoscopy, specify the purpose of the laparoscopic procedure in item (c). 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.

Solicit from the patient and use medical records to record the dates of all pelvic surgeries performed in the last 6 months. The dates of surgery are critical. If there is any doubt as to the true dates of surgeries conducted in the last 6-month period, additional records may be required to code this data with accuracy. Pelvic surgeries conducted prior to the last 6-months should be recorded in item C6 and C7.

Four fields are available to record up to 4 different surgeries, i.e. C2a-C2d. This is programmed as a repeating segment in the DMS and will accept any number of different surgeries. Simply leave the next line on the form blank if there are no more surgeries to record.

b. **Surgical Code 18, UNKNOWN TYPE**: If the patient reports she had a recent pelvic surgery but cannot accurately report or describe sufficiently to allow accurate coding the surgery type by name AND you cannot find documentation in the medical record, record the surgical code as code, 18, UNKNOWN TYPE. These cases will be considered ineligible until a more precise surgical code can be assigned.

d. **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 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.

C3: **Classify the patient's recent pelvic surgery status**: If the patient has not had any recent pelvic surgeries of any kind, you can safely code this item as code 1, **NO RECENT DISQUALIFYING PELVIC SURGERY,** and continue with the screening measures. But, if the patient has had any recent pelvic surgeries (in the last 6-months) each surgery must be classified as either open-pelvic or endoscopic.

If the date of any **open-pelvic surgery** is < 6-**months** from the date of form completion, code this item as code 2 and classify the patient as ineligible. The patient may be re-screened for eligibility at a later date.

If the date of any **endoscopic pelvic surgery** is< 6-**weeks** from the date of form completion, code this item as code 3 and classify the patient as ineligible. The patient may be re-screened for eligibility at a later date.

History of any surgeries specifically for the treatment of Urinary Incontinence:

C4: **History of any surgery specifically for the treatment of urinary incontinence**: Code the item accordingly. You can read to the patient the list of treatments from the Pelvic Surgery for UI Code Table in Attachment C to prompt the patient regarding surgeries for the treatment of urinary incontinence. The Code Table is also attached to the data form. If there have never been any surgeries specifically for the treatment of UI, code this item "NO" and skip to C6. But if the patient reports or there is any evidence of such surgeries, record each by name, surgical code, date of surgery and source.

C5a-e: **Surgeries by name (a), surgical code (b), date of surgery (c) and source code (d)**: For this item you will need to refer to the Pelvic Surgery for UI Codes included in Attachment C. Record each surgery by name and surgical code listed in the Pelvic Surgery for UI Code Table. Make sure all surgeries are spelled correctly and match the codes listed in the appropriate Code Table.

Solicit from the patient and use medical records to record the dates of all UI surgeries ever performed. The types of surgery and accurate dates are of obvious interest to these 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 specifically for the treatment of urinary incontinence but cannot accurately report or describe sufficiently to allow accurate coding the surgery type by name AND you cannot find documentation in the medical record, record the surgical code as code, 38, UNKNOWN TYPE.

d. **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 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.

History of any other pelvic surgeries:

C6: **History of any other pelvic surgery**: Code the item accordingly. You can read to the patient the list of surgeries from the Pelvic Surgery Code Table in Attachment C to prompt the patient regarding other pelvic surgery. The Code Table is also attached to the data form. If there have never been any other pelvic surgeries (i.e. other than in the past 6 months and other than pelvic surgeries specifically for the treatment for UI), code this item no and skip to C8. But if the patient reports or there is evidence of such surgeries, record each by name, surgical code, date of surgery and source.

C7a-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 listed in the Pelvic Surgery Code Table. Make sure all surgeries are spelled correctly and match the codes listed in the Code Table. Item (c) is used to further describe a laparoscopic surgery. If the woman had a laparoscopy, specify the purpose of the laparoscopic procedure in item (c). 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.

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 the surgery type by name AND you cannot find documentation in the medical record, record the surgical code as code, 38, UNKNOWN TYPE.

c. **Source codes**: Record the source code in the last column. If the only source of information is from 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 Site 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.

History of any non-surgical treatments for UI:

C8: **History of any non-surgical treatment for UI:** Code the item accordingly. You can read to the patient the list of treatments from the Treatment Code Table in Attachment C to prompt the patient regarding non-surgical treatments. The Code Table is also attached to the data form. If there have never been any non-surgical treatments for UI, code this item '*NO'* and skip to Section D. But if the patient reports or there is evidence of such non-surgical treatments, record each by name, treatment code, dates of treatment and source.

C9a-e: **Treatments by name (a), treatment code (b), dates of treatments (c) and source code (d)**: 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 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. 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. So, 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.

b. **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 accurate coding the treatment type by name AND you cannot find documentation in the medical record, record the treatment code as code, 58, UNKNOWN TYPE.

d. **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 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.

Section D: Summary of Eligibility Status

Review codes to items B13 and C3 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, continue with the screening measures. If not, no further measurements should be completed.

ATTACHMENT A

Field Design

Patient Referral / Case Finding

Identify potential patients through investigator's clinical practice, colleague referrals, public announcements, advertising and mailings.

Preliminary Screening for Eligibility Part I (Visit BASE)

- Obtain consent for preliminary screening and/or full study consent
- Administer the Preliminary Screening Part I (*Form 01*), which includes the MESA questionnaire to confirm predominant stress UI cases.

Complete the Initiation and Locator Form (Form 00) and the Preliminary Screening Part I (Form 01)

ELIGIBLE / CONTINUE

PREDOMINANT URGE INCONTINENCE

PATIENT MAY BE RESCREENED AFTER TREATMENT

INELIGIBLE OR REFUSAL/END

Preliminary Screening for Eligibility Part II (Visit BASE)

- Complete Preliminary Screening Part II (*Form 02*) for exclusionary conditions and past medical and surgical treatments for urinary incontinence.

Complete the Preliminary Screening Part II (Form 02)

ELIGIBLE / CONTINUE

INELIGIBLE OR REFUSAL/END

Screening for Eligibility Continues (Visit BASE)

- Some sites may complete full study consent at this juncture.
- Eligibility screening continues, including Physical Exam and Stress Test and UDS (*Forms 04 & 05*). These measures may be abstracted retrospectively provided sites conduct the PE measures and UDS per UITN protocol.
- Complete Medication Audit (*Form 03*)
- Patient completes the Baseline Survey Packet Parts I and II (*Forms 07 & 08*)
- Send patient home with the 3-day Voiding Diary (*Form 06A*) and the 24-hour Pad Test Kit.

Complete Forms 03, 04, 05; Patient completes Forms 07 & 08; Distribute Form 06A & Pad Test Kit

ELIGIBLE / CONTINUE

INELIGIBLE OR REFUSAL/END

Screening and Baseline Completion (Visit BASE)

- Be sure the **full** study consent is signed and all screening and baseline measures are completed per protocol
- Complete scoring for Voiding Diary (Eligibility) and coding for the Pad Test (*Form 06*)
- Be sure data entry of all screening forms is complete.

Complete Form 06

Before Surgery Is Scheduled

After completion and data entry of all baseline measures and prior to the day surgery is scheduled:

- Study Coordinator prints out the Authorization for Randomization Report.
- Study Coordinator completes Sections A and B on the Randomization Assignment Form (*Form 09*) and signs the form.
- Form 09 is placed in a predetermined location accessible to the surgeon on the day of surgery.

Complete Sections A & B of Form 09

Randomization and Intervention Measures (Visit SURG)

•On the day of surgery in the operating room:

- •Anesthesiologist confirms ASA eligibility (*Form 09*); and
- •Surgeon/Study Nurse/Designee calls 'hotline' to obtain randomization assignment; and
- •Outcome of randomization [Burch vs. Sling] is documented on UITN data form (*Form 09*)
- •Surgical intervention is performed.

•All operative and immediate post-operative procedures are completed and documented (*Forms 10 & 11).*

Complete Forms 09, 10 &11

Patient Follow-up Visits:
[FU6W, FU03, FU06, FU12, FU18, FU24, (FU30, FU36, FU42, FU48)]

- •Follow-up visits are scheduled for 6 weeks and 3, 6, 12, 18, 24, (30, 36, 42 and 48) months
- •Follow-up data forms are completed for each follow-up
- •Unexpected Events, Adverse Events, Complications and any Retreatment are fully documented

ATTACHMENT B

1990 Nam-Powers-Terrie Occupational Status Scores

ATTACHMENT C

PELVIC SURGERY CODES	
01	Abdominoplasty
02	Anterior repair
03	Cesarean delivery
04	Femoral hernia repair
05	Hysterectomy
06	Inguinal hernia repair
07	Laparoscopy
08	Posterior repair
09	Removal of an ectopic pregnancy
10	Removal of an ovarian cyst
11	Removal of both ovaries
12	Removal of one ovary
13	Supracervical hysterectomy
14	Tubal ligation
18	UNKNOWN TYPE
19	OTHER

PELVIC SURGERY FOR UI CODES	
20	Anterior repair, Kelly plication, suburethral plication
21	Collagen injection
22	Durasphere injection
23	Laparoscopic Burch colposuspension
24	Marshall-Marchetti-Krantz (MMK) bladder suspension
25	Needle suspensions: Raz, Pereyra, Gittes
26	Open Burch colposuspension
27	Sling procedure
38	UNKNOWN TYPE
39	OTHER

TREATMENT CODES	
40	Medicine (drug treatment)
41	Bladder training (including behavior changes involving the timing of urination or changes in fluid intake)
42	Pelvic muscle exercices (Kegel exercices)
43	Electrical stimulation
44	Electromagnetic therapy
45	Biofeedback
46	Acupuncture or other alternative medicine techniques
58	UNKNOWN TYPE
59	OTHER