Question by Question Specifications Guide
Form 209: Eligibility Confirmation and Randomization Check
Version 07/11/05 (D)

I. Purpose

The purpose of the Eligibility Confirmation and Randomization Check Form is to document that pre-randomization requirements have been met and to capture the necessary details of the randomization process. Randomization will not be allowed if a patient has not met all eligibility requirements

II. Administration

A. Timing:

Study staff will complete this form on the day of randomization. This Data Form should only be completed if the patient is eligible by all Baseline Screening measures, or if she is determined to be ineligible by F263 on the day of Randomization.

Forms 200, 201, 202, 203, 204, 205 (completed at Baseline and Randomization), 207, and 208 must be entered into the Data Management System (DMS) prior to randomization. All edits must be resolved before randomization can occur. Additionally, study staff must run the Pre-Randomization Status Report (see Attachment A) for use in completing F209. This Report is located in the DMS under **BE-DRI Study → BE-DRI Reports → Part/Event Reports → BE-DRI Pre-Rand Status Report**. After completing F209, the DMS will generate a Randomization Receipt, which is necessary for completing F210 (see Attachment B for an example of the Randomization Receipt).

B. Source:

All baseline and randomization visit data along with the information provided from the Pre-Randomization Status Report are used as the source for this form.

C. Certification of UITN Examiners and Data Collectors

Study staff who complete F209 must be certified by and registered with the BCC as a UITN BE-DRI Interviewer/Data Collector. The obligations of certification are documented in the QC Plan in the Manual of Operations. Data gathered by non-certified persons may not be entered into the UITN BE-DRI DMS.

III. Section by Section Review

Section A: General Study Information

A1. **Study ID Number:** Affix the patient ID label in the spaces provided in the A1 field. Avoid handwriting ID numbers.

A2. **Visit Number:** The visit number is pre-coded for Form 209 and will always be Visit **RAND**.

A3. **Date Form Completed:** Enter the date that the form was completed. This date must be in the format mm/dd/yyyy. This date must match the date of the Randomization Visit.

A4. **Study Staff Initials:** Enter the initials of the person completing the form. Enter the first initial in the first space provided, middle initial in the second space provided and last initial in the third space provided. If the person doesn't have a middle initial, strike a dash in the second space. If the person's last name is hyphenated or if s/he has 2 last names, enter the initials of the first last name in the third space. Study staff must be a certified BE-DRI Interventionist or Interviewer/Data Collector.

Section B: Eligibility Verification for Medications and Bladder Diary

B1. **Upon review with the patient of her current medication status, did she report any changes or additions that affect eligibility (e.g. use of anticholinergics, tricyclic antidepressants, duloxetine, or cholinergic agonists, OR a change in diuretic dose)?** Review the patient's medication status with her and complete F263 for the Randomization Event. If she reports any changes to or additions of the above medications within the last three months, code yes and proceed to B1a; else, code no and proceed to B2.

B1a. **Specify the medication change or addition that rendered the patient ineligible:** Record the medication change or addition that rendered the patient ineligible according to the protocol requirements for the BE-DRI study.

B1b. **Code:** Record the corresponding medication code, found on the F209 Attachment.

B2. **Is the patient's 7 Day Baseline Bladder Diary Valid?** Code yes or no. If no, the patient is ineligible until the Diary is repeated and a valid measure obtained.

B2a. **Is the patient eligible by diary, i.e., incontinence frequency of at least 7 times per week?** Code yes or no in accordance with the protocol. If "no," the patient is ineligible to participate in the BE-DRI study.

B2aia. **Mesa Stress Symptoms Score:** The data for this field should be abstracted directly from Form 201, field D10. The range will be between 0 and 27. If the Mesa Stress Symptoms Score is greater than 0, then the incontinence type in B2c must be coded as "Mixed."

B2aib. **Did the Patient Report Any "Stress" or "Other" Type Accidents on the Bladder Diary?:** Code yes or no in accordance with the accidents found on the Bladder Diary. If "yes," then the incontinence type in B2c must be coded as "Mixed."

B2aic. **Number of Total Accidents Reported on the Bladder Diary:** The data for this field should be calculated directly from the patient's valid Baseline Bladder Diary, **using only days determined to be valid.** This data should equal the sum of all types of accidents reported on the Diary. If this field is less than 14, then the incontinence frequency in B2b must be coded as "Lower"; if this field is greater than or equal to 14, then the incontinence frequency in B2b must be coded as "Higher."

B2aid. **Number of Valid Diary Days from the Bladder Diary:** The data for this field should be calculated directly from the patient's valid Bladder Diary. Record the number of valid diary days, which must fall between 5 and 7 days.

B2b. **What is the patient's incontinence frequency?** Record the patient's incontinence frequency: either 14 or more episodes of incontinence or less than 14 episodes of incontinence within the timeframe of the diary. If the patient reports fewer than 14 episodes, code "1" for lower incontinence frequency. If she reports 14 or more episodes, code "2" for higher incontinence frequency. Per Operations Memo #014, primary and secondary reviewers should record their initials next to this question once QC is complete.

B2c. **Upon review of the MESA and the diary, what type of incontinence does the patient have, i.e. mixed (at least one stress or other type accident on the diary OR one affirmative response to a stress symptom on the MESA) or urge only?** Using the patient's MESA responses from F201 and the bladder diary, determine if the patient has any indication of stress incontinence in addition to urge incontinence (MESA score >0 or more than one "stress" or "other" type accident). If the patient does have mixed incontinence, code "1". If the patient has strictly urge incontinence, code "2." Per Operations Memo #014, primary and secondary reviewers should record their initials next to this question once QC is complete.

Section C: Eligibility Verification and Currency of Other Baseline Measures

C1. **Is the patient eligible by F201 (G1)?:** Using the Pre-Randomization Status Report, code 1 if the patient is eligible by F201 and 2 if she is not.

C1a. **Date F201 Completed (A3):** Using the Pre-Randomization Status Report, record the date from the "Date of Measure" column for F201. This date must be less than or equal to 3 months (91 days) prior to the date of randomization in order for the patient to be eligible.

C2. **Is the patient eligible by F202 (D1)?:** Using the Pre-Randomization Status Report, code 1 if the patient is eligible by F202 and 2 if she is not.

C2a. **Date F202 Completed (A3):** Using the Pre-Randomization Status Report, record the date from the "Date of Measure" column for F202. This date must be less than or equal to 3 months (91 days) prior to the date of randomization in order for the patient to be eligible

C3. **Is the patient eligible by F203 (B11)?:** Using the Pre-Randomization Status Report, code 1 if the patient is eligible by F203 and 2 if she is not.

C3a. **Date F203 Completed (A3):** Using the Pre-Randomization Status Report, record the date from the "Date of Measure" column for F203. This date must be less than or equal to 3 months (91 days) prior to the date of randomization in order for the patient to be eligible

C4. **Is the patient eligible by F204 (J1)?:** Using the Pre-Randomization Status Report, code 1 if the patient is eligible by F204 and 2 if she is not.

C4a. **Date F204 Completed (J4):** Using the Pre-Randomization Status Report, record the date from the "Date of Measure" column for F204 (this is the date of the first completed measure on F204). This date must be less than or equal to 3 months (91 days) prior to the date of randomization in order for the patient to be eligible.

C5. **Date F205 Completed (A3):** Record the date on which the "RAND" F205 was completed. This date must match the date of randomization.

C6. **Date F206A Started:** Record the date of the first valid diary day. This date is obtained from field C1a on F206. This date must be less than or equal to 3 months (91 days) prior to the date of randomization in order for the patient to be eligible.

C7. **Date F207 Completed (A7):** Using the Pre-Randomization Status Report, record the date from the "Date of Measure" column for F207. This date must be less than or equal to 3 months (91 days) prior to the date of randomization in order for the patient to be eligible.

C8. **Date F208 Completed (A7):** Using the Pre-Randomization Status Report, record the date from the "Date of Measure" column for F208. This date must be less than or equal to 3 months (91 days) prior to the date of randomization in order for the patient to be eligible.

Section D: Signature

D1. **BE-DRI Staff Member's Initials:** Enter the initials of the UITN BE-DRI staff member who completed F209 (This person must be a certified BE-DRI Interviewer/Data Collector or Interventionist). Enter the first initial in the first space provided, middle initial in the second space provided and last initial in the third space provided. If the person doesn't have a middle initial, strike a dash in the second space. If the person's last name is hyphenated or if s/he has 2 last names, enter the initials of the <u>first</u> last name in the third space.

D2. **Signature of the Person in D1:** This form is not complete without the signature of the person named in D1, i.e. the UITN BE-DRI staff member responsible for completing F209.

ATTACHMENT A

Example Pre-Randomization Status Report

Form	Meets eligibility criteria on this form?	Date of measure	Last Day on Which Measure is Valid	Data entry status
F201	No	05/10/2004	08/09/2004	C
F202	Yes	05/15/2004	08/14/2004	C
F203	Yes	07/10/2004	10/09/2004	C
F204	Yes	06/01/2004 (earliest measure)	08/31/2004	C
F205 (Baseline)	N/A	05/10/2004	08/09/2004	C
F207	N/A	07/01/2004	09/30/2004	C
F208	N/A	05/26/2004	08/25/2004	C

REMINDER: The Voiding Diary and F263 must be completed for eligibility prior to randomization. F205 must be completed and entered in the randomization visit for randomization to occur.

If any measure is expired, all screening measures must be repeated.

ATTACHMENT B

Example Randomization Receipt

Instructions: This report should be used to inform the BE-DRI Interventionist of the patient's randomization assignment and to complete F210: Randomization Confirmation

ID: **1116003**
Date of Randomization: **Wed Jul 7 15:38:48 EDT 2004**
Assignment: **Behavior and Drug**
Randomization Confirmation Number: **9724**

Username of the person who randomized this patient: **mmaurao**

This report should be filed with F210 in the patient's BE-DRI Data Forms file.