INSTRUCTIONS FOR RANDOMIZATION FORM
RDM, VERSION A (QxQ)

I. GENERAL INSTRUCTIONS

The Randomization Form is filled out by the study physician (or confirmed and signed by the study physician) after:

a) all screening forms have been entered into the Data Management System (DMS), including the IEC form
b) all lab values are available via a fax from the central lab and/or in the DMS
c) the AMR and OMR assessments have been completed (these forms must be filled out but not necessarily keyed into the DMS in order to randomize a patient).

The RDM verifies a patient’s eligibility by confirming that their eligibility status has not changed from the screening to the baseline visit. A potential participant’s eligibility status is based upon IECA13 (determined by DMS), RDMA1 and RDMA2. Therefore any changes between screening and baseline visits must be updated on the screening forms: VSS, MHX, SCD, DEM and IECA.

Eligibility status can change from eligible to ineligible if:

1) a patient withdraws consent,
2) a medical condition that renders the patient ineligible was not reported at the screening.
3) A new medical condition that renders the patient ineligible has been introduced between the screening and baseline visit.

Eligibility can change from ineligible to eligible if:

1) the patient is unable to successfully score 15 or greater on the UBACC at screening, but returns at a later visit and scores within the acceptable range.
2) A patient who was ineligible is rescreened for eligibility. Refer to the Study Reference Manual (SRM) Section 3.11 for rescreening criteria.
3) With the exception of fasting glycemic, triglyceride and cholesterol values, any abnormal and clinically significant lab values from the screening visit that have been reviewed with the Project Medical Officer (PMO), and the PMO has given permission to randomize.

Once eligibility is confirmed (and IEC form is entered) Item B4 triggers patient randomization in the DMS.
Please Note: The RDM MUST be entered into the DMS in order to randomize and provide the site with study medication dispensing instructions.

When the RDM form has been completed in the DMS: The DMS screen must be printed and given to the medication nurse to be stored in the ‘Study Medication Distribution Notebook’ as it provides the randomization code number and the bottle code number(s) for the oral medication trial.

Header Information: The header information consists of key fields which uniquely identify each recorded instance of a form.

PATIENT ID NUMBER: Affix the pre-printed label to the form. This is a unique 8-character code assigned at the DCC for each study patient. Labels are provided.

FORM CODE: This is a three-letter mnemonic code for the form, which is precoded as “RDM”.

VERSION: This is a one-letter version assigned to the form, which is precoded as “A”.

VISIT: Visit should be filled in according to which visit it is completed.

SEQ #: Fill in the sequence number. It is always 001, unless the patient has come in for an unscheduled visit, in which case the sequence number is 002 (for the second form at that visit).

PATIENT INITIALS: Enter the first, middle, and last initial of the patient. For those with no middle name, use a ‘—’ (dash). For example:

A — Z

VISIT DATE: Enter the date on which the data was collected. Code in numbers using leading zeroes where necessary to fill all boxes. For example, September 6, 2010, would be entered as:

0 9 / 0 6 / 2 0 1 0

II. DETAILED INSTRUCTIONS FOR EACH ITEM

A. ELIGIBILITY

Item 1. Consent status. Check Yes or No. Yes is eligible.

Item 2. Review of patient’s eligibility. Check Yes or No. A “Yes” response will trigger the system to assess eligibility based on the values of IECA13, RDMA1 and RDMA2.

Item 2a. If Item 2 was “No” please indicate the reason here.
**Item 3.** This field is shaded and will be populated in the DMS based on the determination made by the DMS. The Data Management System will not allow this field to be entered by the user. If the patient is eligible, the system will record ‘1’ = eligible and move to Item 4. If the patient is ineligible due to required values on the IEC or RDM, the system will record ‘2’ = ineligible and list the values which make the patient ineligible. If the patient is pending, the system will record a ‘3’ = pending and list the missing values required to determine eligibility.

**B. RANDOMIZATION**

**Item 4.** Do you want to randomize now? Check Yes or No. If Item 3 above is ‘1’ = eligible, then a ‘Yes’ will randomize an eligible patient to a treatment condition. You will receive a message that randomization is complete. A ‘No’ to Item 4 will not randomize the patient and will skip to Item 8. If the patient is not randomized, all existing information in the form will be saved in DMS.

**Item 5.** A randomization code number will appear on the screen on Item 5. The randomization number should be recorded on the paper form as it appears on the DMS screen.

**C. ORAL ANTIPSYCHOTIC TRIAL**

**Item 6.** Oral Antipsychotic Trial—How many medication bottles? After randomization each patient will receive a blinded trial of the oral version of the assigned medication, lasting 4 to 7 days. Each bottle contains 8 pills, *(Risperidone supplied in 2mg over-encapsulated tablets, haloperidol, supplied in 2mg overencapsulated tablets).* Record Y (Yes) to receive a bottle code for the oral antipsychotic. If N (No) is recorded, skip to end of the form.

**Item 7.** Medication Bottle Numbers. The DMS will populate the bottle code number for a Y (Yes) response to Item 6. If an additional bottle is needed for whatever reason, complete and enter an Emergency Oral Refill Form (EOR) in the DMS.

Once randomized, and Item 7 is completed, this form will become locked and can be viewed in “browse only” in the DMS and no data in any of the fields will be allowed to be changed or updated.

**D. ADMINISTRATIVE INFORMATION**

**Item 8.** Staff Code: Enter the first, middle and last initial of the person completing this form. For those with no middle name, use a ‘-‘ (dash).