SOLVD
RANDOMIZATION FORM

VERSION A / 9-1-86

INSTRUCTIONS:

This form is to be used only after the SOLVD BASELINE VISIT FORM has been completed up to Question 39, and the participant is ready to be checked for randomization. Use the SOLVD BASELINE VISIT FORM as a reference for completing this form. Once this form has been completed, telephone the clinic center to determine if the participant is eligible for randomization. See the SOLVD General Instructions for Completing Forms for details. Do not send this form to the clinic center.

SOLVD RANDOMIZATION FORM (screen 1 of 2) (SRF page 1 of 2)

TEMP ID:

A. IDENTIFYING INFORMATION

1. Today's Date:

    Month   Day   Year

2. Date of last SOLVD visit (Visit 2):

    Month   Day   Year

3.1. Last Name:

3.2. First Name:

3.3. Middle Name:

4. Initials of person
    completing this paper form...........

5. Trial for which the
    participant is being considered......

                    Prevention   P

                    Treatment   T

B. ADHERENCE

6.1. Number of pills
         dispensed at Visit 2.........
     (Medication Tolerance Visit)

6.2. Number of pills
         returned today..............
     (Baseline Visit)

6.3. Number of days since Visit 2.......

6.4. Adherence.....................

$$ADHERENCE = \frac{(\text{\# PILLS DISPENSED}) - (\text{\# PILLS RETURNED})}{2 \times (\text{\# DAYS SINCE LAST VISIT})} \times 100$$

NOTE: If the participant's adherence is less than 80%, then he/she cannot be randomized. Review the SOLVD Operations Manual and the Specific Instructions for Completing Forms.

7. Does the participant still
    meet the entrance criteria?.........Yes   Y

                                        No   N

NOTE: The participant must still meet all of the entrance criteria indicated on the SOLVD Eligibility Form to be eligible for randomization.

REVIEW THE ABOVE INFORMATION CAREFULLY BEFORE YOU ATTEMPT TO RANDOMIZE THE PARTICIPANT. THE INFORMATION CANNOT BE CHANGED ONCE THE PARTICIPANT HAS BEEN RANDOMIZED.

8. Are you sure that all information
    entered is correct.................Yes   Y

                                        No   N

If No, make the necessary changes above.

MAKE THE RANDOMIZATION TELEPHONE CALL TO YOUR CLINIC CENTER.

WAS THE RANDOMIZATION OF
THIS PARTICIPANT SUCCESSFUL?..............Yes   Y

                                          No   N

IF NO, RETURN TO THE SOLVD BASELINE FORM, QUESTION 40. ON PAGE 7.

IF YES, PRINT THE RANDOMIZATION NUMBER IN THE BOXES BELOW.
CONFIRM THE INFORMATION BY REPEATING THE TEMP ID, NAME AND
RANDOMIZATION NUMBER BACK TO THE CLINIC CENTER.

RANDOMIZATION NUMBER:

NOTE: CONTINUE WITH THE SOLVD BASELINE FORM, QUESTION 40. ON PAGE 7.