4. Chapter 4: Randomizing Participants

4.1 Introduction

The treatment group a participant is assigned to is determined by a telephone call to the ENRICHD Coordinating Center. Assignments are made by a computer algorithm run at the Coordinating Center. Because the assignment for each participant is determined through a chance process, this procedure is called “randomization.” However, controlled, documented, and accurate execution of this process is absolutely essential to the scientific validity of the trial. If you have any uncertainty about whether a patient is eligible to be randomized or about the procedure to follow, contact your clinical center supervisor or the Coordinating Center before proceeding.

Before patients can be enrolled from a hospital, NHLBI must have received written assurance from the hospital. No treatment assignments can be made for a hospital until NHLBI notifies the Coordinating Center that the information is complete.

Each Clinical Center Staff member must be trained and certified in the use of the system before being authorized to randomize participants. Upon certification, you will receive a four digit “PIN”, which must be used in addition to your ENRICHD staff ID number in order to access the system.

4.1.1 Overview

The ENRICHD Telephone Randomization System (TRS) allows authorized users at ENRICHD clinical centers to make a telephone call to the Coordinating Center, respond to a series of questions using the telephone keypad and receive a treatment assignment for a specified patient. Written confirmation of the assignment will be faxed to the clinical center.

The TRS runs on a computer located at the Coordinating Center and is intended to be available 24 hours a day. In case of a system failure, designated Coordinating Center personnel will perform randomizations manually.
4.2 Using the Telephone Randomization System

4.2.1 Interacting with the System

The system uses pre-recorded speech samples to generate all instructions and prompts. The user responds to questions and provides information by pressing keys on the telephone keypad. The numeric keys are used for most choices. The pound key (#) is used to confirm a response or to indicate the end of a multi-digit response. The star (⋆) key is used to indicate a prior response is incorrect and should be ignored. The system always indicates what keys should be used to respond to a question.

As you become familiar with the sequence of prompts, you can interrupt a prompt at any time by responding with the appropriate key.

4.2.2 Steps in the Telephone Randomization Process

1) Complete the Randomization Worksheet for the participant.

   The System will prompt you to enter most of the information from this sheet. It also provides a place for you to record the treatment assignment provided and a treatment ID number used to verify that the treatment was assigned following the standard ENRICHD process.

2) Call the TRS at 800-472-2595

   You must use a touchtone telephone when calling the Telephone Randomization System. The telephone number is 800-472-2595. The system can process two simultaneous calls. Most phone calls will require less than 5 minutes to complete. Since an average of three randomizations per day are expected, more than two simultaneous calls are extremely unlikely.

   The system should answer the call on the second or third ring. If the line is busy, call back a few minutes later. If the line continues to be busy or if the line rings with no answer, call the Coordinating Center for assistance (see section 4.4, getting help).

   The system will produce an introductory message.

3) Enter your ENRICHD Staff ID number.

   The system will prompt you to enter your three-digit Staff ID number, followed by the # key. Each user from a center will have his own ID. Please use your own ID. Contact the Coordinating Center for additional IDs when new users are certified to use the system.
The entered staff ID number is spoken by the system, you are prompted to confirm or correct.

Press the pound key (#) if the value is correct. If you have made a mistake, press the star key (*) If you press the star key you are asked again to enter your ID. This sequence will repeat until you press the pound key to confirm your entry.

4) Enter your Personal Identification Number (PIN).

The system will prompt you to enter your 4-digit PIN, followed by the # key. Each user from a center will have his own PIN.

The entered PIN is spoken by the system, and you are prompted to confirm or correct.

Press the pound key (#) if the value is correct. If you have made a mistake, press the star key (*). If you press the star key you are asked to reenter your PIN. This sequence will repeat until you press the pound key to confirm your entry.

5) The ID and password are checked against a list of valid IDs and passwords.

If the ID and password are valid, the center for which the user may randomize patients is spoken. You are allowed to randomize patients from your center only.

If the ID or password is invalid, you are asked to enter and confirm the invalid value or values again. You are given three chances to enter a valid ID and password. If you fail to do so, the call is terminated. Check your assigned Staff ID number and PIN with your clinical center supervisor. If you used the correct numbers, contact the Coordinating Center for assistance.

To discourage attempts by unauthorized persons to access the system, the number of unsuccessful attempts at use over time is monitored. If the frequency exceeds a limit, the system is made completely unavailable for a period of time. Users calling during this timeout period hear a message that the system is currently unavailable. Contact the Coordinating Center for assistance.

6) Enter and verify the Eligibility ID for the participant.

The eligibility ID is the combination of the 2-digit center code and the 7 digit Patient ID number. Press the pound key after all 9 digits have been entered.

The eligibility ID entered is spoken.

To insure accurate entry, you are asked to reenter the eligibility ID.
In order to confirm the eligibility ID, two consecutive entries must match. If your two entries are not identical, you will be prompted to try again. You are given three chances to enter two consecutive matching values, or the call is terminated.

7) The eligibility ID is checked for validity:

- the center must be the one for which the user is authorized to enter patients
- the hospital number must be valid for the center and authorized to enter patients
- the patient number must be a valid ENRICHD patient number
- the patient number must not already have been randomized.

8) Enter and verify the last 4 digits of the patient’s social security number.

As with the eligibility ID, you will be prompted to enter the number twice, to ensure it is accurate.

If a participant does not have a social security number, or refuses to provide it, contact the Coordinating Center to receive a substitute code.

9) Enter the information from items 2-9 on the Randomization Worksheet.

These responses are entered only once. They are not confirmed by re-entry.

10) The system checks the responses and determines whether the patient meets the eligibility requirements.

If the patient is eligible, the system speaks the randomization ID and treatment assignment to the user. This information is repeated. Record the treatment assignment and treatment number on items 10 and 11 of the Randomization Worksheet. This information will also be faxed to a designated number at your center.

If the patient is not eligible, the user is informed and given the chance to randomize another patient or hang up to exit the system.

11) The system prompts you to randomize the next patient, or hang up to end the session.
4.3 Getting Help

If you encounter difficulty using the system, contact your clinical center supervisor. If your supervisor is unable to resolve the problem, contact any of these ENRICHD staff:

Marston Youngblood: 919/962-3083
James Schaefer: 919/962-3052
Jim Hosking: 919/962-3085

If you are not successful in reaching anyone, contact the Coordinating Center at 919/962-6971. Ask to speak to someone who can provide assistance concerning ENRICHD randomization.