

	<b>Standard Operating Procedures</b>
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Procedure Category:	Study Activities
Procedure CLN-04-01:	Patient Randomization

**Procedure Overview**

To define the basic procedures related to patient randomization.

**Responsible Individuals**

Study Pharmacists; Qualified MICHHR personnel (including, but not limited to, Study Coordinator and Research Assistant); Director, MICHHR

**Procedure**

The purpose of patient randomization is to reduce potential bias by eliminating the investigative site influence over which treatment is administered to a study patient. In a randomized trial, patients are assigned to a treatment group based upon a predetermined sequence of random treatment assignments. The investigator and research staff generally do not know the order of the treatment group assignments and cannot predict a future treatment assignment. In the case of a trial in which the physician is not blinded to the treatment group assignments, the physician must agree to provide the treatment in the order specified by the randomization code in order to avoid introducing bias.

In randomized trials, treatment group assignment may be made locally or centrally. In the case of local randomization, the person in charge of randomization should be a staff member at the study site who plays no part in the patient care or evaluation aspects of the study. Centrally randomized trials usually involve a statistician who is employed by the sponsor or CRO to make treatment group assignments.

In double blind, centrally randomized clinical trials, the treatment group can be assigned using the following process:

- The patient is found to be eligible for enrollment and signs the informed consent form. The investigator or MICHHR personnel collects baseline data.
- The investigator or MICHHR personnel contacts the central study statistician (or other person responsible for randomization) and provides basic information about the patient.
- The study statistician determines a treatment group assignment and documents the assignment, including the basic patient information. In order to preserve the

Version Number: 003	Implementation Date: November 17, 2000
Page 1 of 3	Revision Date: June 30, 2004
	Review Date: June 30, 2005
Approval Signature, Date:	

	<b>Standard Operating Procedures</b>
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blinding, the treatment group assignment may be communicated directly to the study pharmacist or a patient number may be provided to the investigator, which can be translated into a treatment group assignment by the study pharmacist.

- The study pharmacist prepares the appropriate treatment for the patient and supplies it in a blinded manner to either the investigator or patient.

To preserve the blinding, only the study statistician and study pharmacist may know the patient's treatment group assignment while the study is in progress. If an emergency situation occurs and the investigator believes a patient's treatment group assignment must be unblinded to ensure the best patient care, emergency unblinding for that single patient may occur. The procedures for emergency unblinding should be described in the study protocol or other study documentation.

In order to avoid errors in treatment group assignment that could invalidate the study, the process of randomization must be thoroughly documented. If the study uses telephone randomization, the study statistician must also notify the study pharmacist in writing and/or fax verification of subject randomization. Both the study statistician and study pharmacist must keep written records of treatment group assignments. Throughout the patient dosing process, the statistician's and pharmacist's records should be cross-checked to ensure that each patient is receiving the appropriate treatment.

### Documentation

Documentation for this procedure includes:

- Randomization request forms
- Notification of treatment group assignment from the study statistician
- Study pharmacist randomization materials
- Investigational materials dispensing records
- Emergency unbinding documentation, refer to SOP CLN-04-06

### Deviation Approval

The Director, MICHIR or designee, must approve deviation from this procedure. The Director, MICHIR or designee, must store documentation of the deviation approval.

Version Number: 003	Implementation Date: November 17, 2000
Page 2 of 3	Revision Date: June 30, 2004
	Review Date: June 30, 2005

	Standard Operating Procedures
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Procedure Category:	Study Activities
Procedure CLN-04-01:	Patient Randomization

**Procedure Author**  
Manager, Research Support Core

Version Number: 003	Implementation Date: November 17, 2000
Page 3 of 3	Revision Date: June 30, 2004
	Review Date: June 30, 2005