

	<b>Standard Operating Procedures</b>
---	--

Procedure Category:	Study Activities
Procedure CLN-04-10:	Domiciling of Study Subjects

**Procedure Overview**

This procedure describes the responsibilities of the study site personnel in studies where the study subject is domiciled.

**Responsible Individuals**

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

**Procedure**

In order to ensure controlled study conditions and to adequately monitor subject safety, some studies require that the study subjects temporarily reside at the study site.

When a subject is found to be eligible for enrollment, the informed consent form must be signed before any study procedures are performed. Qualified staff familiarize the subject both with the requirements of the study and with the rules of the domiciling facility. There must be specific guidelines concerning what the subject should and should not bring to the facility.

Upon arrival for domiciling, the subject's valuables are collected for safekeeping, and any contraband is collected and processed according to written procedures.

During the study subject's domiciling, the facility must address all aspects of daily living, including emergency procedures, medication, hygiene, feeding and recreation, in addition to study procedures. Special attention must be given to the subject's medication and nutritional needs, and appropriate equipment and personnel must be present in the case of a medical emergency. Specifically, an emergency resuscitation cart (crash cart) should be accessible at all times, and subjects should be oriented to the facility's emergency evacuation plan.

Some studies have requirements that confine the subject to the domiciling facility, and others studies may limit the contact of study subjects with people outside the study. The protocol should delineate appropriate recreational activities as well as the visitors' policy for subjects involved in the study. Additional considerations may be necessary to prevent interaction between individuals enrolled in different studies.

Version Number: 002	Implementation Date: November 17, 2000
Page 1 of 2	Revision Date: June 30,2004
	Review Date: June 30,2005
Approval Signature, Date:	

	<b>Standard Operating Procedures</b>
---	--

<b>Procedure Category:</b>	<b>Study Activities</b>
<b>Procedure CLN-04-10:</b>	<b>Domiciling of Study Subjects</b>

In all cases, the requirements of the study protocol must be clearly understood by study staff and domiciling facility personnel prior to the study participation by the study subjects.

Subjects must be discharged according to a written procedure that observes the requirements of the study protocol. Similarly, a procedure must be outlined in the event that the subject decides to leave the study facility prior to the completion of the protocol. See GCRC unit policies related to subject leaving Against Medical Advice (AMA).

**Documentation**

- Informed consent form
- Domiciling facility rules
- Domiciling facility intake forms
- Domiciling facility discharge forms

**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.

**Procedure Author**

Manager, Research Support Core

<b>Version Number:</b> 002	<b>Implementation Date:</b> November 17, 2000
<b>Page 2 of 2</b>	<b>Revision Date:</b> June 30, 2004
	<b>Review Date:</b> June 30, 2005