

	<b>Standard Operating Procedures</b>
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Procedure Category:	Study Preparation Activities
Procedure CLN-03-05:	Laboratory Samples Procedures

**Procedure Overview**

This procedure defines the process for collecting, recording, labeling, requisitioning, storing and shipping laboratory samples.

**Responsible Individuals**

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

**Procedure**

Among clinical research protocols, there may be significant variation in laboratory procedures. Each study may require not only a substantially different set of samples and parameters, but may also require the use of either a local laboratory, a centralized laboratory, or both. Always observe the requirements set forth in the study protocol.

Whether a study requires the use of a local laboratory or a centralized laboratory, current laboratory documentation must be on file in the regulatory documents at the study site. These document requirements include:

- All laboratories used must be listed on the FDA 1572. If a laboratory director is named on the 1572, his/her CV must also be present in the regulatory documentation.
- Current reference ranges for all parameters tested must be on file.
- One of the following types of certification must be included:
  - A current CLIA Certificate of Accreditation with an accompanying current CAP (College of American Pathologists) or COLA (Commission on Office Lab Accreditation) Certificate of Accreditation
  - A current CLIA Certification of Compliance along with a current state certificate or license.

Laboratory samples must be collected according to current medical and OSHA (Occupational Safety and Health Association) standards. Many clinical research studies outline strict requirements for the scheduling and sequence of the collection of laboratory samples. In all cases, sample collection must be carefully recorded in

Version Number: 004	Implementation Date: August 25, 2000
Page 1 of 4	Revision Date: June 30, 2004
	Review Date: June 30, 2005
Approval Signature, Date:	

	<h2 style="text-align: center;">Standard Operating Procedures</h2>
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Procedure Category:	Study Preparation Activities
Procedure CLN-03-05:	Laboratory Samples Procedures

the patient chart, and if applicable, in the study progress notes and the study case report forms. Information recorded should include unique patient identification, the date and exact time that the samples were obtained and details regarding what samples were collected.

Proper labeling is necessary to ensure that the laboratory sample has been correctly identified with respect to patient identification and the collection date, and in some cases, the parameters to be tested. In studies employing centralized laboratories, pre-printed labels identifying the protocol and site information may be provided, and sample containers may be identified by color coding or other means to indicate which specific parameters are to be tested. In any case, laboratory sample containers must bear labels that identify the protocol, the patient, and the collection date. This data must be consistent with data recorded in patient charts, study progress notes and case report forms.

For each sample or set of samples, at least one laboratory requisition form must be filled out. A copy of each laboratory requisition form must accompany the sample to the laboratory, and another copy must be filed with the patient's documents. The laboratory requisition form directs the laboratory regarding which parameters are to be tested. In many protocols, not all samples are analyzed by the same laboratory. It is important in these cases to ensure that each laboratory receives the correct sample and requisition form.

In cases where samples are analyzed by a local laboratory, the sample is usually hand-delivered by MICHIR personnel to the local laboratory. MICHIR personnel must take care to observe each sample's stability period and required environmental conditions until the sample is delivered to the laboratory.

If samples are to be analyzed by the UMMC (local) laboratory, each sample must be accompanied with a UMMC laboratory requisition. The requisition must be stamped with the subject's UMHS patient ID card (blue card) and the attached sample label must be transferred from the requisition to the corresponding sample. Once the sample is labeled correctly and the requisition is complete, the 7000 number may be used.

For laboratory samples collected for research, the 7000 number is used in place of the subject's CPI code for billing purposes. If samples collected for research are considered standard of care and are covered by the subject's insurance, the 7000

Version Number: 004	Implementation Date: August 25, 2000
Page 2 of 4	Revision Date: June 30, 2004
	Review Date: June 30, 2005

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

Procedure Category:	Study Preparation Activities
Procedure CLN-03-05:	Laboratory Samples Procedures

number is not used. If samples collected are not standard of care, and solely collected for the purpose of research, or research-related intervention, the 7000 number is used to ensure that neither the subject or his/her insurance company is billed for the processing of samples.

The 7000 number is a unique number given to each IRB approved research study following UMHS grant approval. MICHIR personnel are responsible for obtaining this study specific code. Following attainment of the study chartfields (legacy account number), the study coordinator contacts UMHS Financial/Billing Department to request the study specific 7000 number.

The number is applied to the local lab requisition by crossing out the subject CPI number (ID number), with one single line, and transcribing the 7000 number above it. This will prompt billing of the sample processing to the study research account.

If samples are to be analyzed by a centralized laboratory, the protocol may require that the sample be shipped immediately or stored at the site until many samples are collected and then shipped together. Most centralized laboratories provide all shipping materials, including boxes, airbills, address labels and gel packs. Some types of samples are batched at the site (usually, at the site's laboratory) and shipped in bulk. In these cases, the samples' storage conditions must be carefully monitored to ensure that the laboratory receives a viable sample. For detailed information about sample shipment, refer to the centralized laboratory's study manual.

### **Documentation**

Documentation for this procedure includes laboratory documentation and certification, sample container labels, patient charts, laboratory requisition forms and case report forms.

### **Deviation Approval**

Version Number: 004	Implementation Date: August 25, 2000
Page 3 of 4	Revision Date: June 30, 2004
	Review Date: June 30, 2005

	<b>Standard Operating Procedures</b>
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<b>Procedure Category:</b>	<b>Study Preparation Activities</b>
<b>Procedure CLN-03-05:</b>	<b>Laboratory Samples Procedures</b>

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

**Relevant Definitions**

CAP - College of American Pathologists  
COLA - Commission on Office Lab Accreditation

**Procedure Author**

Manager, Research Support Core

<b>Version Number:</b> 004	<b>Implementation Date:</b> August 25, 2000
<b>Page 4 of 4</b>	<b>Revision Date:</b> June 30, 2004
	<b>Review Date:</b> June 30, 2005