

	Standard Operating Procedures
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Procedure Category:	Study Preparation Activities
Procedure CLN-03-09:	Source Document Requirements

Procedure Overview

This procedure describes the necessary activities performed by research personnel in creating, maintaining and storing source documents for a study.

Responsible Individuals

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

Procedure

1. For each patient enrolled in a protocol, MICHHR personnel create a patient shadow chart. This chart facilitates the proper collection of study data by research personnel.
2. Each shadow chart may contain, but is not limited to, the following protocol-specific study start-up information:
 - Study related surveys/questionnaires
 - Study design flow chart and/or visit calendar
 - Screening sheet for inclusion/exclusion criteria
 - Informed Consent Form (three copies; one copy is given to the patient, the second, a signed original is filed in the research records and the third goes in the patient's hospital chart)
 - Laboratory and radiology (if applicable) requisition forms
 - Data collection forms; study CRFs are used to create protocol-specific data collection documents
 - Specimen labels
 - Compensation vouchers; if applicable
 - Research patient labels to identify research patients
 - Synopsis of the protocol
 - Letters to the patient
 - Instruction worksheet(s) for ancillary department(s) and/or patients

Note: In general, each document is identified by the study sponsor, protocol number and patient number.
3. The following patient-specific information is normally included in the shadow charts:

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Approval Signature, Date:	

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- Patient identification information and demographics.
- Documentation showing that the patient meets the study entrance criteria or alternate justification for enrolling the patient in the study. If the investigator has not had previous contact with the patient prior to study enrollment, the medical history obtained must demonstrate that the patient meets the study entrance criteria.
- Sufficient information to support all data reflected on the case report forms and submitted to the study sponsor. This includes information obtained from tests and examinations such as physical examinations, laboratory results, X-rays, progress notes, consultations, correspondence, information and data on the patient’s condition before, during and after the clinical investigation, all diagnostic tests results, diagnoses made, concomitant or concurrent therapy, and facts that might alter the test article’s effects (e.g. development of an concurrent illness). Refer to the study protocol and CRFs for specific data requirements.
- Documentation of each patient’s exposure to the investigational material, including the date (and time, if relevant) of each administration and the quantity administered.
- Copies of case report forms submitted to the sponsor. These may be filed in the study specific CRF notebook by subject.

Note: All source documents filed in the research record should be stamped “COPY”. All original documents relating to patient care should be filed in the subjects chart and/or electronically per hospital policy.

Documentation

The shadow charts, including both project-specific and patient-specific information, serve as documentation for this procedure.

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

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