

**STANDARD OPERATING PROCEDURES
RESEARCH SUPPORT CORE
MICHIGAN INSTITUTE FOR CLINICAL AND HEALTH RESEARCH
UNIVERSITY OF MICHIGAN**

Protocol #	Title	Version #	Approval Date	Review Date	Version #	Approval Date	Review Date
CLN-01-01	Reviewing Protocols	001	Aug 18,2000	August 18, 2002			
CLN-01-02	Assessing Capability to Provide Research Study Support	001	Aug 18,2000	August 18, 2002			
CLN-01-03	Assessing Workload/Staffing Requirements	001	Aug 18,2000	August 18, 2002			
CLN-01-04	Assessing Access to Patient Population	001	Aug 18,2000	August 18, 2002			
CLN-01-05	Assessing Cost and Profit of Protocol Conduct	001	Aug 18,2000	August 18, 2002			
CLN-02-01	Budget Negotiations	001	Aug 18,2000	August 18, 2002			
CLN-02-02	Study Contract Creation/Negotiations	001	Aug 18,2000	August 18, 2002			
CLN-02-03	Identification of Appropriate and Qualified Personnel	001	April 20, 2000	April 20, 2002	002	August 18, 2000	August 18, 2002
CLN-02-04	Preparation for Sponsor/CRO Pre-Study Visit	001	Aug 18,2000	August 18, 2002			
CLN-03-01	IRB Submission Procedures (External/Internal)	001	Aug 18,2000	August 18, 2002			
CLN-03-02	Preparation/Submission of Regulatory Documents	001	Aug 18,2000	August 18, 2002			
CLN-03-03	Informed Consent Requirements	001	Aug 18,2000	August 18, 2002			
CLN-03-04	Managing Investigational Materials/Supplies	001	Aug 18,2000	August 18, 2002			
CLN-03-05	Laboratory Samples Procedures	001	Aug 18,2000	August 18, 2002			
CLN-03-06	Pharmacy Procedures (Centralized/PI Dispensing)	001	Aug 18,2000	August 18, 2002			
CLN-03-07	Study Supply Storage	001	Aug 18,2000	August 18, 2002			
CLN-03-08	CRF Review	001	Aug 18,2000	August 18, 2002			
CLN-03-09	Source Document Requirements	001	Aug 18,2000	August 18, 2002			
CLN-03-10	Pre-Screening Patients	001	Aug 18,2000	August 18, 2002			
CLN-03-11	Preparing for Sponsor/CRO Study Initiation Visit	001	Aug 18,2000	August 18, 2002			
CLN-04-01	Patient Randomization Procedures	001	Aug 18,2000	August 18, 2002			
CLN-04-02	Drug Accountability	001	Aug 18,2000	August 18, 2002			
CLN-04-03	Serious Adverse Event Reporting	001	Aug 18,2000	August 18, 2002			
CLN-04-04	Patient Recruitment	001	Aug 18,2000	August 18, 2002			
CLN-04-05	Preparing for Sponsor/CRO Routine Monitoring Visits	001	Aug 18,2000	August 18, 2002			
CLN-04-06	Emergency Unblinding Procedures	001	Aug 18,2000	August 18, 2002			
CLN-04-07	Patient Visit Scheduling Procedures	001	Aug 18,2000	August 18, 2002			
CLN-04-08	Patient Completion/Early Termination Procedures	001	Aug 18,2000	August 18, 2002			
CLN-04-09	Preparing for Sponsor/CRO Study Close-out	001	Aug 18,2000	August 18, 2002			
CLN-04-10	Domiciling of Study Subjects (Phase I and Extended Visit Studies)	001	Aug 18,2000	August 18, 2002			
CLN-05-01	Investigator Study File	001	Aug 18,2000	August 18, 2002			
CLN-05-02	Case Report Forms	001	Aug 18,2000	August 18, 2002			
CLN-05-03	Investigator Brochure	001	Aug 18,2000	August 18, 2002			
CLN-06-01	FDA Audit Preparation	001	Aug 18,2000	August 18, 2002			
CLN-06-02	Sponsor Audit Procedures	001	Aug 18,2000	August 18, 2002			
CLN-06-03	GCP/ICH Compliance	001	Aug 18,2000	August 18, 2002			
CLN-06-04	Job Descriptions	001	Aug 18,2000	August 18, 2002			
CLN-06-05	Patient Orientation	001	Aug 18,2000	August 18, 2002			
CLN-06-06	Crash Cart / Defibrillator	002	January 29, 2000	January 29, 2002			