FDA Inspection for Clinical Sites
Checklist

STEP #1
When the FDA calls to schedules a site visit, obtain the following information.

Call date		
Person taking call		
Date of inspection		
FDA Investigator Contact Information	Name	
	Title	
	Telephone	
Additional information obtained		

STEP #2
Ask the FDA inspector the following questions but do NOT make any suggestions.

What trial is being inspected?	
Who is being inspected?	
Why is the inspection being done?	
Does the FDA want specific personnel available?	
Does the FDA want specific documents available? (List on separate sheet if needed)	
Other	

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STEP #3
Contact and send notification to the following

Name	Contact Information
Sponsor	
Principal Investigator	
Research coordinator	
IRB	
Other	

STEP #4
Complete the following tasks.

Date Completed	Task
	Reserve a work space for the FDA away from other study records and research staff
	Coordinate with appropriate affiliate institutions to confirm plans for site visit support
	Prepare study overview
	Prepare a list of subjects including study number, identification number, date enrolled and completed, medical record number
	Prepare a list of the Principal Investigator's current active studies
	Inform staff and determine roles during the inspection
	Create or obtain an organizational chart
	Obtain a list of Standard Operating Procedures (SOPs)
	Ensure training files are available for staff members

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STEP #5
Collect and review the following study documents

Date Collected	Regulatory Files
	Protocol, include all versions & amendments
	Investigator Brochure, all versions
	Informed Consent Form, all versions
	Form FDA 1572, all versions
	CV for all individuals listed on all versions of Form FDA 1572
	Delegation of Authority Log

Date Collected	Communication Files
	Sponsor Correspondence
	CRO Correspondence
	Monitoring Log
	Other

Date Collected	IRB Files
	Initial IRB approval letter with original informed consent form
	IRB approval letter for each protocol amendment or consent change
	IRB approval for each annual approval
	IRB approval of additional documents such as advertisements
	Notification of Serious Adverse Events
	Notification of Deaths
	Acknowledgements of Safety Reports
	Acknowledgements of Study Termination
	Acknowledgements of Final Summary, if appropriate

Date Collected	Laboratory
	Laboratory Certification(s)
	Laboratory normal ranges
	CV of Laboratory Director

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Date Collected	Product Accountability
	Receipt of product
	Storage of product
	Dispensing of product
	Return of product
	Sponsor product accountability log

STEP #6
Review for EACH subject and note any issues to discuss with study team.

Date Reviewed	Document
	Informed Consent Forms for screened subjects
	Informed Consent Forms for enrolled subjects
	Inclusion/exclusion criteria
	Reason for excluded subjects
	CRFs completed for each enrolled subject
	Source documentation for all CRF entries
	Data clarification issues satisfied
	"Notes to File" present as appropriate

Date Reviewed	Document
	Condition of subject at time of entry into study (i.e. were all inclusion/exclusion criteria met)
	Dispensing of investigational produce
	Concomitant medications
	Laboratory reports
	Diagnostic test
	Dosing modifications
	Adverse Events/Serious Adverse Events/Unanticipated Adverse Device Effects/Deaths
	Protocol Exceptions/Violations/Deviations
	Early terminations

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Other information collected.

	Electronic records validation
	Electronic records procedures