CLINICAL QUALITY MANAGEMENT PLAN (CQMP)

STUDY NAME					
PROTOCOL NO.		VERSION NO.		DATE	
INVESTIGATIONAL PRODUCT NAME					
IND NO.		TRIAL PHASE			
SPONSOR(S), NAME AND ADDRESS					
FUNDING ORGANIZATION					
PRINCIPAL INVESTIGATOR, NAME AND CONTACT INFORMATION					

APPROVED BY:

Quality Management Coordinator Name (Printed)

Quality Management Coordinator Signature *Date*

Principle Investigator or Sponsor Name and Title (Printed)

Principle Investigator or Sponsor Signature *Date*

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1. QUALITY MANAGEMENT SCHEDULE AND TOOLS

Describe the quality management activities and schedule, the tools used, checklists required, and the documentation and reporting for this study.

Schedule of Quality Management (QM) Activities

QM ACTIVITY	FREQUENCY			
	EVERY VISIT	QUARTERLY	ANNUALLY	AS NEEDED
Essential document review				
Subject data review				
Quarterly study review				
Annual study review				
Internal assessment review				
QM Summary report				

TOOLS REQUIRED TO DOCUMENT QM ACTIVITIES FOR THIS STUDY

CHECKLISTS REQUIRED FOR THIS STUDY'S QM PROCESS

DESCRIPTION OF THE DOCUMENTATION AND REPORTING PROCESS

2. INFORMAL QUALITY MANAGEMENT ACTIVITIES

Describe the site process(es) for ensuring and documenting that staff are qualified and competent. Note below the training and procedures required:

INSTITUTION-SPECIFIC TRAINING

PROTOCOL-SPECIFIC TRAINING

3. QUALITY MANAGEMENT ACTIVITIES – SUBJECTS

Describe the processes and procedures to ensure each subject study visit adheres to the Study Protocol, before and after visit completion.

SUBJECT RECORD REVIEW

Describe schedule and process for all subject records, including but not limited to eligibility, concomitant medications, adverse and severe adverse events, visit compliance in adherence to the study protocol, and deviations, and study withdrawal or discontinuation.

CONSENT PROCESS DOCUMENTATION AND COMPLETION

Describe the consent documentation review process.

SOURCE DOCUMENTATION COMPLETION

Describe the source document review process.

CASE REPORT FORM (CRF)

Describe the process for quality checks of the CRF, whether paper or electronic. If paper forms are being transferred to an electronic format, describe the process for review. If automatic quality check queries are being run on electronic files, describe the parameters.

4. QUARTERLY QUALITY MANAGEMENT ACTIVITIES

Describe the quarterly quality management activities or add another category for monthly activities, if required. Typical quarterly activities include:

CONSENT PROCESS DOCUMENTATION AND COMPLETION

Describe how x% of consent forms will be reviewed, per quarter.

LAB SPECIMEN REVIEW

Describe the specimen collection, processing, storage, and shipment review process. Reference any protocols here.

EQUIPMENT

Describe the review of maintenance and calibration records.

TESTS / ASSESSMENTS

Describe review of documentation for specific tests and assessments for this study.

CASE REPORT FORM REVIEW

Describe quarterly review of case report forms, and who performs this review.

STAFF TRAINING

Describe staff training requirement quarterly review process.

DOCUMENTATION REVIEW

Describe how the site and study ensures the update of required documentation, such as the Regulatory binder, IRB approvals and reports, and current professional licensure.

5. ANNUAL QUALITY MANAGEMENT ACTIVITIES

Describe the annual quality management review activities and the process for completing them. For example, describe how documents and plan will be updated or reviewed annually for practical updates.

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