Protocol

Original Protocol ☐

Amendment ☐

Amendment ☐

Amendment ☐

Amendment ☐

Curriculum Vitae's

PI ☐

Co-PI ☐

Co-PI ☐

Co-PI ☐

Sub-I ☐

Sub-I ☐

Sub-I ☐

Coordinator ☐

Licensure

PI ☐

Co-PI ☐

Co-PI ☐

Co-PI ☐

Sub-I ☐

Sub-I ☐

Sub-I ☐

Coordinator ☐

Study Logs

Screening/ Enrollment Log ☐

Staff Signature Log ☐

Delegation of Responsibility Log ☐

Monitoring Visit Log ☐

Adverse Event Log ☐

Protocol Deviation Unanticipated Problem or Event Log ☐

Other ☐

IRB

Copies of signed dated submissions ☐

Initial Application ☐

Continuing Reviews ☐

Submission of New Information ☐

Correspondence received from the IRB ☐

Consent Forms

IRB approved ICF version ☐

Version ☐

Version ☐

Version ☐

Foreign language ICF materials ☐

Investigator Brochure ☐

Device Manual ☐

Package Insert ☐

Laboratory Documents

Lab Certification ☐

Lab Directors CV ☐

Laboratory Handling Instructions ☐

Normal Lab reference values ☐

Drug / Device

Drug/Device shipment and receipt records ☐

Device Accountability Log ☐

Drug Accountability Log ☐

Data Collection

Blank set of case report forms ☐

Instructions-completion of case report forms ☐

Source data collection sheets ☐

Study questionnaires ☐

Diaries ☐

Data collection tools ☐

FDA

1571 ☐

1572 ☐

Initial IND Application ☐

Investigator Agreement ☐

Amendments to the application ☐

Adverse Event Reports submitted to FDA ☐

Annual Progress Reports ☐

Form 3674 certification of registration to ClinicalTrials.gov ☐

Financial Disclosure Form ☐

FDA form 3455 ☐

NIH

Copy of the NIH grant application ☐

NIH Progress Report ☐

NIH Progress Report ☐

NIH Progress Report ☐

Sponsor Correspondence

Correspondence to and from the sponsor ☐

Data Safety Monitoring Board (DSMB)

DSMB reports ☐

Auditing reports ☐

Training

CITI Human Subjects training certification ☐

Subjects training ☐

Study Training Log ☐

Training Documentation ☐

Training Certifications for all additional required training ☐