Protocol

Original Protocol
Amendment
Amendment
Amendment
Amendment
<table>
<thead>
<tr>
<th>Role</th>
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<tbody>
<tr>
<td>PI</td>
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<tr>
<td>Co-PI</td>
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<td>Sub-I</td>
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<tr>
<td>Coordinator</td>
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Licensure

PI

Co-PI

Co-PI

Sub-I

Sub-I

Sub-I

Coordinator
# Study Logs

<table>
<thead>
<tr>
<th>Log</th>
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<tbody>
<tr>
<td>Screening/ Enrollment Log</td>
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<td>Staff Signature Log</td>
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<tr>
<td>Delegation of Responsibility Log</td>
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<tr>
<td>Monitoring Visit Log</td>
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<tr>
<td>Adverse Event Log</td>
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<tr>
<td>Protocol Deviation Unanticipated Problem or Event Log</td>
<td></td>
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<tr>
<td>Other</td>
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</table>
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