IND or IDE Monitoring Plan

“Study Title”

Sponsor: University of Arkansas for Medical Sciences (UAMS)

Principal Investigator:

IRB Number:

IND or IDE Number:
I. Purpose of Monitoring Plan

The purpose of this monitoring plan is to present the approach of the Research Support Center for monitoring the specified research study. The plan facilitates compliance with applicable regulations (21 CFR 312 or 812), which require monitors to verify that:

- The rights and well-being of human subjects are protected.
- Reported study data are accurate, complete, and verifiable from source documentation.
- The conduct of the trial is in compliance with the currently approved protocol and all applicable regulatory requirements.

This document identifies key monitoring activities and specifies the data to be reviewed over the course of the study. The assigned monitor(s) will conduct monitoring visits in accordance with this plan.

II. Research Support Center – Monitoring Unit

Study monitoring is a resource offered by the Research Support Center Monitoring Unit (RSC-MU). The primary intent of the RSC-MU is to support study compliance with applicable federal regulations at the University of Arkansas for Medical Sciences and its affiliate sites. The focus of the RSC-MU is on supporting UAMS-sponsored investigator-initiated research studies. RSC-MU services are not directed toward studies monitored by industry sponsors or CROs.

III. Monitoring Approach

a. Methods

This study will be conducted on the UAMS campus (and/or NAME SITE) and will utilize paper Case Report Forms (CRFs), source documents, and regulatory files. Monitoring will occur on-site.
Or
This study will be conducted on the UAMS campus (and/or NAME SITE) and will utilize electronic Case Report Forms (CRFs), source documents, and regulatory files. Monitoring will occur remotely from the Research Support Center.
Or
This study will be conducted on the UAMS campus (and/or NAME SITE) and will utilize a combination of paper and electronic Case Report Forms (CRFs), source documents, and regulatory files. Monitoring will occur on-site and remotely from the Research Support Center when possible.
Or
Other – Describe the data collection method(s) to be used and the monitoring arrangement.

b. Assessment
The following criteria were used in determining the timing, frequency, and intensity of planned monitoring activities:

i. **Category:** This study is being conducted under a UAMS-sponsored IND/Significant Risk IDE/Non-Significant Risk IDE/Single Patient IND/Exempt/Other.

ii. **Study phase.**

iii. **Complexity of study design.**

iv. **Investigator/staff experience.**

v. **Complexity of study population.**

vi. **Data Quantity.**

c. **Changes to Monitoring Plan.**

This monitoring plan may be amended to accommodate the following:

i. **Lack of enrollment.**

ii. **Increased enrollment rate.**

iii. **High volume of protocol deviations.**

iv. **Lack of appropriate action regarding potential issues identified during monitoring visits.**

v. **Stage of study progress.**

vi. **FDA and/or institutional audit preparation or response.**

vii. **Major changes to protocol or investigational plan.**

viii. **Addition or removal of study sites.**

ix. **Additional reasons as determined by the Research Support Center.**

**IV. Scope**

a. **Investigator qualifications**

   Monitors will verify the investigator(s) has adequate qualifications to conduct the trial by:

   i. Ensuring there is a CV and/or other documentation of qualification on file for each investigator involved in the trial.

   ii. Verifying that each CV and/or other documentation of qualification was current at the time of study initiation.

b. **Facilities**

   Monitors will verify that facilities remain adequate throughout the study by:

   i. Verifying that current certifications and normal ranges for the laboratory(ies) performing protocol-required procedures or tests are on file.

   ii. Verifying documentation of the adequacy of laboratories and equipment not covered under CLIA or CAP certifications.

c. **Investigational Product**

   For investigational drugs, monitors will verify that:

   i. Study documents provide information on how subjects are provided with necessary instruction on how to use, handle, store, and return investigational product.

   ii. Verify labels on the drug(s) comply with the requirements for investigational drug labeling.
iii. Pharmacy records match product disposition records.
iv. The investigational product is stored under conditions specified in product labeling or packaging.
v. The time the product has been stored does not exceed the shelf life specified in the labeling or packaging.
vi. Documentation for receipt and return of product is on file.
vii. Manufacturer guidelines or other instructions for handling the product are present.
viii. Records are maintained that indicate product has been supplied only to eligible subjects at protocol specified doses.

Or

For investigational devices, monitors will:
i. Verify labels on the device(s) comply with the requirements for investigational device labeling.
ii. Verify documentation of receipt of the device(s) by the investigator/institution.
iii. Assess the condition of the device.
iv. Ensure tracking records are on file for use and/or dispensation/return of the device(s).
v. Verify management and disposition of damaged or unused devices.

d. Protocol
Monitors will verify that the site is following the approved protocol by:
i. Verifying the current approved protocol is present in the regulatory files.
ii. Comparing data to be collected on Case Report Forms (CRFs) with the current approved protocol.
iii. Verifying the number and type of subjects entered in the study is consistent with criteria defined in the approved protocol.
iv. Verifying that no changes to the approved protocol were implemented without prior review and documented approval from the IRB (except where necessary to eliminate an immediate hazard to trial subjects or when the change involves only logistical or administrative aspects of the trial).

e. Informed Consent
Monitors will verify that written consent was obtained before subjects’ participation by:
i. Verifying the correct version of the IRB-approved consent form was used.
ii. Verifying the date the consent form was signed and dated.
iii. Verify the presence of source documentation detailing the consent process.
iv. Verifying subjects signed and dated an IRB-approved HIPAA authorization document prior to enrollment.

f. Study Staff
Monitors will ensure that study staff is informed about the investigation and authorized to perform assigned tasks by:
i. Noting the identity of all persons and locations involved in data collection by viewing the authorization log kept by the site.
ii. Checking documentation for information about distribution of the currently approved protocol and investigational product information to the study team.

iii. Checking documentation of any protocol specific training of authorized individuals.

iv. Comparing study documents, IRB application, and authorization log to determine if responsibilities have been delegated to unauthorized individuals.

v. Checking the authorization log to verify all authorized personnel are included and have signed the log.

g. Subject Eligibility
Monitors will verify that only eligible subjects are enrolled by:

i. Verifying whether the existence of the condition for which the investigational product being studied is documented by a compatible history.

ii. Comparing the protocol inclusion/exclusion criteria against the source documentation to determine whether the enrolled subject is eligible for inclusion in the study.

h. Enrollment Rate
Monitors will report current enrollment information by:

i. Counting the number of subjects enrolled (defined by this plan as having signed an informed consent form) and comparing this number to the enrollment limit approved by the IRB.

ii. Checking the enrollment log or other documentation provided by the site concerning enrollment statistics (if applicable).

i. Study Records
Monitors will verify trial records are accurate, complete, and current by:

i. Verifying that all current CRFs have been completed and signed/dated appropriately.

ii. Verifying that source documentation was used to complete CRFs.

iii. Verifying the protocol identifies any source data that will be recorded directly on CRFs (if applicable).

iv. Verifying the data collection points required by the protocol are reported accurately on the CRFs and are consistent with source documentation.

v. Verifying the investigator has made required reports and/or submissions to the regulatory authorities.

vi. Comparing the information in the reports to information in the study site regulatory file and/or source documents.

vii. Informing the investigator and/or study staff of any CRF errors and ensuring appropriate corrections are made.

j. Adverse Events
Monitors will verify that all adverse events are appropriately reported by:

i. Verifying that serious adverse events (SAEs) and/or unanticipated adverse device effects (UADES) have been reported to the proper regulatory authorities by reviewing correspondence files and comparing against subject medical records.
ii. Verifying that SAEs and/or UADEs have been reported to the regulatory authorities within the specified time frames as appropriate.

iii. Verifying that any adverse events not meeting the criteria for expedited reporting requirements are captured and reported to the IRB at the time of continuing review.

k. Essential Documents
Monitors will verify that all essential documents are maintained by:
   i. Verifying that all applicable documents exist and are current as of the date of monitoring.
   ii. Comparing site files to the sponsor files.

l. Deviations
Monitors will review all deviations from the protocol or regulatory requirements by:
   i. Verifying subject visits have taken place as stated in the protocol.
   ii. Verifying all tests and procedures have been completed as stated in the protocol.
   iii. Noting any deviations reported by the investigator prior to the monitoring visit.

V. Nature and Extent of Monitoring
a. Timing
   i. A site initiation visit (SIV) is required before enrollment begins.
      Or
      *Omit statement – no SIV required/requested.*
   ii. The first monitoring visit will be scheduled after the first subject is enrolled.
      Or
      The first monitoring visit will be scheduled after the third subject is enrolled.
      Or
      The first monitoring visit will be scheduled within 3 months of dosing.
      Or
      The first monitoring visit will be scheduled within 6 months of the start of enrollment.
   iii. A closeout visit (COV) is required at the end of the study. The IND or IDE will not be withdrawn until closeout activities are complete, as determined by the sponsor. IRB closure prior to the COV is discouraged.
      Or
      A closeout visit (COV) is required at the end of the subject’s participation and will consist of verification that all outstanding queries from previous monitoring visits are resolved.
      Or
      *Omit statement – no COV required/requested.*

b. Frequency
   i. Monitoring visits will take place approximately every 6-8 weeks or at least yearly depending on enrollment.
      Or
Monitoring visits will take place approximately quarterly or at least yearly depending on enrollment.
Or
Monitoring visits will take place approximately every 6 months or at least yearly depending on enrollment.
Or
Monitoring visits will take place yearly or other.

c. **Intensity**
Monitoring will include:
i. Up to 100% subject data verification.
   Or
   Subject data verification of a random sample of up to 75% of enrolled subjects.
   Or
   Subject data verification of up to 50% of study visits.
   Or
   Subject data verification of a random sample of up to 50% of enrolled subjects.
ii. 100% verification of informed consent forms.
iii. 100% verification of SAEs/UADEs.
   Or
   Omit statement.
iv. 100% verification of drug/device accountability records.
   Or
   Omit statement.
v. 100% verification of regulatory files.

VI. **Communication**
a. Prior to departing each visit, the monitor(s) will attempt to conduct a brief exit meeting with the principal investigator and/or designated study staff to discuss the outcomes of the visit.
b. A formal report (Attachment I) reflecting monitoring activities will be completed by the monitor(s) after each visit. This report will be maintained as part of the Sponsor’s files.
c. A follow-up letter summarizing monitoring activities (Attachment II) will be sent to the principal investigator and relevant study staff following the completion of each visit. The letter will include the following at minimum:
i. The date of the activity and individuals present.
ii. A summary of the data or activities reviewed.
iii. A description of any noncompliance, potential noncompliance, data irregularities, or other deficiencies identified.
iv. A description of any actions taken, to be taken, and/or recommended.

VII. **Management of Noncompliance**
a. Monitors will verify that all action items identified at past monitoring visits have been resolved at subsequent monitoring visits, or sooner if appropriate.
b. Monitors will escalate any issues that continually remain unresolved to the Director of the Research Support Center and/or the Vice-Chancellor of Research. Additional oversight bodies may be notified if necessary.

VIII. Data and Safety Monitoring Board (DSMB)

a. This study will not utilize a DSMB.
   Or
   This study will utilize an external DSMB: (specify).
   Or
   This study will utilize the UAMS TRI DSMB.

Attachment 1: Monitoring Report

Attachment 2: Monitoring Visit Follow-Up Letter
University of Arkansas for Medical Sciences – Research Support Center
Monitoring Visit Report

IRB Number:  
Visit Date(s):  

Principal Investigator:  
Staff Contact(s):  
Monitor(s):  
Attendees:  

Visit Type: Initial [ ]  Interim [ ]  Final [ ]  Other [ ]

SCREENING and ENROLLMENT

<table>
<thead>
<tr>
<th>Total Number Consented</th>
<th>Total Number Withdrawn</th>
<th>Total Number Completed</th>
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<tbody>
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A. SOURCE DOCUMENTATION VERIFICATION

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<thead>
<tr>
<th></th>
<th>Yes</th>
<th>No</th>
<th>N/A</th>
<th>Not Monitored</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>1.0</td>
<td>Were all study procedures performed on schedule with the current protocol?</td>
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<td>2.0</td>
<td>Were CRFs verified against source documentation per the current monitoring plan?</td>
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<td>3.0</td>
<td>Have CRFs been completed in a timely manner?</td>
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<td>4.0</td>
<td>Were all CRF corrections completed during this visit?</td>
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<tr>
<td>5.0</td>
<td>Are all laboratory and/or procedure reports on file with the source documents?</td>
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<tr>
<td>5.1</td>
<td>Are all laboratory and/or procedure reports signed/dated by the investigator?</td>
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<tr>
<td>6.0</td>
<td>Did all enrolled subjects meet the eligibility criteria as defined in the protocol?</td>
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<td>7.0</td>
<td>Have any subjects taken exclusionary medications while on treatment?</td>
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<tr>
<td>8.0</td>
<td>Have all queries from the previous visit been resolved?</td>
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<tr>
<td>9.0</td>
<td>Have any subjects been withdrawn since the previous visit?</td>
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<tr>
<td>9.1</td>
<td>Are reasons for withdrawal/premature termination documented?</td>
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Comments:  

Reference Number  Reference Letter  Comment

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### B. VISIT REVIEW SUMMARY

<table>
<thead>
<tr>
<th>Subject ID</th>
<th>List of Visits Verified</th>
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### C. INFORMED CONSENT

<table>
<thead>
<tr>
<th>Question</th>
<th>Yes</th>
<th>No</th>
<th>N/A</th>
<th>Not Monitored</th>
<th>Comments</th>
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</thead>
<tbody>
<tr>
<td>10.0 Have all subjects signed and dated the appropriate IRB-approved</td>
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<td>informed consent document prior to any study procedures?</td>
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<td>11.0 Is this informed consent process documented for each subject?</td>
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<td>12.0 Is documentation present that all subjects received a copy of the</td>
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<td>informed consent document?</td>
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<td>13.0 Have all subjects signed the appropriate revised IRB-approved</td>
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<td>informed consent document?</td>
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<td>14.0 Have all subjects signed the appropriate IRB-approved HIPAA</td>
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<td>Authorization document?</td>
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<td>15.0 Were any informed consent/HIPAA deviations/violations noted during</td>
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<td>this visit?</td>
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<td>15.1 Have all informed consent/HIPAA deviations/violations been</td>
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<td>documented?</td>
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<td>15.2 Have all informed consent/HIPAA deviations/violations been</td>
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<td>reported to the IRB?</td>
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<table>
<thead>
<tr>
<th>Subject ID</th>
<th>Describe protocol deviation/violation.</th>
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# Monitoring Visit Report

## D. Protocol Deviations/Violations

<table>
<thead>
<tr>
<th>Reference Number</th>
<th>Reference Letter</th>
<th>Comment</th>
</tr>
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</table>

### 16.0
Were any protocol deviations or violations found at this visit?

<table>
<thead>
<tr>
<th>Yes</th>
<th>No</th>
<th>N/A</th>
<th>Not Monitored</th>
<th>Comments</th>
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</thead>
</table>

### 17.0
Have all protocol deviations or violations been documented?

<table>
<thead>
<tr>
<th>Yes</th>
<th>No</th>
<th>N/A</th>
<th>Not Monitored</th>
<th>Comments</th>
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</thead>
</table>

### 18.0
Have all protocol deviations or violations been reported to the IRB?

<table>
<thead>
<tr>
<th>Yes</th>
<th>No</th>
<th>N/A</th>
<th>Not Monitored</th>
<th>Comments</th>
</tr>
</thead>
</table>

### Subject ID
Describe deviation/violation.

<table>
<thead>
<tr>
<th>Comments (None)</th>
<th>Reference Number</th>
<th>Reference Letter</th>
<th>Comment</th>
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</table>

## E. Investigational Product

<table>
<thead>
<tr>
<th>Reference Number</th>
<th>Reference Letter</th>
<th>Comment</th>
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</thead>
</table>

### 19.0
Is the investigational product(s)/device(s) being stored under appropriate conditions?

<table>
<thead>
<tr>
<th>Yes</th>
<th>No</th>
<th>N/A</th>
<th>Not Monitored</th>
<th>Comments</th>
</tr>
</thead>
</table>

### 20.0
Are drug/device accountability records present and verified for accuracy?

<table>
<thead>
<tr>
<th>Yes</th>
<th>No</th>
<th>N/A</th>
<th>Not Monitored</th>
<th>Comments</th>
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</table>

### 21.0
Have all randomization and/or blinding procedures been maintained?

<table>
<thead>
<tr>
<th>Yes</th>
<th>No</th>
<th>N/A</th>
<th>Not Monitored</th>
<th>Comments</th>
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</table>

### 22.0
Is the investigational product appropriately labeled?

<table>
<thead>
<tr>
<th>Yes</th>
<th>No</th>
<th>N/A</th>
<th>Not Monitored</th>
<th>Comments</th>
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<table>
<thead>
<tr>
<th>Comments (None)</th>
<th>Reference Number</th>
<th>Reference Letter</th>
<th>Comment</th>
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*September 1, 2011*
### F. ESSENTIAL DOCUMENTS

<table>
<thead>
<tr>
<th>Item</th>
<th>Yes</th>
<th>No</th>
<th>N/A</th>
<th>Not Monitored</th>
<th>Comments</th>
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</thead>
<tbody>
<tr>
<td>23.0</td>
<td>Was the regulatory binder reviewed at this visit?</td>
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<tr>
<td>24.0</td>
<td>Is the original protocol on file?</td>
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<tr>
<td>24.1</td>
<td>Are all protocol amendments or addenda on file?</td>
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<tr>
<td>25.0</td>
<td>Have there been any staff/facility changes since the last visit? If yes, please comment.</td>
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<tr>
<td>26.0</td>
<td>Is a current signed/dated FDA Form 1572 present?</td>
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<tr>
<td>27.0</td>
<td>Are CVs for all investigators filed and current within 2 years of the study start of study?</td>
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<tr>
<td>28.0</td>
<td>Are current medical licenses filed for all investigators (if applicable)?</td>
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<tr>
<td>29.0</td>
<td>Is the delegation of authority log filed and current?</td>
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<tr>
<td>30.0</td>
<td>Is documentation of IRB approval on file for the following:</td>
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<tr>
<td>30.1</td>
<td>Original protocol?</td>
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<tr>
<td>30.2</td>
<td>Protocol amendments/addenda?</td>
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<tr>
<td>30.3</td>
<td>Original informed consent form?</td>
<td></td>
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<tr>
<td>30.4</td>
<td>Revised informed consent forms?</td>
<td></td>
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<tr>
<td>30.5</td>
<td>Annual renewal of approval?</td>
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<tr>
<td>31.0</td>
<td>Is the Investigator Brochure (IB) on file?</td>
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<tr>
<td>31.1</td>
<td>Has the IB been updated as needed?</td>
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<tr>
<td>31.2</td>
<td>Have amendments to the IB been submitted to the IRB?</td>
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<tr>
<td>32.0</td>
<td>Have all applicable progress reports been submitted to the IRB?</td>
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<tr>
<td>33.0</td>
<td>Are financial disclosure forms on file for all investigators?</td>
<td></td>
<td></td>
<td></td>
<td></td>
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<tr>
<td>34.0</td>
<td>Has all correspondence been filed?</td>
<td></td>
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<tr>
<td>35.0</td>
<td>Is required laboratory documentation on file and current?</td>
<td></td>
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<tr>
<td>36.0</td>
<td>Has the Monitor Visit Log been signed/dated by the monitor(s) and the site representative?</td>
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</table>

Comments: (None [ ])

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### G. ADVERSE EVENTS

<table>
<thead>
<tr>
<th>Reference Number</th>
<th>Reference Letter</th>
<th>Comment</th>
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#### 37.0 Have all AEs, SAEs, and UADEs been documented?

<table>
<thead>
<tr>
<th>Yes</th>
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<th>N/A</th>
<th>Not Monitored</th>
<th>Comments</th>
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</thead>
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</table>

#### 38.0 Have all SAEs and UADEs been reported to the IRB as appropriate and within the required timeframe?

<table>
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<th>Comments</th>
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#### 39.0 Have all SAEs and UADEs been reported to the Sponsor as appropriate and within the required timeframe?

<table>
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<th>Comments</th>
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**Subject ID**

Describe SAE or UADE.

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<th>Reference Number</th>
<th>Reference Letter</th>
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**Comments**

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<th>Reference Letter</th>
<th>Comment</th>
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### H. ACTION ITEMS  (None ☐)

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### I. MISCELLANEOUS  (None ☐)

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</tbody>
</table>
University of Arkansas for Medical Sciences – Research Support Center
Monitoring Visit Report

Monitor Name: 

Monitor Signature: 

Date: 

September 1, 2011  

Date

PI
Title
Address
City, State Zip

Protocol:
Monitoring Visit Date:
Monitors Present:
Study Staff Present:

Screening and Enrollment:

Source Documentation Verification:
The following subject data were reviewed during the visit:

Informed Consent:

Site Regulatory Binders- Essential Documents:

Serious Adverse Events/Adverse Events:

Protocol Deviations/Violations:

Drug/Device Accountability:

Action Items:
The next monitoring visit will be scheduled in approximately XXX months/weeks. Please extend my appreciation to Study Staff for their assistance during this visit. If you have any questions, please let me know.

Sincerely,

Monitor Name
Title
UAMS Research Support Center

CC:

Attachment(s)