# Revision History

|  |  |  |
| --- | --- | --- |
| **Requestor** | **Change(s)** | **Date** |
|  |  |  |
|  |  |  |

Study Summary: (protocol summary or CR summary)

Investigator-Initiated

Original Study Approval Date

Original Study Approval Status

Study Approval End Date

Most Recent Study Approval Status

Consent Waived

Consent Documentation Waived

HIPAA Not Applicable

HIPAA Waived

Most Recent IRB Approved Accrual Goal, Local

General Study Information:

1. What is the status of the study?
   1. Study never initiated.
   2. No subjects have been enrolled, no risks have been identified.
   3. The research is permanently closed to the enrollment of new subjects, all subjects have completed all research related interventions, and collection and analysis of private identifiable information is completed.
   4. Other

**If a or b**, [SKIP TO SUBMIT]

**If d**, [CLOSE OUT STUDY CLOSURE REQUEST; GET MESSAGE]

*This study does not meet the criteria for Study Closure at this time. Please follow usual procedures for Continuing Review.*

**If c**, what is the reason for the study closure?

* + 1. Study completed as planned
    2. Study terminated early due to safety concerns
    3. Study terminated early due to slow accrual
    4. Study closed due to sponsor withdrawal

1. [MOST RECENT STUDY APPROVAL STATUS EXEMPT ONLY] Has there been any change, in the opinion of the investigator, which affects this study’s exempt review classification?

**If No**, [GO TO REVIEW AND SUBMIT]

**If Yes**, Describe [GO TO REVIEW AND SUBMIT]

Accrual of Subjects:

1. Is this a chart review study only?

**If Yes**,

* + 1. How many charts have you reviewed?

[SKIP TO STUDY REPORT SECTION]

1. Provide enrollment status for the following:

Number of Subjects Enrolled:

Local

Since activation

Since last approval

Number of subjects enrolled locally since activation of the study:

By Gender

Male

Female

Unknown/ Not reported

By Race

White

Black or African American

Asian

Native American or Alaska Native

Native Hawaiian or other Pacific Islander

More Than One Race

Unknown/Not Reported

By Ethnicity

Hispanic or Latino

Not Hispanic or Latino

Unknown/Not Reported

1. Did study reach the UAMS Enrollment Goal?
2. Select all of the vulnerable populations from which you’ve enrolled subjects locally, since activation of the study.
   * 1. Children
     2. Prisoners
     3. Fetuses / Pregnant women
     4. Cognitively Impaired Persons
     5. Students
     6. Employees
     7. N/A

Study Report:

1. Summarize study progress.
2. Have subjects experienced any benefits since your last report?

**If yes**, please explain.

1. Have there been any unanticipated problems involving risks to subjects or others since your last report?

**If yes**, please explain.

1. Have any subjects withdrawn from the research since your last report?

**If yes**, please explain.

1. Have any subjects or others complained about the research since your last report?

**If yes**, please explain

1. Have there been any publications in the literature relevant to the risks or potential benefits of the research since your last report?

**If yes**, please explain

1. Since your last report, have there been any interim findings?

**If yes**, please explain

1. Since your last report, have there been any multi-center trial reports?

**If yes**, please explain

1. Since your last report, have there been any data safety monitoring board reports?

**If yes**, please explain

1. Since your last report, has there been any other relevant information regarding this research, specifically information about risks associated with the research?

**If yes**, please explain

1. In the opinion of the principal investigator, have the risks or potential benefits of this research changed since your last report?

**If yes**, please explain

1. Since the last report, have there been any internal or local adverse events in the research?

**If yes**, please provide a summary

1. Since the last report, have any protocol deviations or violations occurred in this study?

**If yes**, please provide a summary

1. Has this study been audited by the FDA, NIH, NCI OR other federal agency since your last report?

**If yes**,

* + - 1. What was the date of audit.
      2. Has a report been issued?
      3. Have you submitted a copy of the report?

**If No**, require submitting a copy of the report [\*validation message in review page]

1. Is this study subject to any litigation?

**If yes**,

* + - 1. Has the IRB been notified?

**If No**, please explain.

1. Are there any publications or presentations that have resulted from data collected during this study? (Please upload if answer is YES)

Conflict of Interest:

1. Has there been a change in the financial disclosure status of the Principal Investigator or other members of the Research Staff that has not been reported to the IRB?

**If yes**, please explain.

Document:

Review and Submit:

By signing this document, I hereby attest that the information provided is complete and accurate to the best of my knowledge.

Get message that says,

Your Study Closure form has been submitted. This study closure form will be submitted to IRB Office for review.