STUDY CLOSURE FORM

Study Summary: (protocol summary or CR summary)

Investigator-Initiated [Yes/No] [PULLED NSF]

Original Study Approval Date [Date] [PULLED ORIGINAL APPROVAL]

Original Study Approval Status [Exempt, Expedited, Full Board] [PULLED ORIGINAL APPROVAL]

Study Approval End Date [Date] [PULLED MOST RECENT APPROVAL]

Most Recent Study Approval Status [Exempt, Expedited, Full Board] [PULLED MOST RECENT APPROVAL]

Consent Waived [Yes/No] [PULLED MOST RECENT APPROVAL]

Consent Documentation Waived [Yes/No] [PULLED MOST RECENT APPROVAL]

HIPAA Not Applicable [Yes/No] [PULLED MOST RECENT APPROVAL]

HIPAA Waived [Yes/No] [PULLED MOST RECENT APPROVAL]

Most Recent IRB Approved Accrual Goal, Local [Number] [PULLED MOST RECENT APPROVAL]

General Study Information:

1. What is the status of the study? [CHECKBOXES, SINGLE, REQUIRED]
   1. Study never initiated.
   2. No subjects have been enrolled, no risks have been identified. <no-subject-no-risk>
   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? [YES/NO, REQUIRED]
   1. If No, [GO TO REVIEW AND SUBMIT]
   2. If Yes,

Describe [GO TO REVIEW AND SUBMIT]

Accrual of Subjects:

1. Is this is a chart review or archived tissue sample study only? [YES/NO, REQUIED] {/continuing-review/subject-accrual/no-subject-study/}

If Yes, {/continuing-review/subject-accrual/no-subject-study/y}

How many charts have you reviewed/archived tissue samples have you worked with? [NUMBER, REQUIRED]

{/continuing-review/subject-accrual/no-subject-study/y/number-of-records-accessed}

[SKIP TO STUDY REPORT SECTION]

1. Enrollment Status [CUSTOM-PANEL, REQUIRED]

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

American Indian 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? [Yes/No]
2. Select all of the vulnerable populations from which you’ve enrolled subjects locally, since activation of the study. [CHECKBOXES, MULTIPLE]

Children

Prisoners

Fetuses / Pregnant women

Cognitively Impaired Persons

Students

Employees

Study Report:

1. Summarize study progress. [FREE-TEXT, REQUIRED] {/continuing-review/study-report/any-study-process-date

Be sure to include progress made toward subject accrual goals and anticipated study end date.

1. Have subjects experienced any benefits since your last report? [YES/NO, REQUIRED]{/continuing-review/study-report/any-benefits-to-subjects}

If yes, explain. {/continuing-review/study-report/any-benefits-to-subjects/y/explain}

1. Have there been any unanticipated problems involving risks to subjects or others since your last report? [YES/NO, REQUIRED]

{/continuing-review/study-report/any-unanticipated-problems-involving-risks-to-subjects}

If yes, explain.

{/continuing-review/study-report/any-unanticipated-problems-involving-risks-to-subjects/y/explain}

1. Have any subjects withdrawn from the research since your last report?
   1. If yes, explain.
2. Have any subjects or others complained about the research since your last report? [YES/NO, REQUIRED]

{/continuing-review/study-report/any-subjects-complained}

* 1. If yes, explain

{/continuing-review/study-report/any-subjects-complained/y/explain}

1. Have there been any publications in the literature relevant to the risks or potential benefits of the research since your last report? [YES/NO, REQUIRED]

{/continuing-review/study-report/any-publications-relevant-to-risks-or-benefits-research}

* 1. If Yes, explain

{/continuing-review/study-report/any-publications-relevant-to-risks-or-benefits-research/y/explain}

1. Since your last report, have there been any interim findings? [YES/NO, REQUIRED]

{/continuing-review/study-report/any-interim-findings}

* 1. If Yes, explain

{/continuing-review/study-report/any-interim-findings/y/explain}

1. Since your last report, have there been any multi-center trial reports? [YES/NO, REQUIRED]

{/continuing-review/study-report/any-multi-center-trial-reports}

* 1. If Yes, explain

{/continuing-review/study-report/any-multi-center-trial-reports/y/explain}

1. Since your last report, have there been any data safety monitoring board reports? [YES/NO, REQUIRED]

{/continuing-review/study-report/any-dsmb-reports}

* 1. If Yes, explain

{/continuing-review/study-report/any-dsmb-reports/y/explain}

1. Since your last report, has there been any other relevant information regarding this research, specifically information about risks associated with the research? [YES/NO, REQUIRED]

{/continuing-review/study-report/any-risks-information}

* 1. If Yes, explain

{/continuing-review/study-report/any-risks-information/y/explain}

1. In the opinion of the principal investigator, have the risks or potential benefits of this research changed since your last report? [YES/NO, REQUIRED]
   1. {/continuing-review/study-report/any-risks-or-benefits-changed}
   2. If Yes, explain
   3. {/continuing-review/study-report/any-risks-or-benefits-changed/y/explain}
2. Since the last report, have there been any internal or local adverse events in the research? [YES/NO, REQUIRED]

{/continuing-review/study-report/any-adverse-events}

* 1. If Yes, provide a summary

{/continuing-review/study-report/any-adverse-events/y/explain}

1. Since the last report, have any protocol deviations or violations occurred in this study? [YES/NO, REQUIED]

{/continuing-review/study-report/any-deviations}

If Yes, provide a summary.

{/continuing-review/study-report/any-deviations/y/explain}

1. Has this study been audited by the FDA, NIH, NCI OR other federal agency since your last report? [YES/NO, REQUIED]

{/continuing-review/study-info/is-audited-by-federal-agency/}

* 1. If Yes, what was the date of audit. [DATE-TIME-PICKER, REQUIRED]

{/continuing-review/study-info/is-audited-by-federal-agency/y/date}

* 1. Has a report been issued? [YES/NO, REQUIED]

{/continuing-review/study-info/is-audited-by-federal-agency/y/is-report-issued}

* 1. Have you submitted a copy of the report to the IRB? [YES/NO, REQUIRED]
     1. If No, require submitting a copy of the report [\*validation message in review page]

1. Is this study subject to any litigation? [YES/NO, REQUIED]

{/continuing-review/study-info/study-focuses-on-litigation /}

* 1. If yes, has the IRB been notified? [YES/NO, REQUIED]

{/continuing-review/study-info/study-focuses-on-litigation/y/is-irb-notified}

* + - 1. If No, please explain. [TEXT-AREA, REQUIRED]

{/continuing-review/study-info/study-focuses-on-litigation/y/is-irb-notified/n/explain}

1. Are there any publications or presentations that have resulted from data collected during this study? [YES/NO, REQUIED]
   1. If yes, please upload (check for publication document).

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? [YES/NO, REQUIRED]

{/continuing-review/funding-source/has-coi-changes/}

If Yes, explain.

{/continuing-review/funding-source/has-coi-changes/y/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. The IRB Director or Designee will review your request and provide you with a study status letter.