CONTINUING REVIEW FORM

Study Summary: (protocol summary or CR summary)

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

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

Original Study Approval Status [Date] [PULLED FROM ORIGINAL APPROVAL]\*\*

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

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

Consent Waived [Yes/No]

Consent Documentation Waived [Yes/No]

HIPAA Not Applicable [Yes/No]

HIPAA Waived [Yes/No]

Most Recent IRB Approved Accrual Goal, Local [Number]

[\*\*For Full Board Studies, use date of meeting where board takes Approved or Not Yet Approved, Minor Revisions Required” actions on the study]

Fields should already exist for letters, right?

General Study Information:

1. Would you like to keep this study open at this time? [YES/NO, REQUIRED]

If No [GET MESSAGE]

To close this study, please exit this Continuing Review and submit a Study Closure form instead.

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]

1. What is the status of the study? [CHECKBOXES, SINGLE, REQUIRED]

{/continuing-review/study-status/statuses/status}

1. Study not 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 the research remains active only for long-term follow-up of subjects
4. The research is permanently closed to the enrollment of new subjects, all subjects have completed all research related interventions, and the remaining research activities are limited to data analysis only. <data-analysis-only>
5. 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.
6. Other

Describe

If a or b, [SKIP TO REVIEW AND SUBMIT]

Accrual of Subjects:

1. Is this is a chart review 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? [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]
   1. [Number of Subjects Enrolled]

Locally, since activation:

Locally, since last approval:

[IF MULTISITE STUDY ONLY] At all sites, since activation (if available):

[IF LOCAL SINCE LAST APPROVAL NUMBER IS > THAN IRB APPROVED ACCRUAL NUMBER, GET PROMPT AT REVIEW TO RECONCILE OR TO SUMBIT SEPARATE MODIFICATION]

* 1. [Number of Subjects Enrolled Locally Since Activation]
     1. [By Gender]

Male

Female

Unknow/Not reported

[IF GENDER TOTAL NOT = TO LOCAL SINCE ACTIVATION TOTAL, GET PROMPT AT REVIEW TO RECONCILE]

* + 1. [By Race] (REQUIRED FOR NIH FUNDED STUDIES ONLY)

White

Black or African American

Asian

American or Alaska Native

Native Hawaiian or other Pacific Islander

More Than One Race

Unknown/Not Reported

* + 1. [By Ethnicity]

Hispanic or Latino

Not Hispanic or Latino

Unknown/Not Reported

1. 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}
2. If yes, explain. {/continuing-review/study-report/any-benefits-to-subjects/y/explain}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}

[\* Link to COI]

Document:

List current active protocol(s), and consents documents, and let the PI check the ones that are current.

Help Text:

If this list does not contain the protocol and consent documents that are currently active for this study, please upload them as part of a separate Modification, after submitting your Continuing Review.

Documents [DOCUMENTS-PANEL]

Review:

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 Continuing Review form has been submitted.