# Revision History

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

Basic Information

Investigator-Initiated Study or Not

Original Study Approval Date

Original Study Approval Status

Most Recent Approval Status

Study Approval End Date

Consent Waived?

Consent Documentation Waived?

HIPAA Applicable?

HIPAA Waived?

Most Recent IRB Approved Accrual Goal, Local

General Study Information:

1. Would you like to keep this study open at this time?

**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?
   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?
2. Study not initiated.
3. No subjects have been enrolled, no risks have been identified.
4. 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
5. 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.
6. 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.
7. The study is open and accrual is ongoing.
8. Other, please describe

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

Accrual of Subjects:

1. Is this is a chart review or archived tissue sample study only?

**If Yes**,

* + 1. How many charts have you reviewed/archived tissue samples have you worked with?

[SKIP TO STUDY REPORT SECTION]

1. Date the first subject was enrolled:
2. Enrollment Status
   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]

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.
   * 1. Children
     2. Prisoners
     3. Fetuses / Pregnant women
     4. Cognitively Impaired Persons
     5. Students
     6. Employees

Study Report:

1. Summarize study progress.

*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?

**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**, provide a summary

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

**If yes**, 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?

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.

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.