

Genesys Regional Medical Center
INSTITUTIONAL REVIEW COMMITTEE
REVISION or ADDITIONS REVIEW FORM

Principal Investigator: _____ IRB #: _____

Study Title:

Email: _____ Phone: _

Research Coordinator: _____ Phone _____

1. Revision or Addition Description (check all that apply):

_____ Revision to currently approved protocol **new version date:** _____

_____ Revision to currently approved consent **new version date:** _____

_____ Other additions- (e.g. Advertisement, questionnaires, surveys, HIPAA, etc)

(Note: If addition/change in PI, submit a PI Addition/Change Form)

2. Check all that apply:

_____ This revision involves minor changes only.

_____ This revision does not increase risks to participants enrolled in the study.

_____ This revision does increase risks to participants enrolled in the study (Include explanation in revision)

Describe briefly Addendum & Revision:

Comments:

3. Submit the revised protocol, consents, or any other documents for review.
(Use track changes or HIGHLIGHT revisions)

Signature of PI: _____

Date: _____

Name: