Stanford MEDICINE

Clinical Trial Research Management Group / Cancer Clinical Trial Office
Budget Amendment Intake Form*

Please complete this form and email with required documents to RMG CT Intake rmg_ct_intake@stanford.edu or submit to CCTO as a **REDCap request** if the study budget was completed by CCTO. Contact ccto-finance@stanford.edu for any questions.

STUDY INFORMATION

PI_____ SPO_____ eP _____ RedCap_____

PTA _____ 98/Mnemonic Account ID:_____

Protocol Amendment Version and Date _____

☐Department Initiated Amendment

☐Sponsor Initiated Amendment

IRB Review required? ☐Yes ☐No

Stanford IRB revision submitted? ☐Yes ☐No

Single IRB approved? ☐Yes ☐Pending

IRB Review/Approval Date: _____

PATIENT ENROLLMENT # of Patients Currently Active on Study: _____

CHANGES WITH THIS AMENDMENT (select all that apply)

Protocol Amendment/Changes to Schedule of Events/Calendar:

☐Cohort/Arm(s) Added (see Appendix A)

☐Visits Added, Moved or Removed

☐Hospital Services Added, Moved or Removed

Target Enrollment Change: Increased to: _____ Reduced to_____

☐Billing/Budget changes (ex. Sponsor offers payment for service that requires billing designation change in CA)

☐Invoiceable Items added/amended

☐Change in Effort (on existing arms) *please clarify in comments section below*

☐Inpatient Component Added

☐CTRU services Added/Removed_____CTRU Budget Builder updated: ☐Yes ☐No

** Internal SeRA Funding Increase, No Cost Extension, Sponsor or PI change only? Refer to processes:*
http://med.stanford.edu/rmg/clinical-trials/post-award-management.html

☐Other Changes (please explain)

_____

_____

CONTACT INFORMATION

Department Contact:

Name _____
Email _____
Phone _____

Sponsor Contact:

Name _____
Email _____
Phone _____

TIMELINE

Requested Completion Date: _____

Rationale: _____

Does sponsor require the amendment be executed in order for Stanford to continue with enrollment or receive payment? ☐Yes ☐ No

LOCATION

Will a new/additional location be involved? (e.g. CTRU/ValleyCare) ☐Yes ☐ No

Please List: _____

REQUIRED DOCUMENTS

1. Updated Protocol with Summary of Changes
2. Protocol with Tracked Changes *(if available*)
3. Updated Sponsor Budget/Payment Table (*if* provided by sponsor)
4. Contractual Amendment to original CTA (*if* provided by sponsor)
5. Active Budget and Billing Workbook currently being used for study enrollment (PHI removed)
6. Updated Stanford ICF (*if applicable*) with track changes
7. Updated CTRU Budget Builder document (*if applicable*)

Comments or explanation of changes covered above:

_____

_____

_____

CT RMG / CCTO ONLY

Ankura's Internal Tracking number (ex. SHC-CA-XXX): _____

Is an amendment to the coverage analysis required? ☐Yes ☐ No

Explanation of required documents NOT attached: (e.g. "no sponsor agreement because ACTA used for the original)

_____

_____

APPENDIX A

Information on Additional Arms/Cohorts Being Added

Please describe (ex. new investigational product, new age group, other details):

_____

_____

_____

EFFORT ESTIMATES FOR ADDITONAL ARMS:

Name of New Arm 1_____

Total Number of Patients in: New Arm 1_____

Patient Population: ☐ Adult ☐Pediatric

Coordinator: Hours Per Patient_____ -OR- % Annual Effort Per Study _____

PI: Hours Per Patient_____ -OR- % Annual Effort Per Study _____

Other Name: _____ Hours Per Patient _____ -OR- % Annual Effort per Study _____

Name of New Arm 2_____

Total Number of Patients in: New Arm 2_____

Patient Population: ☐ Adult ☐Pediatric

Coordinator: Hours Per Patient_____ -OR- % Annual Effort Per Study _____

PI: Hours Per Patient_____ -OR- % Annual Effort Per Study _____

Other Name: _____ Hours Per Patient _____ -OR- % Annual Effort per Study _____

Name of New Arm 3_____

Total Number of Patients in: New Arm 3 _____

Patient Population: ☐ Adult ☐Pediatric

Coordinator: Hours Per Patient_____ -OR- % Annual Effort Per Study _____

PI: Hours Per Patient_____ -OR- % Annual Effort Per Study _____

Other Name: _____ Hours Per Patient _____ -OR- % Annual Effort per Study _____

Please copy/add Arms as appropriate.